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# Pharmaceutical Advertising 2022

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**Covington & Burling LLP**

2022

# Chambers Global Practice Guides

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# INTRODUCTION

***Contributed by:*** *Bart Van Vooren and Rosa Oyarzabal,* ***Covington & Burling LLP***

## Introduction

The fifth version of the practice guide on pharmaceutical advertising reflects the field's current importance and complexity. Pharmaceutical advertising as a practice area has in many ways outgrown itself and has come to cover much more than advertising in the strict sense of the word. This guide covers the broad variety of topics that are typically linked to pharmaceutical advertising, including transparency requirements and hospitality rules.

A year into the global pandemic, the complexities of advertising in the digital space must also be addressed. After years of increasing importance, online interactions have come to the forefront of the industry's practice this year and will stay as a fundamental part of the advertising system going forward.

## Increased Scrutiny

In today's reality, where the pharmaceutical industry is under increasing government and especially public scrutiny, the rules on pharmaceutical advertising impact stakeholders in a number of important ways.

### *The sharing of information*

The pharmaceutical industry seeks to communicate on its products or (related) services, both before and after product launch. Questions often arise, including what, and how, the industry can communicate to healthcare professionals and healthcare institutions. What, if anything, can be shared with patients and patient associations, reactively or proactively? Can digital recordings of online events be made available, or proactively be pushed to just any recipient? How can companies that are preparing for launch enter into dialogue with payers? The rules at national level can differ significantly (eg, EU v USA), or in more subtle ways (eg, within various EU member states). Practical experience is therefore essential to navigate these rules.

Patients and healthcare professionals depend on accurate and timely information. A summary on product characteristics or a public assessment report provide important information, but that may often not be sufficient. What additional information can the industry provide to healthcare professionals, proactively or upon their request? Does it matter that a product is close to commercialisation? What could be the impact of the complexity on administering the product, the risk management plan, the orphan status of the product, and so on? Who within the company can engage in that type of conversation, with which counterpart, and in which context? Good advice depends on an exceptionally good grasp of the breadth of pharmaceutical regulation.

### *Research and innovation*

Science and innovation depends on accurate information about research, (clinical) study results, and a good understanding of the post-approval performance of medicinal products. How can the industry and the scientific community co-operate? What are the limits on industry-sponsored research projects? How can the industry communicate scientific advances or major scientific findings, close to authorisation? What about real-world evidence gathered after approval: can companies communicate about their findings, to whom, and how?

Patient organisations have become more sophisticated and increasingly demand to be informed about research, especially in certain disease areas. How can the industry and the patient community co-operate? How can the industry communicate major scientific findings

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to the patient population? How can the industry recruit patients for clinical trials, or inform them about early access opportunities?

### *Virtual meetings*

The sudden and nearly instantaneous replacement of physical meetings with all sorts of virtual formats creates opportunities and challenges for the pharmaceutical sector. A quick response has been seen from the pharmaceutical trade associations to set out some common rules for online interactions. However, laws, codes and regulators are more static, and two years into the pandemic, many countries have not yet adapted their rules to the new reality. This leads the industry to look to general rules for digital services to navigate the fragmented national framework of advertising rules applied to online pharmaceutical advertising.

The industry has faced questions such as: which authority has jurisdiction over a promotional activity that occurs online? Are online events by definition “supra-national”? Now that scientific exchanges occur in digital rooms, are pharmaceutical companies allowed to sponsor these events? What about attendance by HCPs of these events? Is the distribution of materials – proactively or reactively via email (or other media) allowed? And relatedly, can the industry take advantage of the transition to the online space to centralise the distribution of materials in a regional or global manner? How do internal company processes adapt to the new digital reality?

These are difficult questions that require an expert knowledge of the legislation as well as the inner workings of pharmaceutical companies. Legal advisers must also look beyond medicines legislation. In most countries, other areas of laws are also relevant, including general advertising law, commercial practices regulations and anti-bribery rules. The area also builds on a mix of laws, guidance, best practice and self-regulatory initiatives.

## Key Themes

The following themes are common to most jurisdictions covered in this guide.

### *Advertising or communication*

The thin line between "advertising" and "information" is key to the communication strategy of any pharmaceutical company. Where regulators or courts draw the line often depends on subtle nuances in the content, form and context of the advertising. Depending on where the cut-off lies, online information on prescription drugs, for instance, could qualify as direct-to-consumer advertising, which is prohibited in most countries (with a few notable exceptions, such as the USA and New Zealand).

### *Transparency*

As public opinion and regulators are increasingly focusing on the interactions between the pharmaceutical industry and healthcare sector stakeholders, transparency is clearly gaining importance. And yet, the sophistication of transparency rules varies dramatically depending on the jurisdiction. While some countries only impose disclosure obligations on the industry, others put the burden on healthcare professionals instead of companies.

Furthermore, transparency rules are often not legally binding. While the US Sunshine Act has been around for several years, for instance, only a handful of EU member states have sunshine laws. Instead, in most EU member states, transparency is driven by and enforced through the industry's self-regulatory codes.

### *Transition to the digital space*

The transition of activities to the digital space has brought about a number of industry guidance documents. In the absence of concrete rules,

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regulators have approached online activities from the perspective of the general principles of advertising, hospitality and inducement, adapting them to fit the online environment. Given its increased importance, this is an area where regulatory developments are expected to occur. Patient support programmes such as online patient support platforms and applications, as well as knowledge platforms for healthcare professionals, continue to grow in relevance. This remains a grey area that requires careful, country-specific analysis. There is increasingly more enforcement of companies' activities on social media, but the boundaries of what is acceptable are still being defined. In addition, the lack of regulatory consistency between jurisdictions creates a number of hurdles. Careful analysis of the applicable rules is necessary to avoid impeding a regional or even global implementation of these kinds of programmes.

### *Pre-vetting requirements*

The existence of pre-vetting requirements can have an important impact on the medicines' advertising landscape. Complying with pre-vetting rules can be quite burdensome and typically requires careful organisation and planning. Indeed, in some countries, like China, all advertising requires prior approval by the authorities, and the approvals must be renewed on a yearly basis. Within the EU, the rules are very different depending on the member state. In the US, pre-vetting only applies to certain types of medicinal products.

### *Enforcement*

While pharmaceutical advertising is certainly not characterised by particularly high fines, enforcement in this area is quite effective, and often both private and public in nature. In some countries, like Germany, competitors tend to be the most vigorous "watchdogs", commonly bringing suits against each other, claiming damages or injunctive relief. Elsewhere, authorities or self-regulatory bodies play a more active role through fines or other measures. Avoiding reputational damage is also an important driver for compliance in this area. Some regulators (like the FDA and several EU regulators) publish information on non-compliant practices, or order companies to publish a rectification on their website or in medical journals.

### In Conclusion

An advanced and workable regulatory regime for pharmaceutical advertising plays a crucial role in building the much-needed trust by the public in the pharmaceutical sector. It can be a driver of effective and transparent collaboration between the industry and the healthcare community. It goes to the core of the industry's reputation and continuous development. For all those reasons, it is more important than ever that practitioners are aware of the boundaries that authorities and peers expect them to live by.

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**Covington & Burling LLP** offers one of the largest and most comprehensive life sciences practices in the world. Covington's clients in the pharmaceutical industry range from start-up ventures to multinational corporations and trade associations, and for decades they have trusted the firm with their most challenging business problems. They know that they can rely on Covington for practical, efficient solutions, rooted in a sophisticated knowledge of their business, the law and science, which only comes from deep immersion in the industry and decades of dedicated service. From the firm's offices in Brussels, Frankfurt and London, the tight-knit life sciences team offers advice on EU and national laws across the European continent.

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# BELGIUM

## Law and Practice

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# 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

## 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The general legal rules on the advertising of medicines for human use are provided by the Law on Medicinal Products of 25 March 1964 (LMP) (particularly Articles 9 and 10) and the Royal Decree on information and advertising of medicinal products for human use of 7 April 1995 (RDAMP).

Furthermore, the Law of 18 December 2016 on "various provisions on health", which entered into force on 23 June 2017 (the "Sunshine Act") is also of high relevance in the context of pharmaceutical advertising in Belgium. The Sunshine Act imposes an obligation of legal transparency on pharmaceutical companies to document and to (annually) disclose premiums and benefits that were granted to healthcare professionals, healthcare organisations or patient organisations. The Sunshine Act is further executed by the Royal Decree of 14 June 2017 on the execution of the Sunshine Act (the "RD Sunshine Act").

### Self-Regulatory Deontological Codes

Four self-regulatory deontological codes provide specific provisions on pharmaceutical advertising in Belgium. They were issued by the following professional associations: pharma.be, a professional association of innovative pharma companies based in Belgium, the Belgian Association for the Consumer Healthcare Industry (BACHI), which focuses on over-the-counter medicines and healthcare products sold in pharmacies, Mdeon, a common platform between different professional associations and healthcare professionals/organisations and Medaxes, a professional association of Belgium-based generic/biosimilar medicine companies.

### Legal Framework

The focus of this chapter is on the general legal framework for the advertising of medicinal products (including the Sunshine Act) applicable to all pharmaceutical companies in Belgium. The self-regulatory deontological codes referred to above (notably the pharma.be Code of Deontology, which applies to 90% of the Belgian innovative pharmaceutical companies) will be addressed if they add information or insights to further interpret or better understand the general legal framework, contain further material obligations for their members or install relevant a priori or a posteriori approval or control procedures regarding pharmaceutical advertising.

### Advertising to the General Public and Healthcare Professionals

Lastly, the LMP and the RDAMP make a clear distinction between advertising medicinal products towards the "general public" on the one hand, and towards "healthcare professionals" on the other hand. Within the scope of the LMP and the RDAMP, only medical doctors, dentists and pharmacists are considered "healthcare professionals". Nursing personnel are regarded as part of the general public. However, under the Sunshine Act, nurses, paramedics and hospital directors also fall under the definition of "healthcare professionals".

## 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Each of the four self-regulatory deontological codes are binding (only) to the members of the relevant professional associations (provided that Mdeon has been entrusted formal regulatory authority in relation to the granting of visa for sponsoring scientific manifestations under Article 10 LMP, see **9.3 Sponsorship of Scientific Meetings**).

## 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

### 2.1 Definition of Advertising

Article 9 of the LMP provides the following definition of advertising: "any form of door-to-door information, canvassing activity or stimulation which is designed to promote the prescription, release, supply, sale or consumption of medicinal products". Patient information leaflets, product labels and general information regarding health and disease areas with no direct or indirect reference to a medicinal product are however excluded from the definition of "advertising". Information and documentation provided in the context of package changes, compliance with pharmacovigilance requirements, and sales catalogues and pricing lists also fall outside of the definition of advertising, to the extent such information and documentation do not include product specific information.

Also not regarded as advertising is the provision of so-called "unsolicited" medical information about a particular drug product, given by a pharmaceutical company following a patient's or healthcare professional's specific request, as long as such information is strictly necessary to answer such particular request, and it does not contain unsolicited promotional content (for the distinction between information and advertising, see **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**).

The definition and exclusions provided under Article 9 of the LMP are identical to those of Article 86 of Directive 2001/83/EC of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use.

Article 2, Section 2 of the RDAMP further supplements the definition of advertising by naming specific examples, such as providing samples, visiting healthcare professionals, sponsoring scientific conferences and inciting to deliver or prescribe medicines by providing financial or in-kind benefits.

### 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

The difference between information and advertising is extremely relevant for the pharmaceutical sector, since the provision of mere medical information is subject to fewer restrictions and regulations than the advertising of pharmaceutical products. However, in practice, said distinction is often difficult to draw. The test generally used to differentiate both types of communication is the question if the communication promotes or enhances or intends to promote or enhance the sale of a particular pharmaceutical product.

The definition of advertising is commonly interpreted broadly by the supervising authorities, who will often be inclined to assume that any type of medical communication is promotional, unless clearly proven otherwise.

#### General Information

Article 9 of the LMP explicitly provides that general information regarding health and disease areas, with no reference (directly nor indirectly) to a medicinal product, is not regarded as advertising. Therefore, disease awareness campaigns would typically not qualify as advertising, provided that such campaigns cannot be considered as soliciting requests for information from the addressee. A Patient Information Leaflet (PIL) will reasonably not be qualified as a form of advertising, since it is intended to inform the patient about the characteristics of a certain medicinal product after it has been purchased by the patient. Information about patient support programmes, which usually pertain to a specif-

ic medicinal product, should only be provided upon the specific request of the patient. Otherwise, such information will likely be considered to have a promotional purpose.

### Borderline Cases

For borderline cases, pharmaceutical companies often apply the following rules of thumb to mitigate the risk of a re-qualification of "scientific information" into "advertising" by the supervising authorities: ensuring that the communication emanates from the medical affairs department (and not from the sales team) and keeping a written file able to demonstrate (if need be) the clear non-promotional intent of said communication (and the assessment made by the company prior to sending it). The implementation of such rules-of-thumb can, of course, never entirely eliminate the re-qualification risk.

## 2.3 Restrictions on Press Releases regarding Medicines

Given the broad interpretation applied by the supervising authorities, press releases are very often to be considered as advertising medicinal products and must, in such case, comply with the general rules and requirements concerning advertising towards the general public or healthcare professionals, as the case may be. Since it is prohibited to promote prescription-only medicines to the general public (see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public**), no such press releases may be issued in the general media, unless it can be established that they are purely informative (see **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**).

Conversely, it is allowed to publish articles concerning prescription-only medicines in specialised trade magazines that are only consulted by healthcare professionals, as long as the general rules provided in Articles 9 and 10 of the RDAMP are complied with (see **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**).

Finally, the advertisement of unauthorised products or off-label indications is prohibited under Article 9 LMP (see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**). Therefore, a press release concerning such unauthorised products or off-label indications is only allowed if such press release is purely informative and is not to be considered promotional (see **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**).

It is generally accepted that companies may provide the specialised media with updates on their pipeline pharmaceutical products during the development or marketing authorisation phases. Such press releases must, however, be drafted in such a way that they cannot be considered as an advertising tool, inter alia, by only providing objective and scientifically verifiable information and by mentioning the non-proprietary name of the active pharmaceutical ingredient rather than the anticipated trade name of the product.

It is interesting to note that the Belgian Financial Services Market Authority (FSMA) has recently issued specific guidance for (listed) biotech companies regarding the provision of information on their pipeline, following the increasing focus on the pharmaceutical and biotech sector in COVID-times. Pursuant to such guidance, listed biotech and pharmaceutical companies have a regulatory obligation to proactively communicate on their pipeline when concrete development milestones have been reached, which is generally done via press releases. This is based on the more general Belgian Market Abuse Regulation principle, which stipulates that inside information needs to be shared with the

public as soon as possible and false or misleading signals must be avoided.

Notwithstanding this obligation to proactively communicate, companies should be careful and make sure that the communication remains factual, balanced, does not contain any promotional content and is not aimed at encouraging the sale or prescription of the relevant product (see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**).

### 2.4 Comparative Advertising for Medicines

The requirements for legitimate comparative advertising are laid down in Article VI.17 of the Code of Economic Law. Comparative advertisements:

- must compare similar products;
- must compare one or more essential, relevant, verifiable and representative elements of the product (such as the price);
- must not be misleading;
- must not create confusion between the advertiser and the competitor or between their brands, trade names or other distinguishing marks;
- must not discredit or disparage the competitor and its products/activities; and
- must not represent products as being a counterfeit or imitation of products whose brand or trade name is protected.

Moreover, pursuant to the pharma.be Code of Deontology, comparative advertisements must present the comparator product in a way that is fair, complete, scientifically accurate and based on the most recently available data.

Given the general prohibition of advertising non-approved medicines or indications (see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**), making comparative advertisements concerning a medicinal product that has not (yet) been authorised must be deemed illegal (ie, even if such comparison is in line with the above requirements). Comparative scientific statements concerning a medicinal product that has not (yet) been authorised may be permitted if it is purely informative, is scientifically validated (eg, on the basis of objective head-to-head clinical data) and is not to be considered promotional (see **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**).

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

Article 9 LMP explicitly forbids all advertising of medicines that are not yet authorised, including the advertising of a medicine for indications for which it has not (yet) been granted marketing authorisation (off-label indications). However, this prohibition applies only to advertisements and not to medical information. Note also that the provision of unsolicited medical information does not constitute an advertisement of a pharmaceutical product, regardless of who requests such information (see **2.1 Definition of Advertising**). Therefore, a pharmaceutical company can provide a patient/healthcare professional with specific information on unauthorised medicines or off-label indications if such information is provided at the specific, unsolicited request of a patient/healthcare professional, such information does not contain any promotional content and is not aimed at encouraging the sale or prescription of the relevant product and to the

extent the information is necessary to answer the patient's or the healthcare professional's request.

Besides, information on non-authorised medicines or off-label indications can be published in independent scientific (preferably peer reviewed and, in any case, non-commercial) magazines or journals. These publications may not be used as promotional material by a pharmaceutical company (eg, by extending copies of the journal to healthcare professionals).

All other publications of non-authorised medicines or off-label indications will, in principle, be deemed promotional and are therefore illegal.

### 3.2 Provision of Information during a Scientific Conference

It is generally accepted that scientific information on non-authorised medicines or off-label indications (eg, results of clinical studies) can be presented to healthcare professionals during scientific meetings, insofar as the presentation remains strictly scientific and is not (blatantly) intended to promote the relevant medicine. Such intention can be harder to refute when the meeting is (materially) sponsored by the product owner. In addition, it is always preferable to have such presentations brought by an independent expert faculty.

### 3.3 Provision of Information to Healthcare Professionals

In principle, the circulation of information on unauthorised medicines or unauthorised indications, even to healthcare professionals, would qualify as advertising (which in accordance with Article 9 of the LMP is not allowed), unless the information was shared reactively, upon the unsolicited request of a relevant third party.

### 3.4 Provision of Information to Healthcare Institutions

The provision of information on unauthorised medicines or indications to healthcare institutions is likely to be considered an advertisement and in breach of Article 9 of the LMP, unless the healthcare institutions expressly requested this information.

### 3.5 Publication of Compassionate Use Programmes

The publication of the availability of compassionate use programmes or other forms of early access falls under the general prohibition of advertisement of unauthorised medicines (see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**) and is therefore, in principle, illegal.

A pharmaceutical company can however provide information on such early access programmes if such occurs at the specific, unsolicited request of a patient or a healthcare professional, such information does not contain any promotional content and is not aimed at encouraging the sale or prescription of a medicinal product, and such information is necessary to answer the patient's or healthcare professional's request.

Furthermore, it is acceptable that information on early access programmes is published in independent scientific (preferably peer reviewed and, in any case, non-commercial) magazines or journals (see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**).

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Belgian law (Article 9 of the LMP) expressly prohibits the advertising of prescription-only medicines to the general public.

Advertising over-the-counter medicines is permitted, except when such advertisement:

- gives the impression that a medical consultation or surgical operation is redundant;
- suggests that the effects of taking the medicinal product are guaranteed or that no side effects exist;
- suggests that the patient's health can be enhanced by taking the medicinal product or can be affected by not taking it;
- is directed exclusively or primarily at children;
- refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing, but who could encourage the medicinal products' consumption due to their status;
- suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
- suggests that the efficacy or safety of the product stems from the fact that it is natural;
- could lead to an incorrect self-diagnosis; or
- uses improper, alarming or misleading terms or pictorial representations (see Article 7 of the RDAMP).

Pursuant to Article 5 of the RDAMP, certain means for advertising medicinal products are prohibited (irrespective of the public to whom the advertisement is directed), eg, advertising by means of airplanes, billboards, telephone, text messages, fax, email, mailing, children's magazines, leaflets, contests and software programs. It is equally prohibited to promote medicinal products by promising, offering or granting any direct or indirect compensation in case the patient is unsatisfied with the product.

For the sake of completeness, it should be mentioned that the advertising of pharmaceutical products is also governed by the general rules on advertising, included in the Belgian Code of Economic Law; see **2.4 Comparative Advertising for Medicines**.

### 4.2 Information Contained in Pharmaceutical Advertising to the General Public

Generally, all advertisements (both to the general public and to healthcare professionals) must present the characteristics of the medicinal product in such a manner that it is compatible with the Summary of the Product Characteristics (SmPC) and ensures a rational use of the medicinal product (Article 9 of the LMP). Moreover, the applicable legal framework and deontological codes provide that the presentation of a medicinal product in advertisements must be accurate, up to date, objective, sufficiently complete, truthful, verifiable and compatible with the most recent content of its marketing authorisation file, reflect the generally accepted scientific knowledge and be backed by bibliographical data.

Specifically, in terms of advertising of over-the-counter medicines directed at the general public, Article 8 of the RDAMP requires that it should be designed in such a way that it is clear that the message is an advertisement and include the following minimum information:

- the name of the product (as well as the generic name if the medicinal product contains only one active substance);
- the information required for correct use;
- the statement "this is a medicinal product, no long-term use without medical advice";

- an explicit, legible invitation to carefully read the instructions on the package leaflet or on the outer packaging, as the case may be; in the case of radio advertisements, such an invitation must be explicit and clearly audible; and
- the (trade) name of the product's marketing authorisation holder.

There is no legal or deontological rule that requires that the price of the pharmaceutical product is mentioned in the advertisement.

### 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Neither the LMP nor the RDAMP contains provisions on relations with patient organisations. A patient organisation having a healthcare professional among its members should, in any event, be treated as a healthcare organisation to which Article 10 of the LMP applies (see **8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals** and **8.2 Legislative or Self-Regulatory Provisions**). Pharmaceutical companies should make sure that their public interaction with patient organisations within a certain therapeutic area does not qualify as an advertisement to the general public regarding their related drug products.

Chapter 3 of pharma.be's Code of Deontology does contain rules on relations with patient organisations. Pharmaceutical companies may provide financial support to a patient organisation, call on patient organisations for the performance of certain services for the support of healthcare or research or sponsor events organised by patient organisations if such support is covered by a written agreement.

In addition, pharma.be requires its members to make the support it has attributed to patient organisations available to the public on a yearly basis. This transparency obligation in respect of transfers of value to patient organisations is also included in the Sunshine Act, which applies to all companies, not only the members of pharma.be.

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

As mentioned in **4.2 Information Contained in Pharmaceutical Advertising to the General Public**, all advertisements must present the characteristics of the medicinal product in such a manner that it is compatible with the SmPC and ensures a rational use of the medicinal product (Article 9 of the LMP). Moreover, the presentation of a medicinal product in advertisements must be accurate, up to date, objective, sufficiently complete, truthful, verifiable and compatible with the most recent content of its marketing authorisation file, reflect the generally accepted scientific knowledge and be backed by bibliographical data.

#### Mandatory Data to Be Contained in Advertising to Healthcare Professionals

Specifically, for advertisements towards healthcare professionals, Article 9 of the RDAMP specifies that advertisements in the press directed towards healthcare professionals must contain the following essential data, which must cover at least 50% of the total advertisement space:

- the product's name, its qualitative and quantitative composition in terms of active substances and its pharmaceutical form;
- all information regarding indications, posology, contraindications and side effects contained in the SmPC;

- the package leaflet or the labelling in case of a homeopathic medicinal product; and
- the (trade) name of the marketing authorisation holder and the number of the marketing authorisation or product registration.

The FAHMP has issued very specific guidance regarding the layout and readability requirements for advertising of pharmaceutical products (Circular's 407 and 441).

As opposed to advertisements of over-the-counter medicines, advertisements towards healthcare professionals should also contain the applicable retail price per approved formulation/pack size. Such prices must appear in bold, on a contrasting background in the advertisement's upper right-hand corner and should cover at least 0.5% of the print advertisement.

Lastly, advertisements towards healthcare professionals must explicitly mention the date of the product's creation or the date of its last revision.

For the sake of completeness, it must be mentioned that the restrictions on the means of advertising provided under Article 5 of the RDAMP (see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public**) also apply to the advertising towards healthcare professionals.

### 5.2 Reference to Data Not Included in the Summary of Product Characteristics

In accordance with the LMP, all information in an advertisement for medicinal products must comply with the information as set out in the SmPC. Further to the European Court of Justice decision held in Novo Nordisk AS v Ravimiamet (C-249/09; 5 May 2011), it is generally accepted that the inclusion in advertisements directed to healthcare professionals of information, which is not part of the SmPC, is allowed as long as such information confirms, clarifies or supplements (ie, does not directly or indirectly contradict) the specifications made in the SmPC and is not misleading.

### 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

Reference to combined use of products is acceptable if such combined use is authorised for the particular indication for which it is being promoted (otherwise it would constitute an illegal promotion for an unauthorised indication; see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**), this reference does not directly or indirectly contradict the specifications made in the SmPC (see **5.2 Reference to Data Not Included in the Summary of Product Characteristics**) and the promotional claim is presented in an accurate, up to date, objective, sufficiently complete, truthful, verifiable and faithful manner.

### 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

The distribution by a pharmaceutical company to healthcare professionals of scientific papers (or proceedings of congresses) that refer directly or indirectly to a drug product of said company will, in principle, be considered an advert and therefore subject to those rules (including the prohibition of advertising on unauthorised products/off-label indications). Distribution by pharmaceutical companies will also be subject to the rules related to gifts to healthcare professionals.

### 5.5 Medical Science Liaisons

Medical Science Liaisons (MSLs) are regarded as therapeutic area scientific experts within the pharmaceutical company, who act as a liaison between the company and healthcare professionals and other external stakeholders. MSLs are responsible for discussing the company's pipeline, products, patient treatment trends and studies in the therapeutic areas in which the

company is involved, on a peer-to-peer basis with an audience of external clinical and non-clinical stakeholders.

The MSL's communications with healthcare professionals must always comply with applicable legislation. Therefore, the MSL may only respond to unsolicited questions raised by healthcare professionals about unapproved products or off-label uses of approved products and not proactively provide such information. The MSL is, however, allowed to proactively exchange information on ongoing trials and communicate scientific information on the company's products within label.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

For advertisements towards the general public, the applicable approval and notification procedure depends on the medium used for such an advertisement.

If an advertisement is made on the radio and/or television, the company must obtain prior approval from the Ministry of Health (Article 16, Section 1 of the RDAMP), which will base its decision on the advice from the Commission on the Supervision on Advertisement on Medicinal Products. This commission operates as an independent commission within the Federal Agency for Medicines and Health Products (FAMHP). The Ministry of Health must make a decision within 45 days as of the receipt of a complete request for approval (Article 17, Section 5 of the RDAMP).

All other forms of advertisement (of medicinal products) to the general public (eg, in a newspaper or online) should merely be notified to the Ministry of Health 30 days prior to their publication (Article 16, Section 2 of the RDAMP). The Ministry of Health may require the company to provide additional documents in the context of this notification, which could potentially lead to a postponement of the relevant advertisement. The Ministry of Health may also prevent any (intended) advertising, if it does not comply with applicable legal requirements. Both the visa and notification require the payment of a retribution by the company (EUR995.20 and EUR592.33, respectively) and are valid for a period of two years.

As regards advertising towards healthcare professionals, prior notification to or approval by the Ministry of Health is not required.

### 6.2 Compliance with Rules on Medicinal Advertising

Pursuant to Article 13 of the RDAMP, every marketing authorisation-holding company must designate a qualified person (responsible for the information) who will be accountable for the advertising and for providing scientific information on medicinal products for that company. The qualified person must be a pharmacist or physician and registered with the Ministry of Health. Information as well as advertisements to healthcare professionals and the general public should always be ratified in advance by that qualified person.

There are no relevant legal or code requirements to have specific standard operating procedures in place to cover advertising activities.

Also note that pharmaceutical companies must adequately train sales representatives visiting healthcare professionals (including on the scientific aspects of the medicinal products).

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

The general rules for pharmaceutical advertising as already set out, and in particular Article 9 of the LMP and the principles of the RDAMP, also apply to internet advertising.

Book XII of the Code of Economic Law, setting forth the rules on the digital economy, contains more specific rules on electronic advertising (on websites, by e-mail or through other electronic means). Pharma.be also issued guidelines on mandatory information to be included in internet advertising.

In a nutshell, advertisements on a website by pharmaceutical companies must comply with the following rules:

- it must contain a clearly visible, legible and unambiguous statement that it is an advertisement;
- the pharmaceutical company must be identifiable;
- the relevant general requirements for pharmaceutical advertisements must be complied with; and
- the advertisement must have been notified to the Ministry of Health in advance.

### 7.2 Advertising of Medicines on Social Media

For the advertising on medicinal products on social media, see **7.1 Regulation of Advertising of Medicinal Products on the Internet**.

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

No specific rules exist on the required website security for advertisements directed at healthcare professionals. Nevertheless, a company should take all security means to prevent access by the general public to a website that contains information regarding prescription-only medicinal products, as a lack of adequate measures will constitute a violation of Article 9 of the LMP.

The same applies to websites which contain scientific information regarding non-authorised medicines or off-label indications. A company should take all security means to prevent unrestricted access by the general public to such a website, as any provision of scientific information should generally occur based on specific unsolicited request (see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**).

It is a common practice that pharmaceutical companies make certain parts of their website only accessible to healthcare professionals if they log in with their RIZIV/INAMI-number (RIZIV/INAMI is the Belgian National Institute for Health and Disability Insurance).

### 7.4 Provision of Disease Awareness Information to Patients Online

As mentioned in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**, the provision of disease awareness information generally does not qualify as advertisement, as long as no direct or indirect reference is made to a specific medicinal product. Hence, companies are allowed to provide such disease awareness information to patients online. The online provision of information is not subject to any stricter rules than the offline provision of information.

### 7.5 Online Scientific Meetings

No specific rules govern the sponsorship of online scientific meetings or the virtual attendance by healthcare professionals at such events. The principles regarding the sponsorship of scientific meetings (see **9.3 Sponsorship of Scientific Meetings**) hence apply mutatis mutandis to the sponsorship of online scientific meetings. A pharmaceutical company's contribution to online scientific meetings shall logically be limited to the organisational cost (eg, the cost of the meeting host, compensation for the speakers, etc) or the registration fees for the healthcare professional's attendance at the event. It will not be permissible to sponsor or provide any travel, accommodation or meals in the context of an online scientific meeting, since there is no required travel that would justify the provision of such hospitality.

As set forth below (see **9.3 Sponsorship of Scientific Meetings**), any offered hospitality must in any case be subordinate to the scientific purpose of an event. Moreover, since online events will, due to their nature, not entail an overnight stay, no prior visa will have to be obtained from Mdeon.

In light of the COVID-19 pandemic, many congresses are being organised in a virtual manner, or in a hybrid format, allowing participation both in person and virtually. The pharmaceutical industry federations EFPIA, PhRMA and IFPMA have issued specific joint guidance to clarify the rules and principles in relation to virtual events. According to such guidance, it is generally not permitted to provide hospitality to healthcare professionals for virtual events. With respect to information that is shared during such virtual event, the guidance requires that the pharmaceutical company incorporates adequate safeguards in the virtual booth to be able to identify those wishing to view its booth (HCP or Non-HCP) and therefore determine what information is appropriate for such audience.

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

Articles 504 bis and 504 ter of the Belgian Criminal Code provide the Belgian anti-bribery rules concerning the bribery of private legal entities and private individuals (ie, private bribery). These are the anti-bribery rules applicable to pharmaceutical companies.

Furthermore, Articles 246 to 252 of the Belgian Criminal Code provide the rules concerning the bribery of public legal entities and individuals of holding a public function (ie, public bribery). The rules on public bribery will apply to state-owned (university) hospitals, as well as healthcare professionals employed by such hospitals, since they are then considered to hold a public office.

### 8.2 Legislative or Self-Regulatory Provisions

Pursuant to Article 10 of the LMP, it is forbidden, within the framework of the supplying, prescribing or administering of medicines, to offer, supply or promise (in)direct benefits to healthcare professionals and the healthcare organisations where they work. There are, however, certain exceptions to this prohibition, see **9.1 Gifts to Healthcare Professionals**.

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

Article 10 of the LMP contains a broad prohibition to providing premiums or benefits in cash or in kind to "wholesalers, intermediaries, persons who are entitled to prescribe, dispense or administer medicinal products or to institutions where such prescription, dispersion or administration takes place".

Article 10 of the LMP does, however, contain a limited number of exceptions to this prohibition. As such, it is allowed to provide gifts to healthcare professionals to the extent such gift has a very low value and directly relates to the medical profession of the healthcare professional concerned. Other exceptions are the invitation to and the funding of participation in a scientific event, including hospitality (see **9.3 Sponsorship of Scientific Meetings**) and the reimbursement of legitimate services of a scientific nature, insofar as this reimbursement remains within reasonable limits (see **9.7 Payment for Services Provided by Healthcare Professionals**).

During the parliamentary discussions on the LMP it was acknowledged that EUR50 (VAT included) per gift per healthcare professional or organisation, with an absolute maximum of EUR125 (VAT included) per healthcare professional or organisation per year could be considered sufficiently limited. Even though these thresholds were not explicitly withheld in the LMP, these amounts are considered as the standard within the entire sector (also, pharma.be uses these amounts as the maximum amounts for all of its members).

It is not possible to give cash to healthcare professionals, as this cannot be considered "directly related to the medical profession". The Mdeon Code of Ethics further provides for concrete examples of other types of gifts which are generally not deemed appropriate, such as: decorative objects; digital photo frames; iPods; champagne coolers; coffee machines; mp4s; gift vouchers; discount vouchers; cameras; bottles of wine; tickets for the theatre or other cultural, sporting or recreational events; mobile phones; photo scanners; radios; suitcases; sport/travel bags; alarm clocks; cups; and watches.

Gifts that may be appropriate include medical/pharmaceutical scientific reference works, writing instruments, clinical material and professional use IT accessories.

### 9.2 Limitations on Providing Samples to Healthcare Professionals

The provision of free samples is possible, as long as the rules and obligations of Article 12 LMP and the Royal Decree of 11 January 1993 on medical samples are respected.

As a general principle, samples may only be provided to a healthcare professional authorised to prescribe such a product at his specific request – on the condition that a marketing authorisation has been obtained in Belgium for such medicinal products. The provision of samples is limited to eight samples per product (in its smallest available pack size), per year, per treating physician. Additionally, each healthcare professional may receive no more than 600 samples, in total, per year.

### 9.3 Sponsorship of Scientific Meetings

Pharmaceutical companies may, in principle, both sponsor the attendance of healthcare professionals to continuing medical education (including hospitality) as sponsor the associations that organise such continuing medical education (see **9.1 Gifts to Healthcare Professionals**). Article 10 of the LMP, however, determines that this is only allowed if:

- the event is by its nature exclusively scientific;
- the hospitality is strictly limited to the scientific objective of the event;
- the location, date and duration of the event do not create confusion about the scientific nature of the event;
- the financial contribution to the participation (including the offered hospitality) is strictly limited to the official duration of the event; and
- the coverage of the costs are strictly limited to the healthcare professionals concerned by the event.

For events with an overnight stay, a prior visa must be obtained from Mdeon (see **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines**). Mdeon has provided additional guidelines regarding the hospitality that can be offered to healthcare professionals in the framework of a scientific event (eg, the cost of an overnight stay (breakfast and taxes included) is limited to EUR250, cost of lunch is limited to EUR40, cost of a dinner is limited to EUR80, cost of refreshments is limited to EUR20, and travel within Europe should always be in economy class).

These rules are applicable to hospitality offered to Belgian healthcare professionals or healthcare professionals exercising their profession in Belgium, for scientific events in Belgium as well as abroad.

### 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

The hospitality offered within the framework of a scientific congress must be limited to the organisation, payment or reimbursement of the healthcare professional's travel, meals, overnight stay and registration for the congress. The hospitality may in no case comprise the organisation or funding of any cultural, sports or other leisure activities or any other form of entertainment.

### 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Grants and donations to healthcare professionals, healthcare organisations/charitable organisations are not expressly exempt from the prohibition under Article 10 of the LMP.

In practice, however, the industry can provide grants or donations (eg, money to organise an activity, research equipment) for educational, humanitarian or philanthropic purposes to healthcare organisations and charitable organisations. Grants or donations directly to healthcare professionals are not allowed.

The pharma.be Code of Deontology specifies further that these donations are allowed only if they are made available for supporting healthcare or research and if they do not constitute an inducement to recommend, prescribe, purchase, sell, supply or administer medicinal products. A grant or donation can be provided in cash or in kind.

A typical example of a permitted grant would be the financial support of a scientific research project organised by a healthcare organisation. A permitted donation could consist of making available company expertise for free to an NGO for a humanitarian purpose. However, as the scope of the exception to Article 10 of the LMP in relation to grants and donations is not expressly codified in the legal texts, such events should always be evaluated on a case-by-case basis. Donations relating to the day-to-day operations of the healthcare organisation (payment of the salary of the nursing personnel, renovation works in the hospital, etc) should always be considered as borderline at best and treated with appropriate restraint.

### 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Discounts/rebates (including volume-related discounts) are permitted if they are in line with the (general) principles of economic law (in particular those included in the Code of Economic Law) and applicable competition principles (including on abuse of dominance). The rules on advertisement and inducement may, however, still have an impact on the validity of certain discounts. It is, for instance, almost impossible to offer free authorised medicinal products (except in the case of samples, see above, or other very specific circumstances that will require expert regulatory assistance).

### 9.7 Payment for Services Provided by Healthcare Professionals

Paying healthcare professionals for the provision of services is possible if it concerns services of a scientific nature having a legitimate character. Such services could be, eg, speaker engagements, participation in advisory boards, consultancy and clinical trial services.

Specific Mdeon guidelines prescribe that the healthcare professional's compensation should be reasonable, proportionate, consistent, a reflection of the "fair market value of the services and be in line with the scope and duration of the services" (in function of the complexity, level of experience of the healthcare professional, degree of urgency, etc). It is allowable to reimburse reasonable costs incurred by such healthcare professional in the performance of these services, such as travel, meal and accommodation costs. The prescription behaviour of the healthcare professional must not be a factor for determining the applicable compensation. The provision of services by a healthcare professional may not be used as a loophole to provide (prohibited) advantages to healthcare professionals.

### 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

As mentioned in **9.3 Sponsorship of Scientific Meetings**, a prior visa must be obtained from Mdeon in case of hospitality for HCP's for scientific events with an overnight stay.

The provision of expert services by a healthcare professional may be subject to explicit prior approval from such healthcare professional's employer. In such cases, it is recommended to request a proof of such approval from the healthcare professional.

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

This requirement is set out in Chapter 1 of Title 3 of the Sunshine Act. This Act imposes on pharmaceutical (and medical devices) companies, whether Belgian or foreign, the legal obligation to document and annually disclose on the platform betransparent.be the premiums and benefits that they granted (in)directly to healthcare professionals, healthcare organisations or patient associations.

The transparency obligation is applicable to contributions to the costs of a scientific manifestation, fees for services and consultancy and donations or grants provided to – as applicable – healthcare professionals having a practice in Belgium, healthcare organisations established in Belgium or patient organisations established in Belgium. Gifts, meals and drinks offered during a scientific manifestation, samples, and at arms' length market discounts offered for the sale of

medicinal products do not fall within the transparency obligation under the Sunshine Act.

The provision of premiums and benefits must be made public on an individual basis (on behalf of the recipient who received them directly or indirectly). Each company subject to the notification obligation must make public, for each individual beneficiary, the amounts of the premiums and benefits granted during a calendar year.

Multiple deontological organisations have co-created the Belgian Transparency Register (betransparent.be), which is used for all disclosures under the Sunshine Act. As a general principle, companies must disclose the relevant transfers as described above on a yearly basis, and ultimately on May 31st of the year following the calendar year in which the transfer of value has been made. When a premium or benefit was granted to a healthcare professional indirectly, eg, through a healthcare organisation or corporation, the disclosure should still be made in the name of the healthcare professional.

### Disclosure and Transparency

The disclosure must include the name and company number of the company subject to notification, the name and company number/RIZIV-INAMI number of the beneficiary or any other number that allows the FAHMP to identify the beneficiary and the total amount of the attributed premiums and benefits in respect of the relevant calendar year.

Data published on betransparent.be remains public for three years and will be removed afterwards.

In case an envisaged value transfer cannot take place or has to be redeemed following a cancellation due to COVID-19, the disclosure obligation will not apply. Only transfers of value that actually take place should be disclosed in the Belgian Transparency Register.

## 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

Prior to the entry into force of the Sunshine Act, the transparency obligation for pharmaceutical companies was based on self-regulation. Now that the transparency obligations have been anchored in legislation, these are binding upon all companies within the pharmaceutical (and medical devices) sector (including pharmaceutical companies, importers, manufacturers and distributors), irrespective of whether they are based in Belgium or abroad.

Companies that consist of different legal entities (in different countries) may combine their disclosures in a single publication. In this case, the company that makes the disclosure must provide an explanatory note explaining which legal entities (both Belgian and foreign) were grouped in the single publication.

According to Article 3.1.3 of the RD Sunshine Act, companies subject to notification which are established outside the European Union must make the notification by and in the name of an affiliated company established in the European Union or by a legal representative established in the European Union.

The companies subject to the notification obligation are the holders of an authorisation for placing the medicinal products on the market, importers, manufacturers and distributors of medicinal products, persons engaged in the brokering of medicinal products and distributors, retailers and manufacturers (Article 41, Section 1, 1 of the Sunshine Act). Companies that do not yet have a marketing authorisation are hence not subject to the notification obligation.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

Since breaches of the rules on the advertising of pharmaceutical products are penalised with criminal sanctions under the LMP and the Belgian Criminal Code, the Public Prosecutor and the criminal courts are primarily responsible for the enforcement of the pharmaceutical advertising rules.

The public prosecutor will typically only open a file upon request of the FAMHP, which may also propose a settlement with the company instead of requesting prosecution with the prosecutor.

The pharmaceutical professional associations also have a separate set of penalties susceptible to being imposed on their members following a breach of the applicable deontological code. The Committee for Deontology and Ethics in the Pharmaceutical Industry (DEP Committee) of pharma.be, for example, may impose various corrective, supervisory and financial sanctions on its members. It is also possible for individuals (eg, patients) and competitors to submit a complaint against a pharma.be member at the secretariat of pharma.be (for the attention of the Committee for Deontology and Ethics in the Pharmaceutical Industry). The DEP Committee shall then rule on such complaints. An appeal can be brought before pharma.be's Chamber of Appeal.

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Although direct actions by competitors before the court are not expressly organised under the rules governing the advertising of medicines, competitors can initiate proceedings under general torts law or for breaches of the Code of Economic Law that includes general market practices principles, eg, if they believe that a company's advertising is misleading or creates unfair competition. The Code of Economic Law provides remedies such as cease and desist procedures and the request for compensation for damages on the grounds of unfair competition.

In addition, as breaches of the advertisement rules are criminally sanctioned, a competitor can also file a complaint with a view to the initiation of criminal proceedings by the public prosecutor (see **11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe**).

### 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

Infringements of the rules governing the advertising of pharmaceutical products are sanctioned with fines ranging from EUR1,600 to EUR120,000 and imprisonment sanctions from one month to one year for individuals and with fines ranging from EUR4,000 to EUR240,000 for legal entities. Both the beneficiary of an inducement to prescribe (ie, generally a healthcare professional) as the pharmaceutical company providing such inducements can be sanctioned.

### 11.4 Relationship between Regulatory Authorities and Courts

The self-regulatory deontological codes must be considered as independent rules and means of enforcement. Nevertheless, the pharma.be Code of Deontology explicitly determines that no procedures can be started before the pharma.be deontological bodies if another procedure (on similar grounds) was already conducted in front of another competent authority. If a procedure is initiated before the deontological bodies of pharma.be and a separate procedure is initi-

ated before another competent authority during such procedure, the decision by the pharma.be deontological body will be deferred until the other competent authority has taken a decision (Article 78 pharma.be Code of Deontology).

It is also possible that a deontological organisation notifies a breach by one of its members to the regulatory authorities or the public prosecution (this is, for instance, explicitly provided for in the pharma.be Code of Deontology). Of course, regulatory authorities, courts or the public prosecution will only be competent to decide on a breach of a deontological code if it also constitutes a breach of the applicable legal framework (notably the LMP and the RDAMP).

### 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

There are no noteworthy developments in relation to the enforcement of the rules on pharmaceutical advertising.

**QUINZ** is a Brussels-based law firm, founded in 2011, with a strong focus on life sciences. The firm's life sciences team consists of 12 lawyers. Quinz assists the global, regional (EMEA, LATAM, APAC) and local (Belgian, Luxembourg and the Netherlands) legal departments of pharmaceutical companies on a broad array of (strategic, operational, licensing and M&A) transactions throughout the life cycle of a life sciences product. Quinz has also developed a sound expertise in regional and local regulatory work, including pricing and reimbursement, clinical trials, data transparency, marketing authorisation procedures, cGMP and compliance matters, including transfers of value, promotion of drug products, antitrust compliance questions and patient-directed programmes.

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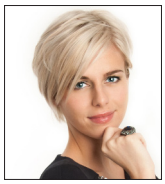

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# BRAZIL

## Law and Practice

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# 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

## 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The manufacturing, distribution, marketing, import and export of medicinal products in Brazil are mainly regulated by the National Sanitary Surveillance Agency ("ANVISA" or the "Regulatory Agency").

The advertising of pharmaceuticals, as well as of other products that may affect health, as provided for in paragraphs 3 and 4 of Article 220 of the Federal Constitution, are subject to legal and regulatory restrictions. The limits that the Regulatory Agency has in the imposition of restrictions on the advertising of non-prescription drugs are the subject of heated debate between the regulated sector and the government, including a few judicial discussions.

The main legal instruments that essentially regulate advertising and the promotion of medicinal products in Brazil are as follows.

### Laws and Decrees

- 6.360/76 regulates the sanitary surveillance to which medicinal products and their ingredients, medical products, cosmetics and cleaning products are subject – the implementation of this law is regulated by Decree 8.077/2013;
- 6.437/77 defines violations of the federal sanitary legislation and establishes the corresponding penalties;
- 8.078/90 the Consumer Protection Code;
- 9.294/96 imposes restrictions on the advertising of medicinal products, products for smoking, alcoholic beverages, therapies and crop-protection products – the implementation of this law is regulated by Decree 2.018/96; and
- 9.782/99 sets forth the statutory competence of the Regulatory Agency, ANVISA – the implementation of this law is regulated by Attachment I of Decree 3.029/99.

### Resolutions and Other Ancillary Regulations Issued by ANVISA

- RDC 096/2008 (as amended by RDC 023/2009) regulates advertising and promotional actions in all their forms and media (some concepts are defined in Normative Instruction ANVISA 05/2009);
- RDC 060/2009 regulates the production, distribution and control of free samples; and
- Ordinance 344/98, issued by the Ministry of Health before ANVISA was created, remains in force and regulates medicinal products containing substances under special control (narcoleptics, anorexigenic drugs, antiretroviral drugs, immunosuppressants, and others), including their advertising and promotion.

### Resolutions of the Federal Council of Medicine – "CFM"

- 2.217/2018 – Medical Profession Code of Ethics.

## 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Self-regulatory codes in Brazil, in general, apply only to members of class associations that have enacted these codes. Pharmaceutical Class Associations that have enacted self-regulatory codes to date are:

- INTERFARMA (Brazilian Association of Research-Based Pharmaceutical Industries);
- ABIMIP (Brazilian Association of Manufacturers of Non-prescription Drugs); and
- SINDUSFARMA (Pharmaceutical Employers Union of the State of São Paulo).

Brazil also has a National Council of Self-Regulation in Advertising ("CONAR") that enacted a code regulating public advertising and, in the

case of pharmaceutical products, applies exclusively to non-prescription drugs that may be advertised to the public in general. In fact, the CONAR code has a chapter specifically directed at the advertising of non-prescription medicines. CONAR's code applies to any advertisement in Brazil, even if the advertiser is not a member of the council.

As a rule, decisions from self-regulatory bodies are not made public, but competent authorities and the judiciary may (and do) use decisions issued by self-regulatory bodies as a basis for their decisions, if these decisions are brought to their attention.

## 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

### 2.1 Definition of Advertising

ANVISA defines the advertising/publicity of pharmaceutical products in Resolution RDC 096/2008, as: "the array of information and persuasive techniques and activities with the objective of publicising knowledge, making a product or trademark more widely known or the object of prestige, aiming to influence the public by means of actions intended to promote and/or induce the prescription, dispensing, purchasing and use of a medicinal product".

### 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Initially, it is important to keep in mind that advertising of prescription drugs to the lay public is prohibited in Brazil. That said, as a rule, information will usually be seen as "advertising" if it includes products' trade marks and standard promotional messages.

The category of "information" includes disease awareness campaigns, related leaflets and other information directed to patients and/or to the general public, which are widely used in Brazil. This includes health-related campaigns by private industries and does not qualify as advertising.

In fact, Brazilian health authorities implement several campaigns each year especially related to vaccines, AIDS prevention, hepatitis, influenza, COVID-19, and tropical diseases. In disease awareness campaigns, it is prohibited to mention any specific trade mark or name of a medicinal product. The campaigns must simply provide an incentive for the population to consult with healthcare professionals for diagnosis or to go to doctors or health clinics (private or public) for vaccinations.

### 2.3 Restrictions on Press Releases regarding Medicines

Press releases are allowed in Brazil and widely used. Although there is no specific legislation regulating this issue, in some cases, health authorities have argued that some releases (or articles published in lay media) were, in fact, disguised "advertising". Because of that, in preparing press releases the use of trade marks or trade names should be avoided in favour of using the name of the active ingredient.

### 2.4 Comparative Advertising for Medicines

Comparative advertising is allowed and RDC 096/2008 sets forth the rules to guide authorised comparisons.

#### Price Comparisons

Price comparisons are only allowed between medicines considered as interchangeable under applicable law and regulations. As a rule, only reference products and generics would be interchangeable. In the case of Brazil, even though

"similar products" (generics bearing trade marks) must demonstrate bio-equivalence to the reference product, the use of comparative advertising is still the subject of some discussion.

### Comparative Advertising

Comparative advertising, in general, must also abide by several different pieces of legislation and regulations, including:

- the Industrial Property Law;
- the Class Associations' Codes of Ethics; and
- the National Code of Self-Regulation in Advertising.

### Self-Regulation and the Code of Conduct

CONAR's National Code of Self-Regulation in Advertising states that all comparative advertising must focus on objective aspects of the products and that the advertiser must be able to prove the conclusions of the comparisons. Also, it is forbidden to deprecate the compared brand or to create confusion between the products.

The INTERFARMA Code of Conduct, for instance, prohibits comparative advertising using third-party brands without their prior consent. However, it does allow comparisons between active ingredients even if indirect identification of brands could be possible. Any decision to engage in comparative advertising must be carefully evaluated.

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

The provision of information about unauthorised medicines and/or unauthorised indications (off-label) are, as a rule, not allowed in Brazil. Some information may be provided in medical events or through press releases but, as mentioned, the use of trade marks should be avoided.

### 3.2 Provision of Information during a Scientific Conference

Information on unauthorised medicinal products and/or off-label information can only be published as scientific information. As a result of this, if the product already has a trade mark, its use should be avoided. The INTERFARMA Code of Conduct sets forth that information on unregistered products or off-label indications may only be used in the context of medical and scientific information at congresses, symposiums or other scientific events.

If any company does disclose information on unauthorised medicines, the audience must be duly and previously informed that the product is not yet available in the market and that its use has not been approved by the regulatory authorities.

### 3.3 Provision of Information to Healthcare Professionals

Although Brazilian pharmaceutical legislation and ancillary regulations strictly prohibit the advertising of medicinal products that have not been registered by ANVISA, products that have not yet been authorised may be discussed at scientific events (congresses, symposiums,

etc), whether the event is sponsored solely by the company responsible for the product or not. These discussions must be restricted to technical information, eg, important findings in ongoing clinical studies, and should not use product trade marks to avoid being perceived as an inducement to prescribe.

It should be noted that the legislation does not mandate a previous request from the healthcare professional for such information. However, the INTERFARMA Code of Conduct states that this type of information, in principle, can only be sent if requested by the professional.

The same rules apply to off-label information. In this case, too, it is advisable not to use the trade mark of the product, but rather just the name of the active ingredient.

### 3.4 Provision of Information to Healthcare Institutions

See **3.3 Provision of Information to Healthcare Professionals**.

### 3.5 Publication of Compassionate Use Programmes

There is no specific regulation on the publication of the availability of compassionate programmes.

It is important to say that while the production, distribution and sale of medicinal products that are not yet registered by ANVISA are prohibited, it is possible for an individual to import non-registered products for their own use, independent of previous authorisation. For this, it is only necessary to provide the importer with a specific prescription from a medical doctor duly registered to practise medicine in Brazil.

Importation for groups of patients can only be made through "compassionate use" or "expanded access" programmes that depend on ANVISA's previous authorisation but, as a rule, no public information is released. These types of programmes are mainly used in relation to patients who have participated in clinical studies, for access to the study drugs after the end of the study, while the product is undergoing registration.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Only over-the-counter (OTC) pharmaceuticals can be advertised to the general public in Brazil. Prescription-only products can only be advertised to prescribing professionals. While no restrictions apply for OTC medicines, advertising guidelines must be followed.

### 4.2 Information Contained in Pharmaceutical Advertising to the General Public

Advertisement of medicinal products to the public in Brazil must always include the following generic warnings: "If the symptoms persist, consult a doctor", and "This is a medicinal product, and its use involves risks. Consult with a doctor and a pharmacist. Read the insert/leaflet".

The above-mentioned warnings must be included. Additional warnings regarding a specific active ingredient may be required by health authorities in relation to any product.

#### Restrictions on Advertising Non-prescription Medicinal Products

The following restrictions also apply to the advertising of non-prescription medicinal products:

- there can be no use of expressions such as "shown in clinical studies" or "scientifically proven";
- the advertising piece cannot suggest that the product would make healthy habits and visits to doctors unnecessary;
- there can be no use of celebrities stating or insinuating that they make use of the product;
- the piece cannot use language that relates the product to excessive intake of alcohol or food;
- there may be no language relating the use of the product to physical, intellectual, emotional or sexual performance or to a person's looks/complexion, except if the product has been approved by ANVISA for these specific properties;
- the piece cannot present visual representations of changes in the human body caused by illnesses or lesions in an abusive, frightening or misleading way; and
- the piece cannot include messages, symbols or images of any nature directed at children or teenagers.

### Restrictions on Advertising to Professionals

Even considering that advertising of a medicinal product can only be made to prescribing professionals, the advertising cannot:

- foster indiscriminate use of medicinal products;
- suggest or stimulate diagnosis; and/or
- suggest that a medicinal product is tasty, yummy or delicious.

## 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

There is very little legislation and/or ancillary regulation on the subject but, as a rule, direct interaction with patients is not allowed (except for through "call centres" or "access/adherence programmes"), while interaction with patient organisations is allowed. The INTERFARMA Code of Conduct, unlike the legislation, does expressly address the issue. For instance, the code expressly prohibits the industry from interfering with the administration of the organisation or participating in it. The code also prohibits an industry from being the sole contributor to any organisation.

Because of the high level of judicialisation of health treatment in Brazil, health authorities have been keeping a close watch on the relationship between the industry and patient associations.

Authorities believe, and in some cases found it to be true, that some donations made to patient support groups were being used to pay legal fees and the expenses necessary for patients to sue the government in order to receive treatment (medicines or medical treatment) not yet available in the public system or not yet registered in Brazil. Note that under the interpretation of the constitution by the courts, the government is obliged to provide medicines, for free, for those that cannot pay for them.

Most police investigations made over the past decade ended without finding hard evidence on the alleged financing of patient associations for the purpose of subsidising judicialisation, but a few cases are still ongoing. Most of these cases refer to "high-cost" and "high-complexity" medicines.

The judicialisation of health is a big issue in Brazil.

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

This is regulated under RDC 096/2008. The required information in advertising to healthcare professionals is:

- brand name;
- name of the active ingredient as it appears in the Common Brazilian Denomination – "DCB";
- ANVISA product registration number;
- indications;
- contraindications;
- warnings related to adverse reactions and interactions with other substances;
- dosage;
- prescription and dispensing classification; and
- date of printing.

Where a promotional piece on a prescription drug highlights the benefits of the product, the piece must also highlight at least one contraindication and one frequent drug interaction.

For vaccines, the advertisement must convey the necessary number of doses for complete immunisation.

Products containing substances under special control, as defined in Ordinance 344/98 (see **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines**), are subject to further regulation.

### 5.2 Reference to Data Not Included in the Summary of Product Characteristics

Advertising to prescribing professionals may contain information related to data held on file or to clinical studies that have not been included in the registration package, or even phase 4 studies. The information, however, must conform to the information (indications, dosage, etc) already approved by ANVISA and must be available for consultation if requested by healthcare professionals or by the authorities. Information that does not conform to the registration package will be deemed as promotion of unauthorised use (off-label).

### 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

Pharmaceutical products in Brazil may only be promoted for the indications that are approved by ANVISA, and such indications are those included in the registration package. That said, for it to be possible to promote any product, even in combination with another product, it would be necessary to amend the product registration to include this "combined use indication" in the product registration package and have it approved by ANVISA.

### 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

These are generally considered as scientific information and, as such, reprints may be distributed to healthcare professionals. There are no specific restrictions, but the reprint should not come in a format that resembles a promotional piece. For the distribution of reprints, a company must have the authorisation of the author or of the media, as the case may be.

### 5.5 Medical Science Liaisons

There are no specific regulations related to medical science liaisons (MSLs) who – in Brazil – are under the same rules applicable to pharmaceutical representatives. Although most MSLs are themselves healthcare professionals, they cannot discuss unauthorised medicines or off-label indications.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

No prior authorisation applies to advertising of medicines. However, RDC 096/2008 sets forth that the organisers of scientific events at which the advertising and promotion of medicinal products will take place, must inform ANVISA three months in advance of any such event, indicating the date and place of the event and the professional categories that will be invited to the event.

### 6.2 Compliance with Rules on Medicinal Advertising

There are no arrangements or standard operating procedures (SOPs) required by law or regulation in Brazil, in relation to advertising or promotional activities.

Companies are free to establish these according to their own policies. Companies are also free to not even implement any SOPs to guide their promotional activities.

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

The internet is regarded as just another form of media and, as such, the same legislation and regulations that apply to the advertising of medicinal products in traditional media in Brazil also apply to advertising on the internet, meaning that only advertising of over-the-counter medicines is allowed.

If companies have internet sites that carry or include any type of promotion or advertisement of medicinal products, they need to ensure that advertising and promotion of prescription products can only be accessed by prescribing professionals.

RDC 096/2008 has only a few regulations that are specific to internet advertising. These regulate, for example, how warnings must appear (even indicating the type of font or requiring the use of bold fonts and capital letters in some specific cases).

In addition, CONAR recently issued its Digital Influencer Advertising Guidelines, which are also applicable to advertising of any medical product using digital influencers, mainly regarding its clear identification as an explicit advertisement.

It should be stressed that ANVISA does monitor the health-related sites of pharmaceutical companies, pharmacies, distributors, clinics, etc, to make sure these rules are followed. However, exercising control over the content of internet sites is difficult as they exist in vast numbers and most of them contain a lot of information and countless different pages and/or links. That said, it is not common to see violation notices or fines applied for non-compliance with internet rules.

### 7.2 Advertising of Medicines on Social Media

See **7.1 Regulation of Advertising of Medicinal Products on the Internet**.

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

As the promotion/advertising of prescription medicines can only be made to healthcare professionals, any website containing adverts of these products must have access controls and restrictions.

### 7.4 Provision of Disease Awareness Information to Patients Online

Online disease awareness campaigns are allowed and, in fact, are very common in Brazil. The Brazilian health authorities are among the more common users of these campaigns and implement several of them each year especially related to vaccines, AIDS, hepatitis, influenza, and tropical diseases. These campaigns can be found on the internet sites of the Ministry of Health, the State Health Department and even municipal health departments.

Note that in online disease awareness campaigns, and/or material provided through this channel, no specific medicinal product or trade mark should be mentioned. The campaigns should simply provide an incentive for the population to consult with healthcare professionals for diagnosis or to go to doctors or health clinics (private or public) for diagnosis or vaccination.

### 7.5 Online Scientific Meetings

The rules applicable to scientific meetings or congresses also apply to online events. Although there are no specific rules issued to online scientific meetings in Brazil, the sponsor should implement the same filters and controls required at presential events of the same nature. That said, these online meetings may or may not be considered international depending on their scope and content. No previous authorisation is needed.

In the same manner applicable to online advertisement of prescription-only drugs, access to online materials must be subject to appropriate controls and restrictions during and after the online meeting or congress.

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

There is no anti-bribery/anti-corruption legislation or regulations specifically applicable to the interaction between pharmaceutical companies and healthcare professionals/organisations, or to the pharmaceutical industry in general.

In Brazil, bribery and corruption are regulated by:

- the Penal Code, as amended by Federal Law 10.467/2002;
- Federal Law 12.846/2013, which penalises actions against national or foreign public administrations (penalties apply to both individuals and organisations); and
- Federal Law 8.249/1992, applicable specifically to public workers/agents.

Anti-bribery/anti-corruption authorities will only investigate breaches related to advertising of pharmaceutical products to the extent that the breach constitutes an action of corruption or bribery.

### 8.2 Legislative or Self-Regulatory Provisions

As per applicable regulations, especially Resolution RDC 96/2008, pharmaceutical companies are not allowed to grant, offer, promise or distribute gifts, benefits and advantages to:

- professionals who prescribe or distribute medicines;
- those who directly sell medicines to consumers; and
- the public in general.

The rules apply to both individuals and/or organisations.

INTERFARMA also expressly regulates the issue in basically the same way as RDC 96/2008. Violation of the INTERFARMA code will subject the company to administrative penalties, eg, suspension or exclusion from the association and a pecuniary penalty that may be extremely steep.

It should be noted that the Federal Medicine Council, which regulates the medical profession in its Code of Conduct and Resolution 1.939/2010, prohibits physicians from participating in any advertisements or promotion of medical information for any promotional purposes and, also, to register patients or enrol them to participate in promotional actions, such as discount programmes.

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

Companies may offer gifts to healthcare professionals. However, as per the applicable regulations, only gifts of nominal value can be offered and these gifts must be of an "institutional" nature, meaning they cannot bear marks or signs that link them to any specific product. Some class associations like INTERFARMA, also require that the gifts:

- be related to the medical practice, which excludes all kinds of office supplies and gifts of a personal-use nature that are not considered directly related to the medical practice;
- are of a symbolic value (around USD50); and
- are limited to three per year per doctor.

### 9.2 Limitations on Providing Samples to Healthcare Professionals

Samples may be provided to healthcare professionals, with a few exceptions:

- samples of non-prescription products;
- biological products; and
- products prepared in compounding pharmacies.

The procedures related to the distribution of samples are clearly regulated in RDC 096/2008 and RDC 060/2009. Products containing substances under special control, eg, narcoleptics, which are included in Ordinance 344/1998 (controlled substances) are subject to additional regulations.

A free sample package must contain 50% of the quantity of an original package. However, in the case of products for chronic diseases and a few others, like contraceptives, samples must have the same quantity of the registered original. Samples of antibiotics must contain a complete treatment for one patient. Applicable regulations require that free sample packages are clearly and indelibly marked with the words "free sample".

The distribution of free samples is limited to ambulatories, hospitals, medical doctors' offices, and dentists' offices. The prescribing professional receiving the samples must sign a document indicating receipt of the samples.

Regulations on samples, especially RDC 060/2009, require that holders of the product registration must keep on file, for a minimum of two years after each lot's expiry date, all documents related to the production, distribution, and pharmacovigilance data of the free samples, even if not distributed, and must send ANVISA, annually, information on the production and distribution of free samples.

### 9.3 Sponsorship of Scientific Meetings

The sponsorship of scientific events by pharmaceutical companies is allowed and is also regulated under RDC 096/2008, although there is no direct or specific regulation that directly mentions hospitality.

The INTERFARMA Code of Conduct is more detailed than the ANVISA regulation and does indicate that locations of primarily touristic appeal are not permitted. No approval from the local affiliate is required.

There is no specific threshold applicable, but the venues and activities must not be excessive or inappropriate for a healthcare event. Under the INTERFARMA Code, events should take place in the country where the organiser is located, except if the choice of a foreign country is justifiable for reasons of security or logistics.

It should be noted that payment or any type of remuneration, direct or indirect, for the time invested in participation cannot be made to participants. Also, payments for travel, accommodation, food, etc, are limited to the participant and cannot be extended to family members or other invitees of the doctor.

### 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies are allowed to organise and sponsor cultural, sports and other events, provided they are under the corporate trade marks of the companies concerned. These types of events cannot be organised using the names or trade marks of prescription-only drugs.

### 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

There is no specific regulation in Brazil with direct and clear wording on this.

However, throughout the applicable legislation and ancillary regulations it is made very clear that promotional actions towards prescribing professionals should not be (or be understood to be) in exchange for prescriptions of any product. In this case, also, it is advisable that grants and donations are regulated by contracts indicating the reason for the grant or donation.

In relation to healthcare institutions, these donations must also be of an institutional nature. In addition, they must clearly not be linked to any requirement or for the effect of serving as an incentive for the recipient institute to promote, advertise or standardise the use of any medicinal product of the donor.

Donations should be covered by contracts that should have a specific clause to make this as evident as possible. The contracts may, and should, define the specific purpose of the donation and include clauses that give the donor the right to audit the use of the donations.

From a regulatory point of view, there is no difference between monetary or equipment donations. Some donations may be subject to taxation and specific rules will apply.

### 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Usually, rebates or discounts are granted to distributors and retailers. The industry is allowed to grant discounts and rebates, provided they are within commercial market practices and in line with the rules set forth in RDC 096/2008.

### 9.7 Payment for Services Provided by Healthcare Professionals

Companies may hire healthcare professionals to render any reasonable and justifiable professional services such as consulting services and

review of dossiers, etc. Payment for the services must be within market practices.

When hiring professional services from healthcare professionals, a contract should be executed clearly defining the services to be provided. If a healthcare provider is hired to give classes and/or presentations at the start of any such class or presentation, the doctor must indicate that they are receiving payment for that service as disclosure of potential conflict of interest.

### 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

Healthcare professionals either linked to government institutions or private companies must observe transparency and the conflict-of-interest norms set forth in their respective employment agreements and in the applicable law. Usually, government employees are prevented from rendering services to any private companies even if there is no apparent conflict of interest. Government employees may give speeches and/or presentations but cannot be paid for these. In some cases, prior authorisation or notification may apply, mostly for healthcare professionals, employed by private companies.

Furthermore, organisers of scientific events at which the advertising and promotion of medicinal products will take place, are also required to inform ANVISA three months in advance of any such event, indicating the date and place of the event and the professional categories that will be invited to the event.

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

Resolution RDC 096/2008 requires that healthcare professionals disclose to events' organisers and participants any sponsorship by companies and/or eventual conflicts of interest.

There is no obligation to disclose the amount or details of any sponsorship. Speakers at events, symposiums, congresses, etc, must, however, disclose if they are sponsored by any company at the start of their presentation and in the records of the event, if they exist.

It is important to point out that INTERFARMA's Code of Conduct recommends making the public receptors of sponsorships and donations.

### 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

See **10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value**. In cases where the donor is a foreign company not subject to Brazilian Law, authorisations and notifications, if any, should be addressed by the grantee.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

Enforcement of advertising rules is mainly exercised by ANVISA. The ANVISA department that holds the authority for supervising and judging advertising/promotional violations is located

under the General Management in Charge of Sanitary Inspection and Supervision ("GGFIS").

As regulated by RDC 096/2008, the authorities also have the power to request that, if corrective statements are required, these will be issued and published by the companies.

Any final administrative decision, as per Brazilian law, may be submitted to the judiciary if the regulated entity/individual believes the administrative decision does not conform to the law. Enforcement may also be sought through class associations such as INTERFARMA, ABIMIP or SINDUSFARMA.

Finally, in the case of non-prescription medicines, enforcement may be sought through CONAR.

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Proceedings may be initiated ex officio by the Regulatory Authority, or by a competitor. Most of the time, the basis is some indication or evidence that the advertising rules have been breached by the accused party. Proceedings can be started before ANVISA and/or before any of the class associations mentioned.

### 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

Penalties imposed by ANVISA will range from:

- a warning;
- the prohibition of advertising; the obligation to provide a rectifying message; suspension from new advertisements; and/or
- the payment of a fine that may range from BRL2,000 to BRL1.5 million.

The penalties imposed will depend on ANVISA's evaluation of the gravity of the violation.

### 11.4 Relationship between Regulatory Authorities and Courts

There is no relationship between the Regulatory Authority and the courts. However, the courts will tend to confirm decisions of the Regulatory Authority or class associations, as they realise that these bodies have a better technical knowledge of the field.

### 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

Recently, there has been a wave of comparative OTC advertisements and, given the speed necessary to block irregular advertising, CONAR has taken the lead in ruling these cases. The most significant decisions were about the veracity of the comparisons and the irregular use of trade marks in the advertisement (one leading case is: CONAR representation 240/19).

**Lopes Muniz Advogados Associados** is recognised as a multi-field action firm, known for solutions that grant security to its clients and give them the confidence they need to face their legal challenges. In the field of life sciences, the firm renders services in the areas of pharmaceutical and biological products, other health-related products (medical devices), food and food supplements. The firm's work model is based on specialised teams, led by one or more partners, that have hands-on participation in finding solutions and in determining strategies for each case, assuring high-quality legal advice. The firm's life sciences area is composed of a team of lawyers with recognised experience in regulatory and sanitary legislation.

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# CHINA

## Law and Practice

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## 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

### 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

Under the PRC legal system, advertising on medicines is subject to the following regulations.

- The Advertising Law serves as the foundation and was promulgated to regulate all types of advertising. It contains general principles and special provisions for pharmaceutical advertising. Regulators issue detailed measures for drug advertisements under the Advertising Law.
- The Drug Administration Law regulates the whole life cycle of a drug, including its advertising and promotional activities.
- The Anti-Unfair Competition Law prohibits unfair competition activities, including fraud, misleading promotions and commercial bribery. This general law applies to the pharmaceutical industry.

The major laws and regulations are:

- the Advertising Law (latest revisions effective in 2021);
- the Anti-Unfair Competition Law (latest revisions effective in 2019);
- the Interim Provisions on Banning Commercial Bribery;
- the Law on the Protection of Consumer Rights and Interests (latest revisions effective in 2014);
- the Drug Administration Law (latest revisions effective in 2019);
- the Regulations on the Control of Advertisements;
- the Implementing Regulations of the Drug Administration Law (latest revisions effective in 2019);
- the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes ("Administrative Measures for Review of Drug Advertisements");
- the Administrative Provisions on Pharmaceutical Directions and Labels;
- the Interim Measures for the Administration of Internet Advertising;
- the Administrative Measures for Online Drug Information Services (latest revisions effective in 2017);
- the Administrative Measures for Record-Filing of Medical Representatives (for Trial Implementation) ("Administrative Measures for Medical Representatives");
- the Administrative Measures for the Receipt of Public Welfare Donations by Health and Family Planning Agencies (for Trial Implementation) ("Administrative Measures for the Receipt of Public Welfare Donations"); and
- the Nine Criteria for the Incorrupt Practice of Staff of Medical Institutions ("Nine Criteria").

In addition to the above laws and regulations, industrial associations and institutions also have their own codes of conduct to regulate members' promotion and advertising activities. These are normally referred to as "industry benchmarks". The major self-regulatory codes for medicine advertising include:

- the R&D-based Pharmaceutical Association Committee Code of Practice (the "RDPAC Code" – latest revisions effective in 2019) – the RDPAC is a member of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA);
- the Code of Ethics for Pharmaceutical Enterprises in China;
- the Code of Ethics for Licensed Doctors in China;

- the Code of Professional Ethics for Licensed Pharmacists in China;
- the Guidance for Application of the Code of Professional Ethics for Licensed Pharmacists in China; and
- the Draft Code of Conduct for Chinese Medical Representatives (which has not yet been officially promulgated).

### 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The self-regulatory codes generally apply to the members of the relevant associations, including member organisations and/or individual members.

For example, the RDPAC Code applies to RDPAC's member companies (although the annotation of the RDPAC Code further notes that the Code covers all relevant company employees as well as subcontractors that carry out tasks on behalf of the company). The Code of Ethics for Pharmaceutical Enterprises in China in principle applies to its member organisations, including RDPAC and other associations.

Other self-regulatory codes apply primarily to individual members. The Code of Ethics for Licensed Doctors in China applies to licensed physicians, licensed assistant physicians, scholars and health administrative personnel, as well as healthcare institutions and certain other organisations. The Code of Professional Ethics for Licensed Pharmacists in China and the Guidance for Application of the Code of Professional Ethics for Licensed Pharmacists in China apply to all licensed pharmacists and other pharmaceutical technicians who temporarily perform the duties of licensed pharmacists.

None of these self-regulatory codes are mandatory. They are contractual in nature and reflect a certain level of industry consensus among a large group of market players. Some of these self-regulatory codes may reflect higher standards than laws and regulations. Others elaborate on issues with respect to which the law is silent, such as the scope of communications allowed with respect to off-label use of medicines and the level of substantiation required for promotional purposes. Certain self-regulatory codes, such as the RDPAC Code, also provide an alternative dispute resolution programme for their members, including panel reviews, mediation and sanctions.

## 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

### 2.1 Definition of Advertising

The definition of advertising under the Advertising Law is broad. Advertising appears to cover any commercial activities whereby business operators or service providers directly or indirectly introduce and recommend products or services they are marketing by using certain forms of media.

The former State Administration for Industry and Commerce (SAIC), now reformed into the State Administration for Market Regulation (SAMR), and the Legislative Affairs Commission of the Standing Committee of the National People's Congress, summarise the characteristics of advertisements in their interpretations of the Advertising Law. They define an advertisement as a commercial activity that:

- is transferred through certain media (including both traditional media and new media), rather than directly between individuals or groups of individuals (eg, speech to specific audiences in a conference; one-to-one oral introduction to patients in a pharmacy);

- points to a specific commodity or service of a business operator as the identifiable beneficiary (the advertiser); and
- is for-profit and promotional purpose, ie, its purpose is to influence the public's attitude towards the commodities or services.

## 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

For the purposes of this section, "information" in the narrow sense refers to the factual description and introduction of products and services. Under the Law on the Protection of Consumer Rights and Interests, consumers are entitled to know the correct information about the products and services, such as the price, place and date of manufacture, and term of validity.

Advertising, however, is about making recommendations for products or services. Its main purpose is to generate a positive attitude in the audience towards the products or services being presented.

### Law Enforcement Perspective on Advertising

From a law enforcement perspective, the "information" part of an advertisement is not subject to legal scrutiny under the Advertising Law. For example, when reviewing the content of an advertisement, the State Administration for Market Regulation tends to carve out the information that is required by laws and regulations to be provided to consumers, and will only scrutinise the rest of the advertisement as a "commercial advertisement".

### Qualifying Events as Advertising

Whether disease awareness campaigns may qualify as advertising depends on whether the event is promotional in nature. If a disease awareness campaign simply provides general disease awareness information, then it is not likely to be regarded as advertising. If the information provided can be either individually or collectively viewed as pointing to a specific product, such information may be considered "drug information" and the campaign may be considered promotional in nature and may fall into the scope of advertising. Under the Administrative Measures for Review of Drug Advertisements, "drug information" may include drug names, diseases to which the drugs are applicable (functions and indications) or other drug-related content.

A disease awareness campaign may be aimed at healthcare professionals, patients or the general public, and there is no legal difference based on the type of audience. In practice, however, if a disease awareness campaign targets the general public, product-specific information is generally not allowed to be mentioned; otherwise, law enforcement is more likely to regard the campaign as advertising. Other compliance requirements are discussed in **7.4 Provision of Disease Awareness Information to Patients Online**.

## 2.3 Restrictions on Press Releases regarding Medicines

The law in China does not prohibit press releases regarding medicines, but promotion of medicines in the disguised form of press releases without prior regulatory approval is restricted. In practice, press releases are allowed only if they contain a strictly factual description of the medicine, such as the completion of clinical studies, the obtainment of relevant market approval, or the launch of a new product in a new jurisdiction. If the content of the press release exceeds such limited scope and includes elements of advertising/promotion, then it may fall into the scope of advertising and become subject to the Advertising Law.

There are generally no differences between press releases available in the specialised trade press and press releases in mainstream media.

### 2.4 Comparative Advertising for Medicines

The Advertising Law explicitly prohibits comparative advertising for medicines with respect to the medicine's efficacy and safety.

Comparison may nevertheless be allowed if the underlying activity is considered to be outside the scope of advertising. Under the RDPAC Code, comparison with other pharmaceutical products is generally allowed if the comparison is based on relevant and comparable aspects of the products and is capable of substantiation. Comparative claims, where possible, must not be misleading.

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

PRC laws do not expressly prohibit the provision of information on unauthorised medicines or unauthorised indications but this is nonetheless prohibited under the Advertising Laws if the sharing or provision of such information constitutes advertising. Under the Advertising Laws:

- almost all drug advertisements are subject to the pre-approval of the local counterparts of the National Medical Products Administration (NMPA; formerly known as China Food and Drug Administration) before release; and
- only advertisements of authorised medicines can be approved by the local NMPA (advertising may not refer to anything that is inconsistent with the medicine's instructions as approved by the authorities).

Therefore, where there is a lack of market authorisation, advertising on unauthorised drugs is unlikely to be approved and permitted by the local NMPA.

As mentioned previously, the definition and concept of "advertising" is vague and could have broad scope. In practice, pharmaceutical companies in China are cautious in providing information on unauthorised medicines or unauthorised indications, to avoid what could constitute illegal advertising. Benchmark practice discourages this activity. For example, the RDPAC Code states that no pharmaceutical product may be promoted for use in China until the requisite marketing authorisation for such use has been given by the NMPA.

Also under the RDPAC Code, in one-on-one visits with healthcare professionals, medical representatives are not allowed to provide information on unauthorised medicines or unauthorised indications without the supervision of medical experts (see **3.3 Provision of Information to Healthcare Professionals**).

### 3.2 Provision of Information during a Scientific Conference

There is no direct legal prohibition against providing information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals.

According to the RDPAC Code, off-label promotion is prohibited, but the prohibition is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. Also, the Code is not intended to restrict the full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigative findings in scientific or lay communications media and at scientific conferences.

Therefore, information on unauthorised medicines or unauthorised indications is generally allowed if it is confined to scientific exchanges and is not promotional in nature. However, if the information is promotional in nature, law enforcement may easily view it as prohibited advertising, especially if there is a large audience.

### 3.3 Provision of Information to Healthcare Professionals

Under Administrative Measures for Medical Representatives, medical representatives are prohibited from misleading doctors on the usage of drugs, exaggerating or misleading the curative effect, concealing known information on adverse drug reaction and the information on adverse drug reaction reported by healthcare professionals. The pharmaceutical company as the marketing authorisation holderof the medicines is required to promptly correct any aforesaid wrongdoing by the medical representatives.

Therefore, when medical representatives are discussing scientific information on unauthorised medicines or indications with healthcare professionals, such information must conform with the aforementioned requirements. It is also advisable to have the competent department of the company review such information in advance, to ensure the accuracy of the contents. The RDPAC Code states that pre-approval of off-label communication with healthcare professionals, whether in oral or written form, should be conducted by or under the supervision of medical experts instead of personnel with commercial functions.

### 3.4 Provision of Information to Healthcare Institutions

Public healthcare institutions in China generally do not procure drugs on their own initiative. Procurement is organised by the government through bidding performed on bidding platforms (including the recent volume-based procurement). Thus, public healthcare institutions usually do not have direct access to information on unauthorised medicines or unauthorised indications for the purposes of preparing budgets. Conversely, the relevant government departments involved in public bidding, such as the NMPA, the National Health Commission and the National Healthcare Security Administration, may access such information.

### 3.5 Publication of Compassionate Use Programmes

The concept of compassionate use programmes is only generally mentioned in the Drug Administration Law as a form of early access for patients. The draft measures regulating the use of medicines in extended clinical trials for compassionate use have not yet been promulgated.

PRC laws do not expressly prohibit the publication of compassionate use programmes, however, if information on a programme that is released to the public cannot be proved necessary for the purpose of an expanded clinical trial for compassionate use, it might constitute advertising, which is not allowed to provide information on unauthorised medicines or unauthorised indications, as discussed in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Not all categories of medicines can be advertised to the general public. The Administrative Measures for Review of Drug Advertisements strictly prohibit advertising for several special categories of medicines such as:

- narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs;
- pharmaceutical precursor chemicals and medicines for drug rehabilitation treatment;
- drugs specially needed by the military and preparations made by military medical institutions;
- pharmaceutical preparations made by healthcare institutions; and
- drugs prohibited from production, sale or use by law.

Advertising of all other prescription-only medicines is only permitted in professional pharmaceutical or medical journals jointly designated by the Ministry of Health and the NMPA. No prescription-only medicines can be advertised in the mass media or promoted in any other manner targeting the general public. Specifically, the Administrative Measures for Review of Drug Advertisements forbid the use of the names of prescription-only medicines to sponsor/title various activities for advertising, and also prohibit the use of any trade mark or trade name identical to the name of a prescription drug to publish any advertisement in a disguised manner in any media other than professional pharmaceutical or medical journals, or the use of such trade mark or trade name in the title of any activity for advertising.

Therefore, only over-the-counter medicines may be advertised to the general public, and such advertising must comply with substantive and procedural legal requirements. Under the Advertising Law, the Drug Administration Law and the Administrative Measures for Review of Drug Advertisements, advertisements for medicines are subject to review and approval from the drug regulatory department of the provincial-level government where the company is located (ie, the local NMPA), which is more fully discussed in **6.1 Requirements for Prior Notification/ Authorisation**.

### Format and Medium of Medicine Advertising

There are also certain restrictions with respect to the format and medium of medicine-specific advertising. For example, medicine-specific advertising cannot be disguised as programmes introducing knowledge about health and well-being and such advertising may not be published in media that targets minors.

Medicine-specific advertising must comply with all the requirements that apply to advertising in general. For example, the Advertising Law states that advertising cannot contain national symbols, words such as “national”, “supreme”, or “best”, or obscene, violent or discriminatory language. Statistical citations and patent references must be true and accurate. In addition, advertising cannot degrade the goods and services of others.

Certain restrictions also apply to the format and medium of advertising in general. All advertisements published through mass media must be prominently marked as “advertisement”, and a distinction must be made by the advertiser between advertisement and non-advertisement information, so as not to mislead consumers. For example, advertising cannot be broadcast or published in the form of news reports.

Outdoor advertisements cannot be placed on military facilities or traffic signs, or in certain areas controlled by national institutions, cultural heritage reserves and scenic spots. Without prior consent or request, advertisements cannot be sent to people’s residences or placed on transportation devices, or sent via electronic messages. Electronic messages must contain the sender’s identity, contact information and ways to unsubscribe from the messages.

### Endorsements

Under the Advertising Law, no endorsement can be made in advertising for medicines, not even

by a healthcare professional. The Administrative Measures for Review of Drug Advertisements further prohibit the use of the names or images of experts, scholars, physicians, pharmacists and clinical nutritionists as a recommendation or endorsement.

## 4.2 Information Contained in Pharmaceutical Advertising to the General Public

As a general principle, all advertisements must be true, lawful and must not contain any false or misleading content. Advertisers are responsible for the veracity and legitimacy of the content.

As advertising of prescription-only medicines is either prohibited entirely or only permitted in professional pharmaceutical or medical journals jointly designated by the Ministry of Health and the NMPA, advertising directed at the general public can only be for over-the-counter medicines.

Under the Advertising Law and the Administrative Measures for Review of Drug Advertisements, pharmaceutical advertising of a drug must include contraindications, adverse reactions and the drug advertisement approval number. For over-the-counter medicines, the advertisement should clearly use the abbreviation "OTC" and the following language: "Please follow the instructions for the drug or purchase and use it under the guidance of a pharmacist". For required content, fonts and colours must be clearly visible and legible. When released on TV, movies, the internet and display screens, such content must be continuously displayed in the advertisement (rather than for only five seconds as required by previous regulations).

Also, pharmaceutical advertising cannot contain: assertions or guarantees of efficacy and safety; specifics about the cure rate or efficacy rate; comparisons with other drugs; endorsement by a spokesperson; or anything else that is inconsistent with the approved instructions.

### Items Prohibited in Pharmaceutical Advertising

The Administrative Measures for Review of Drug Advertisements prohibit all of the following in pharmaceutical advertising:

1) either openly using or using in disguised form the names or images of state organs, functionaries of state organs, military entities or military personnel, and the use of military equipment, facilities, etc for advertising purposes;

2) using the names or images of research institutes, academic institutions, industry associations or experts, scholars, physicians, pharmacists, clinical nutritionists, patients and others for recommendation or as endorsement;

3) using express or implied statements, contrary to valid science, that the product can cure all diseases, adapt to all symptoms and all groups of people, or that it is necessary for normal life and disease treatment;

4) including content that induces unnecessary anxiety and fear among the public about their health status and the diseases they suffer from, or that lead to public misunderstanding that they will suffer from a certain disease or the disease will worsen if they do not use the product;

5) the use of words and expressions like "safe", "safe, non-toxic and with no side effects" and "minor toxic side effects"; or expressed or implied statements that the ingredients are "natural", thus ensuring safety;

6) including content that induces purchase, such as "hot sales", "rush to buy or use on a trial basis", "family necessities", "free treatment" and "free gifts"; comprehensive evaluation such

as "evaluation, ranking, recommendation, designation, selection and awards"; or content such as "refund if not effective" and "insurance with insurance companies" that encourages consumers to arbitrarily and excessively use drugs, health food and formula food for special medicinal purposes; or

7) including content such as the name, address, contact information, service items and service methods of the medical institution, as well as such medical services as free treatment, medical consultation hotline, special out-patient service, etc.

Bullet points two to five might also trigger false advertising claims and subject the advertiser to strict penalties, as discussed in **11.3 Penalties for Violating Advertising Rules and Rules on Inducements to Prescribe**.

### 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Patient organisations registered as formal associations are uncommon in China. Therefore, the law in China is silent on interactions between patient organisations and the industry, such as, whether companies can sponsor patient organisations' meetings.

Interactions between patients and the industry are restricted. Although the RDPAC Code encourages companies to make clinical trial information more publicly available to patients as well as to healthcare professionals, in practice, if a patient makes an enquiry to a pharmaceutical company about its drugs and indications, the company can only provide a consultation response through its medical affairs team and the information must be consistent with the information in the instructions already approved by the authorities.

Regarding the direct distribution of drugs to patients under the Provisions for Supervision of Drug Distribution, prescription-only medicines and a sub-category of over-the-counter medicines are generally prohibited from being offered to patients for free, as in "buy one, get one free", or other quantity-related promotions. Donating prescription-only medicines to patients in a charity activity, such as donations made under patient aid programmes (PAPs), is not explicitly regulated under current Chinese laws and regulations. However, it is widely understood that PAPs are, by nature, a charity activity that aims to provide drug assistance to financially burdened patients seeking to obtain drugs that are critical to their lives. Offering free prescription-only medicines is not prohibited under charitable PAPs conducted by qualified persons.

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Both over-the-counter medicines and prescription-only medicines can be advertised to healthcare professionals (other than the categories for which advertising is entirely prohibited under the Advertising Law and the Administrative Measures for Review of Drug Advertisements). For prescription-only medicines that can only be advertised to healthcare professionals, the advertising should be marked "This advertisement is for medical and pharmaceutical professionals only" in a prominent position.

Otherwise, the requirements and prohibitions for advertising directed at healthcare professionals are similar to the requirements and prohibitions for advertising directed at the general public. The scope of information is subject to the same

Advertising Law and Administrative Measures for Review of Drug Advertisements that were discussed in **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public** and **4.2 Information Contained in Pharmaceutical Advertising to the General Public**.

Some of the prohibitions for advertising directed at the general public may not be applicable to advertising directed at healthcare professionals, such as the one stating that medicine advertisements should not induce unnecessary anxiety and fear among the public about their health status and the diseases they suffer from, or that lead the public to believe they will suffer from a certain disease or the disease will worsen if they do not use the products.

### 5.2 Reference to Data Not Included in the Summary of Product Characteristics

Under the Advertising Law and the Drug Administration Law, drug advertising may not refer to anything that is inconsistent with the medicine's instructions (similar to the summary of product characteristics in Europe) as approved by the authorities. The Administrative Measures for Review of Drug Advertisements specify that, where a drug advertisement involves a drug name, indications or major functions, pharmacological effects, etc, it may not go beyond the scope of approved instructions. Therefore, advertising may not refer to data on file or other clinical studies that are not already included in the instructions.

### 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

Information on combination products needs to be included in a medicine's instructions (similar to the summary of product characteristics in Europe) under PRC law on the grounds that all usage information is legally required to be specified in a medicine's instructions. Therefore, in principle, there should be no information on combination products that is not included in the medicine's instructions, and advertising of such information is prohibited in that it is inconsistent with the medicine's instruction, as discussed in **5.2 Reference to Data Not Included in the Summary of Product Characteristics**.

### 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

The law in China does not prohibit companies from providing reprints of journal articles to healthcare professionals. Although generally allowed under the RDPAC Code, quotations from medical and scientific literature or from personal communications should be faithfully reproduced (except where adaptation or modification is required in order to comply with any applicable regulations or administrative rules, in which case, it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified. Quotations should not change or distort the intended meaning of the author or the significance of the underlying work or study.

### 5.5 Medical Science Liaisons

Medical science liaison (MSL) is not a legal term under PRC law. However, medical representatives as professional personnel may assume some similar functions to those of MSLs as defined in the Administrative Measures for Medical Representatives, such as transmitting relevant information about medicines to healthcare professionals, assisting healthcare professionals in the rational use of the medicines, collecting and giving feedback on the clinical use of drugs and information on the demands of hospitals. The marketing authorisation holder is required to file the information of its medical representatives and the medical representatives from contract sales organisations.

Although the law does not expressly prohibit medical representatives from discussing scientific information on unauthorised medicines or indications with healthcare professionals, according to the Administrative Measures for Medical Representatives, medical representatives are prohibited from undertaking drug sales targets, misleading doctors on the usage of drugs, exaggerating or giving misleading information on the curative effect of a drug, concealing known information on adverse reactions to the drug and information on adverse reactions to the drug reported by healthcare professionals.

As discussed in detail in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications** and **3.3 Provision of Information to Healthcare Professionals**, in practice, pharmaceutical companies in China are cautious about providing information on unauthorised medicines or unauthorised indications to avoid what might be constituted as illegal advertising. It is benchmark practice that the RDPAC Code requires such discussions to be conducted by or under the supervision of medical experts rather than personnel with commercial functions.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

Under the Advertising Law, the Drug Administration Law and the Administrative Measures for Review of Drug Advertisements, drug advertisements are subject to review and approval by the drug regulatory department of the provincial-level government where the company is located (ie, the local NMPA), which must issue an approval number for the drug advertisement. An approval number is required before any drug advertisement can be made. The validity period of the approval must be consistent with the shortest validity period of the medicinal product registration certification or the manufacturing permit, and if no valid period is prescribed in such documents, the valid period for the approval will be two years.

After the approval is granted, the local NMPA will file the approved advertising with the NMPA for record. It is worth mentioning that the Administrative Measures for Review of Drug Advertisements have simplified the review and approval process. For example, apart from the traditional on-site application, application can also be submitted via letter, fax, email, or an e-government platform. Fewer documents are needed for approval. However, the content review will still strictly follow the applicable rules. The Measures also grant that approved advertisements may be published nationwide in accordance with the law.

### 6.2 Compliance with Rules on Medicinal Advertising

There is no legal requirement to adopt standard operating procedures (SOPs) or employ specific personnel. However, according to the RDPAC Code, a designated company employee with sufficient knowledge and appropriate qualifications should be responsible for approving all promotional communications. Alternatively, a senior company employee could be made responsible provided that they receive scientific advice on such communications from adequately qualified scientific personnel. In practice, large and medium-size pharmaceutical companies normally have their own SOPs guiding companies' advertising practices in order to guarantee legal compliance. Legal and/or compliance teams or external counsel may be involved to conduct compliance reviews of certain advertisements.

If the company entrusts an advertising agency to provide advertisement design or production or agent services on a commission basis, the Advertising Law requires advertising agencies and advertisement publishers to inspect and verify the relevant certification documents and check the advertising contents in accordance with the law and administrative regulations.

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

Under the Interim Measures for the Administration of Internet Advertising, internet advertising may take various formats such as text, images, audio, video, or other forms on websites, web pages, or in applications (such as WeChat). In addition to all the restrictions regarding advertising in general, a few additional requirements apply to internet advertising. For example, internet advertising cannot interfere with people's normal use of the network. Online pop-ups should be clearly marked with a closing sign to ensure a one-click closure. Advertisers may not deceive users into clicking on the advertising content. No advertisement or advertisement link may be attached to the emails sent by advertisers or their agents without the recipient's prior permission. It is also prohibited to publish advertisements for prescription drugs on the internet. Pharmaceutical advertising on the internet also requires approval by the local NMPA, subject to the restrictions applicable to drug advertisements (see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public** and **4.2 Information Contained in Pharmaceutical Advertising to the General Public**).

In addition, the entity providing information on pharmaceuticals to online users via the internet is subject to the Qualification for Internet Drug Information Services issued by the competent local NMPA according to the Administrative Measures for Online Drug Information Services.

### 7.2 Advertising of Medicines on Social Media

The Interim Measures for the Administration of Internet Advertising cover advertising on social media as part of "internet advertising". Therefore, advertising on social media is generally allowed to the extent that internet advertising is allowed.

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

The law in China does not explicitly require companies to include access restrictions on websites containing advertising or other information intended for healthcare professionals. In practice, many companies do have this arrangement in place, such as asking whether the user is a healthcare professional or conducting an identification verification before the user can access the contents on specific web pages or columns publishing scientific information on diseases and prescription drugs, to avoid being perceived as advertising prescription drugs to the public on the internet.

### 7.4 Provision of Disease Awareness Information to Patients Online

Provision of disease awareness information and/or materials to patients online is not legally prohibited but might be regarded by law enforcement as advertising if the information provided can be viewed as being promotional in nature or pointing to a specific product, as discussed in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**.

According to a summary of the relevant laws, provision of disease awareness information and/or materials to patients online, or in other ways to the general public, must be compliant with the following requirements:

- firstly, the provision should not include information on drugs, otherwise such provision will constitute advertising subject to approval for pharmaceutical advertising;
- secondly, the provision should not constitute retailing of pharmaceutical products without a distribution licence; and
- thirdly, other general rules on patient education also apply, including diagnosis and treatment not being included, not discrediting competitors, not constituting false promotion, etc.

### 7.5 Online Scientific Meetings

Pharmaceutical companies are generally allowed to sponsor online scientific meetings or attendance by healthcare professionals of these online events. As with sponsoring of off-line scientific meetings, bribery in any form, such as provision of a participation subsidy, is strictly prohibited (see **9.3 Sponsorship of Scientific Meetings**).

PRC law is silent on the criteria required for an online meeting to be viewed as an "international" event. In practice, this generally depends on where the speakers and attendees come from. With reference to the RDPAC Code, it defines an "international" event as a scientific meeting where a significant proportion of the speakers and attendees come from countries other than the country in which the meeting takes place.

PRC law does not explicitly require prior authorisation in relation to healthcare professionals' participation in online scientific meetings, while in practice, pharmaceutical companies normally require doctors to obtain prior consent from their working hospital to ensure healthcare professionals are permitted to participate.

Separately, there are no special statutory requirements on (i) sharing handouts, materials, etc, during an online conference; or (ii) accessing conference recordings, materials, etc, after the date of the conference. For handouts and materials of an advertising nature, see **5. Advertising to Healthcare Professionals**. Also see **3.2 Provision of Information during a Scientific Conference**, which discusses providing information on unauthorised medicines or unauthorised indications.

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

The anti-bribery legal system includes laws on both the administrative and criminal levels.

#### Administrative Law

On the administrative level, the legal framework regulating commercial bribery is set out by the Drug Administrative Law, the Anti-Unfair Competition Law, together with the Interim Provisions on Banning Commercial Bribery, and a number of replies by the former SAIC on the handling of commercial bribery acts. The Drug Administrative Law states that:

- pharmaceutical companies and healthcare organisations may not offer or accept any kick-backs or improper benefits;
- pharmaceutical companies may not offer any improper benefits to healthcare professionals

or other related staff in any healthcare organisation which uses their drugs; and
- healthcare professionals and related staff of a healthcare organisation may not receive any improper benefits from the pharmaceutical companies.

The key provision under the Anti-Unfair Competition Law states that business operators may not resort to bribery, by offering money or goods or by any other means, to any of the following entities or individuals, in order to seek a transaction opportunity or competitive advantage:

- any employee of the counterparty to a transaction;
- any entity or individual entrusted by the counterparty to a transaction to handle relevant affairs; and
- any entity or individual that is likely to take advantage of powers or influence to affect a transaction.

Penalties for violation include fines ranging from RMB100,000 to RMB3 million, confiscation of illegal gains and revocation of business licences in serious cases. The legal representative, main person-in-charge and directly responsible staff may be prohibited from engaging in drug production and distribution activities for life.

### Public Healthcare Institutions

In practice, with respect to public-funded healthcare institutions, law enforcement takes the view that the purchasing of medicines "pierces" through the healthcare institution and should actually be viewed as transactions that take place between the pharmaceutical industry and the patients/medical insurance fund. Under this theory, the patients/medical insurance fund become the counterparty to the transaction, and both healthcare institutions and healthcare professionals, with their power to prescribe medicines to patients, fall into the scope of entities and individuals having the power or influence to affect a transaction. As a result, the general anti-bribery rules apply to benefits provided to healthcare professionals and benefits provided to public healthcare institutions.

### Adverse Records

Other than an administrative penalty, a pharmaceutical entity that conducts commercial bribery may also be discredited with an adverse record of commercial bribery by the provincial health commission. In this case, public medical institutions or medical and health institutions that receive financial funds from local government in that provincial region may not purchase medicines, medical equipment or medical supplies from such pharmaceutical entity within two years after the publication of the adverse records. If a pharmaceutical entity has adverse records of commercial bribery twice or more times within five years, all public medical institutions or medical and health institutions that receive financial funds across the country may not purchase medicines, medical equipment or medical supplies from such pharmaceutical entity. In addition, under the Drug Pricing and Procurement Creditworthiness System issued by the National Healthcare Security Administration, if the pharmaceutical entity takes part in commercial bribery, it will have an adverse credit and may be subject to negative treatment such as a warning, automatic risk heads-up in centralised procurement, and even suspension of listing or procurement, tendering and delivery of drugs.

### Criminal Law

On a criminal level, Criminal Law prohibits both individuals and entities from bribing several types of recipients. These include:

- state functionaries;
- the close relatives of or other persons closely related to a state functionary;

- a former state functionary or close relatives of or other persons closely related to the former state functionary;
- state agencies, state-owned enterprises, public institutions or people's organisations;
- employees of a company; and
- foreign individuals performing official duties or officials of an international public organisation.

Penalties for individuals include fines or confiscation of property and criminal detention or fixed-term imprisonment ranging from three years to life imprisonment. For entities, penalties include fines and criminal detention or fixed-term imprisonment for up to five years for the responsible individuals.

### 8.2 Legislative or Self-Regulatory Provisions

The Drug Administration Law prohibits drug marketing licence holders, drug manufacturers, distributors and their agents from providing any property or other improper benefits to the responsible person, the procurement personnel, physicians, pharmacists and other relevant individuals of a health institution that uses their drugs. The listed categories of individuals are also prohibited from receiving these benefits.

Under the RDPAC Code, if a member company engages healthcare professionals to serve as the company's consultants or advisers, one of the requirements for such an engagement is that the hiring of the consultants or advisers to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply and/or administer any medicine.

In regulatory practice, benefits provided to healthcare organisations for inducement to prescribe may be deemed as improper benefits and are therefore also forbidden. See **8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals** for a detailed discussion.

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

The Interim Provisions on Banning Commercial Bribery promulgated by the SAIC permit gifts of "small value" to be provided in the course of customary business practice and would not consider these to be commercial bribery. However, there is no legal guidance for the maximum amount of "small value".

Gifts (such as sporting or entertainment tickets, social courtesy gifts, etc) for the personal benefit of healthcare professionals, either directly or through clinics and institutions, are prohibited under the RDPAC Code. Providing or offering cash, cash equivalents, or personal services is also prohibited. For these purposes, "personal services" are any type of service unrelated to the healthcare professional's profession which confer a personal benefit to the healthcare professional.

However, promotional aids of minimal value (not more than RMB100 in value per item) and minimal quantity may be provided or offered to healthcare professionals solely for the promotion of over-the-counter medicines (but not prescription-only medicines) if relevant to the practice of the healthcare professional. Similarly, items of medical utility to enhance the provision of medical services and patient care are also conditionally permitted under the RDPAC Code with a limit of RMB500 per item. Even if each individual item is appropriate, such offering should not be made on more than an occasional basis.

### 9.2 Limitations on Providing Samples to Healthcare Professionals

According to the RDPAC Code, samples of a limited quantity of a pharmaceutical product may be supplied directly to healthcare institutions so healthcare professionals can familiarise themselves with the product, but these should be delivered through a qualified third party. Samples should be marked as such so that they cannot be resold or otherwise misused. Member companies should have adequate systems of control and accountability for samples provided to healthcare professionals through healthcare institutions, with respect to the distribution, delivery and acceptance of samples.

### 9.3 Sponsorship of Scientific Meetings

Pharmaceutical companies are generally allowed to sponsor scientific meetings. Under the Administrative Measures for Review of Drug Advertisements, the sponsored event cannot be titled the same as the name of any prescription-only medicine and cannot be titled the same as a trade mark or trade name that is identical to the name of a prescription-only medicine.

Pharmaceutical companies are generally allowed to sponsor attendance of these events by healthcare professionals, but should be careful not to violate the rules against commercial bribery. Under the RDPAC Code, member companies may sponsor healthcare professionals to attend medical interaction programmes if such sponsorship complies with the following requirements:

- the programme itself complies with the requirements in the RDPAC Code;
- the sponsorship of healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees;
- no payments are made to compensate healthcare professionals for time spent attending the programme;
- under no circumstances should a company make any payment or transfer any sponsorship funds directly to a healthcare professional or a hospital department; and
- any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.

### 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Under the Interim Provisions on Banning Commercial Bribery promulgated by the SAIC, commercial bribery includes both monetary bribery and other means, where “other means” refers to non-monetary benefits, such as tours and field trips in China or abroad.

Similarly, under the RDPAC Code, no entertainment or other leisure or social activities may be provided or paid for by member companies. Cultural, sports, or other non-scientific events in relation to scientific conferences may easily fall into the scope of “entertainment or other leisure or social activities” and, therefore, are generally prohibited by the RDPAC Code.

Moreover, under the Nine Criteria issued by the National Health Commission, the National Healthcare Security Administration and National Administration of Traditional Chinese Medicine, healthcare professionals are prohibited from participating in entertainment activities arranged, organised, or paid for by pharmaceutical manufacturers, distributors, or their agents.

### 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Pharmaceutical companies may provide grants or donations to healthcare institutions in accordance with the Administrative Measures for the Receipt of Public Welfare Donations. However, pharmaceutical companies are not allowed to

specifically appoint the healthcare professionals from the healthcare institutions as the recipients of donations.

Under the Measures, the requirements are generally similar for monetary donations and donations of equipment or services from a pharmaceutical companies' perspective. The differences between monetary donations and donations of equipment or services mainly concern the recipient institutions. For example, the recipient institutions are encouraged to use a third-party agency to confirm the value of non-monetary donations, and the ways in which recipient institutions can spend the donations differ depending on the type of donations.

Additionally, in practice, donations of equipment or services may be higher risk than monetary donations, because in addition to potentially violating the Measures, a wrongful donation of equipment or services may also be seen as offering equipment or services in connection with the sale of medicines under the prohibited buy-one-give-one model, thus violating the Provisions for Supervision of Drug Distribution.

### 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

As discussed in **3.4 Provision of Information to Healthcare Institutions**, procurement of drugs in China is organised by the government through bidding on bidding platforms. As healthcare professionals and healthcare institutions are not directly involved in procurement, rebates or discounts provided to them are less common than in some other jurisdictions. Still, the Drug Administration Law explicitly prohibits drug marketing licence holders, pharmaceutical manufacturers, distributors and healthcare institutions from giving or receiving rebates or other improper benefits in the purchase and sale of drugs.

Moreover, under the Nine Criteria, healthcare professionals are prohibited from accepting any rebate offered by pharmaceutical manufacturers, distributors, or their agents in any name or form.

### 9.7 Payment for Services Provided by Healthcare Professionals

It is possible to pay for services provided by healthcare professionals under certain circumstances. For example, companies may invite healthcare professionals who are key opinion leaders in their fields to give lectures or to serve on the company's advisory boards and attend board meetings. Under these circumstances, companies may pay these healthcare professionals speaker fees or consultation fees at fair market value, as applicable.

The RDPAC Code sets out a large number of restrictions on the amount of payment allowed. Chief among these restrictions are: the hiring of the healthcare professional to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply and/or administer any medicine, and the compensation for the services must be reasonable and reflect the fair market value of the services provided.

Companies' SOPs may set out more specific restrictions on the amount of speaker fees, consultation fees and relevant expenses for meals and transportation, and may require employees to provide documents to prove the services provided by the healthcare professionals. For example, the SOP may establish the maximum amounts allowed for domestic and international lectures and meetings. The SOP may also state that, for foreign speakers or consultants, the payment must comply with the fair market value of their respective countries of origin.

### 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

The law in China does not explicitly require prior authorisations or notifications in relation to gifts, hospitality, congresses and related payments described in this section. In practice, however, employers often do require that employees obtain prior consent from their employer before engaging in such activities.

In particular, doctors employed by medical institutions cannot practise outside the registered medical institution without due record-filing, and their personal activities are more closely managed by the registered medical institutions. Their activities in relation to gifts, hospitality, congresses and related payments described in this section will likely require the employer's prior consent.

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

The law in China does not provide explicit disclosure requirements for pharmaceutical companies and there is no specific statutory requirement being applied to such disclosure obligation due to COVID-19.

Having said that, industry benchmark standards can be found in self-regulatory codes. For example, the RDPAC Code states that if material relating to pharmaceutical products and their uses, whether promotional in nature or not, is sponsored by a member company at medical interaction programmes between member companies and healthcare professionals, that material should clearly indicate by whom it has been sponsored. Medical interaction programmes hosted or sponsored by member companies, whether promotional in nature or not, should clearly indicate by whom they have been hosted or sponsored. If a member company sponsors medical interaction programmes organised by a third party, the above disclosure should be made subject to the knowledge and consent of the organiser.

Healthcare institutions that receive donations are subject to disclosure requirements. Under the Administrative Measures for the Receipt of Public Welfare Donations, the recipient institution must establish a publication system for donation information and must publish donation receipt information to the society in an authentic, accurate, timely and complete manner via their web portals or local major news media.

### 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

There are no explicit legal transparency requirements for foreign companies, although certain self-regulatory codes, such as the RDPAC Code, impose disclosure requirements on their member companies. As self-regulatory codes are contractual in nature, whether a company is subject to these requirements depends on whether the company undertakes to enter into the contractual arrangement as one of its members. If a company undertakes to be bound by certain self-regulatory codes, it will be subject to the same transparency requirements regardless of whether the company is domestic or foreign and regardless of whether its products are already on the market.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

#### The SAMR

Until 2018, the SAIC and its local branches were responsible for enforcing the rules on advertising and the rules on inducement. Since the government restructuring in 2018, the SAIC has become part of the State Administration for Market Regulation (SAMR) which, together with its local branches, is responsible for enforcement actions. The restructuring enabled the SAMR to combine the SAIC's enforcement mechanism and the NMPA's familiarity with the pharmaceutical industry, as a result of which, supervision of this industry has been strengthened.

#### The RDPAC Code

The RDPAC Code has also created its own dispute resolution system, providing member companies with the opportunity to file complaints against competitors and to request that the association enforce its rules through the established panel review, mediation, or sanction procedures.

#### The People's Court

In the event that a pharmaceutical advertisement is recognised as false advertising, causing damage to the legitimate rights and interests of consumers, the consumers may file a lawsuit with the people's court and claim for damages.

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Companies can initiate proceedings against competitors in court for advertising infringements on the basis of the Anti-Unfair Competition Law and the Civil Procedure Law. Companies may also file complaints against competitors with the State Administration for Market Regulation or its local branches in accordance with the provisions in the Law on Administrative Penalty. Additionally, member companies may also initiate panel review or meditation procedures as established by the RDPAC Code.

### 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The penalties or measures that regulators or courts can impose for violating medicine advertising rules are mainly found in the Advertising Law and the Administrative Measures for Review of Drug Advertisements. The penalties and measures include ordering the cessation of the publishing of the advertisement, ordering the advertisers to eliminate negative impact, imposing fines, confiscating advertising fees and revoking business licences and approval documents for the advertisement. The penalties can be imposed on the advertiser, the advertising agency, or the advertising publisher (such as TV stations). The penalties imposed are listed in the National Enterprise Credit Information Publicity System for public notification as required by the Administrative Measures for Review of Drug Advertisements.

For example, in the case of false advertising, law enforcement will order that the advertisement be stopped and that the advertiser eliminate the negative impact. The advertiser may be fined the equivalent of three to five times the advertising costs; if the advertising costs cannot be calculated or are obviously low, the amount will be RMB200,000 to RMB1 million. Where violations happen three or more times within two years, or where the circumstances are serious, a fine of five to ten times the advertising cost will be imposed. If the advertising cost cannot be calculated or is obviously low, a fine of RMB1 million to RMB2 million will be imposed, the business licence may be revoked and the local NMPA may

revoke the advertisement's review and approval document and not accept applications from the advertiser for one year.

In serious cases, there may be criminal responsibilities too. For example, false advertising may result in criminal detention or fixed-term imprisonment of up to two years for advertisers, advertising agencies, or advertising publishers. Criminal fines may also be imposed separately or concurrently.

With regard to inducements to prescribe, if a case involves commercial bribery, then the penalties under the Anti-Unfair Competition Law and the Criminal Law discussed above will become relevant.

### 11.4 Relationship between Regulatory Authorities and Courts

There is no direct relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by the courts. The former is not a prerequisite for the latter. Specifically, regarding the RDPAC Code, there has yet to be any case where a court has considered a decision under the RDPAC Code as a basis for the court's decisions.

### 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

From 2017 to now, an increasing number of cases have been investigated and penalised by the law enforcement authorities. This might be relevant to the 2018 government restructuring discussed in **11.1 Pharmaceutical Advertising: Enforcement Bodies**. It is anticipated that cases related to pharmaceutical advertising might increase after the Administrative Measures for Review of Drug Advertisements have been implemented for a longer time and before the advertisers become familiar with the new rules, because they impose new requirements on advertisers and clearer guidance to law enforcement officials.

In practice, the main reasons that penalties are imposed on illegal pharmaceutical advertising include:

- the pharmaceutical advertising is published without approval;
- the pharmaceutical advertising of prescription-only drugs is publicly published on media other than the pharmaceutical or medical journals designated by the Ministry of Health and the NMPA;
- the pharmaceutical advertising does not list contraindications or adverse reactions and goes beyond the scope of its instructions; and
- the drugs advertised are not permitted to be advertised, eg, narcotic drugs, psychotropic drugs, toxic drugs for medical use and radioactive drugs.

In a renowned law enforcement case in recent years, an over-the-counter pharmaceutical company published its pharmaceutical advertising three times on a popular domestic variety show and was fined RMB900,000 for the reasons specified in bullet points one and three above. In March 2021, a branch of the SAMR in Shanghai imposed a fine of RMB200,000 on a pharmaceutical entity for the reasons specified in bullet points one and two above, because the pharmaceutical entity had published an article via online media recommending a prescription-only drug.

**Global Law Office** was one of the first law firms in the PRC, dating back to 1979, and is one of the largest, with around 500 lawyers practising in its Beijing, Shanghai, Shenzhen and Chengdu offices. The life sciences and healthcare (L&H) practice group is one of the leading advisers in China, providing "one-stop" legal services for every area of the L&H industry, including drug R&D, clinical research organisations, pharmaceuticals, life sciences, biotechnology, medical devices, supply producers and distributors, hospitals and other healthcare providers, as well as various investment funds in the L&H sector. Global Law Office advises clients on challenging L&H legal issues, such as regulatory compliance, structuring transactions and contractual arrangements, realisation of pipeline and geographic expansions, capital raising and project financing, M&A, reorganisations, IP protection, licensing and distribution arrangements, settlement of disputes involving adverse effects in clinical trials and medical treatment. The firm has close links to industrial associations and makes recommendations on industry codes of conduct and compliance management standards.

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# Trends and Developments

***Contributed by:***
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## China: the Regulation of Pharmaceutical Advertisements in 2021

In 2021, improvements were made to the regulatory regime governing pharmaceutical advertisements in the People's Republic of China (PRC), with the implementation of clearer rules and a quick-response regulatory system for emerging industries (eg, medical cosmetology). This article summarises the trends and developments in China with respect to pharmaceutical advertisements in terms of both regulatory rules and practices.

## Updates and Trends in the Latest Regulatory Rules

The amendments to the PRC Advertising Law in 2021 imposed harsher penalties for violations of regulatory requirements for advertising but the substantive requirements in the law itself were largely left unchanged. However, the Chinese authorities introduced new substantive requirements and amended other requirements through their issuance of several lower level regulations, decrees and guidelines to be implemented in addition to the PRC Advertising Law. These latest developments in the regulatory rules are set out below.

### *Unification of the regulatory regime of medical products*

In 2020 the State Administration of Market Regulation (SAMR) published the Interim Measures for the Administration of Review of Advertisements on Drugs, Medical Devices, Dietary Supplements and Formula Foods for Special Medical Purposes ("Interim Measures"), which took effect on 1 March 2020. The Interim Measures replaced the previous regulations on the censorship of advertisements for drugs and medical devices. At the same time, dietary supplements as well as formula foods for special medical purposes were also regulated by the Interim Measures.

The updated requirements under the Interim Measures are as follows.

- Any advertisement for a medical device, dietary supplement or formula food with a special medical purpose must explicitly indicate that it is an advertisement. The advertising indicator must continuously mark the advertisement in plainly visible and easily discernible fonts and colours. For instance, an advertisement for a medical device recommended for personal use must conspicuously indicate: "Please carefully read the product instructions or purchase and use the product under the direction of a medical professional." Where there are any contraindications or precautions in the registration certificate for a medical device, the advertisement must conspicuously indicate: "Please see the instructions for details on contraindications or precautions." In addition, advertisements for drugs, medical devices, dietary supplements and formula foods for special medical purposes must conspicuously indicate the advertisement approval number.
- The valid period for advertising approval on dietary supplements has been increased from one year to a period equal to the minimum valid term for the product's registration certificate, recordal certificate or production licence. If no valid term is specified in the certificate or licence, the valid period for advertising approval should be a minimum of two years.

- An online application procedure has been introduced for pharmaceutical advertisements. This online application procedure also simplifies the application process by reducing the number of documents to be submitted.

### *Stricter requirements of medical device advertisements*

To consolidate the regulation of medical device advertisements, the PRC's State Council amended the Regulation on the Supervision and Administration of Medical Devices, which came into effect on 1 June 2021. According to the amended regulations, the content of medical device advertisements must be consistent with the medical device instructions filed or registered with the department in charge of the drug's regulation and administration. Moreover, false, exaggerated or misleading content is prohibited in the advertisement.

### *Regulations on medical cosmetology advertisements*

The SAMR issued the Guidelines for the Enforcement of Medical Cosmetology Advertising (the "Guidelines") on 2 November 2021. The Guidelines place medical cosmetology advertisements under the same legal framework that regulates pharmaceutical advertisements. In the 2021 edition of "Representative Cases of False and Illegal Medical Cosmetology Advertisements", the SAMR reiterated that it would, in the forthcoming year, closely co-operate with other authorities to enhance the regulation of medical cosmetology advertisements and impose harsher penalties on violations.

Specifically, the Guidelines clearly set out the following violations as being subject to close monitoring by the authorities:

- violating good social practices by creating "appearance anxiety", and improperly associating undesirable looks with negative evaluation factors such as "imbecility", "laziness" and "poverty", or making an improper association between outstanding looks and positive evaluation factors such as "high quality", "diligence" and "success";
- advertising any drug or medical device that has not been approved by or filed for recordal with the drug administration authority, or promoting any unapproved medical treatment services;
- raising functional claims or making any guarantees relating to safety and the effects of medical services;
- comparing the image of a patient before facial surgery to an image after facial surgery to boast of the effects of treatment, or using the name and image of an industry association or any other social community or organisation as proof of the effects of treatment;
- using endorsements or recommendations by a so-called "recommendation officer" or "experience officer";
- disguising medical cosmetology advertisements as health-related discussions, interviews, news reports, etc; and
- claiming cosmetology-related disease treatment functions for food, health food, disinfectant products, and cosmetics.

Under the Guidelines, images or titles referring to "doctor" or "expert" may not be used in medical cosmetology advertisements. If an actual doctor or expert is involved in a medical cosmetology advertisement, the advertisement will be considered an illegal advertisement for using a doctor or expert to endorse the medical cosmetology product. If the "doctor" or "expert" is not qualified for medical practice, the advertisement will be considered false or misleading and likewise prohibited.

### *Online promotions*

With the boom in internet technology, the circulation of pharmaceutical advertisements is

no longer confined to traditional print media and TV. Advertisements are also disseminated extensively online through live streaming, digital sources, social platforms, etc. The Chinese authorities have taken note of and responded to these online advertisements. In 2016, the SAMR issued the Provisional Measures for the Administration of Online Live Streaming Marketing. These provisional measures will be replaced by the Draft Measures for the Administration of Internet Advertising, which were published in draft form by the SAMR for public consultation in 2021. Once the draft measures take effect, all online pharmaceutical advertisements will be subject to them.

In addition, authorities in various provinces across China are exploring novel approaches for implementing the law relating to online promotions. For example, some Shanghai officials consider that live-streaming promotions should be distinguished from other forms of video advertising. Specifically, these officials believe that live-streamed promotions are not advertisements under the PRC Advertising Law if the live-streaming is actually instantaneous. However, if the live-streamed promotions are recorded and available for later viewing on the internet, these authorities would be more likely to view the recorded live-streaming as advertisements.

## Key Developments and Challenges in Pharmaceutical Advertisement Practices

In addition to these regulatory updates for pharmaceutical advertisements in China, the following are some observations on the impact on pharmaceutical advertisements of the centralised, volume-based procurement of drugs in China; the pre-approval requirements for pharmaceutical advertisements; and the new administrative penalty law.

### *Impact of centralised, volume-based drug procurement on pharmaceutical advertisements*

The centralised, volume-based drug procurement system established by the Chinese government from 2021 has impacted pharmaceutical advertisements in China. Influenced and motivated by the COVID-19 pandemic, the General Office of the PRC's State Council issued the Opinions on Promoting the Normalisation and Institutionalisation of the Centralised Purchasing of Drugs in Large Quantities in 2021, with the purpose of making drugs more affordable. The long-term goal of the policy is both to suppress drug prices and to satisfy the demand for drugs.

The implementation of this procurement system has significantly reduced pharmaceutical company profits. In response, pharmaceutical companies in China have, to a large extent, slashed their budgets for drug advertising. However, at least for the moment, this centralised, volume-based procurement has had a relatively limited impact on advertising of medical devices and dietary supplements.

### *Challenges in the pre-approval requirement of pharmaceutical advertisements*

According to Article 4 of the Interim Measures, pharmaceutical advertisements require pre-approval from the provincial Medical Products Administration. In practice, only compact advertisements, usually of one page or less, may be approved. To circumvent this de facto restriction on the length of the advertisement, some pharmaceutical companies have adopted two unconventional approaches.

These two unconventional approaches are: (1) inserting the advertising content in scientific or research articles; and (2) circulating promotional information on internal training to the pharmaceutical company's salespersons and distributors and then instructing those salespersons

and distributors to pass on the promotional information and internal training materials to targeted individuals and entities. By doing this, the pharmaceutical companies may argue that the materials or channels do not fall within the scope of advertising as defined under the current regulatory regime.

Nevertheless, there are still risks of violating the law with these two approaches, given that the definition of advertisement under the PRC Advertising Law is actually quite broad. The best industry practices require further consideration and will require further guidance from the Chinese regulatory authorities.

### *Penalty exemptions under the new Administrative Penalty Law*

The PRC Administrative Penalty Law was amended in January 2021, to include a "soft-handed" approach exempting penalties for certain violations, which also has a positive impact on the regulation of pharmaceutical advertisements.

For instance, Article 33 of the PRC Administrative Penalty Law exempts the following violations from penalties:

- minor violations that result in no harmful consequences and that are corrected promptly;
- first-time violations by an offender if the violation has only minor harmful consequences; and
- violations without subjective fault by the offender if the exemption does not contravene any other applicable law or regulation.

This "soft-handed" approach is already being carried out by the authorities in their enforcement relating to pharmaceutical advertisements. For example, the regulatory authorities in Shanghai are now more likely to show leniency towards minor or first-time offences if the violation can be rectified promptly. The Shanghai regulatory authorities are also generally less likely to punish an advertiser that fails to indicate the serial number of the advertising approval for a medical device or drug, as long as the approval itself has been duly obtained, and the failure is not due to wilfulness or gross negligence.

In light of the above, the newly amended PRC Administrative Penalty Law provides some flexibility in administrative penalties relating to minor violations, which may potentially serve as the legal basis for a general loosening of the regulatory environment for pharmaceutical advertisements.

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**Fangda Partners** was founded in 1993 and is a full-service law firm advising on PRC and Hong Kong laws. The firm has approximately 700 lawyers in its five offices in Beijing, Guangzhou, Hong Kong, Shanghai and Shenzhen. Fangda Partners has been at the forefront of the development of commercial law practice in China for over two decades. A selection of notable matters on which the firm has advised include the first initial public offering by a Chinese company involving an international underwriter, the first domestic listing by a company incorporated outside the PRC, the formation of the first open-end mutual fund in China, the first foreign acquisition of a controlling stake in a Chinese public company, the first FRAND litigation involving standard essential patents in China, representing the claimant in obtaining the first pre-litigation injunction in a trade secret infringement case under Chinese procedural law, the first public interest environmental litigation brought by an NGO against a multinational company in China, and the first patent lawsuit at China's new Intellectual Property Court of the Supreme Court.

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# ECUADOR

## Law and Practice

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## 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

### 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The laws and codes that regulate the advertising of medicines in Ecuador are extensive. The main regulatory bodies are:

- the Organic Law of Health;
- the Regulatory Treaty of Medicines ALBA;
- the Organic Statute of the Regulatory and Sanitary Surveillance Agency;
- the National Policy of Medicines Applied in the Health System;
- the Resolution on Procedures in the Marketing of Medicines in General and Biological;
- the Ministerial Agreement 179 on the Promotion of Medications in General; and
- Regulation for the Therapeutic Use, Prescription and Dispensation of Medical Cannabis and Pharmaceutical Products Containing Cannabinoids.

### 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

In Ecuador, there is self-regulation regarding the promotion and advertising of medicines, which has been formulated and put into effect by associations or unions, especially multinationals in the pharmaceutical research industry. Dealing with self-regulation and being dependent on an association applies across the industry, particularly to companies that are part of that association.

These instruments have taken on great importance for associations, their members and for the state, which recognises the importance of self-regulation of companies in the ethical sense and how this makes a difference in transcendental issues, such as access to scientific information, the promotion of products and the interaction of the industry with the different actors in the health system, be these officials, patients or associations. It is for this reason that several of the concepts of self-regulation and Codes of Conduct are regulated by the Health Authority.

Regarding the legal value of the rules imposed by self-regulation, in the first instance, they are part of internal regulation and norms of ethics and anti-corruption (compliance standards). Many of the principles established in self-regulation were in fact inserted in the Organic Code of Health to be discussed in the national assembly. Unfortunately, the aforementioned Code was totally vetoed by the president of the republic and consequently, various rules on promotion and advertising are still part of self-regulation.

## 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

### 2.1 Definition of Advertising

Pharmaceutical advertising is defined as any form of offer – written, electronic, visual or other – aimed at the general public, and aimed at promoting the prescription, dispensation, sale and use or consumption of over-the-counter (OTC) medications. Moreover, it is a commercial activity that is subject to the control of the Health Authority, and it is characterised by delivering commercial information on a specific medicine that must correspond to its true nature, composition, quality or origin, etc, in order to prevent the consumer from purchasing it in error.

In Ecuador, the advertising of medicines subject to prescription is prohibited.

### 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

The difference between advertising and information lies in its purpose. Advertising has an economic purpose, seeking an increase in sales, and informing on the benefits of a particular medicine. Information, however, is training that is not tied to a specific product or brand. Patient programmes are not part of an advertising campaign, as long as they do not seek to profit in any way from the same and do not tie or relate a brand to the initiative.

One important clarification to note is that, in relation to leaflets for patients, these are part of the labelling of medicine. They are subject to the prior approval and control of the Health Authority and are not considered to be part of advertising.

### 2.3 Restrictions on Press Releases regarding Medicines

Ministerial Agreement 179 regulates the promotion of medicines in general. Article 9 authorises the advertising of medicines through the press, for those that are classified as OTC products, processed natural products for medicinal use, homeopathic medicines, and medical devices.

In the past, the authorisation of the Health Authority was required to carry out such advertising through the means of communication described. However, after the Communication Law came into force, this requirement was abolished. The new Communication Law that facilitated the advertising of OTC medicines through the press was published on 20 February 2019.

The only pharmaceutical products that can be advertised through the press are OTC medications, ie, those that are not subject to medical prescription.

Advertising, promotion, endorsement and sponsorship of medicines in general, processed natural products for medicinal use and homeopathic products containing cannabinoids with THC concentrations less than, equal to or greater than 1%, will be subject to the provisions of Ministerial Agreement No 179 or the regulations that replace it.

### 2.4 Comparative Advertising for Medicines

Comparative advertising is allowed as long as it falls within the following parameters:

- the object of the advertising must be medicines, processed natural products for medicinal use, homeopathic medicines, and medical devices, over the counter;
- advertising must be based on authentic studies and information (it is a requirement that the studies that serve as the basis for advertising have been part of the dossier used to obtain the sanitary registration);
- advertising should promote the rational use of medicines;
- the information given by the advertising has to be complete and not generate confusion or induce the consumer to act in error – the information contained in the advertising material may not induce misleading interpretations capable of causing a false, erroneous and/or confusing interpretation in relation to the drug, processed natural products for medicinal use, homeopathic medicines or medical devices;
- the information given by the advertising has to be clear and accessible;
- the advertising must indicate the therapeutic indications or uses of the medicine, which must be written in Spanish using clear language that does not generate confusion for consumers;

- information disclosed must be reliable, accurate, true, up to date and in accordance with the therapeutic indications;
- it complies with the content of the provisions of the health registration certificate as well as the pharmacological report issued by the National Agency for Health Regulation and Control ("ARCSA") during the obtaining of said sanitary registration;
- the use of phrases and images complies with the conditions or use of the product in accordance with the pharmacological report approved by the ARCSA during the obtaining of the sanitary registry, to favour the understanding of the general public;
- the advertising may not use expressions that cause fear or anguish, or suggest that a person's health may be affected by not using the medication; and
- the advertising must obey the regulation of competence and it must not be misleading, subliminal or unfair to competitors – under the current regulation, the offensive comparison of other brands, products, services, companies or organisations is expressly prohibited.

Legal rules such as codes of conduct establish that, if comparative advertising is used, it must be based on scientific information and comparative studies of molecules or products.

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

Information on medications that are not authorised for sale and distribution in Ecuador is allowed only if it is for training purposes. This type of activity cannot be directed towards the general public. It must be restricted to health professionals, the scientific community and other related parties. The general public should not have access to, nor receive, any information or data of this nature from a member of the health industry.

The advertising of medicines the marketing of which has not been authorised by a competent Ecuadorian authority, is not allowed.

### 3.2 Provision of Information during a Scientific Conference

The provision of information on unauthorised medicines or indications is allowed during scientific conferences for healthcare providers, as long as the only objective in sharing such information is academic. The information must be clear and related to the conference being held.

At this type of event, there may be no reference to trade names or specific brands of drug as this could be construed as advertising or promotion, which is not allowed prior to the authorisation of commercialisation.

### 3.3 Provision of Information to Healthcare Professionals

The delivery of information to health professionals in Ecuador is executed through a medical visit or promotion. Active promotion is allowed under the Organic Health Law only for legally obtainable medications, ie, those that have an approved sanitary registration. In conclusion, information on medications or non-approved therapeutic indications can be provided to health professionals only in a reactive manner.

### 3.4 Provision of Information to Healthcare Institutions

Health institutions can only mention and request medications that are authorised.

The delivery of information is allowed, as well as the supply, importation and provision of medicines without a sanitary registration only:

- in cases of sanitary emergency;
- for specialised treatments not available in the country;
- for treatments of catastrophic, rare or orphan diseases;
- for the purposes of human clinical research;
- for the supply of the public sector through international organisations;
- in the case of donations accepted by the national health authority; or
- in the case of hard-to-access drugs, or other cases defined by the national Health Authority.

However, each case will be analysed and a way to accelerate the authorisation process in the market by the Health Authority will be sought.

### 3.5 Publication of Compassionate Use Programmes

Compassionate use is unregulated in local legislation. Regarding early access to a drug, it is understood that this is about availability of the drug before its marketing has been authorised. Access to unauthorised pharmaceutical products is allowed only in cases of sanitary emergency; for specialised treatments not available in the country; for treatments of catastrophic, rare or orphan diseases; for the purposes of human clinical research; in the case of hard-to-access drugs; for the supply of the public sector through international organisations; and in the case of donations accepted by the national Health Authority or other cases defined by the national Health Authority. These cases, which are exceptional, are analysed individually and have specific patients or establishments as beneficiaries.

As a consequence of the above, there is no express rule that allows the availability of compassionate-use programmes or other forms of early access to be published.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

The prohibitions of public advertising in general are prescribed in AM 179. The prohibitions are comprehensive and include the following:

- advertising of medicines, processed natural products for medicinal use, homeopathic medicines and medical devices which are only available under medical prescription;
- campaigns aimed at the general public that induce the use of prescription medications;
- advertising carried out through containers, labels, packaging, inserts or leaflets of other products that accompany medicines, processed natural products for medicinal use, homeopathic medicines, and OTC medical devices;
- offensive comparison with other brands, products, services, companies or organisations;
- advertising that induces indiscriminate use of the product, or provides answers that are not scientifically proven, or suggests the product should be taken on a permanent basis;
- advertising that claims the product has healing properties in chronic diseases;
- advertising that suggests the product prevents disease and recommends its use in healthy people to improve their condition;
- advertising that claims the product used is the only alternative, expressed in phrases and/or slogans that are not covered in the corresponding sanitary registration, such as: “the product of greater choice”; “the only one”; “the most frequently recommended”;

"the best"; "totally reliable"; "the most effective", "famous", "totally safe"; "is good"; and "new" among others;
- that the advertising content includes minors, with the exception of those medications that are addressed to them and for which there is written authorisation from their parents, in accordance with the provisions of the Childhood and Adolescence Code Article 52;
- phrases such as "demonstrated in clinical trials", "clinically proven", "recommended by experts and/or institutions"; in the case of the use of these phrases, the scientific technical information that justifies its use and which is duly approved by the INH in the process of obtaining the sanitary record, must be attached to the request;
- advertising that includes messages such as: "authorised by the National Health Authority", "Ministry of Public Health", etc;
- advertising that induces the use and consumption of medicines, processed natural products for medicinal use, homeopathic medicines, and medical devices based on offers or offers and prizes, including associations with other products;
- use of censored images (naked or half-naked) that promote the acquisition of the product;
- where images and names of health professionals who recommend the use of the medication are used;
- advertising carried out directly in shopping centres, at sporting events, at public shows, and on other similar occasions;
- advertising that affects the image of other products, or threatens the good name of other products, or the prestige of third parties;
- advertising that tries to create a situation of rejection of competing products or their users;
- when advertising mentions active ingredients not contained in the advertised product;
- when it mentions possible adverse or side effects of active ingredients not contained in the advertised product.

During 2021, specific regulations were issued for products containing cannabis; however, these products remain subject to the general rules and may be advertised only if they are registered as OTC products.

In relation to medical devices and biochemical reagents for the detection of COVID-19, the Health Authority has decided that in no case will these fall into an OTC category, and consequently, they cannot be advertised.

### 4.2 Information Contained in Pharmaceutical Advertising to the General Public

The advertising of OTC medicines to the public must have complete, suitable, supported, current and clear information, in Spanish.

The advertising of OTC medicines must contain the following information:

- the name of the product, which must correspond to the one stated in the certificate of sanitary registration;
- the pharmaceutical form, where applicable;
- the dosage, where applicable;
- precautions for use;
- contraindications established in the pharmacological report, or in current pharmacological standards; and
- the warning: "If symptoms persist consult your doctor", if applicable.

In addition, the information that reaches consumers cannot be misleading.

### 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

The Patient Organisation is independent and is not conditioned in any way by the other health agents. In this sense, any type of programme or benefit to the Patient Organisation must be transparent through the competent authority and before the same industry that self-regulates. In this sense, the multinational pharmaceutical industry has assumed self-regulation compliance rules in an organised way, according to the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) standards, which ensures that the actions of companies do not generate undue or inappropriate advantages.

The interaction with patient organisations is not regulated by the state but is part of the self-regulation of the pharmaceutical industry. With regard to restrictions on the interaction between patients or patient organisations and the industry, it is prohibited to:

- to induce the prescription and incorporation or exclusion of medicines in the basic tables of public institutions, and equivalent mechanisms for their own or third-party benefit;
- to induce the purchase of a medicine or health input by institutions of the health sector; and
- to ask patient organisations to be dependent on a member, demanding exclusivity in sponsorships.

In 2021, a reform to the Organic Criminal Code came into force, according to which acts of corruption in the private sector are criminalised. In accordance with this reform, the director, general manager, administrator, main executive, shareholders, partners, legal representatives, attorneys-in-fact, advisers, auditors, sponsoring lawyers or any employee who holds a management position in a private legal entity, non-profit organisation, the government, an association, a foundation or committee who intentionally accepts, receives or requests donations, gifts, presents, promises, rights, fees, contributions, rents, interests, advantages, salaries, gratuities, immaterial benefits or undue economic benefits or other material good, and who omits or commits an act that favours themselves or a third party, in the course of economic, financial or commercial activities, will be punished with imprisonment from five to seven years, and a fine of 500 to 1,000 unified basic salaries of the workers in general.

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

All advertising directed at healthcare professionals must contain the therapeutic indications or uses of the medicine, and this must be identical to the information provided to the competent authority to obtain the sanitary registration.

Confusing language that may cause misinterpretation cannot be used, nor expressions that cause fear or distress, or suggest that health may be affected by not using the medication. Furthermore, the advertised product may not be compared offensively with any competition product.

### 5.2 Reference to Data Not Included in the Summary of Product Characteristics

All advertising must be based on the information provided to obtain the sanitary registration, including the summary of product characteristics. However, additional data on file or other clinical studies not included in the summary

of product characteristics can be provided to healthcare professionals, but not as advertising.

### 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

All advertising must be based on the information provided to obtain a place in the sanitary registry. This includes the summary of product characteristics.

### 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Reprints of journal articles may be provided to healthcare professionals for educational purposes, as long as the information contained in the articles was used to obtain the sanitary registration.

### 5.5 Medical Science Liaisons

Informally, medical science liaisons (MSLs) can proactively discuss scientific information on unauthorised medicines or indications with healthcare professionals, as long as they are not pharmaceutical sales representatives.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

In the past, the authorisation of the Health Authority was required prior to carrying out advertising for medicines. However, currently and since the Communication Law came into force, the requirement to obtain this authorisation has been abolished. The new Communication Law, which facilitates the advertising of OTC medicines through the press, was published on 20 February 2019.

### 6.2 Compliance with Rules on Medicinal Advertising

To advertise products to healthcare professionals, pharmaceutical sales representatives must have professional training in careers related to health and pharmaceutical sciences. They must also wear the corresponding identification during any medical visit.

The Ministry of Health no longer has a record of the sales representatives in the pharmaceutical industry, so this matter is now the responsibility of each company.

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

No specific rules apply to advertising medicinal products on the internet but these do enter the scope of regulation described in **6.1 Requirements for Prior Notification/Authorisation**.

### 7.2 Advertising of Medicines on Social Media

Currently, no specific rules apply to advertising on social media. Furthermore, the content made by citizens on social media is excluded from the scope of regulation and administrative control.

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

Promotion refers to all the informative and persuasive activities deployed by drug manufacturers and distributors, and directed at prescribers with the aim of inducing prescription, including on a website.

Activities to promote medicines digitally must be carried out in compliance with the following legal requirements:

- they must be directed exclusively at health professionals authorised to prescribe which, according to the Organic Law of Health, includes doctors, dentists and midwives;
- they must be carried out by medical representatives duly licensed by the laboratory or directly by the representative house; and
- they must be part of continuing medical education for health professionals authorised to prescribe (optional).

There is no rule that requires access restrictions to be placed on these websites. However, it is recommended that measures be taken, such as requiring the user to enter a username and password, to ensure that the person accessing the website is a health professional.

### 7.4 Provision of Disease Awareness Information to Patients Online

Companies are not allowed to provide disease awareness information and/or materials to patients online.

### 7.5 Online Scientific Meetings

The COVID-19 pandemic has strengthened the use of technology for all purposes, including scientific, medical and educational meetings; but unfortunately, in Ecuador, there is no specific regulation that provides the requirements and conditions that must be met from a health point of view. For this reason, in the case of events organised virtually, companies must abide only by the rules contained in the codes of conduct.

#### Relevant Laws

Leaving aside the health field, online conferences must be governed by two relevant laws: the Organic Law of Communication published on 25 June 2013 and the Law of Electronic Commerce Signatures and Data Messages issued on 17 April 2002.

According to the first, it is established that the law does not regulate the information or opinion that is issued in a personal way through the internet; it is for this reason that, in general, the meetings that take place online are not considered as local events subject to the regulations of Ecuador.

The foregoing may change only if the call and the development of the meeting specify that it is a conference exclusively for health professionals living in Ecuador. In this case, local laws will apply, mainly with regard to promotion, advertising, use of materials, transfer of information related to current health authorisations, etc, which will be directly linked to the obligations of the Health Register holder.

Although what is mentioned in the two previous paragraphs applies to the determination of the local laws that must be complied with, compliance with the ethical and conduct standards is not altered by the mechanism used to conduct the meeting.

#### Electronic Commerce Law

Regarding the invitation, access to the conference and its recordings, the provisions of the Electronic Commerce Law must be taken into account, according to which, for the elaboration, transfer or use of databases, obtained directly or indirectly from the use or transmission of data messages, the express consent of the owner of these will be required. The collection and use of personal data must comply with the rights of privacy, intimacy and confidentiality guaranteed by the constitution of the republic and this law, which may be used or transferred only with the authorisation of the owner or by order of the competent authority.

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

It is strictly forbidden to advertise/promote pharmaceutical products to healthcare professionals who work in the public sector or public healthcare organisations.

In 2021, a reform to the Organic Criminal Code came into force, according to which, acts of corruption in the private sector are criminalised. In accordance with this reform, the director, general manager, administrator, main executive, shareholders, partners, legal representatives, attorneys-in-fact, advisers, auditors, sponsoring lawyers or any employee who holds a management position in a private legal entity, non-profit organisation, the government, an association, a foundation or committee who intentionally accepts, receives or requests donations, gifts, presents, promises, rights, fees, contributions, rents, interests, advantages, salaries, gratuities, immaterial benefits or undue economic benefits or other material good, and who omits or commits an act that favours themselves or a third party, in the course of economic, financial or commercial activities, will be punished with imprisonment from five to seven years, and a fine of 500 to 1,000 unified basic salaries of the workers in general.

Likewise, if any of the people referred to in the previous paragraph receive or accept improper economic benefits to boost one pharmaceutical company over another, they can be sentenced to up to seven years in prison.

### 8.2 Legislative or Self-Regulatory Provisions

The current Regulations for Publicity and Promotion of Medicines, Processed Natural Products for Medicinal Use, Homeopathic Medicines and Medical Devices, which regulate the subject, do not prohibit offering benefits or other inducements to healthcare professionals or organisations, as long as they are justified.

The latest reform established in the Code of Conduct of the pharmaceutical industry, prohibits all kinds of personal gifts.

It is also very important to consider the new crime of corruption in the private sector.

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

The offering of gifts or other items is not regulated by the state. However, the self-regulation of the pharmaceutical industry states the following:

- gifts for personal gain are prohibited;
- promotional items are prohibited in the case of prescription products but allowed for OTC medication if they are relevant to the practice of medicine;
- medical utility items can be delivered twice a year, at most, and only if they do not replace routine business practices that are beneficial to improve the provision of medical services; and
- informative or educational items are allowed provided they are primarily for educational purposes and have no independent value.

All gifts have restrictions on value, which must be modest and adequate.

### 9.2 Limitations on Providing Samples to Healthcare Professionals

Samples provided to healthcare professionals by pharmaceutical companies are subject to certain limitations, such as:

- a ban on delivering biological medicament samples;
- a duty to mark samples in such a way that they cannot be sold or improperly used;
- a responsibility to deliver small quantities of samples only to healthcare professionals authorised to prescribe that product;
- a duty to register and document sample deliveries; and
- an obligation to verify that storage conditions are adequate.

At all times, pharmaceutical companies have to keep in mind that the sole purpose of providing samples must be health professionals' familiarisation with the product, not free promotion.

### 9.3 Sponsorship of Scientific Meetings

Pharmaceutical companies are allowed to organise scientific meetings or congresses and sponsor attendance by healthcare professionals at these events as long as they are of ethical content according to the industry's self-regulation (rather than state legislation). The fundamental purpose of these programmes should be to facilitate the constant learning of health professionals for the benefit of patients. These programmes should not be used to influence or reward health professionals for prescriptions or recommendations of a particular pharmaceutical product.

No company can organise or sponsor events outside the country, unless this is appropriate and justified for logistical or security reasons. Events that include professionals from many countries are justified and allowed. Events abroad should be located in an appropriate place and should not include entertainment and leisure activities.

### 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies are not allowed to organise or sponsor cultural, sports or other non-scientific events in relation to scientific conferences. They cannot provide or pay for social, entertainment or leisure activities.

### 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

The provision of grants or donations to healthcare professionals or healthcare institutions is not regulated specifically for the pharmaceutical industry. The civil rules related to donation of goods would be applied.

### 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

In Ecuador, there are no restrictions on pharmaceutical companies giving rebates or discounts to health professionals or healthcare institutions.

### 9.7 Payment for Services Provided by Healthcare Professionals

Pharmaceutical companies can pay healthcare professionals for their services as long as a contract has been signed that specifies the following:

- the nature of the services;
- the legitimate need for the services; and
- a reasonable remuneration that reflects the market value.

### 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

No prior authorisations or notifications are required by the national competent authorities

(ie, the Agency for Health Regulation and Surveillance, or any other health authority).

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

In Ecuador, pharmaceutical companies are not required to disclose details of transfers of value to healthcare professionals or healthcare institutions.

### 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

In Ecuador, there is no obligation for pharmaceutical companies to disclose the details of any transfer of value to healthcare professionals or healthcare institutions.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

The agencies responsible for regulating and controlling the advertising of non-prescription medications are the following:

- the agency for Health Regulation, Control and Surveillance;
- the Ministry of Health;
- the Superintendence of Market Power Control; and
- the Ombudsman's office.

Similarly, any ruling from these administrative authorities will be known and resolved in the administrative courts.

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

In Ecuador, processes can be initiated for deceptive advertising that occurs when advertising characteristics are not true or verifiable. Similarly, a complaint can be initiated if a prescription drug is advertised. These actions are initiated by the ARCSA, the Ministry of Health, before the Superintendence of Market Control and Power, or the Ombudsman's office.

### 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The public bodies responsible for monitoring and sanctioning can impose fines ranging from ten unified basic salaries to a fine of 10% of the annual turnover of the offending company. Similarly, regulatory bodies may request the forfeiture of the violating product or the temporary or final closure of a company that violates the regulation on advertising and prescriptions.

### 11.4 Relationship between Regulatory Authorities and Courts

Any measure ruled by an administrative authority may be reviewed by the administrative courts if this is required. It is in the power of the courts to ratify or overrule what the administrative authorities dictate, as this is the relationship that exists between the courts and the authorities.

### 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

The public administration, through Executive Decrees 522 and 1159, required pharmaceutical companies to market their medicines as generic once the invention patents had expired. The Competition Authority initiated an investigation

of pharmaceutical companies for alleged breach of the provisions of the decrees. This was the beginning of one of the most important cases in recent years in which, after a year and a half of investigation, the authority ruled in favour of the pharmaceutical companies.

Since the Organic Health Law did not require that companies submit patents or their states before marketing a medicine, the provisions of the decrees were impossible to enforce. With the ruling in favour of the pharmaceutical companies as a clear precedent, both decrees were repealed by the government and there is now no need to mark medicines as generic once the patents have expired.

**Meythaler & Zambrano** has around 36 legal professionals specialised in intellectual property, litigation, antitrust, tax, labour, corporate, public procurement, investigation and healthcare. It has offices in Quito and Guayaquil and belongs to a wide network of law firms in the Americas, Asia and Europe. Meythaler & Zambrano provides comprehensive advice tuned to each client's current situation, which allows it to provide its customers with a huge competitive advantage. Throughout the firm's accredited trajectory, it has advised clients of great international and national prestige.

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# FRANCE

## Law and Practice

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## 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

### 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

In France, the legal framework applicable to advertising relating to medicinal products for human use is mainly to be found in the Public Health Code. The relevant provisions are partly legislative (Articles L.5122-1 to L.5122-16) and partly regulatory (Articles R.5122-1 to R.5122-17). The regulatory provisions must conform with the legislative provisions and, in the event of conflict between these two standards, the legislative provisions take precedence over the regulatory provisions.

The criminal provisions applicable to the advertising of medicinal products can be found in Articles L.5422-3 of the same Code and were amended by the Order of 19 December 2013 on the harmonisation of criminal and financial penalties relating to health products.

In addition to these "hard law" provisions, recommendations issued by the French National Agency for the Safety of Medicines and Health Products (ANSM) clarify this legal framework. These recommendations, which are regularly updated, can be consulted on the ANSM website.

### 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The legislative and regulatory provisions contained in the Public Health Code governing the advertising of medicinal products have general scope and binding legal force.

The ANSM, a public establishment under the supervision of the Ministry of Health, is responsible for ensuring that pharmaceutical companies' laboratories comply with the rules on the advertising of medicines. To this end, the ANSM regularly issues recommendations. While these recommendations have only an interpretative role and are not legally binding, pharmaceutical companies' laboratories are, in practice, required to comply with them, in particular to facilitate the examination of their files by the ANSM when an authorisation to advertise is required.

## 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

### 2.1 Definition of Advertising

Advertising for medicinal products is defined in Article L.5122-1 of the Public Health Code as "any form of information, including solicitation, canvassing or incitement aimed at promoting the prescription, supply, sale or consumption of these medicinal products".

### 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

The provision of information, which does not constitute advertising within the meaning of the Public Health Code, is free. The boundary between the notions of advertising and giving information is blurred, however, because the notion of advertising is interpreted very broadly.

The purpose of the message is the decisive factor in distinguishing advertising from mere information.

The following constitute information and not advertising:

- information provided by pharmacists managing a hospital pharmacy as part of their duties;

- correspondence required to answer a specific question about a particular medicinal product;
- factual information and reference documents relating to packaging changes, pharmacovigilance adverse reaction warnings, and sales catalogues and price lists if there is no information on the medicinal product;
- information relating to human health or human diseases, provided that there is no reference, even indirectly, to a medicinal product; and
- documents relating to legal information concerning the product (eg, a summary of product characteristics).

For example, disease awareness aimed at patients is not subject to the rules governing advertising if it is sufficiently general and not targeted at a specific medicinal product.

### 2.3 Restrictions on Press Releases regarding Medicines

Press releases are permitted, provided they comply with the rules applicable to advertising. Regardless of the target audience, press releases must – if they constitute advertising – be authorised in advance by the ANSM.

Press kits and press releases to promote medicinal products may be sent to journalists by email but may not be presented on pharmaceutical companies' websites if they mention one or more medicinal products.

Real access restrictions must, therefore, be put in place by companies that want to make press releases accessible to journalists. For example, the allocation of a personal access code, given after checking the applicant's status as a media professional, can prevent access by unauthorised persons.

However, institutional press kits or press releases do not constitute advertising. Consequently, they are not subject to authorisation by the ANSM and are authorised to appear on pharmaceutical companies' websites.

### 2.4 Comparative Advertising for Medicines

Comparative advertising may concern two or more medicinal products, under their trade name or under their international non-proprietary name where the trade mark is identifiable, whether they are products of the same pharmaco-therapeutic class or medicinal products with the same therapeutic purpose.

The comparison may be as exhaustive as possible without emphasising favourable elements. It must cover essential, significant, relevant and verifiable characteristics. The advertiser must be able to justify the accuracy, relevance and interpretation of the results of the comparative study.

Comparative advertising must not:

- take undue advantage of the reputation of a competitor's trade mark, trade name, or other distinctive signs;
- lead to the discrediting or disparagement of a competitor's trade marks, trade names, other distinctive signs, or position;
- cause confusion between the advertiser and a competitor or between the advertiser's and a competitor's trade marks, trade names, or other distinctive signs; or
- subject to the provisions on proprietary medicinal products, present medicinal products as an imitation or reproduction of another medicinal product with a protected trade mark or trade name.

Furthermore, comparative advertising to the general public may not imply that the effect of a medicinal product is greater than or equal to that of any other medicinal product on the market.

Failure to comply with these rules exposes the advertiser to civil and criminal penalties.

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

Information on unauthorised medicinal products or indications may be freely provided if it does not constitute advertising. The information must therefore not be intended to promote the prescription, supply, sale or consumption of medicinal products.

Furthermore, the provision of information constituting advertising is not permitted:

- for medicinal products or indications which have not been granted marketing authorisation;
- where the medicine is the subject of an ongoing or future clinical trial; or
- where the medicinal product is the subject of a reassessment of its risk-benefit ratio following a pharmaco-vigilance report, until the end of that procedure (the operating company is obliged to inform health professionals of this reassessment in accordance with the information issued by the ANSM – Article L.5122-3 of the Public Health Code).

In addition, for medicinal products and indications benefiting from marketing authorisation, it will be necessary to ensure that the marketing authorisation does not contain any prohibition or restriction on advertising.

### 3.2 Provision of Information during a Scientific Conference

It is permissible to freely provide information on unauthorised medicinal products or indications at a scientific conference aimed at health professionals if it does not fall within the scope of the definition of advertising.

In this case, publishers of the medical press are required to include a warning on the first page of the information documents sent to professionals that the data resulting from the research has not yet been validated by the French authorities. This publication is made under the responsibility of the publishers and their reading committee.

This being said, it is prohibited to provide information constituting advertising for medicinal products which have not obtained marketing authorisation.

### 3.3 Provision of Information to Healthcare Professionals

It is possible to send information on unauthorised medicinal products or indications as long as this does not fall within the scope of the definition of advertising.

In this case, publishers of the medical press are required to include a warning on the first page of the information documents sent to professionals that the data resulting from the research has not yet been validated by the French authorities. This publication is the responsibility of the publishers and their reading committee.

### 3.4 Provision of Information to Healthcare Institutions

It is permissible to provide information on unauthorised medicinal products or indications to healthcare institutions so that they can prepare budgets, provided that this information does not fall within the scope of the definition of advertising.

### 3.5 Publication of Compassionate Use Programmes

The "compassionate use" programmes referred to in Article 83 of Regulation (EC) No 726/2004 of 31 March 2004, laying down European Community procedures for the authorisation and supervision of medicinal products for human and veterinary use, correspond in France to the early access procedure, which replaces the temporary authorisation procedure for use (ATU) since 1 July 2021.

The early access procedure allows the reimbursement in France of medicinal products that do not yet have marketing authorisation (AMM) or that have one indication that is not covered by the AMM. This derogatory method of reimbursement affects presumed innovative medicines. The granting of this authorisation is decided by the French National Authority for Health ("HAS").

The promotion of medicinal products benefiting from early-access authorisation to prescribers is allowed, in the same way as for medicinal products with an AMM.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Medicinal products may be advertised to the general public provided that they are not subject to medical prescription, that none of their various presentations are reimbursable by compulsory health insurance schemes, and that their marketing authorisation or registration does not contain a prohibition or restriction on advertising to the general public on the grounds of a possible risk to public health.

The advertising of vaccines to the general public is subject to special rules. It is permitted if the following conditions are met:

- firstly, the vaccine appears on a list of vaccines drawn up for public health reasons by decree following the opinion of HAS;
- secondly, the content of the advertising campaigns is in accordance with the opinions of HAS and clearly identifies the mandatory information required by this body; and
- thirdly, the ANSM has authorised the advertising by means of a visa.

### 4.2 Information Contained in Pharmaceutical Advertising to the General Public

Advertising of a medicinal product intended for the general public must contain mandatory information to highlight the advertising nature of the message and clearly identify the product (Article R.5122-3 of the Public Health Code). These particulars must include the name of the medicinal product and the common name of all the active ingredients, the information essential for proper use, an express invitation to read the instructions on the package leaflet or on the outer packaging carefully, a message of caution and, in the case of a generic speciality, a reference to this quality.

There are also prohibited terms listed in Articles L.5122-7 and R.5122-4 of the Public Health Code, such as:

- information that would make a medical consultation superfluous;
- information which suggests that the effect of the medicinal product is guaranteed, that it is free of adverse effects, or that it is superior or equal to another treatment or medicinal product;
- information that suggests that a normal state of health can be improved by the use of the medicine;

- information suggesting that a normal state of health may be affected if the medicinal product is not used;
- information intended exclusively or mainly for children; and
- information referring to a recommendation from scientists, health professionals or persons who, although neither scientists nor health professionals, may by reputation encourage the consumption of the medicinal product concerned, etc.

By way of illustration, it is therefore possible to mention a price on the advertising of medicinal products, when it is not a medicinal product reimbursed by social security.

### 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

There are no binding provisions (ie, legislative or regulatory) restricting interactions between patients or patient organisations and industry.

However, industrial unions have issued "Ethical Charters", which member companies undertake to respect.

In addition, in application of the "transparency" mechanism (Article L.1453-1 of the Public Health Code), companies producing or marketing medicines must make public the agreements concluded with associations of users of the health system as well as the benefits provided (see **10. Pharmaceutical Companies: Transparency**). This provision applies to agreements concluded with "influencers" (ie, people who, in the media or on social networks, present one or more health products in such a way as to influence the public).

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Advertising of medicinal products is in principle permitted to all health professionals who are authorised to prescribe or dispense medicinal products or use them in the exercise of their art.

By way of exception, where a medicinal product is subject to restricted prescribing conditions, advertising may be carried out only among health professionals authorised to prescribe it and among pharmacists working in structures capable of dispensing that medicinal product.

Advertising of a medicinal product to health professionals must be tailored to its intended audience and specify the date on which it was last established and revised. In addition, it must contain certain mandatory information (Article R.5122-8 of the Public Health Code) such as:

- the name of the medicinal product;
- the name and address of the company operating the medicinal product;
- the pharmaceutical form of the medicinal product;
- the qualitative and quantitative composition in terms of active ingredients, with the common name, and the constituents of the excipient, knowledge of which is necessary for the proper administration of the medicinal product;
- the marketing authorisation or registration numbers;
- the essential pharmacological properties with regard to the therapeutic indications;
- the therapeutic indications and contraindications;

- the method of administration and, if necessary, the route of administration, the dosage, adverse reactions, special warnings and precautions for use;
- interactions with other medicinal products;
- the classification of the medicinal product in terms of prescription and dispensing mentioned in the marketing authorisation;
- the limit price for sale to the public when such a price is fixed in accordance with the laws and regulations in force, together with the daily treatment costs; and
- the situation of the medicinal product with regard to reimbursement by social security.

### 5.2 Reference to Data Not Included in the Summary of Product Characteristics

Advertising directed at health professionals may contain claims that are not in the summary of product characteristics if such claims are consistent with the summary of product characteristics.

Thus, claims supplementing the information in the summary of product characteristics may be advertised to health professionals if they confirm or clarify the information in the summary of product characteristics and do not distort it.

It is therefore, in principle, prohibited to refer in advertising to new scientific developments and results which go beyond the information included in the summary of product characteristics. As an exception, it is possible to refer to information or research that is not required in the summary of product characteristics but which is nevertheless useful to health professionals when seeking the most appropriate treatment for their patients.

The ANSM has published recommendations on studies that can be referenced in advertising. Only the following may be used in advertising:

- studies published in a peer-reviewed journal, carried out under the conditions of use of the medicinal product as defined in the product's AMM and other existing standards; and
- unpublished studies which are derived from the marketing authorisation dossier and which are consistent with the wording of the marketing authorisation and, where appropriate, those which are consistent with the conclusions of the Transparency Commission, which gives an opinion on the treatment of medicinal products in France.

### 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

Advertising for combination products or complementary diagnostics that are not included in the summary of product characteristics is possible, if the conditions listed in **5.2 Reference to Data Not Included in the Summary of Product Characteristics** are met.

### 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Companies may provide reprints of journal articles to healthcare professionals under certain conditions:

- the reprint must be a faithful reproduction of the articles concerned; and
- the source must be cited and referenced in an international database and submitted to a reading committee.

### 5.5 Medical Science Liaisons

Medical Liaison Officers are authorised to discuss scientific information on medicinal products with health professionals. However, advertising regulations may apply, particularly if the exchanges with health professionals are the result of a proactive approach by the Medical Liaison Officer.

Pursuant to the Act of 13 August 2004 on health insurance, a quality charter for medical examinations has been drawn up and provides a framework for medical examinations.

Any person carrying out an information activity must perform their missions exclusively by means of dated documents made available to them by the company, validated by the pharmacist in charge, and for which an advertising visa has been granted by the ANSM. Promotional material must be in accordance with the legislation, dated and up to date, and clear about the use of the product.

### Verbal Presentation and Accompanying Documents

The charter requires that the verbal presentation of a medicinal product made by a medical sales representative must be accompanied by the hand-delivery to the healthcare professional of a certain amount of information, in each of the indications of the marketing authorisation, such as:

- a summary of product characteristics;
- a classification of the medicinal product in terms of prescription and dispensing mentioned in the marketing authorisation;
- the maximum price limit for sale to the public;
- the situation of the medicinal product with regard to reimbursement by health insurance bodies or approval by public authorities; and
- the most recent opinion delivered by the Transparency Commission with regard to the medical service provided by the medicinal product.

Other documents may also be submitted, eg, recommendations for good practice or consensus conferences.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

Both to the general public and to healthcare professionals, advertising of medicinal products is subject to prior authorisation by the ANSM, irrespective of the advertising medium used.

This prior authorisation is granted by way of an advertising visa called a “GP visa” for the general public and a “PM visa” for health professionals. Visa applications are deemed to be accepted in the absence of a reply from the director general of the Agency within two months.

The visa is granted for a period of two years and may not exceed the period of validity of the marketing authorisation for the medicinal product concerned.

### 6.2 Compliance with Rules on Medicinal Advertising

In order to ensure compliance with the rules on the advertising of medicinal products, any company operating a medicinal product must set up an advertising department, under the supervision of the pharmacist in charge, which must ensure compliance with the rules on advertising and, in particular, check the scientific validity of the information provided.

The company must keep a copy of each advertisement it publishes for three years from the date of its last publication and must make this copy available to ANSM, together with a sheet indicating the addressees, the method of publication, and the date of first publication.

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

Advertising on the internet for medicinal products is governed by the common provisions applicable to the advertising of medicinal products contained in the Public Health Code, in particular Articles L.5422-1 et seq.

Advertising is therefore subject to an advertising endorsement and must in principle contain all the mandatory particulars (see **4.2 Information Contained in Pharmaceutical Advertising to the General Public** and **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**).

The ANSM does, however, provide for derogations of the compulsory information required on certain media.

#### Authorised Advertising Media

Any media distributed in service (displays, supports for the pharmacy counter, umbrella stands, wall thermometers, etc), internet banners, internet pop-ups or various objects (material used by a health team at a sports event, a vehicle engaged in a sports race, etc) constitute authorised advertising media with the compulsory reduced particulars. These particulars are as follows: the name of the medicinal product, the common name, the indication, the medicinal product, the age limit and specific warnings.

#### *Internet promotion*

The ANSM has drawn up a charter concerning the communication and promotion of health products on the internet and on e-media. The purpose of this charter is to clarify the advertising provisions of the Public Health Code in order to adapt them to this medium.

In practice, the charter requires that the internet user be able to critically analyse the information received in so far as the sites of pharmaceutical companies will henceforth have to display a clear distinction between the information, services and advertising sections. The text also specifies the conditions under which pharmaceutical companies may offer certain services such as access to bibliographic databases, the dissemination of information relating to human health and diseases, and access to other sites via hyperlinks.

The charter allows an operator to set up discussion forums on their website under certain conditions. In particular, the operator is expected to moderate the discussions a posteriori in order to ensure the proper use of the health products referred to therein.

In addition, the operator must put in place means to ensure that remarks that do not comply with the regulations in force do not remain on the website for more than 24 working hours.

### 7.2 Advertising of Medicines on Social Media

The advertising of medicines on social networks is governed by the charter of the ANSM on the communication and promotion of health products on the internet and on e-media.

This charter specifies that the inherent functionalities of social networks lead to linking page content to comments and messages, the content of which is free and not controllable.

Consequently, advertising of a medicinal product to the general public in the form of a “products” page is not possible on social networks, unlike the discussion forums available directly on the operator’s website, as it is impossible to moderate the comments of internet users.

In addition, the "like" option available on some social networks may be perceived as an attestation of healing by the public if it is the profile of a health professional, which is contrary to the Public Health Code.

However, a closed forum between health professionals on social networks is allowed if the operator intervenes through moderation of discussions.

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

Companies are required to implement access restrictions on websites containing advertising or other information intended for healthcare professionals.

For example, the attribution of a personal access code, given after checking the qualification of the health professional, makes it possible to prevent unauthorised persons from accessing these sites.

### 7.4 Provision of Disease Awareness Information to Patients Online

Disease awareness aimed at patients is not within the scope of the definition of advertising if it is sufficiently general and is not targeted at a specific medicinal product.

As regards communication on the internet, the company's website must comply with specific regulations. The site must be designed to distinguish the promotional section from the information and services section.

### 7.5 Online Scientific Meetings

Online scientific meetings do not fall within the scope of a specific national regulation. Despite this, a broader approach to the matter occurs in French legislation in the form of the new "anti-gift" system (see **9.1 Gifts to Healthcare Professionals**). This regulates two components considered as benefits under French law and this can be extended to virtual symposiums when:

- pharmaceutical companies sponsor scientific meetings or congresses attended by healthcare professionals; or
- pharmaceutical companies finance healthcare professionals when virtually attending scientific meetings.

Conversely, pharmaceutical companies may be allowed to make a donation to associations of healthcare professionals or of students organising scientific meetings, pursuing the Order dated 7 August 2020. This Order sets two thresholds:

- EUR8,000 ATI (all taxes included) to finance research activities, funded research or scientific evaluation; or
- EUR1,000 ATI intended for other purposes related to health issues.

Under these limits, the pharmaceutical company must report the gifts and donations made to the association, to the council of the competent professional body, eight days before the congress. Above these limits, an authorisation procedure must take place before the council of the competent professional body within two months before the meeting.

#### Easing Participation

Pharmaceutical companies may ease healthcare professional's participation and online experience by supporting them before, during and after the meeting. This support could qualify as gifts under the "anti-gift" scheme.

This easing incarnates, first, in the hospitality derogation. This provision implies that hospitality is offered directly or indirectly during strictly scientific or professional events or promotional

events by pharmaceutical industries. In addition, the hospitality offered must be reasonable and strictly limited to the principal objective of the event.

In order not to fall under the authorisation procedure, hospitality fees should not exceed EUR1,000 ATI for the registration fees, EUR50 ATI for meals and EUR15 ATI for snacks (knowing that the total amount of these fees must not exceed EUR2,000 ATI).

*Applicability of derogation*

It is worth pointing out that this derogation only applies to healthcare professionals. Therefore, it does not cover healthcare students or healthcare associations that are subjects of the anti-gift system for other matters. Likewise, the principle of hospitality does not apply to healthcare professionals' relatives.

*Attendee bags*

Healthcare professionals' virtual attendance could be furthered by sharing handouts, materials or attendee bags during and after conferences, which may be perceived as gifts.

What may constitute an attendee bag could fall under the negligible value threshold imposed by the Order dated 7 August 2020. Under it, the items' value would not be subject to any specific restrictions whereas above it, these gifts will be prohibited.

Thus, items or materials, like office supplies (under EUR20 ATI/calendar year), books, reviews or review subscriptions (under EUR30 ATI/calendar year) or services linked to the beneficiary's profession (under EUR20 ATI/calendar year) are considered to be negligible value. The total amount of these expenses must not exceed EUR150 ATI/calendar year. If these limits are respected, these gifts may be granted. The negligible value appreciation also depends on the context and the nature of the product offered by pharmaceutical companies during online meetings.

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

General anti-corruption rules are subject to stricter regulations regarding health products due to the existence of the "anti-gift" system.

As indicated in **9. Gifts, Hospitality, Congresses and Related Payments**, the "anti-gift" system was substantially modified by Order No 2017-49 of 19 January 2017, ratified by Law No 2019-774 of 24 July 2019 relating to the organisation and transformation of the healthcare system, and the implementing legislation. The provisions of this Order have applied since 1 October 2020.

The new "anti-gift" scheme prohibits companies from providing benefits, producing or marketing products covered by compulsory social security schemes, or producing or marketing health products listed by Article L.5311-1 of the Public Health Code (whether or not the products are covered) from offering benefits in kind or in cash, in any form whatsoever, directly or indirectly, to all health professionals (dentists, dental surgeons, etc, occupational and psychomotor therapists, nurses, masseur-physiotherapists, doctors, speech and language therapists, and orthoptists, chiropodists, pharmacists, midwives, etc), to students in the health professions, to associations representing these health professionals and students, and to civil servants and employees of the administration. This prohi-

bition applies to both private and public sector health professionals.

### 8.2 Legislative or Self-Regulatory Provisions

The new "anti-gift" scheme prohibits companies that provide benefits, or that produce or market products covered by compulsory social security schemes, from offering benefits to health professionals, students, and associations of health professionals and students – including those involved in the field of their training, learned societies and national professional councils – as well as civil servants and officials of public administrations (see **8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals**).

In addition, companies producing or marketing health products are also subject to the new "anti-gift" scheme, whether or not the products in question are covered.

Conversely, the new "anti-gift" scheme does not prohibit companies from offering benefits to healthcare institutions or patients.

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

The "anti-gift" scheme was amended by Order No 2017-49 of 19 January 2017 relating to benefits offered by persons manufacturing or marketing health products or services, which repealed Article L.4113-6 of the Public Health Code.

The new "anti-gift" scheme specifically prohibits companies that provide benefits, or that produce or market products covered by compulsory social security schemes, or that produce or market health products listed by Article L.5311-1 of the Public Health Code (whether or not these products are covered) from providing benefits in kind or in cash, in any form whatsoever, directly or indirectly, to a health professional, a student, an association of health professionals or students, or civil servants and employees of the administration.

The "anti-gift" scheme does not expressly define the notion of "benefit".

#### Items Not Considered Benefits

However, benefits in cash or in kind which relate to the exercise of the beneficiary's profession and which are of negligible value (defined by an Order dated 7 August 2020 and depending on the benefit's type) are not considered as advantages within the meaning of the "anti-gift" system in force. The new "anti-gift" scheme also stipulates the following as being items not considered as benefits:

- the remuneration, compensation, or expenses for activities provided for in an employment contract or a contract of practice;
- the proceeds from the exploitation or assignment of intellectual property rights relating to a health product;
- commercial benefits offered in connection with the procurement of goods or services; and
- benefits in cash or in kind that relate to the practice of the beneficiary's profession, and of negligible value that does not exceed the amounts provided for, by nature of the benefit, and over a specified period, by the Order dated 7 August 2020.

With the exception of the cases listed above, the "anti-gift" scheme prohibits manufacturers in principle from offering benefits to health professionals, students and associations representing them.

### Benefits Authorised by Way of Derogation

The following benefits in kind or in cash may be authorised by way of derogation and subject to conditions:

- the remuneration, compensation and defrayal of expenses for research activities, research exploitation, scientific evaluation, consultancy, provision of services or commercial promotion;
- donations and gifts in cash or in kind, intended exclusively to finance research activities, the exploitation of research or scientific evaluation activities;
- donations and gifts intended for associations bringing together health professionals and students, with the exception of the national professional councils mentioned in Article L.4021-3 and associations with a purpose unrelated to their professional activity;
- hospitality offered, directly or indirectly, at events of an exclusively professional or scientific nature, or at events promoting health products or services, provided that such hospitality is of a reasonable level, strictly limited to the main purpose of the event and is not extended to other persons, with the exception of students in initial training and student associations; and
- the financing or participation in the financing of vocational training and continuing professional development actions.

## 9.2 Limitations on Providing Samples to Healthcare Professionals

Pharmaceutical companies may provide samples of a product to healthcare professionals for a period of two years following its first actual marketing in France. Only health professionals authorised to prescribe medicines may receive samples (ie, physicians, dentists, midwives, paediatricians, nurses, physiotherapists and hospital pharmacists).

In addition, this discount must comply with the following conditions:

- each supply of samples must be in response to a written, dated and signed request from the recipient;
- only a limited number of samples, up to a maximum of four per year and per recipient, may be submitted, depending on the nature of the medicinal product and the need for the prescriber to become familiar with it;
- each sample must be identical to the smallest package on the market;
- each pharmaceutical establishment supplying samples must organise within its own organisation the control of this supply and the follow-up of the samples; and
- each sample must be accompanied by a copy of the summary of product characteristics.

For medicinal products subject to the conditions of restricted prescription, samples may be given only to pharmacists managing pharmacies for use inside healthcare institutions and to prescribers authorised to draw up the prescription.

The Promotional Information Charter of 15 October 2014, which succeeds the 2004 medical examination charter, prohibits "the handing over of samples of cosmetic products, food supplements and medical devices by persons exercising a promotional information activity by solicitation or canvassing, as long as they present a pharmaceutical speciality".

## 9.3 Sponsorship of Scientific Meetings

The "anti-gift" system not only applies to associations representing health professionals or students (ie, associations responsible for defending the categorical interests of a profession) but also to associations which bring together – but do not represent – those people, particularly learned societies. Therefore, pharmaceutical compa-

nies have to comply with the terms and conditions laid down in the regulations (in particular, in financial terms) for sponsoring scientific meetings and congresses.

Under the new "anti-gift" scheme, funding for the participation of health professionals in a scientific meeting or congress is considered a benefit. However, this benefit may, by way of exception, be permitted if it is of a reasonable level, strictly limited to the main purpose of the event and if it is not extended to other persons.

The benefit of this derogation will be subject to a declaration or to a request for authorisation from the council of the competent professional body (depending on the amount). In the case of a request for authorisation, the application must be submitted no later than two months before the date of the meeting or congress.

### 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies are not allowed to organise or sponsor cultural, sporting or other non-scientific events in connection with scientific conferences where this confers a benefit to healthcare professionals.

### 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Under the new "anti-gift" scheme, it is possible to award grant ordinations to health professionals if they are exclusively intended to finance research activities, the promotion of research or scientific evaluation. The benefit of this derogation will be subject to a declaration or, when the amount exceeds EUR5,000, to a request for authorisation from the council of the competent professional body. In the case of a request for authorisation, the application must be submitted no later than two months before the date of the meeting or congress.

It is also possible to award grants or donations to associations of health professionals, even if they are not intended to finance research activities, or the promotion of research or scientific evaluation. The benefit of this derogation will again be subject to a declaration or to a request for authorisation from the council of the competent professional body, when the amount exceeds EUR8,000 for research, promotion of research or scientific evaluation, or when the amount exceeds EUR1,000 for other purposes related to health. Special rules apply for grants and donations to associations classified in France as "public charities".

The "anti-gift" act does not apply to healthcare facilities. Therefore, pharmaceutical companies may provide grants, donations or gifts to healthcare institutions, subject to compliance with other provisions in force. Law No 2016-1691 of 9 December 2016 on transparency, the fight against corruption and the modernisation of economic life, known as "Sapin II", requires the implementation of an anti-corruption compliance programme for companies based in France employing at least 500 employees and with a turnover of more than EUR100 million.

### 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

The new "anti-gift" scheme specifies that the commercial advantage offered by a pharmaceutical company to a healthcare professional in the context of the commercial relations between them for the purchase of goods or services does not constitute a benefit. Discounts and rebates may, therefore, be granted to healthcare professionals.

However, it should be noted that discounts and rebates granted to pharmacists are capped at 2.5% of the manufacturer's price, excluding tax, for non-generic medicines and 40% of the

manufacturer's price, excluding tax, for generic medicines.

Pharmaceutical companies may also grant such commercial advantages, in the form of rebates or discounts, to healthcare institutions, since the latter are not affected by the "anti-gift" scheme.

### 9.7 Payment for Services Provided by Healthcare Professionals

By way of derogation from the general principle of the prohibition of providing benefits to health professionals, health professionals may be remunerated, compensated or defrayed for services provided if the remuneration granted to them is proportionate to the service provided and if the payment does not disproportionately exceed the costs actually incurred by the health professional. This derogation is subject to a declaration or a request for authorisation from the competent professional body when the amount exceeds EUR200 per hour or EUR800 per half-day or EUR2,000 for the entire contract.

### 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

The new "anti-gift" scheme provides that:

- if the value of the benefits provided for in the agreement is less than a certain amount, the agreement must be declared to the competent professional body; and
- if the value of the benefits provided for in the agreement exceeds a certain amount, the agreement is subject to authorisation by the competent professional body.

The amounts in question are defined by the Order of 7 August 2020 published in Official Journal No 0199 of 14 August 2020 (text No 5).

The required information has to be provided by electronic means only (using IDAHE 2 teleprocedure portal when the beneficiary is a doctor and EPS otherwise).

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

In particular, pharmaceutical companies are required to make public, on a single public website, the amount contained in any agreements they conclude with healthcare professionals and healthcare institutions.

The remuneration granted to healthcare professionals under these agreements and the benefits otherwise offered to them must also be made public on the same site if they are greater than or equal to EUR10.

As those declarations are made ex-post, companies only declare what has been concluded or granted. Therefore, remuneration and benefits that were promised but ultimately not paid out (eg, due to COVID-19) do not have to be declared on the basis of transparency.

The voluntary omission to declare agreements or benefits is punishable under criminal law (Article L.1454-3 of the Public Health Code).

### 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

Transparency requirements apply to any company producing or marketing health products, regardless of the location of its registered office or the existence of an operation or the marketing of health products in France.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

The ANSM, under the supervision of the Ministry of Health, is the competent authority for enforcing the rules on advertising of medicinal products.

In addition, pharmaceutical companies that market pharmaceutical specialities and wish to promote medicines reimbursed by the Health Insurance must follow a certification procedure set up by the HAS.

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Pharmaceutical companies may take legal action against competitors for advertising infringements on several levels. On the one hand, a competitor of the company may be sued before the competent commercial court if the practices in question constitute defamation, disparagement or misleading advertising. On the other hand, criminal proceedings may be brought against a competitor before the criminal court for infringements of the regulations on pharmaceutical advertising.

### 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

#### Penalties for Advertising Offences

Infringements of advertising regulations are subject to administrative sanctions imposed by the ANSM, and financial penalties imposed by the ANSM and the French Economic Committee for Health Products ("CEPS"), which is responsible for setting the price of medicines covered in France, as well as criminal sanctions.

Regarding administrative sanctions, the Director General of ANSM may give formal notice to the person concerned to withdraw the advertisement and regularise the situation and, in a second stage, ban the advertisement.

Criminal and financial penalties are provided for in Articles L.5422-3 et seq of the Public Health Code. For example, fines of EUR150,000 can be imposed for advertising of unauthorised medicines or advertising without a visa.

#### Penalties Applicable to Breaches of the "Anti-gift" Scheme

Pursuant to Article L.1454-8 of the Public Health Code, read in conjunction with Article L.131-38 of the Criminal Code, it is punishable by a fine of EUR750,000 for companies that provide services, or that produce or market products covered by compulsory social security schemes, or that produce or market health products listed by Article L.5311-1 of the Public Health Code, to offer or provide benefits to health professionals or students, or associations of health professionals or students or civil servants. The amount of the fine may be fixed to 50% of the expenses incurred for the practice constituting the offence.

Pursuant to Article L.1454-8 of the Public Health Code, read in conjunction with Article L.131-39 of the Criminal Code, the following additional penalties may also be imposed:

- a permanent ban, for a maximum of five years, on the direct or indirect pursuit of one or more professional or social activities;
- placement, for a period of up to five years, under judicial supervision;
- the permanent closure, or closure for a maximum of five years, of the establishments or one or more of the establishments of the company which were used to commit the acts in question;

- the exclusion of public contracts on a permanent basis or for a maximum of five years; and/or
- the posting of the decision pronounced or its dissemination to the public, either through the written press or by any electronic means of communication.

In addition, legal representatives are also liable to a fine of up to EUR150,000 and two years' imprisonment.

### 11.4 Relationship between Regulatory Authorities and Courts

Should the ANSM identify a breach, it must inform the company concerned, which may make comments. Binding measures may be imposed on a pharmaceutical company by the ANSM to induce it to comply with its obligations or to put an end to its failure to comply.

If the difficulties persist, the ANSM may take the company in question to court.

### 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

Courts interpret the scope of the "anti-gift" scheme very broadly. By way of example, while the "anti-gift" scheme which was in force until 1 October 2020 applied to companies providing benefits, and producing or marketing products covered by compulsory social security schemes, the Court of Cassation has ruled that this scheme is also applicable to companies that produce and/or market products that are not reimbursed directly by social security but are used for the provision of benefits covered by social security (Paris Court of Appeal, 29 March 2017, No 15/8757).

In any event, the scope of the "anti-gift" scheme has been significantly extended with the entry into force of Order No 2017-49 on 1 October 2020.

**GD Avocats** is a Parisian law firm specialising in matters concerning health products and healthcare professionals. The firm was created in 2019 by Bernard Geneste and Marine Devulder, who welcomed a new associate, Maud Vanlierde, in September 2021. Bernard Geneste retired from the firm in January 2022. GD Avocats advises pharmaceutical and medical technology industries on regulatory issues – covering market access, pricing and reimbursement, clinical trials, advertising and compliance – as well as dealing with competition issues. The team also assists clients before French and European courts, in particular, in matters of reimbursement and free movement of health products.

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GD AVOCATS

# Trends and Developments

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## The Legal and Regulatory Landscape for Advertising of Medicinal Products and Medical Devices in France

Laws and regulations from various sources govern the advertising and promotion of health products in France. Indeed, there are general and more specific rules applicable to health products.

On the one hand, the provisions of the French Consumer Code and the French Criminal Code prohibit and generally sanction misleading commercial practices.

On the other hand, specific European regulations or directives, as well as French law (ie, the French Public Health Code (FPHC) and French Social Security Code (FSSC)), specifically regulate the promotion of health products.

Indeed, the FPHC regulates health products, including in particular medicinal products for human use, medical devices (MDs), veterinary products, food supplements, cosmetics and devices, objects and methods presented as beneficial to health.

In addition to that complex and extensive body of legislation, there are numerous – most of them not legally binding – recommendations, guidelines, charters, or ethics codes governing advertising, to which health products operators can or may subscribe at national, European or international level. The most important of these are listed below.

### *Authorities' guidelines and recommendations*

- Guidelines issued by the French National Agency for Medicines and Health Products Safety (ANSM):
  - (a) recommendations on advertisement of medicinal products, medical devices and in vitro medical devices; and
  - (b) charter for the communication and promotion of health products (medicinal products and medical devices) on the internet and e-media.
- Charter for information by canvassing or prospection aiming to promote medicinal products, signed between the Economic Committee for Health Products (CEPS) and the French industry organisation representing pharmaceutical companies ("Leem"), applicable to operators marketing medicinal products reimbursed by the French health insurance scheme.
- Guidelines of the High Authority for Health (HAS) for the certification of activities relating to information gathered by canvassing or prospection aiming to promote medicinal products.
- General recommendations of the General Directorate for Competition, Consumer Affairs and Fraud Control (DGCCRF).
- Rules and recommendations of the professional code of ethics for general advertising issued by the French Professional Regulatory Authority for Advertising (ARPP).

### *Self-regulation guidelines and codes*

- Guidelines and codes issued by the industry organisations, such as EFPIA, MedTech, IFPMA, Leem and SNITEM (French Organisation for the Medical Technology Industry),

along with reference documents, ethical professional provisions and opinions.

Since 2011, there have been no major changes to the rules applicable to health product advertising.

However, some regulations have been completely overhauled and have had an impact on the advertising of health products, eg, the provisions of the new anti-gift act as well as court decisions in the field of promotion and the EU regulation on medical devices. A very surprising fact from 2021 is that the ANSM did not impose any sanctions on operators based on a violation of the advertising provisions, probably due to the context of the pandemic.

## Promotion of Medicinal Products for Human Use

### *High-level overview of the French legal framework*

Article 86 of EU Directive 2001/83 as implemented in the French Public Health Code (FPHC Article L. 5122-1 and R. 5122-1 et seq) defines the promotion of medicinal products for human use as being any form of information, including that derived from canvassing, prospecting or inducement, designed to promote the prescription, dispensation, sale or consumption of medicinal products, except for information provided by hospital pharmacists.

The following are not considered as promotional materials or activities:

- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
- factual, informative announcements and reference material relating, for example, to packaging changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims; or
- information on human health or human diseases with no reference to a medicinal product.

France distinguishes two different mechanisms depending on whether the targeted audience is the general public or healthcare professionals (HCPs).

In both situations, advertising is strictly limited to that authorised for marketing or registered medicinal products for which no benefit/risk ratio reassessment is ongoing.

### *Promotion and advertising to the "general public"*

Promotion and advertising of medicinal products to the general public (the "GP") is possible provided that the medicinal product:

- is not subject to medical prescription;
- is not reimbursed by the French health insurance scheme; and
- is not held back by a prohibition or restriction on advertising to the public due to a possible risk to public health mentioned in the marketing authorisation or registration.

By way of derogation from the above conditions, disregarding their prescription-only or reimbursement status, advertising for vaccines is allowed under specific conditions, along with smoking cessation products, for public health purposes.

GP advertising of medicinal products, including the above-mentioned vaccines, is subject to prior authorisation (namely a "Visa GP") granted by the ANSM.

*Promotion and advertising to HCPs*

The promotion of medicinal products to HCPs (so-called "PM") is not limited with regard to the product prescription or reimbursement status, but it also requires the pre-approval of the ANSM (in the form of a "Visa PM").

Unlike GP advertising rules, the provision of free samples of medicinal products to HCPs is permitted provided that certain legal requirements are met.

*Advertising application process and periods*

Applications to the ANSM for a Visa GP or a Visa PM are carried out online and according to the filing periods (four periods for a Visa PM, eight periods for a Visa GP). The ANSM's director general's decision dated 28 October 2021 sets out the timetable and submission periods for 2022 along with the form and content of applications for approval of advertisements for medicinal products for human use.

In the absence of a decision on a visa application by the director general of the ANSM within two months of the day following the end of the filing period, the visa application is deemed to be accepted.

Both the Visa GP and the Visa PM are valid for two years.

## *What's new in the legal and regulatory landscape?*

*Early access and advertising: awaited clarification*

The modification for consistency purposes of specific advertising legal provisions, triggered by the implementation of the new early-access scheme, was long-awaited by the pharmaceutical industries.

Indeed, the French Social Security Finance Act (LFSS) for 2021, in the scope of a reform initiated in 2020 regarding early and derogatory access of medicinal products in the market, clarified the scope of the criminal penalties (one year's imprisonment and a fine of EUR150,000) applicable to the advertisement of early and derogatory access medicinal products (Article L. 5422-3 and L. 5422-18 FPHC).

The initial scope of the offence included advertising of early and derogatory access medicinal products (early access and compassionate access) disregarding the granting of a marketing authorisation (MA).

Consequently, advertising was forbidden for medicinal products with an MA for the relevant indication pending a reimbursement inscription (FPHC Article L. 5121-12 II.2°). Under the new system, despite the granting of an MA, some medicinal products can benefit from the new early-access legal status.

As of 25 December 2021, the scope of the prohibition has been clarified and the offence is limited only to:

- early-access medicinal products which do not have marketing authorisation for the indication promoted by the advertising (FPHC Article L. 5121-12 II.1°); and
- compassionate-access medicinal products, for the indication under compassionate-use authorisation and for the indication under compassionate prescription scheme (FPHC Article L. 5121-12-1).

This clarification is more than welcome, as the prior scope established an unjustified criminal penalty and was inconsistent with the general principles of advertising.

### *Update of guidelines and recommendations*

The ANSM Guidelines for advertising have not undergone any major modification within the last year.

However, the Professional Ethics Provisions applicable to pharmaceutical companies (the "DDPs") issued by the Leem were updated in 2020 and the new version became applicable as from 1 June 2021. To quote the Leem, the new DDPs "bring together all the ethical commitments applicable to the French pharmaceutical industry".

As provided on the official Leem website, the DDPs incorporate, in particular, the following codes, charters and provisions:

- the new EFPIA Code adopted by the EFPIA Board on 22 March 2019;
- the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code;
- the charter for the communication and promotion of health products (medicinal products and medical devices) on the internet and e-media issued by the ANSM;
- the charter for information by canvassing or prospection aiming to promote medicinal products signed between the CEPS and the Leem; and
- the new French anti-gift scheme which restricts interactions between the pharmaceutical industry and HCPs, and healthcare organisations (HCOs) which was reformed in depth in 2020.

Lately, there has been a particular focus on the status of the medical scientific liaison (MSL), the activities of which are at the boundary of promotional activities and the speeches of which must be strictly restricted and framed.

The Leem Ethics and Compliance Committee of Pharmaceutical Companies (CODEEM), the main task of which is to promote and enforce compliance with the rules of ethics of the pharmaceutical industry, issued a comprehensive opinion in 2017 regarding MSLs.

This non-binding opinion on the ethical clarification of the differences and limits between medical information and promotion regarding the evolution of the roles and obligations of MSLs in their relations with HCPs, was reflected within the DDPs dated December 2019.

As a matter of fact, Section 9 of the currently applicable DDPs dated December 2020 is specifically dedicated to the tasks of the MSLs.

According to Section 9 of the DDPs dated December 2020, "the relationship between MSLs and health professionals must be based on the following principles:

(1) Exchange of quality information that is scientific and non-promotional,

(2) Sharing of expertise necessary to improve the use of the medicinal product or its development".

In addition, a Q&A dedicated to rules applicable to MSLs was updated in November 2020.

This guidance is helpful to identify the limits of each activity regarding local positions and to avoid crossing the fine line between promotion and information.

### *About the lack of financial and administrative penalties*

Since 1 February 2014, the director general of the ANSM has been granted new administrative penalties prerogatives. In this regard, the Agency now has the power to impose financial penal-

ties on operators who do not comply with legal provisions.

The ANSM's decisions in this matter are published on the website of the Agency. These publications are thinly analysed as they provide information on the ANSM's doctrine. However, in 2021, no financial penalties or injunctions related to promotion and advertising infringements were imposed on French operators. This situation may reveal the actual major priorities of the ANSM which seems, in addition to COVID-19, to particularly focus its control on the supply of medicinal products and compliance with the rules for placing MDs on the market.

According to Article L. 162-17-8 of the FPHC, infringements of advertising regulations can also be subject to financial penalties imposed by the CEPS. The CEPS annual report for 2021 has not yet been published but, as the ANSM has not imposed any penalties, the assumption of a lack of penalties on the part of the CEPS does not seem too unrealistic.

## Promotion of Medical Devices and In Vitro Diagnostic Medical Devices

### *High-level overview of the French legal framework*

The FPHC (Article L. 5213-1) defines the promotion of MDs and in vitro diagnostic (IVD) MDs as being any form of information, including canvassing, prospecting or inducement, designed to promote the prescription, dispensation, sale or use of devices, except information provided by hospital pharmacists.

Following the same path as for medicinal products, the following are not considered to be promotional materials or activities:

- labelling and instruction leaflets (IFUs) for MDs and IVD MDs;
- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular MD or IVD MD;
- information relating to warnings, precautions for use and adverse effects identified in the context of vigilance, as well as trade catalogues and price lists, providing they include no product claim; and
- information relating to human health or human diseases, if there is no indirect reference to an MD or an IVD MD.

Since 2011, the general advertising legal provisions set on the FPHC for MDs and IVD MDs have not been subject to any major or significant modifications. Respectively, Articles L. 5213-1 et seq and L. 5223-1 et seq of the FPHC regulate the advertising and promotion of such devices.

Accordingly, promotion and advertising of medical devices is possible for the GP for both reimbursed class I or IIa MDs and MDs not reimbursed by the French health insurance scheme. Except for the derogation described below, prior authorisation is not required for such advertising. However, in any case, advertising MDs class IIb and III is strictly forbidden for the GP.

The promotion of MDs to HCPs (which falls under "PM") does not require any pre-approval by the ANSM, except in the cases described below.

The ANSM will eventually control the GP and PM promotion material. In this case, if the advertisement doesn't comply with the applicable requirements, the ANSM will be able to order the promotional material to be withdrawn after the fact, by following a specific administrative procedure.

By way of derogation in both GP and PM situations, prior authorisation is required for the pro-

motion of MDs that present an important risk to human health. These MDs, listed in a decree dated 24 September 2012, include, for example:

- for the GP – dermal depression fillers; and
- for the PM – implantable cardiac defibrillators and ankle, knee, hip and shoulder prostheses, etc.

The promotion of IVD MDs does not require prior authorisation, except in situations where their failure is likely to cause a serious health risk (eg, self-diagnosis IVD MDs for the GP and some specific reagents and reagent products for PM advertising, as stated in the decree dated 24 September 2012).

Where prior authorisation is required by law, the GP and PM visas for IVD MDs and other MDs are granted for five years, provided that the CE marking (showing that the product meets EEA safety, health and environmental protection standards) is valid.

Unlike medicinal products, applications to the ANSM for promotional materials are not subject to a particular calendar.

### *What's new regarding MDs?*

#### *Reshaping the MD legal framework*

The legal framework has been reshaped by the new Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR), which became applicable as of 26 May 2021.

In parallel, Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (IVD MDR) also came into force on 26 May 2017. A transitional period is ongoing pending the awaited application date fixed by the Regulation of 26 May 2022.

Regarding advertising, the MDR and IVD MDR state the following.

- Both Articles 7 of the MDR and IVD MDR formally prohibit the use of any "text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance" for MD and IVD MDR promotional material. A few examples of misleading conduct are included in the Regulation. This new provision is entirely aligned with the current local French regulations and practices prohibiting deceptive commercial practices as aforementioned.
- Articles 21 MDR and 19 IVD MDR, extend the possibility to present unmarked devices at trade fairs, exhibitions, demonstrations or similar events. Nevertheless, this possibility is only provided for if a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been brought into compliance with these Regulations.

#### *French ordinance to be adopted to implement MDR in-depth expected modifications*

Following the MDR becoming applicable, the French government drafted an ordinance adapting French law to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices.

According to Directive (EU) 2015/1535, this draft ordinance was notified to the EU Commission on 23 December 2021 and published through the Technical Regulation Information System (TRIS). Pursuant to the Directive (EU) 2015/1535, said draft ordinance cannot be adopted before the three-month standstill ending 24 March 2022.

This draft ordinance will have an impact on the FPHC advertising provisions, in particular.

The ANSM will carry out post-marketing surveillance and market surveillance for MDs and their accessories and for the products not intended for medical purposes listed in Annex XVI of the MDR, as follows.

- Accessories to MDs that present an important risk to human health are expressly subject to prior authorisation for their promotion. The violation of this provision, extended to accessories, constitutes both a criminal offence and an infringement under the terms of the draft ordinance subject to, respectively, a financial penalty and imprisonment, and an administrative fine.
- Advertisement to the GP of MDs and their accessories that are reimbursed, covered or financed, even partially, by the French health insurance scheme (except for reimbursed class I or IIa MDs), constitutes an infringement under the terms of the draft ordinance.
- The ANSM will be competent to control, after the fact, by all appropriate means, advertising and promotion of the products not intended for medical purposes, listed in Annex XVI of the MDR. According to the Ordinance, the general power of control of the ANSM will be extended to the products listed in Annex XVI of the MDR, including advertising activities related to them.
- Misleading conducts regarding promotional materials for MDs and their accessories and for the products listed in Annex XVI of the MDR will constitute an infringement subject to a financial penalty under the terms of the draft ordinance.

According to the draft ordinance, the ANSM and the DGCCRF will have shared sanction power with respect to products regulated by the MDR (MDs and products listed in Annex XVI of the MDR).

*About the lack of financial and administrative sanctions (again)*

As for medicinal products, in 2021 no penalties imposed by the ANSM were reported and published on the grounds of advertising regulation infringement for MDs or IVD MDs.

*Updated guidelines*

The ANSM recommendations have not been updated since the application date of the new MDR and IVD MDR.

However, as of 1 January 2022, all provisions of the MedTech Code are applicable to member companies of SNITEM, including non-corporate members of MedTech Europe (approximately 500 out of 2,000) – see below for the practical implications.

*New charter dedicated to information and promotion of MDs, effective as of 8 March 2022*

The LFSS for 2018 created Article L 162-17-9 of the FSSC which required the establishment of a new charter to ensure the quality of professional practices of persons responsible for presenting, providing information on, or promoting MDs for individual use, health products other than medicinal products and associated services.

Decree No 2018-864 of 8 October 2018 on presentation, information or promotion practices for health products and any associated services specified the procedures for negotiating, approving, renewing, or denouncing such Charter.

Negotiations between the stakeholders, ie, relevant professional organisations and the CEPS, involved in the adoption of the Charter were long and not at all easy. In fact, negotiations were unsuccessful, and the French Ministry of Health and Social Insurance was left to set out the terms of the Charter. As a result, the long-awaited Charter was eventually adopted by an

Order dated 4 March 2022, applicable as of 8 March 2022.

The Charter aims to provide a better framework for commercial, promotional, presentation or information practices relating to all products and services mentioned on the reimbursement List of Products and Services (LPP) referred to in Article L 165-1 of the CSS, whether or not they are subject to the regulations relating to CE marking, and which could otherwise be detrimental to the quality of care, or lead to unjustified expenditure for the French health insurance scheme.

According to Article L 162-17-9 of the FSSC, a financial penalty can be imposed by the CEPS if a company does not comply with the provisions of the Charter.

Under conditions to be determined by the HAS, a certification reference framework is to be established to ensure that certified operators subject to the Charter comply with its provisions.

The certification bodies will be the recipients of any infringements observed and sanctioned by the CEPS, as well as any financial penalties resulting from them.

The amount of the penalty may be up to 10% of the turnover excluding tax achieved in France by the operator in the last financial year for the product(s) or service(s) relating to the infringement.

## Recent Developments and Points of Attention

### *Substantial modification to anti-kickback regulation applicable to health products industries*

The new French anti-gift legal framework has finally come into force pursuant to the publication of the long-awaited decree dated 1 October 2020.

For the record, the anti-gift law prevents companies manufacturing or marketing healthcare products or providing healthcare services from granting benefits, in particular to HCPs and HCOs. This framework has existed under French law since 1993 and was frequently updated, until it was completely reshaped by the ordinance No 2017-49 of January 2017 (ratified by Law No 2019-774 of 24 July 2019). This new framework redefines the strict conditions under which certain benefits can be granted to HCPs and HCOs by healthcare companies. The new regulation imposes either a prior declaration or a prior authorisation to be submitted to the relevant professional board or relevant competent authority (regional health agency), depending on the amount of the benefit to be provided to the recipients.

The implementation of this new scheme represents a huge effort for the competent authorities in charge of assessing declarations and issuing, when applicable, the relevant authorisations.

As an example, during 2021, the French national physicians' organisation issued over 44,000 recommendations pursuant to benefit declarations and more than 6,000 authorisations.

Additionally, several guidelines have been issued by the authorities and professional organisations in order to implement, as well as possible, the extended scope of the new anti-gift scheme. In particular:

- the FAQ of the DGCCRF and Directorate of Health Care Supply (DGOS) dated December 2021; and
- the information note of the French Ministry of Health dated 11 September 2020.

However, French operators are still confronted by practical and technical issues regarding the application of the new scheme.

Despite those difficulties, the DGCCRF and its decentralised services carried out compliance controls during 2021. To date, no sanctions have been imposed, the main reason being that the conclusions of such controls have not yet been finalised. Following a communication of the DGCCRF, compliance controls should continue in 2022.

However, the DGCCRF is not the only public body authorised to monitor compliance with the French anti-gift scheme, and sanctions to operators imposed by other authorities may be made public at a later stage.

### *MedTech Ethics Code came into force as of 1 January 2022 for an important part of MD operators*

In 2015, the European trade association representing the medical technology industry (ie, in-vitro diagnostics and medical devices manufacturers operating in Europe) published the MedTech Europe Code of Ethical Business Practice.

This code of ethics, which became binding for MedTech Europe (MTE) corporate members on 1 January 2017, "regulates all aspects of the industry's relationship with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), to ensure that all interactions are ethical and professional at all times and to maintain the trust of regulators, and – most importantly – patients".

In France, since 1 January 2022, all provisions of the MedTech Code have been applicable to SNITEM member companies (ie, 557 members with a significant position in France), which includes non-corporate members of MTE.

The MedTech Code lays down stricter rules than those governing interactions between HCP/HCO and IVD MD and MD operators in France.

Accordingly, relevant operators subject to the MedTech Code will no longer be able to provide direct financial support for individual HCPs to attend third-party organised educational events.

With the new French anti-gift scheme, the IVD-MD and MD industries have had to anticipate every interaction along with the expected delay for the competent authority to authorise or respond to a declaration of interaction between an HCP and IVD-MD/MD operator. In any case, feedback from the authority is considered prior to the implementation of the regulated interaction.

The requirements of the MedTech Code represent a real challenge for operators subject to its provisions.

In light of these provisions, the process to grant an indirect sponsor will need to start sooner. The SNITEM estimates that the delay between the signature of the grant agreement with the third-party beneficiary and the event date is between four and eight months.

Detailed processes are required to be implemented internally within relevant operators in order to comply with all the ethical and legal requirements. The French transparency regulation remains applicable and relevant operators are required to publish every benefit granted, even indirectly, to HCP/HCO events.

### *Online sales service relating to medicinal products for humans who are not subject to medical prescription*

In France, online sales of medicinal products have been governed by Articles L 5121-5, L 5125-33 et seq and R 5125-70 since 2013.

Recently, the landscape was deeply modified by the impact of the decisions issued by the CJEU, the Paris *Cour d'Appel* (Court of Appeal, 17 Sep-

tember 2021) and the *Conseil d'Etat* (French Administrative Supreme Court).

These changes are positive for French pharmacists who were calling on the French government for clarification and harmonisation of the rules applicable in France to both French providers of online sales services relating to medicinal products not subject to medical prescription, and other member states' providers of that service.

Below are the main steps leading to the current scheme.

- 2019 and 2020 – the CJEU to enact that the enforceability of restrictive measures to the freedom to provide services adopted by a member state is subject to prior notification to the EC and member states where relevant service providers are established (judgments of the court: 19 December 2019, Airbnb Ireland, C390/18, and 1 October 2020, C649/18).
- 2021 – the CJEU stated that a member state of destination of an online sales service may not prohibit pharmacies established in another member state from using paid referencing on search engines and price comparison websites. The position of the CJEU was followed on 17 May 2021, by the decision of the supreme French administrative court;
- 2021 – the French government eventually notifies the EC and EU member states of the French national rules, measures and restrictions applicable to the online dispensing and sale of medicinal products in the French territory (this notification subjects other member states' providers of online sales services relating to medicinal products to the same restrictions as their French counterparts);
- 2022 – from this point on, the following rules, restrictions and measures can be validly enforced in France against providers established in another member state:
  - (a) to limit advertising as long as it does not prevent providers of online sales services relating to medicinal products not subject to medical prescription from carrying out any advertising outside their pharmacy;
  - (b) to prohibit promotional offers consisting of a discount on the total price of an order of medicinal products when reaching a certain amount, provided that "such a prohibition is sufficiently circumscribed and particularly targeted solely at medicinal products and not at mere para-pharmaceutical products"; and
  - (c) to require a health questionnaire to be included in the process of ordering medicinal products online.

## Conclusion

The regulatory environment of advertising of medicinal products and medical devices has been modified despite the scattered changes affecting the applicable rules.

MDR implementation, along with the charter dedicated to providing information on and promoting medical devices, and the implementation of a restrictive framework for the provision of direct financial support of individual HCPs to attend third-party organised educational events will undoubtedly have a significant impact on the mindset and internal organisation of MD operators.

The COVID-19 pandemic, along with the recent CJEU decisions, will facilitate and contribute to the expansion of online sales of medicinal products in French territory, in a clarified framework.

**Valencia Avocat** is a Parisian law firm that acts exclusively for companies in the field of life sciences and healthcare. The firm assists its clients on regulatory issues relating to clinical trials, early access and market access, promotion and advertising, compliance, legal structuring, pharmaceutical activities, and associated agreements. The firm also assists clients in product liability cases and litigation against the French health administration. The practice of Valencia Avocat is particularly focused on market-access issues related to price and reimbursement of health products, and litigation against health authorities' decisions, such as early access decisions, withdrawals, modifications, suspension of marketing authorisations, refusal of inscription of medicinal products on reimbursement lists before the French Administrative Supreme Court, price set up for reimbursed medicinal products, and health authorities' penalties. The firm works in English, French and Spanish.

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# GERMANY

## Law and Practice

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## 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

### 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The main law in Germany regulating advertising on medicines is the Law on Advertising in the Health Sector (*Heilmittelwerbegesetz* or HWG). In addition to the *Heilmittelwerbegesetz*, the German Law against Unfair Competition (UWG) that, inter alia, contains advertising rules in general also applies to pharmaceutical advertising.

Pharmaceutical advertising is also the subject matter of several self-regulatory codes, such as:

- the FSA Code of Conduct on the Collaboration with Healthcare Professionals (FSA Code of Conduct HCPs);
- the FSA Code of Conduct on the Collaboration with Patient Organisations (FSA Code of Conduct Patient Organisations);
- the Code of Conduct of the Members of *Arzneimittel und Kooperation im Gesundheitswesen* ("AKG Code HCPs"); and
- the Code of Conduct concerning co-operation with patient organisations (AKG Code Patient Organisations).

FSA stands for *Freiwillige Selbstkontrolle für die Arzneimittelindustrie eV* (voluntary self-regulation for the pharmaceutical industry), a private industry association of which the majority of pharmaceutical companies in Germany are a member. Typically, these companies are also members of the *Verband Forschender Arzneimittelhersteller* (VFA), the German Association of Research-based Pharmaceutical Companies.

The *Arzneimittel und Kooperation im Gesundheitswesen eV* (Medicinal Products and Co-operation in the Healthcare Area, AKG) is another self-regulatory organisation. Members are typically members of the *Bundesverband Pharmazeutische Industrie* (BPI), the German Pharmaceutical Industry Association.

### 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Self-regulatory codes apply to members of the self-regulatory organisation only. Membership in such associations is voluntary.

In practice, pharmaceutical companies that adhere to a self-regulatory code, such as the FSA Codes of Conduct, usually take these rules very seriously when assessing the legal boundaries for promotional activities.

In case of a breach of these rules, a proceeding according to the applicable self-regulatory code can be started. Legal consequences under the FSA Codes of Conduct are, for example, fines and – in case of a severe breach – public reproofs. Depending on the case, a breach of a self-regulatory code can also indicate (but does not necessarily entail) an act of unfair competition which enables competitors and industry and consumer associations to start civil legal actions.

## 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

### 2.1 Definition of Advertising

There is no statutory definition of advertising in the HWG. Courts usually refer to the definition in Article 86(1) of Directive 2001/83/EC on the community code relating to medicinal products for human use. According to this definition, advertising of medicinal products shall include "any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of

medicinal products". This shall include, in particular:

- the advertising of medicinal products to the general public as well as to persons qualified to prescribe or supply them;
- visits by medical sales representatives to prescribers;
- the supply of samples;
- the provision of inducements to prescribe or supply medicinal products;
- the sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products; and
- the sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.

Based on this definition, and in line with the traditional German understanding of healthcare advertising, courts usually analyse whether certain information has the purpose of promoting the sale of a medicinal product or a medical device.

## 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

German courts tend to interpret the aforementioned definition of product advertising broadly and the threshold for a communication in the life science sector to be qualified as advertising is low. This is explained by the aim of the HWG to avoid risks for individuals and the general public associated with an incorrect self-medication (irrespective of whether these risks exist in the individual case), as well as to prevent sick individuals from taking wrong decisions with regard to the use of medicinal products under the influence of inappropriate advertising. According to the German Federal Supreme Court (*Bundesgerichtshof*), the great value of public and individual health, as well as the importance of the risks associated with healthcare advertising, make a broad application of the Healthcare Advertising Code necessary.

### Legal Exceptions for Non-promotional Information

The law itself (and similarly the FSA Code of Conduct HCPs) provides guidance on which communication shall be considered as non-promotional information: pursuant to Section 1(5) of the HWG, the law does not apply to correspondence and documents that do not serve a promotional purpose but that are needed to answer a specific question about a particular medicinal product. This includes the answers of a company to questions asked by patients and HCPs, even if such answers may contain a positive message regarding a specific product (so that they might have a promotional effect).

According to Section 1(8), the HWG also does not apply to the labelling of a product (*Kennzeichnung*), the package leaflet (*Packungsbeilage*), the Summary of Product Characteristics (SmPC, *Fachinformation*) and the health authorities' public assessment report. However, such documents may only be made available to the general public upon request or, if the information is available on the internet, it may only be accessible to someone who is actively searching for it. And pursuant to Section 1(6) and (7) of the HWG, information contained in ordering forms for electronic commerce that are necessary for the ordering process, as well as sales catalogues and price lists that do not contain more information than necessary for the identification of a product, do not constitute advertising.

### Separating Advertising and Non-promotional Information Communication

For all other cases, to separate between advertising falling under the Healthcare Advertising

Code and lawful information, it needs to be analysed whether the communication:

- is product-related (*produktbezogen*), and
- is intended, among other purposes, to also promote the prescription, the supply, the sale or the consumption of a specific medicinal product.

Consequently, even a scientific publication from a medical journal can be advertising if a company is using it for promotional purposes.

Usually, the fact that a specific product is mentioned by its name is considered to be a strong indicator that a communication is product advertising. But even if advertising only names the active pharmaceutical ingredient or contains clear allusions of a specific product (such as its usual packaging and advertising colour and design), this may be sufficient to qualify the advertisement as being product-related so that the HWG rules apply.

Vice versa, a communication (such as a company's website) that focuses on the company, its economic situation and prospects, including its product range (*Imagewerbung*), but not on one or a few specific products does not fall under the rules for pharmaceutical advertising. This is particularly relevant for investor-related information. German courts usually recognise the legitimate need of a company to provide information on its research activities and pipeline projects to existing and potential investors. However, the more a communication relates to the characteristics and functioning of a specific product, the higher the risk that it will be qualified as product advertising.

## 2.3 Restrictions on Press Releases regarding Medicines

Like any other company communication, press releases can qualify as product advertising, in which case the rules for pharmaceutical advertising apply. This includes, in particular, the prohibition to promote a prescription-only product to the general public, the prohibition to advertise unauthorised medicines and the prohibition of misleading advertising.

However, as explained in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**, it is widely accepted that there is a legitimate interest of pharmaceutical companies to inform HCPs, investors and press and media about important developments of the company and scientific milestones. A press release that objectively informs about an important research activity, in particular about the conduct or the outcome of a relevant clinical study, may in many cases be qualified as company advertising (*Imagewerbung*) to which the law on pharmaceutical advertising is not applicable.

There remains a legal uncertainty, however. Care should therefore be given when publishing press releases directly or indirectly relating to prescription-only and/or unauthorised medicines. To be on the safe side, some companies publish such press releases only on secure websites granting access only to HCPs.

## 2.4 Comparative Advertising for Medicines

Comparative advertising for prescriptive and non-prescriptive medicines is not allowed if the advertising is directed to the general public. Comparative advertising addressed to HCPs is allowed but needs to observe important restrictions.

Pursuant to Section 6 of the UWG, any comparative advertising needs to fulfil a defined catalogue of criteria. Among others, the advertising must compare products intended for the same purpose; it may only compare, in an objective

manner, relevant, verifiable and representative features. Furthermore, it may not take unfair advantage of the trade marks of a competitor or discredit or denigrate their products or business circumstances.

In addition, and based on the general prohibition of misleading advertising, German courts require that a promotional claim for a medicinal product is substantiated by reliable scientific evidence. For comparative advertising, this means that the comparison needs to be based on a clinical head-to-head study. For more details for criteria clinical studies must meet, see **5.2 Reference to Data Not Included in the Summary of Product Characteristics**.

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

Section 3a of the HWG, as well as Section 9 of the self-regulatory FSA Code of Conduct HCPs, forbid any advertising for an unauthorised medicinal product. This explicitly includes any advertising for indications or dosage forms that are not covered by an existing marketing authorisation ("off-label advertising").

Therefore, providing information on unauthorised medicines or indications is only possible as long as such information is not promotional. In light of the strict standards of German courts, a company's communication focused on a specific medicinal product risks being qualified as of a promotional nature. Such communication should therefore concentrate on general and objective information as to the company's research activities and clinical trials, but without mentioning the name of the as-yet-unauthorised new product or otherwise focusing on a product in a way that can be interpreted as product promotion.

With regard to the prohibition of "off-label advertising", the crucial question is whether a claim advertises a separate indication or whether it only promotes a certain (new) effect of a product. If the advertising directly or indirectly claims a certain indication, this is forbidden as long as the product has not been authorised for this indication. If the advertising only promotes a (new) effect of a pharmaceutical, this is not considered as off-label advertising as long as the advertised effect does not go beyond the authorised indication.

### 3.2 Provision of Information during a Scientific Conference

Courts and scholars recognise the legitimate interest of pharmaceutical companies to have a regular exchange with the scientific community with regard to recent research results. If companies inform in an objective, non-promotional manner about the outcome of clinical studies and the information does not focus on a specific product, there are good arguments that such information does not fall under the rules for pharmaceutical advertising.

However, German law does not generally exempt information provided to the scientific community from the prohibition to advertise unauthorised medicines or indications. The more a communication creates the impression that it is (also) intended to promote to future prescribers the effectiveness of a yet to be approved medicinal product, the greater the risk that it would be qualified as illicit advertising for an unauthorised medicine.

### 3.3 Provision of Information to Healthcare Professionals

Pursuant to Section 1(5) of the HWG, the rules on pharmaceutical advertising do not apply to correspondence and documents that do not serve a promotional purpose but that are needed to answer a specific question about a medicinal product. Based on this rule, companies may provide scientific information regarding an unauthorised medicinal product or indications in response to specific and unsolicited queries from HCPs (ie, reactively).

However, sending information on unauthorised medicines or unauthorised indications to HCPs proactively will be considered as illicit off-label advertising.

### 3.4 Provision of Information to Healthcare Institutions

There is no rule or principle in German law allowing companies to provide healthcare institutions with information on unauthorised medicines or indications. To the contrary, if the aim of a certain information is to prepare institutions (eg, hospitals, for the upcoming approval of a certain medicine so that the institution can prepare budgets), courts and authorities might argue that the one important aim of such information is to prepare the future customers for the launch. In such a case, there is a substantial risk that such communication can be qualified as unlawful advertising for an unauthorised product.

### 3.5 Publication of Compassionate Use Programmes

If the information relates to specific products/APIs, the information will likely be qualified as product advertising by German courts. Such product related information on compassionate use programs (or other forms of early access) would then be illicit off-label advertising pursuant to Section 3a of the HWG.

However, if the communication in question is not product-related but only consists of general information about compassionate use as such and the availability of compassionate use programs, it would not fall under the rules for pharmaceutical advertising. For more details for the assessment whether a communication is product-related and thus promotional, see **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Under German law, product-related advertising of prescription-only medicines is limited to physicians, pharmacists and persons who are authorised to trade in these products ("qualified HCPs"). Any advertising of prescription-only medicinal products directed at less-qualified HCPs, such as nurses, and at patients ("the general public") is prohibited under German law (Section 10 of the HWG). Only non-prescription medicinal products (OTC medicines) may be advertised to the general public.

Product-related advertising activities of medicinal products, whether prescription-only or OTC medicines, have to comply with general principles on advertising as mainly set forth in the UWG. Furthermore, pursuant to Section 3 of the HWG, advertisements must not be misleading; ie, any promotional claims according to which medicinal products are attributed a therapeutic efficacy or effects must be substantiated with clinical data.

### Medicine-Specific Advertising Rules

Advertisements directed at the general public shall, in particular, also comply with medicine-specific advertising rules that are mainly set forth in Section 11 of the HWG. For example, any comparison with the medicinal products of competitors according to which the promoted medicinal product corresponds to or is even superior to the competitor's product is prohibited vis-à-vis the general public. Moreover, advertisements to the general public must not refer to recommendations or testimonials by scientists, HCPs or celebrities, as such information may encourage the consumption of medicinal products.

In addition, advertising claims must not use statements made by third parties, such as letters of thanks or recommendations, if this is done in a misleading manner. Furthermore, the use of medical case histories and references thereto are prohibited, if this is misleading or can lead to an incorrect self-diagnosis. Advertisements using contests, prize draws or other procedures the result of which is dependent on chance are also prohibited. The distribution of medicinal products, samples or respective vouchers to the general public is not compliant with German law, either. Advertising measures to the general public must not be aimed predominantly at children under the age of 14.

Finally, pursuant to Section 10(2) of the HWG, any promotional claims directed at the general public and relating to psychotropic active ingredients that may cause dependency and that are intended to eliminate insomnia or mental disorders are prohibited under German law.

## 4.2 Information Contained in Pharmaceutical Advertising to the General Public

Advertisements, regardless of whether referring to prescription-only or OTC medicines and whether directed at HCPs or the general public, must contain the following mandatory information (*Pflichtangaben*) as stipulated in Section 4 of the HWG: the pharmaceutical company's name and registered place of business, the name of the medicinal product, its composition, therapeutic indications, contraindications as well as side effects (if any), warnings (if such warnings need to be labelled on containers and outer packaging) and the indication "prescription-only" (if applicable). According to the FSA Code of Conduct HCPs, the advertising of a medicinal product shall also state the date on which the aforementioned information was drawn up or last revised. Such mandatory information must be clearly set out, well separated from the other advertising claims and easily legible. Under German law, the price of the medicine is not such mandatory information.

In this context, the HWG provides for one exception in Section 4(6) of the HWG: advertisements that are intended solely as a "reminder" (*Erinnerungswerbung*) do not have to contain the aforementioned mandatory information. An advertisement is intended as a reminder if it exclusively refers to the name of the medicinal product or if it refers additionally only to the pharmaceutical company's name or trade mark or to the active pharmaceutical ingredient.

Any advertising directed at the general public must also contain – well separated from the other advertising claims and easily legible – the following advice: "For further information on risks and side effects, please read the package leaflet and consult your physician or pharmacist".

## 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Pursuant to Section 6 of the FSA Code of Conduct Patient Organisations, companies shall respect the patient organisation's neutrality and independence. As a result, patient organisations

shall retain complete control over the content of their work when collaborating with pharmaceutical companies. Such collaborations must not involve recommendations for individual prescription-only medicinal products or groups of such products. The appearance of member companies' representatives at patient organisations aiming at making promotional references to prescription-only medicinal products is prohibited as well.

Furthermore, any collaboration between industry and patient organisations shall proceed in a transparent and open manner (Section 8 of the FSA Code of Conduct Patient Organisations). Consequently, companies shall conclude written agreements stipulating the base elements, such as type and scope of the collaboration. This applies particularly to payments, such as sponsorships or payments for consultation, to patient organisations.

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Any advertising for medicinal products (be it directed to HCPs or consumers) must – subject to few exceptions – contain mandatory information (*Pflichtangaben*) as stipulated in Section 4 of the HWG (see **4.2 Information Contained in Pharmaceutical Advertising to the General Public**). In addition, pursuant to Section 6 HWG, any advertising directed at HCPs referring to scientific or medical publications (eg, articles from a medical journal on the results of a clinical study) must clearly name the authors, the time of publication and the correctly quoted reference.

Beyond these obligations, there is no obligatory content for advertising directed at HCPs. For example, German law does not require advertising to include the price of the medicine.

#### Scientific Evidence and Clinical Studies

It is important to note, however, that advertising claims relating to medicinal products, regardless of whether directed to HCPs or the general public, must be based upon sufficient and reliable scientific evidence. This applies in particular to promotional claims in which medicinal products are attributed a therapeutic efficacy, qualities, certain effects or other benefits. Advertising claims that are not justified by sufficient and reliable scientific evidence are likely to be considered misleading.

Scientific evidence usually means clinical studies. In order to be accepted as sufficient evidence, such studies must be designed as randomised, controlled and double-blind clinical trials with an adequate statistical analysis that has been published and is thus opened towards scientific discussions. If this "gold standard" is not met, the advertising needs to make sufficiently clear that it is based on scientific data that is not published or on scientifically limited information. This applies, in particular, to retrospective analyses, such as subgroup analyses or meta-analyses in which data generated in different studies is pooled, or for data on file. The limitations of such data need to be clearly pointed out in the advertisement.

It is, from a legal perspective, not necessary to refer explicitly to data and/or clinical studies that justify the promotional claim. However, if such data and/or clinical study publications are mentioned – for example, in a footnote – this reference must be complete, correct and able to serve as scientific evidence for the promotional claim. If the reference does not justify the claim, German courts will consider the claim, regard-

less of whether it can be scientifically substantiated by another study, as misleading only for formal reasons, as recipients are not able to verify (based on the information presented in the advertisement) if the promotional claim made is scientifically substantiated or not.

### 5.2 Reference to Data Not Included in the Summary of Product Characteristics

In Germany, the content of the SmPC as approved by the competent authority gives important guidance as to the state of scientific knowledge at the time the marketing authorisation was issued. German courts therefore assume that promotional claims are in principle legitimate if they can be based on the SmPC, as long as there are no new scientific findings that prove the content of the SmPC to be outdated.

That does not mean, however, that all data referred to in an advertising must be contained in the SmPC. According to the European Court of Justice (ECJ) and German courts, advertising may also refer to data and studies that are not included in the SmPC, provided that the statements used in the advertisement confirm or further clarify the information contained in the SmPC. The advertisement must be compatible with SmPC and may not distort it. For example, according to the SmPC for a diabetes mellitus medicine, the product has a proven, significant effect on the blood sugar level. If new clinical studies not yet cited in the SmPC show that the blood sugar-lowering effect is even higher than as described in the SmPC, this higher effect may be advertised without being considered as off-label promotion.

### 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

Advertising which refers to combination products or companion diagnostics that are not included in the SmPC will highly likely be qualified as illicit off-label advertising in Germany. Courts will consider such advertising as a promotion for unauthorised dosage forms and/or to be in conflict with the particulars listed in the summary of product characteristics. The Higher Regional Court of Hamburg, for example, once ruled that a promotion for a product in an authorised indication which only names that single product, although, according to the SmPC, the product is authorised only in combination with a further product, is illegal off-label advertising. Vice versa, it is very likely that a German court will find that advertising referring to combination products or companion diagnostics that are not included in the SmPC are also off-label.

### 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

There are no specific statutory rules for the distribution of journal articles to HCPs as such. However, under German law, the offer or provision of gifts or other benefits to HCPs is prohibited (see **9. Gifts, Hospitality, Congresses and Related Payments**).

The FSA Code of Conduct HCPs provides for an exception: Pursuant to Section 15a of this code, informational and educational materials, such as journal articles, may be provided if such materials are inexpensive, have a direct connection with the professional activity of the respective HCP and are genuinely linked with patients' care. If these conditions are met and if the distribution is, consequently, not intended to influence the physician's prescribing or therapeutic decisions, there are good arguments that pharmaceutical companies may provide reprints of journal articles to HCPs. However, there is no specific statutory rule in this regard. Therefore, it should be carefully assessed in the individual case whether the aforementioned conditions are met.

### 5.5 Medical Science Liaisons

MSLs to discuss scientific information on unauthorised medicines or indications with HCPs are in principle allowed as long as the MSL aims at an information exchange (and not at a unilateral provision of information from a company to an HCP) and if such exchange does not have a promotional but a scientific purpose. Otherwise, the information exchange will be considered as illicit off-label advertising.

Moreover, the MSL must observe German anti-bribery rules: There should always be a written contract in place covering and describing the consultancy services provided by the HCP and clarifying that there is no connection between the provision of services and any possible decisions on the purchase or prescription of medicinal products. Most importantly, the amount of remuneration needs to be transparent and adequate, see **9.7 Payment for Services Provided by Healthcare Professionals**.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

Under German law, advertising for medicines is not subject to prior authorisation from or notification to a competent regulatory authority. The German system is based on a prior self-assessment by the pharmaceutical company responsible for the advertising and a full legal review of the advertising in civil litigation, self-regulatory body or administrative proceedings.

### 6.2 Compliance with Rules on Medicinal Advertising

Section 74a of the German Code on Medicinal Products (*Arzneimittelgesetz* or AMG) enhances the obligation of any pharmaceutical entrepreneur placing finished medicinal products on the market to appoint an information officer, who is responsible for ensuring compliance of the scientific information on the medicinal product. Advertising for medicinal products falls, inter alia, under the scope of responsibilities of the information officer.

The information officer has to have the necessary expert knowledge and reliability required to perform their activities.

In case of a violation of company-related obligations deriving from, for example, medicinal advertising law, a company's owner can be held responsible if they have not provided for arrangements that secure compliance with the rules on medicinal advertising and if such a violation would have been prevented or hindered by such arrangements. Therefore, an owner needs at least to institute a hierarchical structure of supervisors monitoring compliance with the company-related obligations to avoid liability.

Thus, it is established practice within the German pharmaceutical industry to have in place standard operating procedures for medicinal advertising and to document the compliance with these SOPs. The review and approval process has to involve several internal functions and stakeholders – and the review/approval has to be documented. Review and approval by at least the medical department, the legal department and the information officer is necessary.

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

For advertising on the internet the general rules and provisions on advertising apply. However, in accordance with German case law, certain peculiarities apply.

#### Mandatory Information (Pflichtangaben)

Certain pieces of information have to be displayed in an advertisement for medicinal products. According to German courts, there is an exception for advertising for medicinal products on the internet. To be in compliance with the rules of the HWG, it merely has to depict a visible link that directly and without detours leads to the mandatory information and that is labelled appropriately.

#### Advertising Restrictions regarding the General Public and Publication of the Package Leaflet on the Internet

According to a verdict of the ECJ, it is permissible for companies to release information on prescription drugs on their websites if such information is only accessible to someone who is actively searching and demanding for it and if such information only consists of the accurate presentation of the packaging of the medicinal product, the literal and complete reproduction of the package insert or the summary of product characteristics as approved by the authorities. Thus, information released on company websites that is subject to a selection or rearrangement by the company and that has not been released to inform on but rather to promote the company's products is still prohibited.

### 7.2 Advertising of Medicines on Social Media

Due to a lack of specific rules, the general restrictions apply. Unless an access control or access restriction is technically feasible, advertising of medicines on social media is limited to OTC products, as advertising for prescription-only medicinal products is not allowed to the general public.

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

Given the fact that any advertising for prescription-only medicines is limited to HCPs under German law, it is necessary to restrict access to websites which refer to prescription-only medicines. The HWG does not provide for a specific mechanism to restrict access. However, restricting access by providing a simple tick-box question (eg, "Are you a healthcare professional?") would not be accepted as sufficient by courts. In practice, established access control systems with registration requirements (such as DocCheck) are used by most companies in Germany

### 7.4 Provision of Disease Awareness Information to Patients Online

Online disease awareness information aimed at patients is allowed as long as it informs generally about a certain condition as well as prevention and a variety of treatment options.

However, as soon as the information qualifies as product advertising by naming or describing, explicitly or implicitly, a specific product, or by focusing on statements that products to treat the condition are available, it clearly risks being seen as product advertising to the public.

### 7.5 Online Scientific Meetings

There is no statutory law specifically regulating online scientific meetings. In the absence of any specific rules, the general rules apply. See rules

on sponsoring of scientific meetings, online or offline, in **9.3 Sponsorship of Scientific Meetings**.

For any information materials provided at international virtual conferences (which are attended by participants from different countries) German law is applicable, if a noteworthy number of German HCPs attend the meeting. In this case the materials aimed at German HCPs are likely considered to have an effect on the German market. There is no publicly available German case law determining a fix number of German participants necessary.

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

German law contains general anti-bribery rules contained in the German Criminal Code (*Strafgesetzbuch* or StGB) that may also apply to interactions between pharmaceutical companies and HCPs and specific rules for the pharmaceutical sector. Regarding the latter, statutory law provisions and self-regulatory provisions exist.

For the legal risk analysis there are important differences between the public and private sector. In essence, for the interaction with HCPs qualifying as public officials, the standards are very strict, while for privately employed or self-employed HCPs, slightly more leeway seems possible.

Section 331 of the StGB stipulates that a public official or a person entrusted with special public service functions who demands, allows themself to be promised or accepts a benefit for themselves or for a third person for the discharge of an official duty shall be liable to imprisonment not exceeding three years or a fine. The offence of offering or giving such bribes is inversely contained in Section 333 of the StGB. Fulfilling Section 331/333 of the StGB does not require a concrete action or omission taken by the public official.

By contrast, Section 332 of the StGB stipulates that a public official or person entrusted with special public service functions who demands, allows themselves to be promised or accepts a benefit for themselves or for a third person in return for the fact that they performed or will perform an official act and thereby violated or will violate their official duties shall be liable to imprisonment from six months to five years. This offence, which is mirrored in Section 334 of the StGB for the person giving such a bribe, is stricter than the general bribery provision.

#### HCPs Qualifying as Public Officials, etc

HCPs can qualify as public officials or persons entrusted with special public service functions. In essence, from a practical perspective, HCPs employed by publicly owned hospitals or medical institutions, such as a university hospital or a municipal hospital, may often qualify as such public official. The interaction between pharmaceutical companies and such HCPs should be closely monitored.

For the private business sector, Section 299 of the StGB prohibits the taking and giving of bribes in commercial practice. According to Section 299(1) of the StGB, whosoever, as an employee or agent of a business, demands, allows themselves to be promised or accepts a benefit for themselves or another in a business transaction as consideration for according an unfair preference to another in the competitive purchase of goods or commercial services shall be liable

to imprisonment not exceeding three years or a fine. Section 299(2) of the StGB mirrors the prohibition for the person giving such bribe.

This general anti-bribery rule may typically apply to interactions with HCPs or other members of the healthcare profession who are employed by a private hospital or medical institution.

The responsibility for violations of these criminal law provisions always falls on a human being. An organisation cannot be held liable under German criminal law. However, in practice this does not mean that providing illicit benefits to organisations may not be covered by criminal law provisions. In such cases, the competent authorities and courts typically hold liable the person acting on behalf of the company or institution or the person in a management or monitoring function.

## 8.2 Legislative or Self-Regulatory Provisions

### Criminal Law

As regards sector-specific anti-bribery rules, the German legislator introduced in 2016 a new provision in the Criminal Code according to which also self-employed HCPs, eg, physicians in private practice, can commit bribery according to the general rules.

Under Section 299a of the Criminal Code, liability is found in any HCPs requiring state-organised training to carry out their profession or to bear a specific professional title who – in pursuing their profession – demand, allow themselves to be promised or accept a benefit for themselves or another as consideration for according an unfair preference to another in domestic or foreign competition by prescribing medicinal products, remedies and therapeutic products or medical devices; by purchasing medicinal products or therapeutic products or medical devices intended for direct application by the members of the healthcare profession or their assistants; or by referring patients or specimens for testing.

Conversely, under Section 299b it is a criminal offence to offer, promise or grant such benefit to any of the above-mentioned persons. Whereas under Section 299a, only persons belonging to the group of people mentioned in that provision can be criminally liable, under Section 299b any person can be an offender (eg, employees of companies dealing in pharmaceuticals, medicinal products or biotechnology or wholesale companies co-operating with HCPs). The list of healthcare professions is long and includes doctors and pharmacists, as well as physiotherapists and nurses.

The entry into force of the new regulations has marked a turning point for the practice of law. Since then, for activities that were not previously criminal offences and were therefore often tolerated, the risk profile has considerably changed for members of the healthcare profession and the life sciences industry.

### HWG

The HWG in principle forbids giving incentives or advertising gifts to doctors. Pursuant to Section 7(1) of the HWG, it is, subject to certain exceptions, prohibited to offer or give advertising gifts or other benefits to consumers or HCPs in connection with the promotion of medicinal products or medical devices. It is also prohibited for HCPs to accept these advertising gifts or benefits.

Section 7(1) of the HWG states some exceptions to this prohibition. In particular, it is acceptable to provide low-value advertising gifts or benefits. According to applicable case law, the value acceptable is widely considered to be EUR1. Moreover, Section 7 of the HWG allows a company to grant a volume-related discount in kind or in money, but only subject to the following

conditions: rebates in kind are prohibited for all kinds of pharmacy-only pharmaceuticals, which means that they are only possible to medical devices and pharmaceuticals that may be sold outside pharmacies. Rebates in money are prohibited if they are granted against the German Ordinance on Pharmaceutical Prices (*Arzneimittelpreisverordnung*).

Breaches constitute an administrative offence and can be punished with fines of up to EUR50,000 a case by the competent administrative authorities. This applies not only to the doctor, but also to the company offering the incentive. Civil law cease and desist claims asserted by competitors constitute a further risk.

### Professional Code of Ethics

Doctors are subject to the Medical Association's professional code of conduct, which contains detailed rules governing co-operation with third parties, such as pharmaceutical companies. Under this code, doctors may not demand or accept gifts or other benefits if this were to give the impression that the independence of the doctor's decision has been influenced.

If a doctor breaches the professional code of conduct, they face disciplinary measures that can result in serious penalties, including a formal warning, a maximum fine of EUR50,000 and the declaration of unworthiness to exercise their profession in the most serious cases.

The latter can lead to the doctor's licence to practise medicine being revoked.

The involvement of pharmaceutical companies in a breach of a professional code of conduct committed by a doctor (eg, by providing gifts or payments) can trigger civil law cease and desist claims asserted by competitors. This aspect should not be underestimated as it seems that pharmaceutical companies have become increasingly aware of this issue.

### Social Law

Manufacturers may not give doctors any incentives in connection with prescribing medical devices (Section 128(2), Fifth Book of the Social Code). If a doctor also breaches their duties while acting for the healthcare service, they could face disciplinary proceedings before the National Association of Statutory Health Insurance Physicians. Depending on the gravity of the misconduct, disciplinary measures can include a warning, a fine of up to EUR10,000 or a suspension of the doctor's practice certificate for up to two years.

### Industrial Codes of Conduct

The pharmaceutical industry has put in place strict regulations for co-operation with doctors. For example, pursuant to the FSA Code of Conduct HCPs, a doctor may not receive a fee or any other non-cash benefit for prescribing or recommending a drug to patients. For any breach of this rule, the FSA's arbitration board can impose fines and administrative fines of up to EUR400,000.

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

For the legal risk analysis of concrete measures in the interaction between pharmaceutical companies and HCPs, the standard to assess whether a practice is still permissible or already illicit varies depending on the legal qualification of the HCP. In essence, for the interaction with HCPs qualifying as public officials, the standards are very strict, while for privately employed or self-employed HCPs, slightly more leeway seems possible.

For any form of commercial interaction with HCPs, and in particular for the grannting of any sort of benefit, it is highly recommended to adhere to the four basic principles of healthcare compliance, namely the principles of documentation, transparency, separation and equivalence should always be respected. Moreover, it is highly recommended, if not required, to ask the HCP to provide an authorisation of the employer or administration.

Offering gifts to HCPs bears a considerable legal risk. Gifts in the form of cash will very likely be considered unacceptable by authorities and the courts, irrespective of the amount. Providing gifts to HCPs qualifying as public officials also bears the risk of triggering a suspicion of violation of Section 331 of the StGB and of criminal proceedings being started. Moreover, the HWG does not allow the offer or supply of gifts or other benefits – or the acceptance of such gifts or benefits. However, it foresees a limited number of exceptional rules, eg, with regard to promotional gifts of minor value.

In addition, the Professional Rules for German Physicians prohibit the acceptance of any gifts or benefits that might influence their prescribing or therapeutic decisions, or which could be considered as a reward for such previous decisions. Furthermore, the FSA Code of Conduct HCPs generally prohibits the provision and acceptance of any kind of benefits with respect to hospital physicians that is granted in the context of their work, especially as consideration for carrying out purchasing or prescription decisions.

## 9.2 Limitations on Providing Samples to Healthcare Professionals

The provision of samples is limited pursuant to Section 47, paragraphs 3 and 4 of the AMG. Pharmaceutical companies may provide samples of medicinal products to HCPs, but only in small numbers and upon their written request. Samples may be provided with a maximum amount of two packages per year, it is understood that the packages must be of the smallest commercially available size and be labelled as samples. The supply of such samples must be recorded by the company. In addition, samples may only be provided accompanied by a professional information sheet according to Section 11a of the AMG.

## 9.3 Sponsorship of Scientific Meetings

In the absence of concrete stipulations in German statutory law, authorities and courts often make reference to the FSA Code of Conduct HCPs, which contains specific rules for financial support of scientific meetings or congresses. If these rules are respected, a company has good reasons to argue that it complied with the industry standards and did not provide inappropriate inducement to the organiser or the participating HCP, which could otherwise be considered an indication of bribery.

The FSA Code of Conduct HCPs differentiates between in-house scientific events or seminars and external scientific events.

### In-house Training Events

Generally speaking, pharmaceutical companies may invite HCPs to their own training events who are particularly concerned with said companies' research areas, pharmaceuticals and their therapeutic indications (in-house training events). The company may only pay reasonable travel and accommodation costs for the invited physicians if the job-related, scientific character of the in-house training event clearly takes centre stage. During such training events, reasonable hospitality arrangements for the participants are also possible. However, the company must neither finance nor organise any entertainment and leisure time programmes for the participants.

The participation of the invited persons and the event programme must be documented. Accommodation and hospitality must not exceed reasonable limits and must be of minor importance in relation to the job-related, science-orientated purpose of the in-house event. The selection of the conference location and conference venue as well as the invitation of HCPs must be made exclusively based on factual criteria. For instance, the leisure offerings of the conference venue do not qualify as such a reason. Further, the companies are to avoid conference locations that are known for their entertainment value or are considered extravagant.

#### Third-Party Job-Related Training Events

With regard to job-related training events of any third party (external training events), it is recognised that pharmaceutical companies may invite HCPs to attend such events. Also in this regard the FSA Code of Conduct HCPs contains provisions that reflect industry standards: the invitation may only include reasonable travel expenses, necessary accommodation (if necessary, including hotel breakfast) and participation fees charged by said third party if the scientific character of these events clearly takes centre stage and if the company has a relevant interest in such a participation.

The company may only assume the costs if the event provides a link to the member company's field of activities as well as a link to the expertise of the event participant. Member companies must not support directly or indirectly any entertainment programmes by paying participation fees for HCPs.

If the HCP also acts as a speaker (active participation), the pharmaceutical company may in addition pay an appropriate honorarium compensating for the services rendered.

### 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies must neither finance nor organise any entertainment or other non-scientific events in relation to scientific conferences (eg, theatre, concert or sports events).

### 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

It is widely recognised that, as an exception to the general rule for the provision of gifts and other benefits to HCPs or institutions, a company may grant donations to healthcare institutions if these donations are made:

- to healthcare institutions that are recognised as non-profit organisations;
- only for the purpose of research and teaching, to improve health and patient care, or to realise advanced and further training or charitable purposes;
- to official bank accounts held by the healthcare institution and supervised by their administration; and
- dependent on the prior approval of the hospital administration.

The FSA Code of Conduct HCPs contains some more specific rules in this regard. According to its Section 25, donations (monetary or donations in kind) as well as other unilateral monetary benefits or benefits in kind to institutions, organisations or associations, whose members are HCPs (eg, medical–scientific associations) and/or perform medical services or research (eg, hospitals or university clinics), need to comply with the following requirements (besides the compliance with relevant other legal requirements): serve the aims of healthcare or comparable aims (including, for example, the aims of research, teaching and further training), are correctly documented, whereby this documentation is to be kept for a minimum period of five years after the contractual relationship has ended and are not misused as

an incentive to influence therapy, prescription or procurement decisions. Donations to individual HCPs are not permissible.

In essence, these rules apply to monetary donations and donations of equipment and services. For equipment and services, it will in practice be harder to justify, though, how the donation was appropriate because there is a close link to the sale of the pharmaceutical product. Thus, at least a violation of Section 7 of the HWG needs to be carefully considered.

### 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Section 7 of the HWG contains specific rules defining whether and to what extent rebates may be granted to HCPs and institutions, see **8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals**. In essence, for medicinal products subject to price ordinance, it is not possible to grant rebates. For other medicinal products and devices, rebates in kind and in money are in principle permissible.

### 9.7 Payment for Services Provided by Healthcare Professionals

There are different legal considerations to make with regard to paying HCPs for the service they render. In principle, it is allowed under German law and in line with the codes of conduct to receive services from a HCP – such as consultancy, speaker or study services – and to pay for such services. However, to avoid any misunderstandings and suspicion from the outset, it is crucial to ensure that for any service rendered by a HCP, the applicable principles and rules are respected. From a formal point of view, there should always be a written contract in place covering the service.

The services should be described in sufficient detail and the agreement should contain language clarifying that there is no connection between the provision of services and any possible decisions on the purchase or prescription of medicinal products. Most importantly, the amount of remuneration needs to be transparent and adequate. An hourly fee calculated on the basis of the medical fee schedule (*Gebührenordnung für Ärzte*) leads to an hourly rate of approximately EUR120. Agreeing compensation on this level would likely only pose a low risk. Exceeding the threshold – eg, by arguing that the HCP in question is very competent and recognised – can be argued, but poses a certain risk with regards to anti-bribery provisions.

### 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

It is recommended, if not required, to ask the HCP to provide an authorisation of the employer or administration. This is essential if the receiving HCP qualifies as a public official. For HCPs employed by a private hospital or institution, it is also highly recommended for reasons of transparency to obtain such approval by the management.

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

German statutory law does not contain provisions that would oblige pharmaceutical companies publicly to disclose the transfer of value to HCPs or institutions. Thus, pharmaceutical companies active on the German market are

in principle not required to make the transfer of value to HCPs or institutions public.

Different rules apply to those pharmaceutical companies that are members of the FSA. They have voluntarily agreed to a Transparency Code. According to the Transparency Code, all payments in kind by the pharmaceutical industry to physicians and other HCPs are to be made public. The FSA member companies have to document all direct and indirect payments, and benefits in kind, made to HCPs or organisations of the healthcare system from the areas of:

- research and development;
- donations and grants;
- sponsoring and other forms of financial support;
- invitations to advanced training events, sponsoring; and
- fees for services and consulting.

The figures are published once a year.

The transparency rules do not contain any exceptions for COVID-19 incidences (eg, cancelled events).

### 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

The requirements apply to those pharmaceutical companies that are members of the FSA, irrespective of whether they are based in Germany or abroad, and irrespective of whether they have products on the market or not.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

The HWG is a federal administrative law that as such is enforced by the competent authorities in the 16 federal states (*Bundesländer*).

In practice, however, the rules on advertising and inducement are primarily enforced by civil courts. According to longstanding and established case law, if a company (allegedly) violates a provision of the HWG, such violation is at the same time an act of unfair competition under Sections 3 and 3a of the UWG. As a consequence, many (alleged) HWG violations are pursued among competitors or by industry and consumer protection associations (such as the *Zentrale zur Bekämpfung unlauteren Wettbewerbs*) out of court and through civil litigation. In light of the usually high time pressure in advertising cases, many of the court cases are interim injunction proceedings.

#### Enforcing HWG Rules at Civil Law Level

In fact, there has been a long tradition of enforcing the HWG rules at a civil law level and the vast majority of court decisions in the field of pharmaceutical advertising are judgments of the German Regional Courts (*Landgerichte*), Higher Regional Courts (*Oberlandesgerichte*, acting as courts of appeal) and the Federal Supreme Court (*Bundesgerichtshof*).

Moreover, an offence against the prohibition of misleading advertising under Section 3 of the HWG can – under particular circumstances – also lead to criminal proceedings. In these rare cases, the competent bodies to initiate an investigation are the locally competent state prosecutors. Judgments are pronounced by the local district or the regional court.

Finally, there are arbitration boards established by self-regulatory industry associations that adjudicate on violations of industry codes of conduct. A famous example is the *Schiedsstelle* of the FSA.

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

If a company (allegedly) violates a provision of the HWG, such violation is at the same time an act of unfair competition under Sections 3 and 3a of the UWG. This law gives companies the possibility to bring cease and desist claims as well as damages claims directly against their competitors and to pursue these claims in civil courts. A cease and desist claim can also be brought by industry associations as well as consumer protection associations against companies. However, action may not be taken by individuals.

In case of a breach of an industry code, companies, associations and individuals can initiate proceedings against members of the relevant self-regulatory organisation before the organisation's arbitration board. The company initiating the arbitral proceeding does neither have to be a member of the organisation nor have subjected itself to the rules of the organisation.

Depending on the individual case, a breach of a self-regulatory code can also indicate an act of unfair competition under the UWG. This allows competitors as well as industry and consumer protection associations to bring a civil law claim against the member of the self-regulatory organisation. Whether a breach of a self-regulatory code is indeed "unfair" in terms of the UWG is ultimately to be evaluated by the civil court.

Furthermore, companies, associations and individuals can direct themselves to the competent health authorities and inform them about (alleged) advertising infringements. It will be up to the authority to decide whether it will start administrative proceedings or not. In case such proceedings end with an administrative decision against the advertising company, this company may go on to appeal before the competent administrative court.

### 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

In civil litigation based on an infringement of the UWG, courts can grant injunctive relief by issuing a cease and desist order (*Unterlassung*), which is the most important remedy in practice. The court can also impose remedial action by the defendant (*Beseitigung*), including a seizure of any infringing advertising material and the publication of corrective statements, and allow the plaintiff to publish the court decision if they are able to demonstrate a legitimate interest in this respect. Finally, the plaintiff may claim an account of any profits made by the infringer and if they are able to prove that they suffered any measurable damages from the unlawful advertising (which is rarely the case), the court may award damages.

The arbitration boards of self-regulatory bodies can impose the sanctions provided for in their code of procedure or the code of conduct. The board of currently the most relevant self-regulatory body for the pharmaceutical industry, the FSA, for example, may grant injunctive relief (cease and desist orders) and issue fines of EUR5,000 up to EUR200,000 and, in exceptional cases, an additional financial sanction of EUR5,000 up to EUR200,000 (in second instance, EUR400,000) to be donated to a charitable organisation. In cases of a severe or repeated violation of the FSA rules, the board of second instance may issue a public rebuke.

Finally, the rules of the HWG may also be enforced by the public authorities through administrative offence proceedings (*Ordnungswidrigkeiten-verfahren*), which rarely happens in practice. Negligent or wilful violations of the advertising rules can lead to fines of up to EUR50,000. If the violation is committed through a misleading advertisement, the sanctions are different: an intentional violation is a criminal offence punishable by imprisonment of up to one year or by a fine; in case of negligence, misleading advertising can be punished by an administrative fine of up to EUR20,000.

## 11.4 Relationship between Regulatory Authorities and Courts

A competitor is free to bring action before a civil court and an arbitration body of a self-regulatory association. The proceedings before a court and before an arbitration body can take place independently from each other. Likewise, the authorities may initiate administrative proceedings irrespective of whether there is or has been any civil court or self-regulatory action.

Experience shows, however, that companies often choose between filing a complaint with a self-regulatory body or bringing a civil law claim and do not pursue both paths in parallel. Breaches of the self-regulatory code by way of inappropriate gifts and inducements are often brought to the arbitration bodies of self-regulatory associations such as the FSA, whereas cases of misleading or off-label advertising as well as advertising to the general public are often the subject matter of civil court proceedings.

## 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

There are no particularly relevant enforcement trends in Germany at the moment.

**CMS Hasche Sigle** is one of the largest German law firms and forms a part of CMS Legal, a global firm with 77 offices in 43 countries and more than 4,800 lawyers. CMS Germany is recognised as having strong centres of excellence in respect of pharmaceuticals and medical, with important teams in Hamburg, Cologne and Düsseldorf. The life sciences team in the Hamburg office consists of 20 lawyers, with specialists in the areas of, inter alia, drug advertising and unfair competition, business development deals and co-operation agreements, IP, trade secrets, product liability, regulatory, compliance and anti-bribery, reimbursement and competition law. The team has substantial experience in pharmaceutical advertising litigation and advising clients on marketing and advertising strategies, while healthcare compliance has been another strong focus of recent years.

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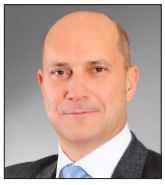

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# JAPAN

## Law and Practice

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# JAPAN CONTENTS

# 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

## 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The advertising of medicines in Japan is regulated by both Japanese laws and regulations as well as self-regulatory codes created by trade associations in the pharmaceutical industry. The main law that regulates pharmaceutical advertising is the Pharmaceuticals and Medical Devices Act (Act No 145 of 10 August 1960, as amended) (the "PMD Act"). The major self-regulatory codes include the codes created by the Japan Pharmaceutical Manufacturers Association (JPMA) and those created by the Japan Self-Medication Industry (JSMI).

### Laws and Regulations

In Japan, the Act against Unjustifiable Premiums and Misleading Representations (Act No 47 of 19 May 1997, as amended) (UPMRA) provides some general rules concerning advertising. However, in the case of pharmaceutical advertising, the PMD Act, which is the main law that regulates drugs, has several special articles that regulate pharmaceutical advertisements. More specifically, Articles 66, 67 and 68 of the PMD Act provide for the following.

#### *The prohibition of advertisements for unauthorised drugs*

The PMD Act states that no person shall advertise the name, manufacturing process, indications or performance of a drug before obtaining the necessary marketing authorisation from the Japanese government.

#### *The prohibition of false or exaggerated advertisements*

The PMD Act states that no person shall, explicitly or implicitly, advertise, describe or circulate the name, manufacturing process, indications or performance of a drug using false or exaggerated statements.

#### *The prohibition of advertisements endorsed by a doctor*

The PMD Act states that the advertisement, description or circulation of statements giving the false impression of an endorsement by a medical doctor or other person of the efficacy or performance of a drug shall be prohibited.

#### *The prohibition of obscene statements or diagrams*

The PMD Act states that no person shall use obscene statements or diagrams or those suggesting illegal abortions in connection with the advertisement of drugs.

#### *The regulation of advertisements for drugs for designated diseases*

The PMD Act states that no person shall advertise to the general public drugs intended for use in the cure of cancer, sarcoma or leukaemia, and that are likely to be highly dangerous if used without the direction of medical doctors or dentists.

#### *Administrative fines*

The PMD Act was amended on 17 November 2019 to introduce administrative fines for violations of the regulations on false or exaggerated advertising as well as cease and desist orders against pharmaceutical companies to correct improper advertising, among other revisions. These amendments came into effect on 1 August 2021.

#### *The MHLW*

The Ministry of Health, Labour and Welfare (MHLW) is the competent governmental authority with regard to medicines in Japan and has promulgated the PMD Act Enforcement Ordinance, the PMD Act Enforcement Regulations and various other notices for the enforcement of

the PMD Act. One among these is the "Standards for Appropriate Advertising concerning Medical Goods" (Notification No 0929-4 of the Pharmaceutical Safety and Environmental Health Bureau of 29 September 2017) (the "Standards"), which were issued by the MHLW in the form of an official notice and which have as their central function the regulation of pharmaceutical advertising.

### *The Standards*

The Standards provide the standards of conduct that must be adhered to by any person or entity when advertising drugs. The Standards consist of two parts: The first part relates to the interpretation of "False or Exaggerated Advertisements", under Article 66 (1) of the PMD Act and the second part sets forth rules to prevent misuse, drug abuse and the deterioration of drug reliability.

The first part of the Standards sets forth specific rules regarding:

- expressions relating to product name;
- expressions relating to manufacturing process; and
- expressions relating to indication, dosage, administration and safety.

The second part of the Standards prescribes the rules or restrictions regarding:

- the inducement of excessive use or abuse of drugs;
- advertising prescription-only medicines;
- expressions relating to performance on advertising to the general public;
- drug addictiveness warnings;
- precautions;
- slander of other companies' products;
- endorsements by healthcare professionals;
- premium advertising;
- unpleasant advertising;
- email advertising;
- statements on television or radio programmes; and
- the use of a drug as a cosmetic or as food.

### *The Detailing Guidelines*

In order to prevent dissemination of inappropriate information during the course of promotion activities, the MHLW issued its new "Guidelines Concerning Detailing Activities of Ethical Drugs" (the "Detailing Guidelines") on 25 September 2018. The Detailing Guidelines took full effect on 1 October 2019 and include:

- basic principles for detailing activities;
- responsibilities of company management, including organisational measures (such as establishing independent supervisory divisions for monitoring the activities), employee training and record keeping;
- responsibilities of individuals who conduct detailing activities; and
- guidelines on offering information on unauthorised drugs and off-label uses.

## Self-Regulatory Codes

With regard to prescription-only medicines, a trade association of leading Japanese pharmaceutical research companies issues the major self-regulatory codes. In particular, the JPMA Code of Practice (the "JPMA Code") is the main regulatory code that regulates pharmaceutical advertisements. The JPMA Code has two chapters. The first chapter is the Code of Practice (the "JPMA Code of Practice") and the second chapter is the Promotion Code (the "JPMA Promotion Code"). This code establishes the rules that all member companies must comply with when promoting prescription-only medicines.

The JPMA has also issued several additional guidelines relating to pharmaceutical promotion. For example, among these are the Guidelines for the Drafting of Prescription Pharmaceuti-

cal Products Informational Material (the "JPMA Drafting Guidelines"), see **5. Advertising to Healthcare Professionals**.

With regard to advertising over-the-counter (OTC) medicines, the Japan Self-Medication Industry (JSMI), a trade association of Japanese over-the-counter manufacturers, issued the Guidelines for Proper Advertising of Over-the-Counter Medicines (the "OTC Guidelines"). The OTC Guidelines apply to the advertising of non-prescription drugs to the general public. In particular, the OTC Guidelines regulate advertising through newspapers, magazines, television, radio, websites and other forms of mainstream media to ensure the appropriateness of publicity and advertising activities of non-prescription drugs.

### 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

A self-regulatory code will apply to the member companies of the particular trade association that created the code. For example, the codes created by the JPMA apply only to pharmaceutical companies that are JPMA member companies.

Conduct that violates self-regulatory codes does not necessarily violate Japanese laws and regulations; such conduct is only illegal if it independently violates Japanese laws and regulations. However, a violator may face sanctions under the self-regulatory codes, potentially damaging its reputation.

## 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

### 2.1 Definition of Advertising

Notice No 148 dated 29 September 1998, issued by the Pharmaceutical Safety Bureau of the MHLW, defines "advertising" for the purposes of the PMD Act. This notice states that "advertising" has all of the following three characteristics:

- it has a clear intention to induce customers to make purchases;
- the product names of particular medicines are clearly expressed; and
- it can be seen by the general public.

### 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Advertising and other information are distinguished by the above definition of "advertising". First, advertising must be clearly intended to induce customers to make purchases, for example, it is not likely that a book in a medical library describing certain drugs and targeted at researchers would have such an intention. As to the second requirement – the clear expression of product names – it may be met even in cases where particular product names are not mentioned; this would be the case if the general public could recognise particular medicines based on the pictures or descriptions of those medicines shown in the advertisement. Finally, the third requirement (the ability to be seen by the general public) would not be likely to be satisfied if the relevant information is only provided to patients in a hospital, since the narrow scope of its distribution would limit the potential for the information to reach the general public.

Disease-awareness campaigns and other patient-facing information do not qualify as "advertising" under the PMD Act unless they

satisfy all three parts of the definition of advertising set-out above. For example, if a disease-awareness campaign informs the public in a general way about a certain disease and does not name specific medicines, it is not considered "advertising" under the PMD Act. However, a disease-awareness campaign that provides patient-facing information concerning prescription-only medicines to the general public would run a risk of being "advertising" under the PMD Act. In this regard, the JPMA Code of Practice suggests that the content of disease awareness activities targeting ordinary citizens and patients be closely inspected from the planning stages so that they will not be considered prohibited advertising.

### 2.3 Restrictions on Press Releases regarding Medicines

Press releases regarding medicines are not prohibited. However, if a press release satisfies the three parts of the definition of advertising mentioned in **2.1 Definition of Advertising**, both the regulations concerning advertising under the PMD Act and the Standards will apply.

Generally, the restrictions under the PMD Act are more stringent when the target audience is the general public than when the target audience is healthcare professionals. For example, advertisements for pharmaceutical products used for cancer, sarcoma or leukaemia aimed at the general public are prohibited under Article 67 of the PMD Act.

### 2.4 Comparative Advertising for Medicines

Comparative advertising for medicines is not prohibited but it is restricted by Japanese law and self-regulatory codes. According to the Commentary of Article 9 of the Standards, a pharmaceutical company's comparative advertising must only feature its own products and the advertising must specify the name of those products. Comparisons with competitors' products are prohibited. In addition, when a pharmaceutical company compares two of its own products, the company must ensure that it provides a sufficient explanation of the products.

Further, the JPMA Promotion Code stipulates that comparative advertising "shall be based on scientific data and, in principle, shall be made using generic names".

Finally, the Consumer Affairs Agency has issued general guidelines for comparative advertising. These guidelines suggest that a comparative advertisement shall be considered a Misleading Representation prohibited under the UPMRA if:

- it makes comparisons using unproved or unprovable facts;
- it emphasises unimportant matters as if they were important or makes comparisons based on an unfair selection of products; or
- it merely slanders or defames competitors' products.

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

Article 68 of the PMD Act expressly prohibits advertising unauthorised medicines or unauthorised indications. However, providing information on unauthorised medicines or unauthorised indications that falls outside the definition of "advertising" under the PMD Act is allowed.

### Guidelines for Providing Information

The Detailing Guidelines include the following conditions for providing information on unauthorised medicines and unauthorised indications:

- separating information on unauthorised medicines and unauthorised indications from other promotion activities;
- providing such information only to individuals who have actually requested it;
- providing only accurate information that is based on scientific and objective evidence, without omissions, emphasises, exaggerations or misleading summaries;
- providing information relating to a clinical trial involving a pharmaceutical company only if the research adheres to Good Clinical Practice, the Clinical Research Act or other equivalent rules;
- providing negative information such as information relating to adverse effects;
- clearly indicating that such indication, dosage or method of administration has not been approved; and
- preparing and maintaining records detailing information that has been provided on unauthorised medicines and unauthorised indications.

### Cases Permitting Additional Information

The JPMA Promotion Code requires that member companies may only provide certain information, such as indication, dosage and administration, which may not deviate from the approved label for the relevant drug. However, the Commentary of the JPMA Promotion Code lists several cases in which the provision of other information is permitted if the information is provided for the purpose of promoting the right to know about scientific/medical advancements for both medical/pharmaceutical experts and the general public. These cases include:

- presenting research findings at academic societies or scientific journals;
- displaying exhibition materials at an international academic society (limited to unapproved drugs which have been approved in at least one country);
- supplying previously reviewed academic literature; and
- disclosing information to stockholders as required by law.

Moreover, the Commentary notes that, even if the activity consists of providing information as permitted above, the company must take special care not to be involved in any inappropriate promotional activities for its own commercial purposes.

## 3.2 Provision of Information during a Scientific Conference

The aforementioned Commentary of the JPMA Promotion Code lists two cases in which providing information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals is allowed.

The first case is the presentation of clinical research results during a scientific meeting. However, seminars sponsored by pharmaceutical companies are not covered by this exception.

The second case is the display, by a pharmaceutical company, of educational samples of an unapproved medicine at an exhibition during an international scientific meeting. This only applies, however, when such an unapproved medicine has been approved in at least one other country. If no countries have approved the product, the company may not display a sample of the product. In addition, the pharmaceutical company may not distribute samples of unap-

proved medicines and related scientific materials to anyone during the meeting.

As mentioned in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, the Detailing Guidelines provide certain conditions on providing information on unauthorised medicines or unauthorised indication and such conditions will apply to the provision of information during a scientific conference.

### 3.3 Provision of Information to Healthcare Professionals

The aforementioned Commentary of the JPMA Promotion Code allows the supply, by a pharmaceutical company, of peer-reviewed scientific journal articles, such as reprints of medical journals, upon the request of a medical doctor. However, companies shall not proactively induce a medical doctor to request such scientific journal articles.

As mentioned in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, the Detailing Guidelines provide certain conditions on providing information on unauthorised medicines or unauthorised indication.

### 3.4 Provision of Information to Healthcare Institutions

There are no Japanese laws or self-regulatory codes that expressly regulate the sending of information on unauthorised medicines or indications to healthcare institutions to enable them to prepare budgets. Given that there are no laws or self-regulatory codes that permit such transmission of information, there remains a risk that such conduct would be considered a "promotional activity on unauthorised medicines or unauthorised indications", which is prohibited under Article 68 of the PMD Act.

### 3.5 Publication of Compassionate Use Programmes

Japan's compassionate use programme is intended to promote the expansion of clinical trials for patients who are interested in using unapproved products but are unable to join a clinical trial because they do not meet the inclusion criteria. This expanded trial system applies to investigational products that have gone through or are currently going through a clinical trial that is in the final stage of development; generally clinical trials conducted to verify efficacy and safety after indications and dosage and administration have been established through a separate series of studies ("Main Trials").

In order to provide such patients with information on the ongoing Main Trials or expanded trials, the PMDA will publish on its website certain information, such as a description of the investigational product (investigational ingredient code), contact information for the trial sponsor, subject disease, and scheduled period of the trial. Provision of such information by pharmaceutical companies is allowed "reactively" (ie, only upon actual request from healthcare professionals, patients, etc) and under strict compliance with all requirements stipulated in the Detailing Guidelines as explained in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**. Accordingly, publication of such information by pharmaceutical companies is not permitted.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

#### Advertising Prescription-Only Medicines

Advertising prescription-only medicines to the general public is prohibited in Japan. Article 5

(1) of the Standards expressly prohibits such advertising. In addition, Article 67 (1) of the PMD Act prohibits advertising drugs for specified diseases and regenerative medicines to the general public.

### Advertising Over-the-Counter Medicines

Advertising OTC medicines to the general public is not prohibited but is restricted by the PMD Act and the Standards, as well as by self-regulatory codes.

Advertising for OTC medicines is subject to the rules concerning advertising under the PMD Act and the Standards, which are described above in **1. Pharmaceutical Advertising: Regulatory Framework**. In this regard, it should be noted that Article 6 of the Standards stipulates a particular restriction on advertisements to the general public concerning the efficacy of drugs for diseases that cannot be expected to be cured without a doctor's or dentist's diagnosis or treatment. This Article provides that any such advertisements targeted to the general public must not suggest that the diseases can be cured without such a diagnosis or treatment.

In addition, the OTC Guidelines regulate advertising through newspapers, magazines, television, radio, websites and other forms of mainstream media to ensure the appropriateness of the publicity and advertising activities for non-prescription drugs.

## 4.2 Information Contained in Pharmaceutical Advertising to the General Public

There is no law or regulation that provides exactly what information must be included in pharmaceutical advertising aimed at the general public. However, under the PMD Act and the Standards, if advertising contains information as to the names of the products, their manufacturing process or their indication, dosage, administration or safety, the advertising must follow the following rules:

- companies shall use only authorised brand names or the generic names of the relevant products – in addition, names listed on the Japanese Pharmacopeia may also be used for products that do not require marketing authorisation ("Non-Authorised Products");
- companies shall describe the manufacturing process accurately and not in a way which could lead the general public to mistakenly believe in the superiority of the product;
- Article 3 (1) and (4) of the Standards prohibit companies from using expressions that are beyond the scope of or deviate from the authorised indication, dosage, administration or safety of the products (ie, "off-label promotion");
- for Non-Authorised Products, Article 3 (2) and (4) of the Standards provide that companies shall not use expressions beyond the scope of the product's efficacy, dosage, administration or safety as generally recognised in the field of medicine or pharmacy; and
- the Standards include several other relevant rules, including prohibitions on certain claims relating to efficacy or safety of products and prohibitions on slander and/or defamation of competitors' products.

Beyond the question of what information to include, the OTC Guidelines identify specific statements that are required or prohibited in advertisements for each category of OTC medicines. For instance, advertisements for cold medicines must use the phrase "relief of cold symptoms" but not "this will not make a patient sleepy". Also, advertisements for cold medicines on television or through streaming video on the internet must display the statement "this product shall be used after receiving an explanation from a pharmacist and after carefully reading the

warning label" for one second or more with clear and distinct characters.

As for the price of the medicine, this information can be mentioned in advertising aimed at the general public, although doing so is not required by laws or self-regulatory codes.

### 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

There are no laws or regulations that expressly impose restrictions on interactions between patients or patient organisations and industry.

As for the main self-regulatory codes, the JPMA Code of Practice sets forth the rules concerning collaboration with patient groups. First, when a pharmaceutical company has any relationships or collaboration with patient institutions, the company must respect the independence of the institutions and the company's activities must meet a high ethical standard. Further, the company must make an effort to promote sufficient mutual understanding with patient groups regarding the purpose and scope of the collaboration.

Second, the fact of the sponsorship itself is required to be disclosed. Further, the purpose and scope of the sponsorship shall be agreed upon between both parties and shall be made in writing and recorded in order to ensure transparency. Finally, the member companies that are collaborating with patient organisations shall establish internal company guidelines based on the "Guideline on Collaboration with Patient Organisations" issued by the JPMA.

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

There is no national law or regulation that explicitly provides which information must be included in pharmaceutical advertising directed at healthcare professionals.

However, if such advertising contains information relating to the names of the products, the manufacturing process and the indication, dosage, administration or safety of or in relation to the drugs, as well as other relevant items, the advertising shall be subject to the Standards, as described in **4.2 Information Contained in Pharmaceutical Advertising to the General Public**.

As for self-regulatory codes, the JPMA Drafting Guidelines provides that advertising directed at healthcare professionals must contain the following information in principle:

- name of the product (both brand name and generic name);
- therapeutic category;
- regulatory classification;
- indications;
- dosage/administration;
- warnings/contraindications/precautions;
- presence on the National Health Insurance (NHI) reimbursement price list;
- name of marketing authorisation holder (contact and address for more product information);
- limitation of administration period;
- conditions for approval; and
- creation date of the advertisement.

Even if an advertisement is intended to promote only the name of a product, statements made in the advertisement shall contain at least the name of the product (both brand name and generic name), therapeutic category, regulatory classification, presence on the NHI reimbursement price list, and the name of the marketing authorisation holder (contact and address for more product information).

### Specific Prohibited Statements

Beyond the question of which information to include, the JPMA Promotion Code identifies specific statements that may or may not be used in advertisements to healthcare professionals. For example, it prohibits stating that "there are few adverse reactions" without also citing the conditions of use or without providing a summary of relevant data, including the relevant adverse reactions, to back up such a safety claim. The JPMA Promotion Code also attempts to promote the quality and clarity of the information being presented. For example, the advertising materials must not only emphasise the efficacy of the product but must also include product safety information, including adverse reactions, in order to create a fair and balanced statement of the advertising. Further, the contact and address for seeking more information on the product must be described clearly.

### Price

As for the price of the medicine, the advertising must mention whether or not the medicine is registered on the NHI reimbursement price list, rather than the price itself.

## 5.2 Reference to Data Not Included in the Summary of Product Characteristics

Reference in pharmaceutical advertisement to data on file or other clinical studies not included in the Summary of Product Characteristics is not prohibited. However, references to data on file or clinical studies are limited in certain ways by law and by self-regulatory codes.

First, the general rules on advertising (such as prohibition of false or exaggerated advertisements and advertising that recommends unapproved drugs or off-label uses) under the PMD Act will apply.

Second, references to data on file or other clinical studies shall be subject to the specific regulations provided by the JPMA Drafting Guidelines. For example, statements shall only concern indications approved in Japan. In addition, the study must be published in a peer-reviewed journal.

## 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

In Japan, combination products are treated as one product (ie, pharmaceutical, medical device or regenerative medicine product) and will have one Summary of Product Characteristics. The fact that a diagnostic is a companion diagnostic for certain drug must be included in the Summary of Product Characteristics.

## 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Reprints of journal articles for healthcare professionals are subject to the conditions set forth in both laws and regulations and self-regulatory codes. Major restrictions on reprints are as follows:

- the reprint must be authorised by the author(s) under copyright law;
- the contents of the journal article shall not violate the PMD Act. In particular, the contents of the journal article shall not be false or exaggerated advertising, advertising that recommends unapproved drugs or off-label uses or advertising that slanders and/or defames competitors' products; and

- in principle, the reprint must be related to the company's own product and supplied in response to a request from a healthcare professional. In other words, a pharmaceutical company must refrain from actively inducing a healthcare professional to request such a reprint.

### 5.5 Medical Science Liaisons

There is no national law or regulation that specifically refers to or governs the activities of Medical Science Liaisons (MSLs) or Medical Affairs (MA) activities in Japan. However, in keeping with global practice, the number of pharmaceutical companies establishing MA sections and MSLs in Japan has been on the rise recently. Against this background, the JPMA issued a "Consensus Statement on Medical Affairs Activities" and "Consensus Statement on Medical Science Liaison Activities" (JPMA MSL Statement) on 1 April 2019. In the JPMA MSL Statement, an MSL is defined to mean "a person who belongs to a division independent from the company's commercial divisions and whose main role is to interact with external experts in the field of medicine or science".

The JPMA MSL Statement also provides that MSL activities should not be aimed at promoting sales of the company's drugs. As the definition shows, an MSL's main role is to interact with external experts. However, this does not mean that MSLs are prevented from responding passively (but not proactively) to requests from other healthcare professionals, including requests for information on unauthorised medicines or indications. When MSLs provide any such information on unauthorised medicines or indications at the request of healthcare professionals, they must comply with the requirements under the Detailing Guidelines as explained in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

In Japan, advertisements for medicines do not require prior authorisation from, nor notification to, any regulator.

### 6.2 Compliance with Rules on Medicinal Advertising

The Detailing Guidelines require that companies establish internal systems to ensure appropriate conduct with respect to promotion activities. This includes establishing a "promotion supervisory department" responsible for monitoring promotional materials and promotion activities, which must be separate from the company's sales and marketing division. Companies are also required to set up a "review and supervisory committee", which must include members who are independent of the company, to provide independent advice to the promotion supervisory department. In addition, the Detailing Guidelines require, among others:

- preparation of standard operating procedures for promotional activities;
- preparation and maintenance of business records (including records of any verbal explanations made during detailing activities);
- prior review and approval of marketing materials by the promotion supervisory department based upon advice from the review and supervisory committee;
- periodical training for both employees and officers; and
- establishment of a telephone tip-line to field complaints about promotional activities.

The JPMA Promotion Code also requires that JPMA member companies establish internal

systems to comply with relevant laws, regulations and industry self-regulations, appoint a promotional material officer and establish an in-house oversight system so that only reviewed promotional materials and advertisements are used.

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

Generally, the same laws, regulations and self-regulatory codes concerning pharmaceutical advertising will also apply to advertising on the internet for medical products. In addition, the Commentary to the JPMA Promotion Code provides specific rules concerning access restrictions on internet-accessible information related to prescription-only medicines.

As advertising prescription-only medicines to the general public is prohibited, when a pharmaceutical company provides healthcare professionals with product-related information concerning prescription-only medicines through the internet, the company must restrict access to the relevant websites so that only healthcare professionals have access to such information.

The question, therefore, is what is considered a sufficient access restriction. In this regard, the Commentary provides the conditions set forth below; if all these conditions are satisfied, then an access restriction will be considered sufficient:

- the name of the pharmaceutical company is provided, the website states that the information is targeted at healthcare professionals and the person intending to access the information understands that the information is targeted at healthcare professionals;
- the information is appropriate for healthcare professionals; and
- if a company website targeting healthcare professional's links to an external website, the contents of the external website and the external website itself are appropriate for healthcare professionals and the owner or author of the external website can be clearly verified.

As long as a pharmaceutical company uses a sufficient access restriction, it is not required to use any particular method of establishing passwords.

### 7.2 Advertising of Medicines on Social Media

Generally, the same laws, regulations and self-regulatory codes concerning pharmaceutical advertising will also apply to pharmaceutical advertising on social media. The JPMA Code of Practice in particular describes several issues to which pharmaceutical companies must pay close attention when advertising through social media.

The JPMA Code of Practice defines "social media" as media formed by interactive communication mainly through the internet, where the users, including individuals, send various information. The main feature of social media is that an individual can easily and promptly send information to the general public. Due to this characteristic of the medium, inappropriate information, including false information, may be broadly transmitted to the general public without any confirmation of the accuracy of the information. Therefore, the JPMA Code of Practice requires member companies to take all responsibility for such social media content and before advertising on social media the companies must confirm that all relevant subsidiaries, parent com-

panies, affiliates, planning companies, agencies, employees, etc, comply with the JPMA Code.

Further, the JPMA Code of Practice requires that member companies pay special attention to the following:

- compliance with the PMD Act and the Standards;
- when a member company plans or supports social media activities, that company shall take responsibility for verifying the appropriateness of published content including content posted by third parties and shall take appropriate steps (including take-downs) in the event that inappropriate information is posted, such as information relating to unapproved use, slander and/or defamation of other companies' products or information regarding adverse events;
- only information that has passed careful scrutiny by the appropriate department within the company shall be released; and
- when a company is acting as a sponsor, it shall clearly indicate its company name.

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

As mentioned in **7.1 Regulation of Advertising of Medical Products on the Internet**, pharmaceutical companies must include access restrictions on websites containing advertising, or other information intended for healthcare professionals, since advertising prescription-only medicines to the general public is prohibited.

### 7.4 Provision of Disease Awareness Information to Patients Online

Generally speaking, the provision of disease awareness information and/or materials to patients online is subject to the same laws, regulations and self-regulatory codes as apply to those activities offline. As mentioned in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**, the JPMA Code of Practice suggests that the content of disease awareness activities targeting ordinary citizens and patients be closely inspected from the planning stages so that they will not be considered prohibited advertising.

### 7.5 Online Scientific Meetings

There are no specific laws, regulations or self-regulatory codes in Japan that address online scientific meetings. As a result, online scientific meetings would be subject to the same laws, regulations and self-regulatory codes that apply to in-person scientific meetings.

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

pharmaceutical companies and healthcare professionals or organisations are provided in the Penal Code (Act No 45 of 24 April 1907, as amended). In addition, pharmaceutical companies are expected to comply with the National Public Service Ethics Code (the "Ethics Code"). Further, the Unfair Competition Prevention Act (Act No 47 of 19 May 1993, as amended) (UCPA) provides rules regarding bribery to foreign officials. These regulations apply only to benefits provided to recipients who are individuals (eg, public officers).

#### Penal Code

Article 198 of the Penal Code is the basic anti-bribery regulation that directly applies to officers or employees of pharmaceutical companies.

Article 198 provides that any person who gives, offers or promises to give a bribe to a public official shall be punished by imprisonment with labour for not more than three years or a fine of not more than JPY2.5 million.

Bribery under the Penal Code is broadly defined. It covers not only money or goods but also any benefit (material or immaterial) sufficient to satisfy a person's desires. "Public Official" is also broadly defined. The term includes not only national or local government officials but also individuals deemed government officials under special laws.

### National Public Service Ethics Code

The Ethics Code is a code established by the Cabinet based on the National Public Service Act for the purpose of maintaining the integrity of, and citizens' trust in, public service. The Ethics Code prohibits national public officials from receiving money or goods from interested parties. In some situations, pharmaceutical companies can be considered such "interested parties". The Ethics Code provides for some exemptions, including, among others:

- accepting gifts that are distributed widely to the public as promotional goods or as souvenirs; and
- accepting souvenirs at a large dinner party.

Pharmaceutical companies are expected not to participate in conduct that violates the Ethics Code in order to prevent illegal acts by national public officers.

### Unfair Competition Prevention Act

Article 18 (1) of the UCPA prohibits any person from giving, offering or promising to give any benefit to a foreign public official to have that foreign public official act or refrain from acting in relation to the performance of his or her official duties, in order to make any illicit gains in business with regard to an international commercial transaction. An employee of a pharmaceutical company who violated Article 18 would face imprisonment with labour for up to five years and/or a fine of up to JPY5 million. Further, the pharmaceutical company itself may also be subject to a fine of up to JPY300 million.

## 8.2 Legislative or Self-Regulatory Provisions

The UPMRA and the Fair Competition Code concerning Restriction on Premium Offers in the Ethical Pharmaceutical Drugs Marketing Industry (the Fair Competition Code) regulate offering benefits or other inducements to prescribe to healthcare professionals or organisations. The JPMA Promotion Code contains similar rules. These regulations apply to benefits provided both to individuals and organisations.

### UPMRA

Article 4 of the UPMRA allows the Prime Minister to restrict the offering of premiums in various ways, including through a prohibition. Under Article 6 (2) of the UPMRA, the Cabinet issued a public notice: "Restrictions on the Offering of Premiums in the Ethical Pharmaceutical Drugs, Medical Devices and Sanitation Inspection Industries". The notice prohibits pharmaceutical companies from offering articles, services or other premiums to healthcare institutions as a means of inducing unjust transactions beyond what is commercially reasonable for the usage or sanitary inspection of ethical pharmaceutical drugs.

### Fair Competition Code

"Fair competition codes" are self-regulatory codes set up by the business associations of specific industries based on the UPMRA restrictions on the provision of premiums. Generally, fair competition codes will include UPMRA rules as well as supplemental rules not provided under the UPMRA depending on the nature of the

products and transactions in the relevant industry. The pharmaceutical industry established the Fair Competition Code, which pharmaceutical companies are currently complying with.

The Fair Competition Code provides that pharmaceutical companies shall not offer premiums to healthcare professionals or institutions as a means of unjustifiably inducing drug transactions. If, however, based on standard commercial practices the offers of economic benefits are considered to be discounts, after-sale services or benefits in connection with the drugs, they are no longer categorised as offers of premiums. In addition, even if money, goods or economic benefits are considered premiums, there are some cases in which offering premiums is permitted (several examples are listed). In addition, if premiums are "small sum offerings", offering them will not violate the Fair Competition Code.

#### The JPMA Promotion Code

The JPMA Promotion Code has several provisions regarding offering benefits to healthcare professionals or institutions. It regulates, among other issues:

- the total amount of sample drugs that can be supplied;
- food, drinks, and gifts that can accompany lectures;
- gift-giving; and
- provisions of cash or its equivalent that may negatively affect the proper use of drugs.

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

The Fair Competition Code and the JPMA Promotion Code regulate offering gifts to healthcare professionals.

The Fair Competition Code lists several examples of permitted gift giving activities, including the following:

- offers of articles or services that are necessary for the use of or for enhancing the benefits of ethical pharmaceutical drugs;
- offers of medical or pharmaceutical information on ethical pharmaceutical drugs; and
- offers of articles or services not considered extravagant or excessive in relation to seminars, or the payment of expenses for individuals to attend such seminars, which are organised for medical or other similar institutions in order to promote the understanding of certain ethical pharmaceutical drugs.

The JPMA Promotion Code prohibits member companies from offering healthcare professionals and medical institutions, among other entities, any goods that could potentially negatively affect the appropriate use of drugs or damage drug credibility.

### 9.2 Limitations on Providing Samples to Healthcare Professionals

The Fair Competition Code and the JPMA Promotion Code impose limitations on providing samples to healthcare professionals.

The Enforcement Rules and the Operating Standards of the Fair Competition Code provide the basic rules for offering samples of drugs. In the case of product samples for reference the following rules apply:

- the number of units of the drug contained in one package must not exceed the maximum number allowed;
- the number of packages provided shall be the minimum necessary for the purpose of providing samples;
- if the drug is provided through a wholesaler, the destination medical institutions must be

designated by the pharmaceutical company; and
- pharmaceutical companies must supply the relevant drug information to the recipient healthcare professionals.

Similar rules apply to the provision of clinical drug samples.

The JPMA Promotion Code states that member companies must provide only the minimum amount of samples and must also provide the relevant drug information.

### 9.3 Sponsorship of Scientific Meetings

Pharmaceutical companies are allowed to sponsor scientific meetings or congresses and/or attendance by healthcare professionals to these events, but only in a limited capacity and in strict compliance with the Fair Competition Code and the JPMA Promotion Code.

With regard to a seminar for healthcare professionals concerning a pharmaceutical company's own drugs, the company can provide non-extravagant articles or services and can bear some related expenses. For example, companies may provide tea and snacks or lunch boxes, hold small social gatherings, cover transportation and accommodation expenses and compensate the lecturer. The seminar should be held in an appropriate place in light of its purposes it would be sensible to avoid a resort, a place for sightseeing or a location overseas for this reason (the JPMA Promotion Code expressly provides that pharmaceutical companies shall, in principle, hold such seminars in Japan). Even if such seminars are permitted to take place abroad, the payment of travel expenses must be limited to the travel expenses of healthcare professionals who will provide information on the company's drugs to all participants.

### 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

The rules under the Fair Competition Code set forth the types of entertainment/hospitality that pharmaceutical companies may or may not provide to healthcare professionals. By way of example, providing entertainment such as karaoke or golf, for example, is prohibited.

### 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Pharmaceutical companies may provide grants or donations to healthcare professionals or healthcare institutions subject to the restrictions under the Fair Competition Code and the JPMA Promotion Code.

Under the Fair Competition Code, pharmaceutical companies may not provide donations to healthcare professionals or healthcare institutions as a means of unjustly inducing drug transactions. The question of whether the donations have such a purpose is decided based on detailed criteria provided in the Operating Standards of the Fair Competition Code.

With regard to monetary donations, according to the Operating Standards criteria, pharmaceutical companies may make monetary donations to healthcare institutions within the bounds of standard commercial practice; such donations would not be considered a means of unjustly inducing drug transactions.

With regard to non-monetary donations, the Operating Standards criteria state that pharmaceutical companies may voluntarily provide their own drugs to healthcare institutions in the case of a disaster and to the medical faculty of universities as long as doing so meaningfully contributes to the students' lessons.

Under the JPMA Promotion Code, pharmaceutical companies shall not provide donations to

healthcare professionals or healthcare institutions which may influence the appropriate use of drugs.

### 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

In practice, pharmaceutical companies in Japan usually sell their drugs to wholesalers, who in turn sell the drugs to healthcare institutions. Thus, since pharmaceutical companies do not tend to sell directly to healthcare institutions, any rebates or discounts would mostly be provided to wholesalers rather than healthcare institutions. As to such rebates or discounts provided to wholesalers, the Anti-monopoly Act (Act No 54 of 14 April 1947, as amended) may prohibit certain conduct such as adjusting the discount or rebate amount in exchange for the wholesaler agreeing to follow a suggested price.

### 9.7 Payment for Services Provided by Healthcare Professionals

Under the Fair Competition Code, pharmaceutical companies may offer remuneration or expenses for research or certain studies. Also permitted are expenses for post-marketing surveillance for prescription-only medicines, as well as advertising fees for advertising drugs in journals. Such payments must meet the criteria provided in the Enforcement Rules and the Operating Standards of the Fair Competition Code. For instance, remuneration must be appropriate in light of the content of the relevant research.

The JPMA Promotion Code requires that any remuneration must be appropriate in relation to the services provided. Pharmaceutical companies must not pay healthcare professionals to provide consulting services only as a way of covertly providing them prohibited monetary benefits.

### 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

No prior regulatory authorisations or notifications are required for the activities described in this section.

With regard to employer consent, pharmaceutical companies have internal company rules which regulate providing gifts, hospitality, donations or other payments/services to healthcare professionals and institutions. Such internal rules may require obtaining prior consent from or notification to the companies' compliance divisions.

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

#### The Clinical Research Act

The Clinical Research Act (Act No 16 of 14 April 2017), which took effect on 1 April 2018, requires that pharmaceutical companies and their subsidiaries disclose certain transfers of value to healthcare professionals and institutions in connection with specified clinical research. Clinical research includes human trials examining the efficacy or safety of pharmaceuticals but would not include a clinical trial for new drug conducted under the PMD Act.

Specified clinical research is defined as clinical research funded by pharmaceutical companies, clinical research on unapproved drugs or clinical research concerning off-label use of a drug.

Transfers of value which must be disclosed under the Clinical Research Act include research

funds for specified clinical research, donations provided during the term of or within two years after specified clinical research, and fees for writing, lectures or other services provided during the term of and within two years after specified clinical research. The recipients of payments covered by the regulation include healthcare providers involved in specified clinical research, healthcare institutions or other organisations to which a principal investigator belongs, and organisations managing the specified clinical research. The transfers of value for specified clinical research made in each fiscal year shall be disclosed the following fiscal year on the company's website.

### The JPMA Transparency Guideline

The JPMA "Transparency Guideline for the Relation between Corporate Activities and Medical Institutions" (the "Transparency Guideline") requires that JPMA member companies disclose certain information regarding transfers of value made to healthcare professionals or healthcare institutions.

The Transparency Guideline further requires that each member company create its own internal "transparency policy" based on the Transparency Guideline. Therefore, each JPMA member company has established its own internal transparency policy and has been disclosing information on transfers of value it has made to healthcare institutions based on this internal policy.

#### *Transfer categories*

The Transparency Guideline creates five different categories of transfers of value (fees or expenses). For each category the relevant fees or expenses must be disclosed in detail. The five categories are:

- research and development expenses (such as those for clinical trials for new drugs);
- academic support expenses (such as donations to academic societies);
- manuscript/writing fees (such as fees for writing manuscripts containing scientific information regarding the pharmaceutical companies' own drugs);
- expenses related to the provision of information (such as expenses for lectures and seminars); and
- other expenses (such as for hospitality as a social courtesy).

The types of transfers of value to be disclosed include not only cash but also medicines, medical devices and other goods. Value transferred through a third party, such as a subcontractor or foundation, must be disclosed as well.

#### *Recipients and disclosure*

The recipients of payments covered by the Transparency Guideline include healthcare institutions (such as hospitals and pharmacies), research institutes (such as medical and pharmaceutical departments of universities), healthcare associations (such as medical associations and pharmacists' associations) and persons engaged in medical care and nursing care (such as doctors and nurses) and life-science researchers. The transfers of value made in each fiscal year shall be disclosed in the following fiscal year through the company's website.

## 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

As the transparency requirements under the Clinical Trial Act would apply only to the marketing authorisation holder and its subsidiaries, the requirements would not apply to foreign companies or companies that do not sell products on the market in Japan.

The transparency requirements under trade association rules such as the above-mentioned

Transparency Guideline only bind members of such trade associations. Accordingly, the transparency requirements under the self-regulatory rules will not apply to foreign companies and/or companies that do not yet have products on the market, unless such companies are members of trade associations with transparency requirements.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

Each Japanese law has one or more government agencies that are responsible for enforcement (ie, the regulatory authority). With regard to the PMD Act, as well as the Standards, the MHLW and the competent prefectural governor are the regulatory authorities. In the case of the UPMRA, the Prime Minister, the Consumer Affairs Agency, the Japan Fair Trade Commission and the competent prefectural governor are the regulatory authorities.

The main role of courts in administrative law enforcement (including for the PMD Act) is to impose criminal penalties on companies and their employees that violate the law. In the case of a serious violation, the regulatory authority will ask the Public Prosecutor's Office to prosecute the company or its employee, and the Public Prosecutor's Office will file charges against the company. The court will then render a final judgement.

With regard to the enforcement of self-regulatory codes, the codes usually establish an organ that is in charge of enforcing the code. In the case of the JPMA Promotion Code, the JPMA Code Compliance Committee is responsible for enforcement. As for the Fair Competition Code, the Fair Trade Council of the Ethical Pharmaceutical Drug Marketing Industry (the "Fair Trade Council"), which consists of the pharmaceutical companies designated by the code, is responsible for the code's enforcement.

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

In Japan, pharmaceutical companies may initiate civil litigation proceedings against their competitors before courts for certain types of advertising infringements based on the UCPA.

Under the UCPA, a company whose business interests have been infringed or are likely to be infringed by a competitor's:

- dissemination of information or advertising likely to mislead the public as to the quality, content or manufacturing method of its goods or services (UCPA Article 2 (1) (xiv)); or
- announcement or dissemination of a falsehood injurious to its business reputation (UCPA Article 2 (1) (xv)) may seek an injunction against the competitor suspending or preventing the infringement (UCPA Article 3 (1)).

The company may also claim damages to its business interests resulting from intentional or negligent infringement related to the above conduct.

For example, a pharmaceutical company may file a lawsuit in Japanese court seeking an injunction and/or compensation of damages against a competitor if the competitor creates an advertisement containing falsehoods or slander regarding the pharmaceutical company's products.

## 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

### Penalties or Measures Imposed by Regulators

In practice, Japanese regulatory authorities, such as the MHLW or the Prime Minister, will most likely issue an administrative "guidance" in the first instance against a pharmaceutical company found to be in violation, which is basically an official request to remedy the illegal conduct. If the company does not follow such guidance, the authority will then issue an administrative "disposition."

Under the PMD Act the MHLW or the competent prefectural governor may take the following administrative dispositions, among others:

- order a pharmaceutical company that violated the PMD Act to comply with a "business improvement order" (eg, an order to improve internal review systems for advertisements) (Articles 72-4);
- order a pharmaceutical company that advertised a pharmaceutical product before obtaining the necessary marketing authorisation (prohibited under Article 68) to take certain measures to prevent any such violation in the future (Article 72-5); and
- withdraw a pharmaceutical company's manufacturing and/or marketing licence or suspend all or part of its business for a certain period, as determined by the MHLW, for a company that violated the PMD Act (Article 75).

In addition, as mentioned in **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines**, the amendments of the PMD Act, which became effective on 1 August 2021, include administrative fines for violations of the regulations on false or exaggerated advertising as well as cease and desist orders against pharmaceutical companies engaged in such improper advertising.

A company that has had its manufacturing and/or marketing licence withdrawn has the right to appeal such a disposition above under the Administrative Appeal Act (Act No 160 of 15 September 1962, as amended).

#### *The JPMA Code Compliance Committee*

The JPMA Code Compliance Committee may take actions against pharmaceutical companies that violate the JPMA Promotion Code to address the companies' violations in accordance with the "Rules of Actions against the Breach of the Promotion Code". Actions the aforementioned committee may take include, among others, serious warning, suspension of membership or expulsion from the JPMA.

#### *The Fair Trade Council*

The Fair Trade Council may order companies violating the Fair Competition Code to take certain measures. If the violator does not comply with such an order, the council may impose a penalty, including a fine of up to JPY1 million or expulsion from the council. The council may also request the Consumer Affairs Agency to take necessary actions.

### Penalties Imposed by Courts

Courts may impose criminal penalties on pharmaceutical companies and/or on their officers and employees who violate the relevant laws. The major criminal sanctions for the violation of pharmaceutical advertising rules and rules on inducements to prescribe are as follows:

- false or exaggerated advertising and advertising for an unauthorised drug: imprisonment with labour for not more than two years and/or a fine of up to JPY2 million (PMD Act Article 85);

- advertising to the general public pharmaceutical products intended for use in the cure of cancer, sarcoma or leukaemia: imprisonment with labour for not more than one year and/or a fine of up to JPY1 million (PMD Act Article 86);
- violation of a cease-and-desist order from the Secretary General of the Consumer Affairs Agency: imprisonment with labour for not more than two years or a fine of up to JPY3 million (UPMRA Article 36);
- bribery of a public official: imprisonment with labour for not more than three years or a fine of up to JPY2.5 million (Penal Code Article 198); and
- bribery of a foreign public official: imprisonment with labour for not more than five years and/or a fine of up to JPY5 million (UCPA Article 21 (2) (vii)).

While only individuals are subject to criminal sanctions under the Penal Code, both individuals and companies may be subject to criminal sanctions under the PMD Act, the UPMRA and the UCPA (PMD Act Article 90 (ii), UPMRA Article 38 (1) and UCPA Article 22 (1) (iii)).

## 11.4 Relationship between Regulatory Authorities and Courts

The procedures before and measures taken by the self-regulatory authority and the courts are conducted separately and independently.

## 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

The MHLW is strengthening its enforcement activities in relation to pharmaceutical advertising. In 2016, the MHLW began monitoring the advertising of ethical drugs in order to identify violations early and encourage voluntary measures on behalf of the pharmaceutical companies and trade associations. This endeavour included the appointment of an anonymous healthcare institution to identify problematic items in advertisements and promotional information provided by pharmaceutical companies, including on their websites or in specialist journals.

On 1 October 2019, the MHLW expanded the monitoring activity above to include information from any healthcare institution on a voluntary basis. As a result of these monitoring activities, the MHLW identified 14 cases, including 17 problematic materials, in 2020.

In addition, as mentioned in **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines**, the MHLW issued the Detailing Guidelines in 2018 and amended the PMD Act in 2019 to include administrative fines for violations of the regulations on false or exaggerated advertising as well as cease and desist orders against pharmaceutical companies engaged in improper advertising.

*The views and opinions set forth herein are the personal views or opinions of the authors; they do not necessarily reflect views or opinions of the law firm with which they are associated.*

**Jones Day** assists with all facets of clients' marketing, promotion, and advertising efforts by devising marketing strategies, developing packaging and labelling, obtaining internal and governmental approvals and implementing compliant advertising campaigns, including print, radio and television advertising, website development and social media platforms. The firm's life sciences team helps clients to preserve their advertising position and challenge infringing competitors. Its lawyers provide assistance with pharmaceutical, medical device and biological regulations, including counselling and representation on diverse issues such as product development, product clearance and approval, clinical trials, biosafety, licensing agreements, facility and establishment registration, product listing, government inspections, product and ingredient notifications, recalls, corrective actions, regulatory and due diligence projects, and audits and compliance with good manufacturing practices and the quality systems regulation. The team has successfully defended clients against FDA enforcement actions, including warning letters, seizures, product recalls, inspections, civil monetary penalties, adverse agency determinations, consent decrees and corporate integrity agreements.

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# MEXICO

## Law and Practice

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# 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

## 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

In Mexico, the General Health Law (GHL) is the federal legislation that regulates advertising in connection with medicines as well as other medical products, including devices. This federal law is grounded by the Mexican Constitution (*Constitución Política de los Estados Unidos Mexicanos*); Article 4 of which establishes healthcare protection as a human right.

The Mexican healthcare law system is based on the principle that the protection of people's health is a human right. Provisions related and applicable to advertising on medicines are part of the GHL; this law has several similar regulations that apply to different aspects and issues related to healthcare (such as research, regulatory matters and healthcare services). Therefore, in addition to the dispositions of the GHL, there is a particular regulation on advertising of healthcare products (*Reglamento de la Ley General de Salud en Materia de Publicidad*). In certain cases, such as pricing the provisions of the consumer protection law, it might apply. Issues related to the accuracy of the information submitted to consumer are regulated by the Federal Law of Consumer Protection (*Ley Federal de Protección al Consumidor*).

The National Chamber of the Pharmaceutical Industry (CANIFARMA) groups pharmaceutical companies in Mexico. Its members must comply with several codes, including:

- the Ethics and Transparency Code;
- the Good Promotional Practices Code; and
- the Code of Interactions with Patient Associations.

Such regulations only apply to members of CANIFARMA – compliance with their terms is not binding, pursuant to the terms of Mexican legislation; they contain precise obligations with respect to advertising practices.

## 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

CANIFARMA codes apply only to members of the chamber – their dispositions do not apply to healthcare professionals (HCPs), healthcare institutions or third parties that are not members of such association. CANIFARMA is a Mexican commerce and industrial chamber, the affiliation to which is strictly voluntary. Companies of the pharmaceutical industry are not obliged to join it under the terms of Mexican law. In order to be admitted to such association, the members must accept compliance with all its codes, including the ones applicable to ethics and good promotional practices.

CANIFARMA codes are not mandatory pursuant to the terms of the Mexican constitution, nor the GHL or any other legal provision. For Mexican pharmaceutical companies being members of CANIFARMA is logical due to its visibility before the Mexican government as well as with other industries and sectors. CANIFARMA is the official link and representative of the pharmaceutical industry. With the above factors in mind, being a member and complying to the terms of its regulations is valuable to its members. It is important to mention that breach of such codes does not automatically represent a breach of Mexican legislation. One key provision of such codes is the members' duty to comply with the terms of Mexican law.

## 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

### 2.1 Definition of Advertising

The regulation of the GHL includes two concepts. One is advertising and the other is the definition of advertising or "commercial".

#### Advertising

The activity that incorporates all creation process, planification, execution and diffusion of commercials in media, with the purpose of promoting the sale and consumption of products and services.

#### Commercial

The message directed to the public, or to a segment of it, with the purpose of informing about the existence or the characteristics of a product, service or activity for its commercialisation and sale or to create a reaction.

### 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Under the terms of the GHL and its regulations, the difference between advertising and information is that information related to a healthcare product is considered advertising; conversely, information about healthcare in general and/or general awareness of illnesses is not considered as advertising. The regulations of the GHL are clear to determine that information of healthcare products is considered promotional activity even if there are not advertising phrases and/or suggestions to use such products. Information about good healthcare practices or disease awareness are not considered as advertising. The Mexican regulatory authority has interpreted that information that mentions a product even by its generic name is considered as advertising and is therefore subject to the applicable legal terms and limitations.

#### Distinction between Target Audiences

There is a clear distinction about the advertising activities that could be performed depending on the target audience. Any information related to medicines that requires a medical prescription in order to be sold (Rx pharmaceutical products) can only be delivered to HCPs. This restriction includes the information that contains either the generic and/or the trademark of the correspondent product. Advertising and Information related to over-the-counter (OTC) products can be directed to the general public with a prior permit from the regulatory authority.

The specific law/regulation regarding promotional activities mandates that the same must be grounded and supported. No information on Rx pharmaceutical products could be used or released to the public. If a company owner of a pharmaceutical product launches a campaign to such general audience, it assumes full responsibility to comply with the terms of the applicable law, being the holder of the correspondent marketing authorisation. In the case of Rx, products can only be directed to an HCP.

Nowadays the use of social media platforms is common, if they allow access to the public, the only messages that could be performed are the ones related to OTC products.

#### PSP Programmes

With respect to patient support programmes (PSP), in Mexico in the past years several pharmaceutical companies have developed programmes to support patients during their medical treatment. These programmes are sensitive from the legal point of view, as well as for applicable self-regulatory codes, due to the following:

- the PSP must not advertise directly or indirectly Rx pharmaceutical products; and
- the only purpose of the PSP must be to provide support to the patient, including

discounts, remainders of medical appointments, laboratory analysis, and couching for a heathy life. Subscription to PSP's must the proposed directly by HCP.

Finally, information about health and diseases is not considered as advertising, provided that the same does not directly or indirectly promote pharmaceutical products, or in any matter could be considered as a subliminal information to provoke the use of pharmaceutical products.

### 2.3 Restrictions on Press Releases regarding Medicines

Press releases are considered an advertising activity and are therefore subject to the applicable regulations; the specific law/regulation regarding promotional activities mandates that the same must have the scientific and technical information that support the message. No information on Rx pharmaceutical products could be used or released though press releases if the same are directed to the public and/or have public access, regardless of if the intention was only to refer to an HCP. If a company owner of a pharmaceutical product launches a campaign on social media, they assume full responsibility to comply with the terms of the applicable law, being the holder of the correspondent marketing authorisation.

The regulations on marketing of healthcare products defines as broadcast or public medium (*medio de difusión*) as those used to disseminate marketing adverts to the public including TV, movies, radio, press, magazines, public adverts on streets as well any other means of communication whether electronic or any other IT technology. If the social media platform is accessible by the public, the only messages that could be broadcast are the ones related to OTC products, no matter if the message is made through a press release.

### 2.4 Comparative Advertising for Medicines

Even though comparative advertising for medicines is not specifically forbidden, making comparisons between medicines might be considered as a trade mark administrative infraction, since the intention of such an advert might be intended to damage the reputation and image of one of the products being compared.

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

Mexican law requires a marketing authorisation for a medicine to be manufactured, distributed and used. These activities include advertising. Due to the aforementioned, advertising of unauthorised medicines or new non-authorised indications is not permitted.

It is not allowed to provide information about an unauthorised medicine or unauthorised Indications.

### 3.2 Provision of Information during a Scientific Conference

As mentioned, Mexican law requires a marketing authorisation for a medicine to be manufactured, distributed and used. These activities include advertising; it is generally thought that if the medicine is not authorised the information cannot be provided at a scientific conference of HCPs.

### 3.3 Provision of Information to Healthcare Professionals

As a general rule, if the medicine is not authorised, the information cannot be provided to HCPs.

### 3.4 Provision of Information to Healthcare Institutions

See **3.3 Provision of Information to Healthcare Professionals**.

### 3.5 Publication of Compassionate Use Programmes

It is not allowed to publish the availability of compassionate use programmes. The same might be classified as advertising of a medicines, therefore, are subject to the terms of the GHL applicable to advertising of medicines.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Mexican legislation allows only marketing adverts or information related to OTC pharmaceutical products. In the case of Rx, products can only be directed to HCP. In my opinion if any media platform allows access to the public, the only messages that could be presented are the ones related to OTC products.

The classification of a medicine being an OTC product or a prescription-only medicine is given by the regulatory authority when analysing and approving a marketing authorisation.

#### Prescription Medicines

- Controlled medicines: the prescription is special and issued by the Ministry of Health.
- Controlled medicines: the prescription is retained by the pharmacy.
- Medicines whose prescription is stamped three times and the last time it is retained.
- Medicines that for their sale require a medical prescription that is not retained.
- Antibiotics: following a ruling published in the Official Federal Gazette on 27 May 2010, the Ministry of Health determined that antibiotic medicines may only be sold after a medical prescription is presented, which will be retained by the pharmacy at the end of the treatment.

It should be noted that all the above medicines are considered prescription-only medicines.

#### OTC Medicines

- OTC medicines sold only in pharmacies that do not require a prescription to be shown.
- OTC medicines sold in establishments that are not pharmacies, which do not require a prescription to be shown.

#### Legal Principles of Advertising Medicines

The main legal principles of advertising of medicines pursuant to the terms of the GHL and the applicable regulation are as follows.

- The information that is provided in the advertising must be verifiable. The information about the security, efficacy and quality of a medicine must previously be approved by the healthcare regulatory authority.
- Free of dialogues, texts, sounds, images and other descriptions that cause or could cause error or confusion because they are deceptive or abusive and should not mislead.
- The content must be for guidance and education.
- Shall not attribute to them preventive, therapeutic, rehabilitative, nutritional, stimulant or other types of qualities that do not correspond to their function or use, as established in the applicable provisions or in the marketing authorisation granted by the authority.

- Indicate or suggest that the use or consumption of a product is a decisive factor for changing people's behaviour.
- Refer to the real characteristics, properties and uses or those recognised by the Ministry, of the products, services and activities, in Spanish, in clear and easily understandable terms for the public to whom it is directed.

### Purposes Requiring the Provision of Health Information

Provide health information on the use of the products and the providing of the services, which must correspond to any purposes indicated in the respective authorisation.

- Indicate the necessary precautions when the use, handling, storage, holding or consumption of the products may cause risk or harm to people's health. The HCP and/or the patient should be warned about the potential effects and risks involved in the use of the medicine.
- The assertions that refer to the benefits derived from the purchase, use or consumption of a product, would be obtained immediately or in a specified period, must have technical or scientific support that can prove them.
- Avoid using categorical or superlative terms that encourage error or confusion for consumers with respect to the performance, characteristics or conditions of the advertised product. A categorical term will be understood as one that is asserted or denied absolutely. When upon using these terms, objective assertions are also used, or reference is made to studies, samples and/or tests, such information must be verifiable. Thus, avoiding the use of phrases such as "The best", "The only", "100% percent safe" or others of a similar nature.
- Avoid discrediting, by false assertions, other companies, products or industrial or commercial activity of any other person or company and its products, services, activities or circumstances or its brands, trade names or other distinctive signs through its content or in the form of presentation or dissemination.

### Basic Legal Divisions

The advertising of medicines and dissemination materials have a basic legal division.

- To the public in general: medicines or other health products that for their sale do not require a medical prescription (ie, OTC medicines, protheses, orthoses, and medical device functional aides).
- Advertising directed to health professionals.

OTC medicines:

- must comply with the marketing authorisation and authority prior specific permit to perform the advertising; and
- should not be deceptive, exaggerated or tendentious.

Prescription medicines:

- may only be advertised to health professionals; and
- must omply with the terms granted within the marketing authorisation and the information to prescribe, approved by the Federal Commission to Prevent Sanitary Risks (*Comision Federal para la Protección Contra Riesgos Sanitarios* or COFEPRIS) (summary of the medicine's information known as information for prescribing ((IPP) is the acronym in Spanish)).

## 4.2 Information Contained in Pharmaceutical Advertising to the General Public

The information that can be used in advertising of medicines is the one included and approved

by the regulatory healthcare authority during the process of the review and analysis of the correspondent marketing authorisation. Only the approved information and therapeutic indications of a medicine can be used in advertising.

The price of a medicine can be advertised. The information about the security, efficacy and quality of a medicine must be have the technical and scientific support, as well as be approved be approved by the Mexican healthcare authority. The key document for purposes of advertising activities is the marketing authorisation.

### 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

There is not a specific legal restriction for interactions patients, patients' organisations and industry. The limitations will be with public institutions as well as public servants.

With respect to the industry codes (CANIFARMA), there is one specifically referred to the interactions between industry and patient organisations. This code contains rules an certain limitations for such interactions, including:

- no promotion of Rx medicines to patients or their associations;
- keeping records of agreements, contributions and in general interactions with these organisations;
- having internal policies that regulate the interactions;
- no editorial participation in sponsored publications;
- when sponsoring meetings or seminars, these should take pace in adequate non-luxury sites not known for being only for entertainment purposes – such sponsorship should be reasonable; and
- paying the financial contribution to the association, not directly to a patient.

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

The information that can be directed to an HCP is the one approved by the healthcare authority and contained in the marketing authorisation, of which an important part is known as information for prescription. These data are submitted by the applicant of the marketing authorisation; the medicine will be approved together at the same time. Basically, the data is needed to prescribe the medicine, and includes generic and trade names, indications, manufacturer, formula, contraindications, possible adverse reactions and events.

The price of a medicine can be informed to the HCP. The information that cannot be provided to a HCP is the one not approved by the authority, such as: non-approved indications and possible adverse reactions of a third product.

### 5.2 Reference to Data Not Included in the Summary of Product Characteristics

Advertising needs to refer to the Summary of Product Characteristics (*SmPC/Información para Prescribir*). If clinical or scientific information is used, the same must coincide with the correspondent summary.

### 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

It is not permitted to advertise on combination products or companion diagnostics that are not included in the Summary or Product Characteristics, the company is only allowed to advertise the product itself with the indications that are approved by the Mexican regulatory authority in the marketing authorisation.

### 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Companies can provide reprints of journal articles if the same contain information regarding diseases, general heathcare matters and medicines information, in this case, the same must be in accordance to the one contained in the SmPC.

### 5.5 Medical Science Liaisons

MSL are not clearly included and regulated by the HCL or its regulations, however they would follow the same pattern and principals of pharmaceutical advertising; therefore, any information to be provided to HLP even in scientific discussions must comply with the law, particularly, and be limited to the approved information in the marketing authorisation as well as in the information to prescribe. In the case of self-regulatory provisions, CANIFARMA includes terms and obligations for its members, for not providing information related to unauthorised medicines or indications to healthcare professionals.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

The advertising approval system is as follows:

- for ads or materials related to OTC products a prior permit must be submitted; and
- if the material refers to Rx products a notice will need to be submitted, before the advert is published/broadcast.

The competent authority for all regulatory healthcare matters is COFEPRIS.

### 6.2 Compliance with Rules on Medicinal Advertising

Under the terms of the Mexican healthcare law, including GHL and its regulations, there are no legal requirements to have internal policies and/or standard operating procedure that regulates advertising activities.

In respect of these, the CANIFARMA codes contain certain obligations, including, for example: Written rules for the delivery of free samples, interactions with medical associations and control of promotional events.

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

There is not a specific law/regulation for the use of advertising on the internet. If the internet is used for messages or adverts, the GHL and its regulations apply to information and publicity made with respect to goods, services and healthcare products that will be used by humans. This information should be accurate and not mislead the public, at the same time must be grounded and supported.

The regulations on marketing of healthcare products defines as broadcast and/or public medium (*medio de difusion*) as those used to disseminate marketing adverts to the public including TV, movies, radio, press, magazines, public adverts in streets as well any other mean of communication whether electronic or any other IT technology.

Such legislation allows only marketing adverts or information related to OTC pharmaceutical products. In the case of Rx products, they can only be directed to HCP. If the IT platform allows

access to the public, the only messages that could be performed are the ones related to OTC products, no information related to Rx products and their therapeutic indications should be published.

### 7.2 Advertising of Medicines on Social Media

The same rules apply as to the internet. As mentioned above, such legislation allows only marketing adverts or information related to OTC pharmaceutical products. In the case of Rx products they can only be directed to HCP. If the social media platform allows access to the public, the only messages that could be published are the ones related to OTC products. This includes Twitter, Facebook and WhatsApp. For legal purposes social media is considered a broadcast medium (*medio de dufusión*).

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

If the information submitted is intended for HCP, and is related to Rx medicines, the company must assure that the websites contain solid restrictions to prevent access to the general public.

### 7.4 Provision of Disease Awareness Information to Patients Online

The companies are allowed to provide disease awareness information online, as long as there is no mention to the generic name and/or the brand of the Rx pharmaceutical product. If the company wants to provide disease awareness information in which the generic and/or brand of an OTC product is mentioned, the company needs prior authorisation that allows providing that information to the general public. Information related to RX products is forbidden.

Providing disease awareness information to the public is a sensitive matter, since it might be considered as advertising, therefore the same should not directly or indirectly promote pharmaceutical products, or in any matter could be considered as subliminal information to provoke the use of pharmaceutical products. If a company projects to provide on-line disease awareness information, it is advisable to get an authority written ruling.

### 7.5 Online Scientific Meetings

There is no specific regulation for online scientific meetings in Mexico. Pharmaceutical companies are allowed to sponsor scientific meetings, provided the information to be presented is in the scope of the specific marketing authorisation as well as the authorised information for prescription. The handbooks and related information to be provided must only be the one approved by the health care authority as information for prescription. An event will be considered "national" if the same is organised and/or sponsored by a Mexican institution and/or company.

Online scientific meetings organisers must assure that all attendees are health care professionals, therefore each of them must provide with the correspondent information. Only health care professionals can attend such meetings, due to the fact that the information to be provided is not allowed to be shared to the general public.

Online meetings under the terms of Mexican law are not considered as international events. If the same are organised by a Mexican institution or company, local regulations will apply.

There is no prior authorisation required, with the exception of online meetings organised inviting public servants that are health care professionals, in this particular case, the prior authorisation of the public institution where the professionals render their services is needed. There must be rules of access, such a pre-registration that

assure the participation of only of health care professionals.

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

The Mexican anti-bribery legislation is contained in a group of laws that are known as the national anti-corruption system. Within this mechanism there is one federal law – the Federal Law of Administrative Responsibilities. This legislation prohibits to give any benefit, gift or retribution to a public servant and applies to HCPs working for public institutions. In addition, public servants need to avoid any relation that might represent a conflict of interest with their public duties. The concept of conflict of interest applies to both individuals or public organisations.

Under the terms of their provisions, CANIFARMA codes include the obligation of its members to avoid giving benefits, that is, contributions that might have the intention to get a benefit, in return, such as incentivising the prescription of a company's medicines. These anti-bribery rules apply to relations with HCPs or public or private sector organisations.

When dealing with HCPs in Mexico, an important division must be taken in consideration:

- HCPs working for public institutions; and
- HCPs with a private practice.

The private sector is considered made up of companies as well as business projects that do not draw on public funds, ie, the investment does not come from economic resources of any government institution.

### 8.2 Legislative or Self-Regulatory Provisions

After many years of debate and discussion, in 2015 and 2016, alongside the creation of new legislation, important amendments to the constitution were integrated into Mexican anti-bribery legislation to create a group of laws that are known as the national anti-corruption system. As mentioned, this mechanism has the specific purpose of preventing and prosecuting corruption. The Federal Law of Administrative Responsibilities prohibits giving any benefit, gift or retribution to a public servant. This limitation applies to HCPs working for public institutions. This law clearly establishes the concept of conflict of interest between the professional activities of an HCP and the relation with the pharmaceutical industry.

In 2008 the Ministry of Health issued regulations that prohibited pharmaceutical companies directly giving any goods to public HCPs. The invitation to participate in scientific activities and congresses must be approved by the administrative authorities. In addition, public servants need to avoid any relation that might represent a conflict of interest with their public duties. The concept of conflict of interest applies to both individuals or public organisations.

A clear conflict of interest will be considered if the HCP who has any interaction with the pharmaceutical industry participates in a decision-making process to approve a medicine. This applies also to a public procurement procedure or the analyses of its inclusion in a national formulary.

CANIFARMA codes included under the terms of their provisions the obligation of its members to avoid giving benefits, that is contributions

that might have the intention to get a benefit, in return, such as incentivising the prescription of a company's medicines. These anti-bribery rules apply to relations with HCPs or public or private sector organisations.

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

As mentioned in the preceding paragraphs, the Federal Law of Administrative Responsibilities prohibit give any benefit, gift or retribution to a public servant, this limitation applies to HCPs working for public institutions. In addition, public servants need to avoid any relation that might represent a conflict of interest with their professional activities and their interaction with companies of the pharmaceutical industry.

In 2008, the Ministry of Health issued regulations that prohibit giving any goods to public HCPs. The participation in scientific activities, including seminars must be scrutinised and approved by the administrative authorities. In addition, public servants need to avoid any relation that might represent a conflict of interest with their public duties.

In the case of HCPs who act in the private sector – ie, having their own medical practice – the CANIFARMA codes establish that it is possible to offer gifts that do not have a significant cost (ie, gimmicks).

### 9.2 Limitations on Providing Samples to Healthcare Professionals

In the case of public institutions, companies cannot directly provide samples to HCP. The delivery must be made through administrative authorities of the healthcare institution.

In case of HCPs with private practices, CANIFARMA's codes mandate the following:

- not delivering free goods as an incentive or pressure to prescribe certain medicines;
- provide samples in reasonable amounts for the purpose to help the HCP to get familiar with the product and to initiate a medical treatment;
- such samples must not be commercialised; and
- strong control policies should be created, as well as personnel, that keep records and monitor these samples.

### 9.3 Sponsorship of Scientific Meetings

Companies can sponsor scientific meeting as congresses, HCPs can attend. The main principle of these activities is to keep them for educational and scientific purposes, not with the intention to motivate the participants to benefit a pharmaceutical company and encourage the prescription of medicines in exchange for the participation in such events.

In case of HCPs in private practice such events should take pace in adequate non-luxury sites not known for being for entertainment and must have a scientific purpose. The context and purpose of the event should be educational and not for the objective to entertain HCPs. The participation must be free of any influence or given as an incentive to prescribe medicines or benefit a company.

In case of HCPs working for public institutions, the event should be authorised by administrative bodies of the institution and have the limits mentioned above. The participation must be free of any influence or given as an incentive to prescribe medicines or benefit a company in a public tender of public procurement procedure or to include certain product in a national formulary.

### 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

The cultural, sports or non-scientific events must not be the main objective and should not occupy more than 20% of the time conference.

### 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Companies in the pharmaceutical industry can provide grants and donations to healthcare institutions. The key factor in both the public and private sectors is to avoid conflict of interest and to use the monetary, equipment or services contribution to get back a benefit, such as:

- prescriptions of medicines;
- benefits or advantages in public tenders or public procurement procedures;
- approvals of marketing authorisations; and
- inclusions in national formularies.

### 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Such restrictions do not necessarily apply themselves, the legal issue will come if the discount is granted to an HCP with a potential conflict of interest, such as getting prescriptions of medicines in exchange.

In the case of healthcare institutions, it is valid to give rebates and discounts in compliance with anti-trust regulations, for example, that the rebate is given under free competition basis and not with the specific intention to damage a third party or obstruct the free access to goods.

### 9.7 Payment for Services Provided by Healthcare Professionals

It is possible to contract services to be rendered by an HCP. As mentioned for other cases, is important to establish the difference between professionals from the public and the private sector.

In the case of HCP of the public sector, is possible to contract for such services if there is not a conflict of interest that might illegally benefit a company, for example, services of an HCP who participates in the following decisions:

- to include a medicine in a national formulary;
- authorisation of a marketing authorisation; or
- granting a public contract to acquire a medicine or healthcare product.

In case of an HCP with a private practice, CANIFARMA codes allow getting these types of services and the correspondent payment. The purpose or intention must not be to get the benefit the company in an inadequate manner, such as:

- influence the HCP to prescribe certain products;
- buy or recommend them; or
- damage the image of a product of a third party.

The payment should have a fair market value and be related only with the service.

### 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

In case of services to be contracted with public HCP a previous authorisation of the superior is required.

Samples of medicines as well as gimmicks to be given to a public HCP will need to be delivered to the administrative authorities of the healthcare institution, not directly to the HCPs. This is a matter that implies that before performing this activity, the correspondent internal body will need to approve the same.

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

Legally, pharmaceutical companies are not required to disclose, under regular or periodic basis, details of transfers of value to HCPs. The GHL, and not its regulations, establish such obligations. The possibility exists that an administrative or judicial authority might request such disclosure in case of a specific legal procedure or litigation – such a request must be legally grounded and be precise and detailed request of disclosure. For example:

- the disclosure might be requested by the Secretariat of Public Function (in cases of corruption investigations);
- the Federal Economic Competition commission (in cases of anti-trust investigations); and
- some requests based on a tax audit.

The CANIFARMA codes include transparency obligations, such as the obligation of companies to disclose upon request by the Ethics Council, contracts and payments or transfers of value to HCPs. In my opinion such requests must be grounded and be specific to the cases, not being an open request of disclosure, nor an ongoing periodic obligation.

### 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

Transparency requirements from Mexican authorities apply to companies doing business in Mexico and such requirements are not related to having products in the market and are linked to their commercial activities.

In the case of CANIFARMA their members already have products in the market; therefore, as members are subject to the terms of the correspondent codes.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

The Mexican regulatory authority with legal responsibility to enforce all the applicable regulations on advertising is COFEPRIS.

In cases that involve prices as well as claims that might affect directly the consumer, the Federal Consumer Protection Agency might have a joint jurisdiction over an individual case, for example, advertising that is consider misleading the consumer.

If a sanction is imposed, for example a fine and or a seizure or a product, a company will have the right to battle the case before federal courts and the right to a constitutional relief in case of a constitutional violation.

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

There are three scenarios:

- if the advertising infringements are any of regulatory healthcare provisions the company might file complaint before COFEPRIS;
- if the infringement involves infractions to the Federal Law of Consumer Protection, ie, misleading advertising that might damage the consumer, an additional complaint might be filed before the Federal Consumer Protection Agency;

- if in addition to the above if the advertising might affect a trade mark or reputation of a company there is an administrative recourse to claim the infraction that could be filed before the National Institution of Industrial Property.

All the above proceedings have different instances that might end in litigation before federal courts, including constitutional reliefs.

### 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The administrative authorities in charge of enforcing laws and regulation applicable to advertising of medicines might impose the following sanctions:

- administrative preventions;
- fines that might be from approximately USD5,200 to USD55,000 per infraction;
- temporarily or definitive shutdown of the company;
- seizure of a product or entire stock;
- request to recall the correspondent products;
- in case of an advertising material or campaign that might be considered to mislead the final consumer (ie, a deceptive ad), there could be a fine of up to 10% of the company's sales;
- media companies must ensure that the advertising transmitted has the corresponding permit or a notice has been filed with COFEPRIS; and
- COFEPRIS has the authority to order the media to immediately suspend, in 24 hours, the advertising of medicines that might be in breach of the GHL.

### 11.4 Relationship between Regulatory Authorities and Courts

The procedures or measures taken by the self-regulatory authority and the procedures or measures taken by courts are not linked. Both types of authorities have their jurisdiction and forum. The Mexican Courts will act based on the terms of the Constitution; the GHL and its regulations as well as the consumer protection law. Their resolutions and final judgments will be binding to the sanctioned company.

In the case of a self-regulatory authority (CANIFARMA), the industry codes have procedures and sanctions that will be applicable only to members of such chamber. An infraction to the self-regulatory codes does not imply an action of Mexican federal courts or administrative authorities. At the same time, a final judgment of a court will not automatically imply the initiation of a procedure for sanction before the CANIFARMA's Ethics Council.

### 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

In recent years COFERPIS issued a ruling that might be interpreted as an intention to allow advertising of Rx medicines to the general public; however, the law and the regulations must be changed, and the rules are currently still the same: advertising of Rx medicines can only be directed to HCPs.

The Mexican regulatory authority regularly prosecutes and sanctions advertising of medicines or products that pretend to be medicines – without having a marketing authorisation – which do not have the claimed therapeutic effects or in worst case scenario are not medicines at all.

COFEPRIS as well as the Ministry of Health has the clear intention to combat so-called "miracle products" that are in the market pretending being medicines or having non-proven therapeutic effects. In the past, TV broadcast companies have allowed advertising of these products with the obvious damage to the consumer.

At the same time, the Federal Consumer Protection Attorney Office is active to prevent misleading advertising that might damage the consumer.

During 2021 there were not significant changes to the Pharmaceutical Advertising regulations in Mexico.

On 3 June 2021, a new law was enacted, related to transparency and the combat of improper activities, when contracting publicity (*Ley para la Transparencia, Prevención y Combate de Prácticas Indevida en Materia de Contartación de Publicidad*). The purpose of this new law is to prevent that marketing agencies and media companies might improperly control marketing means and spaces. Due to the above, as of the enactment of this law, pharmaceutical companies (among others), must directly contract and hire media companies to market their products in the different means and marketing spaces (such as TV, radio, newspapers, internet and social media). The marketing agencies cannot directly buy such marketing spaces for purposes to resell the same. Such agencies could only act on behalf of pharmaceutical companies. It must be noted that this Law applies to any kink of advertising and not only of pharmaceutical products.

**Santillana Hintze Abogados, S.C.** is based in Mexico City. Founded 15 years ago, its areas of expertise include health law, regulatory, advertising, licensing, black market issues and prosecution, anti-bribery compliance and personal data protection and compliance. It advises life sciences companies involved in the pharmaceutical and medical devices industry, as well as industry associations, on legal matters related to biotechnology. The practice group consists of 20 lawyers specialising in healthcare law, with a team dedicated exclusively to administrative litigation matters, including advising and litigating on public procurement and public tenders of pharmaceuticals and medical devices. The firm's lawyers are experienced in health law, corporate law, personal data compliance, FCPA and competition matters, advising clients that are among the most prominent pharmaceutical and medical devices companies and demand highly specialised legal advice relating to the latest laws and regulations in this rapidly developing field.

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# Trends and Developments

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## Pharmaceutical Advertising Regulations in Mexico

### Overview

The pharmaceutical industry has become one of the most important sectors in the world, since medicines are part of our daily lives, used not only to cure or stop disease, but also to prevent and relieve symptoms. As most countries have regulatory mechanisms for this industry to protect against the pursuit of unnecessary, excessive or harmful consumption of medicines in general, this article aims to describe the general regulation of pharmaceutical products in Mexico from an advertising perspective.

### Introduction

The regulation of advertising in Mexico is not a new issue, as for decades the competent authorities have legislated and issued various types of provisions and regulations in order to establish the guidelines that must be met by suppliers of products and services for the welfare of the consuming public.

In general, Mexico has a Federal Consumer Protection Law (FCPL), which establishes the objectives of promoting and protecting the rights and culture of the consumer, seeking equity, clarity and legal certainty in relations between suppliers and the general public.

Even though this law does not have a specific chapter regarding the guidelines that any product or service must comply with in terms of advertising, it establishes the general principle that information or publicity related to goods, products or services that are broadcast by any media or in any form must be truthful, verifiable, clear and free of text, dialogue, sounds, images, trademarks, designations of origin and other descriptions that lead or may lead to error or confusion due to misleading messages and abusive advertising practices.

According to the FCPL, misleading or abusive information or advertising is understood as that which refers to characteristics or information related to any good, product or service that may or may not be true, misleads or confuses the consumer due to inaccurate, false, exaggerated, partial, artificial or tendentious content.

Based on the foregoing, it is possible to say that the advertising of any product or service, regardless of its nature, field of application or characteristics, must comply with the principles of truthfulness and not mislead the consumer, rules which are equally applicable to to pharmaceutical products.

### Applicable Legislation

In addition to the FCPL, there is a regulatory framework for the advertising of pharmaceutical products, which is mainly found in the following provisions:

- the General Health Law (GHL);
- the General Health Law Regulations regarding Advertising (RGHL); and
- the Official Mexicans Standards (NOMs).

It should be noted that even though these constitute the main legal framework for the advertising of pharmaceutical products, there are other laws and regulations that also apply. For instance, the Federal Law for the Protection of Industrial Property establishes the prohibition

to use any denomination as a trademark that can cause confusion or mislead the consumer regarding the characteristics of the product. This obligation applies not only when the trademark is filed, but also if the trademark is registered, since at the moment of the declaration of use (applicable for trademarks filed after 10 August 2018) or renewal, it must be declared that the goods/services are non-deceptive and are free of bad faith.

On the other hand, the Regulation in the Field of Medical Supplies, establishes that in addition to the fact that a trademark in pharmaceutical products cannot clearly or veiledly include the composition of the drug or its therapeutic qualities, it must be different from other trademarks in at least three letters of each word.

The advertising of pharmaceutical products is not a matter regulated only by the government, but also associations formed by members of the pharmaceutical industry, such as:

- the National Chamber of the Pharmaceutical Industry (CANIFARMA); and
- the Council of Ethics and Transparency (CETIFARMA).

CANIFARMA and CETIFARMA have issued different codes of ethics and conduct to regulate this industry in the advertising field, namely:

- the Code of Ethics and Transparency of the Pharmaceutical Industry;
- the Code of Good Promotional Practices; and
- the Code of Good Practices of Interaction of the Pharmaceutical Industry with Patient Organisations.

Even when the regulations issued by the associations are not mandatory, if a member of the association does not comply with these codes, it can be suspended or excluded as a member of the chamber.

Lastly, the Advertising Council is a public-service organisation which includes representatives from academia, the business sector, the scientific community, media and consumer groups and the Ministry of Health. This Council is focused on the issuance of different criteria and opinions for the optimal use of ethics in pharmaceutical advertising strategies.

### Advertising

Advertising is defined as providing information with the intention to promote the sale or consumption of a product. Legally, it is “the activity comprehending any process of creating, planning, executing, and circulating of ads in media channels which aims to promote the sales or consumption of products and services”, according to Article 2 of the RGHL.

This means that any activity that fulfils this description shall be regulated by the RGHL and other applicable regulations and, even when there is not a specific rule regarding electronic or online advertising, the activities through this media shall fulfil the general advertising rules in accordance with the RGHL.

Any advertisement of a pharmaceutical product must be approved by the competent authorities, including the Federal Commission for Protection against Sanitary Risks (COFEPRIS), which is an agency linked to the Ministry of Health and with control of the advertising of pharmaceutical products.

COFEPRIS is also the competent authority for regulating the authorisation of the manufacture and commercialisation of pharmaceutical products. The safety and efficacy of the products must be demonstrated by standard clinical trials, according to the rules established in the

GHL, the Regulation of the RGHL and the NOMs related to the medicine manufacture in order to obtain the authorisation to sell the product and subsequently the advertising approval.

If the product is not manufactured in Mexico, the import of drugs, health products or raw materials for drugs must be also approved by COFEPRIS for sale and marketing in our country. This means that parallel imports of medicinal products are not allowed in our legal system, since the import of medicinal products always requires authorisation. The exceptions to this rule are very limited for lab tests, clinical trials, special treatments for illnesses with low prevalence, personal use or donations.

In addition to COFEPRIS, there are other authorities responsible for ensuring compliance with legal provisions, such as the Federal Agency for Consumer Protection (PROFECO), which is responsible for protecting and defending consumer rights, or the General Attorney Office (FGR), which is responsible for implementing measures against health crimes.

### Characteristics of Advertising in Pharmaceutical Products

Advertising shall be consistent with the characteristics or specifications that establish the applicable provisions for pharmaceutical products, namely it shall not:

- attribute preventive, therapeutic, rehabilitative, nutritional, stimulating or other qualities, which do not correspond to their function or use;
- indicate or suggest that the use or consumption of the pharmaceutical product is a determinant factor to modify a person's behaviour;
- indicate or explicitly or implicitly lead to the belief that the pharmaceutical product has the ingredients or the properties it lacks; or
- encourage or put at risk the physical or mental integrity or dignity of persons.

Advertising will be guiding and educational, for which it must:

- refer to the characteristics, properties and effects, in Spanish, in clear terms which are easily understandable for the public to whom it is addressed;
- provide health information on the use of the pharmaceutical product, which must correspond, when appropriate, to the indicated purposes of the granted authorisation;
- indicate the necessary precautions when the use, handling, storage, possession or consumption may cause risk or damage to people's health;
- contain information on the specifications for the proper use of the product, as well as the health damages that could be caused; and
- be written in negative literary forms when it comes to warning the consumer about the risks that the product may represent.

Advertising shall be verifiable and therefore cannot:

- mislead the consumer;
- hide the necessary contraindications;
- exaggerate the features or properties of the pharmaceutical product;
- indicate or suggest that the use of the pharmaceutical product is a determinant factor of the individual's physical, intellectual or sexual characteristics; and
- establish comparisons between products whose ingredients are different, which could lead to health risks or damage.

The legends or health messages that must appear in the advertising of pharmaceutical products will be subject to the following provisions.

- In advertisements that are broadcast on television and in films, the written captions must appear for a minimum duration equivalent to a quarter of the total duration of the ad, appear in contrasting colours, be placed horizontally, with regular Helvetica font that is not condensed and equivalent to 40 points per letter in size, in proportion to a 14-inch television screen.
- The auditory legends must be pronounced in the same rhythm and at the same volume as the ad, in clear and understandable terms.
- In printed advertisements, the legends must have the characteristics referred to above and adhere to the following sizes:
  (a) for billboards measuring at least 1,290 mm x 360 mm, the legend will be 60 points high and must be adjusted in proportion to the size of the advertisment;
  (b) for any other print advertising, the text must be no smaller than 20 points high in proportion to a page that measures 21.5 cm x 28 cm; and
  (c) for electronic advertising, for every four spaces there must be one with the precautionary legend placed in a similar size and proportion to the product's advertisement.
- In radio advertising, the legends will be an integral part of the advertisement and will be pronounced in the same rhythm and at the same volume as the voice of the latter, in clear and understandable terms.
- The legends and messages contained in Computer or telecommunication media advertising must comply with the above regulations.

If the authority so requires, any statements made in the advertising about the quality, origin, purity, conservation, nutritional properties and benefits of the pharmaceutical products must be verified, as well as the target group to which the publicity is directed. The advertising company responsible must present the technical and scientific information requested by the authority.

### Classification of Advertising

For pharmaceutical products, advertising is classified as:

- Advertising aimed at health professionals, which includes:
  (a) information about the pharmaceutical product and its use; and
  (b) the diffusion of medical or scientific information for advertising or promotional purposes.
- In this case, the medical information shall be addressed to health professionals, through film, recorded or printed materials, by means of objective demonstrations, exposures or exhibitions on human diseases, and their prevention, treatment and rehabilitation.
- Advertising aimed at the general public, which includes the advertising of medicines that do not require a medical prescription to be purchased.

Drug advertising aimed at the general public may include the description of diseases specific to human beings, diagnosis, treatment, prevention or rehabilitation expressed in the terms of the produts' health record and in language appropriate to the target audience. These messages must always identify the issuer with the product's trademark or its corporate name.

Advertising aimed at health professionals may only be broadcast in the media for this sector, including dictionaries of pharmaceutical products and medication guides, and must be based on the information for the prescribed medications.

The advertising of medicines aimed at the general public must:

- fulfil the indications approved by the health authorities in the authorisation of the product;
- include in the visual form for print, audio for radio, as well as the visual and audio forms for film and television, the legend: "Consult your doctor", as well as express the corresponding precaution when the use of medications represents a danger in the presence of any co-existing clinical or psychological conditions; and
- in film and television, one of the legends can be included in visual form and the other in auditory form.

Pharmaceutical product advertising will not be authorised when:

- it is showed as a definitive solution in the preventive, curative or rehabilitative treatment of a certain disease;
- it indicates or suggests its use in relation to symptoms other than those expressed in the health authorisation of the product;
- it promotes consumption through raffles, contests, collectibles, or other events in which luck is involved;
- it promotes consumption by offering any other product or service in exchange;
- it makes use of statements or testimonials that may confuse the public and are not properly supported; and
- it uses cartoon techniques that may confuse and induce minors to consume the products.

### Authorisation

The authorisation for the advertising of pharmaceutical products is granted by the Ministry of Health and shall be issued within 40 days of the application being filed. The Ministry of Health is able to request additional information or documents in order for the authorisation to be granted. The authorisation will implicitly be granted if a requirement or unfavourable response is not issued by the Ministry of Health after the above-mentioned term.

The authorisation for the advertising of pharmaceutical products is indefinitely granted. Therefore, those responsible are not allowed to introduce any modification to the authorised advertising that would vary the characteristics that served as the basis for the granting of the authorisation, except if such modification is ordered by another authority, which must be made known to the Ministry of Health prior to it being broadcast.

Authorisation will not be required for gift samples (understood as the copies of the products), which are used for the purpose of making them known through free distribution and which meet the requirements. The same specifications apply as for the public sale of the original products, the only difference being the gif samples contain a smaller unit number.

### Sanctions

The Ministry of Health and COFEPRIS are empowered to take the following actions against the advertising of pharmaceutical products:

- the suspension or withdrawal of the publication of an advertising activity in breach of the law within 24 hours;
- request that the accountable person modify the advertising that is presumably in breach of the legal regulations;
- conduct inspection visits to verify the enforcement of the legal regulations; and
- impose a fine from 2,000 up to 16,000 units of measurement (UMA = USD4.80).

Even when these actions and penalties are only established in the RGHL, the legal framework foresees others, such as the seizure of advertis-

ing and products, additional fines, the suspension or closure of an establishment and even civil and criminal liability that can be executed by the Ministry of Health and COFEPPRIS and other authorities, eg, the Mexican Institute of Industrial Property, PROFECO and the Attorney General's Office (FGR).

## Conclusion

While pharmaceutical products are a mechanism for preserving individual health and wellbeing, we must not forget that they are also merchandise. That is why any advertising for a health product, including drugs, plays a fundamental role in public information.

The main objective of pharmaceutical advertising is to attract the greatest number of product consumers and, because it is directed to potential users who may be diminished by their sick condition, they are successful in accomplishing that goal without respecting the difference between medical publicity and that which is used for other products. Therefore, the government's role has to be primarily focused on the individual protection that is independent of the final user without ignoring the commercial purposes of the products.

The legal framework allows enterprises in the sector to publicise their products in all media channels, however the particularity of this subject must be considered as well as the multiple regulations that cover these activities, including government legislation and the codes and other code-bodies of chambers and associations.

COFEPRIS has played an important role in the monitoring and compliance of advertising regulations. This organism has executed agreements with pharmaceutical companies to implement the autoregulation principle in this sector and the execution of actions, enforcement, verification and imposition of fines to those companies that look to misinform consumers about the pharmaceutical product and its benefits and indications.

**Basham, Ringe y Correa** is a full-service law firm with strong presence in Latin America. Established in 1912, it has more than 100 years of experience assisting clients in doing business throughout Mexico and abroad. The firm has four main offices in Mexico – in Mexico City, Monterrey, Queretaro and Leon – with a team of 120 lawyers. Basham's clients include prominent international corporations, many of them on the Fortune 500 List, medium-sized companies, financial institutions and individuals. The firm's lawyers actively participate in worldwide associations, as well as in international transactions. The firm provides regulatory counsel and litigation relating to manufacturing, import, distribution, marketing, labelling, and advertising of pharmaceutical products, medical devices, pesticides, fertilisers, cosmetics and household cleaning products, veterinary products, seeds, foods, beverages, alcohol and tobacco. Basham's multidisciplinary practice team consists of lawyers, chemists and biologists, who ensure a comprehensive vision of client cases from a technical, regulatory and legal point of view through meaningful collaboration.

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# POLAND

## Law and Practice

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## CONTENTS

# 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

## 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

In Poland, the key provisions regulating the advertising of medicinal products are contained in the Pharmaceutical Law (*Ustawa Prawo farmaceutyczne*; the PhL). In this complex law regulating various topics and implementing the Polish Law Directive 2001/83, chapter 4 is entirely dedicated to the promotion and advertising of medicinal products (MPs). The provisions of the PhL are completed with the Regulation of the Minister of Health on the advertising of MPs (*Rozporządzenie Ministra Zdrowia w sprawie reklamy produktów leczniczych*; "the Regulation").

Also of note is the Law on radio and television (*ustawa o radiofonii i telewizji*), which includes a number of provisions regarding advertising medicines on radio and television and the sponsoring of broadcasts by pharmaceutical companies. The Law on preventing unfair competition (*Ustawa o zwalczaniu nieuczciwej konkurencji*) regulates promotion and advertising in general and may be used by competitors. Another legal law, which in turn may be used by consumers, is the Law on preventing unfair market practices (*Ustawa o przeciwdziałaniu nieuczciwym praktykom rynkowym*).

Promotion and advertising of medicines is also subject to ethical codes adopted by pharmaceutical industry associations. The key codes are:

- the Employers' Union of Innovative Pharmaceutical Companies (INFARMA) Code of Good Practice (*Kodeks Dobrych Praktyk*) ("the INFARMA Code"); and
- the Medicines for Europe Code of Ethics (*Kodeks etyki Medicines for Europe*), adopted by the Polish Association of Pharmaceutical Industry Employers (PZPPF).

INFARMA represents 25 pharmaceutical firms conducting research and development activities and manufacturing innovative medicines.

The INFARMA Code has been drafted in accordance with the guidelines of the European Federation of Pharmaceutical Industries and Associations (EFPIA). Its updated version is applicable as of 1 January 2021.

The PZPPF is an association of 18 domestic manufacturers of pharmaceuticals (generics and biosimilars) and a member of the European association Medicines for Europe. Domestic members of Medicines for Europe, such as the PZPPF, are required to apply the Code from 1 January 2022.

Given the international nature of this publication, we will focus our discussion on the provisions of the INFARMA Code.

## 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The provisions of the INFARMA Code are binding on pharmaceutical companies that are members of INFARMA. Other firms that are incorporated in Poland may voluntarily commit to observe its provisions by submitting an accession declaration to INFARMA. Other entities may apply the provisions of the Code as a set of standards, the voluntary respect of which ensures compliance of their operations with high ethical standards. The Code is not addressed to healthcare professionals (HCPs) or healthcare organisations (HCOs), but only to pharmaceutical companies. In terms of advertising, it covers the advertising of prescription-only medicines.

The provisions of the Code cannot be considered binding law. However, they set certain standards in the industry and are often helpful in the practical implementation of legal regulations with a higher level of requirements. Breaching a provision of the Code alone, which at the same time cannot be considered a violation of the regulatory requirements, may result in disciplinary proceedings conducted according to the Code.

The Medicines for Europe Code of Conduct is binding on members and affiliate members of PZPPF. Pharmaceutical companies that are not members of Medicines of Europe or its associated members (such as PZPPF) may voluntarily observe the provisions of the Code.

## 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

### 2.1 Definition of Advertising

The PhL provides a broad definition of the advertising of MPs. It is any activity consisting of providing information or encouraging the use of an MP with the aim of increasing the number of prescriptions or the supply, sale or consumption of MPs. Therefore, there are two key elements that must be combined: (i) kind of activity (provision of information or inducement), and (ii) the purpose of the activity (increasing sales, consumption, etc).

The PhL lists a number of examples of pharmaceutical advertising, such as the advertising of medicines addressed to the general public or to HCPs and persons engaged in supplying MPs (mainly pharmacists); visits by medical representatives to HCPs and persons engaged in the supply of MPs; the distribution of samples of MPs; and the sponsorship of promotional meetings for HCPs and persons engaged in supplying MPs.

In the numerous decisions of the chief pharmaceutical inspector (*Główny Inspektor Farmaceutyczny;* the GIF), the regulatory authority responsible for supervising pharmaceutical advertising in Poland, advertising is considered very broadly. In particular, information only, including even an indirect inducement to use a specific product, is considered advertising. The attractive manner of presenting information, use of specific colours, fonts, the size, channel of dissemination of information will be all taken into account while assessing whether a communication has a promotional nature or not. The purpose of communication will be a qualifying factor permitting in establishing whether it is advertising or not. The purpose does not need to be explicit – the intentions of the author of the communication are assessed, or even, in some cases, its effects.

Only communications allowing a specific MP to be identified (even if indirectly) are considered advertising. Therefore, those using a proprietary name of a medicine and marked with a logo or trademark of a specific MP are likely to be regarded as advertising, especially if addressed to the general public.

### 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

An analysis of the GIF's decisions and administrative courts' judgments on advertising of medicines suggests a very broad interpretation of the term advertising for MPs. A piece of information will be considered advertising if it is distributed with the aim (both direct or indirect, or even secondary or incidental) of inducing someone to use an identifiable MP mentioned in the communication. The GIF very often assumes that such aim has been proven, despite the pharmaceutical company claiming otherwise.

Disease awareness campaigns and patient-facing information are also assessed using the same

criteria, ie, whether an intention (both direct and indirect) to increase sales, consumption or use of a medicine can be established (usually, very little is sufficient). Use of the product's trademark or name will almost always result in assuming the promotional nature of a communication. The target audience may be helpful in assessing the nature of the communication, however, the intentions of the pharmaceutical company, also measured based on the communication's effects (such as an increase in sales or number of prescriptions), will be a key factor. It is irrelevant whether the target audience is the general public or HCPs only.

The PhL includes a list of determined categories of communication that will not be considered advertising. These include:

- information placed on external packaging (labelling) and patient leaflets, provided they conform with the marketing authorisation;
- correspondence accompanied by informative materials that are not of a promotional nature and are needed to answer specific questions about a particular MP;
- informative non-public announcements relating to packaging changes, adverse reaction warnings, provided they do not include references to MP properties; and
- statements relating to human and animal health or diseases, provided there is no reference, even indirect, to MPs.

Please note, however, that the content of a patient leaflet placed in an external communication, depending on circumstances (especially if accompanied by the product's trademark), may qualify as advertising.

With respect to disease awareness campaigns (eg, educational campaigns on vaccinations) and patient support programmes, whether or not they would be considered advertising would largely depend on their wording. As far as they include general statements on a disease and information on its treatment, adverse reactions, etc, and do not include specific product claims (usually mentioned using its proprietary name) information on its indications or an inducement to use the product, these may fall under one of the exceptions listed above. Disease awareness campaigns and other patient-facing information should not include any promotional content and should be free from any inducement to use an identifiable product.

The GIF adopted a broad interpretation of whether a product referred to in an educational campaign may be identifiable (and so materials distributed as part of a campaign may be, but do not need to be, regarded as advertising). For example, a product may be identifiable if:

- its name is included in the website address of the campaign; and
- there is a link to the product's website or the products list of the campaign's sponsor on the campaign website.

According to the GIF, use of the word "educational" does not exclude a qualification of a material distributed as part of a campaign as pharmaceutical advertising, since its content and purpose will be the key factors rather than its name or form.

Interestingly, the Polish administrative courts do not always share the very strict assessments made by the GIF. In one of its judgments, an administrative court held that despite use of the proprietary name in the materials distributed as part of an educational campaign, the materials should not be considered advertising, since the promotional intent of the sponsor of the campaign has not been proved. Even if an effect of the campaign was an increase in the sales of an MP mentioned in this campaign, this alone can-

not be regarded as proof of the sponsor's promotional intentions (in that case, however, the sponsor was not a pharmaceutical company, but a non-profit organisation).

Educational materials, not including any promotional content, addressed to patients who have already obtained a prescription for the medicine referred to in such material, which are to be handed to individual patients by the treating physician and which are fully compliant with the patient leaflets are likely to be accepted.

### 2.3 Restrictions on Press Releases regarding Medicines

Press releases will be assessed similarly to other types of communications issued by a pharmaceutical company regarding a specific MP. Therefore, they are governed by the general rules applicable to pharmaceutical advertising, such as, the prohibition to promote prescription-only medicines to the general public. To avoid allegations of incompliance, press releases concerning prescription-only medicines should only be distributed to authorised recipients such as HCPs and persons engaged in the supply of MPs (eg, pharmacists). It should be noted that in line with the decisions issued by the GIF, almost all announcements addressed to the general public and allowing the identification of an MP are considered medicinal advertising and, therefore, should meet all applicable requirements.

However, an administrative court, after having assessed a complaint brought by a pharmaceutical company on a decision issued by the GIF, held that this company was allowed to address a press release to the general public regarding a prescription-only medicine, issued in reply to discrediting information on its medicine published by another company. It should be noted that the press release was a one-off publication and appeared in the same media as the discrediting material. The court held that the intention of the company was to protect the reputation of the medicine and not to promote it.

Certain press releases will also be accepted as allowed in company advertising. A pharmaceutical company will be allowed to make objective updates and information available to the general public about, eg, outcomes of R&D activities, clinical trials, products in the pipeline and other significant developments, provided that no inducement to use an MP is included in the communications.

### 2.4 Comparative Advertising for Medicines

There is only one regulatory restriction concerning comparative advertising of medicines and it is related to the advertising addressed to the general public only. It states that advertising of an MP should not contain any claim suggesting that the effects of taking it are better than, or equivalent to, those of another treatment or MP.

It should be noted that not only comparing effects of treatment with specific products mentioned by their names will be prohibited, but also comparing such effects with regard to medicines that are identifiable (not necessarily mentioned by their name). Claims on the same effects of compared medicines, or of a given pharmaceutical form of a medicine versus another form, are also prohibited. In contrast, such comparative advertising will not be restricted if addressed to HCPs or pharmacists.

Irrespective of the above pharmaceutical sector-specific provision, the Law on preventing unfair competition allows for comparative advertising (defined as advertising allowing to identify, either directly or indirectly, competitor's goods or services), but only under specific conditions. In particular:

- it cannot be misleading, compares a number of goods or services meeting the same needs or designed for the same purpose in a way which is accurate and may be proven, based on objective criteria;
- it compares, in an objective way, relevant, verifiable and typical features of compared goods, including their prices;
- it does not discredit goods, activities, trademarks, names, distinguishing features or circumstances concerning a competitor; and
- it does not take unfair advantage of the trademarks or name or other distinguishing features of a competitor.

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

The PhL strictly prohibits promoting MPs which are unauthorised in Poland (that did not obtain marketing authorisations), and those which are authorised without the need to obtain a marketing authorisation (such as medicines brought from abroad to treat individual patients, authorised with special consents issued by the Minister of Health). The advertising of an MP cannot include information that does not comply with the Summary of the Product Characteristics (SmPC). This means a prohibition to promote medicines in their off-label indications, but also to include any other information that may be regarded as not complying with the SmPC. Claims in off-label indications, in which an MP is reimbursed in Poland, may also be considered illicit advertising due to incompliance with the SmPC, even if reimbursement (granted under a decision issued by the Minister of Health) is an official confirmation that the product may be used in such off-label indication.

A pharmaceutical company which obtained a reimbursement decision for its product in an off-label indication or with a dosage scheme or other terms of treatment deviating from the SmPC may notify HCPs only through simple and objective notifications on reimbursement (eg, with a link to the reimbursement list or content of the drug programme), without any other promotional content or inducement to use the medicine in such newly reimbursed indication (or dosage form or other).

### 3.2 Provision of Information during a Scientific Conference

Conveying scientific information on unauthorised medicines or unauthorised indications is accepted only as part of an exchange of information at scientific events. Sometimes, pharmaceutical companies sponsor presentations given by HCPs who address such topics. However, in such cases the HCPs are required to provide the full information on the current registration status of the medicine (making it clear that discussed claims relate to unauthorised indications or dosage forms, for example).

### 3.3 Provision of Information to Healthcare Professionals

Sending information on unauthorised medicines or unauthorised indications to HCPs should always be assessed taking into account the risk of it being considered advertising. In this respect, our comments included in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications** and **5.2 Reference to Data Not Included in the Summary of Product Characteristics** fully apply, irrespective of whether the provision of information to HCPs is done proactively or reactively.

It should be noted that the sending of information reactively in response to a specific query may fall under one of the exceptions referred to in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**, provided that no promotional content or material accompanies it.

### 3.4 Provision of Information to Healthcare Institutions

The provision of information on unauthorised medicines or unauthorised indications is allowed only if explicitly addressed to HCPs. The provision of such information to administrative personnel of HCOs would not be allowed, regardless of the purpose.

### 3.5 Publication of Compassionate Use Programmes

Compassionate use programmes are not yet officially allowed in Poland, however, a new draft law on clinical trials, published in January 2022, finally implement them into the Polish law. Their application will require a prior consent to be granted by the regulatory agency in Poland.

Even after this law becomes binding, publishing information on the availability of treatment with a medicine which is not yet authorised, or one including an unauthorised indication (like in a compassionate use programme) will be illicit, since it would be considered forbidden advertising of a non-authorised medicine. Therefore, only HCPs treating patients will be allowed to inform patients about the availability of these programmes and the specific medicines used in them.

However, if information on a compassionate use programme does not include any references to identifiable medicines, it may not be regarded as advertising at all (see our comments in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**). Similar comments would apply to early access programmes.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

The PhL provides for a number of general requirements with respect to the advertising of MPs, relating to both advertising to the general public and to HCPs, and the detailed restrictions that apply to advertising to the general public.

#### General Requirements Applicable to Pharmaceutical Advertising

Advertising of an MP cannot be misleading, should present the product objectively and encourage its rational use. It cannot be addressed to children or include any element addressed to them. It is also prohibited to conduct pharmaceutical advertising consisting of offering or promising any benefits (see also **8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals** and **8.2 Legislative or Self-Regulatory Provisions**). Misleading advertising is one of the most common allegations and has been the grounds of numerous GIF decisions.

The PhL allows for a so-called reminder, which is an additional advertising material that may follow a full advertisement. While the ordinary advertising should meet all the applicable requirements, a reminder should include only the name of the medicine, its international nonproprietary name and the trademark. It cannot include any claims, references to indications, pharmaceutical form, dosages or other promotional elements.

### Prohibition of Adverting of Certain Categories of Medicines to the General Public

The prohibition to advertise to the general public covers:

- prescription-only medicines (except for determined listed vaccinations);
- MPs reimbursed from public funds; and
- medicines containing psychotropic or narcotic substances.

OTC MPs may be advertised to the general public, subject to a number of restrictions.

### Prohibited References and Prohibited Reliance on Authorities' (Experts') Opinions

Advertising of a medicine to the general public cannot consist of:

1. the presentation of the product by publicly known persons, scientists, persons with medical or pharmaceutical education or persons suggesting that they have such an education; or

2. references to recommendations of persons listed in point 1.

## 4.2 Information Contained in Pharmaceutical Advertising to the General Public

Advertising to the general public should contain, at least:

- the name of the MP;
- the name of the active substance, and in case of a product containing more than three active substances, the term: "composite product";
- the qualitative and quantitative composition of active substances(safe for a combination product);
- the pharmaceutical form;
- therapeutic indications;
- contra-indications; and
- the name of the marketing authorisation holder (MAH).

The above data must comply with the SmPC, or with the documentation approved in the process of granting the market approval (if there is no SmPC).

The prices may be mentioned, but it is not required and the market practice in this respect varies.

All advertising to the general public should be accompanied by special warnings that have a determined wording, varying slightly depending on the form of the dissemination (audio, audio-visual or visual). The essential wording in English would be: "Read the package leaflet or consult a doctor or pharmacist before use, as any medicine used improperly may threaten your life or health".

The Regulation provides for very detailed requirements concerning where these warnings should be placed, their minimum size and duration, etc (these depend on the form of dissemination).

The advertising of an MP addressed to the general public cannot contain any material that suggests that:

- a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;
- the health of even a healthy subject can be improved by taking the medicine;
- the health of the subject could be affected by not taking the medicine (this prohibition does not apply to vaccination campaigns);
- the MP is a foodstuff, cosmetic or other consumer product; and
- the safety or efficacy of the MP is due to the fact that it is natural.

The advertising of an MP addressed to the general public cannot contain any material that ensures that:

- it implies that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or MP;
- it could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- it refers, in improper, alarming or misleading terms, to claims of recovery; and
- it uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of an MP on the human body or its parts.

### 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Apart from the prohibition to advertise prescription-only medicines to the general public, the binding laws in Poland do not include any provisions on interactions between the pharmaceutical industry and the patients.

Instead, such interactions are the subject of provisions contained in the industry's ethical codes. The INFARMA Code broadly addresses the interactions of pharmaceutical companies with patients or patient organisations (PO). The aim of respective provisions is to ensure the independence (in terms of their judgement and activities) of the PO and transparency of such interactions (with regard to the objectives and scope of any collaboration). Such interactions should be based on mutual respect, with the views and decisions of each partner having equal value. They cannot concern promotion of MPs. Any financial and non-financial support provided must always be clearly acknowledged. The provision of financial or non-financial support to a PO, whether directly or indirectly (eg, through an advertising agency), requires the execution of a contract.

Signatories of the INFARMA Code must not influence the text of PO material they sponsor in a manner favourable to their own commercial interests. This does not preclude them from correcting substantive errors in PO material. In addition, at the request of POs, they may co-operate in the preparation of material, always subject to the reservation that such co-operation must be fair and balanced from a scientific perspective.

With respect to events organised or sponsored by or on behalf of a signatory of the INFARMA Code for POs (among others), see our comments in **9.3 Sponsorship of Scientific Meetings**.

The INFARMA Code also prohibits the donation of gifts to PO personnel and provides for terms and conditions of grants and donations to POs and sponsorship of PO personnel attending events (see our comments in **9.1 Gifts to Healthcare Professionals** and **9.3 Sponsorship of Scientific Meetings** that would also apply to interactions with POs).

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

All advertising, including that addressed to HCPs, must meet the requirements referred to in **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public**.

The following persons would be entitled to review the advertising dedicated to HCPs:

- physicians;
- certain nurses (meeting determined criteria) who are authorised to issue prescriptions for determined medicines; and
- persons dealing with the supply of MPs (in particular, pharmacists).

One of the key requirements for advertising to HCPs is that it includes information compliant with the SmPC. It should also contain information on the supply classification of the product and, in the case of reimbursed products, its official retail price and the maximum amount of patient co-payment (in practice, for pharmacies' medicine, this amount will be the fixed amount rather than the maximum). Therefore, the retail price must only be provided in the case of reimbursed medicines.

Any documentation delivered to HCPs (relating to the advertising of an MP) should include data which are accurate, up-to-date, verifiable and complete enough to permit its addressee to assess the therapeutical features of the medicine on by themselves. It should also state the date on which the documentation was drawn up or last revised. Quotations, tables and drawings originating from scientific journals or other scientific works should be faithfully reproduced and include respective references.

Any promotional material addressed to HCPs should include:

- the name of the MP and its common name;
- the qualitative and quantitative composition of the excipients and the additives which are essential for the proper administration of the product;
- the pharmaceutical form;
- therapeutic indications or indications for use;
- dosages and method of administration;
- contra-indications;
- special warnings and precautions for use;
- adverse reactions;
- the MAH; and
- the marketing authorisation number and the name of the authority granting it.

It should also be noted that ethical codes (such as the INFARMA Code) include numerous and detailed provisions concerning advertising to HCPs.

### 5.2 Reference to Data Not Included in the Summary of Product Characteristics

It is quite common in the advertising of MPs to include references to various clinical studies. However, this is only allowed under a condition that data, information or sources to be referred to must be verifiable for the recipient of the advertising. Referenced clinical studies do not have to be included in the SmPC. In addition, any claims, including any outcomes or findings from referenced clinical trials, must be compliant with the SmPC. This does not mean that any information or claims must reproduce the wording of the SmPC, however, such information or claims should confirm or provide more details in relation to the information included in the SmPC; they must be consistent with and not distort the information.

If the outcomes of the clinical trials are not consistent with the content of the SmPC of the advertised medicines, these cannot be quoted, referred to or even discussed in the advertising. Any claims relying on such outcomes may only be the subject of scientific papers or materials addressed to HCPs. It is prohibited to include these in any advertising materials and the Polish supervisory authority is very strict in this respect.

Considering that all data referenced in the advertising addressed to HCPs should be verifiable and accessible, enabling the recipient to form its own judgement, references to data on file, even if consistent with the SmPC, are prohibited.

### 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

The advertising of combination products relying on claims not included in the SmPC may be considered as advertising incompliant with SmPC and, therefore, prohibited. In this respect, our comments in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications** and **5.2 Reference to Data Not Included in the Summary of Product Characteristics** fully apply.

With respect to a companion diagnostics, it should be clear to the recipient that such a diagnostics is not a part of the MP (the advertising should not be misleading), in particular, it should not mislead the user or the patient with regard to the device's intended purpose, safety and performance. In the case of any claims on a diagnostic device, the applicable requirements for advertising medical devices should be met.

### 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Pharmaceutical companies may provide reprints of journal articles to HCPs. However, should these include any claims on an MP that could be considered as inconsistent with its SmPC, these reprints cannot be accompanied by any promotional materials or content concerning this product.

In contrast, should the claims on an MP included in such reprints confirm or clarify in more detail the data and information included in the SmPC, without distorting, challenging or arguing with these, these reprints may be accompanied by promotional materials concerning the medicinal product. Such accompanying materials should meet all requirements applicable to advertising to HCPs.

### 5.5 Medical Science Liaisons

In principle, Medical Science Liaisons (MSLs) (usually called Medical Directors, or Directors for Medical Affairs) would be allowed to engage in the exchange of scientific information with HCPs. However, information provided by MSLs, should it include any claims on unauthorised medicines or unauthorised medications, cannot contain any promotional content and should be clearly separated from the promotional and supply activities of the company, otherwise there is a risk that it might be considered prohibited off-label advertising.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

In Poland, there is no obligation to seek prior authorisation from a regulator or to make any notification of an anticipated advertising. Ensuring that advertising is compliant with the applicable requirements is the exclusive responsibility of the MAH.

### 6.2 Compliance with Rules on Medicinal Advertising

The PhL provides for a general obligation on the MAH to ensure that any advertising conducted by it is compliant with the regulatory requirements. More specific provisions require that the MAH employs, for positions of medical and marketing representatives, only persons possessing sufficient scientific knowledge enabling them to convey complete and accurate information about promoted MPs (no other specific qualifications are required). The MAH is also required to employ someone to be responsible for providing information about the MPs placed

on the market by the MAH (again, no specific qualifications are required).

The MAH should store mock-ups (samples) of any advertising for two years following the end of the calendar year in which the advertising was distributed (published) and ensure that any decisions of the supervisory authority are enforced without delay. Only the MAH, or an entity acting on behalf of the MAH, may engage in pharmaceutical advertising.

Polish law does not require MAHs to adopt any specific policies or procedures regarding the approval of advertising. In practice, most firms voluntarily (or following the requirements of applicable ethical codes) adopt standard operating procedures regulating the internal process of approving all promotional materials and dedicate personnel to review the promotional materials. Detailed responsibilities of such personnel and the approval process are usually clearly defined in SOPs or other internal policies.

The INFARMA Code includes numerous provisions regarding the obligations of MAHs aimed at ensuring compliance with the regulatory requirements, such as:

- the MAH's personnel should be trained and familiar with the requirements in accordance with the Code and with the applicable laws; and
- the MAH must establish a service (eg, medical department) with appropriate scientific knowledge to be in charge of information about its MPs and the approval of promotional materials.

The MAHs are free to decide how best to establish such service(s) (ie, whether there is one service in charge of both duties or separate services with clearly delineated duties), taking into account their own resources and internal organisation. The scientific service must include a medical doctor or, where appropriate, a pharmacist.

In line with the INFARMA Code, all promotional materials must be approved for compliance with the Code, applicable laws and the SmPC; such approval should also ensure fair and truthful presentation of the facts about the MP. The Code also includes detailed requirements regarding medical representatives employed by the MAHs.

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

There are no specific regulatory requirements applicable to the adverting of medicines on the internet. Therefore, it should meet respective regulatory requirements applicable to advertising.

In the case of advertising addressed to HCPs (eg, advertising of prescription-only medicines), MAHs are required to ensure that their online advertisement is accessible only to HCPs, however, the regulatory provisions do not include any specifics with regard to how to restrict the access.

In many cases the GIF held that restrictions adopted by MAHs were insufficient. In particular, if access to restricted content required that the viewer simply answered "yes" to a question of whether they are an authorised HCP, this was considered incompliant. Promotion on the internet, access to which was only restricted that way, was considered to be addressed to the general public, so if it concerned a prescription-only medicine, this resulted in the issuing of a

decision ordering such advertising be immediately removed.

In practice, a very commonly used restriction is an obligation not only to confirm that the recipient is a HCP, but also to enter the physician's licence number. However, since this number is available in a public register, the risk that this will also be held insufficient cannot be fully excluded.

### 7.2 Advertising of Medicines on Social Media

Polish law does not include any provisions on medicinal advertising on social media. Therefore, all the regulatory requirements, without any exception, would also apply to such advertising.

Considering the general prohibition to promote prescription-only MPs to the general public, any promotional content concerning such MPs on social media will, in principle, be illicit (unless sufficient measures permitting restricted access to specific groups would be implemented).

Advertising of OTC medicines on social media should meet applicable requirements, including those on the required content of the advertising medicine and warnings (see **4.2 Information Contained in Pharmaceutical Advertising to the General Public**). Pharmaceutical companies, if using social media, do not place any content relating to specific products, but rather general information on diseases or health, or their other activities (eg, corporate social responsibility). A company's corporate advertising on social media is permitted.

The INFARMA Code includes detailed guidelines for its signatories, split into various digital channels (social media, blogs, podcasts, webinars, direct channels and discussion forums). One guideline is to ensure transparency; in particular, if the pharmaceutical company has sponsored a communication or materials concerning MPs this should be clearly indicated. The signatory of the Code should be able to differentiate what content is appropriate for the different digital channels and the respective audiences. All laws and regulations in this regard must be complied with in the same way as for other media.

Information made available via a digital channel should be regularly updated and should clearly display, for each page or item, as applicable, the date on which such information was most recently updated. Whenever a company provides information on a digital channel, its involvement should be clearly stated. With respect to social media described in the Code as websites or applications on which people can interact on social networks (eg, Facebook, Twitter, Snapchat, LinkedIn, YouTube, Instagram), they are considered to be aimed at the public and therefore used to reach or interact with the public. A social media platform can also be a closed channel for a targeted audience where the verification of the audience is required before providing access.

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

Pharmaceutical companies are required to ensure the restriction of access on websites containing advertising or other information intended for HCPs. There is no specific provisions in Polish law besides the general requirement that advertising intended for HCPs should be disclosed in a manner not permitting access of persons to whom it is not addressed.

In practice, usually only the content of patient leaflets and SmPCs is disclosed on pharmaceutical companies' websites, without any promotional content. Such promotional content appears in magazines and medical journals in their online editions, at virtual stands or online events, etc. It is a market standard to require the

user, before granting access to online content potentially containing medicinal advertising or information concerning prescription-only medicines, to confirm their professional status as a HCP and to enter the physician's licence number. Please also see **7.1 Regulation of Advertising of Medicinal Products on the Internet** for more detailed comments in this respect.

### 7.4 Provision of Disease Awareness Information to Patients Online

Pharmaceutical companies are allowed to provide disease awareness information or materials to patients online, however, the risk of regarding the material as pharmaceutical advertising should always be considered. In particular, it is important to observe the strict prohibition to address all advertising of prescription-only medicines, products containing psychotropic and narcotic substances, and reimbursed products to the general public.

With regard to OTC products, if material or information made available online allows a specific MP to be identified and it may be considered promotional, all requirements applicable to pharmaceutical advertising should be observed. In this respect, our comments included in **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public** and **4.2 Information Contained in Pharmaceutical Advertising to the General Public** will fully apply.

### 7.5 Online Scientific Meetings

Online scientific meetings are not regulated in Poland. Therefore, general rules on the exchange of scientific information (see **3.2 Provision of Information during a Scientific Conference**), promotion of MPs to HCPs (see **5. Advertising to Healthcare Professionals**), and sponsorship of scientific events attended by HCPs, would apply here (see **9.3 Sponsorship of Scientific Meetings**). Such online meetings are commonly held, especially during the COVID-19 pandemic, and pharmaceutical companies do sponsor such events or HCPs' attendance.

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

General anti-bribery rules included in Polish law apply to interactions between pharmaceutical companies and HCPs or HCOs. First, both the provision and promise of a bribe (a material or a personal benefit) to a public official (an individual) in relation to their official position is a crime penalised in the Polish Criminal Code. In certain cases, HCPs may be considered as public officials. The Criminal Code does not include specific provisions on bribing HCPs.

The Reimbursement Act is more specific in this respect, but only penalises activities related to reimbursed products (including MPs). It includes several provisions severely penalising the provision, promise or acceptance of a material or personal benefit in relation to the procurement or supply of reimbursed MPs or in exchange for activities affecting the supply of such MPs, or in exchange for issuing prescriptions.

### 8.2 Legislative or Self-Regulatory Provisions

In line with the PhL, the advertising of MPs cannot consist of offering or promising to offer any benefits, either directly or indirectly, in exchange for an acquisition of an MP, or delivery of proofs confirming such acquisition. Another provision states that it is strictly forbidden to address any advertising consisting of providing, offering or promising any material benefits, gifts (for

exceptions, see our comments in **9.1 Gifts to Healthcare Professionals**) or any other bonuses, awards, trips, or to organise or sponsor any kind of promotional meetings where hospitality exceeds the main purpose of such meeting to any persons authorised to issue prescriptions (HCPs) or persons dealing with the supply of MPs. It is also illicit to accept such benefits.

These provisions are aimed at prohibiting the provision of any inducement to prescribe or supply MPs, and mainly concern inducements to individual recipients; however, the GIF's practice suggests that this prohibition may also be applied to inducements addressed to entities supplying MPs.

The INFARMA Code also contains a number of provisions on prohibited inducements in relation to HCPs. The following activities cannot constitute an inducement to recommend or prescribe, purchase, supply, sell or administer specific MPs:

- grants and donations;
- contracts executed with HCPs, HCOs and POs or POs' representatives, and related to the retaining of the given person to provide the relevant service; and
- provision of informational or educational materials and items of medical utility (defined in the Code).

Medical representatives are prohibited from using any inducement to gain a meeting.

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

Permitted hospitality at sales meetings and scientific events is described in **9.3 Sponsorship of Scientific Meetings**. The PhL allows for the provision of items whose material value (including VAT) does not exceed PLN100 (approximately EUR22), provided that they are relevant to the practice of medicine or pharmacy and are branded with the company's or product's logo. In line with the GIF's decisions, the market value of such items is taken into account and not the actual paid price.

The INFARMA Code explicitly prohibits the provision of gifts. Gifts of a personal nature (eg, tickets for sports events or entertainment, presents marking milestones or occasions) may not be given, whether directly or indirectly, to HCPs, HCO personnel or PO personnel. Giving or offering of cash, cash equivalents, and of personal benefits is also prohibited.

The Code's provisions are more stringent with regard to small items of insignificant value than the regulatory requirements. A gift of a promotional character is an object given for promotional purposes (other than the educational materials specified in the Code). In the context of the promotion of MPs, presenting or offering such objects to HCPs, HCO staff, or PO representatives, is entirely prohibited. The Code makes the only exception for ballpoint pens, notebooks, tote bags or folders of insignificant value inscribed with company logos. Only these items may be provided for note-taking in the course of meetings organised exclusively by a signatory of the Code.

### 9.2 Limitations on Providing Samples to Healthcare Professionals

The PhL allows for the distribution of free samples of MPs to HCPs, under certain conditions. First, it is forbidden to distribute samples of medicines containing psychotropic or drug substances. Both prescription-only and OTC medicines may be sampled. Secondly, free samples can only be provided in response to a

written request from a physician, addressed to a medical or sales representative. Those supplying samples are required to keep records of dispensed samples.

The number of samples of each medicinal product is limited to five packs per year. Each sample should be no bigger than the smallest presentation authorised in Poland (which means that only the smallest authorised presentation can be a free sample). This requirement poses practical problems, especially if the smallest authorised presentation is not available on the market for any reason (Directive 2001/83/EC requires that each sample is identical to the smallest presentation on the market, which allows the use of the smallest available presentations, even if a smaller one has also been authorised). It is illicit to sample blister foils alone or divide presentations for sampling purposes. The sample should be marked "free sample – not for sale" and shall be accompanied by a copy of the SmPC.

The provisions of the INFARMA Code include a number of more stringent provisions regulating sampling.

### 9.3 Sponsorship of Scientific Meetings

Pharmaceutical companies are allowed to sponsor scientific meetings or congresses. Similarly, sponsoring HCPs' attendance at these events is permitted. Certain conditions apply to both categories of sponsorship, however, while the legal provisions are very general, the ethical guidelines and market practices are much stricter.

The PhL's provisions are rather limited and general. They state only that it is not permitted to organise or sponsor promotional meetings providing hospitality exceeding the purpose of such meetings. They do not mention scientific events, however, in practice these principles also apply to such events.

Excessive hospitality is, therefore, prohibited. The market practice and ethical codes allowed for the elaboration of detailed rules on how permitted hospitality should be understood. It is broadly admitted that such events should be held in locations and venues which are not extravagant, luxurious, or tourist attractions. Pharmaceutical companies should only cover limited expenses connected with attending such events, ie, participation fees, accommodation, meals and travel expenses. They should not sponsor any additional extraordinary attractions or entertainment that may accompany such events, and they should not cover any costs of HCPs' family members or companions attending the event.

The INFARMA Code includes numerous provisions regarding sponsorship of events and permitted hospitality. In line with these, any events organised or sponsored by or on behalf of a signatory of the Code for HCPs, HCOs, and POs must be held in locations and venues conducive to the main purpose of the event, avoiding those that are generally seen as "renowned" for their entertainment facilities or as "extravagant". A signatory of the Code may not organise or sponsor an event to be held outside Poland unless organisation of the event abroad is justified by organisational or substantive considerations such as: most of the invitees are from outside Poland, or availability of resources or specialised expertise in the given location. Hospitality may not be excessive – the INFARMA auxiliary criteria concerning classification of hospitality at venues define the INFARMA procedures for events certification.

Hospitality offered to events' participants should be reduced to covering the cost of travel, meals, accommodation and registration fees associated with participation in the substantive part of the event. Signatories of the Code may not provide or offer to HCPs, HCO personnel or PO

representatives any meals (food and beverage) the value of which, per person and per meal, exceeds the limits defined in accordance with the host country principle (PLN200, VAT included – for meals offered in Poland).

Hospitality may only be extended to entitled event participants, and not to persons accompanying them or to their family members. Travel, meals, accommodation and registration fees entailed in the participation in the event of an accompanying person may only be covered on the same terms in exceptional cases associated with health reasons (eg, disability or injury).

### 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Considering the restrictions regarding permitted hospitality at scientific events attended by HCPs, pharmaceutical companies are not allowed to organise or sponsor cultural, sports or other non-scientific events in relation to scientific conferences, even if the regulatory provisions do not include details of permitted hospitality.

According to the INFARMA Code, hospitality may not include sponsoring or organisation of entertainment (eg, sports events or recreation).

### 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

The regulatory provisions do not address grants or donations to HCPs or HCOs. In principle, grants and donations to an individual HCP will not be permitted, considering that they will be considered an inducement to prescribe MPs, or a prohibited benefit. In contrast, grants and donations to HCOs will be considered permitted, but certain conditions should be met to avoid an allegation of illicit inducements.

Once again the provisions of the INFARMA Code include useful guidelines that may be used by a pharmaceutical company wishing to provide a grant or donation. First, the Code clearly prohibits any grant or donation from being provided to individuals. Grants and donations are only allowed if they:

- are made for a clearly defined purpose of supporting healthcare, research or education;
- are documented and kept on record by the donor or grantor; and
- do not constitute an inducement to recommend or prescribe, purchase, supply, sell or administer specific MPs.

### 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

The PhL's provisions regulating pharmaceutical advertising do not include any restrictions on the right to give rebates or discounts to HCPs or HCOs, especially in the context of the prohibition to provide any benefits or inducement (there is no provision reflecting the one included in Directive 2001/83 stating that existing measures or trade practices relating to prices, margins and discounts should not be affected by provisions prohibiting benefits or inducements). However, it is widely accepted that giving rebates or discounts is an ordinary market practice and does not constitute the provision of prohibited benefits or inducement. Notwithstanding, HCPs may only purchase a limited portfolio of MPs (the supply in MPs is channelled through pharmaceutical wholesalers and pharmacies).

In principle, the Reimbursement Act prohibits the provision of rebates and discounts with regard to products that are the subject of reimbursement, regardless of the beneficiary of such rebates or discounts.

## 9.7 Payment for Services Provided by Healthcare Professionals

Pharmaceutical companies are allowed to pay for the services provided by HCPs, in exchange for the services provided.

The regulatory provisions do not include any details of possible co-operation between pharmaceutical companies and HCPs. However, it should be taken into account that any payment made to a HCP should be in exchange for a real service that this company requires, and it should reflect the market value of this service, otherwise there is a risk to hold that such payment has been made as an inducement to increase sales of an MP, or other similar activities, which could be qualified not only as a violation of the PhL, but even, in certain circumstances, as a bribe (see **8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals** and **8.2 Legislative or Self-Regulatory Provisions**).

The INFARMA Code includes detailed rules of contracting services from HCPs, HCOs, POs and/or PO representatives. Contracting would only be allowed if the services are provided for the purpose of supporting healthcare, research or education, and do not constitute an inducement to recommend or prescribe, purchase, supply, sell or administer specific MPs. The services may concern the provision of services of experts, advisors or consultants, services such as speaking at, or chairing meetings, involvement in medical or scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research.

The INFARMA Code includes a number of requirements concerning the content of the contracts for such services (they should be concluded in writing, before the services are delivered, their scope and respective fee should be provided).

The criteria for selecting service providers should be directly related to the identified need; persons responsible for selecting them should have the expertise necessary to evaluate whether a particular individual meets those criteria. Documentation concerning the contract should be kept. The retention of the given person to provide the relevant service may not be an inducement to recommend or prescribe, purchase, supply, sell or administer a particular medicinal product; remuneration should reflect the fair market value of the services. Pretended contracts executed for the sole purpose of contriving a basis for payments to HCPs or PO representatives are prohibited.

## 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

Signing a contract with a HCP does not require employer consent or regulatory authority approval.

Instead, the INFARMA Code requires that its signatories, whenever they employ HCPs on a part-time basis who are still practising their profession, obligate such persons to declare their employment arrangements with the signatory of the Code whenever they write or speak in public about a matter that is the object of their retention, or any other matter relating to that signatory of the Code and to notify this fact to their employers and to other entities if such person represents the interests of their employer.

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

There are no regulatory provisions requiring pharmaceutical companies to disclose details of transfers of value to HCPs or HCOs.

This obligation has been provided for in the INFARMA Code. Its signatories must provide, on an individual basis for each clearly identifiable recipient (including HCP and HCO), information about the amounts attributable to determined transfers of value to the recipient for each calendar year. The transfer of value, with regard to HCPs, covers the contribution to costs related to events (such as sponsorship of HCPs' attendance to such events), and fees paid to HCPs for their services and consultancy.

In cases where information about a transfer of value cannot be disclosed individually, they should be disclosed on a collective basis. Information on transfers of value related to research and development is provided on an aggregate basis.

### 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

Transparency requirements are only applicable to signatories of the INFARMA Code, they are not regulatory requirements. The Code only applies to signatory pharmaceutical companies whose registered seats are in Poland. Whether a medicinal product has already been placed on the Polish market is not relevant in this regard.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

The responsibility for enforcing the rules on advertising in Poland is on the GIF as the head of pharmaceutical inspection. Its detailed and numerous tasks, including supervision of pharmaceutical advertising, are determined in the PhL.

The GIF issues administrative decisions in which it may order:

- that the dissemination of pharmaceutical advertising held incompliant with the regulatory requirements is stopped;
- that the decision ordering that incompliant advertising is stopped is disseminated where the incompliant advertising was initially disseminated;
- a rectification of the advertising which included errors; and
- all infringements in the advertising are removed.

All the above decisions are immediately effective. In practice, the vast majority of all decisions issued by the GIF order that the dissemination of a pharmaceutical advertising held incompliant with regulatory requirements is immediately stopped.

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Proceedings before the GIF in cases regarding medicinal advertising are initiated by the authority ex officio. In fact, they are often initiated following a letter from a competitor. The letter is not a formal complaint, and the competitor will not

be a party to such proceedings or be notified of the final decision.

It is common to bring lawsuits against competitors under the Law on preventing unfair competition. First, an interim injunction is sought and, finally, a court judgment ordering the adverting infringing a competitor's interests be stopped. The possibility of obtaining an interim injunction is attractive since it can be obtained relatively quickly.

### 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The PhL provides for a number of criminal sanctions for breaching determined provisions on advertising.

A fine (up to PLN1, 080 000) may be imposed on those who:

- as part of pharmaceutical advertising, deliver or promise to deliver material benefits to HCPs (persons authorised to issue prescriptions) or persons dealing with the supply of MPs;
- promote MPs while not being an entity authorised to conduct pharmaceutical advertising;
- promote medicines which are not authorised on the territory of Poland;
- conduct advertising incompliant with the SmPC;
- do not keep the mock-ups (samples) of the advertising materials which were distributed or published;
- do not keep records of the distributed samples;
- do not comply with the decision of the supervisory authority concerning incompliant advertising;
- distribute samples to unauthorised persons; and
- address advertising of prescription-only medicines, reimbursed medicines, or medicines containing psychotropic or narcotic substances to the general public.

### 11.4 Relationship between Regulatory Authorities and Courts

Proceedings before the GIF are administrative proceedings. A party that is not happy with the decision it received may apply for a reassessment of the matter (no appeal is available).

A company that does not agree with a decision issued by the GIF (the initial one or the one issued following the application for the matter to be reassessed) may file a complaint to an administrative court. Administrative courts do not issue material judgments (they cannot modify an administrative decision), they may just waive the decision which was held breaching a material or a procedural provision, so the matter is reassessed by the authority who issued it. A party has a right to appeal against a judgment of the administrative court to the Supreme Administrative Court.

### 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

The vast majority of decisions issued by the GIF concern the following allegations:

- misleading advertising;
- advertising to the general public of prescription-only medicines (following insufficient restriction of access to such advertising); or
- provision of information incompliant with the SmPC or exceeding or modifying the SmPC.

There has been no change in this trend.

For many years, decisions of the GIF were published and disclosed on the authority's website. Since April 2020, decisions concerning pharmaceutical advertising are no longer published.

**Monika Duszyńska Kancelaria Adwokacka** is a boutique law firm focusing on the life sciences sector, particularly pharmaceutical and medical devices manufacturers. It assists both innovative and generic companies. The firm has three senior lawyers who provide daily support in commercial and regulatory areas, covering all kind of contracts a pharmaceutical company may require in intellectual property (licences and registration dossiers, drafting R&D agreements, etc) and regulatory issues, pharmaceutical advertising, clinical trials and reimbursement. The firm also advises on distribution and manufacturing of medicines. Examples of recent work include (i) advising on a change of the distribution model for a company offering orphans, (ii) revising clinical trial templates used in Poland by a global innovative company, and (iii) advising on commercial and regulatory terms of procuring a substitute medicine to be used in hospital settings, including obtaining of import approval, negotiations with the supplier, and terms of delivery on the Polish market.

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Law for Lifesciences

# PORTUGAL

## Law and Practice

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# 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

## 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

### Legislative Acts

- Decree Law 176/2006 of 30 August, as amended, which establishes the legal regime applicable to medicines;
- Decree Law 5/2017 of 6 January, which establishes the advertising principles and a prohibition on National Health Service (NHS) hospitals from requesting and receiving benefits from the pharmaceutical industry and from other health technologies companies, except if such receipt is previously authorised by the competent authority (local regulatory authority) and does not harm their impartiality and neutrality; and
- Decree Law 330/90 of 23 October, as amended, which approves the Advertising Code.

### Administrative Regulations

In addition, some specific matters are regulated by administrative regulations issued by the regulatory authority, the National Authority of Medicines and Health Products, IP (*Autoridade Nacional do Medicamento e Produtos de Saúde* or "Infarmed"), and the Secretary of State of Health.

### Self-Regulatory Codes

The Portuguese Pharmaceutical Industry Association (*Associação Portuguesa da Indústria Farmacêutica* or "APIFARMA") approved the following self-regulatory codes:

- the Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interaction with Healthcare Professionals and Institutions, Organisations or Associations Comprising Healthcare Professionals;
- the Code of Conduct for the Relations between the Pharmaceutical Industry and Patient Associations, Patients' Advocates, Patients' Experts, Patients and Caregivers; and
- the Code of Good Practice for Communication.

## 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The self-regulatory codes identified in **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines** are ethical standards and they are binding for the APIFARMA's associated members.

# 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

## 2.1 Definition of Advertising

Advertising of medicines is defined in Article 150 (1) of Decree Law 176/2006 of 30 August, as amended, as any form of information, prospection or incentive which is within the scope of, or has the effect of, promoting the prescription, dispensation, sale, acquisition or consumption of medicines in any of the following circumstances:

- before the public in general;
- before wholesale distributors and healthcare professionals (HCPs);
- through the visit of medical sales representatives to HCPs;
- through the provision of samples or commercial bonuses to wholesale distributors and HCPs;
- through the granting, offer or promise of pecuniary or in-kind benefits, except when their value is insignificant;
- through the sponsorship of promotional meetings attended by HCPs;

- through the sponsorship of congresses or meetings of a scientific nature attended/participated in by HCPs, namely, through the direct or indirect payment of the respective hosting costs; and
- through reference to the commercial name of a medicine.

### 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Portuguese laws and regulations do not make a clear distinction between advertising and information. Therefore, the definition of information, for this purpose, must be understood as included in the definition of advertising, once the disclosed information corresponds to the criteria established in Article 150 (1) of Decree Law 176/2006 of 30 August.

However, Article 151, No 1-d) of Decree Law 176/2006 of 30 August foresees that information relating to human health or human diseases, provided it does not refer to or mention, even indirectly, a medicine, is not subject to advertising regulations, which is deemed to mean that this information does not qualify as advertising. Therefore, disease awareness campaigns and other patient-facing information, as long as they comply with the quoted Article 151, No 1-d), do not qualify as advertising.

In addition, APIFARMA's Code of Ethics, specifically Article 4, No 3, foresees the exclusion from the prohibition of advertising medicines not yet authorised, or off-label information, the right of pharmaceutical companies to inform the scientific community about advances in the field of medicinal products and therapeutics, therefore permitting the disclosure of the results of scientific research they are carrying out for that purpose. Therefore, it deems that data on the advances of scientific research in the field of medicinal products and therapeutics should also be qualified as information, instead of advertising.

Case-by-case analysis is strongly recommended.

### 2.3 Restrictions on Press Releases regarding Medicines

Press releases are not specifically addressed by Portuguese law, regulations or self-regulatory codes. Therefore, press releases issued by pharmaceutical companies should comply with the general rules applicable to advertising activity, namely, concerning the respective content and the audience.

### 2.4 Comparative Advertising for Medicines

Comparative advertising of medicines can only be addressed to HCPs and is therefore prohibited from being disclosed to the general public. In accordance with APIFARMA's Code of Ethics, comparative advertising should be based on relevant and comparable aspects. It cannot be misleading or defamatory, and the comparison of medicines should be based on the medicines' characteristics and specifications, instructions for use, technical documentation or credible clinical data.

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

The advertising of unauthorised medicines or unauthorised indications (off-label advertising) is not permitted. However, as explained in **2.1 Definition of Advertising**, the dissemination of

information on advances in scientific research in the field of medicinal products and therapeutics is permitted, since the constraints mentioned are met. Such information may solely be disclosed to, and accessible by, the scientific community.

### 3.2 Provision of Information during a Scientific Conference

The information mentioned in **2.1 Definition of Advertising** may be disclosed to HCPs in any context, as they are, for this purpose, part of the scientific community.

### 3.3 Provision of Information to Healthcare Professionals

See **3.2 Provision of Information during a Scientific Conference**.

### 3.4 Provision of Information to Healthcare Institutions

Taking into consideration the prohibition on advertising unauthorised medicines or indications (see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**), providing such information to healthcare institutions for the purpose of preparing budgets, etc, is not permitted.

### 3.5 Publication of Compassionate Use Programmes

Taking into consideration the prohibition on advertising unauthorised medicines or indications and the limits mentioned in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, the publishing of such information is not permitted. Compassionate use is solely permitted in the scope of clinical trials.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

It is forbidden to advertise the following to the general public: prescription-only medicines; medicines containing substances defined as drugs or psychotropic substances (at international conventions for drugs and psychotropic substances); and medicines under reimbursement by the state.

Advertising of other medicines to the public must be unequivocally identified as such, expressly indicating the specific medicine.

Comparative advertising of medicines to the general public is prohibited.

Regarding what information is mandatory and what is prohibited – in advertising to the general public – see **4.2 Information Contained in Pharmaceutical Advertising to the General Public**.

### 4.2 Information Contained in Pharmaceutical Advertising to the General Public

Advertisements for medicines directed at the general public must contain, as a minimum, the following information:

- the name of the medicine, as well as its common name, if the medicine contains only one active substance, or the brand;
- essential information on the rational use of the medicine, including therapeutic indications and special precautions; and
- advice to the user to carefully read the information on the packaging and in the leaflet, and a warning about the need to consult a

physician or pharmacist in case of doubt or persistence of symptoms.

Advertising to the public in general cannot contain any element that:

- leads to the conclusion that a medical consultation or surgery is unnecessary, in particular, by offering a diagnosis or by suggesting treatment by mail;
- suggests that the effect of the medicine is guaranteed without adverse reactions or secondary effects, with superior or equivalent results in comparison to another treatment or medicine;
- suggests that the average health condition of a person may be harmed if the medicine is not used, except in the case of vaccination campaigns approved by the local regulatory authority;
- is exclusively or mainly targeted at children;
- refers to recommendations of scientists, HCPs or other individuals who could, because of their celebrity status, encourage the consumption of the medicinal products;
- treats the medicinal product as a food, cosmetic or body hygiene product or as any other product;
- suggests that the safety or efficacy of the medicine derives from it being a natural product;
- induces an incorrect self-diagnosis, by a description or detailed representation of a person's medical history;
- refers, in an abusive, daunting or misleading way, to statements or guarantees of recovery; and
- uses, in an abusive, daunting or misleading way, visual representations of human body changes caused by diseases or lesions, or by the effect of a medicine on a human body or parts of it.

### 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Pharmaceutical companies may, as a general principle, interact with patient organisations. However, such interactions must occur within the limits and constraints established by Decree Law 176/2006 of 30 August and APIFARMA's Code of Conduct, which establish several rules on such interactions.

The limits and constraints are generally established to prevent interactions with patient associations that qualify as a form of information, prospection or incentive which is within the scope of, or has the effect of, promoting the prescription, dispensation, sale, acquisition or consumption of medicines, in the terms ruled by Article 150 (1) of Decree Law 176/2006 of 30 August.

In this regard, it should be highlighted that APIFARMA's Code of Conduct prohibits the promotion of prescription-only medicines before a patient association, but foresees that such medicines may be promoted to HCPs who assist or co-operate with patient associations. In the same sense, the events promoted by the industry in which patient association representatives participate, cannot be of a promotional nature. Furthermore, the partnerships, services supply and financial support granted by the industry must be under a written contract. Companies in the industry cannot be the sole financing entity of any of the activities and events promoted by a patient association.

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Advertising to HCPs must include, in a legible way in the respective advertising material, the following:

- the name of the medicine;
- the essential information compatible with the summary of product characteristics ("SmPC");
- the classification of the medicine concerning the dispensation regime of the same, namely, if it is a prescribed medicine, when applicable;
- the respective reimbursement regime; and
- the date of the issuance of the advertising.

The information contained in the advertising material must be accurate, updated, verifiable and sufficiently complete to allow the recipient to correctly assess the therapeutic value of the medicine. The references and the illustrative material of medical publications or scientific works used in advertising support must be correctly reproduced and should mention the respective source.

### 5.2 Reference to Data Not Included in the Summary of Product Characteristics

Advertising material may refer to data or studies not mentioned in the summary of product characteristics, provided that the information complies with that mentioned in **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**, and no contradiction is found between the summary of product characteristics and the information provided on the data on file and on the clinical studies.

### 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

Since combined advertising would be qualified as off-label advertising, which is prohibited as explained in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, any reference to a combination of products or companion diagnostics not included in the summary of product characteristics is not admissible.

### 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

In Portuguese law and regulations there are no specific rules regarding the reprinting of journal articles. However, assuming that the reprints are of scientific journal articles, it is believed that such reprints may be provided if referring to human health and diseases or to scientific information relevant to the practice of medicine.

### 5.5 Medical Science Liaisons

The activity of medical science liaisons (MSLs) is not specifically regulated by Portuguese law or regulations. However, regarding MSLs, pharmaceutical companies should comply with the general rules applicable to the advertising activities already described.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

The market holders, or holders of medicine registers, are required to submit one sample of each advertising material relating to each medicine within ten days of respective distribution starting dates.

In the context of the sponsorship of congresses, symposiums or any actions or events of a scientific nature or aimed to directly or indirectly promote medicines, the sponsor company must communicate the sponsorship to Infarmed ten business days before the event.

Vaccination campaigns or promotional campaigns of generic medicines aimed at the general public are to be approved beforehand by Infarmed. If not, such campaigns could be classified as prohibited advertising activity.

### 6.2 Compliance with Rules on Medicinal Advertising

Pharmaceutical companies are not legally required to establish standard operating procedures (SOPs) governing advertising activities. However, they are required to have a scientific service responsible for the information related to medicines and for maintaining complete and detailed records of all the advertising of medicines with indications of the target audience, channel and date of first dissemination. The same scientific service must ensure that the advertising activities comply with all the obligations imposed by the law and codes, and that the medical sales representatives have appropriate professional qualifications.

The scientific service should keep advertising records for a five-year period and should make such records available for consultation or inspection by the local regulatory authority. The scientific service is also required to co-operate with this authority and other competent authorities, in all that is deemed necessary within the scope of the authorities' respective legal powers. The scientific service should preferably be supervised by a qualified person (a physician or a pharmacist, as established by Article 3 of APIFARMA's Code of Ethics).

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

Decree Law 176/2006 of 30 August expressly addresses advertising on the internet. However, this should obviously follow the general rules applicable to advertising activities described previously.

In addition, a local regulatory authority issued two informative circulars establishing specific rules on advertising through the internet and other digital channels. Accordingly, pharmaceutical companies may publish information, accessible by the general public, in the following ways:

- exclusively on the respective institutional website and not on social media or on any other disclosure support; and
- the information to be disclosed, jointly and simultaneously, must solely contain the faithful reproduction of the packaging of the medicine and the literal and full reproduction of the medicine leaflet and/or of the summary of the medicine characteristics, as authorised.

Advertising on websites and social media of medicines containing substances defined as drugs or psychotropic substances at international conventions for drugs and psychotropic substances, is forbidden.

### 7.2 Advertising of Medicines on Social Media

Pharmaceutical companies cannot use social media to advertise medicines (see **7.1 Regulation of Advertising of Medicinal Products on the Internet**).

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

Access restrictions are not specified by the law or regulations, however, companies should take all the necessary measures to ensure that the general public has no access to advertising intended for HCPs and must ensure that the information disclosed complies with the general rules applicable to advertising medicines (to HCPs and to the general public) described in the previous sections.

### 7.4 Provision of Disease Awareness Information to Patients Online

Since disease awareness information is beyond the scope of the advertising activities regulation (see **2.1 Definition of Advertising**), companies may provide disease awareness information to patients online, as long as the general rules are met (namely, the absence of any direct or indirect reference to a medicine).

### 7.5 Online Scientific Meetings

Online scientific meetings are not specifically regulated under Portuguese law or regulations, but are subject to the general rules applicable to conventional scientific meetings and to the rules applicable to advertising activities in general.

Concerning the international or national nature of online scientific meetings, despite the lack of legislation, they are held in accordance with local practice and local regulatory authority understanding. If the promoter/organiser of such meetings is a national entity, the same should comply with the applicable local law and regulations on advertising and with the principles of conventional scientific meetings.

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

The anti-bribery rules applicable to the interactions between pharmaceutical companies, HCPs and healthcare organisations are, in general, the rules defined in the Portuguese Criminal Code and specific legislation on anti-bribery, applicable to both sectors: public and private.

### 8.2 Legislative or Self-Regulatory Provisions

According to Portuguese law, as a general rule (Article 158 (1) of Decree Law 176/2006 of 30 August), the marketing authorisation holder, the company responsible for the information or promotion of a medicine, and the wholesale distributor are prohibited from – directly or indirectly – giving or promising HCPs or their patients, prizes, offers, bonuses or pecuniary or in-kind benefits, except if the same are cumulatively of insignificant economic value (under EUR60) and relevant for the medical or pharmaceutical practice (exceptions are defined in **9. Gifts, Hospitality, Congresses and Related Payments**). The same prohibition falls on HCPs, who are prevented from receiving such benefits under the quoted Article 158 (2).

In accordance with Article 9 of Decree Law 5/2017 of 6 January, public hospitals and services and bodies of the Ministry of Health cannot request, or directly or indirectly receive, any pecuniary or in-kind benefit from pharmaceutical companies or health technology companies that either impair or might impair their impartiality, except if previously granted with the specific authorisation of the local regulatory authority.

Any form of inducement to prescribe medicines is forbidden.

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

Following on from **8.2 Legislative or Self-Regulatory Provisions**, pharmaceutical companies may sponsor the participation of HCPs in scientific or educational events, promoted by pharmaceutical companies or by third parties. Such sponsorship is limited to the registration and hosting costs, ie, travel, lodging and meals.

According to APIFARMA's Code of Ethics, the support for such costs can only be granted to the HCP(s) who will attend the event concerned, and the costs are to be restricted to the main purpose of the event and cannot include entertainment events.

The length of stay covered cannot surpass a period of one day either side of the event and the event cannot be held in a location or tourist resort that is best known for its leisure, entertainment or sports facilities.

The cost of the meals within the national territory cannot exceed EUR60 per meal (EUR90 at international events, except when the legislation or the Code of Ethics in effect in a specific foreign country establishes a higher amount for the meal cost, which will therefore be applicable).

In addition to this, pharmaceutical companies may only give pecuniary or in-kind grants or donations to HCPs if the same are cumulatively of insignificant economic value (under EUR60) and relevant to the medical or pharmaceutical practice.

### 9.2 Limitations on Providing Samples to Healthcare Professionals

The provision of samples is, under Portuguese law, subject to the following conditions:

- the number of samples provided each year to each HCP cannot be more than four, if the lowest number is not defined by the marketing authorisation;
- the samples are to be requested by the HCP in a written document, duly dated and signed;
- the samples cannot be larger than the smallest presentation of the medicine under commercialisation;
- the samples' packaging must contain the references "Free Sample" and "Prohibited Sale" or other similar words;
- the samples must be accompanied by a summary of product characteristics;
- the samples can only be provided within the two years following the start of the commercialisation of the medicine; and
- the provision of samples of medicines containing drugs or psychotropic substances is prohibited.

### 9.3 Sponsorship of Scientific Meetings

Pharmaceutical companies may sponsor scientific meetings or congresses organised by third parties. However, even if the same take place abroad, the local regulatory authority must be informed of all granted sponsorships in the ten days before the event.

As established by Decree Law 1767/2006, the sponsorship of congresses, symposiums or any actions or events of a scientific nature that directly or indirectly promote medicines, must be mentioned in the promotional documentation of such events, in the documentation to be provided to the attendees and in the documents and reports that might be published after the events. APIFARMA's Code of Ethics contains similar provisions in this regard.

The Code of Ethics establishes that the sponsored events should take place in premises suitable for the main purpose of the event or action, and that places and/or developments that are known for their leisure, entertainment or sports facilities should not be chosen.

Pharmaceutical companies may also support HCPs' attendance of such events, limited to the registration and hosting costs, see **9.1 Gifts to Healthcare Professionals**.

### 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

The sponsorship or organisation of cultural, sports or other non-scientific events (even if in relation to scientific conferences) is expressly prohibited.

### 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Besides those referred to in **9.1 Gifts to Healthcare Professionals**, no other grants or donations are permitted.

Regarding healthcare institutions, it is possible to provide support, both monetary and non-monetary, with the aim of supporting healthcare services, research activities or continuing medical education.

However, in accordance with Article 9 of Decree Law 5/2007 of 6 January, NHS hospitals cannot request or receive, directly or indirectly, pecuniary or in-kind benefits from pharmaceutical companies, health technology companies or from related companies where such actions may harm the impartiality and neutrality of the hospitals. When impartiality and neutrality are not at risk, a previous authorisation to receive the benefit should be requested by the NHS hospital's management bodies to the local regulatory authority (Infarmed).

### 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Price discounts or rebates are expressly considered as beyond the scope of the rules on advertising of medicines. However, pharmaceutical companies can offer discounts to healthcare institutions in the context of an established commercial relationship, but not to HCPs, as the companies are prevented from executing sales to the same.

### 9.7 Payment for Services Provided by Healthcare Professionals

Pharmaceutical companies can enter into professional services agreements with HCPs in order to acquire expert services. HCPs can also be paid for acting as an active participant (speaker, moderator, etc) in a scientific or training event. However, the payments cannot constitute financial compensation for the prescription of medicines.

In accordance with APIFARMA's Code of Ethics, the payment of HCPs must be reasonable and must reflect the market value of the services to be provided by the same.

### 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

Sponsorships of congresses, symposiums or any actions or events of a scientific nature or aimed to, direct or indirectly, promote medicines must be communicated by the sponsor company to Infarmed ten business days before the event.

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

The entities under the scope of Decree Law 176/2006, among them pharmaceutical companies, must report to the local regulatory authority all benefits of EUR60 or above, granted to HCPs, healthcare organisations, patient organisations, workers of the National Health Service and bodies or services of the Ministry of Health or of the National Health Service.

Such report is to be filed via a specific transparency platform within 30 working days following the effectiveness of the benefit (payment of the benefit or granting of the benefit in the case of granting of goods or rights assessable in cash). The information to be reported is the following: name and data of the beneficiary, nature of the benefit and amount granted.

Beneficiaries will be asked via email by the local regulatory authority to validate – or not – receipt of the benefit. In the case of non-validation, the authority is to be informed of the reason. If the recipient remains silent, the benefit is considered tacitly accepted.

Benefits are defined in Article 159 of Decree Law 176/2006 of 30 August, as any advantage, value, good or right assessable in cash, regardless of whether in the form of a prize, sponsorship, subsidy, fee, subvention or any other form.

No additional regulations were issued by local regulatory authorities regarding COVID-19, in view of which, reports are still to be executed within the established legal deadline.

### 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

Transparency requirements apply to all market holders or to respective local representatives granting benefits to individuals and entities identified in **10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value**. Hence, if the market holder is a foreign entity, the report on the granting of benefits to Portuguese HCPs, or to the entities identified in the previous point, is still required.

Companies that do not have any products placed on the market and are not operating under a wholesale distribution licence or register, do not fall under the legal provisions on transparency. Such companies are prevented from promoting medicines within the Portuguese market and therefore cannot grant benefits to the individuals or entities mentioned in the previous point.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

The public competent authority for enforcing the rules on advertising is Infarmed.

The self-regulatory body is APIFARMA.

The competent court to decide on any issued related to the rules on advertising will depend on the specific claim under decision: as a general rule, the acts issued by Infarmed should be challenged before the administrative courts; however, if a sanction decision on the scope of an administrative offence procedure is at stake, it should be challenged before the Competition, Regulation and Supervision Court (according to the available jurisprudence). For civil liability law-

suits, if applicable, the civil courts are competent (see **11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements**).

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Proceedings may be initiated before any of the bodies identified in **11.1 Pharmaceutical Advertising: Enforcement Bodies**, depending on the specific violation and whether the respective requisites are met in each case:

- Infarmed is the authority responsible for punishing infringements of the law and public regulations;
- APIFARMA's Ethics Council may impose penalties on respective members for infringements of respective codes; and
- competitors may take action in relation to advertising infringements through civil liability lawsuits.

The same conduct may qualify as an infringement of the law and public regulations, and of APIFARMA's Code of Ethics provisions, in which case, proceedings may be conducted in parallel, making the respective decisions autonomous.

### 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The fines range from a minimum of EUR2,000 to a maximum of 15% of the business volume of the infringer or EUR180,000, whichever is the lower maximum.

General accompanying sanctions may also be imposed (depending on the seriousness of the infraction and the level of fault):

- loss in favour of the state of illicit objects, equipment and devices;
- interdiction, for a maximum period of two years, of activity of the infringing company;
- deprivation of the right to participate in public tenders for a maximum period of two years; and
- suspension of authorisations, licences and other titles attributing rights for a maximum period of two years.

Accompanying sanctions specific to the case of infringement of advertising legal provisions may also apply:

- the decision on the imposing of fines may also determine the publication on social media of the essential elements of the condemnation;
- advertising of the relevant medicine may be suspended for a maximum period of two years;
- a procedure to exclude the relevant medicine from the reimbursement regime by the state may also be initiated; and
- the infringer's medical sales representative may be prevented from visiting public hospitals and services, in the case of violation of the legal regime of such visits.

### 11.4 Relationship between Regulatory Authorities and Courts

There is no relationship between the procedures before, or measures taken by, the self-regulatory entity and the measures taken by the courts.

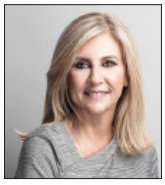
As the association of the pharmaceutical industry, APIFARMA has a supervisory function and enforces its codes upon its members. The procedures, decisions and penalties have a deontological nature and are completely independent of the ones taken by public entities (such as Infarmed or the courts).

### 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

Infarmed and APIFARMA do not disclose their decisions on advertising or on any other topic concerning infringements of the applicable law and established rules. Therefore, there are no identifiable trends in relation to pharmaceutical advertising.

**Morais Leitão, Galvão Teles, Soares da Silva & Associados** (Morais Leitão) is a leading, full-service law firm in Portugal, with a solid background of decades of experience. Its reputation among both peers and clients stems from the excellence of the legal services provided. The firm's work is characterised by unique technical expertise, combined with a distinctive approach and cutting-edge solutions that often challenge some of the more conventional practices. Morais Leitão's team consists of over 250 lawyers spread between its headquarters in Lisbon and additional offices in Porto and Funchal. Due to its network of associations and alliances with local firms and the creation of the Morais Leitão Legal Circle in 2010, the firm can also offer support through offices in Angola (ALC Advogados), Cabo Verde (VPQ Advogados) and Mozambique (MDR Advogados).

## AUTHORS



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# Trends and Developments

***Contributed by:***
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***VdA see p.240***

## Advertising, Digitalisation and Patient Empowerment: New Trends for the Pharmaceutical Industry in Portugal

### *Introduction*

The Portuguese legal regime applicable to the advertising of medicinal products has its origins in the European Union legal framework, resulting from the transposition of Directive 2001/83/EC (the "Directive").

While this should lead us, in light of the extremely narrow margin of freedom given to member states in the transposition of the Directive – particularly concerning promotion rules – to a common legal framework, unfortunately that is not the case for Portugal.

The Portuguese legislator, in certain aspects, clearly went beyond what the Directive provides. Among these, and with particular relevance, are the notion of advertising and the extension of the prohibition of pharmaceutical companies from being allowed to grant benefits to healthcare professionals (HCPs) and patients.

These specificities of the Portuguese legal framework significantly impact the activities of pharmaceutical companies in Portugal.

As an example, the disclosure of scientific information, a sensitive topic throughout the EU, faces additional hurdles in Portugal. Similarly, certain initiatives freely carried out by pharmaceutical companies throughout the EU, are often barred from being implemented in Portugal, as is the case with patient support programmes.

### *The notion of advertising*

Under Portuguese law, the underlying purpose of a given initiative developed by pharmaceutical companies is completely immaterial to its qualification as advertising. In other words, if an initiative promotes a given medicine, it will fall within the notion of advertising, even if this is not its intention. Should it be designed to promote a medicine, it is undoubtedly advertising. However, initiatives which are not intended as such, but which directly or indirectly have as an effect an increase in the purchase, dispensation or consumption of a medicinal product, will also fall under the notion of advertising.

The law provides for very few exceptions. In line with the Directive, only the labelling and information leaflet, correspondence required to reply to a specific query, information related to packaging, warnings or adverse reactions, price lists and information related to human health or diseases – provided that these do not make any indirect or direct reference to a medicine – are excluded from the scope of promotion rules.

As a result of this extremely broad definition of advertising, any disclosure of information directly or indirectly related to a product made by pharmaceutical companies both to the scientific/medical community and to patients, may result in the application of advertising rules.

### *The thin line between informing and advertising*

This extremely thin line between information and advertising poses several challenges to pharmaceutical companies and is a relevant setback in the dissemination of information and knowledge.

One of the clearest examples of said challenges is the disclosure of information regarding ongoing clinical research or regarding medicines which are still undergoing regulatory approval, even if at the early stages.

While the prohibition of off-label advertising is a common standard within the EU, in Portugal, the possibility of pharmaceutical companies informing the scientific/medical community of research that is being carried out or of potential new therapies which could have a significant impact on the treatment of patients – even if made in an objective and balanced manner – is severely limited.

Given the broad definition of advertising, any communication of this nature can be considered off-label advertising and is therefore prohibited. Consequently, the debate regarding new medicines and ongoing clinical research is very often made behind closed doors and no incentive is given for a more public, comprehensive and transparent discussion on future available treatments within the scientific/medical community. Disclosure of scientific advances is therefore often severely compromised.

A further example of these challenges is related to disclosure of information by pharmaceutical companies to the general public.

Another standard within the EU is the prohibition of advertising of prescription drugs to the public. Disclosing purely objective and educational information on a given prescription drug, such as educational material with precautions and/or instructions for the administration of the medicine, if not within the scope of a Risk Management Plan, entails a very significant risk of being condemned by the Regulatory Agency. The latter is very conservative when it comes to the enforcement of promotion rules, particularly when patients are involved.

In a digital world such as the one we live in, where boundaries have to a great extent lost their meaning, and where information that is prohibited in Portugal is attainable by a simple click, one cannot but question such a state of affairs.

### *Risks and benefits of a more flexible approach – COVID-19*

COVID-19 undoubtedly shook this approach.

Everywhere in the media one could read/hear about the virus, the potential treatments that eventually proved not to be treatments after all, the vaccines, their mechanisms and their side effects. Topics which are usually only discussed within the scientific community were now discussed in public, by the general public, and by "experts" who often had limited knowledge of science. Opinions were formed, some to be rapidly dismissed, others to persist. The lack of trust in the scientific community also increased. Movements challenging scientific and medical evidence were widespread, and "science" finally found a place in the public debate.

The authorities have, to a certain extent, allowed and promoted the debate, both in the disclosure of information which is usually reserved for HCPs, and by allowing the media and pharmaceutical companies to publicly discuss available or experimental vaccines and/or medicines for the prevention and/or treatment of COVID-19, without initiating any action against the pharmaceutical companies. This was, however, an exception, which could easily be justified by a pandemic of unprecedented scope.

Nevertheless, certainly lessons can be learned. It is key to inform, it is key to raise awareness, yet it is also key to prevent and block misinformation. The public, patients, are a vulnerable target.

Finding the right balance is the real challenge – not for pharmaceutical companies, but for the

legislator and regulators. And it is all the more complex in the digitalised, empowered-patient scenario that presently exists.

### *Patient empowerment*

Traditionally, pharmaceutical companies essentially engaged with HCPs and healthcare organisations (HCOs), focusing all their communication strategy on reaching this audience.

The pharmaceutical industry has now evolved in a different direction. Pharmaceutical companies have been slowly, steadily and increasingly concentrating on patients and patient organisations. Focus is now on the patient journey and experience, and patients are now at the very heart of pharmaceutical activity (beyond the pill).

Meanwhile, patients are following the same path. Patients are now more eager to get involved with the scientific/medical community, demanding a seat at the table to discuss the availability of treatments, their efficacy and what type of healthcare they have access to. They no longer solely rely on their physician's advice and want to understand their alternatives, what is most suitable for them. Patients now want to make informed choices.

As a result, patients have also become advocates for certain treatments for diseases. They have now gained a very audible voice and their position is taken into account by the media, the regulator, and the medical community in general.

The legal framework, however, has remained static and has not followed such an evolution. Pharmaceutical companies have therefore been faced with yet another challenge: how to reach patients.

Advertising and even purely objective information, if branded, is not an option. Supporting patients through patient support programmes (as they are commonly known), which can bring significant benefits to patients and which often fill in deficiencies or inefficiencies in the healthcare system, bringing added value for all, is severely restricted in Portugal.

Patient organisations have therefore increasingly gained importance, with pharmaceutical companies seeing these as one effective way to reach out to patients. The result: a strong increase in collaboration between patient organisations and the pharmaceutical industry in the last few years, be it through the sponsorship of events, the provision of services by patient organisations, or by joint collaboration devoted to disease-awareness campaigns.

Suddenly, we are no longer dealing only with patient organisations, and new "players" have joined the mix in the form of patient advocates, patient experts, patients and caregivers.

Once more, however, the legislator and the regulator have remained static, ignoring this new reality – for them, patient advocates, patient experts, patients and caregivers continue to be no more than the public in general.

In the absence of a legal framework, the pharmaceutical industry has resorted to self-regulation and has approved yet another code of ethics specifically addressing the relationship between pharmaceutical companies, patient organisations, patient advocates, patient experts, patients and caregivers.

### *Digitalisation*

Before the COVID-19 pandemic, pharmaceutical companies had already started to invest in their online communication strategy, but the pandemic has certainly accelerated such investment.

Pharmaceutical companies are aiming both at HCPs, with congresses and webinars in virtual

settings, and also at the general public, by setting up social media accounts, recording podcasts and organising online awareness campaigns. Influencers have also played their part, engaging with pharmaceutical companies to promote over-the-counter medicines or to assist in disease-awareness campaigns.

The digital world provides challenges of its own, however.

Patients who are actively seeking more medical and scientific information can now find this in the digital arena, with free and immediate access to cross-border information and advertising on medicines which may or may not be available in Portugal. However, this is without the mediation of an HCP. Without the scrutiny of the medical and scientific community, patients are left to evaluate on their own the accuracy of the information they have access to.

Pharmaceutical companies want and seek to participate in this digital world and believe that this online presence will be both beneficial for their own communication strategy and also for patients, who will have access to more reliable sources of information.

However, the challenge is how to adjust the traditional rules to this new reality. The legal regime applicable to pharmaceutical advertising was made for a different world.

In Portugal, in contrast to what has happened in other countries, the regulator has not issued any guidance on how to handle or tackle this digital world and it interprets and applies the rules in exactly the same manner as in the past.

With a lack of specific guidance from the regulator, pharmaceutical companies have again resorted to self-regulation, and the Pharmaceutical Industry Association issued guidelines on the use of digital channels in June 2021. This set of guidelines aims to align the legal and ethical regime with the digital reality.

***Contributed by:*** *Francisca Paulouro and Ana Isabel Lopes,* ***VdA***

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# SPAIN

## Law and Practice

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## CONTENTS

# 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

## 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

Advertising of medicinal products in Spain is regulated by a combination of laws, guidelines of the regulatory authorities and codes of conduct adopted on a voluntary basis by the pharmaceutical industry.

### General Rules

General rules on advertising are comprised in General Law 34/1988 on Advertising and Law 3/1991 on Unfair Competition. The provisions related to the advertising of medicinal products contained in EU Directives have been implemented in Spain through Royal Decree 1416/1994. The Ministry of Health issued an Instruction in 1995 (Circular 6/1995, amended by Circular 7/99) regarding the interpretation of such Royal Decree.

In addition, Spanish autonomous regions (Spain is divided into 17 autonomous regions) are competent for the implementation of rules on advertising of medicinal products; in this regard, some autonomous regions have adopted guidelines reflecting the position of the regional authorities on the advertising of medicinal products (the most remarkable guidelines are the ones issued in the regions of Madrid and Catalunya). Furthermore, Ministry of Health has issued a Guide on the advertising of over-the-counter medicinal products (last updated version published in 2019). Royal Legislative Decree 1/2015, approving the consolidated text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices is also noteworthy as it sets forth the sanctions for breach of the rules on advertising of medicinal products.

### Codes of Conduct

Spanish trade associations of different sectors of the pharmaceutical industry have adopted codes of conduct regulating interactions with healthcare professionals (HCPs), healthcare organisations (HCOs), and patient organisations (POs). Farmaindustria, the Spanish innovative medicinal products industry association, has issued a Code of Practice for the Pharmaceutical Industry (Code of Farmaindustria) regulating the advertising of prescription-only medicinal products as well as interactions between pharmaceutical companies and HCPs, HCOs and POs.

The Code of Farmaindustria has been recently updated by a 2021 version, introducing some new aspects regarding areas such as social media and the digital environment, relationships between companies and HCPs, POs, and the media. Conversely, AESEG, the Spanish generic medicinal products industry association, and ANEFP, the Spanish over-the-counter medicinal products industry association, among others, have also published their own codes of conduct on the promotion of medicinal products.

## 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Self-regulatory codes of conduct apply and have binding effects on companies that are members of the trade association that issued them and on companies that have voluntarily adhered to a code. Companies subject to a self-regulatory code are also responsible for their affiliates and third parties acting on their behalf complying with the code when they perform promotional activities in Spain and/or they interact in any way with HCPs, HCOs and/or POs in Spain.

## 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

### 2.1 Definition of Advertising

According to Royal Decree 1416/1994, advertising of medicinal products includes any form of informative offer, commercial research or inducement designed to promote the prescription, dispensation, sale or consumption of medicinal products.

In particular, advertising of medicinal products includes:

- advertising directed to the general public;
- advertising directed to persons qualified to prescribe or dispense medicinal products;
- visits by medical sales representatives or informative agents of the companies to persons qualified to prescribe or dispense medicinal products;
- supply of samples of medicinal products;
- sponsorship of promotional meetings where persons qualified to prescribe or dispense medicinal products attend;
- sponsorship of scientific meetings attended by persons qualified to prescribe or dispense medicinal products, and, in particular, payment of their travel and accommodation expenses in connection therewith; and
- any inducement to prescribe or dispense medicinal products by granting, offering or promising any benefit, in money or in kind, except when its actual value is minimal.

### 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Royal Decree 1416/1994 states that the following informative activities will not be considered as advertising of medicinal products and, therefore, that they are not subject to the rules that apply to such advertising:

- the labelling and the leaflet of the medicinal product;
- correspondence, together with any document of a non-promotional nature (for example, scientific articles) needed to respond a specific question about a particular medicinal product, provided that such correspondence/documents are true, not misleading and refer only to the question asked;
- information and documents specifically related to changes in packaging, adverse reaction warnings in the framework of pharmacovigilance, sales catalogues and price lists, provided that no other information on the medicinal product is included; and
- information regarding human health or diseases, provided there is no reference, even indirectly (for example, by mentioning its active substance), to the medicinal product.

In addition, the Code of Farmaindustria states that the following informative activities will not be considered as advertising of medicinal products:

- the SmPC;
- information provided by physicians to the patients on certain medicinal products that, due to the complexity of dosage, route of administration, etc, require providing additional information, and only if such information is intended to improve adherence to treatment;
- corporate advertising, meaning advertising which relates to the company, provided there are no references, not even indirect ones, to specific medicinal products;
- texts written and produced by journalists in their professional work, provided that there is no contractual relationship between the firm responsible for editing or the author of the information and the owner of the medicinal product and/or its trade mark;

- reprints, literal translations of scientific articles and abstracts published in recognised scientific sources or in congresses, provided that they do not include any additional element such as: the name of the medicinal product of the company regardless of the way in which it is included (link, additional paper, etc), highlights, and trademarks or promotional claims; and
- information on new lines of research mentioning the active ingredient and its properties provided to HCPs or patients, provided that its distribution is a condition mentioned in the authorisation of commercialisation, or that its distribution has been approved by the health competent authorities.

Finally, the description of research initiatives in corporate brochures or other informative documents accessible to the public is also commonly accepted as information by the Spanish authorities, as long as such description is objective and reasonable according to the usages of the sector and non-promotional in tone.

## 2.3 Restrictions on Press Releases regarding Medicines

Press releases are a controversial issue in Spain and should be analysed on a case-by-case basis. According to the Code of Farmaindustria, and the rulings of the Jury of Advertising, a specialised body within an association for self-regulation in advertising called Autocontrol (the Jury of Advertising is responsible for hearing cases relating to the breach of provisions of self-regulatory codes, such as the Code of Farmaindustria), if the information on a medicinal product refers to a newsworthy event such as relevant step in the research and/or authorisation process of such medicinal product, which is relevant for the financial performance of the company, is clearly directed to potential investors, shareholders and/or future employees, and has a non-promotional tone, then it may be considered as corporate information, and, therefore, may be published in non-scientific journals directed to the general public as it is not considered as promotion, but information.

### Determining whether a Press Release Is Advertising

However, if there is a contractual relationship between the company and the media where a press release is published, the press release will be deemed to be an advertising material and must therefore be subject to the rules regarding this activity. Besides considering whether or not there is a contractual relationship with the media, there are other factors to bear in mind in order to determine whether or not the press release has a promotional nature. These include the following:

- if the press release is aimed at promoting the consumption of a product;
- if the statements contained in the article are made by experts hired by the company;
- if the tone is laudatory; and
- in case of various publications, if their content is very similar suggesting that the media did not add further journalistic content, then the chances of it being considered promotional increase substantially (Ruling of Jury of Advertising of Autocontrol in Gilead v VIIV. 2DR-JULUCA®-DOVATO®, dated 25 June 2020).

### Guide for Interacting with the Media

The Code of Farmaindustria includes, as Annex III, a Guide with a list of recommendations for companies when interacting with the media. When certain conditions are met as explained in this Guide, press releases may be considered as having an informative nature (not promotional). For instance, it is recommended that the trademark of the medicinal product, or its active ingredient, is only prudently and propor-

tionately mentioned: twice maximum and not in the headings.

### 2.4 Comparative Advertising for Medicines

Under the Law 3/1991 and the Code of Farmaindustria, comparative advertising directed to HCPs is allowed provided that the products or characteristics compared are comparable, essential and relevant, the comparison is objective, scientifically proven and verifiable from sources immediately accessible to the competitor and the general tone of the advertisement is balanced and fair.

The competitor's brand name or trade mark can be used as part of the comparison, provided that such use is proportionate and is not made with the objective of taking an unlawful advantage of the reputation of the competitors' brand name or trade mark. However, there is no legal or deontological provision requiring an express reference to the trade mark of the medicinal product, as comparative advertising allows to refer to a competitor either explicitly or implicitly (Ruling of Jury of Advertising of Autocontrol in Sanofi-Aventis v Italfarmaco – Hepaxane®, dated 8 January 2020).

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

Advertising of medicinal products which have not obtained a marketing authorisation is not allowed. In some specific cases, regulatory authorities, as well as the provisions of the Code of Farmaindustria, accept the possibility of companies making information available to HCPs and HCOs prior to the approval of the medicinal products if it is merely scientific information, instead of an advertising activity. However, it is advisable to take a rather restrictive approach regarding these activities, as any materials containing promotional statements will undoubtedly be considered as advertising.

Additionally, according to Royal Decree 1015/2009, which regulates the use of medicinal products in special situations, marketing authorisation holders must not distribute any type of information which may directly or indirectly stimulate the use of the medicinal product in conditions different from those approved in its SmPC.

### 3.2 Provision of Information during a Scientific Conference

Objective and non-promotional scientific information on unauthorised medicinal products or unauthorised indications may be provided during congresses or meetings organised by a prestigious scientific society, provided certain conditions are respected.

Conversely, regulatory authorities and the provisions of the Code of Farmaindustria accept that promotional materials on medicinal products authorised in countries other than Spain may be distributed during international congresses or meetings held in Spain, provided that the congress or meeting is attended by numerous professionals from other countries, that the materials are written in the language of the country where the product is approved or in English, and that the materials include a clear warning indicating (at least in Spanish) that the medicinal product is not marketed or authorised in Spain.

Although the Code of Farmaindustria does not set a minimum font size for this warning, this is something that must be checked by comparing

the letters used in the waring to the ones used in the rest of the messages. Including this warning as a footnote using a small font size is not enough (Ruling of Jury of Advertising of Autocontrol in Glaxosmithkline v Astrazeneca CD-PS 1/20 Symbicort®, dated 7 July 2020).

### 3.3 Provision of Information to Healthcare Professionals

Any company may respond to specific requests for information from the HCPs, provided the conditions mentioned in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information** are met. Information must be provided reactively and not proactively. It's advisable to deal with these matters through the medical affairs department of the company rather than through its sales or marketing departments.

### 3.4 Provision of Information to Healthcare Institutions

There are no specific provisions in Spanish law or in the Code of Farmaindustria regarding the provision of information on unauthorised medicinal products or indications to HCOs. In practice, regulatory authorities and the provisions of the Code of Farmaindustria accept that objective information on a medicinal product may be provided to HCOs prior to its approval, in order to prepare their budget, provided it does not contain promotional statements.

### 3.5 Publication of Compassionate Use Programmes

Advertising compassionate use programmes is prohibited under Spanish law. Royal Decree 1416/1994 prohibits any advertisement of medicinal products which have not yet obtained a marketing authorisation. Also, even when referring to the access of a medicinal product authorised in another country (different than Spain), Royal Decree 1015/2009, regulating the use of medicinal products in special situations, expressly prohibits the holder of the marketing authorisation in the country of origin to make any advertising on the use of the medicinal product.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Advertising of prescription-only medicinal products and/or publicly financed medicinal products directed at the general public is prohibited under Royal Legislative Decree 1/2015, Royal Decree 1416/1994 and the Code of Farmaindustria.

On the contrary, non-prescription medicinal products which are not publicly financed may be advertised to the general public. Furthermore, advertising of medicinal products to the general public for any of following therapeutic indications is not allowed:

- tuberculosis;
- sexually transmitted diseases;
- other serious infectious diseases;
- cancer;
- chronic insomnia; and
- diabetes and other metabolic illnesses.

According to Royal Decree 1416/1994, any advertising material directed to the general public must clearly indicate that it is an advertisement and that the product advertised is a medicinal product.

### 4.2 Information Contained in Pharmaceutical Advertising to the General Public

Messages must contain at least the complete name of the product, the name and/or logo of the marketing authorisation holder, the therapeutic indication of the product, the composition of the

product, an invitation to read the instructions of the leaflet and to consult a pharmacist, and any additional recommendations that the Ministry of Health may determine in order to prevent risks and to promote the rational use of the product.

Additionally, Royal Decree 1416/1994 states that advertising to the general public must not contain any statement which:

- gives the impression that a medical consultation or surgical procedure is unnecessary;
- suggests that the effects of taking the medicinal product are guaranteed, does not have side effects or are better than, or equivalent to, those of another treatment or medicinal product. Adjectives such as "perfect", "maximum", "unique", "safe" or "total" are expressly prohibited;
- suggests that a person's health may be improved by taking the medicinal product or that it could be negatively affected by not taking the medicinal product;
- suggests that the use of a medicinal product may enhance sports abilities;
- is directed exclusively or mainly to children;
- suggests that the medicinal product is a foodstuff, cosmetic or other consumer product, or that the safety or efficacy of the medicinal product is due to the fact that it is a natural substance;
- could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or by the action of the medicinal product;
- includes promises of a cure, exaggerated testimonies on the virtues of the product, or recommendations of scientists, HCPs, or celebrities; or
- mentions that the product has obtained a marketing authorisation in any country or any other authorisation.

Reminder advertisements, the purpose of which is merely to remind the target audience about the name of the medicinal product, is acceptable only for products sufficiently known and which have been promoted for at least two years, can only include the name of the medicinal product. According to the Guide on advertising of OTC medicinal products published by the Ministry of Health, a blurred image of the packaging is also acceptable in such kind of advertising, provided that the only information clearly visible is the name of the product, the logo of the pharmaceutical company, and the identifying colours of the product.

### 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

There are no provisions in Spanish law regarding restrictions on interactions between patients or patient organisations and the pharmaceutical industry.

However, the Code of Farmaindustria states that any collaboration between companies and POs must be formalised in a written agreement, stating the purpose of the collaboration, the activities to be performed by each of the parties, the financial amount of the collaboration, a description of any relevant indirect support provided by the company and the sources and purposes of the support. Additionally, companies must have an internal process for the approval of these collaborations, and must not be the exclusive sponsor of a PO, nor try to influence in the content of the publications issued by a PO.

Meetings with patient support groups must be held at appropriate venues, avoiding those which are extravagant or renowned for their entertain-

ing facilities. It is not acceptable to organise events at venues outside Spain, unless most of the participants come from outside Spain, or a relevant resource or expertise is located abroad. However, organising an event outside Spain due to a relevant resource being located at the place where the event is going to be held, requires the prior approval by the Farmaindustria's Deontological Surveillance Unit.

Hospitality offered by the company must comply with the same requirements referred to in **9.1 Gifts to Healthcare Professionals**.

Hospitality must only be made available to accompanying persons if they attend as helpers of patients. Payment of such kind of expenses has to be made through the PO. Hospitality cannot include social, entertaining or cultural events, except for reasonable welcome cocktails, working meals and gala dinners.

### Scientific Meetings

In case of virtual meetings, all kinds of hospitality are forbidden.

It is forbidden to offer money to merely compensate the time spent by patients to attend the meeting.

It is also possible to pay PO for expert services (for example, participating in advisory boards, acting as speaker/moderator at scientific meetings and educational activities), provided that the following requirements are met:

- enter into a written agreement stating the nature of the services and the criteria to calculate the amount of payment;
- the purpose of the services must be cooperating with health assistance and/or research;
- the legitimate need for such services must be clearly identified;
- the criteria used to choose the expert must be related to the identified needs, and the person in charge of the selection must have the necessary expertise to evaluate the candidates. The experts hired must be approved by the internal supervisor of the company;
- the number of experts hired must not exceed the number reasonably necessary to achieve the identified objectives;
- the company must keep documental records of the services provided;
- the hiring of POs must not be linked to their participation in a promotional event for a medicinal product;
- the hiring of patients must be carried out through the POs;
- the payment to PO must not entail an inducement for the PO to recommend the medicinal products of the company;
- the remuneration paid must be at market prices and taking into account the hours of work and the responsibilities undertaken by the expert;
- payments in kind can only be accepted exceptionally upon prior authorisation from Farmaindustria's Deontological Surveillance Unit; and
- it is recommended that the agreement includes a clause by means of which the expert undertakes to declare that they provide services to the company every time he or she writes or publicly asserts any matter related with the company.

### The Code of Farmaindustria

According to the Code of Farmaindustria, offering money or any kind of gift or services for personal benefit to patients or the representatives of POs is forbidden.

Also, the Code of Farmaindustria contemplates that any material or publication directed to patients must comply with the following requirements:

- it must help patients to get a better understanding of their disease development and improve their life quality. Its content, therefore, must be related to patients' health, specific illnesses, hygienic-sanitary measures or healthy habits;
- it must expressly reflect whether they have been sponsored by a company;
- it must clearly and evidently prove that its main objective is to be a support tool for people affected by a certain disease; and
- it must be formative and informative and must visibly include messages that express that they are guidance and informative materials that cannot be interpreted as a substitute for the diagnosis or advice of an HCP.

Additionally, under the Code of Farmaindustria companies must publish a list of the POs that the company supports, and the POs with which it has entered into a services' agreement. Such publication must include a sufficiently detailed description of the support provided by the company to each PO and the amounts annually paid to each PO for its services.

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

According to Royal Decree 1416/1994, advertising directed to HCPs legally entitled to prescribe or dispense medicinal products must include:

- the name of the product;
- the name and address of the marketing authorisation holder;
- the qualitative and quantitative composition of the product;
- essential data according to the SmPC, including complete clinical data, indications for use, cautions and relevant contraindications;
- the different dosages and pharmaceutical forms in which the product is available;
- the prescription and dispensation regime applicable to the product;
- the retail price and the conditions under which the product is publicly financed; and
- the estimated cost of treatment if it is possible to determine it.

Messages must be precise, balanced, honest, objective, based on adequate scientific evaluation, and sufficiently complete as regards the therapeutic value of the product.

Reminder advertisements, acceptable for products sufficiently known which have been promoted for at least two years, can only include the name of the medicinal product and the International Common Denomination if the product contains only one active substance, as well as the logo of the product and the company. No other statements may be included, but the regulatory authorities and the bodies in charge of enforcing the rules of the Code of Farmaindustria do accept including pictures of the packaging.

### 5.2 Reference to Data Not Included in the Summary of Product Characteristics

Under Spanish rules, using data on file is not allowed for promotional purposes.

However, an advertisement may refer to studies not included in the SmPC of the product, provided that such studies do not contradict the information included in the SmPC (Ruling of Jury of Advertising of Autocontrol in Gilead v ViiV Healthcare New 2DR Era, dated 14 February 2019). In any case, studies must be adequately reflected in the promotional material, in a way that its addressee may by themselves verify the truthfulness and accuracy of the information.

### 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

Advertising the use of one medicinal product in combination with another one is legally permitted as long as the advertising materials/message are consistent with the SmPC of both products. It is not required for the SmPC to include a specific reference to studies regarding the combined use of medicinal products, as long as such use is compatible with the SmPC (Ruling of Jury of Advertising of Autocontrol in Gilead v ViiV Healthcare New 2DR Era, dated 14 February 2019).

Also, it is legally permitted to advertise medicinal products that include a medical device, provided that the advertisement is consistent with the SmPC of the medicinal product and with the intended purpose of the medicinal device.

### 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Companies can provide reprints of journal articles to HCPs. However, under the Code of Farmaindustria, reprints cannot contain printed, stamped or electronically-linked trade marks or trade names of medicinal products, advertising slogans, or other advertising materials related or not to the information.

### 5.5 Medical Science Liaisons

Medical science liasons (MSLs) must not proactively discuss scientific information on unauthorised medicines or indications with HCPs. MSLs can provide information to HCPs (provided the conditions mentioned in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information** are met) in order to respond to specific questions asked by the HCPs. Information must be provided reactively and not proactively.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

Advertising directed to HCPs qualified to prescribe or dispense medicinal products does not need to be approved in advance by a regulatory or industry authority. However, companies placing advertisements must send a copy of the advertisement to the health authority of the Spanish autonomous region where the company is located, assuming the responsibility for ensuring that only HCPs entitled to prescribe or dispense medicinal products have access to the relevant publication. The Ministry of Health may, in exceptional circumstances, make the advertising of a specific product subject to prior approval. Any decision of this nature must be duly justified and shall affect all products having the same composition.

Since July 2013, advertising directed to the general public does not need to be approved in advance by the authorities.

This is without prejudice of the fact that any advertising will be subject to control ex-post by the authorities and sanctions may be imposed if it does not comply with the provisions of the law. Additionally, according to Royal Decree 1416/1994, companies must send an annual index summarising all their advertising activities to the health authority of the Spanish autonomous region where the company is located.

### 6.2 Compliance with Rules on Medicinal Advertising

Royal Decree 1416/1994, as well as the Code of Farmaindustria, state that the marketing authorisation holder must have a scientific service in charge of the management of the information

related to the medicinal products marketed by the company.

The scientific service of the company must fulfil the following obligations:

- revise and control any promotional materials in order to ensure that they comply with the legal requirements;
- ensure that the medical sales representatives and any personnel involved in the promotion of medicinal products or in interaction with HCPs, HCOs and/or POs have been adequately trained;
- compile all information regarding the medicinal products marketed, including the maintenance of a registry of the requests for and supply of samples; and
- supply the regulatory authorities with the information and assistance they require, and ensure that the decisions of the regulatory authorities on these matters are immediately and fully complied with.

Under the Code of Farmaindustria, companies are obliged to have a written procedure to monitor compliance with the Code. Additionally, the Code recommends that the different departments (marketing-sales, medical, regulatory, legal, finance-administrative) get involved in the committees, policies or internal procedures that the company implements on these matters.

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

Broadly speaking, advertising activities on the internet are subject to identical requirements as those which are performed through traditional channels.

As regards advertising directed to HCPs through the internet, the company must use valid channels within a context that is basically scientific or professional. Those channels must be intended exclusively for HCPs authorised to prescribe or dispense medicinal products, and those HCPs should need to identify themselves in order to have access to the information. Pharmaceutical companies can also establish an HCPs status verification system in order for HCPs to have access to the information.

Companies will also be liable for the content of the websites accessed through links from the company's website.

Some provisions of Royal Decree 870/2013, which regulates the sale of OTC medicinal products through the internet, may also apply.

### 7.2 Advertising of Medicines on Social Media

The same rules applicable to other kinds of advertising apply to advertising through social media. In particular, advertising of prescription-only medicinal products on social media which the general public may access is not allowed.

The Code of Farmaindustria imposes on companies the obligation to adequately train its employees on how to behave in the digital environment. In this regard, pharmaceutical companies must have good-practice internal guides directed to their employees and any person acting on their behalf or under its control or by virtue of an agreement. The company must also train its employees to prevent them from posting inappropriate content on their personal social networks, such as comments on competitors' products or off-label promotion.

Also, under the Code of Farmaindustria, pharmaceutical companies must clearly and unequivocally inform HCPs and employees attending the

meetings organised or sponsored mainly by the company, about the prohibition of publishing promotional content related to the meetings on social media. It is advisable including safeguards in the agreements entered with speakers and attendees.

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

According to the Spanish law, the company must ensure that those parts of its website which contain promotional information about prescription-only medicinal products may only be accessed by HCPs entitled to prescribe or dispense such products. Conversely, it has been commonly accepted, following the guidance issued by the Pharmaceutical Committee, that the unmodified and unabridged publication on the website of information which has been authorised by relevant authorities (for example, the SmPC, the package leaflet, the public assessment reports, price lists) will normally not be considered as advertising and can, therefore, be openly published on the internet.

Under the Code of Farmaindustria, a clearly legible warning must also be included in those parts of the website directed to the HCPs only, indicating that the information is intended exclusively for the HCPs legally entitled to prescribe or dispense medicinal products and, therefore, that specialised training is required for the correct interpretation of the information. Persons who access the content must identify themselves as HCPs entitled to prescribe or dispense medicinal products. Pharmaceutical companies can also establish an HCPs status verification system in order for HCPs to have access to the information.

### 7.4 Provision of Disease Awareness Information to Patients Online

Any information or material provided online to patients must comply with the requirements referred to in **4.3 Restrictions on Interactions between Patients or Patient Organisations and Industry**.

### 7.5 Online Scientific Meetings

Spanish law does not include any provision regarding online scientific meetings.

According to the Code of Farmaindustria, scientific online meetings must comply with the same requirements applicable to non-virtual meetings.

In addition, the Code of Farmaindustria provides some specific requirements applicable to online scientific meetings:

- it is forbidden to offer any kind of hospitality in online meetings, this applies to meetings organised or mainly sponsored by the company, as well as to meetings organised by third parties; and
- the notification of online scientific events to the Code of Practice Surveillance Unit is not compulsory.

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

Under the Spanish Criminal Code companies may be subject to criminal liabilities for bribes offered or given by their employees, directors or other persons under their control to public officials or to private persons.

The penalties that may be imposed on a company for a bribe, which are independent from the penalties that may be imposed on the persons that have committed or participated in the bribe, may be as high as four times the amount of the profit obtained by the company.

However, a company may be exonerated from criminal liability if it demonstrates that prior to the bribe being offered or given, it adopted a compliance system that satisfied the conditions and requirements of the Spanish Criminal Code, in order to offer or give the bribe the persons involved fraudulently eluded the compliance system and there was no serious breach of the supervision and control duties contemplated in the compliance system.

### 8.2 Legislative or Self-Regulatory Provisions

According to Royal Legislative Decree 1/2015 and the codes of conduct it is prohibited for any person with a direct or indirect interest in the production, manufacture and/or placing on the market of medicinal products to directly or indirectly offer to HCPs involved in the cycle of prescription, dispensing and/or administration of medicinal products (or to their relatives or cohabitants) any kind of inducement, bonus, discount, reward or benefit, except for gifts, hospitality and discounts which fulfil the requirements set forth in **4.3 Restrictions on Interactions between Patients or Patient Organisations and Industry**, **9.1 Gifts to Healthcare Professionals**, **9.2 Limitations on Providing Samples to Healthcare Professionals**, **9.3 Sponsorship of Scientific Meetings** and **9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions**. This prohibition will likewise apply when the offer is made to HCPs prescribing medical devices.

Offering benefits to HCOs and POs is acceptable, provided these benefits are not an inducement to buy, recommend and/or use the products of the company.

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

#### Gifts

According to Royal Decree 1416/1994, a gift to HCPs entitled to prescribe or dispense medicinal products may only be offered when the cost of the gift is insignificant and the gift is relevant for the practice of medicine or pharmacy.

The Code of Farmaindustria offers further guidance and provides that offering gifts to HCPs is only permitted provided that the items have stationary or professional use, are not related to a prescription-only medicinal product and have a market price that does not exceed EUR10. Moreover, such gifts may not be given to HCPs in the context of the promotional and informative visits made by sales representatives of companies, nor in the framework of a congress or meeting organised by a third party, if such visit or event relates to prescription-only medicinal products.

As an exception, it is allowed to give memory cards containing informative or formative material, provided its value does not exceed EUR10. Pens and notepads can be provided in meetings organised by the company, provided that they do not include information regarding prescription-only medicinal products and that their market price does not exceed EUR10.

#### Educational Materials

Educational materials and items of medical utility can be given as a gift provided that

- they are relevant to the practice of medicine or pharmacy;
- they benefit patient care;
- they do not alter or modify the routine business practice of the recipient; and
- their market price does not exceed EUR60.

The offer to HCPs of such gifts is excluded from the transparency obligations referred to in **10. Pharmaceutical Companies: Transparency**.

### Hospitality

Except in case of online events, hospitality may also be offered to HCPs at professional or scientific events, provided that it is reasonable and moderate, and strictly limited to necessary logistical means that allow HCPs to attend the event. Hospitality offered may only include payment of real costs of travel, registration and accommodation (hospitality may be only extended to the day after or before the event).

Payments for meals that costs more than EUR60 (taxes included) per person, as well as payments for five-star hotels, five-star grand luxury hotels, sports resort hotels, theme park hotels and/or winery hotels, are prohibited. Payment for cultural, leisure or entertainment activities is also prohibited.

The company must pay these expenses directly to the services providers. No monetary reimbursement can be made to the HCPs attendees for expenses incurred to suppliers, except in the case of minor travel costs (eg, taxis, mileage, etc), which are properly justified/evidenced. Hospitality may not be extended to persons other than the HCP attendees.

## 9.2 Limitations on Providing Samples to Healthcare Professionals

Royal Decree 1416/1994 states that delivery of free samples can only be made on an exceptional basis, and provided that the prior authorisation from the AEMPS is obtained. Authorisation by the AEMPS may be granted only for medicinal products which:

- have a new active substance;
- have a new pharmaceutical form, concentration dosage, or administration route which represents a therapeutic advantage; or
- have new therapeutic indications.

The following requirements/restrictions apply:

- supply of samples must be in response to a written request, signed and dated, from HCPs entitled to prescribe medicinal products;
- only a maximum of ten samples for each medicinal product each year per HCP, during a maximum period of two years after the granting of the marketing authorisation for the medicinal product, is allowed;
- companies must maintain an adequate system of control and accountability;
- samples must not be bigger than the smallest presentation of the product authorised in Spain;
- each sample must be marked “free sample–not for sale” and its reimbursement sticker must have been annulled; and
- samples must be accompanied by a copy of the SmPC and by updated information on its price, conditions of reimbursement by the Spanish National Health System and, if possible, estimated cost of treatment.

No samples of medicinal products containing psychotropic or narcotic substances may be supplied.

The provision to HCPs of samples is excluded from the transparency obligations for the companies of Farmaindustria referred in **10. Pharmaceutical Companies: Transparency**.

### 9.3 Sponsorship of Scientific Meetings

According to Spanish regulations, companies may sponsor scientific meetings or congresses, as well as organise informative, professional and/or scientific meetings. Such sponsorship must be stated in all documents related to the event, as well as in any published derivative work.

It is also possible to pay necessary travel, accommodation and enrolment costs to HCPs attending such congress or meetings. According to Royal Decree 1416/1994, hospitality must be reasonable in level (it must not exceed what recipients would normally be prepared to pay for themselves) and remain subordinate to the main scientific objective of the event. Recipients must indicate the funds received and the source of financing in the publication of papers and lectures in the congresses and meetings. A company may be held responsible for the contents and hospitality arrangements for a meeting or congress if such event has been organised and/or mainly sponsored by such company.

The Code of Farmaindustria provides further guidance:

- payments of HCPs travel, accommodation and enrolment costs must be made directly to the provider of these services, except for minor travelling expenses duly justified;
- no payment can be made for the time incurred by the HCP attending the event;
- hospitality may be granted only for the duration of the event and one additional day;
- scientific activities must cover at least 60% of an eight-hour working day;
- tourist locations, sports resorts and the like should be avoided. In addition, it is not acceptable to organise events at venues outside Spain, unless most of the participants come from outside Spain, or the congress or expertise object to the event is located abroad (prior approval by the Farmaindustria's Deontological Surveillance Unit may be needed); in such cases, the company must abide by the rules of the code of conduct applicable in the country where the event is located – a limit of EUR60 (VAT included) is established for meals and luncheons per guest;
- hospitality must not be extended in any case to accompanying persons;
- payment of reasonable fees and reimbursement of out-of-pocket expenses is possible for speakers and moderators; and
- companies must comply with the transparency obligations referred in **10. Pharmaceutical Companies: Transparency**.

### 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

The hospitality offered to HCPs cannot include the organisation of social, entertaining or cultural events, except for reasonable welcome cocktails, working meals and gala dinners.

### 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

According to Spanish regulations, grants or donations to individual HCPs are strictly prohibited, except for gifts, samples, and hospitality offered to HCPs provided such gifts, samples and/or hospitality fulfil the requirements set forth in **9.1 Gifts to Healthcare Professionals**, **9.2 Limitations on Providing Samples to Healthcare Professionals** and **9.3 Sponsorship of Scientific Meetings**. Grants or donations to HCOs are acceptable, provided they are not offered as an inducement to buy, recommend and/or use the products of the company.

The Code of Farmaindustria provides specific rules as regards grants or donations to HCOs. The Code allows donations and/or the funding of the cost of medical or technical services to institutions, organisations, associations and foundations whose members are HCPs and/

or which provide services of sanitary, social or humanitarian assistance, research or teaching, subject to certain conditions, the most relevant of which are that the gift or donation:

- must not be offered as an inducement to prescribe, recommend or use any particular product;
- must be for the internal use of the institution in general, and not for the use of an individual (portable electronic devices are expressly excluded); and
- must be recorded in a document to be kept by the company.

It is advisable to show these transactions in a written agreement so that the terms under which the funding is awarded are explicit and transparent. Companies must comply with the transparency obligations referred to in **10. Pharmaceutical Companies: Transparency** regarding the offer of grants or donations to HCOs.

### 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

With regard to retail pharmacies, only reasonable volume-related discounts and discounts for early payment are acceptable, provided that such discounts do not induce the purchase of the product in prejudice of its competitors, and are reflected in the corresponding invoice. The reasonability of the discount must be analysed on a case-by-case basis. Companies must also keep a record, which has to be interconnected with the Ministry of Health, of all discounts offered to pharmacies for medicinal products that are financed by the National Health System.

With regard to supplies to hospitals, discounts are subject to the public procurement system.

### 9.7 Payment for Services Provided by Healthcare Professionals

It is possible to pay HCPs for expert services (for example, participating in advisory boards, acting as speaker or moderator at scientific meetings, educational activities, expert meetings, etc), under the following conditions:

- it is necessary to enter into a written agreement stating the nature of the services and the criteria to calculate the amount of payment;
- the legitimate need for such services must be clearly identified;
- the criteria used to choose the expert must be related to the identified needs, and the person in charge of the selection must have the necessary expertise to evaluate the candidates – the experts hired must be approved by the scientific service of the company;
- the number of experts hired shall not exceed the number reasonably necessary to achieve the identified objectives;
- the company must keep documental records of the services provided;
- the payment to HCP must not entail an inducement to promote the prescription, dispensation, sale or consumption of medicinal products;
- the remuneration must be at market prices and taking into account the hours of work or service actually employed and the responsibilities undertaken by the expert; payments must be explicit and transparent, and a proper invoice must be issued by the HCP, while payments in kind can only be accepted exceptionally upon prior authorisation from Farmaindustria's Deontological Surveillance Unit; and
- it is recommended that the agreement must include a clause by means of which the HCP undertakes to declare that they provide services to the company every time they write or publicly assert any matter related to the

company; and companies must comply with the transparency obligations referred to in **10. Pharmaceutical Companies: Transparency** regarding the payments made to HCPs related to said provision of services.

Annex IV of the Code of Farmaindustria includes a Guide for action for companies when contracting services to HCPs and HCOs. Annex IV includes a list with some of the different kind of services that may exist and the criteria that pharmaceutical companies must comply with.

In addition, this Guide establishes a series of questions (23 in total) that companies must be able to answer affirmatively, to ensure that they comply with the provisions of the Code regarding these contracts. These questions are set out in line with IFPMA's "Guidance on Fees for Services".

### 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

According to the Spanish rules, HCPs which provide their services in HCOs depending on the public health system may be obliged to obtain an authorisation of their employer in order to accept the hospitality offered by a company or to provide a service for a company. HCPs are the ones affected by these obligations and not the companies.

Under the Code of Farmaindustria, the companies must inform Farmaindustria's Deontological Surveillance Unit in the following cases:

- the company organises the assistance to a congress or event of at least 20 people; and/or
- the HCPs hired by the company for a given project are more than ten.

In case of meetings or events that are part of projects that have already been notified by pharmaceutical companies, these do not need to be notified again in accordance with the principle of non-duplication.

Communication will be voluntary in case of training activities or scientific meetings that are carried out virtually.

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

The Code of Farmaindustria has implemented the EFPIA rules on disclosure of transfers of value from pharmaceutical companies to HCPs, HCOs, and POs. Consequently, since 2015, companies are obliged to document and publish on their website (first publication was actually made in 2016) all transfers of value made during the previous year – meaning any direct or indirect payment or grant, either cash or benefits in kind, and regardless of its purpose – whose recipient is a HCP or HCO. The only payments excluded from this obligation are:

- those associated with commercial transactions with distributors, retail pharmacies, as well as certain transactions with HCOs;
- activities related to products or medicinal products that are not prescription-only medicinal products; and/or
- activities not detailed in Appendix I of the Code of Farmaindustria, such as, the provision of gifts, samples, dinners or luncheons.

Disclosure must be made on an individual basis, except for transfers of value related to R&D. Spanish authorities on personal data protection

has ruled that companies must inform HCP on the disclosure of their personal data. However, there is no need that the HCP consents to the disclosure of their personal data.

AESEG has also implemented in its own Code the Medicines for Europe rules on disclosure of transfers of value from pharmaceutical companies to HCPs, HCOs, and POs.

There are no exceptions regarding the disclosure obligation due to COVID-19 incidences.

### 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

Transparency requirements described above apply to transfers of value to HCPs, HCOs, and POs performed by companies associated to Farmaindustria/AESEG and/or which have voluntarily adhered to the Codes of Farmaindustria/AESEG. They also apply to transfers of value to Spanish HCPs, HCOs, and POs performed by their affiliates, except for the case that such affiliates already publish such transfers of value in accordance with their national code of conduct. The fact that the company does not yet have products in the market is irrelevant for this purpose.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

Except for the rules resulting from the industry codes of conduct, the responsibility for enforcing the rules on advertising and inducements lies with the health authorities of the Spanish autonomous regions and courts.

The Codes of Farmaindustria, AESEG and ANEFP are enforced by self-regulatory bodies in agreement with Autocontrol, an association for self-regulation in advertising.

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Any advertising in breach of the General Law 34/1988 on Advertising will be considered as an unlawful act under the Law 3/1991 on Unfair Competition. The actions that may be taken before the courts for breach of the Law on Advertising and for breach of the Law on Unfair Competition (which may be taken individually or on a cumulative basis) have been unified in order to avoid any conflict between jurisdictions:

- action of cessation or prohibition;
- action of declaration of the unlawfulness of the advertising;
- action of removal of the effects produced by the unlawful advertising; and
- action of rectification of any deceitful, incorrect or false information contained in the unlawful advertising, including the publication of the court ruling.

This is without prejudice of the right to claim damages, if the advertiser has acted wilfully or negligently and/or unlawful enrichment, if applicable.

The referred actions may be brought by any person or company who is affected by the unlawful advertising and, in general, those who have a legitimate interest. These actions may also be brought by consumer associations or other associations when the interests of their members are affected, but they will not have the right to claim damages.

The issues which have been discussed more frequently under these procedures involve the

distinction between advertising and information on products, the conformity of advertising materials to the contents of the SmPCs, and the conditions under which comparative advertising is fair. Another area on which various rulings have been adopted refer to the limits on hospitality that may be offered to HCPs.

### Raising Issues

Under the Codes of Farmaindustria, AESEG and ANEFP, companies have agreed not to file complaints against each other directly before the ordinary courts or the health authorities without first raising the issue with the bodies in charge of enforcing these codes.

## 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The regulatory authorities are rather strict in scrutinising materials which companies notify to them, and they may suspend an advertisement if they consider it to be in breach of the rules. Furthermore, if the advertisement constitutes a risk for the health or security of consumers, the authorities may order the publication of the ruling and a corrective statement where the advertisement was published.

### Failure to Comply

Failing to comply with the rules governing the medicinal products advertising and/or inducements may also result in administrative sanctions. The general rule is that a breach of the law on this matter may result in a fine being imposed. The amount will depend on various factors including negligence, if the breach was intentional, if there was fraud or connivance, if a failure to comply with previous requests made by the authorities exists, the company's turnover, the number of persons affected, the damage caused, and the profits obtained from the infringement. In some cases, criminal sanctions may apply.

### Challenging Decisions

Decisions taken by regulatory bodies may be challenged through an administrative appeal and through judicial review. In some cases, the administrative appeal is compulsory and has to be filed within a month from the date on which the decision was notified. When the administrative appeal is only optional, the interested party may go directly to court within two months from the date on which the decision was notified. During the court case an injunction may be sought. The chances of obtaining an injunction largely depend on whether the applicant shows that it will suffer irreparable harm in the event that the injunction is not granted.

Under the Codes of Farmaindustria, AESEG and ANEFP, the procedure may conclude with the declaration of the unlawfulness of the advertising, as well as with a fine, the amount of which will be set considering a variety of factors. The damage that a breach of the rules may cause to the image of the industry is one of the criteria to which the Code of Farmaindustria refers. The competent body to impose these measures and sanctions is the Jury of Advertising, a specialised body within Autocontrol. The rulings of the Jury of Advertising are made public through its website.

## 11.4 Relationship between Regulatory Authorities and Courts

The Codes of Farmaindustria, AESEG and ANEFP state that, prior to raising the issue before the regulatory authorities or the courts, the companies adhered to these codes must first file their claims against the advertising practices of other companies before the bodies in charge of enforcing these codes of conduct.

Notwithstanding the foregoing, the regulatory authorities may investigate matters on their own initiative, even if they are being assessed by any self-regulatory body, and may also take up mat-

ters based on an adverse finding of any self-regulatory body. Conversely, the Jury of Advertising must refrain from assessing any issue which is being or has been assessed by the regulatory authorities or the courts.

### 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

During the last few years, there has been rather few cases regarding advertising of medicinal products in Spanish Courts and in Autocontrol. The last ruling of Autocontrol under the Code of Farmaindustria was issued in mid-2020.

On 30 June 2021, the High Court of Justice of the Basque Country issued a very interesting judgment (which is a firm judgment, as it was not appealed before the Spanish Supreme Court) clarifying, inter alia, that Spanish law does not prohibit the advertising of products which have been granted a MA, even when its price and reimbursement decision is still pending from the MoH. Following this judgment, the Code of Farmaindustria changed its Q&A section (Question 10) by indicating that the advertising of a medicine in these circumstances is not against the Code provided that such advertising includes a waring in this regard and is aimed at HCPs and a warning. For more information about this judgment, context and conclusions in connection thereof, see **Spain Trends & Developments**.

**Faus & Moliner** is a modern boutique law firm, specialised in dealing with legal matters typical of the pharmaceutical industry and other companies which operate in the life sciences sector. Faus & Moliner, which was founded in 1997, focuses on pharmaceutical law, commercial contracts, corporate transactions, corporate governance, compliance, competition law, public procurement, product liability, advertising, litigation and arbitration. The firm advises pharma and healthcare clients, acts on behalf of large companies and smaller biotech start-ups, and is frequently called upon to advise public authorities on matters such as draft legislation.

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# Trends and Developments

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## Introduction

The latest trends and developments in connection with pharmaceutical advertising in Spain concern the following matters:

- the advertising of prescription-only medicinal products to healthcare professionals (HCPs) once they have received marketing authorisation (MA) but before the price and reimbursement decision is issued by the Ministry of Health (MoH);
- visits by medical sales representatives of the companies to HCPs;
- advertising of medicinal products in social media; and
- other foreseeable legislative changes.

This article analyses each of these matters, providing background information and relevant context when needed.

## Advertising of Prescription-Only Medicinal Products to HCPs before the Price and Reimbursement Decision Is Taken by the MoH

### *Relevant context*

In Spain, prescription-only medicinal products cannot be placed in the market right away once MA has been granted (either by the European Commission under the centralised procedure or by the Spanish Medicines Agency (AEMPS) under a national procedure, a mutual recognition or decentralised procedure).

The consolidated text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices, approved by Royal Legislative Decree 1/2015 states that prior to placing the product in the market, the MA holder or its local representative must offer such product to the MoH so that the MoH may decide whether to reimburse it or not. In the affirmative, the MoH shall issue a decision (a "P&R Decision") fixing also the maximum price for the units of such product that will be reimbursed. Units that are not reimbursed (ie, private patients or other sales outside the National Health System) may be sold at the price notified to the MoH provided the MoH does not oppose to it on the grounds of protection of public interest.

Royal Legislative Decree 1/2015 is not entirely clear as to whether a product may be placed in the market before the P&R Decision is taken. As a matter of administrative practice, the MoH understands that this is not possible. This would also impede private patients to have access to the product until the MoH issues the P&R Decision. Companies tend to respect this administrative practice, and commercial launches of products in Spain do not take place until the P&R Decision has been taken.

Conversely, products that have obtained MA but that are not commercially available in Spain for any reason (the fact that the MoH has not yet decided whether to reimburse them or not would be one of them) may be made available to patients under a named-patient system, similar to the one that applies for unapproved products. The availability of medicinal products in these situations is regulated by Spanish Royal Decree 1015/2009. In these cases, the supply is approved by AEMPS at the request of a hospital or a regional heath authority following an individual prescription, and the product may be supplied at the price agreed between the company and the hospital or the regional health authority.

The possibility of advertising a product after MA has been issued but before a P&R Decision is adopted, has been the subject of controversy in Spain mainly due to the interpretation given by the Spanish authorities of some provisions contained in Royal Decree 1416/1994 regarding the minimum information that must be included in any advertising of medicines aimed at HCPs.

In this regard, Article 10.2 of Royal Decree 1416/1994 states that any advertising of medicinal products to HCPs must include information, "*about the price and reimbursement conditions and, whenever possible, about the estimated cost of the treatment".* When referring to this requirement, Article 10.2 states that this information must be provided "if applicable".

Relying on this, some authorities in Spain have understood that advertising may not take place until a P&R Decision has been taken. In some cases, some authorities have even stated that advertising cannot take place until the product is effectively placed in the market.

This position was also followed by the Jury of Autocontrol (a specialised body responsible for hearing cases relating to the breach of provisions of self-regulatory codes) when applying the Code of Farmaindustria (Farmaindustria is the Spanish innovative medicinal products industry association, which has issued a Code of Practice for the Pharmaceutical Industry regulating the advertising of prescription-only medicinal products as well as interactions between pharmaceutical companies and HCPs, HCOs and POs).

According to some of rulings of the Jury of Autocontrol, for example, the case Cephalon Pharma, S.L.U. v Prostrakan "Abstral", dated 8 October 2009, the advertising of authorised medicinal products for which a P&R Decision was pending is regarded as a breach of the Code of Farmaindustria.

### *Latest trends*

A recent judgment issued by the High Court of Justice of the Basque Country on 30 June 2021 – which is final as no appeal was filed against it – has opened the debate on this matter and put into question the criteria held by Spanish authorities and by the Jury of Autocontrol.

This judgment was issued in a case filed by Farmaindustria against an Order governing visits by medical sales representatives to HCPs in the Basque Country. The appeal was filed because Farmaindustria considered that the Order did not allow medical sales representatives to promote, at such visits, authorised medicinal products for which a P&R Decision was pending. The High Court rejected the appeal concluding that neither the Order not any other Spanish applicable law prohibit the advertising of products that have received MA, even if a P&R Decision is pending.

Interestingly, the court states that when interpreting Article 10.2 of Royal Decree 146/1994, relevance must be given to the words "if applicable" contained in such provision, meaning that the information about the price and reimbursement conditions must be given only if such information is available when the advertising is made. The court also states that the absence of a P&R Decision cannot be an obstacle for authorized advertising the medicinal product to HCPs.

The Judgment is highly relevant because it reaches this conclusion not only based on the wording of the law but also on the basis of its spirit and general purpose.

In this sense, the court states that requiring that medical representatives inform HCPs always about the price and reimbursement conditions of the product would significantly limit the adver-

tising, and that patients and society in general would risk not being able to enjoy the latest treatments in the shortest time possible. The court also states that the objective of advertising medicinal products is to provide HCPs with technical-scientific information as needed to be able to judge for themselves about their therapeutic value, and this objective, the court says, must be achieved in connection with every medicinal product that has obtained a MA, regardless of whether it is reimbursed or not.

Considering this Judgment, Farmaindustria modified the Q&A section of its Code of Practice, and answer (last paragraph) to question 10 now reads as follows:

"In cases where, following marketing authorisation, a resolution on financing and price is pending in the SNS, the promotion of a new medicine or a new indication does not constitute an infringement of the Code provided that the advertising aimed at persons authorised to prescribe or dispense medicines includes information on this circumstance."

Therefore, under the Code of Farmaindustria, advertising authorized medicinal products to HCPs when the P&R Decision is still pending is possible, provided that such advertising includes a warning about such circumstance.

### *Foreseeable future*

As mentioned before, medicinal products which have obtained a MA but are not commercially available in Spain (for example due to the MoH not yet having decided on their reimbursement), may be made available to patients under a named-patient system similar to the one that applies for unapproved products. Access to these products is governed by Royal Decree 1015/2009, regulating the availability of medicinal products in special situations.

A joint interpretation of Articles 17 and 22 of Royal Decree 1015/2009 may lead to the conclusion that marketing authorization holders must not advertise products which although have been authorized in Spain, are not yet commercially available.

Because of this, we cannot exclude that some administrative authority in Spain tries to argue that advertising of products in this situation would be a violation of Royal Decree 1015/2009.

However, in our opinion, there are solid legal grounds to contest such position including, without limitation, the fact that Royal Decree 1015/2009 is only an administrative regulation which cannot impose a prohibition on advertising unless such prohibition is also contemplated in a Law. Royal Legislative Decree 1/2015 prohibits advertising unauthorised products, and thus the contents of article 22 of Royal Decree 1015/2009 conforms to the law; but given that Royal Legislative Decree 1/2015 does not prohibit advertising authorised products for which a P&R Decision is pending, Royal Decree 1015/2009 cannot establish such prohibition ex novo. Otherwise, an administrative regulation (which lacks the rank of a Law) would be limiting the right of companies to inform about their products in this situation and to advertise them.

Also, the reasonable interpretation of Article 22 of Royal Decree 1015/2009 is that it applies only to medicinal products that have not been granted a MA valid in Spain, but it does not apply to authorised products in respect of which a P&R Decision has not yet been taken.

Just as this article is going to press, we are aware that the health authorities of the Madrid region have issued public statements indicating they do not feel bound by this judgment and that their opinion remains that advertising cannot be

made until the P&R decision has been taken by the MOH.

### Visits by Medical Sales Representatives of Companies to HCPs

#### *Relevant context*

The legal definition of "advertising of medicinal products" includes, among other activities, the visits made by medical sales representatives to HCPs.

According to Royal Decree 1416/1994, these visits are defined as the way of relating between pharmaceutical companies and HCPs in connection with the information and advertising of medicinal products, based on the transmission of proper technical knowledge to enable objective assessment of the therapeutic value.

Medical sales representatives must comply with certain legal requirements, which can be summarised as follows:

- They must promote the adequate use of medicinal products.
- They must be adequately trained by the company and must have sufficient scientific knowledge to be able to provide information that is precise and as complete as possible about the medicinal products they promote.
- During each visit, they must provide or have available for the HCPs the SmPC of the medicinal products they present, as well as information on the different pharmaceutical forms and dosages, the prescription and dispensation regime, the price and reimbursement conditions (if applicable) and when possible the treatment's cost estimate.
- They must transmit to the scientific service of the company any information about the use of the medicinal products they advertise, such as adverse reactions reported to them during the visit.

In addition to the national rules, some Spanish autonomous regions (Spain is divided into 17 autonomous regions) – who are competent for the implementation of rules on advertising of medicinal products – have implemented local regulations establishing rules regarding the schedule, number, and notification/authorisation, by competent authorities, of visits by medical sales representatives permitted to each company. This has resulted in certain conflicts of competence between national and regional rules.

#### *Conflict of competence*

While legislation on medicinal products, including advertising and promotion thereof, is the exclusive competence of the Spanish national authorities, the autonomous regions have competences in areas such as social security, hospital management and pharmaceutical planning that can impact or interfere with the visit to HCPs by medical sales representatives.

These regional competences have been used by the regional authorities as the basis to issue their own regulations on visits to HCPs by medical sales representatives, conflicting (in some cases) with the Spanish national exclusive competences.

#### *Latest trends*

Because of this conflict of competence, there are many of the regional regulations on this matter which have been declared null and void by the Spanish Courts of Justice of the relevant autonomous regions.

The latest case involving a conflict of competence on this matter was the one made by the High Court of Justice of the Basque Country, dated 30 June 2021 (previously mentioned), which partially repelled the Basque regulation on visits to HCPs by medical sales representatives.

There are other autonomous regions whose regulations on visits by medical sales representatives to HCPs have been partially repelled for similar reasons, such as the ones corresponding to the regions of Madrid, Castilla-La Mancha and la Rioja. All these regional regulations aimed to set operational rules to organize visits to HCPs by medical sales representatives, including procedures for notification and/or authorisation by competent authorities, or the requirement for companies to comply with visiting schedules previously approved by such authorities. The Basque regulation on visits to HCPs by medical sales representatives that has been repelled also included provisions to this same effect.

Notwithstanding the above, we are aware that the authorities of Madrid are still applying the requirements of the above-mentioned regulations. In this region, authorities claim that companies must still notify in advance their visiting schedules to HCPs by medical sales representatives and that failure to do so will have the effect of preventing companies from performing such visits.

### Advertising of Medicinal Products in Social Media

#### *Relevant legal context*

In Spain, there are no legal rules specifically concerning the advertising of medicinal products in social media. However, logically, such way of advertising is subject to the same rules applicable to such advertising in any other means.

Notwithstanding the lack of legal specific provisions, there are certain guidelines particularly referring to the advertising of medicinal products in social media. In this regard, the Code of Farmaindustria contains specific provisions concerning social media and the digital environment. According of these specific provisions of the Code of Farmaindustria, companies have the obligation to adequately train their employees on how to behave in the digital environment. To this end, companies must have good-practice internal guides for their employees and for any person acting on their behalf or under their control or by virtue of an agreement. Companies must also train their employees to prevent them from posting inappropriate content on their own personal social networks, such as comments on competitors' products or off-label promotion. As regards responsibility, companies may be held liable for the content posted online by the company itself or by a third party in the name of the company if the latter is directly or indirectly controlled or financed by the company.

Also, under the Code of Farmaindustria, companies must clearly and unequivocally inform HCPs and employees attending the meetings organised or sponsored mainly by the company, about the prohibition of publishing promotional content related to the meetings on social media. To this end, it is recommended to include safeguards in the agreements entered with speakers and attendees.

Apart from the Code of Farmaindustria, the regional authorities of Catalonia have issued monographic guidelines concerning information and advertising of medicinal products through certain social networks. These guidelines are social media-specific: in particular, they refer to LinkedIn, Twitter and Instagram.

According to the LinkedIn's guidelines, this social network can be used to promote prescription medicinal products to HCPs if a restricted group is created to that end, specifying the rules governing the group. Among such rules, there must be a disclaimer on the fact that the access to the group is restricted to HCPs and an express prohibition to share the materials outside the channels of the group. The creation of this group must be notified to the competent authorities.

Regarding Twitter's guidelines, the use of this social network for the purpose of distributing information of prescription medicinal products is not recommended since the content can easily be shared with the general public. The guidelines advice to use Twitter just for corporate and health messages.

Regarding Instagram's guidelines, this network should not be used to promote and spread information on prescription medicinal products since it does not contain access restriction features regarding the materials posted.

### *Latest trends*

In December 2021, the regional authorities of Catalonia issued an update to the Catalonian monographic guidelines on information and advertising of medicinal products through social media.

The recent update of these guidelines was made to include an express confirmation that spreading scientific information through these channels is permitted provided that there is no promotional or advertising content related to prescription medicinal products where access cannot be restricted or limited to HCPs.

The update also informs that the three social networks referred can be used by companies to include links to their websites. Regarding LinkedIn, the update also informs that this social network allows users to send publications to other users by previously selecting the addressee of the messages, offering the companies the possibility to select the addressee by criteria such as: HCPs v general public, work sector, years of experience, interests and locations. Also, regarding LinkedIn, the update provides the possibility for companies to present webinars, provided that companies has segmented the target audience for such content.

## Foreseeable Legislative Changes

According to Law 50/1997 on the Government, the Spanish government must annually approve a Regulatory Plan containing the legislative or regulatory initiatives to be submitted for approval in the following year. In this regard, the Spanish government published its Regulatory Plan ("Plan") at the beginning of 2022. The Spanish government may approve other legislative initiatives that do not appear in the Plan; however, this must be duly justified.

In relation to the legislative initiatives foreseen in the Plan for 2022, some of them will affect the advertising of medicinal products. In this regard, the Plan foresees that the following legislative initiatives will be approved:

New regulation on the advertising of medicinal products for human use and medical devices

Currently, the advertising of medicinal products for human use is regulated under Royal Decree 1416/1994. As regards the advertising of medical devices, there are currently no regulations which are specific on this matter (this is currently regulated in certain provisions contained in Royal Decree 1591/2009 on medical devices, as well as in Royal Legislative Decree 1/2015).

According to the Plan, the Spanish government plans to approve a new Royal Decree addressing both the advertising of medicinal products for human use, and the advertising of medical devices.

The Spanish government highlights that this legislative initiative aims to update the current legislation and to undertake a comprehensive regulation of the advertising of medicinal products for human use and medical devices to both the general public and HCPs. It also proposes to better define the competences of the central and regional governments in the different areas of

action in the field of advertising. Finally, it is proposed to adapt the regulations to technological developments, in particular to the predominance of digital and audio-visual media.

This regulation would repeal Royal Decree 1416/1994, currently in force. In addition to updating and modernising the regulation of advertising of medicinal products for human use, according to the Plan, the Spanish government wants to specifically regulate the new channels where medicinal products are currently being advertised, which have emerged with social media and the internet.

In relation to the advertising of medical devices, the Spanish government published in June 2021 a draft of the new Royal Decree on medical devices, with the aim of adapting it to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. According to the draft, the entire Royal Decree 1591/2009 was going to be repealed, except for the articles on advertising, promotion, incentives and sponsorship of scientific meetings for medical devices. The Spanish government justified this exception on the grounds that a new regulation was being drafted that would specifically regulate the advertising of medical devices.

Considering this, it looks like the new Royal Decree on the advertising of medicinal products for human use and medical devices will not be left on the shelf. The Government will likely activate this initiative in order to comply with the obligation to review medical devices national legislation according to Regulation (EU) 2017/745.

One of the areas that will be convenient to clarify (for example, via this new Royal Decree on advertising of medicinal products for human use and the advertising of medical devices) is which regional authorities are competent for enforcing the rules concerning the advertising of medicinal products. Currently, there are controversies as to whether such authorities are the ones where the company has its registered offices or the ones where the advertising activity is carried out.

### *New regulation on the availability of medicinal products in special situations*

The Plan also foresees an amendment to Royal Decree 1015/2009, regulating the availability of medicinal products in special situations. The new regulation aims to better define the different ways to access medicinal products in the so-called "special situations" and the different categories included in each of them (compassionate use, off-label prescription and access to products not approved in Spain but legally marketed in other Member States).

As regards the advertising of medicinal products, the current regulation contains certain provisions prohibiting the advertising of products not approved in Spain but legally marketed in other Member States. Also, as mentioned before (Section 1 – Advertising of prescription-only medicinal products to HCPs before the price and reimbursement decision is taken by the MoH), the interpretation of certain provisions contained in this Royal Decree may lead to the conclusion that it is further prohibited to advertise products which have been authorised in Spain but are not yet commercially available. As previously commented, it is believed that there are solid legal grounds to contest this interpretation. However, we also consider that this interpretation is due to the fact that the current wording is confusingly drafted. Although the Plan does not mention it, these provisions may be amended as well.

**Faus & Moliner** is a modern boutique law firm, specialised in dealing with legal matters typical of the pharmaceutical industry and other companies which operate in the life sciences sector. Faus & Moliner, which was founded in 1997, focuses on pharmaceutical law, commercial contracts, corporate transactions, corporate governance, compliance, competition law, public procurement, product liability, advertising, litigation and arbitration. The firm advises pharma and healthcare clients, acts on behalf of large companies and smaller biotech start-ups, and is frequently called upon to advise public authorities on matters such as draft legislation.

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# SWEDEN

## Law and Practice

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# 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

## 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The Medicinal Products Act (2015:315) establishes the general requirements on advertising of medicinal products. Advertising must be in accordance with good marketing practice, be up-to-date, objective, balanced and not be misleading. Further clarifications are found in the Swedish Medicinal Products Agency's (MPA) Regulation LVFS 2009:6 on the marketing of medicinal products for human use, which implements Directive 2001/83/EC on the Community code relating to medicinal products for human use.

The Swedish Radio and Television Act (2010:696) contains limitations with regards to advertisements of medicinal products through, eg, teleshopping (which is prohibited), and sponsorships of TV advertisements.

Moreover, the Marketing Practices Act (2008:486) sets out general rules that are applicable on all products and services, including medicinal products. According to this Act, advertising must comply with good marketing practice and all marketing claims must be accurate and therefore not misleading. The Act also regulates matters relating to, eg, comparative advertisement and special offers.

### Rules Pertaining to Medicinal Products

The Swedish Association of the Pharmaceutical Industry (LIF) has adopted the Ethical Rules for the Pharmaceutical Industry (the "LER Rules"), which govern advertising and information of medicinal products towards healthcare professionals and to the general public. The Information Examiner Committee (IGN) and the Information Practices Committee (NBL) are the two regulatory bodies that supervise compliance with the LER Rules. The LER rules, and the decisions from IGN and NBL, are not legally binding but they are, however, recognised by the pharmaceutical industry and should be seen as a complementing set of rules to current legislation and will be considered by Swedish courts when assessing good marketing practice.

The LER Rules and decisions from the committees may also be considered by Swedish courts when determining, eg, good marketing practice. The Code of Advertising and Marketing Communication Practice issued by the International Chamber of Commerce (the "ICC Rules") is also considered by Swedish courts when determining good marketing practice.

## 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The LER Rules apply to members of LIF as well as to the Association for Generic Pharmaceuticals and Biosimilars in Sweden (FGL) and Innovative Smaller Life-science companies (IML).

Only members may be subject to sanctions under the LER-rules, eg, penalty fees. However, the committees of LIF can review matters relating to medicinal products from non-members although these non-members cannot be subject to any sanctions.

The LER Rules are not legally binding. However, as stated in **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines**, the LER Rules are recognised within the pharmaceutical industry and they may be applied by courts in order to determine, eg, good marketing practice.

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## 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

### 2.1 Definition of Advertising

Regarding the definition of advertising, LVFS 2009:6 makes a reference to directive 2001/83/EC and cites the Directive's definition of advertising of medicinal products. Accordingly, advertising of medicinal products includes "any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products".

Examples of what could constitute advertising under LVFS 2009:6 may be advertising of medicinal products to the general public or healthcare professionals, visits by sales persons to healthcare professionals, sponsorship of promotional meetings attended by healthcare professionals or supply of samples. From the expression "any form" it can be concluded that the definition of advertising of medicinal products is very broad.

The Marketing Practices Act defines marketing practice as "advertising and other measures in commercial activities which are intended to promote the turnover of, and access to, products, including a trader's acts, omissions, or other measure or behaviour before, during or after the sale or delivery of products to consumers or traders".

### 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

There is no sharp line between information and advertising. Information is part of a broader scope and may fall within the relevant marketing provisions. According to the preparatory works, where there is ambiguity on whether or not a statement is to be considered as advertising, the Act should be interpreted in the light of directive 2001/83/EC.

The decisive criteria in order to distinguish between advertising and information (which, as a rule, does not fall under the advertising rules) is the purpose of the communication. The assessment of whether the communication has a promotional purpose or not should be based on an assessment of all the relevant circumstances on a case-by-case basis. If the information does not have a promotional purpose or includes non-commercial information, it may fall outside the relevant marketing provisions.

The content in, eg, patient leaflets or information regarding patient support programmes may be considered as advertising if, for example, the information can be seen as an inducement designed to promote the prescription, supply, sale or consumption of medicinal products, ie, having a promotional purpose.

#### Activities Not Covered by "Advertising"

In LVFS 2009:6, examples of activities that are not covered by the term "advertising" can be found. Correspondence or material of non-promotional nature, which is necessary to answer a specific question regarding a medicinal product, is not considered as advertising. Neither is factual and informative announcements or material relating to, eg, pack changes, adverse-reaction warnings as part of general drug precautions or trade catalogues part of the term advertisement provided that this information does not include any claims of the medicinal product. Furthermore, information regarding human health or diseases, eg, disease awareness campaigns, are not covered by the term advertising provided that the information does not include any direct or indirect reference to medicinal products.

Further, mere factual and informative messages on, eg, the product packaging are not consid-

ered as advertising provided that there are no claims (eg, regarding effects) about the medicinal product and that the information otherwise comply with relevant legislation.

### Vaccinations

With regards to vaccinations of humans against infectious diseases, the LER Rules states that such campaigns are not regarded as marketing of a certain medicinal product provided that the purpose is to provide the general public with necessary information regarding protection against infectious diseases through vaccination. Another requirement hereto is for instance that the product name, the product logotype or similar distinctive marks or features such as administration method are not included in the information.

### Target Audience

The actual definition of advertising does not differ depending on if the information is aimed towards the general public or to health care professionals. However, lawfulness of the advertising depends on whether the advertising is aimed towards the general public or health care professionals, see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public** and **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**.

## 2.3 Restrictions on Press Releases regarding Medicines

In general, Swedish legislation or self-regulatory codes do not set out any specific restrictions on what type of marketing activities that are allowed. Irrespective of type and form, any advertisement must be in compliance with the applicable advertising rules, such as the Medicinal Products Act as well as LVFS 2009:6, the Marketing Practices Act and the LER Rules.

A press release may only be addressed to journalists, ie, it may not be sent or distributed to healthcare personnel or county council/region representatives. Both the IGN and NBL have in several cases concluded that press releases published by pharmaceutical companies, or which are made available by pharmaceutical companies, through a specific link targeting journalists, do not constitute advertising and thus fall outside the scope of the LER Rules. Whether or not a press release falls within the scope of the LER Rules is assessed on a case-by-case basis. If the press release is of scientific nature and is presented in a clear and objective way and does not promote the pharmaceutical company's own product and does not discredit another company's medicinal product, it will likely fall outside the scope of the LER Rules.

## 2.4 Comparative Advertising for Medicines

Comparative advertisement is allowed under Swedish law under certain conditions.

### The Medicinal Products Act

The Medicinal Products Act includes general requirements that advertising must be up-to-date, objective, balanced and not be misleading. These requirements must be considered when a medicinal product is compared with another medicinal product. According to LVFS 2009:6, it is not permitted, in relation to advertising to the general public, to claim that a medicinal product is better, or equal to, another treatment or medicinal product.

### The Marketing Practices Act

The Marketing Practices Act includes general provisions relating to comparative advertisement between two traders. The Act implements Directive 2006/114/EC concerning misleading and comparative advertising. A trader can directly or indirectly refer to another trader or such trader's products provided that the comparison is

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not misleading, objectively relates to relevant, verifiable and distinguishing characteristics of the products and does not discredit the other trader's business or product.

### The LER Rules

The LER Rules contain specific rules regarding comparisons of medicinal product information towards the general public and healthcare personnel concerning, eg, effects, active ingredients and cost of treatment. Generally, the comparison must be performed in a fair way and be relevant, objective and truthful.

A comparison may not mislead the recipient. This entails that the:

- objects that are subject to the comparison are specified and, if necessary, the name of the medicinal products and generic names of the compared products are stated;
- facts which the comparison is intended to highlight and the limitations with which the comparison is encumbered must be stated in such a way that the comparison cannot be misleading;
- comparisons of properties of synonymous medicinal products, or of medicinal products with the same indications, must provide a comprehensive and fair view of the compared properties; and
- comparison of certain properties may not lead to incorrect or misleading conclusions regarding properties that are not subject to the comparison.

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

The Medicinal Products Act prohibits advertising of medicines or indication(s) that have not been authorised for sale in Sweden. All advertising must correspond with the Summary of Product Characteristics (SmPC), as well as with the authorised indication(s), of the authorised medicinal product.

Distribution of information on unauthorised products or indication(s) and which entails a promotional purpose may be considered as unlawful pre-launch advertising or off-label advertising, eg, IGN has concluded that a press release (which usually falls outside the LER Rules, see **2.3 Restrictions on Press Releases regarding Medicines**) regarding a medicine candidate be regarded as commercial information and, thus, the prohibited advertising of an unauthorised medicine.

### 3.2 Provision of Information during a Scientific Conference

As stated in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, it is prohibited to advertise unauthorised medicines or indications, including during a scientific conference. However, if the provided information has a purely informational purpose, without any references to or claims regarding a specific medicinal product, it may be permissible. In light of the broad interpretation of advertising, such provision of information should be performed with great care.

According to an opinion by LIF, information regarding pipeline drugs (ie, drug candidates that a pharmaceutical company has under discovery or development) is not accepted within commercial areas, eg, at exhibition stands at conferences.

It was previously possible, under certain circumstances according to the LER Rules, to refer to a medicinal product, authorised in another country than Sweden, at a conference taking place in Sweden (a "congressional exemption"). However, following a ruling in the Court of Appeal (judgement No 546-21) on 27 September 2021, where the Court of Appeal concluded that the congressional exemption is contrary to the Medicinal Products Act, LIF decided on 13 October 2021 to remove this exemption from the LER Rules.

### 3.3 Provision of Information to Healthcare Professionals

As stated above, advertising of unauthorised medicines or indications is in general prohibited. This prohibition applies to advertising to healthcare professionals, as well as advertising to the general public. Sending unsolicited information on unauthorised medicinal products or indications to healthcare professionals may thus constitute unlawful pre-launch or off-label advertising.

Individual correspondence, accompanied by material of non-promotional nature if necessary, does not fall under the advertising provisions if it is required in order to respond to a specific query regarding a medicinal product. Accordingly, a pharmaceutical company may respond to a specific query from a healthcare professional concerning, eg, off-label use. The response shall not go beyond the specific query.

### 3.4 Provision of Information to Healthcare Institutions

As stated, unsolicited communications with healthcare professionals may be deemed as unlawful pre-launch or off-label advertising.

However, LVFS 2009:6 provides an exemption concerning price lists, which may be of relevance. Under this exemption, factual and informative announcements and reference material relating to, eg, trade catalogues and price lists, are not considered to be advertisements provided that they do not include product claims.

### 3.5 Publication of Compassionate Use Programmes

Compassionate Use Programmes, ie, allowing the use of an unauthorised medicinal product for patients who have a disease with no satisfactory authorised therapies, may be available in Sweden under strict conditions. The MPA is the competent authority.

There are no specific provisions relating to the publishing of a compassionate use programme or other forms of early access. In the light of the broad interpretation of the term advertising, information regarding a medicinal product's use in connection with a compassionate use programme may be deemed unlawful off-label or pre-launch advertising. This assessment must be made on a case-by-case basis.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

The Medicinal Products Act explicitly prohibits advertising of prescription-only medicines (except for vaccination campaigns on human infectious diseases) towards the general pub-

lic. The prohibition also includes advertising of medicinal products or indications that have not been authorised for sale in Sweden and advertising of medicinal products targeting children.

According to the LER Rules, information on prescription-only medicines can only be provided to the general public via the Pharmaceutical Specialities in Sweden's Farmaceutiska specialiteter i Sverige (FASS) website, to the extent the information complies with the requirements under Swedish legislation. It is also permitted to provide information through, eg, brochures if the information is intended to be handed to a patient by healthcare personnel to facilitate the patient's correct use of the medicine.

To ensure public access to this information, a pharmaceutical company may provide information regarding such products on a website (pre-approved website) administered by a pharmaceutical company provided that pre-examination and pre-approval has occurred. This pre-approval system has been introduced by LIF. Any pharmaceutical company that complies with the LER Rules may apply for a pre-approval. The company is not allowed to actively market the website. Instead, the user must seek the information on its own.

Advertising of over-the-counter (OTC) medicines is allowed in Sweden but subject to comprehensive regulation. As a general rule, all advertising must be up-to-date, objective, balanced, must not be misleading and must correspond to the SmPC.

### 4.2 Information Contained in Pharmaceutical Advertising to the General Public

When advertising a medicinal product that addresses the general public, it must be made clear that the message is an advertisement and that the product is a medicinal product.

The content of the advertising shall not be construed in a way that could result in the medicinal product being used in a harmful way or that could result in people not seeking appropriate care. Furthermore, the advertising must correspond to the SmPC in all respects.

According to LVFS 2006:9 and the LER Rules, the advertising must at least contain the following information:

- the name of the medicinal product and the generic name if the medicinal product only contains only one active ingredient;
- information that is necessary to facilitate the correct use of the medicinal product including any necessary warnings or limitations of use. Such information can relate to the need for contact with the healthcare for a diagnosis before treatment or if treatment does not have any effect within a certain time, limitations in treatment for children and pregnant women or limitations in the duration of the treatment;
- an explicit and easy-to-read invitation to take note of the package leaflet or the outer packaging, as the case may be;
- its dosage form;
- contact information of manufacturer or applicable representative;
- information on the year of publication of the information or, if applicable, the date when the webpage was last updated; and
- if the advertising concerns an OTC medicinal product that has an effect against a disease or symptoms of a disease, which requires contact with the healthcare for diagnosis or treatment or a recommendation to consult a physician prior to the use of the product.

The price of a medicinal product may be disclosed in an advertisement, but this is not mandatory.

### Prohibited Information in Advertising

According to LVFS 2009:6, advertising of medicinal products to the general public may not contain any information that:

- gives the impression that it is not necessary to consult a doctor or that a surgical operation is unnecessary;
- suggests that medicine effects are guaranteed, are without adverse reactions or are better than, or equivalent to, another treatment or product;
- suggests that a person's health can be enhanced by taking the medicine;
- suggests that a person's health may be affected without taking the medicine (with the exception for vaccination campaigns);
- refers to recommendations by, eg, scientists or health professionals or other persons, who, because of their celebrity, could increase the use of the medicinal product;
- suggests that the medicinal product is equal to any foodstuffs, cosmetics or other consumer goods;
- suggests that the safety or effect of the medicinal products is due to the content being derived from nature;
- could lead to a wrong self-diagnosis, eg, by describing a case history;
- contain exaggerating or misleading claims on cure; or
- contain exaggerating or misleading visual representations of changes in the human body caused by disease or injury.

## 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Interaction between pharmaceutical companies and patients is covered by the applicable advertising provisions targeting the general public (in which, eg, patients and all members of patient organisations are included). For instance, advertising of prescription-only medicines is explicitly prohibited, and a pharmaceutical company is not allowed to provide free samples to patients when advertising a medicinal product.

### Co-operation and Collaboration

The LER Rules contain a comprehensive set of ethical rules with regards to co-operation between pharmaceutical companies and patients/the general public, user organisations or interest groups, such as disability and patient organisations. Collaborations can, eg, take place around joint disease information activities (meetings, development of patient support programmes or information materials, etc) and joint opinion formation and advocacy work within the framework of a limited activity. In the event of collaboration, an organisation should, if relevant, be contacted or engaged in the first instance.

However, the rules also apply to collaboration with patients who are not members of or represent an organisation, as well as to collaboration with related parties to the patient. The term "related party" herein refers to persons from the patient's family, relatives, partner, close friends, etc, and others such as a voluntary support person (but not healthcare personnel in their role as service providers). These rules aim to ensure that collaborations, information and training are designed in a way that the parties' independence from each other is not jeopardised or doubted from a legal or ethical point of view. This entails that any collaboration project cannot consist of the main part of an organisation's business and/or economy.

The LER Rules regarding collaborations apply to pharmaceutical companies and comprise collaborations such as research, training, consultancy, information and educational material and market studies.

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### *Transparency and contract*

A collaboration between pharmaceutical companies and organisations should be regulated in a written agreement containing provisions regarding, eg, the purpose of the collaboration, financing, rights and obligations. Such agreement must be signed by both parties before any collaborative activities are carried out. Any agreement should be kept available for third parties via a short version in LIF's collaboration database. It is the obligation of the pharmaceutical company concerned to publish the information in the database in accordance with the relevant classification in the database, after the agreement has been signed by all parties and no later than the day the collaboration is carried out.

All projects are published for three years, before being automatically unpublished. All consultation with an individual patient or related party, eg, lecture, advisory board, or other consultation, in its role as a patient or related party, is published according to the same procedure, without any personal data.

### *Economic and other support*

Regarding economic and other support, such support may only be provided to specified projects. A pharmaceutical company may not provide economic or other support that:

- intends to finance the organisation's daily and regular operations;
- results in an organisation's business being unable to continue after the termination of the collaboration agreement;
- causes circumstances of dependency between the parties; and
- exceeds the costs for the activities under the collaboration.

Travel and accommodation for, eg, meetings/conferences for individual participants may not be paid for by pharmaceutical companies or requested by individual participants or patient organisations. Participants in meetings may not be offered a fee by pharmaceutical companies and participants are not entitled to receive or request a fee for their participation. Pharmaceutical companies may only offer such meetings that are connected to the pharmaceutical company's areas of business.

### *Consultation*

When a pharmaceutical company engages a representative of an organisation, a patient or a representative from the general public (eg, a related party) for consultation, the pharmaceutical company must ensure that there is a legitimate need for the assignment. The purpose shall be the exchange of knowledge and experience, for instance that a personal medical experience is shared by the patient and/or related party, that users who have tested a specific aid (eg, an app), or other patient support, provide feedback to the company about its functionality.

The purpose of a consulting assignment must not be to influence or train the consultant. Thus, it is important to note that the engagement may not constitute encouragement to promote a product or a pharmaceutical company. If the assignment concerns a lecture/patient story directed to health institutions or the general public, the consultant may only share the experience of their, or related ones', illness and possible care, not about specific medicines, treatments or vaccinations. Prior to the engagement, the enquiry must be made to the responsible persons within the organisation who shall decide whether to accept the assignment.

A written agreement should be concluded between the organisation of the representative and the pharmaceutical company, regulating the remuneration for the assignment, which should be reasonable in relation to the performed work and time spent. The pharmaceutical company

may pay for travel, boarding and accommodation relating to the consultation assignment provided that the costs are moderate. No other benefits, remunerations or gifts may occur. In relation to public announcements, the pharmaceutical company must announce that the representative is a consultant of the pharmaceutical company.

*Information and educational materials*

In aids and patient support programmes, no gift items may be provided, offered or promised to organisations and their representatives or patients/related parties. However, product-neutral information and educational materials and aids may be distributed provided that the material is:

- of a value not exceeding SEK450; and
- constitutes relevant information for the general public/patient, eg, regarding a disease.

Pharmaceutical companies may provide product-neutral patient support programmes of various kinds to patients, eg, materials, applications, lectures, support, etc, with the primary purpose of safeguarding patient safety and improving the patient's ability to manage their illness. A product-specific patient support programme for prescription-only medicines may only be provided to patients who have been prescribed the product, which may be ensured by information about the patient support programme being provided by the relevant healthcare institution.

*General rules*

The general rules for co-operation, collaboration must be transparent. In all information materials and invitations, it must be made clear that it is a collaborative project. These rules also apply to advertising or PR agencies.

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

The Medicinal Products Act and LVFS 2009:6 set out general rules for advertising of medicinal products to healthcare professionals. In particular, LVFS 2009:6 states that all advertising must include essential information that corresponds to the SmPC and the supply classification of the medicinal product. The documentation relating to the advertising must include the date it was drawn up or last revised.

The advertisement must be accurate, up-to-date, verifiable and sufficiently complete in order for the recipient to form their own opinion about the product's therapeutic value. Furthermore, any quotations, tables or other illustrative material from medical journals or other scientific works that are used in the advertising must include the source.

The LER Rules contain slightly more detailed rules on what information advertising must include. Provided that the FASS catalogue text or the SmPC is not reproduced, the information must, as a minimum, encompass the following data according to the LER Rules:

- the product's name;
- its dosage form and, if required, its strength (it is required to include the strength if the product, eg, is offered in different strengths);
- its active ingredients, indicated by the generic name;
- a balanced statement of the product's characteristics, including particulars of the pharmacological group or other accepted group affiliations and indication/area of indications;

- warnings and restrictions in relation to the use of the product;
- name and contact information (address or telephone number or web address) of the manufacturer or of its representative who is responsible for the medicinal product information in Sweden;
- information on the year of publication or the date when the webpage was last updated if advertising occurs on the internet;
- information regarding the date the SmPC was compiled or reviewed;
- the status of the product (whether it is a prescription-only or OTC medicine);
- if the product is included in the Swedish benefits system, including any restrictions, and if it is included in the benefits system, the sales price for the subsidised package (it is, however, not necessary to state the price as such); and
- a reference to fass.se for further information.

Advertising directed to health care professionals that do not constitute licensed health care personnel has been considered incorrect in IGN's review.

### 5.2 Reference to Data Not Included in the Summary of Product Characteristics

As a rule, advertisements of medicinal products may not contain information, such as therapeutic indications, pharmacological properties or other characteristics, which conflict with the SmPC.

However, according to a decision from NBL, references to new studies that which did not constitute the basis in the SmPC is allowed in accordance with the judgment from the Court of Justice of the European Union in case C-249/09, Novo Nordisk AS v Ravimiamet. In light of this judgment, it can be concluded that claims in advertising may under certain conditions supplement the information in the SmPC. This is conditional upon the fact that that those claims confirm or clarify – and are compatible with – the SmPC information and do not distort it. This possibility is limited to advertising that are targeting persons qualified to prescribe or supply medicinal products.

Notwithstanding the above, advertising to persons with no specific medical knowledge must in all parts correspond to the SmPC. It is, however, not necessary to have a literal conformity between the advertising and the SmPC, but the advertising must have factual support in the SmPC.

### 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

There are no explicit rules which address advertising of combination products or companion diagnostics. The general rule is however that advertisements of medicinal products may not contain information such as therapeutic indications, pharmacological properties or other characteristics, which conflict with, or are not included in, the SmPC.

### 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

As a main rule, information relating to human health or diseases, eg, in a form of a reprint of a journal article, will not be considered as advertising, provided that there is no direct or indirect reference to medicinal products. The same applies to correspondence, accompanied with non-promotional material, which is required to respond to a specific query from a healthcare professional regarding a medicinal product. It should, however, be noted that journal articles concerning unauthorised medicinal products or indications may constitute unlawful pre-launch or off-label advertising.

Furthermore, the LER Rules contain rules regarding the distribution of information and educa-

tional material to healthcare professionals. Such material may be provided if it is of a value not exceeding SEK450, is of a direct professional relevance to the recipient and to the direct benefit of patient care.

### 5.5 Medical Science Liaisons

The general rule is that advertising of unauthorised medicines or indications is prohibited. For instance, providing unsolicited information on unauthorised medicinal products or indications to healthcare professionals may constitute unlawful pre-launch or off-label advertising. Accordingly, the lawfulness of MSLs will depend on whether the discussion of scientific information is purely informational and does not have a commercial purpose. However, if the discussions are considered to be an inducement to, eg, prescribe off-label use for a specific product, it will be deemed unlawful. This will be assessed on a case-by-case basis.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

Advertising of medicinal products is not subject to prior authorisation from or notification to public authorities. However, according to the LER Rules, in order for the IGN to perform its task as a supervising regulatory body, pharmaceutical companies are required to send new medicinal product information to IGN, such as publications, advertisements, invitations, mailings or information on websites. This applies to information to both the general public and to healthcare professionals.

### 6.2 Compliance with Rules on Medicinal Advertising

There are no rules for arrangements or requirements regarding ensuring compliance with rules on medicinal advertising.

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

The same rules are applicable on advertising of medicinal products irrespective of the medium used, ie, the applicable provisions are technology-neutral in this respect. Accordingly, the Medicinal Products Act, LVFS 2009:6, the Marketing Practices Act and the LER Rules will apply to advertising on the internet and social media.

Moreover, LIF has adopted interpretative documents which provide guidance on how the LER Rules should be applied on advertising in digital media, eg, through social media platforms, mobile applications and podcasts.

### 7.2 Advertising of Medicines on Social Media

There are no specific restrictions in relation to advertising of medicines in social media channels. Such advertisement must always comply with the Medicinal Products Act, LVFS 2009:6, the Marketing Practices Act and the LER Rules.

It should be noted that social media, in its general use, is considered to target the general public. However, certain platforms provide the possibility to target the advertising against a specific group, such as healthcare professionals. For instance, closed groups can be used on Facebook and Sponsored InMail can be used on LinkedIn.

LIF's interpretative documents highlight a few aspects that should be considered in relation to advertising on social media. For example, it is stated that posting texts regarding new findings may be unlawful pre-launch advertising. Furthermore, it is stated that a pharmaceutical company is responsible for the content on the applicable social media platform. This means, for instance, that if someone is commenting on the company's post, the company is responsible to remove the comment, eg, if it concerns information regarding a prescription-only medicinal product, which may target the general public. Also, if a pharmaceutical company uses "social influencers" in its advertising, it is stated that the company is responsible for the content in the influencer's communication.

### Demands on Visual and Digital Advertising

A clickable "green box" enables advertisements for OTC medicines on smartphones, tablets, in two steps. The main advertisement must contain mandatory information about reading the package leaflet and indication, and contain a reference to an extended field where other mandatory information is presented. In order to comply with these guidelines, the advertisement must have the following format:

- the advertisement must be marked with a green field in the entire width of the advertisement which should constitute at least one fifth of the total area of the advertisement;
- the green field is marked with a standardised symbol, a white-coloured cross in a white circle, and the following heading "Over-the-counter medicine", as well as the text "Read the package leaflet carefully before use";
- the green field must contain a clickable field or the possibility to scroll on to the remaining part of the mandatory information, marked, eg, with the text "read more here"; and
- the advertisement and the mandatory information must appear together in a uniform manner and all text reproduced in the advertisement must be easy to read.

## 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

At the moment, it is not a requirement to implement access restrictions. An identification request is adequate. However, it may be useful to include access restrictions to ensure that the advertising is not targeting the general public.

Further, if a restricted access website includes forum functionalities where website users can discuss a pharmaceutical company's medicines that are authorised for sale in Sweden, this may be associated with difficulties. If healthcare personnel, eg, start discussing off-label prescribing, this may constitute prohibited advertising, for which the pharmaceutical company is responsible.

A pharmaceutical company may not allow healthcare personnel to participate in medicine information and/or express themselves as a guarantor of a particular medicine or advocate a particular treatment. If, eg, the forum contains too much information about a particular medicine, this may indirectly be interpreted as advertising. This implies that the pharmaceutical company would have to monitor the forum and remove any inappropriate posts, even if access is restricted.

## 7.4 Provision of Disease Awareness Information to Patients Online

The same rules are applicable on advertising of medicinal products irrespective of the medium used, ie, the applicable provisions are technology-neutral in this respect. Information and/or materials regarding human health or diseases, eg, disease awareness campaigns, are not covered by the term advertising and is thus allowed provided that the information and/or materials

do not include any direct or indirect reference or claim regarding medicinal products.

### 7.5 Online Scientific Meetings

Online scientific meetings are not separately regulated in Sweden. The regular provisions regarding scientific meetings in the LER Rules apply, eg, in relation to restrictions and requirements for sponsorship, please refer to **9.3 Sponsorship of Scientific Meetings**. In relation to information materials, etc, provided during an event, the general rules apply, thus it is not allowed to offer gifts to health care professionals. However, information and educational material may be provided only if the material is of a value not exceeding SEK450, is of a direct professional relevance to the recipient and to the direct benefit of patient care. Further, advertising of unauthorised medicines or indications is in general prohibited.

This prohibition applies to advertising to healthcare professionals, as well as advertising to the general public. Sending unsolicited information on unauthorised medicinal products or indications to healthcare professionals may thus constitute unlawful pre-launch or off-label advertising. Pharmaceutical companies should include a statement explaining to participants when entering their event to help them understand the context by which the material was developed and to highlight that the content may not be applicable to their country.

#### National/International Events

Depending on, eg, whether the event is marketed exclusively in Sweden or internationally, and whether invitations are sent to Swedish healthcare professionals only or even to international professionals, an online conference may be considered a national or international event. As stated in **3.2 Provision of Information during a Scientific Conference**, during an international event, it can, eg, be possible to refer to a medicinal product authorised in another country than Sweden. It is thus recommended that organisers enable attendee classification for their events.

#### Prior Authorisation or Approval

No prior authorisation requirement is applied, neither is the new (as of January 2021) requirement from EFPIA for international congresses to be approved through the e4Ethics system, before a sponsorship is carried out (the requirement applies to physical congresses with more than 500 participants and from more than five countries). It is the responsibility of the pharmaceutical company (if the meeting is arranged by such company) to ensure that content presented at the company's meeting is in accordance with the LER Rules. Ways to ensure this in advance is, eg, to brief lecturers and supervise presentation material.

If lectures are recorded to make the information available afterwards, there is also a responsibility to control the material and remove any parts that would be contrary to the LER Rules (for instance, off-label topics that appear through, eg, questions in the discussion part).

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

The anti-bribery rules are set out in Chapter 10 of the Swedish Penal Code. Under these rules, it is unlawful for an employee or person performing an assignment to receive, accept a promise of or demand an undue benefit for the performance of their employment or duties (bribe-taking). Conversely, it is unlawful for a person to provide,

promise or offer an undue benefit to any of the aforementioned persons (bribe-giving). It should be noted that it is not relevant whether the bribe is of any benefit to the receiving person.

Bribe-taking and bribe-giving constitute two independent crimes, irrespective of whether one would accept the bribe, or vice versa. The rules apply to both the private and public sector.

The rules only apply if the recipient is an individual and not if the recipient is an organisation or a company. However, these entities may be subject to a corporate fine if the company directors have knowledge or should have knowledge that employees are engaging in unlawful activities without taking any action.

Lastly, both the Medicinal Product Act, LVFS 2009:6 and the Marketing Practices Act set out rules on good marketing practice. Giving a bribe to increase the sale of a medicinal product may for example violate such marketing practice and thus be unlawful under these rules.

### 8.2 Legislative or Self-Regulatory Provisions

The offering of benefits is generally not recognised in Sweden. Offering benefits to healthcare professionals should therefore take place with great restraint, towards recipients in both the private and public sectors. The Swedish Penal Code, which is described in **8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals**, is interpreted against the code of conduct within the industry.

Furthermore, the LER Rules set out comprehensive provisions regarding the co-operation between pharmaceutical companies and health care professionals in relation to, eg, meetings arranged by pharmaceutical companies or healthcare companies, consultation and assignments and collaborative projects. These provisions also regulate the offering of, eg, meals, alcohol, recreational activities, donation and grants, etc. All employees, as well as senior management, in the healthcare sector and pharmaceutical companies are subject to these rules. According to the LER Rules, the basis for all co-operation is documentation, transparency, reasonability and it must benefit all parties.

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

It is not allowed to offer gifts to health care professionals. However, information and educational material may be provided only if the material is of a value not exceeding SEK450, is of a direct professional relevance to the recipient and to the direct benefit of patient care.

Items of medical utility may be provided with the purpose of educating employees and for the care of patients provided that they are of a value not exceeding SEK450 and not routinely used in the recipient's business.

Furthermore, there are comprehensive restrictions in relation to offering of, eg, goods, meals and travels towards healthcare professionals.

In any event, the above material may not be offered or distributed as an incentive to recommend, prescribe, purchase, sell or administer medicinal products.

### 9.2 Limitations on Providing Samples to Healthcare Professionals

According to LVFS 2009:6 and the LER Rules, free samples of authorised medicinal products in Sweden may only be provided to:

- those with a pharmacy authorisation or persons responsible for medicinal products at a pharmacy;
- pharmacists at hospital pharmacies (the sample can however only be provided by a healthcare professional);
- other retailers who are authorised to sell the medicinal product; and
- to persons authorised to prescribe the medicinal product.

A pharmaceutical company may only provide a package of the smallest size and the number of samples per product to the same person is limited to one sample per year. In addition, medical samples may only pertain to new products (ie, a product that has been publicly available for less than two years). Each medical sample must be marked with the text "free medical sample, not for sale" or similar and it must be accompanied by the SmPC.

Furthermore, a medical sample may only be provided following a written, dated and signed request by the recipient and a careful check must be made to ensure that the person sending the request is authorised to prescribe or dispense the medicinal product. A medical sample may not constitute an incentive to recommend, prescribe, purchase, sell or administer medicinal products.

## 9.3 Sponsorship of Scientific Meetings

A pharmaceutical company can organise or pay for meetings targeting healthcare professionals. This entails that a company may finance, eg, venue, lectures, study material and meals that are necessary to carry out the meeting.

A main and general condition for arranging or sponsoring a meeting is that the scientific and professional programme constitutes the dominant part and purpose of the meeting. The meeting may only regard the company's own business areas.

### Meals and Travel

Meals should be moderate, and they may only be served in connection with the meetings. Alcoholic drinks must be limited and only be served in connection with meals (spirits may never be offered).

Travel and accommodation for participants may not be financed by the company or requested by the participants. Further, participants may not be offered fees from the pharmaceutical company and the participants are not allowed to request fees for their participation.

### Sponsor Events

Pharmaceutical companies may arrange or sponsor events taking place abroad if the majority of the participants come from another country than Sweden or if relevant knowledge or experience cannot be obtained in Sweden. The choice of location and venue must be reasonable. For instance, seasonal leisure resorts and other luxurious or exclusive places should be avoided (eg, a ski resort during the winter season). The same applies to locations where major international events are being held in connection with the meeting (eg, sports events).

### Events by Healthcare Institutions

For events jointly arranged by the healthcare institutions and the industry, eg, meetings organised by the healthcare institutions, including its professions, and the industry where the parties share responsibilities and costs, there is no sponsorship situation as all parties are deemed organisers.

## 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies are not allowed to finance social or recreational activities in con-

nection with meetings (and they may not be requested by healthcare professionals). However, simple social activities (eg, background music or local performances) are allowed if they are not organised or requested by the pharmaceutical companies.

### 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Donations to the healthcare sector are permitted provided that they are made to support research and development. The support in this regard must be intended to be used for real research and development and it may not be given on vague grounds, eg, to a healthcare association which "works towards more research" within a certain area.

Donations may not be provided or requested with the purpose of financing healthcare professionals' or healthcare institutions' social activities or regular business operations. Furthermore, there cannot be any connection between the donation and past, present or future use, recommendation, sale or prescription of the donor's products or services. In addition, the donation may not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

### 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

The general limitations on gifts and other benefits as described above will, in principle, ensure that rebates and discounts cannot be provided to healthcare professionals.

There is no explicit prohibition with regards to rebates and discounts to healthcare institutions. It has occurred that county councils ("Regions") (which are handling the purchase of medicinal products) have entered into agreements with pharmaceutical companies where the company has provided a discount on a medicinal product. These agreements have been subject to criticism, in particular concerning medicinal products that are included in the Swedish benefits system.

Consequently, the Swedish government and the Swedish Association of Local Authorities and Regions (SALAR) have temporarily concluded an agreement stating that no agreements regarding discounts on medicinal products included in the Swedish benefits system may be entered into between Regions and pharmaceuticals companies. If agreements are concluded, the government's financial contribution to that Region will decrease, with an amount corresponding to the discount.

Furthermore, there may be instances where discount arrangements may give rise to unlawful inducements, eg, if a discount applies only after a healthcare provider has purchased a certain amount of products.

### 9.7 Payment for Services Provided by Healthcare Professionals

The LER Rules contain provisions regarding employees and executives in the healthcare sector and their engagements with pharmaceutical companies, eg, in relation to research, education, conferences, product development and their participation on advisory boards. In order for a pharmaceutical company to engage the healthcare professional, there must be a legitimate need to carry out the assignment.

The assignment must be agreed upon in writing between the healthcare professional, its employer and the pharmaceutical company. The agreement should explicitly specify the services to be carried out and how remuneration is to be regulated. Any remuneration must be reasonable in relation to the nature of the assignment and the time spent. Any reimbursement of expenses

must follow the employer's rules for travel and expenses. No other benefits, remuneration or gifts may be provided. If the healthcare professional carries out the assignment as part of normal work duties, the compensation must be paid to the employer.

In the agreement referred to above, there must be an obligation for the healthcare professional to declare that they are a consultant to, or a part-time employee of, the company when they express an opinion in public on a topic relating to the assignment. Also, a consultant should be urged to be transparent with their assignment in relation to other assignments mandated by public authorities or expert bodies.

The engagement with the healthcare professional may not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

### 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

When engaging a healthcare professional for an assignment, consent must be obtained from the healthcare professional's employer through a written agreement, see **9.7 Payment for Services Provided by Healthcare Professionals**.

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

The LER Rules implement the 2013 EFPIA code of disclosure whereby value transfers in the form of, eg, sponsorships, donations and remunerations for consulting services will be made public. Pharmaceutical companies acting on the Swedish market must therefore publicly disclose the persons or organisations in Sweden that have received value transfers in a given year and the total value of these value transfers.

#### Value Transfers

A value transfer refers to direct or indirect transfers in cash or in kind, to or for the benefit of recipients, which are made in development or sale of a medicinal product for human use, irrespective of whether the purpose is promotional.

In relation to value transfers to healthcare professionals, the pharmaceutical company must report the name and address where the person is mainly operating, consultancy fees and expenses for assignments, eg, travel and accommodation.

In relation to value transfers to healthcare organisations, the pharmaceutical company must report the name (eg, hospital, clinic, association) of the organisation, where the organisation mainly carries out its business, donations, contributions to expenses of certain activities (eg, sponsorship costs), consultancy fees, and expenses for assignments, eg, travel and accommodation.

#### Meals, Travel and Accommodation

There is no obligation to report meals (in relation to, eg, conferences), information and education material or items of medical utility. Conference fees as well as financing of travel and accommodation in connection with meetings/conferences are not relevant for Sweden since such arrangements are no longer allowed (since 1 January 2015), see **9.3 Sponsorship of Scientific Meetings**.

The disclosure shall be made in accordance with the template in appendix 1 to the LER Rules. It must be made in Swedish, but it is recommended that it is done in English as well. The disclo-

sure can be made in either LIF's co-operation database or on the pharmaceutical company's website. If disclosure is made on the website, a link to the report must be made in LIF's co-operation database.

Note that there are no exceptions to the disclosure obligation due to COVID-19 incidences, ie, if a value transfer has taken place, it must be reported as such, even if, eg, a possible event was cancelled.

### GDPR

In light of the General Data Protection Regulation (EU) 2016/679 (GDPR), private companies as well as public authorities must comply with comprehensive new legal requirements on the processing of personal data. This has an impact on the publishing of value transfers. According to LIF's opinion, written consent is required from the relevant healthcare professional (eg, a consultant) in order to disclose a value transfer. With regards to healthcare institutions, eg, hospitals, clinics, organisations or a limited liability company, consent is not required according to LIF.

## 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

Disclosure must be made in accordance with rules of the national code that is applicable in the country where the recipient has its principal place of business or its seat. If any of these two are located in a country other than Sweden and if the pharmaceutical company lacks the ability to disclose the value transfer through a group company in the country of destination, the pharmaceutical company must disclose the value transfer in accordance with the LER Rules.

The above rules are applicable to pharmaceutical companies that are members of LIF, the FGL, IML and EFPIA.

# 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

## 11.1 Pharmaceutical Advertising: Enforcement Bodies

The MPA is responsible for the supervising and enforcement of the compliance under the Medicinal Products Act and regulations issued under it, eg, LVFS 2009:6. In case of unlawful advertising, the MPA has authority to issue prohibitive injunctions combined with a conditional fine for non-compliance. Decisions by the MPA can be appealed to the Administrative Court in Uppsala.

The Swedish Consumer Agency is responsible for enforcing the general rules on advertising. The Swedish Consumer Agency is led by a Director General who is also the Consumer Ombudsman who represents consumer interests and has authority to issue prohibitive injunctions combined with a conditional fine for non-compliance with the Marketing Practices Act. Decisions by the Consumer Ombudsman can be appealed to the Patent and Market Court. The Consumer Ombudsman may also, under certain conditions, pursue legal action in court, where the Patent and Market Court and the Patent and Market Court of Appeal are the competent courts.

IGN and NBL are the self-regulatory bodies under LIF. IGN's competence comprises the review of medicinal product information and determines, on its own initiative or after complaints, whether the pharmaceutical companies' marketing activities comply with good marketing practice. It may also refer a matter to the NBL. NBL's competence includes, eg, handling appealed matters from IGN or LIF's compliance officer and being first and last instance in matters where a public authority has filed a complaint regarding advertising of medicinal products.

The rules relating to inducements in criminal cases are enforced by prosecutors under the Penal Code in civil courts (district courts, courts of appeal and the Supreme Court).

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

A company may file a complaint to the MPA, which may decide to initiate a supervisory matter. A company may also initiate legal actions for, eg, unfair advertising before Act before the Patent and Market Court. Furthermore, it is possible to notify IGN on advertising that is not compliant with the LER Rules.

### 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The main sanction for violations of the advertising rules in the Medicinal Products Act is a prohibitive injunction combined with a conditional fine for non-compliance.

Furthermore, the Marketing Practices Act include numerous sanctions depending on the nature of the violation. For instance, the provisions regarding misleading advertisement may results in the following sanctions issued by the Patent and Market Court:

- prohibitive injunction, which normally is issued with a conditional fine, which according to the Court's practice generally amounts to approximately EUR100,000, however, the conditional fine may be adjusted according to the circumstances on a case-by-case basis;
- special fine (fine for disruptive marketing practices). If imposed, the amount of a market disruption charge is calculated on the basis of the trader's turnover; the amount varies, on a case-by-case basis, from approximately EUR1,000 to EUR1 million but cannot exceed 10% of the trader's yearly turnover; and
- third party damages provided that the trader has intentionally or negligently violated the prohibition on, eg, misleading marketing and that another trader or a consumer have suffered damages thereby.

An action before the Patent and Market Court may be pursued by the Consumer Ombudsman, a competitor, a consumer or a trade or consumer association. It should also be noted that both the MPA and the Consumer Ombudsman may issue an injunction combined with a conditional fine, which the trader may accept in order to avoid legal proceedings in court.

Many matters are handled by the IGN and NBL. Both individuals and pharmaceutical companies may pursue an action before IGN. IGN's and NBL's competence derives from contractual relationships with the members. Under this authority, IGN and NBL may fine members who violate the LER Rules. Fees determined by the IGN and NBL may not exceed SEK500,000.

### 11.4 Relationship between Regulatory Authorities and Courts

As stated in **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines**, the LER Rules are recognised by the pharmaceutical industry and the decisions from IGN and NBL may be considered by courts in relation to, eg, good marketing practice.

Proceedings initiated before IGN or NBL may be filed in parallel with a proceeding before a court or a public authority.

### 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

No deviating enforcement trends relating to the rules governing advertising of medicinal products have been noted in Sweden. However, it

should be noted that the increased use of social media has led to a number of enforcement actions the past few years as well as recently updated social media and digital advertising guidelines by LIF. The social media guideline describes the most widely used digital channels in Sweden, eg, social media platforms, mobile applications and podcasts, and how they can be used to communicate to the public as well as to healthcare professionals.

The digital advertising guideline imposes a standard for the visual design of digital advertising, with the purpose of ensuring a balance between advertising messages and mandatory information, which satisfies user-friendliness and all regulatory and industry ethical requirements, despite the limited size of screen and advertising space, that advertising in mobile devices entails. Since the development of digital channels is rapid, documents are continuously updated, and it is valuable for pharmaceutical companies to stay updated in relation to these guidelines.

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**Advokatfirman Vinge KB** is a full-service business law firm with offices in Stockholm, Gothenburg, Malmö, Helsingborg and Brussels. The firm's intellectual property and life science groups, which consist of approximately 35 lawyers, have expertise in marketing-related consultancy in specialised sectors such as the biotechnology, pharmaceuticals and med-tech industries and have extensive experience of legal market assessments, including advertising campaigns, product launches, product liability, compliance, marketing and advertising strategies. Vinge offers a full-service IP concept within three key areas: contentious, non-contentious and prosecution (patent prosecution in collaboration with patent agency firms). Biotechnology, pharmaceuticals and medtech are a few of the key practices areas, and the team is continuously assisting both national and international pharmaceutical companies with negotiation and drafting a wide range of pharmaceutical-related agreements as well as advertising and compliance within the pharmaceutical sector.

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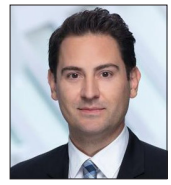

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VINGE

# SWITZERLAND

## Law and Practice

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## CONTENTS

# 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

## 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The advertising of medicines in Switzerland is mainly governed by the Federal Act on Medicinal Products and Medical Devices ("TPA") and the Ordinance on Advertising of Medical Products ("AWV").

Furthermore, there are also general legal provisions that must be adhered to in connection with advertising, such as the Federal Act against Unfair Competition ("UWG"). In addition, provisions in connection with advertising can also be found in the Ordinance on Healthcare Insurance ("KVV") and the Federal Act on the Medical Profession ("MedBG").

The Swiss Agency for Therapeutic Products ("Swissmedic") has published several guidelines with regard to advertising on medicines.

Both the Code of Conduct of the Pharmaceutical Industry in Switzerland ("Pharma Code") and the Code of Conduct of the Pharmaceutical Industry in Switzerland on Cooperation with Healthcare Professional Circles and Patient Organisations ("Pharma Cooperation Code") are self-regulatory codes and contain provisions in connection with the advertising of medicines. Revised versions of the Pharma Code and the Pharma Cooperation Code came into force on 1 January 2021. Furthermore, the Guidelines on Collaboration between the Medical Profession and Industry (2013 version) by the Swiss Academy of Medical Sciences ("SAMW") comprise provisions regarding clinical research, basic and postgraduate medical training and continuing medical education, consultancy activities and acceptance of payments in cash or in kind.

## 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Both the Pharma Code and the Pharma Cooperation Code were adopted by the Associations of the Pharmaceutical Industry in Switzerland. The signatories of the Pharma Code and of the Pharma Cooperation Code are listed online (eg, on www.scienceindustries.ch). These codes bind the vast majority of pharmaceutical companies in Switzerland and contain detailed provisions with regard to the authority of the Code Secretariat in case of breaches of the codes as well as the procedures to follow (Rule 7 Pharma Code; Rule 5 Pharma Cooperation Code).

The Guidelines on Collaboration between the Medical Profession and Industry by the SAMW are relevant for healthcare professionals. They are applicable to all members of the *Foederatio Medicorum Helveticorum* (FMH), which is the professional association of more than 42,000 Swiss doctors and the umbrella organisation of over 70 medical organisations (Article 18 of the Code of Professional Conduct of the FMH).

# 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

## 2.1 Definition of Advertising

Advertising of medicines is defined as all information, marketing and incentivising measures aimed at promoting the prescription, supply, sale, consumption or use of medicines (Article 2 littera a AWV). However, general information on health and diseases without any direct or indirect references to individual medicines as well as catalogues or price lists that do not contain any medical data are not considered to constitute advertising. Furthermore, the packaging material and the drug information are also not deemed to be advertising (Article 1, paragraph 2 AWV).

Monetary benefits to healthcare professionals and healthcare organisations may be considered advertising. However, except for sample packaging, this form of advertising is regulated by the Ordinance on Integrity and Transparency in Relation to Therapeutic Products ("VITH"), not by the AWV.

## 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

General information on health and diseases is not considered to be advertising as long as there are no direct or indirect references to individual medicines. Therefore, general information will become advertising if an active substance is named in connection with a measure aiming at promoting the sale of a particular medicine containing the said active substance.

Since the packaging material and the drug information are not subject to the AWV, they may – in principle – be made available to the public in connection with general information on health and diseases. However, if packaging material and drug information are made available in connection with information on a particular disease and possible treatments, they may be considered to be a direct or indirect reference to an individual medicine and therefore to constitute advertising. If general information on health and diseases fulfils the criteria of completeness, objectivity and balance, a link to the homepage of "swissmedicinfo" would, however, be conceivable.

In light of the mentioned rules, disease awareness campaigns and other patient-facing information do not qualify as advertising if there are no direct or indirect references to individual medicines.

### Advertising to Target Groups

With regard to advertising to the public, general information on health and diseases may not contain any references to prescription medicines (Article 32, paragraph 2 lit a TPA; Article 14 AWV).

Advertising aimed exclusively at people prescribing or dispensing these pharmaceuticals (ie, healthcare professionals) is, in principle, permitted for all types of medicines (Article 31, paragraph 1 lit a TPA).

## 2.3 Restrictions on Press Releases regarding Medicines

Press releases regarding individual medicines are allowed in principle. However, if a press release falls within the definition of advertising, ie, if the information provided aims at promoting the prescription, supply, sale, consumption or use of a medicine, the restrictions with regard to advertising must be adhered to. In particular, press releases accessible to the public may not contain any references to prescription medicines. As such, press releases referring directly or indirectly to prescription medicines must be exclusively accessible to healthcare professionals and must have password protection (as is the case for advertising to healthcare professionals; Article 5a AWV).

If articles and contributions from other media about a company or its medicines are offered on the website of that company (press reviews), the content of these articles and contributions is attributed to that company in terms of advertising law. Therefore, the provisions of the AWV are fully applicable to such press reviews (Swissmedic Journal 8/2006, page 796 et seq).

Furthermore, advertising must be recognisable as such; advertising and editorial contributions must be clearly separated (Article 5, paragraph 4 AWV).

### 2.4 Comparative Advertising for Medicines

Statements relating to comparisons with other medicines are generally permitted if they are scientifically correct and based on equivalent clinical trials or data collections. Clinical trials must have been conducted in accordance with the rules of good clinical practice and be published or accepted for publication. Data collections (such as meta-analysis or practical experience reports) must have been published in a scientifically recognised specialist medium. If studies used for comparison purposes are based on experiments in vitro or on animals, this must be openly disclosed (Article 7 AWV).

Furthermore, it is prohibited to disparage others, their goods or prices by making incorrect, misleading or unnecessarily offensive statements or to take measures that are likely to cause confusion with their goods. It is also prohibited to compare oneself, one's goods or prices in an incorrect, misleading, unnecessarily disparaging or similar manner with others, their goods or prices. Such advertising would constitute unfair competition (Article 3, paragraph 1 lit a, d and e UWG).

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

All information given in advertising must be in accordance with the drug information most recently approved by Swissmedic. In particular, only indications and application possibilities approved by Swissmedic may be advertised (Article 32, paragraph 1 lit c TPA; Article 5, paragraph 1; and Article 16, paragraph 1 AWV).

### 3.2 Provision of Information during a Scientific Conference

Information on unauthorised medicines can be provided during a scientific conference directed at healthcare professionals. However, no promotion of such medicines is allowed. The same applies to new indications, possible applications, dosages, pharmaceutical forms and packaging of a medicine. With this information, it must always be clearly stated that this medicine, or the new indication, possible application, dosage, pharmaceutical form or packaging for the medicine has not yet received marketing authorisation from Swissmedic (Article 32, paragraph 1 lit c TPA; Article 5, paragraph 1 AWV; and Rules 26.2 and 26.3 Pharma Code).

### 3.3 Provision of Information to Healthcare Professionals

Sending information on unauthorised medicines to healthcare professionals is permitted. However, no promotion of such medicines is allowed. The same applies to new indications, possible applications, dosages, pharmaceutical forms and packaging of a medicine. With such information, it must always be clearly stated that this medicine, or the new indication, possible application, dosage, pharmaceutical form or packaging for the medicine has not yet received marketing authorisation from Swissmedic (Article 32, paragraph 1 lit c TPA; Article 5, paragraph 1 AWV; and Rules 26.2 and 26.3 Pharma Code).

### 3.4 Provision of Information to Healthcare Institutions

Healthcare institutions in Switzerland generally do not need to prepare budgets for medicines because the majority of medicines are listed in the "list of specialities" (SL) and therefore reimbursed by compulsory healthcare insurances. The prices of these listed medicines are deter-

mined by the authorities, generally after their approval and before their release on the Swiss market. Consequently, there is no reason to send information on unauthorised medicines or unauthorised indications to healthcare institutions solely for budget reasons. It is thus likely that such information would be considered to be prohibited advertising to the public (Article 16, paragraph 1 AWV).

### 3.5 Publication of Compassionate Use Programmes

Patients who are to be treated with a product that has been successfully tested in clinical trials in Switzerland but has not yet received marketing authorisation, can be treated outside a clinical trial. For this purpose, the sponsor of the clinical trial must apply for a temporary licence for the use of pharmaceuticals in accordance with Article 9b, paragraph 1 TPA. The authorisation is granted by Swissmedic and allows the sponsor to make this pharmaceutical available for use in Switzerland.

All information given in advertising must be in accordance with the drug information most recently approved by Swissmedic. In particular, only indications and application possibilities approved by Swissmedic may be advertised (Article 32, paragraph 1 lit c TPA; Article 5, paragraph 1; and Article 16, paragraph 1 AWV).

Publishing the availability of compassionate use programmes to the public is unlawful promotion.

When informing healthcare professionals about the availability of compassionate use programmes or other forms of early access, such information should solely be communicated with the healthcare professional directly or, in case of an institution, through the medical department and not through the sales or marketing department, otherwise, the information about the unauthorised medicines could be considered an advertisement, which is prohibited.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

#### Forbidden Advertising

Advertising directed at the general public for prescription-only medicines is prohibited, whereas advertising for over-the-counter medicines is permitted. Advertising directed at the general public is deemed unlawful for medicines that contain narcotic or psychotropic substances and for medicines that may not, on account of their composition and their intended use, be used without the intervention of a doctor for the necessary diagnosis, prescription or treatment. This also applies to medicines that are frequently the object of abuse or that lead to an addiction or dependence. Furthermore, all advertising is deemed unlawful if it is misleading or contrary to public order and morality; if it may incite an excessive, abusive or inappropriate use of medicines; or if it is for medicines that may not be placed on the market in Switzerland (Article 31, paragraph 1 lit b and Article 32 TPA; Article 14 AWV).

#### Exclusion from the SL

According to the KVV, medicines that are advertised to the public will not be included in the SL. Medicines included on the SL will be deleted if the marketing authorisation-holder directly or indirectly advertises the medicine to the public (Article 65, paragraph 2 and Article 68 paragraph 1 lit d KVV). A medicine that is not listed on the SL is not covered by compulsory healthcare insurance.

### Unfair Competition Provisions

All advertisements directed at the public are further subject to the provisions regarding unfair competition. Any behaviour or business conduct that is deceptive or otherwise contrary to the principle of good faith and that affects the relationship between competitors or between suppliers and customers is deemed unlawful (Article 2 UWG). In particular, any company that disparages another company, its goods or prices by making incorrect, misleading or unnecessarily offensive statements or that takes measures that are likely to cause confusion with its own goods, acts unfairly. It is further prohibited to compare a company or a company's goods or prices in an incorrect, misleading or unnecessarily disparaging or comparative manner with others, their goods or prices (Article 3, paragraph 1 lit a, d and e UWG).

## 4.2 Information Contained in Pharmaceutical Advertising to the General Public

### General Requirements

All information in advertising, especially indications and possible applications, must be in accordance with the drug information most recently approved by Swissmedic. The presentation of the properties of a medicine as described in words, images and sounds must be factually correctly and without exaggeration. The advertising must be recognisable as such and clearly distinguishable from editorial contributions. A medicine, an indication, a dosage, a galenic form or a package may be advertised as "new" for 18 months after its first authorisation in Switzerland and it must be clearly indicated what this attribute refers to.

Medicines in supply categories C and D must be clearly presented as such and any advertising for these medicines must include at least the name of the product, the authorisation-holder and at least one indication or possible use. It must further include the explicit and legible reference, in the case of a medicine with a package leaflet, "This is an authorised medicine. Read the package leaflet" or, in the case of a medicine without a package leaflet, "This is an authorised medicine. Read the information on the package" (Article 16 AWV).

### Advertising in Electronic Media

There are certain special provisions for advertising of medicines of categories C and D in electronic media. For television commercials and cinema advertising, a note with the following message must be displayed at the end: "This is an authorised medicine. Read the package leaflet" or, in the case of a medicine without a package leaflet, "This is an authorised medicine. Ask a specialist for advice and read the information on the package". This notice must be displayed legibly on a neutral background in a font block size of at least one third the size of the overall picture.

In the case of cinema advertising, the notice should be in at least the font size customary for subtitles and, at the same time, this notice must be clearly spoken. In the case of radio spots, a note with the following wording must be inserted at the end: "[product name] is an authorised medicine. Ask a specialist for advice and read the package leaflet" or, for medicines without a package leaflet: "[product name] is an approved medicine. Ask a specialist for advice and read the information on the package". This notice must be spoken in a manner that is easily comprehensible.

Advertising on electronic display boards must display the following message at the end: "This is an authorised medicine. Ask a specialist for advice and read the package leaflet" or, for medicines without a package leaflet: "This is an authorised medicine. Ask a specialist for advice and read the information on the package". This

notice must be displayed legibly on a neutral background in a text block at least one third the size of the advertisement and for at least five seconds (Article 17 AWV).

### Advertising with Authorisation Status

While medicines in supply categories C and D must use the reference to their authorisation status in any advertisements, medicines in supply category E may not use their authorisation status in advertising (Article 17a AWV).

### Brand Advertising

In advertising that is only intended to recall a certain brand, only the product name or additionally the name of the marketing authorisation-holder may be mentioned. Brand advertising is not permitted in cinemas, on the radio or on television (Article 18 AWV).

### Radio and Television Advertising

Advertising on radio and television for medicines for human use containing alcohol and intended for oral use is only permitted if the maximum single dose of these products according to the recommended dosage contains less than 0.5 g of pure alcohol (Article 20 AWV). Advertising directed at the general public may not include indications or applications for which a medical diagnosis or treatment is required. It may not be obtrusive, blatant or appear to be an editorial contribution.

### Prohibited Advertising

Orders for medicines may not be accepted on the occasion of home visits, exhibitions, lectures or the likes. Furthermore, the direct distribution of medicines for the purpose of sales promotions as well as vouchers and competitions are prohibited. Finally, advertisements may also not include any invitation to contact the marketing authorisation-holder. Some of the mentioned prohibitions do not, however, apply to medicines in category E (Article 21 AWV).

### Prohibited Elements of Advertising

Advertisements may not make a medical examination or surgical intervention appear superfluous, promise a guaranteed effect or claim that the product has no undesirable effects. In addition, advertising may not raise the expectation that the effect of a medicine corresponds to another treatment or to the effect of another medicine, or that it is superior to them. It also may not give rise to the expectation that the condition of a healthy person will be improved with, or that their condition will deteriorate without, the use of the medicine.

Advertisements may never be aimed mainly or exclusively at children or adolescents, or mention scientific publications, clinical studies, expert opinions, reports or recommendations by scientists, healthcare professionals, well-known personalities or medical–pharmaceutical lay persons. Furthermore, they may not show persons in the professional clothing of medical personnel, druggists or medical assistants or during medical activities specific to the profession.

The use of misleading, fictitious or not recognised titles or distinctions is prohibited, as well as any phrases that may induce fear. The advertisement may not equate the medicine to food, feed, care products or other commodities or suggest that the safety or efficacy of the medicine is due to the fact that it is a “natural product” or the like. In no way may the advertisement lead to a false self-diagnosis through the presentation of a medical history nor may it use in an abusive, alarming or misleading manner visual representations of changes that the human body or parts thereof have undergone as a result of disease, injury or the effect of a medicine. Finally, the number of persons treated may not be disclosed (Article 22 AWV).

### 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

The Pharma Cooperation Code applies to, among others, co-operation between pharmaceutical companies and patient organisations. It states that such co-operation and the pecuniary benefits granted in return must not constitute an inducement to recommend, prescribe, acquire, supply, sell or administer specific medicines. Pharmaceutical companies may not offer, promise or grant any inappropriate benefits to patient organisations including, in particular, any gifts (either in cash or non-cash considerations; Rule 15 Pharma Cooperation Code).

#### Financial Support

The Pharma Cooperation Code contains various further provisions and principles in this regard in Rule 3. An important principle is the independence of patient organisations. Pharmaceutical companies may not demand to be the sole pharmaceutical company to provide financial or other support to a patient organisation, both for overall support and support for individual projects. Furthermore, pharmaceutical companies may neither require patient organisations to promote certain specific prescription-only medicines nor may they agree to requests in this regard made by patient organisations. In addition, the aims, scope and agreement on support and partnerships must be evidenced in writing and be transparent.

Pharmaceutical companies must disclose the annual pecuniary benefits that they have granted to individual patient organisations and make such information accessible to the public for at least three years after the date of disclosure.

#### Consultancy

The Pharma Cooperation Code further states that consultancy and services by patient organisations are permitted only if such consultancy tasks or services are provided to support healthcare or research. The need for the consultancy tasks or services must be justified and clearly designated and documented in the written agreement. The scope of the consultancy tasks or services must be no greater than is reasonably necessary to satisfy the specified requirement. Furthermore, the contractually retained pharmaceutical company must record the consultancy tasks and services provided and make expedient use thereof.

The compensation for the consultancy tasks or services must be reasonable and may not exceed the normal market value of such consultancy tasks or services. In this connection, no sham contracts may be concluded to justify payments to patient organisations. The pharmaceutical companies must include provisions in their contracts with patient organisations stipulating that the patient organisation must disclose the fact that it has provided paid consultancy tasks or services for the pharmaceutical company whenever it writes or speaks in public on a topic that is the subject of the contract or on other matters that relate to the particular pharmaceutical company.

#### Events and Hospitality

In connection with events and hospitality, the Pharma Cooperation Code specifies that events are to be held on premises that are appropriate and conducive to the main purpose of the event. Their choice should be guided primarily by space and infrastructure availability with a view to the appropriate performance of the main purpose. Premises that are famous for their entertainment facilities or regarded as extravagant are to be avoided.

Hospitality in connection with events must be confined to the journey, subsistence, accommodation and participation fees. In principle, hospitality may only be granted to persons who are

entitled to it as participants. Hospitality must not include the support (sponsorship) or organisation of entertainment (eg, sport or leisure activities). In principle, pharmaceutical companies may not organise or sponsor events that are held outside Switzerland.

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

As a general rule, all advertising is deemed unlawful if it is misleading or contrary to public order and morality; if it may incite excessive, abusive or inappropriate use of medicines; or if it is for medicines that may not be placed on the market in Switzerland (Article 32, paragraph 1 TPA). All information given in advertising to professionals must be in accordance with the drug information most recently approved by Swissmedic. In particular, only indications and possible applications approved by Swissmedic may be advertised. If the drug information has not yet been published, the marketing authorisation-holder must include the complete content of the drug information last approved by Swissmedic in the advertisement. Advertising to professionals must be precise, well balanced, factually accurate and provable. The statements must not be misleading, and supporting documents must be made available to healthcare professionals upon request. Advertising must be recognisable as such and must be clearly distinguishable from editorial contributions. Advertising statements must be based on and reflect the current state of scientific knowledge.

Advertising statements may only refer to clinical trials that were conducted in accordance with the rules of good clinical practice and that have been published or accepted for publication, and to data collections, such as meta-analysis or reports on practical experience, that have been published in a scientifically recognised specialist medium. These publications must be quoted verbatim, completely and with their exact source. It must be indicated that the healthcare professionals can request a complete copy of the examination report and the corresponding references from the company.

#### "New" Medicines

A medicine, an indication, a dosage, a galenic form or a package may be advertised as "new" for 18 months after the first authorisation in Switzerland. The information must clearly indicate what this attribute refers to. Advertising of complementary medicines must be based on scientifically recognised specialist media or recognised monographs of complementary medicine. Advertising statements in this regard must contain a reference to the respective therapy direction (Article 5 AWV).

#### Mandatory Information

Advertisements to healthcare professionals must contain certain information. It is mandatory to include the name of the product, the active ingredients with the short designations (DCI/INN or designation of the most recent edition of the Pharmacopoeia; or, in the absence thereof, other generally recognised short designations approved by Swissmedic), the name and address of the marketing authorisation-holder and at least one indication or possible use, as well as the dosage and the method of application.

Furthermore, a summary of restrictions on use, adverse reactions and interactions must be added. The supply category is to be indicated along with a statement that detailed information is to be found in the published drug information, cit-

ing the list in Article 67, paragraph 3 or Article 95b TPA as a reference (Article 6 AWV).

### 5.2 Reference to Data Not Included in the Summary of Product Characteristics

Advertising may refer to clinical trials or data collections that are not included in the summary of product characteristics. However, advertising statements must be based on and reflect the current state of scientific knowledge. They may only refer to clinical trials conducted in accordance with the rules of good clinical practice and published or accepted for publication, as well as to data collections such as meta-analysis or reports on practical experience published in a scientifically recognised specialist medium.

These publications must be quoted verbatim, completely and with the exact source. It must be indicated that the healthcare professionals can request a complete copy of the examination report and the corresponding references from the company (Article 5, paragraph 5 AWV).

### 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

Advertising may refer to combination products or companion diagnostics that are not included in the summary of product characteristics.

However, with regard to advertising to the public, general information on health and diseases may not contain any references to prescription medicines (Article 32, paragraph 2 lit a TPA; Article 14 AWV).

### 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

If articles and contributions from other media about a company or its medicines are offered on the website of that company (press reviews), the content of these articles and contributions is attributed to that company in terms of advertising law. Therefore, the provisions of the AWV are fully applicable to such press reviews (Swissmedic Journal 8/2006, page 796 et seq). The same holds true for reprints of journal articles provided to healthcare professionals. Consequently, the restrictions that apply to advertising to healthcare professionals must be adhered to in connection with such reprints of journal articles. In particular, advertising must be recognisable as such. Therefore, advertising and editorial contributions must be clearly separated (Article 5, paragraph 4 AWV).

### 5.5 Medical Science Liaisons

In Switzerland, there are no special obligations regarding medical science liaisons (MSLs). However, it can be said that it is permitted to discuss scientific information on unauthorised medicines or indications with healthcare professionals if the purpose of the discussion is to obtain scientific input. Nevertheless, it should always be ensured that these discussions are conducted with the healthcare professional directly or, in the case of an institution, with the medical department and not with the marketing and sales department.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

Advertising directed at the general public pursuant to Article 15 lit a (advertisements in newspapers, magazines and books, brochures, posters, newsletters, etc) and lit c AWV (advertising using electronic media such as image, sound and data carriers, as well as application software) for analgesics, sleeping aids, sedatives, laxatives and anorexics must be submitted to Swissmedic for approval prior to publication if the drug information mentions a potential for

abuse or dependence. Swissmedic may require a marketing authorisation-holder who seriously or repeatedly infringes the provisions governing the advertising of medicines to submit to Swissmedic, for a reasonable period of time, all drafts of the planned advertising in the form specified by Swissmedic for review and approval prior to its appearance (Article 23 AWV).

### 6.2 Compliance with Rules on Medicinal Advertising

#### Designated Responsible Person

The marketing authorisation-holder must designate a person who is responsible for advertising the medicines they have placed on the market. This person must have scientific, medical or other appropriate professional training or experience. This person must ensure that the advertising of medicines complies with the according provisions and that Swissmedic's instructions are complied with immediately and in full.

This person must provide Swissmedic with all the required documents and information upon request and ensure that its pharmaceutical representatives are properly trained and comply with the obligations stated in the AWV. Finally, this person must keep a copy of each distributed advertisement for six months after its last intended use, as well as a register of all recipients, the method of distribution and the date of first distribution (Article 25 AWV).

#### Scientific Service

The Pharma Code further states that pharmaceutical companies must set up a scientific service that is responsible for information about their medicines and their promotion to healthcare professionals. The scientific service includes a doctor or, if suitable, a pharmacist or scientist who is responsible for ensuring the conformity of all promotional and information materials with the Pharma Code before they are deployed (Rule 62 Pharma Code).

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

Advertising of medicines on the internet without any access restriction is considered to be advertising to the public (see Article 15 lit c AWV). Therefore, the rules applicable to advertising to the public apply.

If articles and contributions from other media about a company or its medicines are offered on the website of that company (press reviews), the content of these articles and contributions is attributed to that company in terms of advertising law. Therefore, the provisions of the AWV are fully applicable to such press reviews (Swissmedic Journal 8/2006, page 796 et seq).

### 7.2 Advertising of Medicines on Social Media

In Switzerland, advertising on social media must comply with the general rules applicable to advertising on the internet. Therefore, the same restrictions apply as to advertising on the internet.

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

Advertising to healthcare professionals may not be made publicly accessible on the internet. It must be provided with an appropriate technical and password-protected access restriction and may only be made available to doctors, dentists, veterinarians, chiropractors, apothecaries, druggists/pharmacists and other persons authorised to dispense or apply medicines according to Articles 24 and 25 TPA and Article 52, paragraph 2 of the Ordinance on Medicinal Products (VAM; Article 5a AWV).

### 7.4 Provision of Disease Awareness Information to Patients Online

General information on health or on diseases is not considered to be advertising, provided that it does not relate directly or indirectly to specific medicines (Article 1, paragraph 2 lit c AWV).

Companies willing to inform patients about a disease should ensure that they launch an entire campaign informing patients about the disease and its precautions, etc. Promoting a specific medicine would, however, infringe Article 32, paragraph 2 lit a TPA in most cases.

### 7.5 Online Scientific Meetings

Online scientific meetings are not explicitly regulated in Switzerland. It can therefore be assumed that the general rules pursuant to Article 55, paragraph 2 lit b TPA and Articles 5 and 6 VITH, apply. Consequently, pharmaceutical companies may offer healthcare organisations contributions for continuing medical education, provided that the contributions:

- are not offered, promised or granted to a single healthcare professional, but to the organisation employing the healthcare professional;
- are based on a written agreement stating the intended use;
- are used exclusively for the intended purpose;
- are not subject to conditions or requirements concerning the prescription, dispensing, use or purchase of certain prescription medicines;
- are transferred to a designated account of the organisation to which the healthcare professionals do not have individual access; and
- are shown in the accounts of the organisation.

Furthermore, it must be ensured that the organisation providing continuing medical education can decide on the type of education and the participating healthcare professionals independently.

The same applies to sponsoring the virtual attendance by healthcare professionals at these events. Such contributions are permitted if they are agreed on in writing and the participating healthcare professionals or the organisations employing them make an appropriate contribution to the costs of the event (Article 55, paragraph 2 lit b TPA; Article 6, paragraph 1 VITH).

#### Guidelines for Online Meetings

Although Switzerland does not have any specific regulations for online scientific meetings, the Swiss business association, scienceindustries, has enacted some guidelines and recommendations regarding the handling of digital channels.

Since online meetings are not comparable to physical congresses, it may be possible to waive a cost-sharing fee even for events lasting more than half a working day (in deviation from Article 6, paragraph 3 lit b VITH).

In some cases, Swissmedic has classified interactive, electronic and audio-visual training and access to self-study (e-learning and webinars) as benefits of monetary value which are permitted if they do not exceed the amount of CHF300 per healthcare professional per year, or if the healthcare professionals pay the excess themselves.

Many companies seem to have established a cost contribution practice for conferences. In such cases, the cost-sharing calculation is based on the costs that a company has to pay to provide one or more online meetings. The total costs are then divided by the number of people attending and a fifth (for continuing education) or a third (for postgraduate education) is charged to each respective professional (Article 6, paragraph 2 VITH).

Under no circumstances may such sponsoring aim to induce to recommend, prescribe, buy, supply, sell or administer specific medicines

(Rule 15.1 Pharma Code and Pharma Cooperation Code).

### International Participation

Online solutions simplify international participation in above-mentioned events. In the case of international participation, some rules of the Pharma Code must be observed. Information materials that are given out at events with international participation may refer to medicines that are authorised in other countries but not in Switzerland, or that are authorised in Switzerland under different conditions.

Such materials require a reference to the countries where the medicine is authorised and to the fact that the medicine concerned is not authorised in Switzerland, or that it is authorised under different conditions in Switzerland. Furthermore, it is necessary to refer to the possible differences in authorisation requirements and the government-approved professional information in the country or countries where the medicine concerned is authorised (Rule 27 Pharma Code).

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

The bribery offences in criminal law can be found in Article 322 ter et seq of the Swiss Criminal Code (StGB). Article 322 octies StGB (bribery of private individuals) and Article 322 novies StGB (accepting bribes) regulate private corruption and include the criminal liability of both the bribing and the bribed person. The bribed person must be "an employee, partner, agent or any other auxiliary of a third party in the private sector" (Article 322 octies StGB and Article 322 novies StGB).

A doctor with a public function (eg, in a public hospital) may also fall under the active and passive bribery provisions for Swiss public officials (Article 322 ter and Article 322 quater StGB). With regard to Swiss public officials, the acceptance and granting of advantages (so-called climate care/feeding) is also punishable (Article 322 quinquies and Article 322 sexies StGB).

### 8.2 Legislative or Self-Regulatory Provisions

For persons who prescribe, dispense, use or purchase for this purpose prescription medicines, and organisations employing such persons, it is prohibited to claim, be promised or accept any undue advantages for themselves or for the benefit of a third party. Similarly, it is forbidden to offer, promise or grant an undue advantage to any such person or organisation for their benefit or for the benefit of a third party (Article 55, paragraph 1 TPA; Article 3 et seq VITH). All discounts granted to persons or organisations prescribing, supplying, using or purchasing therapeutic products for that purpose must be shown in the accounts of the selling and the purchasing persons and organisations and, upon request, be disclosed to the Federal Office of Public Health (FOPH) (Article 56, paragraph 1 TPA; Article 10 VITH).

However, benefits of modest value that are related to medical or pharmaceutical practice are permitted (Article 55, paragraph 2 lit a TPA). Benefits of modest value must not exceed CHF300 per healthcare professional per year (Article 3, paragraph 1 VITH).

Persons who exercise a university medical profession in the private sector and under their own professional responsibility are obliged to exclusively protect the interests of patients and to

act independently of financial advantages when collaborating with members of other healthcare professions (Article 40 lit e MedBG).

### Obligation to Pass on Financial Advantages

Healthcare professionals must, in principle, pass on direct or indirect financial advantages granted to them by pharmaceutical companies to patients or healthcare insurances with regard to medicines covered by compulsory healthcare insurance (Article 56, paragraph 3 lit b KVG). Under certain conditions, such advantages may be passed on only partially (Article 56, paragraph 3 bis KVG; Article 76a et seq KVV).

### Self-Regulatory Provisions

The Pharma Cooperation Code states that benefits must not constitute an inducement to recommend, prescribe, acquire, supply, sell or administer specific medicines. Pharmaceutical companies may not offer, promise or grant any inappropriate benefits to healthcare professionals, healthcare organisations or patient organisations including, in particular, any gifts (either in cash or non-cash considerations). However, pharmaceutical companies may offer objects, information and training materials of moderate value to healthcare professionals if they are intended solely for medical or pharmaceutical activity, or if they are used for postgraduate or continuing education in medicine or pharmacy, and if they are, in both cases, also beneficial to patients.

The same holds true for writing implements and note pads of modest value that are made available to participants at events by pharmaceutical companies; these writing implements and note pads may, however, not bear any references to the pharmaceutical company or to particular medicines (Rule 15 Pharma Cooperation Code).

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

Benefits of modest value that are related to medical or pharmaceutical practice are permitted (Article 55, paragraph 2 lit a TPA). Such benefits must not exceed CHF300 per healthcare professional per year (Article 3, paragraph 1 VITH).

In connection with a professional discussion, it is permissible to pay for catering costs not exceeding CHF100 (Article 7, paragraph 2 VITH, Rule 15.4 Pharma Code and Pharma Cooperation Code).

### 9.2 Limitations on Providing Samples to Healthcare Professionals

Only a small number of sample packages may be distributed per medicine, per year and per healthcare professional. They may be distributed only on the initiative of the healthcare professional and upon their written request. Sample packages must be clearly and permanently marked as a “free sample”. They must contain the necessary information and texts on the container and packaging material, as well as an approved package leaflet.

In the case of medicines that may be marketed without a package leaflet, the sample package must contain the required information on the container and the packaging material. The sample package must be accompanied by the drug information last approved by Swissmedic or contain a reference to its publication in the list in accordance with Article 67, paragraph 3 or Article 95b TPA. Sample packages must always correspond to the smallest approved package size and may not be sold.

The supply of sample packages containing psychotropic substances or narcotics is subject to

the provisions of the Narcotics Control Ordinance. The marketing authorisation-holder must ensure that records are kept of the distribution of sample packages (Article 10 AWV).

According to Swissmedic, the following quantities qualify as a "small quantity": a maximum of five packages per healthcare professional, per year and per medicine, in the first two years after market introduction, and a maximum of two packages per healthcare professional, per year and per medicine from the third year onwards.

### 9.3 Sponsorship of Scientific Meetings

Contributions for participation in events for postgraduate or continuing education of experts are permitted, provided they are agreed in writing and the participating healthcare professionals or the organisations employing them make an appropriate contribution to the cost of the event (cost contribution). It is prohibited to reimburse the cost contribution in whole or in part, to cover indirect participation costs such as loss of work or income, to cover the costs of supporting programmes that are not clearly of secondary importance, and to cover the costs of travel, accommodation, meals or supporting programmes of persons accompanying the participating healthcare professional. The cost contribution may be waived for healthcare professionals who provide an equivalent service during the event and for events that are held in Switzerland and that last for half a day (Article 55, paragraph 2 lit b TPA; Article 6 VITH).

The Pharma Code states that events that are organised or sponsored by pharmaceutical companies in Switzerland and that are aimed purely at participants from Switzerland should – in principle – take place in Switzerland. Refreshments or meals (including beverages) may be offered only to the participants of the event and must be modest and reasonable according to the customary local standards (in Switzerland, a maximum of CHF100 per healthcare professional per meal). The events should take place at appropriate venues conducive to the main purpose of the event and not be extravagant (Rules 15.4, 31 and 32 Pharma Code; Rule 34 Pharma Cooperation Code; Guideline II 6 of the SAMW).

### 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies must not offer or pay for any entertainment or other leisure or hospitality activities (Article 6, paragraph 4 lit c VITH; Rule 32.5 Pharma Code; Rule 34.5 Pharma Cooperation Code; Guideline II 6 of the SAMW).

### 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

For persons who prescribe, dispense, use or purchase prescription medicines for this purpose, and organisations employing such persons, it is prohibited to claim, be promised or accept any undue advantages for themselves or for the benefit of a third party (Article 55, paragraph 1 TPA; Article 3 et seq VITH). However, benefits of modest value that are related to medical or pharmaceutical practice are permitted (Article 55, paragraph 2 lit a TPA). Such benefits must not exceed CHF300 per healthcare professional per year (Article 3, paragraph 1 VITH).

Financial contributions for research, education and infrastructure are not regarded as undue advantages, provided that certain criteria are met (Article 55, paragraph 2 lit b TPA). Contributions are permissible if the following criteria are met (Article 4 lit a–f VITH):

- the contributions are not offered, promised or granted to an individual professional, but to the organisation that employs the professional;
- the contributions are based on a written agreement stating the intended use;

- the contributions are used solely for their intended purpose;
- the contributions are not subject to conditions or requirements relating to prescription medicines;
- the contributions are transferred to a designated account of the organisation, to which professionals do not have individual access; and
- the contributions are shown in the accounts of the organisation.

Pharmaceutical companies must, however, fully disclose all pecuniary benefits that they grant (Rule 15.6 Pharma Code; Rules 15.6 and 24 et seq Pharma Cooperation Code).

### 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

For persons who prescribe, dispense, use or purchase prescription medicines for this purpose, and organisations employing such persons, it is prohibited to claim, be promised or accept any undue advantages for themselves or for the benefit of a third party. Similarly, it is forbidden to offer, promise or grant an undue advantage to any such person or organisation for their benefit or for the benefit of a third party (Article 55, paragraph 1 TPA; Article 3 et seq VITH). All discounts granted to persons or organisations prescribing, supplying, using or purchasing therapeutic products for that purpose must be shown in the accounts of the selling and the purchasing persons and organisations and, upon request, be disclosed to the FOPH (Article 56, paragraph 1 TPA; Article 10 VITH).

Healthcare professionals must, in principle, pass on direct or indirect financial advantages to patients or healthcare insurances with regard to medicines covered by compulsory healthcare insurance (Article 56, paragraph 3 lit b KVG). Under certain conditions, such advantages may be passed on only partially (Article 56, paragraph 3 bis KVG; Article 76a et seq KVV).

### 9.7 Payment for Services Provided by Healthcare Professionals

Pharmaceutical companies may entrust healthcare professionals with consultancy tasks or services, such as papers and the conduct of meetings; medical or scientific studies; clinical trials; training and participation in consultancy bodies; and provide reasonable compensation for expenditure incurred by them in this connection according to the usual standards.

Such compensation must be based on a written agreement setting forth the nature and extent of the service and the compensation, and be in reasonable proportion to the consideration. Services may not be compensated if:

- the healthcare professional performs such services for their own benefit;
- they must be performed due to legal obligations; or
- they are otherwise remunerated.

Compensation is permitted for:

- services in connection with the purchase of prescription medicines, such as the assumption of logistics expenses, storage costs or storage risk;
- teaching, expert opinions and consulting activities or the performance of scientific studies and clinical trials;
- practical experience reports published in a scientifically recognised professional medium; and
- participation in advisory committees, workshops or in market research, provided there is no advertising purpose (Article 55 paragraph 2 lit c TPA; Article 7 VITH).

According to the Pharma Code and the Pharma Cooperation Code, pharmaceutical companies must fully disclose all pecuniary benefits. They must stipulate in the agreement that the recipients of the pecuniary benefits agree to disclosure (Rule 41 Pharma Code; Rules 21 and 24 et seq Pharma Cooperation Code; see Guidelines III 1–7 of the SAMW).

### 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

No prior authorisations or notifications (eg, regulatory authority approval) are required in relation to any of the activities described in this section. However, whether the consent of an employer is required also depends on the contract between the healthcare professional and the employer.

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

All discounts granted to persons or organisations prescribing, supplying, using or purchasing therapeutic products for that purpose must be shown in the accounts of the selling and the purchasing persons and organisations and, upon request, be disclosed to the FOPH (Article 56, paragraph 1 TPA; Article 10 VITH).

Furthermore, healthcare professionals must, in principle, pass on direct or indirect financial advantages to patients or healthcare insurances with regard to medicines covered by compulsory healthcare insurance (Article 56, paragraph 3 lit b KVG). Under certain conditions, such advantages may be passed on only partially (Article 56, paragraph 3 bis KVG; Article 76a et seq KVV).

According to the Pharma Cooperation Code, pharmaceutical companies are required to fully disclose pecuniary benefits to healthcare professionals and healthcare organisations annually and to keep such information accessible to the public for at least three years after disclosure. The disclosure must, in principle, be made on an individual basis and clearly identify the recipients and the amounts paid. The remuneration for the agreed service or consultancy tasks and the compensation for costs incurred by the service providers must be disclosed separately. The disclosure is to be made on the company's website (Rule 24 et seq Pharma Cooperation Code).

So far, no exceptions to the disclosure obligation have been granted due to the COVID-19 pandemic.

### 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

The transparency requirements apply to foreign companies only if they sell medicines in Switzerland. They also apply to companies that do not, as yet, have products on the market.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

Swissmedic is the regulatory authority responsible for enforcing the rules on advertising as stated in the TPA and the AWV (Article 66, paragraph 1, Articles 82 and 90, paragraph 1 TPA). The FOPH is responsible for monitoring the prohibition of promising and accepting undue benefits, and the cantons are responsible for monitoring the retail trade (Article 66, paragraph 1, Article 82, paragraph 1 and Article 90, paragraph 1 TPA). In addition, the customs authorities are entitled

to detain medicines at the border, in open customs warehouses or duty-free warehouses if the recipient or sender in Switzerland is suspected of violating the provisions on the import, placing on the market or export of medicines with the contents of the consignment (Article 66, paragraph 4 and Article 90, paragraph 1 TPA).

As a general rule, the Federal Administrative Court adjudicates appeals against decisions of Swissmedic, the FOPH and the Federal Customs Administration and the Federal Court adjudicates appeals against decisions by the Federal Administrative Court (Article 84 TPA).

The Code Secretariat is the self-regulatory body that is responsible for the implementation of the Pharma Code and the Pharma Cooperation Code (Rule 7 Pharma Code; Rule 5 Pharma Cooperation Code).

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Swissmedic, the FOPH and the Federal Customs Administration can initiate proceedings against companies for advertising infringements. They have the authority to take administrative measures and to initiate criminal prosecution (Articles 66 and 90, paragraph 1 TPA). Companies may, however, also initiate proceedings against competitors for advertising infringements before the Code Secretariat, which is responsible for the implementation of the Pharma Code and the Pharma Cooperation Code.

If advertising of competitors constitutes unfair competition according to the UWG, companies can initiate proceedings before civil courts.

### 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

A custodial sentence not exceeding three years or a monetary penalty can be imposed on any person who wilfully violates the prohibition of undue advantages according to Article 55 TPA (Article 86, paragraph 1 lit h TPA).

A fine not exceeding CHF50,000 can be imposed on any person who wilfully infringes the obligation of transparency according to Article 56 TPA or who wilfully contravenes the regulations on the advertising of medicines (Article 87, paragraph 1 lit h and b TPA).

In addition, Swissmedic, the FOPH and the Federal Customs Administration may take all administrative measures necessary to enforce the TPA. In particular, they may raise objections and set an appropriate time period for restoring the state of law, suspend or revoke licences and marketing authorisations, and close down establishments. Furthermore, the authorities may also seize, hold in official storage or destroy medicines that endanger health or that do not conform to the regulations of the TPA, as well as prohibit the distribution, dispensing, import, export and foreign trade from Switzerland of medicines, order their immediate recall from the market, or order the publication of recommendations of conduct to prevent damage. Finally, they may seize, hold in official storage, destroy or prohibit the use of illegal advertising media and publish the prohibition at the expense of the responsible parties, as well as temporarily or permanently prohibit the advertising of a specific medicine in the event of serious or repeated infringements of the provisions of the TPA, and publish the prohibition at the expense of the responsible parties (Article 66, paragraphs 1 and 2 TPA).

In addition, Swissmedic may require a marketing authorisation-holder who seriously or repeatedly

infringes the provisions governing the advertising of medicines to submit to Swissmedic, for a reasonable period of time, all drafts of the planned advertising in the form specified by Swissmedic, for review and approval prior to its appearance (Article 23 AWV). Furthermore, the bribery offences in criminal law (Article 322 ter et seq StGB) apply as well (see **8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals**).

### 11.4 Relationship between Regulatory Authorities and Courts

Both the Pharma Code and the Pharma Cooperation Code state that pharmaceutical companies that undertake to comply with these codes acknowledge their rules of enforcement if proceedings are started for breach of a code. As long as relevant proceedings are pending, they will not, in principle, refer the matter at the same time to a state authority or to a court on the grounds of breach of the Swiss legal order. However, the safeguarding of rights, which may be endangered or defeated by compliance with these principles of conduct, is reserved.

### 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

For a long time, Swissmedic has been the main enforcement authority for violations of the TPA. Since 1 January 2020, the FOPH has been granted the power to enforce the new provisions on integrity and transparency in the field of therapeutic products, making it likely that the enforcement of the law will be strengthened.

However, due to the COVID-19 pandemic, the FOPH has not yet had the opportunity to start enforcing the new provisions on integrity and transparency in the field of therapeutic products. This has allowed many companies to review their contracts and to amend them in the past two years.

As there are many uncertainties in connection with these new provisions, it will be interesting to see what the FOPH considers permissible and what priorities it will have when enforcing the new provisions.

**Walder Wyss Ltd** has more than 240 legal experts at its offices in Zurich, Geneva, Basel, Berne, Lausanne and Lugano. The firm has a team dedicated to life sciences and pharmaceutical regulatory law, including healthcare insurance law. The key areas of practice in relation to the pharmaceutical advertising sector are pharmaceutical regulatory law, healthcare insurance law, and the law regarding research on humans and clinical trials, stem cells and blood components, genetic testing, transplantation, special nutrition, medical devices and reproductive medicine. The firm has established www.lifesciencelaw.ch, a website dedicated to all legal issues surrounding life sciences, where case law is discussed and where interested parties can find publications written by the team.

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# Trends and Developments

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## The Main Drivers in Swiss Pharmaceutical Advertising

### *Background*

The pharmaceutical advertising landscape is undergoing significant changes. The regulation of pharmaceutical advertising is being challenged by new and increasingly sophisticated demands. The "pen-and-notepad" days when promotional practice and regulation predominantly focused on direct advertising and gifts are definitely over. In their wake, pharmaceutical advertising is becoming evermore multifaceted and complex, as it develops towards fully integrated and often digital stakeholder relationship-solutions, and at the same time, it is becoming increasingly relevant to neighbouring legal fields such as compliance, litigation and investigations, as well as information governance and data protection.

Crucially, co-operation between the industry and various stakeholders along the entire therapeutic products development and value chain is gaining ever-greater importance. Never has this become more prominent than during the ongoing COVID-19 pandemic: since 2020, at an unprecedented speed, manufacturing and distribution licences and market authorisations have been granted or assessed in Switzerland in connection with the first COVID-19 vaccines and therapeutics. Without manifold co-operation between the industry, research and healthcare professionals, as well as their organisations, research and development would have advanced far less quickly, and therapeutic products would have been less well targeted and would have entered the market much later.

Statistics of the regulatory disclosures of pecuniary benefits granted by pharmaceutical companies in Switzerland show that the amounts paid to healthcare organisations are high (CHF105.3 million in 2019) as compared to the rest of Europe and continue to increase, while the payments to HCPs (CHF11.5 million in 2019) and for research and development (CHF69.1 million in 2019) remain relatively stable. It is therefore all the more important that all parties involved in such collaboration act according to high ethical standards. This was recalled again when, for example, in 2020 allegations arose that a physician at a Swiss university hospital was involved in the clinical testing of medical devices while, at the same time, holding economic interests in the respective manufacturers.

### *Patients as customers*

Complementing the traditional focus on prescribers, patients and their organisations are increasingly being recognised as the true customers of healthcare. As patient-focused alliances become more widespread, integrity and transparency will become ever more crucial. This affects the entire therapeutic products life cycle, from the identification of unmet medical needs, to research and development, to the launch – where better informed regulatory approval discussions and patient-centred value stories come into focus – and the commercialisation, including generation of real-world product knowledge, improvement of the patient experience and treatment adherence, and support for access and reimbursement.

### *Digitalisation*

The pharmaceutical advertising landscape is also shaped by the progress in digital technolo-

gies. Digital engagement of patients and healthcare professionals can take many forms, such as marketing and communication to raise disease and brand awareness, patient community-building on social media, patient education and training, support for treatment adherence and monitoring, patient-generated health data, wearables, apps and devices, pharma-as-a-service, big data, as well as personalised and precision medicine.

At the same time, a new style of patient advocacy is gaining traction, fuelled in part by the new digital means available, but also driven by the increasing focus of the pharmaceutical industry on rare diseases and orphan drugs.

### *The regulatory environment*

In a regulatory environment shaped by a ban on direct-to-consumer advertising of prescription drugs, such as in Switzerland, pharmaceutical companies seek to navigate this challenging landscape with multiple different strategies, including disease awareness programmes, dissemination of scientific drug information and indirect communication through healthcare professionals, healthcare organisations, patients, and patient organisations. Meanwhile, the limits for permissible pharmaceutical advertising are narrow, and enforcement in the area is active, with competitors frequently bringing claims against each other and authorities issuing fines and other orders. Reputational considerations play an important role, too, and put a spotlight on integrity and transparency in particular.

In Switzerland, a series of regulatory and self-regulatory measures and initiatives have recently been, and are still being, put into effect to reflect these changes in the pharmaceutical advertising landscape. They are spread over various different, and partially disparate, regulations, guidelines and best practice codes. This makes navigating the landscape dependent, in large part, on legal and regulatory expertise as well as extensive practical industry experience.

### New Regime on Integrity and Transparency

As of 1 January 2020, a new integrity and transparency regime was introduced into the recently amended Therapeutic Products Act (TPA). The amended regulation shows obvious parallels with the criminal law on corruption in the Criminal Code (CC). The new Ordinance on Integrity and Transparency in the Therapeutic Products Sector (OIT) contains the implementing provisions.

### *Factors influencing treatment*

To enhance integrity, the granting and acceptance of pecuniary advantages in connection with prescription medicinal products are prohibited if they can influence the choice of treatment. Article 55 paragraph 2 TPA and Articles 3 et seq OIT explicitly describe the advantages that are considered permissible. These are, for example, advantages of modest value that are relevant for medicinal or pharmaceutical practice, support for research, education and training as long as certain criteria are met, and compensation for equivalent services in return. Price discounts and refunds granted on the purchase of therapeutic products, too, are permitted if they do not influence the choice of treatment. Healthcare professionals are obliged to pass on these benefits to their patients or their insurers. As a result of a parallel amendment to the Health Insurance Act (HIA), healthcare professionals can agree with insurers to use a smaller portion of the obtained advantages for quality improvement measures (Article 56 paragraph 3 lit b, paragraph 3 bis HIA). As a second core element of the new regime, the granting and acceptance of price discounts and rebates for the purchase of therapeutic products (medicinal products and medical devices) must in principle be made transparent to the Federal Office of Public Health (FOPH) upon request (Article 56 TPA; Article 10 OIT).

### *Violations*

Violations of Articles 55 et seq of the TPA may trigger administrative measures or criminal sanctions against the acting individuals (Articles 66 et seq, Article 86 paragraph 1 lit h, Article 87 paragraph 1 lit h TPA), or even against the companies or their management (Articles 6 et seq Administrative Criminal Law Act; Article 102 CC).

### *Clinical trials*

Beyond the realm of therapeutic products marketing, integrity provisions apply in particular in connection with clinical trials of therapeutic products (Articles 53 et seq TPA; Human Research Act). Persons involved in clinical trials with medicinal products and medical devices, including the sponsor, have to maintain scientific integrity and in particular have to disclose conflicts of interest (Article 3 Clinical Trials Ordinance (ClinO), Article 3 paragraph 1 lit a Ordinance on Clinical Trials with Medical Devices, amended as per 26 May 2022 to also apply to in vitro diagnostics).

## Increasingly Strict Self-Regulation for the Majority of Swiss Pharmaceutical Companies

Pharmaceutical self-regulation is dominated by the Pharma Code and the Pharma Cooperation Code of the Pharmaceutical Industry in Switzerland ("Pharma Codes"). These codes cover the entire range of medicinal products, ie, both prescription and non-prescription, patented originals as well as generics and biosimilars, but not medical devices, and they have been adopted by the respective industry associations:

- scienceindustries (*Wirtschaftsverband Chemie Pharma* Life Sciences);
- Interpharma (*Verband der forschenden pharmazeutischen Firmen der Schweiz*);
- vips (*Vereinigung Pharmafirmen in der Schweiz*);
- ASSGP (*Schweizerischer Fachverband für Selbstmedikation*); and
- Intergenerika (*Schweizer Verband der Generika und Biosimilar Firmen*).

Members of the European Federation of Pharmaceutical Industries and Associations (EFPIA) are required to sign the respective country codes. Accordingly, the majority of pharmaceutical companies in Switzerland are bound by the Pharma Code (127) and the Pharma Cooperation Code (60).

The Swiss Academy of Medical Sciences (SAMS) Guidelines on collaboration between the medical profession and industry are currently being completely revised in accordance with the new integrity and transparency provisions of the TPA and the OIT, as well as international recommendations and industry codes. Their scope of application is also to be extended beyond physicians to cover other healthcare professionals such as nurses.

### *Above and beyond legal requirements*

While state law and regulations focus on protecting human health in connection with the use of therapeutic products, self-regulation is intended to prevent undue competition and unethical market behaviour. The Codes generally reflect the legal requirements, but often go beyond them. A Code Secretariat is entrusted with supervision of compliance with the Codes (Section 7 Pharma Code; Section 5 Pharma Cooperation Code).

In broad terms, the Pharma Code contains the general integrity rules both in the analogue and digital spheres, and the Pharma Cooperation Code contains the requirements for disclosure and transparency of pecuniary benefits to healthcare professionals, healthcare organisations and patient organisations. Unlike the Pharma Code, the Pharma Cooperation Code is limited to interactions in the context of prescription medicinal products (Section 11.2.1). This is because the purpose of disclosure is generally understood

to create transparency with regard to any influences on prescribing behaviour.

### *Integrity and transparency*

Following the above-mentioned revision of the TPA and the coming into force of the new integrity and transparency regime pursuant to the OIT, as well as the Code Consolidation of EFPIA, the Pharma Codes have also been comprehensively revised. The revised codes came into force on 1 January 2021.

The Pharma Code has traditionally adopted a stricter approach to integrity than that adopted by state regulation. For example, it completely prohibits any offer or payment for entertainment and other leisure or hospitality activities (Section 32.5). The integrity provisions of the revised Pharma Code (Section 15) have now been updated and further tightened to align with Article 55 of the TPA and the OIT.

Accordingly, donations and grants (ie, money, assets or services not intended as compensation for a contribution that is delivered in support of healthcare, scientific research or medical training) may only be awarded to healthcare and patient organisations, but never to healthcare professionals (with the exception of support contributions for participation in continuing education and training, Article 6 OIT). Their range of permissible purposes has been restricted, and they have to be documented in writing in order to avoid a misuse of funds (Sections 15.5 et seq Pharma Code).

In order to clarify that allowances for meals are only permissible in consideration of an equivalent service (Article 7 OIT), such allowances are now only permissible in the context of expert discussions and events, whereby the limit per healthcare professional per meal has been reduced to CHF100 (Section 15.4 Pharma Code). This goes beyond statutory law, which allows this limit to be exceeded, subject to a written agreement. Furthermore, a new bid on multi-sponsoring has been introduced, whereby healthcare and patient organisations may not generally be required to exclusively support a pharmaceutical company (Section 15.7 Pharma Code).

As regards transparency, the self-regulatory obligation to disclose pecuniary benefits to healthcare professionals and healthcare organisations in the context of prescription medicinal products (Sections 24–29 Pharma Cooperation Code) has traditionally gone beyond Article 56 of the TPA and Article 10 of the OIT, which are limited to the disclosure of price discounts and rebates and do not apply to pecuniary benefits in their entirety. The revised Pharma Cooperation Code now aligns the disclosure requirements for pecuniary benefits to patient organisations to those for healthcare professionals and healthcare organisations (Section 36.1). This is in line with EFPIA's plans to standardise the disclosure requirements for healthcare professionals, healthcare organisations and patient organisations. To achieve as much transparency as possible, disclosure should, wherever possible, be made on an individual basis (Section 25.1). In fact, average consent rates to transparency disclosure by healthcare professionals and healthcare organisations are high in comparison with other European countries.

## Thin Line between Information and Advertising

In Switzerland, advertising of prescription medicinal products to the general public is prohibited (Article 31 paragraph 1 TPA; Articles 3, 14 Ordinance on Advertising of Medicinal Products (OMPA); Sections 21 et seq Pharma Code). This is why the often thin line between information and advertising is particularly key to the co-operation and communication strategies of pharmaceutical companies.

Advertising of medicinal products is defined as all information, marketing and incentivising measures aimed at promoting the prescription, administration, sale, usage or application of specific medicinal products (Article 2 lit a OMPA). All advertising must be in accordance with the information about the medicinal product, and may only promote the indications and possible applications most recently approved by the Swiss Agency for Therapeutic Products (Swissmedic; Article 32 paragraph 1 lit c TPA; Article 5 paragraph 1, Article 16 paragraph 1 OMPA; Sections 23.1 et seq Pharma Code). An activity qualifies as pharmaceutical advertising if a multitude of people are influenced by certain measures or if incentives are created that are intended to lead these people to change their consumption behaviour. Even the mere provision of information on the possible uses of medicinal products constitutes advertising if it is intended and able to influence consumer behaviour. That said, not every piece of information that creates a link to a specific medicinal product always qualifies as advertising. The boundary between information and advertising cannot be determined in an abstract manner, but depends on the entire circumstances of the individual case (Federal Administrative Court C-5490/2015, 28.3.2017, at 6.4.1; C-2798/2020, 27.8.2021, at 6.1.6 et seq).

### *Interactions between pharmaceutical companies and stakeholders in the healthcare sector*

Against this background, the focus in modern industry practice is on the following direct and indirect interactions between pharmaceutical companies and the various stakeholders in the healthcare sector:

- patient engagement;
- pre-approval information to healthcare professionals;
- scientific engagement with healthcare professionals and healthcare organisations;
- continuing medical education and training;
- post-approval studies; and
- media releases, investor presentations and securities disclosures.

In recent practice, there has been a general tendency towards fully integrated digital customer relationship-solutions that span across channels and functions and include marketing, sales, medical, service, clinical and commercial. Current legislation and case law do not yet adequately reflect this trend.

### *Patient and pre-approval information*

Patient engagement, such as disease awareness campaigns and similar patient communications that are limited to generic information about health, diseases, etc, is allowed in principle as long as it avoids any direct or indirect reference to individual medicinal products (Article 1 paragraph 2 lit c OMPA).

Pre-approval information to healthcare professionals (eg, at a medical conference or through medical science liaisons) and the media is allowed in principle if the aim is to provide or obtain scientific input on unauthorised medicinal products or indications, thereby avoiding any promotional activities, and as long as it is clearly stated that the medicinal product, indications, possible application, dosage, pharmaceutical form or packaging have not yet received marketing authorisation from Swissmedic. To that end, care has to be taken that the information is provided directly to healthcare professionals or to the medical department of a healthcare organisation, and not to its marketing or sales department or even to patients. The same applies in principle to so-called managed access programmes, such as for compassionate use (Article 9b paragraph 1 TPA). In order to reflect this situation in a systematically correct way, the revised Pharma Code moved the rules on pre-approval information about medicinal products

from the events section (Section 3), where they were traditionally placed, to the section on professional promotion of, and information about, medicinal products (Section 26).

### *Scientific engagement*

In the field of scientific engagement, ie, scientific interactions between pharmaceutical companies and prescribers, the revised Pharma Code incorporates the previous recommendations in the context of distribution of advertising to healthcare professionals. Accordingly, professional promotion may only address those healthcare professionals and healthcare organisations that may reasonably be assumed to need, or be interested in, specific information in the performance of their activities. Digital communication, including through social media, must, whenever possible, be disseminated with the recipients' prior consent (Section 29).

The revised Pharma Code also implements the requirements for continuing medical education and training which have been developed in the context of the EFPIA Code of Practice. While the revised Pharma Code recognises the importance of, and the need for, participation and contributions by the pharmaceutical industry in medical training and education, it maintains that such activities may not count as promotion, that the pharmaceutical industry is responsible for making its activities known, and that the content must be fair, balanced and objective and allow conclusions about different theories and accepted opinions (Section 31).

Furthermore, the revised Pharma Code introduces certain clarifications in the context of post-approval studies using authorised medicinal products, which are again based on the EFPIA Code of Practice. These clarifications are of particular interest in the context of real-world evidence studies that seek to obtain clinical evidence regarding the usage and potential benefits or risks of a medicinal product, such as from product and disease registries, health records, patient-generated data – including in home-use settings and through apps – as well as insurance claims and billing activities. In order to ensure their integrity, such studies have to comply with recognised scientific standards and methods (Section 57). Equally, if professional promotion refers to investigations such as meta-analyses (combining the results of multiple scientific studies), pharmaco-economic studies (evaluating the cost and effects of therapeutic products) or field reports from practice, these must have been published in a recognised scientific medium (Section 25.7).

### *Challenging communication*

Lastly, with growing competition among pharmaceutical companies in many areas, there has been a greater willingness to challenge hitherto unchallenged communication forms such as media releases and even investor presentations and securities disclosures, in particular in connection with marketing authorisations or reimbursement decisions. Such releases are allowed in principle, even if they relate to individual medicinal products, as long as they do not constitute advertising within the meaning of Article 2 lit a of the OMPA. Thereby, the precise limits where information ends and advertising starts can be difficult to establish. This delimitation can become even trickier where information obligations to investors under applicable stock exchange regulations have to be weighed against the prohibition under the therapeutic products law of advertising prescription drugs to the general public.

In this context, Swissmedic ruled that the information must be strictly limited to scientific, technical, organisational or financial aspects of a company's activities that are of interest to investors, and that they must under no circumstances be aimed at promoting a medicinal

product. In the context of any presentation of new medicinal products or substances in development, as well as of the future prospects and focal points of research and development activities, only the product name, the active ingredient (Denominatio Communis Internationalis) as well as the therapeutic area or field of application may be given. Information addressed to investors and financial analysts may contain details and forecasts regarding turnover, market share and sales volume, but no further statements on the therapeutic benefit of medicinal products (Swissmedic Guidelines for the advertising of medicinal products on the internet, 2007/09).

In addition to the restrictions on communication motivated by public health, conflicts between competitors under unfair competition law are also increasingly coming to the fore, as determined by the Pharma Code and the Federal Act against Unfair Competition.

## Opportunities and Challenges by Digitalisation

There is no dedicated or comprehensive regulation for pharmaceutical advertising in the digital space in Switzerland. That said, the issues have been addressed in various regulatory and self-regulatory initiatives, most recently by the Pharma Codes Secretariat in its (non-binding) January 2021 Recommendations for using digital channels: professional promotion, continuing education and social media ("Recommendations").

First and foremost, digital advertising raises complex questions of cross-border application of law. While the provisions on pharmaceutical advertising of the TPA and the OMPA are generally considered to be enforced only for websites with Swiss domain names, the Recommendations recognise the particular nature of digital media that makes it difficult to limit its geographic sphere of influence. Accordingly, they adopt the general recommendation to structure such information or promotional measures to comply with the national regulations for the geographic area that is their primary target. They recognise the established practice that websites of country organisations focus on a national audience, while the websites of corporate group entities address a wider, more international audience and should at least comply with the national laws that apply at the corporations' headquarters. At the same time, the recommendations stress that information disseminated digitally should be structured so as to ensure that it meets other implicit conditions, which could mean that such information has to meet the requirements of several legal systems at the same time (Chapter A.1).

The Recommendations adopt the general principles of responsibility and transparency. With respect to the former, companies are responsible for all medicinal product information and advertising initiated by them, regardless of the channel that is used. This applies to links to other websites as well as to interactive communication platforms (such as blogs and social media) and electronic media activities of their employees (Chapter A.2; see also Swissmedic Guidelines for the advertising of medicinal products on the internet, 2007/09). The latter means that, when using digital channels, the owner or sponsor of the channel must always be identified by way of its physical and electronic address (Chapter A.3; see also Section 23.7 Pharma Code).

### *Electronic advertising*

According to conventional understanding, electronic advertising, such as on the internet or via social media, without any access restriction, qualifies as advertising to the general public (Article 15 lit c OMPA). In 2019, the OMPA was amended to specify that, in order for professional advertising via electronic means to be compliant, its access must be restricted, by appropriate technical and password protections,

to professionals authorised to dispense or apply medicinal products (Article 5a OMPA; Chapters A.4, B.2 Recommendations). The same applies to media releases and press kits in which direct or indirect reference is made to specific prescription medicinal products. These may only be accessible to media professionals and must be password-protected (Swissmedic Guidelines for the advertising of medicinal products on the internet, 2007/09).

Swiss legal literature discusses the question of whether, in the age of electronic advertising, the distinction as to whether an advertisement is to be understood as public or professional should be based more on the content of the advertisement and its presentation than on access, including the distinction between push- and pull-information (dissenting: Federal Supreme Court 2A_20/2007, 9.5.2007, at 8). The new Recommendations address various digital communication channels in particular, such as e-mail, websites, webinars, podcasts, blogs, apps and social media, and they propose solutions to specific problems that may arise with regard to their use (Chapter B).

## Harmonisation of the Rules for Medical Devices

Medical devices have traditionally been regarded as less hazardous than medicinal products. This has led to inconsistencies in the regulation of advertising between these two categories of therapeutic products. However, the issue has been recognised, and attempts at greater harmonisation are underway.

While Article 56 of the TPA on transparency applies to therapeutic products in general, only prescription drugs, but not medical devices, are currently subject to Article 55 of the TPA and the respective provisions of the OIT, despite the commonality of the underlying concern, ie, to ensure that treatment decisions are not influenced by economic incentives. Parliament decided to amend Article 55 of the TPA and the OIT to subject persons, and their employer organisations, that prescribe, dispense, use and purchase for this purpose medical devices to the same integrity requirements that apply to medicinal products. The entry into force of the revised provisions is not expected before 2025. Until such time, potential sanctions are regulated in particular by the general bribery provisions of the CC (see Articles 322 ter et seq, 322 octies et seq), which in the meantime leads to different legal standards, especially in the area of benefits and advantages granted to healthcare organisations.

### *Advertising for medical devices*

In the context of the entry into force on 26 May 2021 of the new Medical Devices Ordinance, provisions on advertising for medicinal products introduced (Article 69) respectively are due to be enacted (see Article 62 of the draft of the new Ordinance on In Vitro Diagnostics).

Advertising for medical devices may also be subject to self-regulation, namely the Swiss Medtech Code of Ethical Business Practice of the industry association Swiss Medtech, which has been established in line with the Code of Ethical Business Practice of MedTech Europe. The purpose of the Ethics Code is to increase transparency and protect integrity in all interactions between members of Swiss Medtech and healthcare professionals, as well as healthcare organisations. It will ensure that treatment decisions are made independently. The self-regulation of the medical profession, too, will address medical technology in greater depth. A comprehensive revision of the SAMS Guidelines on collaboration between the medical profession and industry is currently underway.

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## Conclusion

In principle, as set out above, the trends and developments in pharmaceutical advertising in Switzerland are shaped by three basic factors:

- firstly, by the recognition that co-operation with the various stakeholders – from patients to healthcare professionals and their respective organisations – is a key factor for innovation, effectiveness and efficiency, but also for potential abuse, in the healthcare sector;
- secondly, by an increasing demand for integrity and transparency and respective regulatory intervention; and
- thirdly, by data-driven approaches that are facilitated by new digital solutions and that, at the same time, require adequate regulatory responses.

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# TAIWAN

## Law and Practice

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## CONTENTS

# 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

## 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

In Taiwan, advertising of medicines is mainly regulated by the Pharmaceutical Affairs Act, the Enforcement Rules of Pharmaceutical Affairs Act, the Consumer Protection Act, the Fair Trade Act, and the Principles for Dealing with Online Pharmaceutical Advertising. In addition, advertising of medicines is also regulated by the IRPMA Code of Practice (the "Code"), a self-regulatory code published by International Research-Based Pharmaceutical Manufacturers Association (IRPMA), which establishes general principles regarding marketing and promotion of medicines.

## 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The IRPMA is a non-profit, non-governmental organisation comprising European, American, Japanese, and Taiwanese research-based pharmaceutical companies. The Code is drafted based on the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice, and it establishes ethical standards for promoting pharmaceutical products to healthcare professionals. In addition to member companies of IRPMA, the distributors, commissioned agents or representatives acting on behalf of all IRPMA member companies should also comply with the Code.

# 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

## 2.1 Definition of Advertising

"Advertising" refers to disseminating promotional messages or content by communication means, including television and radio, films, slides, newspapers, magazines, flyers, posters, signboards, computers, facsimiles, electronic videos, electronic voicemails or other methods to unspecific persons or the general public. Under the Pharmaceutical Affairs Act (the "Act"), the term "pharmaceutical advertisement" refers to advertising the medical efficacy of medicaments to unspecific persons (general public) by communication means aiming to solicit and promote the sale thereof. Also, any interviews, news reports or propaganda containing any information implying or suggesting medical efficacy are regarded as pharmaceutical advertisements. If an information is sufficient to establish a link to a specific medicament and promote consumer use, such information will be considered as pharmaceutical advertising. Only pharmaceutical businesses are allowed to advertise pharmaceuticals.

## 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

The relevant authority has clarified the difference between information and pharmaceutical advertising via administrative orders: if the information meets the following requirements, such information shall not be considered pharmaceutical advertising:

- the information is for the purposes of health promotion or disease prevention with a health education function;
- the information does not involve specific names of the medicaments; and

- the information has an obvious separation from the pharmaceutical advertising content.

The aforementioned "obvious separation" should be determined with respect to the effects as shown on a case-by-case basis and with the following requirements also being met:

- the pharmaceutical advertisement and the information shall not be published on the same page or on consecutive pages;
- the pharmaceutical advertisement and the information shall not be broadcast consecutively (there shall be other advertisements broadcast between the pharmaceutical advertisement and the information) nor have the same person to perform or endorse them, which would mislead the consumers to think that the "two" advertisements are the same "one"; and
- shall avoid any measures misleading the consumers to believe that the pharmaceutical advertisement and the information are the same.

In addition, if the advertisements of the same medicament are shown on different media and their overall effect meets the definition of "pharmaceutical advertisement" as stated above, then these advertisements should comply with the related laws and regulations on pharmaceutical advertising. For example, if a TV advertisement does not contain the name and the efficacy of a medicament, but such information is provided via consulting a hotline or health education manuals, then the TV advertisement shall be still regulated by related laws and regulations on pharmaceutical advertising.

### Disease Awareness Campaigns and Other Patient-facing Information

Based on the above, whether the disease awareness campaigns and other patient-facing information qualify as advertising depends on the circumstances. Generally speaking, no differences apply depending on the target audience. If the purpose of the campaign/information is health education (health promotion or disease prevention), the campaign/information does not involve specific medicaments, and there is obvious separation with no misleading information, then such campaign/information would not be considered "pharmaceutical advertising".

## 2.3 Restrictions on Press Releases regarding Medicines

Press releases regarding medicines are permitted in Taiwan. Once the press release regarding medicines via media is deemed as "pharmaceutical advertising" as defined at **2.1 Definition of Advertising**, it shall subject to restrictions on pharmaceutical advertising. The details of restrictions on pharmaceutical advertising are illustrated at **4.2 Information Contained in Pharmaceutical Advertising to the General Public** and **6.1 Requirements for Prior Notification/Authorisation**.

As to the issue of the target audience, pharmaceutical advertising of prescription medicines is only allowed in medical academic journals. For details on advertising prescription medicines, please see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public**.

## 2.4 Comparative Advertising for Medicines

Comparative advertising for medicines is allowed in Taiwan if it is inspected by the relevant authority in advance. Additionally, such advertising must comply with the Principles of Comparative Advertising as set forth by the Fair Trade Commission. For example, a pharmaceutical business shall not make any untrue or misleading statements to promote products in an advertisement, and the business cannot compare its products with products of other pharmaceutical businesses based on different

standards or grades. A pharmaceutical business must take care when claiming its product is "the best", as such description constitutes comparative advertising.

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

According to the Enforcement Rules of the Pharmaceutical Affairs Act (the "Enforcement Rules of the Act"), text and images used in a pharmaceutical advertisement are limited to the name of the drug, its dosage form, prescription content, usage quantity, usage method, efficacy, guidelines and packaging, and the name and address of the manufacturer, as initially approved by the central relevant health authority; the name of the firm and the number of its drug permit licence and the advertisement approval document shall be published simultaneously or disseminated together with the pharmaceutical advertisement. According to the Code, no pharmaceutical product shall be promoted for use in a specific country until the requisite approval for marketing for such use has been given in that country. As such, in Taiwan, it is forbidden to have pharmaceutical advertisements for unauthorised medicines or unauthorised indications.

However, it is still possible to provide information about unauthorised medicines or unauthorised indications in a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings, in scientific or lay communications media and at scientific conferences, or during a public disclosure of information to stockholders and others. An unauthorised medicine and unauthorised indication can be introduced if such introduction will not be deemed as pharmaceutical advertising.

### 3.2 Provision of Information during a Scientific Conference

As indicated in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, it is possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals as long as such information will not constitute pharmaceutical advertising. Also, according to the "Ethics Code of Medical News or Research Published by Medical Institutions and Health Professionals", medical institutions and health professionals are allowed to quote such information and the source during a scientific conference as long as it is recognised by credible academic journals or institutions. The Code states that promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the event takes place, or which are registered under different conditions, provided that the following conditions are observed:

- host country regulations should permit such an arrangement;
- the meeting should be a truly international, scientific event with a significant proportion of the speakers and attendees from countries other than the country where the event takes place;
- promotional material for a pharmaceutical product not registered in the country of the event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally;

- promotional material which refers to the prescribing information (indications, warnings, etc) authorised in a country or countries other than that in which the event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and
- an explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

### 3.3 Provision of Information to Healthcare Professionals

As indicated in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, it is forbidden to have pharmaceutical advertisements for unauthorised medicines or unauthorised indications, regardless of whether the target is healthcare professionals or not. However, it is allowed to provide such information to healthcare professionals as long as it will not constitute pharmaceutical advertising (see **3.2 Provision of Information during a Scientific Conference**). According to the Code, continuing medical education (CME) helps ensure that healthcare professionals obtain the latest and most accurate information and insights on therapeutic areas and related interventions that are critical to the improvement of patient care and overall enhancement of the healthcare system. When providing content to CME activities and programmes, such material must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognised opinions. Content must consist of medical, scientific or other information that can contribute to enhancing patient care.

### 3.4 Provision of Information to Healthcare Institutions

As indicated in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, it is forbidden to have pharmaceutical advertisements for unauthorised medicines or unauthorised indications, regardless of whether the target is healthcare institutions or not. It is possible to provide information to healthcare institutions as long as it will not constitute pharmaceutical advertising. See details at **3.2 Provision of Information during a Scientific Conference** and **3.3 Provision of Information to Healthcare Professionals**.

### 3.5 Publication of Compassionate Use Programmes

It is not expressly prohibited to publish the availability of compassionate use programmes. However, considering: (i) the compassionate use programme is applied under the circumstance that there is no domestic appropriate drug or alternative treatment; and (ii) the compassionate use programme must be applied by the medical care institutions to the central competent health authority for its special approval to manufacture and import the specific drug for the prevention of a chronic or seriously debilitating disease, or a life-threatening disease, the publication of the availability of compassionate use programmes or other forms of early access must not constitute pharmaceutical advertising or such publication must meet the related laws and regulations of pharmaceutical advertising.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

In Taiwan, any pharmaceutical business that wishes to advertise medicines, whether they are over-the-counter medicines or prescription medicines, must first apply for approval from the relevant healthcare authority. After obtaining approval, the pharmaceutical business can

advertise and promote such medicines. The governmental approval process is illustrated at **6.1 Requirements for Prior Notification/ Authorisation**. The Code provides standards for promotional information:

- promotions must be consistent with locally approved product information;
- promotions must be clear, legible, accurate, balanced, fair and sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the pharmaceutical product; and
- the advertiser must be able to substantiate the claimed efficacy.

Moreover, prescription medicines are only allowed to advertise in medical academic journals, not to the general public. As for online advertising of prescription medicines in medical academic platforms, according to the administrative order, the platform must have installed an administrative measure to ensure that only registered healthcare professionals are allowed to view such advertisements.

Advertisements shall not make any misleading or untrue statements to the audience. Any violation is subject to penalties under the Fair Trade Act, the Consumer Protection Act and the Civil Code.

## 4.2 Information Contained in Pharmaceutical Advertising to the General Public

### Obligatory Information

Before publishing or broadcasting a pharmaceutical advertisement, a pharmaceutical business must submit all text, drawings or images constituting an advertisement to the relevant health authority for approval, and no modifications or alterations to the approved contents are allowed during the term being permitted to publish or to broadcast. The name of the firm, the number of its drug permit licence and the advertisement approval document shall be published simultaneously or disseminated together with the advertisement; the text and images used in a pharmaceutical advertisement are limited to the name of the drug, its dosage form, prescription content, usage quantity, usage method, efficacy, guidelines and packaging, and the name and address of the manufacturer, as initially approved by the central relevant health authority; the efficacy claimed in the text of an advertisement for Chinese medicine materials must be limited to the efficacy stated in the Compendium of Materia Medica.

### Prohibited Information

Pharmaceutical advertising shall not do any of the following:

- publicise the medicament by making use of the name of anther person(s);
- warrant the efficacy or functions of the medicament by making use of materials or information contained in a book or publications;
- publicise the medicament by means of releasing an interview or news report; or
- publicise the medicament by any other improper means.

Additionally, pharmaceutical advertisements cannot contain any of the following:

- content involving efficacy related to sexual intercourse;
- content involving exchanging the drugs for prizes or any incentives whatsoever that are likely to encourage drug abuse;
- content involving any representation that the use of a particular drug will cure a particular disease or will improve a person's health or physiology in a particular area, or untrue or misleading statements; and
- exaggeration of a drug's efficacy or safety.

### 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

There is no law or regulation expressly imposing restrictions on interactions between patients or patient organisations and industry. However, salespersons employed by a pharmaceutical business are permitted to promote sales only after their employment has been registered with the relevant health authority of the municipality or county (city). The salespersons may only promote sales to pharmacies, pharmaceutical firms, health and medical care institutions, medical research institutions, and institutions whose registrations have been approved by the relevant health authorities. Salespersons can only sell drugs manufactured or resold by the pharmaceutical business in which they are employed, and cannot conduct any act of peddling, street vending, tearing seals of medicaments, repackaging medicaments without authorisation, or illegally advertising medicaments.

As the law does not establish the definition of "promoting sales", there is still room for direct interaction between patients or patient organisations and industry, so long as the interactions do not involve "promoting sales". The Code also allows interactions between patients or patient organisations and the industry, as long as all interactions with patient organisations are ethical, and the independence of patient organisations must be respected; being the sole funder of the patient organisation or any of its programmes is not allowed.

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Same rules apply to both advertising to the general public and to the health professionals. Contents or information that must be included or that is prohibited are indicated at **4.2 Information Contained in Pharmaceutical Advertising to the General Public**. In addition, prescription medicines are only allowed to advertise in medical academic journals, not to the general public. For online advertising of prescription medicines in medical academic platforms, the platform must have installed an administrative measure to ensure that only registered healthcare professionals are allowed to view such advertisements (see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public**).

### 5.2 Reference to Data Not Included in the Summary of Product Characteristics

In Taiwan, the content of pharmaceutical advertising of a specific medicine must be exactly the same as the content that has been inspected and reviewed by the relevant authority. The text and images used in pharmaceutical advertising are limited to the name of the drug, its dosage form, prescription content, usage quantity, usage method, efficacy, guidelines, packaging, and the name and address of the manufacturer, as approved by the central relevant health authority. Therefore, if the data or other clinical studies are not approved by the relevant authority, they cannot be referred to in the pharmaceutical advertisement. However, there is still room for the use of such information, as long as it complies with related laws and regulations as indicated at **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, **3.2 Provision of Information dur-**

**ing a Scientific Conference** and **3.3 Provision of Information to Healthcare Professionals**.

### 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

As indicated at **5.2 Reference to Data Not Included in the Summary of Product Characteristics**, the content of pharmaceutical advertising must be exactly the same as the content that has been inspected and reviewed by the relevant authority. If such information is not approved by the central relevant health authority, it cannot be referred to in the pharmaceutical advertisement. However, there is still room for the use of such information, as long as it complies with related laws and regulations as indicated at **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, **3.2 Provision of Information During a Scientific Conference** and **3.3 Provision of Information to Healthcare Professionals**.

### 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

According to the Code, medical journals or textbooks for academic use can only be offered to individual hospital departments (Benchmarks of Code of Practice). In addition, if the content involves any "pharmaceutical advertising", the company must comply with the relevant rules governing pharmaceutical advertising.

### 5.5 Medical Science Liaisons

Unlike the promotion of sale by pharmaceutical business salespersons, which needs to be registered according to the Act, there are no specific laws or regulations regulating the conduct of medical science liaisons (MSLs). There are no laws or regulations prohibiting MSLs from proactively discussing scientific information on unauthorised medicines or indications with healthcare professionals, as long as the conduct of the MSLs does not constitute pharmaceutical advertising and such conduct complies with the related laws and regulations as indicated at **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, **3.2 Provision of Information during a Scientific Conference** and **3.3 Provision of Information to Healthcare Professionals**. However, if MSLs are "promoting sales", the MSLs shall also be registered regardless of whether the company refers to them as salespersons or not.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

Advertisements for medicines are subject to prior authorisation from the relevant health authorities. See **4.2 Information Contained in Pharmaceutical Advertising to the General Public** for information that needs to be submitted for approval. No publication or dissemination of pharmaceutical advertising may take place until a pharmaceutical business with a drug permit has completed an application form and submitted the same with photocopies of the drug permit and the approved labelling, usage instructions, packaging, the content of the advertisement and a review fee to the relevant health authority and has obtained approval from that health authority. Also, the term of validity of pharmaceutical advertisements approved by the relevant health authority is one year, which shall commence from the date of issuance of the approval document. An extension may be applied for by the business and approved by the issuing relevant health authority. Each period of extension shall not exceed one year. The central or direct municipal relevant health authority is in charge of approval (and rejection) of pharmaceutical advertisements.

### 6.2 Compliance with Rules on Medicinal Advertising

There is no requirement to adopt SOPs or to employ specific personnel to complete the process of applying for pharmaceutical advertisement approval from the relevant health authority. However, an applicant applying for such approval must be the pharmaceutical business which holds the drug permit for the drug that is to be advertised.

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

In addition to the general rules specified in the Act and the Enforcement Rules of the Act, advertising on the internet for medicinal products is specifically regulated by the "Principles for Dealing with On-line Pharmaceutical Advertising" (the "Principles").

The Principles provide as follows.

- A pharmaceutical business is allowed to advertise drugs or medicines on its official website without first applying for an approval, but the content of the advertisements must be identical to the drug permits, and the business must post photos of the drug's packaging.
- As well as advertising on its official website, a pharmaceutical business is allowed to advertise non-prescription medicines on websites targeting the general public by first applying for the approval set forth at **6.1 Requirements for Prior Notification/Authorisation**. For prescription medicines, in addition to having the approval, prescription medicines can only advertise in medical academic platforms which have an administrative measure to ensure that only registered healthcare professionals are allowed to view such advertisements. For example, the online platform must require member IDs or professional licence numbers to permit access to the webpage showing the advert for the prescription medicines.

### 7.2 Advertising of Medicines on Social Media

Pharmaceutical advertising on social media is allowed, so long as the advertisements comply with the rules indicated above such as **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public** and **7.1 Regulation of Advertising of Medicinal Products on the Internet**.

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

If a pharmaceutical advertisement contains prescription medicines, the website must have installed an administrative measure such as a requirement to enter a member ID or professional licence number to ensure that only healthcare professionals have access to such advertising content.

### 7.4 Provision of Disease Awareness Information to Patients Online

As indicated in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**, pharmaceutical companies are allowed to provide disease awareness information and/or materials to patients online, as long as the information is not pharmaceutical advertising and:

- is for the purposes of health promotion or disease prevention with a health education function;
- does not include specific names of the medicaments; and

- has obvious separation from the pharmaceutical advertising content.

On the other hand, if the disease awareness information and/or materials to patients would be considered as "pharmaceutical advertising", the laws and regulations governing pharmaceutical advertising must be complied with.

### 7.5 Online Scientific Meetings

According to the Code, the purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an "Event") for healthcare professionals organised or sponsored by a pharmaceutical business should be to provide scientific or educational information and/or to inform healthcare professionals about products, as do online scientific meetings. Promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the Event takes place, or which are registered under different conditions, provided that the following conditions are observed:

- the host country regulations should permit such an arrangement;
- the meeting should be a truly international, scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place;
- promotional material (excluding promotional aids) for a pharmaceutical product not registered in the country of the Event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally;
- promotional material which refers to the prescribing information (indications, warnings, etc) authorised in a country or countries other than that in which the Event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and
- an explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

The interaction between healthcare professionals/healthcare organisations and and pharmaceutical companies is mainly regulated by the Medical Care Act, the Physicians Act, and the Guidance for Interaction between Physicians and Vendors, all three of which only provide high-level principles. Corruption under the Criminal Code was previously applied to healthcare professionals at public hospitals, but such application ceased in 2008. The offence of breach of trust under the Criminal Code might still be applied in some particular circumstances. The Code also provides some self-regulatory details regarding such interactions.

#### Medical Care Act

The Medical Care Act aims to advance the comprehensive development of the medical care industry, the reasonable distribution of medical care resources, improvement of the quality of medical care, protection of the rights of patients and the promotion of the national health. It requires "[m]edical care institutions and their staff to refrain from taking advantage of oppor-

tunities resulting from medical practice to gain improper benefits". This applies to both individuals and organisations, but only provides general principles regarding the prohibition against "gaining improper benefits". Medical care institutions and the staff thereof who violate the aforementioned shall be subject to a fine of no less than NTD50,000 (approximately USD1,666) and no more than NTD250,000 (approximately USD8,333).

### Physicians Act

The Physicians Act establishes the standards for qualifications, management, practice and duty of physicians. It applies only to physicians and not healthcare institutions. A physician guilty of violating medical ethics in their professional practice shall be disciplined by the Medical Association or the relevant authority. This Act also provides a high-level limitation on the interactions between healthcare professionals and pharmaceutical companies.

### Administrative Guidance

In 2006, Taiwan's Department of Health (DoH, which is now the Ministry of Health and Welfare) announced the Guidance for Interactions between Physicians and Vendors. The Guidance states the rules to be followed with respect to the attendance of physicians at medical seminars held by vendors, the receiving of gifts from vendors, the rules for doctors who are invited to provide consultation to pharmaceutical companies, and the principles for physicians and healthcare organisations to follow while conducting research sponsored by vendors. A physician who violates the Code will be disciplined by the Medical Association.

### Corruption According to the Criminal Code

If the individual accepting bribes is a government employee, corruption, according to the Criminal Code, might apply. There was a time when healthcare professionals working in public hospitals were considered government employees. However, as confirmed by the Supreme Court in 2008, healthcare professionals at public hospitals are not considered civil servants as defined in the Criminal Code. Nevertheless, if the healthcare professional has duties in an administrative or management position at the public hospital, such as with respect to procurement, the individuals can be charged with corruption if they accept bribes.

### Breach of Trust of the Criminal Code

If the healthcare professional accepting gifts or money from pharmaceutical companies acts against their professional practice, which then causes damage to the hospital, the healthcare professional may be deemed to have committed a breach of trust. This applies only to individuals and not to organisations, regardless of whether the healthcare professional works for a public or private hospital.

### IRPMA Code of Practice

The Code provides standards for the ethical promotion of pharmaceutical products to healthcare professionals helping to ensure that member companies' interactions with healthcare professionals and other stakeholders are appropriate and perceived as such, as well as considerable details regarding acts that pharmaceutical companies must do and must refrain from doing while interacting with healthcare professionals, and the principles for interactions with healthcare professionals. Specific sections include events and meetings, sponsorships, guests, fees for services, gifts, samples provided to healthcare professionals and the monitoring duty of the pharmaceutical companies with respect to the samples they provide, rules covering clinical research and transparency, among others.

### 8.2 Legislative or Self-Regulatory Provisions

Legislative provisions regarding the matter of benefits provided to healthcare professionals or healthcare organisations are mainly contained in the Medical Care Act and the Physicians Act, which only provide general and high-level limitations. The Medical Care Act could apply to both individuals and organisations, while the Physicians Act applies only to physicians. Corruption or breach of trust under the Criminal Code might apply in some particular circumstances, but only to individuals.

The Guidance for Interactions between Physicians and Vendors provides more details on this matter. It restricts physicians' and healthcare organisations' behaviours regarding benefits, but not those of pharmaceutical companies. In terms of self-regulatory provisions, the Code provides the most details regarding the offering of benefits by pharmaceutical companies. The Code restricts the behaviours of pharmaceutical companies in this regard.

Both the Guidance for Interactions between Physicians and Vendors and the Code prohibit offering cash or cash equivalents such as gift certificates. The Code also prohibits offering personal benefits, such as sporting or entertainment tickets and electronic items and cultural courtesy gifts, such as gifts given on traditional festivals or flowers and funeral scrolls for funerals.

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

The Taiwan legal framework only has general provisions that limit interactions between healthcare professionals and pharmaceutical companies. The Guidance for Interactions between Physicians and Vendors and the Code provide more specific information, as addressed below.

The Medical Care Act and the Physicians Act provides a high-level requirement that medical care institutions and their staff shall not take advantage of opportunities resulting from medical practice to gain improper benefits. Also, healthcare professionals must not violate medical ethics in their professional practice.

According to the Guidance for Interactions between Physicians and Vendors, physicians are allowed to accept gifts on the basis that such gifts:

- shall not violate the laws and the policies of the Medical Association or Guild;
- shall be reasonable in consistency with local practice, and shall not be expensive;
- shall not be cash or cash equivalents; and
- shall not involve an agreement or implication that a particular medical product will be used or that patients will be referred to a particular premises.

Briefly, the core concept is reasonableness and avoiding situations of quid pro quo. Although there is no specific monetary limit set, gifts of cash or cash equivalents are clearly forbidden.

The Code also provides that "[p]ayments in cash, cash equivalents (such as gift certificate) or personal services (any service unrelated to the healthcare professional's profession and that confer a personal benefit to the healthcare professional) must not be offered to healthcare professionals. Gifts for the personal benefit of healthcare professionals (such as sporting or entertainment tickets, electronic items, etc) must not be provided or offered." In addition, as from 16 May 2018, the Code forbids promotional aids (as defined in benchmarks 6.(2), promo-

tional aids are inexpensive small items bearing the name of the pharmaceutical companies or pharmaceutical products) from being provided to healthcare professionals, requiring that medical supplies cannot be provided to healthcare professionals for their personal use.

### 9.2 Limitations on Providing Samples to Healthcare Professionals

According to the Regulations on Management of Medicament Samples and Gifts, a medicament that meets one of the following requirements can be declared as a medicament sample:

- the pharmaceutical firm is applying for registration or improvement of manufacturing technology purposes;
- due to business needs, the pharmaceutical firm, academic research or trial institute, contract research organisation, medical academic group or teaching hospital is applying for solely research or trial purposes;
- a specialised teaching hospital or teaching hospital at or above the regional level is applying for purposes of diagnosis and treatment of patients with critical or catastrophic illness;
- a patient applying for personal uses, certified by a medical institution (medical devices that should be operated by a physician or professional are excluded);
- a medical device company applying for specific exhibitions or demonstration purposes;
- a pharmaceutical firm applying for educational promotion purposes, given that the medicament has been issued a licence in accordance with the stipulations of the Act; or
- an application for purposes of public safety or public health or due to major disasters.

To be imported or manufactured, medicament samples must have obtained approval from the TFDA in advance. In addition, the Regulations provide as follows.

- Medicament samples or gifts that have been approved may not be sold, transferred or used for other purposes.
- Medicament samples for technical improvement purposes may not be used for clinical purposes.
- For approved medicament gifts and medicament samples for educational promotion purposes, their package inserts, labels and packaging styles shall be consistent with those registered in the original permit licence. The package volume for medicament samples for educational promotion purposes may not exceed the minimum registered packaging volume.
- For medicaments approved as samples or gifts, the outer packaging shall be clearly marked with text stating “Sample” or “Gift”. On samples for clinical trial purposes, text stating “For clinical trial” shall be marked.

The Code also provides principles regarding the offering of samples, as set out below.

- Subject: the healthcare professionals receiving samples of the medicine at issue shall have the power to prescribe the medicine.
- Labelling: the samples offered shall be clearly labelled as “samples”.
- Monitoring and other responsibilities: the pharmaceutical company is required to maintain a monitoring system for tracking which healthcare professional possesses the samples.

Pharmaceutical companies offering samples are not allowed to collect clinical information from samples offered and may not provide any reward to healthcare professionals receiving such samples.

### 9.3 Sponsorship of Scientific Meetings

The Guidance for Interaction between Physicians and Vendors allows doctors to attend

medical meetings held or sponsored by pharmaceutical companies, so long as the following principles are met.

- The main purpose of the meeting is regarding the improvement of medical quality, promoting the interests of patients and professional information exchange. In addition, at least two-thirds of the meeting time shall be spent on discussion of the topics as set forth/advertised.
- Sponsorship accepted by a healthcare professional is limited to registration, travel expenses and meals. If a healthcare professional is invited as a speaker or host, a speaker's fee or hosting fee is acceptable.
- The organiser of the meeting is required to disclose the name of the sponsors and inform attendees of the relationship with/between the organiser, speaker, host and sponsor.
- Any material published by healthcare professionals at the meeting must be based on scientific positivism and cannot be affected by the sponsor. Statements regarding alternative diagnosis/treatment must be made fairly.
- The organiser of the meeting or attending doctors must reject any improper intervention by the pharmaceutical companies related to the content of the meeting, the way the meeting proceeds and the selection of speakers.

The Code allows pharmaceutical companies to hold or sponsor events or meetings under certain limitations, as set out below.

- The purpose of the event must be related to science and education.
- Meetings abroad are not allowed except for international scientific congresses and symposia that derive participants from many countries. All events must be held in an appropriate venue conducive to the stated scientific or educational objectives and the purpose of the event or meeting. Renowned or extravagant venues must be avoided.
- Promotional information that appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products that are not registered in the country where the event takes place, or which are registered under different conditions, provided that the following conditions are observed:
  (a) host country regulations should permit such an arrangement;
  (b) the meeting should be a truly international, scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place;
  (c) promotional material (excluding promotional aids) for a pharmaceutical product not registered in the country of the Event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally;
  (d) promotional material which refers to the prescribing information (indications, warnings, etc) authorised in a country or countries other than that in which the Event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and
  (e) an explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.
- Pharmaceutical companies are also allowed to sponsor healthcare professionals to attend events, provided:
  (a) the event complies with the requirements in this Code as described at **7.1 Regula-**

**tion of Advertising of Medicinal Products on the Internet**;
(b) sponsorship of healthcare professionals is limited to payments for travel, meals, accommodation and registration fees;
(c) no payments are made to compensate healthcare professionals for time spent attending the Event; and
(d) any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.

### 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

As set out above, the Guidance for Interactions between Physicians and Vendors allows healthcare professionals to attend events held or sponsored by pharmaceutical companies, provided that the purposes of such events are related to improvements of medical quality, promoting the interests of patients and professional information exchanges. The Code also requires that the purposes of events held or sponsored by pharmaceutical companies be related to science and education. No entertainment or other leisure or social activities should be provided or paid for by member companies. Thus, pharmaceutical companies are not allowed to organise or sponsor cultural, sports or other non-scientific events, and healthcare professionals are also not allowed to attend such non-scientific events, if their attendance is sponsored by pharmaceutical companies.

### 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

The Guidance for Interactions between Physicians and Vendors allows healthcare professionals or healthcare institutions to conduct research sponsored by pharmaceutical companies, provided that:

- the research and publication of the results thereof complies with the law, ethics and the requirements of the Helsinki Declaration and strictly adheres to clinical judgement;
- the reward for conducting the research shall be evaluated based on the time and effort expended, but, not based on the results of the research;
- the name(s) of both the direct or indirect sponsor(s) shall be announced together with the publication of the results of the research;
- the healthcare professionals or healthcare institutions and the pharmaceutical company shall fully communicate before the research; and
- the pharmaceutical company shall not restrict the publication of the research results.

The Code states that pharmaceutical companies are allowed to offer items of medical utility to healthcare professionals if such items are of modest value, do not offset routine business practices, and are beneficial to enhancing the provision of medical services and patient care, such medical utility must not bear the name of product (both of branded and generic name) but may bear the company logo.

Both the Guidance for Interactions between Physicians and Vendors and the Code prohibit offering cash or cash equivalents (such as gift certificates) to healthcare professionals. Neither the Code nor the Guidance has relevant content regarding donations of equipment or service from pharmaceutical companies.

### 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Though there is no specific restriction with respect to rebates or discounts, both the Guidance for Interactions between Physicians and Vendors and the Code prohibit offering cash or

cash equivalents to healthcare professionals. Thus, giving rebates is not allowed.

In addition, the requirements under the Medical Care Act and the Physicians Act indicated in sections **8. Pharmaceutical Advertising: Inducement/Anti-bribery** and **9. Gifts, Hospitality, Congresses and Related Payments** would apply. If a healthcare professional receives a rebate or discount which is considered to be an "improper benefit" or as "violating medical ethics", they could be subjected to the imposition of a fine in an amount no less than NTD50,000 (approximately USD1,666) and no more than NTD250,000 (approximately USD8,333) and may be disciplined by the Medical Association or the relevant authority.

Furthermore, healthcare professionals at public hospitals who are in charge of administrative or management affairs may be found guilty of corruption if they accept rebates. Also, healthcare professionals at public or private hospitals may be found to be in breach of trust for their receipt of rebates if the legal requirements for a breach of trust are met.

### 9.7 Payment for Services Provided by Healthcare Professionals

The Guidance for Interactions between Physicians and Vendors allows doctors to act as consultants to pharmaceutical companies or to provide advice, provided that:

- professional judgement shall not be affected due to acting as consultant or providing advice to the pharmaceutical company;
- obligations to patients shall not be neglected due to acting as consultant or providing advice to the pharmaceutical company; and
- subordination or any other relationship with the pharmaceutical company shall be laid open in any speech and/or publication of articles or reports.

The Code has relevant requirements, including:

- a written contract or agreement must be agreed upon in advance of the commencement of the services, which agreement or contract specifies the nature of the services to be provided and the basis for payment of those services;
- a legitimate need for the services must be clearly identified and documented in advance;
- the criteria for selecting consultants must be directly related to the identified need, and the consultants must have the expertise necessary to provide the service;
- the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
- the hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine; and
- the compensation for the services must be reasonable and must reflect the fair market value of the services provided.

The Q&A section of the Code also contains a services fee schedule for healthcare professionals, which provides as follows.

- For international congress held overseas, the international norms should be applied. For the symposia held in Taiwan, the international norms can only be applied when the international event is organised by an international society and it is not a satellite programme within the international event. Otherwise, the honorarium for local speaker should be limited up to NTD5,000/hour.
- Chairperson/moderator of the advisory board and who may concurrently serve as advisory board member: may be paid up to NTD20,000 (up to NTD10,000 per event as member, up to NTD10,000 as the Chairperson).

- Chairperson/moderator and who may concurrently serve as a lecturer: NTD5,000/hour as a lecturer, up to NTD10,000 as the chairman/moderator per event.

### 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

Except for the importation or manufacture of medicament samples, which must have obtained approval from the TFDA in advance, none of the activities referred in this section are presently required by laws or regulations to have prior authorisation or notification.

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

There is no particular law or regulation or self-regulatory code that requires pharmaceutical companies to disclose transfers of value to healthcare professionals or healthcare institutions. The Guidance for Interactions between Physicians and Vendors, however, requires the following.

- Regarding the event or meeting sponsored by a pharmaceutical company, the organiser of the event or meeting must disclose the name of the sponsors and inform attendees of the relationship/s between the organiser, speaker, host and sponsor (Article 2(3)).
- Where healthcare professionals are invited to be consultants or to provide advice to pharmaceutical companies, the subordination or any other relationship with the pharmaceutical company shall be laid open in any speech or publication of articles or reports (Article 5(3)).

### 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

The above-mentioned Guidance for Interactions between Physicians and Vendors at **10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value** does not distinguish between foreign companies or companies that do not yet have products on the market. Nevertheless, Article 2(3) applies only to the organiser of the event or meeting and Article 5(3) applies only to healthcare professionals.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

For the rules on advertising, the central or direct municipal relevant health authority is in charge of enforcing the Act. The Fair Trade Commission will enforce any penalties for violations of the Fair Trade Act. Administrative disputes related to violations of pharmaceutical advertising rules are adjudicated by the Administrative Courts.

With regard to inducement, the Medical Care Act and the Guidance for Interactions Between Physicians and Vendors is enforced by the Ministry of Health and Welfare. The Physicians Act is enforced by the Ministry of Health and Welfare and the Taiwan Medical Association. The IRPMA Code of Practice is enforced by the IRPMA.

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

If infringement by a competitor involves a fair trade/competition order, the company can bring a complaint to the Fair Trade Commission (FTC), and the FTC will collect evidence and make a decision as to whether to issue an administra-

tive order to fine the competitor for its violation of the Fair Trade Act. If a competitor is not satisfied with the administrative order, it may sue the FTC, and such cases will be heard by the High Administrative Court. If infringement by a competitor constitutes the behaviour as stated in the Fair Trade Act, that is "for the purpose of competition, make or disseminate any false statement that is capable of damaging the business reputation of another", the company may even file a criminal complaint with the competent district prosecutor's office pursuant to the Fair Trade Act.

If the infringement by a competitor involves general civil issues, such as disparaging the company's goodwill or the making of untrue statements, the company may sue the competitor in the local civil courts.

If the infringement by a competitor involves intellectual property rights or trade secrets, the company may sue the competitor in the Intellectual Property and Commercial Court.

### 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

General penalties for violating advertising rules under the Act are as follows.

- Anyone who is not a pharmaceutical business but makes a pharmaceutical advertisement is subject to a fine in an amount ranging from NTD200,000 (approximately USD6,666) to NTD5 million (approximately USD1,666,666); no pictorial or literal description or propaganda regarding the medical efficacy of any product other than the medicaments defined in this Act shall be made, otherwise, the violator shall be issued a fine ranging from NTD600,000 to NTD25 million and the violating products shall be confiscated and destroyed.
- Anyone who makes a pharmaceutical advertisement without first obtaining approval from the relevant authority, and anyone who violates the rules by advertising prescription medicines on any media other than in educational journals, and anyone who includes prohibited content in the advertisement will be subject to a fine in an amount ranging from NTD200,000 (approximately USD6,666) to NTD5 million (approximately USD1,666,666).
- Media businesses who help to post or play any pharmaceutical advertisement which has not been approved by the relevant authority will be subject to a fine in an amount ranging from NTD200,000 (approximately USD6,666) to NTD5 million (approximately USD1,666,666), and if the media business continues posting or playing said advertisement, it will be subject to a fine in an amount ranging from NTD600,000 (approximately USD20,000) to NTD25 million (approximately USD833,333); under the same Article, any media business that violates the rules by not keeping the record of the advertisement for six months will be subject to a fine in an amount ranging from NTD60,000 (approximately USD2,000) to NTD300,000 (approximately USD10,000).
- In addition to the above, the relevant authority may announce the name of the violator and the medicine, and may revoke the drug licence if the violation is serious; the medicine at issue will also be precluded from application for approval for pharmaceutical advertising for a period of two years.

Penalties under the Fair Trade Act are as follows.

- Anyone who makes untrue or misleading statements in an advertisement will be subject to a fine in an amount ranging from NTD50,000 (approximately USD1,666) to NTD25,000,000 (approximately USD833,333), and if such person fails to correct its action

after imposition of the fine, said person shall be subject to another fine in an amount ranging from NTD100,000 to NTD50 million until its action is corrected. This is likely to happen with respect to endorsement or comparison advertisements. In addition to the above punishments, doctors or pharmacists are subject to disciplinary measures by their professional associations for violating their professional duties by making untrue or misleading statements in connection with endorsements for medicines.

- Anyone making or disseminating any untrue statement for the purpose of damaging the business reputation of another business is subject to both criminal and administrative penalties. For criminal liability, the violator will be subject to detention or imprisonment for no more than two years and may be fined an amount of no more than NTD50 million. For administrative liability, the violator will be subject to a fine in an amount ranging from NTD50,000 (approximately USD1,666) to NTD25 million (approximately USD833,333), and if it fails to correct its action after the fine, it will be subject to another fine in an amount ranging from NTD100,000 to NTD50 million until its action is corrected. This is likely to happen in connection with comparison advertisements.
- Anyone engaging in any deceptive or obviously unfair conduct that is able to affect the trading order will be subject to a fine in an amount ranging from NTD50,000 (approximately USD1,666) to NTD25 million (approximately USD833,333), and if it fails to correct its action after the fine, it will be subject to another fine in an amount ranging from NTD100,000 to NTD50 million until its action is corrected. This is likely to happen in connection with comparison advertisements.

Regarding inducement, medical care institutions and the staff thereof who violate the Medical Care Act will be subject to a fine of no less than NTD50,000 (approximately USD1,666) and no more than NTD250,000 (approximately USD8,333). According to the Physicians Act, a physician found guilty of violating medical ethics in their professional practice will be disciplined by the Medical Association or the relevant authority. The Guidance for Interactions Between Physicians and Vendors was established according to the Physicians Act. Thus, the penalties or measures applicable for violations of the Guidance will also refer to the Physicians Act.

There is no statutory punishment for violating the requirements of the IRPMA Code of Practice, however, IRPMA has its own Code of Practice Committee. If the Code of Practice Committee confirms the violation of the Code, each violation shall be punishable by a fine of NTD200,000.

## 11.4 Relationship between Regulatory Authorities and Courts

The procedures or measures taken by the self-regulatory authority are not necessarily related to the procedures or measures taken by the courts. One can present the material of procedures or measures taken by the self-regulatory authority to the court, but any violation of the laws and regulations must be heard and decided by a court. The procedures before the court must follow the law and the court can take compulsory measures, while the procedures taken by the self-regulatory authority are self-imposed and, unlike the court, the self-regulatory authority cannot take compulsory measures.

## 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

In the past two years, there have been no significant changes of enforcement in relation to pharmaceutical advertising. However, the regulation of medical devices was shifted from the Pharmaceutical Affairs Act to the Medical Devices Act. The Medical Devices Act came into effect on

1 May 2021. According to the Medical Devices Act, its provisions shall apply to the management of medical devices, and the provisions of the Pharmaceutical Affairs Act governing medical devices shall no longer be applicable.

**Formosa Transnational** is a full-service law firm in Taipei established in 1974. The firm provides legal assistance to high-profile clients from all over the world, including the USA, EU, UK, Japan, Korea, Singapore and China. With an elite team of 90 attorneys, the firm's practice includes all types of compliance checks, dispute resolution, fundraising, investments, mergers and acquisitions, employment, competition, franchising, data protection and privacy, and corporate social responsibility, among other fields of law. Its technology law department possesses a strong background in technology and extensive experience in IP laws with its IP attorneys and in-house engineers and scientists. The firm's professionals provide comprehensive services with respect to intellectual property matters such as IP management, prosecution and litigation for patents, trade marks, copyrights, domain names and trade secrets, and advise businesses engaged in all sectors of the pharmaceutical industry and many other industries.

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# THAILAND

## Law and Practice

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# 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

## 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

### Laws Regulating Advertising on Medicines

In Thailand, the main pieces of legislation governing the advertising of medicines are:

- Drug Act BE 2510 (1967), as amended ("Drug Act") – Sections 88-90; and
- Regulations of the Thai Food and Drug Administration on Advertisements of Drugs for Sale BE. 2545 (2002) ("Advertisement Rules").

### Codes Regulating Advertising on Medicine

Although there are no self-regulatory codes on advertising medicines which apply to the entire pharmaceutical industry, pharmaceutical companies that are members of the Pharmaceutical Research and Manufacturers Association ("PReMA") must comply with the PReMA Code of Sales and Marketing Practice. The current version is 12th edition – 2019 ("PReMA Code").

## 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Pharmaceutical companies that are members of the PReMA must comply with the PReMA Code.

- The PReMA Code provides the standards for the industry's practice of promotional activities, including organising conferences for healthcare professionals (HCPs), interaction with HCPs, etc.
- Many pharmaceutical companies, including non-members of PReMA, tend to follow the same standards as a courtesy and to ensure fair competition within the industry.
- Although the PReMA Code is not considered to be law, and the Thai Food and Drug Association (FDA) does not have the authority to enforce it, a violation of the PReMA Code may be reviewed by the PReMA Committee, which has the power to sanction its members.

# 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

## 2.1 Definition of Advertising

The Drug Act does not provide a specific definition of "advertisement". In the view of the Thai FDA, any activities undertaken, organised or sponsored by a pharmaceutical company with the objective to encourage the prescription, supply or administration or consumption of its pharmaceutical product(s) through all methods of communications (including the internet) are considered an advertisement.

The FDA's Advertisement Rule 2002 explains that advertising may be classified into two main categories:

- advertisements targeted at the general public – permissible for household remedy drugs (similar to over-the-counter (OTC) drugs in other countries); and
- advertisements targeted at healthcare professionals – applicable for both household remedy drugs and non-household remedy drugs (eg, pre-packed drugs, dangerous drugs and specially controlled drugs).

In Thailand, drugs are divided into four categories based on the channel of distribution.

- "Household remedies" which are equivalent to OTC drugs. Products in this category can be sold without a prescription and do not require to be dispensed by a pharmacist.
- "Pre-packed drugs" which are not "dangerous drugs" or "specially controlled drugs" can

be sold without a prescription at a drugstore but must be dispensed by a licensed practitioner (ie, a medical doctor, dentist, nurse, veterinarian or pharmacist).
- "Dangerous drugs" can be sold without a prescription, but must be dispensed by a pharmacist only. The majority of pharmaceutical products in Thailand fall in this category.
- "Specially controlled drugs", which may result in potentially harmful effects if misused, can be dispensed by prescription only. Furthermore, some specially controlled drugs are only available in hospitals.

### 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Information such as on a disease awareness campaign is not considered to be advertising, as long as the materials are unbranded and are not intended to promote the use of a product through advertising. There are no differences based on the target audience (eg, HCPs or the general public).

### 2.3 Restrictions on Press Releases regarding Medicines

Restrictions on press releases differ depending on the drug category and target audience. As mentioned in **2.1 Definition of Advertising**, only household remedy drugs (or OTC drugs) can be advertised directly to the general public (eg, through mainstream media). Advertisements for non-household remedy drugs are limited to HCPs only.

#### Restrictions on Press Releases of Household Remedy Drugs

There are no restrictions on press releases or media releases related to household remedy drugs. Nonetheless, the material or media is subject to FDA review and approval before dissemination.

#### Restrictions on Press Releases of Non-household Remedy Drugs

Press releases or media releases related to non-household remedy drugs wherein the general public (or layperson) is a target audience, are not allowed by the Thai FDA. Advertisements of non-household remedy drugs are limited to HCPs only.

However, the above provision does not prevent pharmaceutical companies from responding to media enquiries or sharing the scientific/technical achievements of their drug products in a current, accurate and balanced manner (Chapter 13.2 on Media Release, PReMA Code).

### 2.4 Comparative Advertising for Medicines

In Thailand, comparative advertising for all types of goods and services is generally not allowed and this is particularly true of highly regulated goods such as pharmaceuticals. According to the FDA's Advertisement Rules, advertisements that compare or discredit a competing medicine are prohibited. Any comparison implying a therapeutic advantage that is not in fact justified must be avoided. Disparaging references to other products or manufacturers must also be avoided.

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

It is not possible to advertise information on unauthorised medicines or unauthorised indications (off-label use).

### Restrictions on Unauthorised Medicines

No pharmaceutical products or medicines can be promoted for commercial purposes until market authorisation approval of the product has been obtained from the Thai FDA.

### Restrictions on Unauthorised Indications (Off-Label Use)

Promoting or advertising a pharmaceutical product for use other than for the purpose approved by the Thai FDA is restricted under the Drug Act and Advertisement Rules. Specifically, the Drug Act states that an advertisement for the sale of a pharmaceutical product may not falsely or exaggeratedly show its therapeutic properties.

However, these provisions do not prevent pharmaceutical companies from sharing or exchanging scientific information on unauthorised medicines or unauthorised indications with HCPs. Materials that contain only scientific information and are scientific or educational in nature (ie, do not include any references to product branding or the company) would not be deemed an "advertisement" under the Drug Act and would therefore not need to obtain pre-approval from the Thai FDA.

## 3.2 Provision of Information during a Scientific Conference

Information an unauthorised medicine or an unauthorised indication for academic purposes, provided by an academic researcher, is acceptable. On the other hand, provision of the information by the company without a request from HCPs, or at a company-sponsored event, is not allowed.

Such information should be provided or discussed only when there is a request from HCPs. To mitigate risk, it is advisable to:

- present balanced information scientifically relating to the topic, such as giving updates on the treatment of a certain disease, covering all relevant drugs and treatment methods, without the tone of promoting non-approved products or indications;
- use a generic name as opposed to the product's trade name or trade mark; and
- avoid displaying any brandings, logos, banners, slogans or statements that may be construed as promotional in nature.

## 3.3 Provision of Information to Healthcare Professionals

As for **3.2 Provision of Information during a Scientific Conference**, pharmaceutical companies are not allowed to proactively send information on unauthorised medicines or unauthorised indications to HCPs. Pharmaceutical companies may only respond to unsolicited requests from HCPs or medical associations for scientific information on unauthorised medicines or unauthorised indications.

## 3.4 Provision of Information to Healthcare Institutions

Information on unauthorised medicines or unauthorised indications should not be presented to healthcare institutions. Pharmaceutical companies may send such information only upon receiving a written request from the healthcare institution.

## 3.5 Publication of Compassionate Use Programmes

There are no specific restrictions on publication of the availability of a compassionate use programme. Nonetheless, it is advisable to comply with the general rules for advertising a pharmaceutical product through HCPs. This strict and conservative approach will help to reduce legal risk.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

As a general rule, drug advertisements (either directed at the general public or HCPs) must be reviewed and approved by the FDA before dissemination. The main restriction on advertisements targeted at the general public is that these advertisements are only permissible for household remedy drugs.

Non-household remedy drugs (such as dangerous drugs and specially controlled drugs) cannot be advertised to the general public. Direct-to-consumer marketing activity for non-household remedy drugs is limited to activities that help create disease awareness or improve patient education and basic healthcare education.

#### Summary of Restrictions on Advertisements Directed at the General Public

Sections 88–89 of the Drug Act state that advertisements must not:

1) claim that a medicine can miraculously or absolutely treat, cure, or prevent a disease or illness;

2) exaggerate or falsely declare properties of the medicine;

3) give the impression that the drug has a substance as its main or component ingredient that it either does not have or has in a lower quantity than is believed to be present;

4) give the impression that it is an abortifacient or a strong emmenagogue (promoting menstrual flow);

5) give the impression that it is an aphrodisiac or a birth control drug;

6) present therapeutic claims for a dangerous or a specially controlled drug;

7) contain certification or endorsement of its therapeutic properties by any other person; and

8) show a drug's therapeutic properties as being capable of curing, mitigating, treating or preventing diseases (or symptoms of them) identified by notification from the Minister of Public Health under Section 77 of the Drug Act (eg, cancer, diabetes, paralysis, psychiatric disorders, blood pressure disorders, AIDS, health conditions related to neurological disorders, or cardiovascular, lung, kidney, spleen or liver disorders, etc).

Points (1), (4), (5), (6), (7) and (8) above do not apply to advertisements directed at HCPs.

The FDA's Advertisement Rules prescribe that advertisements must not:

- be contrary to tradition, such as local beliefs, norms, and morals;
- persuade patients to consume the product more than necessary or create a misunderstanding that the product should be used regularly;
- make a comparison that would defame other products;
- cause consumers to misunderstand that the drug is equivalent to other products, such as food or cosmetics; or
- encourage acts or activities contrary to law.

### 4.2 Information Contained in Pharmaceutical Advertising to the General Public

#### Information that Cannot Be Advertised to the General Public or Consumers

- Therapeutic claims of dangerous or specially controlled drugs;
- therapeutic claims related to the drug being an abortifacient or a strong emmenagogue;
- therapeutic claims related to the drug being an aphrodisiac or a form of birth control;
- therapeutic claims related to diseases for which advertisement is prohibited under a notification from the Minister of Public Health (eg, cancer, diabetes, paralysis, psychiatric disorders, blood pressure disorders, AIDS, health conditions related to neurological disorders, or cardiovascular, lung, kidney, spleen or liver disorders, etc); and
- other statements as prescribed in the FDA's Advertisement Rules.

#### Information that Can Be Advertised to the General Public or Consumers

- Name(s) of the active ingredient(s) – International Non-proprietary Names (INN) and approved generic drug names are acceptable;
- brand name;
- composition of drug product, eg, name or amount of inactive ingredient(s);
- therapeutic claims or indications;
- dosage or treatment regimen;
- name and address of manufacturing site or distributor;
- advertisement approval number granted by the Thai FDA;
- if there is a citation for reference, the required statement must be: "For further information, please see the full version of the reference or the package insert";
- price; and
- other statements as prescribed in the FDA's Advertisement Rules.

### 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

The laws and self-regulatory code (PReMA Code) do not restrict interaction between pharmaceutical companies and patients or patient organisations.

#### Declaration of Involvement

When working with patient organisations, companies must ensure that the involvement of the company and the nature of that involvement is clear from the outset. Companies may provide financial support for patient organisation meetings provided that the primary purpose of the meeting is professional, educational, and scientific in nature, or otherwise supports the mission of the patient organisation.

#### Written Documentation

If companies provide financial support or in-kind contributions to a patient organisation, it is advisable to have in place written documentation setting out the nature of the support, including the purpose and funding of any activity.

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Advertisements for dangerous drugs and specially controlled drugs can only be targeted at HCPs. However, only products that are registered in Thailand can be promoted to HCPs. No pharmaceutical products can be promoted until the required marketing authorisation has been obtained.

### Information that Cannot Be Advertised to HCPs

- exaggeration or false declaration of the properties of the medicine (including off-label use and unauthorised indications);
- comparisons that would defame other drug products;
- statements that persuade consumers or HCPs to use the drug persistently and unnecessarily, or lead consumers to understand that it is appropriate to take the drug regularly; and
- misleading statements demonstrating that the drug has a substance as a main or component ingredient that it either does not have or has in a lower quantity than believed to be present.

For further information on advertising restrictions, see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public**.

The same information can be advertised to HCPs as can be advertised to the general public. For a detailed list, see **4.2 Information Contained in Pharmaceutical Advertising to the General Public**.

## 5.2 Reference to Data Not Included in the Summary of Product Characteristics

There is no restriction on referring to scientific data that is not included in the summary of product characteristics (SPC). Scientific data includes academic publications (eg, official pharmacopoeias, textbooks, journals, research studies, experimental results, etc). Nonetheless, this scientific data must not be contrary to the information as approved in the SPC.

Presentations of scientific data should follow these general requirements:

- scientific data or references used as proof or support of content in an advertisement must be accurate, reliable and in accordance with international principles;
- advertising content must align with the details in the product leaflet or package insert (eg, dosage, therapeutic properties, indications, etc) and experimental results;
- for statistical studies, the full statistical data must be specified (eg, p-value, sample size, etc);
- the name of the experimental study must be shown, and the name of the sponsor must be disclosed; and
- the statement "For further information, please see the full version of the package insert or relevant technical documents" must be added.

## 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

Drug advertisements may refer to combination products or companion diagnostics, as long as the advertising material has received prior approval from the Thai FDA. In order to obtain advertising approval, scientific evidence substantiating the advertising of combination products must be provided to the Thai FDA.

Assuming that the combination product or companion diagnostic is a medical device, the advertisement must be reviewed and approved per the relevant medical device legislation as well.

## 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

There is no restriction specifically on providing HCPs with educational information or reprints of journal articles. However, companies should provide reprints of journal articles only after receiving a request from an HCP. Furthermore, companies should ensure that the journal article is accurate, balanced and does not focus on a particular product or contain unfair comparisons.

### 5.5 Medical Science Liaisons

Thai law does not restrict discussion or interaction between medical science liaisons (MSLs) and HCPs. Nonetheless, as mentioned earlier, information on unauthorised medicine or indications should not be explicitly presented. Therefore, MSLs should not proactively discuss unauthorised medicines or indications with HCPs. MSLs may discuss such information only upon receiving an unsolicited request from an HCP.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

#### Competent Authorities

The government agencies responsible for monitoring the advertising of drug products are:

- the Thai FDA; and
- the Public Health Provincial Office (for advertisements in provinces other than Bangkok).

Both regulatory authorities are under the supervision of the Ministry of Public Health (MOPH).

#### Requirements

Advertising for medicines directed at the general public or HCPs must receive prior authorisation from the Thai FDA or the Public Health Provincial Office (for advertisements in that particular province).

All advertising materials must be submitted for prior authorisation by filing an application together with the advertising materials for the FDA's review and approval before dissemination. The advertising licence is valid for a period of five years and is not renewable.

For more information regarding advertising requirements, see **4. Advertising Pharmaceuticals to the General Public** and **5. Advertising to Healthcare Professionals**.

### 6.2 Compliance with Rules on Medicinal Advertising

To reduce legal risk, companies should comply with the general rules for advertising a pharmaceutical product found in the following:

- the Drug Act;
- the Regulation of the Food and Drug Administration Re: Requirements on Advertising of Drugs BE 2545 (2002); and
- the PReMA Code.

There is no requirement to adopt SOPs or employ specific personnel to ensure compliance with rules on the advertising of medicines.

The PReMA Code suggests that companies are responsible for ensuring internal compliance with all provisions of the PReMA Code and rules on the advertising of medicines. Specifically, a designated company employee with sufficient knowledge and appropriate qualifications should be responsible for approving all promotional communications. Alternatively, a senior company employee may also be made responsible on the condition that they receive scientific advice on the promotional materials and communications from adequately qualified scientific personnel (Chapter 14 Company Procedures and Responsibilities, PReMA Code).

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

Advertising on the internet for medicinal products is regulated under the Drug Act, FDA's Advertisement Rules and the PReMA Code (the same provisions as imposed for other advertising media).

Only household remedy drugs can be advertised online directly to the general public. For non-household remedy drugs, all direct-to-consumer marketing activities are prohibited.

For further information, regarding advertising requirements/restrictions, see **4. Advertising Pharmaceuticals to the General Public**.

### 7.2 Advertising of Medicines on Social Media

As for **7.1 Regulation of Advertising of Medicinal Products on the Internet**, only household remedy drugs are allowed to be advertised through social media. Advertising for medicines classified as non-household remedy drugs is not allowed on social media.

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

Websites with advertisements or other information only intended for healthcare professionals must include access restrictions in order to allow only the intended target audience to view the information.

### 7.4 Provision of Disease Awareness Information to Patients Online

Under the PReMA Code, companies are allowed to provide disease awareness information or materials to patients online, on the condition that the information or materials adhere to the highest standards of accuracy and support the role of healthcare professionals. Furthermore, websites providing general information to the public must be general and cannot include product promotional information or individual medical advice (Chapter 13.4 Telephone Hotline and Website, the PReMA Code).

### 7.5 Online Scientific Meetings

Pharmaceutical companies are allowed to sponsor scientific meetings and congresses. There are no specific criteria for distinguishing international events from national events. In general, an online conference may be considered an international event if the event is organised by multinational organisers and it features speakers from other countries.

To host a scientific meeting or congress, companies do not need to obtain prior approval from the regulatory authority. However, advertising materials to be disseminated at the event may be subject to FDA review and approval if the materials fall within the scope of advertising.

In response to the COVID-19 pandemic forcing meetings to move online, on 21 September 2020 the FDA published a circular that clarified what types of advertising materials were approved for use in virtual meetings. The circular outlines prior authorisation requirements for the display of materials during the online conference, stating that online materials used in teleconferences or virtual meetings must still be submitted to the FDA for approval, regardless of whether the materials were previously approved by the FDA for other publication formats (eg, as printed materials).

The advertisers must also submit the following documents for review by the FDA:

- a pledge that they will follow the conditions for additional media platforms; and
- a copy of their drug advertising licence for the advertising material currently approved by the FDA.

After the FDA has approved the material for use on additional media platforms, the advertising or promotional material must display the approval number of the advertising licence.

Only material that does not contain the trade name or company name and is used only for educational purposes, is free from the requirement for FDA pre-approval.

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

The main anti-bribery laws that apply to interactions between pharmaceutical companies and HCPs are:

- the Penal Code;
- the Organic Act on Counter Corruption BE 2561 (the "OACC"); and
- the Act on Offences Relating to the Submission of Bids to State Agencies BE 2542 (the "Submission of Bids Act").

The bribery addressed in these laws all relates to wrongful payments involving government officials. The Penal Code and OACC criminalise giving bribes to government officials. These laws also criminalise the acceptance of bribes by government officials. The Submission of Bids Act further criminalises bribes related to public procurement. Thailand does not criminalise "private-sector" bribery (ie, when the bribe giver and bribe receiver are both private sector parties). However, an exception to this would be if the private sector bribe giver and bribe receiver are involved in bidding for a government project. The general elements of these laws are as follows.

#### Giving, Offering, or Agreeing to Give a Bribe

The Penal Code and the OACC prohibit giving, offering or agreeing to give property or any other benefit to induce state officials or assembly members to perform, avoid or delay an act that contradicts their functions. The definition of "state official" in the OACC also includes foreign state officials and international organisation officials.

Under the OACC, a legal entity can be criminally liable for the wrongful activity of its employees, agents and others acting on behalf of the entity (called "associated persons" in the law), even if the associated person gave the bribe without management's authorisation. In such a case, the legal entity can be liable for the bribery if the associated person committed the act for the benefit of the legal entity, and the entity did not have proper internal measures (ie, an anti-corruption compliance programme) to prevent the bribe.

The Submission of Bids Act prohibits offering or agreeing to give property or any other benefit to induce another person to dishonestly participate or not participate in the submission of bids for the benefit of any person.

#### Demanding or Accepting a Bribe

The Penal Code and the OACC prohibit state officials and assembly members from demanding, accepting or agreeing to accept property or any other benefit that affects his or her duties. The definition of "state official" in the OACC also

includes foreign state officials and international organisation officials.

The Submission of Bids Act extends the prohibition to any person from demanding, accepting or agreeing to accept property or any other benefit. To be guilty under the Submission of Bids Act, the bribe receiver must have the intention of demanding, accepting, or agreeing to accept property or any other benefit to dishonestly participate or not participate in submission of bids for the benefit of any person.

### Intermediaries

The Penal Code and the OACC prohibit an intermediary from demanding, accepting, or agreeing to accept property or any other benefit as compensation for influencing a state official and assembly member to perform or not perform his or her duties for an advantage or disadvantage for anyone. The definition of "state official" in the OACC also includes foreign state officials and international organisation officials.

### Permitted Gifts/Benefits to State Officials

Under the OACC a state official can receive property or any other benefit from a person who is not a relative of the state official when it:

- is given on an "ethical basis" under the circumstances; and
- does not exceed THB3,000 in value per occasion, and is meant for the general public.

An example of "ethical basis" is when giving or receiving a gift is generally considered "proper" under social norms in Thailand, and when the gift/benefit is not intended to influence an official (ie, is not a bribe in disguise).

## 8.2 Legislative or Self-Regulatory Provisions

Under the PReMA Code, gifts and other items provided to HCPs must never constitute an inducement to prescribe, recommend purchase, supply, sell, or administer a pharmaceutical product. Pharmaceutical companies should not provide direct sponsorship for HCPs to attend sporting or other entertainment events, as this can be seen as inducement. Lastly, company representatives and organisations must not employ any inducement or subterfuge to gain a contract from an HCP and must not be paid for that purpose.

# 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

## 9.1 Gifts to Healthcare Professionals

Pharmaceutical companies may only offer gifts to HCPs under certain situations and with monetary limitations. Payment in cash or cash equivalents (such as a gift voucher) must not be offered to HCPs, and gifts for the personal benefit of HCPs are prohibited.

However, gifts to HCPs and institutions for customary and acceptable local occasions are allowed on an infrequent basis. The value of such gifts, the nature and type of which should be related to the particular customary occasion, must not exceed THB3,000 per healthcare professional, per occasion according to the PReMA Code.

### Frequency

The restriction under the PReMA Code is that medical representatives must not employ any inducement or subterfuge to gain a call; neither should any fee be paid for that purpose.

### Provision of Hospitality

There are no explicit restrictions on provision of hospitality, but the PReMA Code stipulates that sponsorship of healthcare professionals is limited to payment of legitimate travel, registra-

tion fees, meals and accommodation only for the period and location of the sponsored event. Reimbursement of expenses against official receipts is possible, but no cash advance to an HCP is allowed.

### Other Indirect Incentives

Indirect incentives are not allowed to be given to HCPs.

## 9.2 Limitations on Providing Samples to Healthcare Professionals

The Drug Act does not address the issue of pharmaceutical companies providing free samples to HCPs. However, the PReMA Code provides that samples of products may only be supplied to a healthcare professional upon their consent. The size and quantity of the sample supplied should be appropriate for the following:

- to allow the HCP to become familiar with the presentation and appearance of the product;
- to provide to patients for initiation of therapy; or
- to conduct an agreed-upon clinical evaluation of the product.

All samples delivered by sole distributors or medical representatives, or via mail or courier, should be securely packed and must be signed for by the receiver.

Under the PReMA Code, the term "drug sample" means a unit of a drug that is not intended to be sold and is intended for one of the reasons stated above. No person may sell or trade, or offer to sell or trade, a drug sample.

## 9.3 Sponsorship of Scientific Meetings

Generally, pharmaceutical companies are allowed to sponsor scientific meetings or congresses and attendance by HCPs at these events. It is also permissible to sponsor healthcare professionals to attend an international congress, and to invite them to a satellite symposium at a congress they are already attending.

However, it is prohibited to run an overseas stand-alone company-sponsored meeting for HCPs where all (or nearly all) of the attendees or speaker(s) are from Thailand.

Furthermore, the PReMA Code contains a guideline that symposiums and congresses (local and international) initiated by a pharmaceutical company (local only), its regional office, or its corporate headquarters, must devote at least 75% of the total time to scientific sessions, outside of reasonable travel time. Any hospitality, entertainment or gimmick provided by drug companies, either directly or through sponsorship or arrangement with the meeting organisers, must be secondary to the educational purposes of the meeting and not considered extravagant by local standards.

Invitations to attend medical and scientific meetings must only be given to HCPs. Sponsorship must be limited to the payment of travel, meals, accommodation and registration fees. Guests may not be invited, and the expenses of persons accompanying the attendee may not be paid.

## 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies should not provide direct sponsorship for HCPs to attend sporting or other entertainment events, as this can be seen as inducement.

## 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Pharmaceutical companies may provide donations directly to a healthcare institution (but not individual HCPs) upon the institution's request to support activities for HCPs, as long as it can be demonstrated that there is a link to scientific

education, patient benefit or the improvement of healthcare services.

### 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Pharmaceutical companies are allowed to give discounts and rebates to HCPs and healthcare institutions in Thailand. Discounts or rebates associated with the sale of pharmaceutical products must be made by account payee cheque, bank transfer to a bank account associated with the respective hospital, or invoice (PReMA Code).

### 9.7 Payment for Services Provided by Healthcare Professionals

According to the PReMA Code, payment for services provided by HCPs must be agreed prior to their work as consultants and advisers providing services such as speaking at or chairing meetings and events; involvement in medical or scientific studies, clinical trials or training services; participation at advisory board meetings; or participation in market research involving remuneration. The following criteria from the PReMA Code must be satisfied when paid services are provided by HCPs:

- a written contract or agreement of the services must outline the nature of the services and the basis of payment for these services;
- a legitimate need for the services must be clearly identified and documented in advance;
- the criteria for selecting HCPs must be directly related to the identified need, and selected professionals must have the expertise necessary to provide the service;
- the number of HCPs providing the service must be only what is reasonably necessary to achieve the identified need;
- the engagement of the HCP(s) for the services must not be an inducement to prescribe, recommend, purchase, supply or administer any medicine; and
- the payment provided for the services must be reasonable and must be at an accepted, fair market rate (Chapter 7.3 Fee for Services, PReMA Code).

### 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

Pharmaceutical companies can offer gifts, sponsorships, donations and payment to HCPs for services provided without prior authorisation or notification involving the regulatory authority.

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

Pharmaceutical companies are not required to disclose details of transfers of value to HCPs or healthcare institutions.

### 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

Transparency requirements do not apply to foreign companies or companies that do not yet have products on the market.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

#### Regulatory Authorities

See **6.1 Requirements for Prior Notification/ Authorisation**.

#### Self-Regulatory Authorities

PReMA has an important role in supervising marketing activities which violate the PReMA Code. The Sales and Marketing Ethics Committee reviews the provisions of the PReMA Code after seeking input from interested parties at least every three years.

If a complaint regarding a breach of the PReMA Code is filed by another PReMA member, the complaint will be administered by the PReMA chief executive officer and the Code of Conduct Committee (CCC). When the allegedly breaching company or complainant disagrees with the decision of the CCC, they may request a second-instance ruling. The resubmission must be made in writing, along with any new evidence, within ten days of receiving the notification from the PReMA CEO. If new evidence or arguments are put forward, the other party will be invited to provide comments within 30 days. The decision of the CCC at this stage will be final.

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

In most cases, Thai law views violations of advertising requirements as a harm against the general public or an individual consumer. Harm against the general public is enforced by the state, as represented by the Thai FDA and most likely the responsible division of the Royal Thai Police. One or both of these would undertake the enforcement either by summary fines or by referring a criminal action to the court through the public prosecutor. If the violation also injures a consumer, then the consumer may bring a civil case against the advertiser, typically through consumer proceedings, which are more streamlined than general civil and commercial proceedings.

An advertising violation may also be a competitor's cause of litigation if the competitor itself is injured by the advertising, such as comparative advertising (which is generally prohibited) that is also libellous against the competitor.

### 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The Drug Act sets out penalties or measures that regulators can impose for the violation of advertising rules for medicines and rules on inducement. The secretary-general of the Thai FDA can issue a written order to cease any advertisement deemed to be contrary to the Drug Act. If it is determined that the advertisement misled the public, the Thai FDA can order the violator to issue a corrective advertisement.

Violation of the Drug Act's marketing provisions is subject to a fine of up to THB100,000. Calculation of the fine depends on the amount of time it takes the advertiser to act after receiving a warning or notice of violation, and the number of occurrences of other wrongdoings. For example, if a promotional booth uses three posters and two gimmick gifts that have never been submitted for FDA approval, the violator could be fined for a combination of the five offences.

For PReMA members, if a complaint regarding a breach of the PReMA Code is filed by another PReMA member, the complaint will be administered by the PReMA chief executive officer and the organisation's CCC, which may sanction PReMA members.

Upon the decision of the CCC, the PReMA CEO may order one or more of the following actions:

- referring the complaint to the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA);
- referring the complaint and the CCC's findings to the head office and regional office of the offending company;
- suspending the offending company's membership of PReMA for up to three years;
- debarring the offending company from membership of PReMA;
- requiring a written undertaking that the practice complained about will be discontinued on or before a date to be determined by the CCC; and
- requiring retraction statements, including corrective letters and advertising, to be issued by the company, subject to the approval of the CCC prior to release.

It is the company's responsibility to ensure that the requirements of the CCC are met and to immediately inform and provide evidence to PReMA of their fulfilment.

PReMA may also fine the company up to THB100,000 (EUR2,480) for a first offence or up to THB500,000 (EUR12,395) for a second offence within a 12-month period. The imposed fine is to be paid within 30 days of being issued, subject to any appeal that may be lodged.

## 11.4 Relationship between Regulatory Authorities and Courts

Procedures before the self-regulatory authority are considered internal undertakings of a private entity (ie, an association). As such, the measures taken by the self-regulatory authority are, unlike an arbitral award, not enforceable by the court without a trial.

## 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

While enforcement actions against pharmaceutical advertising in Thailand are taken regularly, there has not been any recent trend pointing to a change of policy, organisational structure, or the market landscape.

**Tilleke & Gibbins** is a South-East Asian regional law firm with over 200 lawyers and consultants practising in Cambodia, Indonesia, Laos, Myanmar, Thailand and Vietnam. The firm provides full-service legal assistance to investors and companies that drive economic expansion in Asia. Established in Bangkok in 1890, today Tilleke & Gibbins is a major international firm with offices in six countries that prioritises understanding its clients' businesses and working with them towards their commercial goals. The firm is known for its deep local knowledge and commitment to this fast-developing part of the world, which is especially valuable to global companies needing to navigate unfamiliar markets and regulatory environments in South-East Asia. Clients who engage Tilleke & Gibbins are given a team of advisers who provide clear, practical advice; who are responsive in communications; who represent them with integrity; and who guide their clients through the available options to arrive at the most effective course of action, whether this means following well-established procedures or applying an innovative approach.

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# UK

## Law and Practice

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## CONTENTS

# 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

## 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

### Laws

Part 14 of The Human Medicines Regulations 2012/1916 (HMR) sets out the main UK laws on the advertising of medicines (The Medicines (Advertising of Medicinal Products (No 2)) Regulations 1975/1326 and The Medicines (Labelling and Advertising to the Public).

The Medicines and Healthcare Products Regulatory Agency (MHRA) Blue Guide (the "Blue Guide") explains the legal provisions and helps with interpretation and application of the laws that relate to the advertising of medicinal products.

The Cancer Act 1939 includes prohibits certain advertisements relating to cancer treatments.

General consumer advertising laws apply equally to advertising of pharmaceuticals to the public. In relation to non-broadcast advertising, these include the Trade Descriptions Act 1968 and the Consumer Protection from Unfair Trading Regulations 2008. In relation to broadcast advertising, the Broadcasting Acts 1990 and 1996 and the Communications Act 2003 apply.

However, the rules and their enforcement in relation to pharmaceutical advertising in the UK has been largely developed through self-regulatory schemes.

### Self-Regulation

#### *Advertising Standards Authority (ASA)*

The ASA is responsible for administering the UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (the CAP Code) which is written and maintained by the Committee of Advertising Practice. The Broadcast Committee of Advertising Practice (BCAP) similarly writes and maintains the Code of Broadcast Advertising (the BCAP Code). These codes relate to all advertising to the general public, but also include specific provisions relating to the advertising of medicinal products.

#### *Industry codes*

The Association of the British Pharmaceutical Industry (ABPI) Code applies to prescription medicines and is enforced by the Prescription Medicines Code of Practice Authority (PMCPA) which operates independently of the ABPI.

The Proprietary Association of Great Britain (PAGB) is the largest UK trade association for over the counter (OTC) medicines. PAGB has two codes applicable to pharmaceutical advertising:

- the PAGB Consumer Code for Medicines (for advertising directed to consumers); and
- the PAGB Professional Code for Medicines (for advertising directed to professionals).

## 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

### Industry Codes

The ABPI Code applies to members of the ABPI, and the ABPI represents suppliers of more than 80% of all branded medicines used by the NHS. Membership and affiliate membership of the ABPI are conditional upon an agreement to adhere to the spirit and letter of the ABPI Code. Non-members can also formally agree to abide by the code and the jurisdiction of the PMCPA and do so to fall under the judgement and sanction of the PMCPA rather than of the UK regulator, the MHRA. Around 60 non-member companies have made such an agreement. Any person can make a complaint under the ABPI

code, although most are made by competitors and by healthcare professionals.

The PAGB Code similarly applies to members of the association, and both they and authorised associate members of PAGB working with them can submit advertising copy for review and clearance to PAGB.

### General Advertising Codes

The CAP and BCAP codes apply to public non-broadcast and broadcast advertising respectively. The ASA is funded by the advertising industry and has an arrangement with the communications regulator, Ofcom, pursuant to which the ASA is given responsibility to regulate TV and radio advertising. Any individual or business can complain to the ASA, but the ASA also monitors advertising.

Clearcast approves television advertising pursuant to the UK Code of Broadcast Advertising.

Radiocentre is the industry body for UK commercial radio and is responsible for ensure that medicines advertising on the radio is compliant with the UK Code of Broadcast Advertising.

### Relationship with Legislation/MHRA

The MHRA works closely with the self-regulatory bodies in the Medicines and Devices Advertising Liaison Group (MDALG) which meets once or twice a year to develop guidance and a common understanding of the applicable law and publishes its minutes online.

## 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

### 2.1 Definition of Advertising

"Advertising" is defined in regulation 7 of the HMR as "anything designed to promote the prescription, supply sale or use of that product". Regulation 7(2) of the HMR includes a list of activities that are considered to be advertising such as:

- door-to-door canvassing;
- visits by sales reps;
- supply of samples;
- inducements to prescribe or supply medicinal products;
- sponsorship of promotional meetings attended by those qualified to prescribe or supply medicinal products; and
- sponsorship of scientific congresses, including payment of travelling and accommodation expenses of persons qualified to prescribe or supply medicinal products.

Regulation 7(3) clarifies that the following are not considered an "advertisement":

- a medicinal product's package or package leaflet;
- reference material and announcements of a factual and informative nature; or
- correspondence, which may be accompanied by material of a non-promotional nature, answering a specific question about a medicinal product.

Furthermore "publication" in relation to an advertisement is defined in regulation 277(1) of the HMR, "in relation to an advertisement, means the dissemination or issue of that advertisement— (a) orally; (b) in writing; (c) by means of an electronic communications network within the meaning of the Communications Act 2003; or (d) in any other way, and includes causing or procuring such publication by or on behalf of another person". Advertising offences all relate to "publishing" an advertisement that breaches the HMR.

The Blue Guide adds that labelling and package leaflets are not considered advertising if they meet the requirements of part 13 of the HMR. The Blue Guide also clarifies that any person, not just the manufacturer or distributor, might breach THMR if they promote a medicine, and this includes individuals, journalists, publishers and public relations agencies.

The ABPI Code does not define "advertising" but defines promotion, in paragraph 1.17, as: "any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines".

This includes:

- journal and direct mail advertising;
- the activities of representatives, including any electronic or printed material used by them;
- the supply of samples;
- the provision of inducements to prescribe, supply, administer, recommend, buy or sell medicines by the gift, offer or promise of any benefit or bonus, whether in money or in-kind;
- the provision of hospitality for promotional purposes;
- the sponsorship of promotional events/meetings;
- the sponsorship of scientific events/meetings, including payment of travelling and accommodation expenses in connection therewith; and
- all other promotion.

The PAGB Consumer Code also does not define "advertising" but includes a list of items and activities that are considered materials that are covered by the code, including social medial, text messages, websites, advertorials, and materials written by third parties but in relation to which members have had the opportunity to comment and to request amendments.

## 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Labelling and package leaflets meeting the requirements of part 14 of the HMR are not considered to be advertising.

Disease awareness and health education campaigns that do not make product claims are not considered to be "advertising". Appendix 7 of the Blue Guide provides detailed guidance which states that these campaigns must avoid the use of brand names and must not relate just to a limited range of treatments as this is likely to lead to the prescription of a specific prescription only medicine or medicines. While a disease awareness campaign might refer to available treatment options, this should not encourage individuals to request a particular medicine, but rather should focus on raising awareness of symptoms or risk factors so that early diagnosis might be sought.

## 2.3 Restrictions on Press Releases regarding Medicines

### Laws

Press releases for prescription medicines are not specifically prohibited, but the MHRA requires that they should be made about a prescription medicinal product only where the press release is genuinely newsworthy. They must not be used to promote prescription only medicines, but rather should promote balanced medica coverage.

Section 7.7 of the Blue Guide requires that press releases provide the context for use of the medicine and the population for which it has been licensed, setting the product and results in the context of alternative treatments and current medical practice. Brand name use should be minimised, and the content should be factual and not sensationalised. Healthcare profes-

sional (HCP) statements should be balanced and informative, and perspectives from any patient should focus on the impact the disease has on them, and not on the specific medicine.

Appendix 5 of the Blue Guide is addressed to journalists and patient organisations writing about medicines as even though neither will usually have commercial links with the product, they can still breach the HMR. The guidance is to inform rather than to promote, to provide balanced factual and accurate reporting without encouraging readers to seek a particular product and without exaggerating the potential benefits of a medicine.

The Blue Guide accepts the need for business press releases intended to keep shareholders informed and states that these should identify the commercial importance of the information and should be factual and balanced.

### Self-Regulatory Industry Codes

The ABPI code states that it is good practice to reference the summary of product characteristics with a press release, and manufacturers should consider including references "to other credible sources of information about a condition or a medicine". This is again to provide a balanced perspective.

The PAGB Code distinguishes between PR on the consumer facing part of a website, and those in a dedicated press section. Only the former requires PAGB pre-approval. However, PAGB consider that a HCP's recommendation is not acceptable in consumer-facing PR, and nor is any celebrity endorsement.

## 2.4 Comparative Advertising for Medicines

### Comparisons in Advertising to the Public

Section 5.6 of the Blue Guide states that comparative claims against another named product are prohibited in advertising to the public. This means that only claims that relate to a category of products might be made in advertisements of medicines to the public.

The PAGB Codes do not permit comparisons that denigrate another ingredient, product or product category. The PAGB Consumer Code also requires that comparisons are made only where the point of difference is sufficiently significant to be meaningful to consumers. If the comparative claim is made in a context that allows a competitor to be identified, then the advertiser must provide information to the consumer which allows the consumer to verify the claim. The PAGB Professional Code requires that hanging comparisons are not made: the product category being compared should be made clear.

### Comparisons in Advertising to Professionals

The Blue Guide (4.3) states that comparative claims might only be made where they relate to the licensed use, they can be substantiated and are either included in the SmPC and are not inconsistent with the SmPC. Where new data shows a comparison that is contrary to what is stated in the SmPC, the SmPC must be updated before the comparison might be made.

ABPI code requires that comparisons are not misleading, are accurate, fair and can be substantiated and do not create confusion between products or trade marks and no unfair advantage is of the reputation, brand or marks of a competitors is gained.

### General Laws and Codes on Comparative Advertising

As a general legal principle applicable to all products, comparative advertising is permitted subject to compliance with the Business Protection from Misleading Marketing Regulations 2008 (SI 2008/126) and the Consumer Protection form Unfair Trading Regulations 2008 (SI

2008/1277). However, comparisons of one medicine against even a category of medicines must be approached with care. The principles under these general advertising laws include that:

- the comparison must not be misleading (meaning that it does or is likely to deceive);
- that it does not mislead by omission
- that the comparison is fair: that the products meet the same needs or are intended for the same purpose (in this case the same indication and intended patient population);
- there is an objective comparison of one or more material, relevant, verifiable and representative features of the products;
- it does not discredit or denigrate the marks or names or features of the other product; and
- it does not take unfair advantage of a trade mark, trade name or other distinguishing marks.

A breach of the general laws on comparative advertising can lead to one or more of the following actions by the competitor, although these are less likely to succeed where the comparison is to a category or medicines:

- passing-off;
- trade mark infringement;
- trade libel;
- malicious falsehood; and
- copyright infringement.

The CAP Code states that even comparisons with an unidentifiable competitor must not mislead or be likely to mislead the consumer and the selected elements for comparison must not give the advertiser an unrepresentative advantage.

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

It is not permitted to provide information to patients or consumers on unauthorised medicines or unauthorised indications. All advertising must comply with the SmPC (regulation 280 HMR).

Clause 3.1 of the ABPI Code states that a medicine must not be promoted prior to grant of a marketing authorisation. Clause 11.2 of the ABPI Code states that the promotion of indications not covered by the marketing authorisation for a medicine is prohibited. Section 4.1.1 of the PAGB Consumer Code includes similar provisions.

Under the ABPI Code clause 1.17, information on unauthorised medicines or indications might only be given to HCPs in response to an unsolicited written question from that HCP but only if the response relates solely to the subject matter of the enquiry, is accurate, does not mislead and is not promotional in nature. Such responses are not considered to constitute "promotion".

### 3.2 Provision of Information during a Scientific Conference

Regulation 278 of the HMR does not permit the advertising of medicines without a marketing authorisation.

Clause 3.1 of the ABPI Code permits the "legitimate exchange of medical and scientific information during the development of a medicine". This is on the basis that the activity does not constitute promotion. A conference constituted

of a passive audience of HCPs to which a presentation on a medicine in development is given is likely to be seen as promotional and therefore not permitted. Conversely, a small advisory board of HCPs with the relevant specialism who provide their clinical views on the indication and products in development in relation to specific requests for advice is more likely to be considered a permitted legitimate exchange on the basis that this is not a promotional activity.

### 3.3 Provision of Information to Healthcare Professionals

See **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**.

There is a limited exception to the law and codes on prohibiting the display or provision of informant on unauthorised medicines or unauthorised indications to HCPs, which is in relation to international events/meetings held in the UK. Clause 11.3 of the ABPI Code and paragraph 6.11 of the MHRA Blue Guide state that at such meetings, information might be provided or displayed if the following criteria are met:

- the event/meeting must be truly international, of high scientific standing and with a significant proportion of the attendees from countries outside the UK where there is a relevant licence;
- the medicine or indication must be relevant and proportional to the purpose of the event/meeting;
- the lack of UK marketing authorisation must be clearly and prominently indicated in all materials;
- approved prescribing information must be readily available for a medicine authorised in the UK, even though it will not refer to the unlicensed indication;
- the names must be given of countries in which the medicine or indication is authorised (including at least one major developed country);
- it must be stated that registration conditions differ from country to country; and
- the material must be certified as required by the Code.

### 3.4 Provision of Information to Healthcare Institutions

Clause 3.1 of the ABPI Code permits the provision of advance information to NHS organisations where that information is solely directed to the budget decision makers (not prescribers):

- involved in the purchase of medicines;
- who need to estimate their likely budgets in advance; and
- where those changes may significantly affect their level of expenditure such as through changes in the patient pathway and/ or service delivery.

The information that might be provided must relate to a product:

- containing a new active substance; or
- a new active substance prepared in a new way; or
- is to have a significant addition to the existing range of authorised indications; or
- is to have a novel and innovative means of administration;

The communication should:

- state whether or not the medicine has a UK marketing authorisation;
- state the likely cost or savings and budgetary implications (which must represent a significant change on likely expenditure);
- be factual and limited to an adequate but succinct account of the product's properties, with mentions of other products only being

made to put the new product or indication into its therapeutic context;
- not be promotional in style; and
- not include mock-up drafts of the SmPC or package leaflets.

### 3.5 Publication of Compassionate Use Programmes

Unlicensed medicines which are provided under a compassionate use or other early access programme cannot be promoted (Regulation 280(4) of the and Clause 11.1 of the ABPI Code). The programmes themselves cannot be promoted where this would amount to promotion of an unlicensed medicine, which will be likely in most cases, with the exception of public health campaigns, such as for the COVID-19 vaccines.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

It is prohibited to publish an advertisement for a medicinal product unless there is an applicable marketing authorisation in place (Regulation 279 of the HMR). Any advertisement for a medicinal product must (Regulation 280 of the HMR):

- comply with the SmPC;
- encourage rational use of the product by presenting it objectively and without exaggerating its properties; and
- not be misleading.

Regulations 283 to 292 of the HMR relate to the advertisement of medicines to the public. Restrictions on such advertising include advertisements:

- likely to lead to use for the purpose of inducing an abortion (Regulation 283 of the HMR);
- likely to lead to use of a prescription only medicine (Regulation 284 of the HMR);
- for narcotic of psychotropic substances (Regulation 285 of the HMR)
- that state or imply the necessity of a medical consultation or surgical operation;
- that offers to provide a diagnosis or suggest a treatment by post or electronic communication;
- that could lead to erroneous self-diagnosis;
- that suggest the effects of the medicinal product:
  (a) are guaranteed;
  (b) are better than or equivalent to those of another identifiable treatment or medicinal product; or
  (c) are not accompanied by any adverse reaction;
- that uses in terms that are misleading or likely to cause alarm, pictorial representations of changes in the human body of the disease or injury or the action of the medicinal product on the human body;
- the suggest the health of a person who is not suffering from any disease or injury could be enhanced by taking the product, or that their health could be affected by not taking the product;
- that suggest the medicinal product is a food, cosmetic or other consumer product or that its safety or efficacy due to it being natural;
- including recommendations by scientists, HCPs or celebrities; and
- that are directed principally at children.

Consumer advertising is required to identify clearly that it is an advertisement, and the product is a medicinal product (Regulation 291 of the HMR).

Under the Cancer Act 1939, Section 4 specifically prohibits the publication of any advertisement offering to:

- treat any person for cancer; or
- prescribe any remedy for cancer; or
- give any advice in connection with the treatment of cancer.

Licensed vaccine products approved by health ministers as part of a government-controlled vaccination campaign are exempt from the prohibition on advertising prescription-only medicines.

## 4.2 Information Contained in Pharmaceutical Advertising to the General Public

### Laws

Regulation 291(2) of the HMR requires any advertisement of a medicinal product to include the following (see Annex 3 of the MHRA Blue Guide also):

- the name of the product;
- if there is only one active ingredient, the common name of the active ingredient;
- information necessary for the correct use of the medicinal product;
- an express and clear invitation to read carefully the instructions on the package or the package leaflet, as applicable; and
- for products with a Great Britain licence that are not also licensed in Northern Ireland or are prescription-only in Northern Ireland, a statement that the product is not available of not available without prescription in Northern Ireland, as applicable.

The advertisement should be clear that the material or message is an advertisement and the product advertised is a medicine.

MHRA Blue Guide (Appendix 3) provides detailed guidance on advertising medicines which might be promoted for use during pregnancy. The appendix applies both to consumer and professional advertising.

### Self-Regulation

The PAGB Consumer Code (Section 1.5.15) includes the following additional requirements for including in advertisements for non-prescription-only products:

- therapeutic indication in line with the SmPC;
- products for conditions that are difficult to self-diagnose should state that people should obtain a doctor's diagnosis before using the product for the first time, particularly where this is stated in the SmPC;
- smoking cessation products should refer to the need for willpower to quit smoking successfully; and
- promotion of medicines during pregnancy are only acceptable where a positive statement in Sections 4.1 or 4.6 of the SmPC supports such use, and advertisements must encourage a cautious approach; and
- any other wording required as a condition of the marketing authorisation.

## 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

### Guidance on the Law

The MHRA Blue Guide includes guidance for patient organisations in Appendix 5. This sets out the expectation that they will have robust procedures to ensure that they retain their independence from pharmaceutical companies, even if those companies provide them with support.

This means that any information provided by patient organisations should be under their editorial control to avoid it becoming promotional in nature and therefore subject to the medicinal product advertising laws. Patient organisations should also not actively encourage patients to seek a particular product from their doctor.

Patient organisations are also likely to be subject to Charity Commission rules.

### ABPI Code

Pharmaceutical companies are required to respect the independence of patient organisations and are not to promote or request the promotion of a particular prescription only medicine (Clause 27.1). They must not influence the text of patient organisation material to favour its own interests (Clause 27.4) but might contribute to the drafting of patient organisation materials from a fair and balanced scientific perspective.

There must be a written agreement for all sponsorships, donations and grants to patient organisations (Clause 23.2).

The ABPI Code includes disclosure requirements imposed on manufacturers for interactions with patient organisations (Clause 4.4, 24.6 and 29). Manufacturers are required to document and annually publish on the company website on a national or European level:

- summary details of the monetary value of support to patient organisations, including in relation to sponsorship of events/meetings (Clause 10.11); and
- fees and expenses for the provision of contracted services by individuals representing patient organisations and the total amount paid per patient organisation per calendar year.

It is prohibited to provide gifts to individuals associated with patient organisations (Clause 3.5). Donations and grants are only permitted to patient organisations if they (Clause 24.3):

- are made for the purpose of supporting healthcare, scientific research or education;
- do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines;
- are prospective in nature;
- do not bear the name of any medicine (the company name is acceptable); and
- are the subject of a written agreement detailing all the main elements of the arrangement (Clause 27.2) and which is certified.

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

#### Information Required by law

Schedule 30 of the HMR details the information to be included in advertisements to HCPs. This includes:

- the number of the marketing authorisation;
- the name and address of the marketing authorisation holder;
- for an advertisement in Great Britain, a statement that the product is authorised under a UKMA(GB);
- the classification of the product:
  (a) general sale (G);
  (b) prescription only (POM);
  (c) pharmacy only (P);
- the name of the medicine;
- the list of active ingredients, using their common names and placed immediately adjacent to the most prominent display of the name of the product;
- one or more indications consistent with the marketing authorisation;
- a succinct statement of the SmPC (which must be printed in a clear and legible manner and placed so that their relationship to the claims and indications can be readily appreciated by the reader) on:
  (a) adverse reactions, precautions and relevant contra-indications;
  (b) dosage and method of use relevant to the

indications in the advertisement; and
(c) if not obvious, the method of administration; and
- the cost of either a specified package or quantity or recommended daily dose (except if more than 15% of the publication circulates outside the UK).

Schedule 30 of the HMR is clarified by Annex 4 of the MHRA Blue Guide.

### ABPI Code

Clause 12 of the ABPI Code restates the above list and adds the following items to be included in promotional materials:

- any warning issued by the Medicines Commission, the Commission on Human Medicines, the Committee on Safety of Medicines or the MHRA and that is required to be included in advertisements;
- the date the prescribing information was drawn up or last revised;
- the INN must appear immediately adjacent to the most prominent display of the brand name in bold type of a size such that a lowercase x is no less than 2mm in height or in type of such a size that the non-proprietary name or list of active ingredients occupies a total area no less than that taken up by the brand name;
- in digital material the prescribing information might either be included directly or via a clear and prominent, direct, single click link;
- promotional material on the internet must include a clear prominent statement as to where the prescribing information can be found;
- prescribing information must appear on at least one of the pages in a printed journal advertisement and for those pages where it is not visible, there should be a reference on the outer edge of the page for where to find the prescribing information, with lower case x no less than 2mm in height;
- the prominent statement "Adverse events should be reported. Reporting forms and information can be found at [website address which links directly to the MHRA Yellow Card site]. Adverse events should also be reported to [relevant pharmaceutical company]"; and
- where required the inverted black equilateral triangle for products requiring additional monitoring.

Note that for an abbreviated advertisement to HCPs, meaning one that does not exceed 420cm2, truncated information might be included rather than the full lists above (regulation 295 of the HMR). These are referred to as "short form" advertisements in the Blue Guide and for which all information in Annex 5 must be given. These advertisements might only appear as an integral part of a publication and cannot be a loose insert or placed on the internet. Some innovative products which are new to the market in the last two years might be subject to an agreement with the MHRA that a short form advertising form will not be used.

### Information Prohibited by Law

The Blue Guide prohibits advertising which states or implies that a product is "safe" (paragraph 6.6).

## 5.2 Reference to Data Not Included in the Summary of Product Characteristics

Promotional material to HCPs might refer to published studies, if clear references are given. The materials might also refer to "data on file" if this data is not contrary to the SmPC and this must be provided within ten working days of a response to a request from an HCP (Clause 14.3 ABPI Code).

### 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

The European Union SmPC guideline Section 4.1, Therapeutic Indications states: "If the product's indication depends on a particular genotype or the expression of a gene or a particular phenotype, this should be stated in the indication." European Union SmPC guideline Section 5.1, Clinical Particulars, provides a summary of clinical trial information. Sometimes the predictive biomarker which was used and its brand name and or manufacturer are included, but the practice is not consistent and is not an absolute requirement. Once the In vitro Diagnostics Regulations 2017/746 (IVDR) are in force and companion diagnostics are regulated under it, those diagnostics will recognise in their instructions for use (IFU) the specific medicines for which they are authorised companions.

Advertisements referring to medicinal products used in combination products must not include claims for the medicinal product that are not in the SmPC.

### 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Reprints might not be provided proactively unless the articles have been peer reviewed (Clause 16.5 ABPI Code). Reprints should be accompanied by prescribing information listed in Clause 12.2 of the ABPI Code.

### 5.5 Medical Science Liaisons

Medical science liaisons (MSLs) are subject to the same rules as any other employee of a manufacturer and therefore not permitted to proactively discuss scientific information on unauthorised medicines or indications with healthcare professionals. Only discussions which are unsolicited individual written enquiries might be responded to.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

#### Prior Authorisation/Vetting by the MHRA

Medicines advertising is not generally subject to prior authorisation by the MHRA. Prior vetting of advertisements can be requested by the MHRA and is sometimes undertaken in the following circumstances:

- a newly authorised product, subject to additional monitoring, is placed on the market (this is always applied for new active substances);
- upon reclassification; and
- where there have been previous advertising breaches.

#### Industry Bodies

The ABPI or PMCPA do not as a rule authorise or vet advertisements, although the PMCPA monitors published advertising and meetings.

PAGB membership is conditional upon all over-the-counter medicines advertising aimed at consumers being approved by PAGB prior to release (PAGB Consumer Code 1.4).

#### Other Self-Regulatory Bodies

Clearcast clears finished television advertisements against the UK Code of Broadcast Advertising. Radiocentre clears all advertisements featuring health claims and for medicines, medical devices and treatments before they are broadcast on the radio. The ASA offers a free but non-compulsory advice service against the UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing.

### 6.2 Compliance with Rules on Medicinal Advertising

Regulation 281(2) of the HMR requires that authorisation holders establish a scientific service to compile and collate all information relating to the product. Regulation 281(3) of the HMR requires medical sales representatives to be given sufficient training and to have sufficient scientific knowledge to ensure the information they provide is as precise and complete as possible.

The ABPI Code requires members to establish a scientific service with a registered medical practitioner or a pharmacist registered in the UK and who will collate information received about the product (Clause 4.1).

Clause 8 of the ABPI Code requires all promotional materials to be certified by a registered medical practitioner or pharmacist registered in the UK, or a dentist for dental products. The certifier must be independent of the creation of the advertising and their details and qualifications must be notified in advance to the Advertising Standards and Outreach Unit, Vigilance and Risk Management of Medicines Division of the Medicines and Healthcare products Regulatory Agency (MHRA), and to the Prescription Medicines Code of Practice Authority (PMCPA). Changes in the names of nominated certifiers must be promptly notified.

The following promotions/ materials must be certified to say that the final form of the material has been examined and that they believe it complies with the ABPI Code, is not inconsistent with the marketing authorisation and SmPC and is a fair and truthful presentation of the facts about the medicine:

- all events or meetings involving travel outside the UK;
- educational material for the public or patients which relates to diseases or medicines but is not intended as promotion for those medicines;
- material relating to working with patient organisations;
- material relating to collaborative working;
- material and items for patient support and associated supplementary information; and
- the written agreement for donations and grants.

Material in continuous use must be recertified at least every two years.

#### Training

The ABPI Code Clause 9 requires all employees and contractors engaging in the preparation or approval of the Code to be fully conversant with the Code and with pharmacovigilance requirements. All sales representatives must be given adequate training and have adequate scientific knowledge and must take an exam within their first year of employment and pass it within two years to at least level 3. Details of the numbers of representatives who have passed an examination and the exam status of the others must be provided to the PMCPA on request.

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

#### The Legal Position

The MHRA considers that material posted on UK websites and/or aimed at the UK audience is subject to UK medicines advertising legislation (paragraph 5.10 of the Blue Guide).

Prescription only medicines might only be advertised on websites directed at HCPs (as determined by the nature of the content). It is not a requirement that such material is access restrict-

ed but is preferred (paragraph 6.3 of the Blue Guide). Websites with content for both consumers and including HCP advertising should have separate sections and should be clearly marked for the target audience. Where HCP materials are openly available, adequate non-promotional information should be provided in public areas to avoid consumers needing to access the sections for HCPs. There should be no direction of the public to materials for prescription only medicines that are intended for HCPs. Journals intended for HCPs and published online are considered as directed to HCPs, but each page should state that they are so directed.

### Company Websites

The Blue Guide paragraph 7.5 provides guidance on company websites and permits the following to be included in the publicly available areas:

- disease-related information;
- patient information leaflets (PILs), SPCs and public assessment reports (PARs) for their POM products; and
- other non-promotional reference information about the product that fairly reflecting current evidence about the product and its benefit risk profile.

The ABPI Code applies to websites of:

- a UK company/with a UK company's authority, or
- an affiliate of a UK company, or with the authority of such a company, and it makes specific reference to the availability or use of the medicine in the UK (Clause 1.2 of the ABPI Code).

Clause 12.6 ABPI Code requires that internet material includes a clear prominent statement of the location of the prescribing information.

### Consumer Internet Advertising

PAGB (1.5.12, rule 53) consider that the following fall within the remit of its Consumer Code and an off-line version needs to be provided for review:

- brand websites and social media, including brand home pages (but not if the product is not mentioned);
- banner advertising;
- press releases intended for internet publication which are under the editorial control of the company; and
- pay-per-click advertising, such as that used on internet search engines.

Note that user reviews are not considered "advertising" unless adopted by the company, which they will be considered to be if the company curates the content, even if simply deleting certain reviews.

All internet content must include the essential information outlined in **4.2 Information Contained in Pharmaceutical Advertising to the General Public**, but where there are significant space restrictions it may be acceptable to include the essential information one click away (PAGB 1.5.15).

Space limited advertising is not considered appropriate for making:

- comparative claims other than sales claims;
- claims which require additional qualification;
- direct invitations to use a product; or
- encourage user to read further information such as "Find out more about Brand X".

Where mobile advertisements consist of a series of swipable or scrollable tiles, it may be acceptable to place the essential information on the tile at the end of the series.

### 7.2 Advertising of Medicines on Social Media

See **7.1 Regulation of Advertising Medicinal Products on the Internet**.

Note that all paid-for posts (even without full creative control by the company) must be identified as advertising by using #ad. Care must be taken with retweets and "likes" to avoid celebrity endorsement of products, meaning companies should only do so if there is no implication that they used the product (PAGB Code 1.5.9).

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

See **7.1 Regulation of Advertising Medicinal Products on the Internet**.

### 7.4 Provision of Disease Awareness Information to Patients Online

There are no specific permissions or prohibitions on posting disease awareness information and/or materials online, so that the general rules apply, see **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**.

### 7.5 Online Scientific Meetings

There are no specific rules for online meetings in relation to pharmaceutical products.

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

The UK Bribery Act 2012 (Bribery Act) is the general law prohibiting the making of offers, promises or financial or other advantage to another person where the advantage is intended to induce improper performance of a function or activity and/ or where it is known or believed that acceptance of the advantage would itself constitute the improper performance of a relevant function or activity (Section 1). It is equally an offence to request, agree to receive or accept that advantage (Section 2). The provisions apply to people both in public service and to private businesses and both individuals and entities can be subject to sanctions of the Bribery Act.

The Bribery Act has extra-territorial effect so that acts engaged in abroad by individuals or companies with sufficient proximity to the UK will also fall within the remit of its provisions.

There is a separate offence of "bribery of foreign public officials", which in the context of medicines can include regulators, and those employed by public hospitals (Section 6).

Companies commit a criminal offence under the Bribery Act if they fail to prevent bribery (Section 7). It is a complete defence to that offence if the company can show that it had in place adequate procedures designed to prevent persons associated with the company (anyone performing services for or on behalf of the company, such as employees, agents or subsidiaries) from undertaking the questionable conduct. This underlines the need for good corporate governance, compliance policies and procedures.

The UK's NHS publishes provisions on conflicts of interest for compliance by entities within and individuals employed by the NHS. These include Managing Conflicts Of Interest: Revised Statutory Guidance For CCGs 2017 and Managing Conflicts Of Interest in the NHS Guidance For Staff and Organisations, which include notification requirements on those individuals.

### 8.2 Legislative or Self-Regulatory Provisions

#### Laws

Regulation 300(1) of the HMR provides that "a person may not, in connection with the promotion of medicinal products to persons qualified to prescribe or supply them, supply, offer or promise to such persons any give, pecuniary advantage or other benefit unless it is (a) inexpensive; and (b) relevant to the practice of medicine or pharmacy". HCPs are also not permitted to solicit or accept such gifts (Section 300(4)). There are similar restrictions on the provision of hospitality at meetings, which must be strictly limited to provision to HCPs and for the main purposes of the meeting but is defined to include sponsorship of attendance and payment of travelling or accommodation expenses. Breaches of these provisions are a criminal offence.

#### The ABPI Code

Clause 19 of the ABPI Code prohibits inducements and inappropriate payments and the provision of items to HCPs and other relevant decision makers.

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

#### MHRA Blue Guide

Paragraph 6.15 discusses Section 300 of the HMR and defines "inexpensive" to mean items not costing the company more than GBP6 and representing a similar value to the recipient. Items relevant to the practice of medicine are those that have a clear business use, such as pens, notepad, calculators, diaries, calendars and coffee mugs.

#### ABPI Code

Clause 19.2 permits patient support items to be provided to HCPs (not admin staff) if they are documented and certified in advance. The items must be inexpensive (no more than GBP10 excluding VAT) and directly benefit patient care, may include the company but not any product name unless essential for the item's correct use. The items must not be given out from exhibition stands.

Separately, patient access schemes are permitted if they meet requirements of the ABPI Code.

Promotional aids might be given to HCPs and other decision makers. Under the ABPI code, in contrast to the MHRA Blue guide, it is not permitted to provide mugs, stationery, computer accessories, diaries or other items for use in the home or car, and equally items for use with patients such as surgical gloves are not permitted, nor must toys for waiting children be provided. Thus, only literature intended for patients might be provided in relation to prescription medicines. Memory sticks might be provided with saved promotional material as long as the volume of memory capacity is compatible with that material. It is also not permitted to provide HCPs with text books, unless part of a donation or grant for research and compliant with the relevant provisions. Equally, the provision of items to practices for long term or permanent loan should be avoided.

### 9.2 Limitations on Providing Samples to Healthcare Professionals

#### Laws

Regulation 298 of the HMR permits the giving of samples solely to those qualified to prescribe medicinal products and for the purpose of acquiring experience in dealing with the product in question. There are then additional conditions applied to the giving of samples:

- on an exceptional basis only;
- in response to a written request from, and signed and dated by, the recipient;
- only a limited number of samples of the product in question are supplied to the recipient in that year;
- the sample is no larger than the smallest presentation of the product that is available for sale in the relevant region (Great Britain or Northern Ireland);
- it is marked "free medical sample – not for resale" or bears a similar description;
- is accompanied by a copy of the summary of the product characteristics; and
- the product is not a narcotic or psychotropic substance.

### ABPI Code

Clause 17.2 reiterates the legal provisions, but adds further conditions:

- no more than four samples of a particular medicine to be provided to an individual health professional during a single year;
- samples of a particular medicine may be provided for no longer than two years after the HCP first requested it, except if it is an extension of an existing product, when that might be "new" if, eg, additional strengths and/or dosage forms, but not simply additional pack sizes;
- samples sent by post must be secured against opening by young children; and
- samples must not be provided simply as an inducement, but for the sole purpose of treating patients.

Companies are required to have adequate systems of control and accountability for the samples they distribute. These must show the number of samples supplied to each HCP.

## 9.3 Sponsorship of Scientific Meetings

See **8.2 Legislative or Self-Regulatory Provisions** for the legal provisions and which are restated in the Blue Guide at paragraph 6.16 and note that the Blue Guide defines "advertising" to include sponsorship of meetings.

See **3.3 Provision of Information to Healthcare Professionals** for the content of international meetings.

### ABPI Code

The ABPI Code permits companies to hold, sponsor or support delegates to attend events and meetings that meet the Code requirements. There are several conditions applicable to these meetings and events:

- the event/meeting must have a clear educational content;
- the programme not the associated hospitality or venue should attract delegates;
- the content must be appropriate and relevant;
- the venue must be appropriate and conducive to the main purpose of the event/meeting and not lavish or extravagant;
- any associated subsistence (food and drink), accommodation and travel costs must be strictly limited to the main purpose of the event/meeting, of secondary consideration, appropriate and not out of proportion to the occasion (see Clause 10.7);
- companies must not sponsor, support or organise entertainment (such as sporting or leisure activities, etc); and
- any hospitality provided must not extend to an accompanying person unless that person qualifies as proper delegate or participant at the meeting in their own right.

The cost of any subsistence (food and drink) provided must not exceed GBP75 per person, excluding VAT and gratuities.

## 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies are not permitted to sponsor cultural, sports or other non-scientific events in relation to or which are concurrent with scientific conferences (ABPI Code, Clause 10.1) as this would be considered an improper inducement (see **9.1 Gifts to Healthcare Professionals**).

## 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

### ABPI Code

The ABPI code permits donations and grants to institutions, but not to individuals. These are permitted for supporting healthcare, scientific research or education and must not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines. They must be prospective in nature and each subject to a specific and certified written agreement. The company must keep a record of the donation or grant, and they must be disclosed annually (see **10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value**).

## 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

### MHRA Blue Guide

Paragraph 6.14 of the Blue Guide provides guidance on examples to which regulation 300 of the HMR will apply. Thus, cash returns to individuals and other personal benefits "in lieu" of discounts such as preferential loans, share options, shopping vouchers, gifts or special prices for travel, insurance, office equipment or computer software would constitute an offence under the HMR. Equally a points scheme based on the volume of purchases is likely to be a breach.

The Blue Guide also clarifies that the offence might be committed by corporate and unincorporated bodies as well as individuals and includes manufacturers and distributors of medicines, including wholesale dealers.

### ABPI Code

The ABPI Code adds that schemes which enable health professionals to obtain benefits in relation to the purchase of medicines are not acceptable, even if they are presented as alternatives to financial discounts. This would include the provision of gift vouchers, but also personal rebates.

## 9.7 Payment for Services Provided by Healthcare Professionals

It is possible for companies to pay for bona fide services provided by HCPs. The requirement not to bribe an HCP to inappropriately prescribe is subject to the provisions of The Bribery Act (see **8. Pharmaceutical Advertising: Inducement/ Anti-bribery**). Furthermore, the ABPI Code, Clause 24 imposes the following conditions:

- a prior written agreement must be agreed specifying the legitimate need, the services and the payment to be made;
- the criteria for selection of the particular HCP (and the number if several) must relate to the services and their expertise and be necessary to achieve the need of the company;
- the company must maintain records of the services and payments;
- remuneration for the services must be reasonable and reflect the fair market value of the services provided; and
- the agreement must also require the HCP to declare that they are contracted by the company when they write or speak in public about the company, including if they are an employee of the company whilst continuing to practise medicine.

## 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical

### Companies, Healthcare Professionals and Healthcare Organisations

The NHS conflicts of interest codes (see **8.2 Legislative or Self-Regulatory Provisions**) require that their employees and contractors notify hospitality and fees for services received from manufacturers.

The Manufacturers are not under any obligation under the laws or codes to provide prior notifications of their activities with HCPs and HCOs.

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

Transparency is not currently a legal requirement in the UK but is one that is imposed under the ABPI Code. The code requires public annual disclosure of sums paid and benefits given to health professionals and other relevant decision makers and health care organisations such as:

- (Clause 24.4) UK individuals, organisations, etc, for contracted services, such as HCPs and individuals contracted to patient organisations;
- (Clause 4.4) patient organisations;
- (Clause 4.5) individual members of the public, including patients and journalists;
- (Clause 10.10) support of UK health professionals and other relevant decision makers in relation to attendance at events/meetings;
- (Clause 10.11) contributions to costs related to events/meetings (sponsorship) paid to healthcare organisations, patient organisations or organisations managing an event/meeting on their behalf (even if the identity of a support HCP is unknown to the company) and individuals representing patient organisations (including donations, grants and collaborative working (Clause 20.5)); and
- (Clause 25.4) payments made to contracted individuals in relation to market research.

Individuals must be identified, and fees and expenses reported separately.

Disclosures must be made annually on a publicly available website within six months of the end of the calendar year to which they relate and must remain in the public domain for at least three years. Records of disclosures must be retained for at least five years after the end of the calendar year to which they relate.

### 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

The ABPI Code is intended to apply to companies promoting medicines in the UK. Therefore, companies that do not yet have products on the market will not be members of the ABPI and will not be subject to the transparency requirements.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

The MHRA enforces the HMR and can choose to do so through the courts. Regulation 303 of the HMR provides for criminal penalties of unlimited amount or imprisonment for up to two years for breaches of the laws regarding samples, medical sales representatives and inducements or hospitality. The MHRA can also require that a corrective statement is issued.

The MHRA generally only takes matters to court in the most egregious cases as it prefers to work with companies to ensure that they promote cor-

rectly and will therefore more likely impose a vetting requirement on repeat offenders.

The Bribery Act is also applicable to inducements and hospitality may be enforced by the Serious Fraud Office.

The ABPI Code is operated by the independent PMCPA which handles complaints about breaches through its own processes. Sanctions imposed include one or more of:

- the audit of a company's procedures for compliance with the Code;
- a requirement for the pre-vetting of future material;
- recovery of material from those to whom it has been given;
- the issue of a corrective statement;
- a public reprimand;
- advertising in the medical, pharmaceutical and nursing press of brief details of a public reprimand; and
- suspension or expulsion from the ABPI.

## 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

The UK does not have a regime for unfair competition actions. However, complaints can be made by competitors to any of the MHRA, the PMCPA or PAGB, depending on which is appropriate given the product and/ or the nature of the complaint.

## 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

See **11.1 Pharmaceutical Advertising: Enforcement Bodies**.

## 11.4 Relationship between Regulatory Authorities and Courts

See **11.1 Pharmaceutical Advertising: Enforcement Bodies**.

## 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

The MHRA is particularly interested in websites offering medicinal treatment that extend to advertising pharmaceutical products. They are also concerned with the advertising of unlicensed medicines.

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## Law and Practice

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## CONTENTS

# 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

## 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

### FDA's Authority over Prescription Drug Advertising and Promotion

The Federal Food, Drug, and Cosmetic Act (FDCA) grants the US Food and Drug Administration (FDA) broad authority over the advertising and promotion of prescription drugs. FDA regulations, found in Title 21 of the Code of Federal Regulations (CFR), outline the requirements for prescription drug advertising and promotion. FDA guidance documents, found on the FDA's website and published in the Federal Register, describe specific FDA policies related to prescription drug marketing.

The FDA's Office of Prescription Drug Promotion (OPDP) is charged with ensuring that prescription drug advertising and promotion is truthful, balanced and not misleading. The OPDP provides written advisory comments on proposed promotional materials, reviews complaints about alleged violations, and issues untitled or warning letters citing false or misleading promotional materials.

### FTC's Authority over Promotion of OTC Drugs

The Federal Trade Commission (FTC) Act (FTCA) prohibits "unfair or deceptive acts or practices in or affecting commerce", including the dissemination of false advertising for drugs. Under a joint FDA/FTC Memorandum of Understanding, the FDA holds primary jurisdiction over the labelling of all drugs and the advertising of prescription drugs, while the FTC maintains primary authority over the advertising of non-prescription drugs (also known as over-the-counter (OTC) drugs); see **2.1 Definition of Advertising**.

### Other Sources of Oversight of Drug Promotion

State consumer protection laws, both civil and criminal, also prohibit false or misleading advertising.

The Lanham Act (15 USC 1125(a)) allows competitors and other entities that have suffered commercial harm to sue for false or misleading advertising.

Promotional activities may implicate the criminal Anti-Kickback Statute (42 USC 1320a-7b) and the Civil Money Penalties Statute (42 USC 1320a-7a); see **8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals**. Violations of the Anti-Kickback Statute may also result in violations of the civil False Claims Act (31 USC 3729). The False Claims Act includes a whistle-blower provision allowing private citizens to bring claims on behalf of the United States and share in the government's recoveries resulting from such claims.

## 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Pharmaceutical advertising and promotion are also subject to voluntary guidelines issued by trade associations or medical professional associations. These guidelines address a variety of issues, ranging from funding continuing medical education, engaging physicians as speakers or consultants, and giving gifts or items of value to physicians.

While the FDA's and FTC's rules are enforced through law, voluntary self-regulatory codes and professional guidelines establish standards of acceptable behaviour but hold no legal authority. The Pharmaceutical Research and Manufacturers of America (PhRMA) has a Code on Interactions with Healthcare Professionals

("PhRMA Code") which provides guidelines for pharmaceutical companies when interacting with healthcare professionals (HCPs). Though the code is voluntary, the US Department of Health and Human Services' Office of Inspector General (OIG) endorsed its use in a 2003 guidance document. Thus, many pharmaceutical companies adopt the PhRMA Code as company policy and some states have made it mandatory for pharmaceutical companies operating within their borders.

Other third-party guidelines relevant to communications about pharmaceuticals include:

- PhRMA's Direct to Consumer Advertising Principles;
- PhRMA's Principles on Responsible Sharing of Truthful and Non-Misleading Information;
- the Accreditation Council for Continuing Medical Education (ACCME) Guidelines; and
- the American Medical Association (AMA) Guidelines.

In addition, the National Advertising Division (NAD), a non-judicial, advertising industry self-regulatory body, adjudicates advertising disputes brought by consumers, competitors or the NAD itself. Although the NAD has jurisdiction to hear challenges to prescription and OTC drug advertising, historically, NAD challenges have primarily targeted OTC drug advertising.

## 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

### 2.1 Definition of Advertising

The FDA's authority under the FDCA includes oversight of promotional labelling for all drugs and advertising for prescription drugs. Section 201(m) of the FDCA defines drug labelling as "all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article". Courts have defined "accompanying" broadly to include most types of promotional materials, including brochures, literature reprints, mailers, printed or digital sales aids, emails, slide decks, videos, websites, and social media posts.

The FDCA does not define advertising; however, FDA regulations provide examples such as "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems".

### 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

The FDA recognises certain limited categories of "non-promotional" communications that constitute neither labelling nor advertising and are, therefore, not subject to the requirements for prescription drug promotion under the FDCA.

One example of "non-promotional" information is disease awareness communications, which are communications disseminated to consumers or HCPs that discuss a particular disease or health condition, but do not mention any specific drug or make any representation or suggestions concerning a particular drug. The FDA's long-standing policy is that disease awareness communications should be perceptually different (eg, different colour schemes, graphics, etc) and should appear physically separate from any branded advertising and promotion to avoid converting the disease awareness communication into implied promotion and advertising.

For additional examples of "non-promotional" communications, see **3.3 Provision of Information to Healthcare Professionals**, **3.4 Provision of Information to Healthcare Institutions**

and **3.5 Publication of Compassionate Use Programmes**.

### 2.3 Restrictions on Press Releases regarding Medicines

In general, the FDA expects press releases discussing a specific approved drug to comply with FDA regulatory requirements for promotional labelling, including being truthful and not misleading, maintaining fair balance between risks and benefits, and providing full disclosure of relevant contraindications, warnings, precautions and adverse events.

Press releases about investigational drugs (eg, announcing significant clinical study results or the filing of a new drug application with the FDA) should be non-promotional in intent, tone and context, and avoid promotional claims and commercial objectives. The press release should truthfully and accurately present all material information. Press releases that make conclusory statements regarding the safety or efficacy of the investigational drug, mischaracterise study data, or fail to adequately disclose the investigational status of the drug, could be viewed as pre-approval promotion, and thus misbrand an investigational drug under the FDCA.

### 2.4 Comparative Advertising for Medicines

Generally, the FDA requires that any comparative efficacy or safety claim be supported by adequate and well-controlled head-to-head studies or a large multi-centre trial. The FDA does not typically permit a claim of superior efficacy or safety based solely on the differences in the FDA-approved labelling of drugs or a comparison of results from two different studies. Comparative claims should be clinically relevant to indicated patients and must not be false or misleading.

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

The FDCA prohibits the introduction of a drug into interstate commerce that is intended for a use that has not been approved by the FDA. FDA regulations prohibit the promotion of an investigational (unapproved) drug as safe or effective for the purposes for which it is under investigation. This includes drugs that have never been approved, as well as unapproved indications for drugs that are approved for a different use.

Despite a broad prohibition on the promotion of unapproved drugs and indications, the FDA's current approach permits non-promotional communications about unapproved drugs and indications under the principles of scientific exchange. Importantly, a range of permissible communications qualify as scientific exchange, including scientific publications and presentations, support for independent scientific and medical education, responding to unsolicited requests for information, distributing scientific or medical publications on unapproved uses and/or risks, listing information on ClinicalTrials.gov, and communications with payors in advance of approval.

### 3.2 Provision of Information during a Scientific Conference

Factual and non-promotional presentations, posters, and abstracts about unapproved drugs or indications that are submitted to a scientific conference are typically regarded as legitimate scientific exchange.

In addition, it is common practice for pharmaceutical companies to host booths or exhibits at scientific conferences, which may include a medical information booth. A medical information booth should be non-promotional, staffed by scientific or medical personnel who may respond to unsolicited questions about unapproved drugs and off-label uses.

## 3.3 Provision of Information to Healthcare Professionals

As noted in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, although the FDA strictly prohibits the promotion of unapproved drugs and uses, it allows non-promotional scientific exchange, including the following limited "safe harbours" through which manufacturers can distribute or support information to HCPs about unapproved (off-label) uses of approved drugs.

### FDA Off-Label Reprints Guidance – Proactive Distribution of Off-Label Reprints to HCPs

The FDA permits the proactive distribution of off-label reprints under recommendations stated in three guidance documents:

- "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices" (2009);
- "Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices" (draft guidance; 2014) (hereafter "Off-Label Reprints Guidance"); and
- "Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products — Recommended Practices" (draft guidance; 2014) (hereafter "Risk Information Reprints Guidance").

#### *Off-Label Reprints Guidance*

The Off-Label Reprints Guidance provides recommendations for the distribution of off-label scientific or medical journal articles, scientific or medical reference texts, and clinical practice guidelines. Each type of publication is subject to specific recommendations to ensure that distribution is appropriate.

Generally, off-label reprints should not be false or misleading and should not pose a significant risk to public health. The source of the publication should be considered, and should not be letters to the editor, special supplements funded by the manufacturer, or abstracts. Additionally, reprints should be provided in a complete and unabridged format, without alteration. Off-label reprints should be distributed in a non-promotional manner, and accompanied by a copy of the product's FDA-approved labelling – also known as the "prescribing information" or "package insert" (PI) – and a range of disclosures, including that the reprint discusses off-label uses of the company's product. Refer to the FDA's Off-Label Reprints Guidance for details.

#### *Risk Information Reprints Guidance*

The Risk Information Reprints Guidance permits the distribution of reprints about new risk information that may refute, mitigate, or refine risk information in the FDA-approved labelling. The reprint should meet the range of standards presented in the FDA's Risk Information Reprints Guidance, including that it is published in an independent, peer-reviewed journal and based on appropriate study design and methodology.

Risk information reprints should be distributed in a non-promotional manner, and accompanied by a copy of the product's PI and a range of disclosures, including that the information is not consistent with risk information in the FDA-approved labelling and the FDA has not reviewed the data.

Refer to the FDA's Risk Information Reprints Guidance for details.

#### FDA Unsolicited Requests Guidance – Reactive Distribution of Off-Label Information

Under the FDA's 2011 draft guidance, "Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices", the FDA permits companies to respond to unsolicited requests for information on unapproved, off-label uses of approved prescription drug products. The guidance outlines the FDA's position and recommendations on:

- distinguishing solicited versus unsolicited requests;
- distinguishing public versus non-public requests; and
- responding to unsolicited requests.

#### Independent Scientific Education

The FDA's 1997 guidance, "Industry-Supported Scientific and Educational Activities", makes clear that the FDA will not regulate industry-supported scientific activities that are independent of the influence and control of the supporting company. The guidance outlines a number of factors that the FDA will consider in evaluating the independence of industry-sponsored scientific activities, including those that may discuss unapproved drugs or off-label uses of approved drugs.

### 3.4 Provision of Information to Healthcare Institutions

The FDA's 2018 guidance, "Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Other Similar Entities – Questions and Answers", established a safe harbour that expressly permits manufacturers to disseminate certain information about investigational drugs and unapproved uses of approved drugs to payor audiences prior to approval.

Communications disseminated in compliance with the guidance will not be considered violations of the prohibition on promotion of an investigational drug. The types of information about investigational drugs and unapproved uses of approved drugs that may be disseminated pre-approval to payors include: proposed indication, anticipated timeline for FDA approval, pricing, patient support programmes, patient utilisation projections, and results of clinical studies. All information provided must be "unbiased, factual, accurate and non-misleading" and must be accompanied by a clear statement of the drug's investigational status and stage of development.

### 3.5 Publication of Compassionate Use Programmes

Compassionate use or "expanded access" programmes establish a pathway for a patient with an imminently life-threatening condition or serious disease or condition to access an investigational drug when the treatment is unavailable in clinical trials and there are no other similar or sufficient therapy alternatives.

Under the 21st Century Cures Act, companies developing investigational drugs are required to publicly publish an expanded access policy on the company website and/or the Reagan-Udall Foundation's Expanded Access Navigator website for the investigational drug.

The published policy must include:

- contact information for the manufacturer or distributor;
- the procedure for submitting requests;
- the general criteria that the manufacturer or distributor uses to evaluate the requests;
- the length of time anticipated to respond to the request; and
- a hyperlink or other reference to the clinical trial record containing all the required information that must be submitted to ClinicalTri-

als.gov about expanded access availability for the drug.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Advertising to the general public, also commonly referred to as direct-to-consumer (DTC) advertising, is permitted in the United States. Companies may promote prescription drugs to the general public provided that the communication meets the following fundamental requirements.

- On-label or consistent with label: Advertising and promotion of prescription drugs must be consistent with the intended use for which the product is approved by the FDA, as established in the drug's FDA-approved labelling (ie, the PI). The labelling provides information on how to use the product safely and effectively for the approved indication, including but not limited to the patient population, dosage and administration. Advertising and promotion that discuss uses of the product that are not contained in or consistent with the FDA-approved labelling are regarded as unlawful "off-label" promotion. Refer to the FDA's 2018 guidance, "Medical Product Communications That Are Consistent With the FDA-Required Labeling – Questions and Answers" (CFL Guidance), for details; see **5.2 Reference to Data Not Included in the Summary of Product Characteristics**.
- Fair balance: The FDA regulations require prescription drug promotion and advertising to present a "fair balance" between product benefits and risks, ensuring that such information appears comparable in depth, detail and context. Promotional materials are misleading if they fail to present information about risks associated with a drug with a prominence and readability reasonably comparable with the presentation of information related to the effectiveness of the drug. Refer to the FDA's 2009 draft guidance, "Presenting Risk Information in Prescription Drug and Medical Device Promotion", for details.
- Adequately substantiated: Traditionally, all advertising and promotional claims about the safety or efficacy of a prescription drug have been required to be supported by substantial evidence or substantial clinical experience, which is the FDA's approval standard for prescription drug products. Under the CFL Guidance, claims should be supported by at least scientifically appropriate and statistically sound evidence.
- Otherwise truthful and not misleading: If prescription drug advertising and promotion is false or misleading in any particular, it will be considered misbranded under the FDCA and subject to enforcement.

Although not a requirement, the FDA strongly recommends the use of consumer-friendly language, and avoidance of technical language, scientific terms and medical jargon, in consumer-directed advertising and promotion.

The promotion of OTC drugs must also adhere to the product's approved labelling or monograph, as applicable. In addition, such promotion must be truthful and not misleading, including that all advertising claims are substantiated by competent and reliable scientific evidence. The FTC maintains regulations and guidelines governing consumer advertising to ensure that communications are not deceptive or misleading.

### 4.2 Information Contained in Pharmaceutical Advertising to the General Public

Consumer-directed prescription drug advertising and promotion must contain the following

core elements, as required by the FDCA and FDA regulations.

### Core Elements

#### *Proprietary and established names*

The placement, size, prominence and frequency of the proprietary (brand or trade) and established (generic) names for prescription drugs are specified in FDA regulations, with additional recommendations in the FDA's 2017 guidance, "Product Name[,] Placement, Size, and Prominence in Promotional Labeling and Advertisements".

#### *Quantitative composition*

Advertising and promotion must include the quantitative amount of each ingredient of the advertised drug. Companies commonly include this information as part of the product logo.

#### *Brief summary*

Printed DTC advertisements must include information in "brief summary" that discloses each side effect, warning, precaution and contraindication. To fulfil this requirement, DTC print advertisements traditionally included the complete risk-related sections from the product's PI. To fulfil the adequate directions for use requirement, a copy of the PI has traditionally been provided. Contrary to these traditional approaches, the FDA's 2015 revised draft guidance, "Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs", recommends that DTC printed promotional labelling and advertising utilise a "consumer brief summary" focused on the most important risk information, rather than an exhaustive list of product-related risks, presented in a way most likely to be understood by consumers. In addition, a copy of the PI is no longer recommended.

#### *Major statement*

Advertisements broadcast through media such as television, radio, or telephone communications systems must disclose the product's major risks in a clear, conspicuous and neutral manner in either audio or audio and visual. This is referred to as the "major statement". In addition, the advertisement must present a brief summary or, alternatively, make "adequate provision" for consumers to obtain the PI. The FDA's 1999 guidance documents, "Consumer-Directed Broadcast Advertisements" and "Consumer-Directed Broadcast Advertisements – Questions and Answers", provide recommendations for satisfying the adequate provision requirement through a toll-free telephone number, concurrent print ad in a widely distributed publication, on a website, and/or in consultation with an HCP.

#### *Adverse event reporting disclosure statement*

DTC print advertisements must include the following MedWatch statement printed in conspicuous text: "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088".

### Reminder Labelling and Advertising

Under FDA regulations, reminder labelling and advertising is exempt from the general requirements above if it is limited to the proprietary and established names of the drug, and does not include any indications, disease state information, dosage, or other product representations. Additional optional information includes quantitative ingredient statements, dosage form, quantity of package contents, price, the name and address of the manufacturer, and price information.

Importantly, reminder labelling and advertising is not permitted for a prescription drug with a boxed warning in its FDA-approved labelling.

### 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Interactions between pharmaceutical companies and patients and/or patient organisations are permitted in the United States, subject to the variety of limitations discussed in this chapter. For product-related advertising and promotion, communications must be on-label/CFL, fair and balanced, adequately substantiated and not otherwise false or misleading; see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public** and **4.2 Information Contained in Pharmaceutical Advertising to the General Public**. In addition, interactions must not implicate the Anti-Kickback Statute by inducing patient organisations or patients to recommend or use the advertised product; see **8. Pharmaceutical Advertising: Inducement/ Anti-bribery** and **9. Gifts, Hospitality, Congresses and Related Payments**.

Companies may also communicate with patients and patient organisations, such as patient advocacy groups, in a non-promotional manner to respond to unsolicited requests for information (see **3.3 Provision of Information to Healthcare Professionals**) or to provide information about clinical studies for recruitment purposes.

In addition, companies interacting with patients must abide by applicable federal and state privacy laws and avoid providing advice for the diagnosis, treatment, care or prognosis of an individual, which would be regarded as unlawfully engaging in the practice of medicine.

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Rules for the advertising and promotion of prescription drugs to HCPs are generally the same as those that apply to advertising and promotion to consumers, including the fundamental requirements (see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public**):

- on-label or consistent with label;
- fair balance;
- adequately substantiated; and
- otherwise truthful and not misleading.

Prescription drug promotion and advertising to HCPs must also provide adequate directions for use, a requirement that is met by providing a copy of the FDA-approved labelling (ie, the PI).

Advertising and promotion targeting HCPs must also contain some of the same core elements as DTC advertising and promotion, including proprietary and established names and quantitative composition; see **4.2 Information Contained in Pharmaceutical Advertising to the General Public**. Unlike DTC advertising, a "brief summary" for HCP-directed print advertisements should follow the FDA's traditional approach, which includes reprinting the complete risk-related sections of the PI with the ad, but there is no requirement to include the MedWatch statement.

#### Promotion and Advertising to Payors

Under the FDCA, a company may provide healthcare economic information (HCEI) related to a product's indication to payor audiences, provided that it is supported by competent and

reliable scientific evidence. The pathway to promote HCEI to payors grants some flexibility from the standard approach, but is still subject to other rules of prescription drug promotion. Refer to the FDA's 2018 guidance, "Drug and Device Manufacturer Communications with Payors, Formulary Committees, and other Similar Entities – Questions and Answers", for details.

### 5.2 Reference to Data Not Included in the Summary of Product Characteristics

As previously mentioned, promotional communications for prescription drugs must include only information about the drug that is either within the drug's FDA-approved label (on-label) or consistent with the label (CFL). The CFL Guidance explains a three-factor test to determine whether product-related information is CFL. If a product communication fails any of the three factors below, it is not considered CFL and risks being off-label.

- How does the information in the communication compare to the information in the FDA-approved label – does it suggest a different indication, patient population, limitations and directions for use/handling, and/or dosing or usage regimen?
- Does the information suggest use of the drug in a manner that could increase the potential for harm to health relative to the information reflected in the drug's FDA-approved label?
- Do the directions for use in the FDA-approved label enable the product to be safely and effectively used under the conditions suggested in the communication?

In order to be distributed as CFL, the information must be substantiated by "scientifically appropriate and statistically sound" (SASS) evidence; be factually accurate; be presented with appropriate context, including disclosure of any limitations of the data, analyses and conclusions; and be otherwise truthful and not misleading. Examples of information that may be considered CFL include comparisons, adverse reactions, onset of action, long-term safety or efficacy, patient subgroups, patient compliance or adherence, and patient perceptions, convenience and mechanism of action.

### 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

As noted, all promotional communications should be on-label or CFL. If the FDA-approved labelling of a combination product does not include details of each of the individual products in the combination, the company should evaluate the information under the CFL Guidance and consider potential off-label risks; see **5.2 Reference to Data Not Included in the Summary of Product Characteristics**.

### 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

If a reprint is on-label or CFL, it may be used in a promotional manner, subject to the basic requirements for advertising and promotion directed at HCPs. If a reprint discusses an unapproved use of the product (ie, off-label), then it might be distributed under FDA's established safe harbour for off-label reprints; see **3.3 Provision of Information to Healthcare Professionals**.

### 5.5 Medical Science Liaisons

The primary responsibility of a Medical Science Liaison (MSL) is scientific engagement and education with HCPs, focusing on specific therapeutic areas, disease states and/or products in support of their company's product pipeline and portfolio. However, MSLs are often also used to help support scientific initiatives, such as identifying and recruiting potential sites and investigators for company-sponsored studies, scientific and medical advisory boards, and internal training and education, among others.

In general, an MSL may engage HCPs proactively or reactively consistent with the FDA's policy on off-label communications, but their interactions should not be promotional; see **3.3 Provision of Information to Healthcare Professionals** and **3.4 Provision of Information to Healthcare Institutions**. Specifically, MSLs may proactively discuss with HCPs therapeutic areas and disease states generally, as well as approved uses of approved products. Proactive discussions of investigational drugs or unapproved uses of approved drugs are generally not regarded as permissible activities for MSLs, as these proactive communications could be perceived as pre-approval or off-label promotion.

A significant role of MSLs is reactive interactions with HCPs, in which an MSL responds to unsolicited requests for scientific or medical information; see **3.3 Provision of Information to Healthcare Professionals**.

Importantly, the role and responsibilities of an MSL are neither commercial, nor promotional. The separation between medical and commercial functions is critical to preserving the legitimacy of MSL scientific exchange activities.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

In general, there is no requirement for prior notification or authorisation for prescription drug advertising and promotion; however, there are limited exceptions:

- companies whose advertisements have violated FDA or FTC standards in the past may be asked to pre-clear their advertisements in the future;
- prescription drugs approved under the accelerated approval process are subject to a "presubmission" requirement (ie, promotional materials must be submitted to the FDA prior to the intended date of dissemination or publication); and
- DTC television advertisments must be submitted for pre-dissemination review (in a 2012 draft guidance, "Direct-to-Consumer Television Advertisements – FDAAA DTC Television Ad Pre-Dissemination Review Program", the FDA outlines the pre-dissemination review process and the category of television advertisements for which pre-dissemination review is required).

Importantly, companies always have the option to voluntarily submit proposed promotional labelling or advertising to the FDA for advisory review.

#### 2253 Submission

The FDA's post-marketing reporting regulations require pharmaceutical companies to submit prescription drug promotional labelling and advertising materials to OPDP at the time of first use. This submission must be made using a completed Form FDA 2253 and must include a copy of the promotional material and the product's current PI.

### 6.2 Compliance with Rules on Medicinal Advertising

FDA regulations governing current Good Manufacturing Practices (CGMPs) require strict controls over labelling issued for use in drug product labelling operations. Although this regulation is typically applied to FDA-approved labelling (ie, PI), it should also be used for the development of promotional labelling.

It is best practice to adopt internal policies and standard operating procedures for managing the review, approval and use of promotional labelling and advertising. Typically, this is a cross-functional activity that includes representatives from legal, regulatory, medical and compliance departments within the company.

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

In general, the FDA's standard advertising and promotion rules apply to advertising and promotion on the internet. The FDA expects prescription drug websites to include risk information on the same screen as efficacy information; to provide a prominent link to the PI; to distinguish sites intended for US audiences and international audiences; to ensure that all claims, images and graphics are CFL; and to avoid links to off-label information.

Separately, the FTC has published several guides governing disclosures on the internet and social media, including ".com Disclosures: How to Make Effective Disclosures in Digital Advertising" (2013) and "Disclosures 101 for Social Media Influencers" (2019).

### 7.2 Advertising of Medicines on Social Media

The FDA permits advertising and promotion of prescription drugs on social media. Generally, the FDA's standard advertising and promotion rules apply, regardless of the social media platform being used.

The FDA has also issued guidance documents relevant to the use of social media for prescription pharmaceutical promotion.

- "Fulfilling Regulatory Requirements for Post-marketing Submissions of Interactive Promotional Media" (2014) describes when firms will be held responsible for social media content, including user-generated content (UGC), and how to submit interactive social media content via Form FDA 2253.
- "Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices" (2014) asserts that the FDA's long-standing rules regarding disclosure of risk information apply even in the context of character-limited communications (eg, Twitter, sponsored links). If there are insufficient characters to adequately communicate risk information for a particular drug, then character-limited communications may not be a "viable promotional tool" for that drug.
- "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices" (2014) describes how companies can address incorrect information posted about their products on social media or the internet by third parties unaffiliated with the company.

In addition, a number of FDA enforcement letters have cited companies for failing to adequately disclose risk information on social media, including Facebook, Instagram and YouTube. Notably, a 2014 warning letter to Zarbee's illustrates the potential for companies to be held responsible for independent UGC (eg, social media comments) if they endorse those statements by "liking", "sharing", or positively commenting on them.

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

There is no requirement to include access restrictions on pharmaceutical promotional websites intended for HCPs. However, it is common

industry practice to include an interstitial page (eg, pop-up webpage) for viewers to confirm they are an HCP before accessing the page.

### 7.4 Provision of Disease Awareness Information to Patients Online

It is common practice in the USA for pharmaceutical companies to develop disease awareness websites, social media pages, or online advertising directed to consumers. In general, the same rules that apply to traditional forms of disease awareness communications apply to online disease awareness content; see **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**.

### 7.5 Online Scientific Meetings

The same rules apply to promotion and advertising in online scientific meetings or congresses as in in-person settings. For virtual events, promotional materials should be reviewed according to traditional FDA advertising and promotion rules, but with the digital format in mind. In addition, given that geographic limitations are inherently more fluid in a virtual setting, companies should consider clear disclosures in materials and presentations regarding the intended audience, particularly if the product approval status or indication differs outside of the United States.

As with traditional in-person conferences, the AKS (see **8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals**) and PhRMA Code apply to the provision of items of value (eg, items for attendees) or other hospitality associated with a virtual scientific meeting or congress; see **9. Gifts, Hospitality, Congresses and Related Payments**.

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

#### Anti-Kickback Statute

The Anti-Kickback Statute (AKS) (42 USC 1320a-7b) prohibits individuals and entities from knowingly and wilfully soliciting, receiving, offering or paying any remuneration (directly or indirectly, overtly or covertly, in cash or in kind), in order to induce the provision of a good or service that is reimbursable under a federal healthcare programme, including Medicare and Medicaid. The scope of the AKS is broad and applies to any individual or entity (including manufacturers, healthcare providers and organisations, and lay persons) that provides, offers, solicits or receives remuneration with improper intent. The courts have broadly interpreted the AKS to cover any arrangement where even one purpose of remuneration, though not its sole or primary purpose, is to provide value for the referral, purchase, use or recommendation of goods or services reimbursed by Medicare or Medicaid.

"Remuneration" includes anything of value and there is no de minimis exception. Remuneration includes gifts, payments and other things typically thought of as benefits, but also broadly includes price reductions (such as discounts or rebates) and free or below-cost products and services.

#### Safe Harbour Regulations

The OIG has promulgated final "safe harbour" regulations specifying certain types of arrangements/remuneration that will not be considered to contravene the AKS. The safe harbours include, among others, protection for certain

discounts/rebates, warranties, employment and services arrangements. If an arrangement satisfies all the criteria of a safe harbour, it will be immune from criminal prosecution and civil exclusion under the AKS. Failure to satisfy any safe harbour does not necessarily mean that the arrangement violates the AKS; however, arrangements falling outside a safe harbour present a legal risk and may be more likely to be scrutinised as violations of the kickback prohibition. There are both criminal and civil penalties for violating the AKS.

### State Statutes

Various states have also enacted similar anti-kickback statutes that apply to inducements related to healthcare items and services (including drugs) reimbursed by private insurance, not just those reimbursed by a federal or state healthcare programme. Requirements under state law must be reviewed on a state-by-state basis.

### Civil Monetary Penalties

Similar to the AKS, the Civil Monetary Penalties (CMP) provisions of the Social Security Act (42 USC 1320a-7a) prohibit the offering or provision of inducements to federal healthcare programme beneficiaries and impose monetary penalties on entities that offer or transfer remuneration to such a beneficiary, when they know or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of items or services paid for by certain government programmes.

### Distinctions between the AKS and CMP

A few distinctions between the AKS and the CMP are notable. Firstly, the CMP law prohibits inducements only to Medicare and state healthcare programme beneficiaries (Medicaid), not all federal healthcare programme beneficiaries. Secondly, the CMP law may have indirect application (ie, the law is triggered if the person providing the remuneration knows or should know that it is likely to induce the beneficiary to order the item or service from a particular provider, practitioner or supplier). Thus, a pharmaceutical manufacturer, which is not a provider, practitioner, or supplier, could implicate the statute if it offered or gave remuneration to a beneficiary that it believed would be likely to induce the beneficiary to order an item or service from a particular provider, practitioner or supplier (eg, to choose a particular physician or pharmacy).

## 8.2 Legislative or Self-Regulatory Provisions

Because the penalties for violating the AKS and related civil statutes can be severe (including potentially leading to incarceration and/or exclusion from participation in federal healthcare programmes), there is a strong benefit to self-regulation.

Firstly, the OIG issued compliance guidance for pharmaceutical manufacturers – in part, to provide notice about activities that are likely to violate the AKS or CMP law. Companies self-regulate by developing internal policies and procedures that establish compliant practices and require auditing and monitoring of activities to ensure compliance. Secondly, the PhRMA Code sets forth voluntary guidelines for companies to stake out industry positions on common activities that should not be deemed to violate the AKS or CMP law. Finally, companies can adopt self-reporting protocols, consistent with guidelines from the OIG and the US Department of Justice, to self-report internally identified wrongdoing. Addressing potential fraud and corruption via internal policy and procedure, or by self-reporting to US authorities, can significantly help to mitigate potential allegations and/or penalties in the event of wrongdoing.

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

#### Under the PhRMA Code

The PhRMA Code expressly prohibits gifts that are intended for the personal benefit of HCPs, including practice-related items of de minimis value (eg, pens, pads, mugs, etc). Under the PhRMA Code, only items that "advance disease or treatment education" for patients may be furnished without charge to HCPs.

However, the PhRMA Code allows manufacturers to pay for or reimburse meals or travel expenses for HCPs in limited situations. Modest meals are generally permissible under the PhRMA Code only when they are provided in conjunction with an "informational presentation or discussion conducted by company representatives or their immediate managers working in field sales" in the HCP's office; in conjunction with an HCP's travel or meetings for consulting, training or speaking services on behalf of the manufacturer pursuant to a written agreement; or in conjunction with an HCP's attendance at a speaking or training event of the manufacturer. In these situations, meals should be modest, occasional, without attendance of spouses or guests, in a location that is conducive to educational or business content, subordinate in time and focus to the presentation, service or training at issue, and eaten on the premises (ie, no takeaway or two-hour meals for a 30-minute presentation). The PhRMA Code also prohibits companies from providing or paying for alcohol at meetings or presentations with HCPs.

Similarly, covering or paying for "reasonable" travel expenses is generally permissible under the PhRMA Code when made for an HCP's travel for meetings or services involving consulting, training or speaking services on behalf of the manufacturer pursuant to a written agreement. Travel expenses should not be covered for personal expenses or for individuals travelling with the HCP.

#### Under the AKS and Similar State Laws

Under the AKS and similar state laws, there are no express protections for remuneration in the form of gifts, free samples, grants or donations to support scientific meetings, research, or cultural, sporting, or other non-scientific events, or free or below-cost products or services, even when the value may be de minimis. Because many of these are common forms of business within the pharmaceutical industry, the PhRMA Code provides some level of protection for certain common arrangements in addition to specific regulatory safe harbour protections. Although it has been generally accepted by federal enforcement agencies, the PhRMA Code is not law or regulation. Thus, activities expressly condoned by the PhRMA Code, while not immune from prosecution, are less likely to be pursued by federal authorities, while activities prohibited by the PhRMA Code pose significant risks under the AKS.

### 9.2 Limitations on Providing Samples to Healthcare Professionals

The Prescription Drug Marketing Act (PDMA) permits a manufacturer to provide samples directly to a licensed healthcare practitioner or institution that requests the samples, signs for or formally acknowledges receipt of the samples, agrees to legally prescribe and dispense the samples, and does not resell the samples or bill patients or health insurance for them. The purpose of facilitating samples should generally be to ensure that patients and HCPs can reasonably evaluate whether a particular drug is appropriate for a particular patient. Samples should not be used as gifts or improper inducements for HCPs to prescribe a particular product, as such uses could violate the AKS.

### 9.3 Sponsorship of Scientific Meetings

Pursuant to the PhRMA Code, a manufacturer may provide financial support to third parties hosting scientific or educational conferences or meetings, including those for continuing medical education (CME). The PhRMA Code specifically provides that "a company should develop objective criteria for making CME grant [or support] decisions to ensure that the program funded by the company is a bona fide educational program and that the financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment", such as by covering the cost of attendance for specific HCPs.

### 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

The PhRMA Code expressly prohibits the support of HCP participation in cultural, sports or other non-scientific events.

### 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Grants or donations to HCPs or institutions, whether monetary or in-kind, generally fall within the broad definition of "remuneration" under the AKS. While it is not the policy of federal or state agencies to prosecute bona fide charitable donations and altruistic grants, these arrangements can raise serious issues under the AKS if any purpose of the funding is related to generating business from the recipient or individuals involved with the recipient. Because there are no protections for grants or donations under the statutory exceptions or regulatory safe harbours of the AKS, manufacturers should be mindful of the following:

- a grant or donation should be made only to charitable or non-profit organisations that would use the funding in accordance with their charitable/non-profit mission; and
- no purpose of the grant or donation should be to influence clinical or purchasing decision-making or to otherwise generate business for the manufacturer (some manufacturers demonstrate this by funding grants and donations from non-sales and marketing budgets; establishing and using a grants committee comprised of only non-commercial personnel; carefully documenting each grant and donation, including its intended purpose; and ensuring that there is no "return on investment" analysis with respect to grants or donations; among others).

### 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Discounts and rebates to HCPs and institutions are protected from violating the AKS if they meet all the requirements of a statutory exception (42 USC 1320a-7b(b)(3)(A)) or regulatory safe harbour (42 CFR 1001.952(h)). In general, to be protected, a discount or rebate must:

- be a reduction in the amount a purchaser is charged for an item or service based on an arm's length transaction;
- be disclosed to the purchaser in advance of any purchase being made and not paid prior to the purchase being made (ie, no upfront rebates or "pre-bates");
- not be paid in cash or cash equivalents (except for rebates paid by cheque);
- not be for the purpose of inducing the purchase of a different good or service, unless both items/services are reimbursed by the same federal healthcare programme using the same payment methodology, and the discount is fully disclosed to federal programmes;
- not be in exchange or payment for services;
- not result in the sale being made at a (net) price that is below the manufacturer's cost for

manufacturing, marketing and distributing the product(s); and
- be structured to provide the price reduction to the buyer within a year of the purchase of the product to which it relates.

In addition, the manufacturer must clearly inform the buyer of its obligations under the safe harbour to report the discount to federal agencies, as required, and must refrain from doing anything to impede the buyer from meeting its reporting obligations.

### 9.7 Payment for Services Provided by Healthcare Professionals

In order to receive AKS protection under the personal services and management contracts safe harbour (42 CFR 1001.952(d)), compensation for a services arrangement must meet all of the specific regulatory requirements, including:

- having a written agreement that expressly defines the services to be provided for a term of at least one year;
- that the contracted services are commercially reasonable in the absence of other business or referrals generated between the parties;
- the methodology for determining the compensation to be paid over the term of the agreement is set in advance, consistent with fair market value and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties; and
- the services must not involve any other violation of law.

The PhRMA Code provides additional guidance to help protect arrangements that cannot meet safe harbour protections, including factors that support the "existence of a bona fide consulting arrangement".

### 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

The provision of products or services without charge by a manufacturer to an HCP may result in in-kind "remuneration" that implicates the broad scope of the AKS. In analysing whether or not services may constitute remuneration, a manufacturer should consider whether the services intended purely for the reasonable and expected support of the manufacturer's product for a patient, might instead be intended to take the place of internal services or efforts that the HCP would ordinarily be expected to provide at their own cost and expense. The former types of arrangements arguably would not result in remuneration under the AKS, while the latter may implicate the broad scope of the statute.

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

The federal Physician Payments Sunshine Act ("Sunshine Act") and its implementing regulations require certain pharmaceutical and biologic manufacturers to annually report to the Centers for Medicare and Medicaid Services (CMS) certain information about payments or transfers of value provided directly or indirectly to covered recipients during the previous calendar year. "Covered recipients" under the Sunshine Act and its implementing regulations include US physicians and teaching hospitals, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anaesthetists, and certified nurse midwives.

In addition to the federal reporting requirements, several states, including Connecticut, the District of Columbia, Massachusetts, Minnesota and Vermont, also require manufacturers to track and annually report certain information about payments or transfers of value provided to HCPs and healthcare organisations in the respective state. The specific transparency requirements vary from state to state. There are also several jurisdictions that require pharmaceutical representatives to be licensed/listed with local agencies, including Chicago, the District of Columbia, Nevada and Oregon. Many of these local requirements include transparency obligations for licensed/listed representatives, who are required to track and annually report certain information about their communications and interactions with HCPs.

### 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

The federal Sunshine Act requirements apply to foreign companies if the entity "operates in the United States" and meets the definition of an "applicable manufacturer". Determination of how transparency laws apply to entities based outside the United States should be conducted on a case-by-case basis considering the entity and any subsidiaries. Some state laws mirror the federal Sunshine Act requirements while other state laws are less clear but generally apply to manufacturers providing transfers of value to HCPs licensed by the state.

As a general matter, the federal Sunshine Act and state transparency laws do not apply to companies that do not yet have marketed products.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

See **1.1 Laws and Self-Regulatory Codes Regulating Advertising of Medicines** for information on regulatory and enforcement bodies for pharmaceutical advertising and promotion.

Both the Department of Justice (DOJ) and the OIG have authority to enforce the Anti-Kickback Statute, the Civil Money Penalties Law, and the False Claims Act. The DOJ has jurisdiction over both criminal and civil enforcement actions, while the OIG has authority with respect to civil actions. State attorneys general may take enforcement actions under similar state laws.

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

In most instances, FDA enforcement against unlawful promotion and advertising begins with an enforcement letter issued by the OPDP of the FDA. Repeat or egregious violations may prompt the FDA and FTC to initiate enforcement proceedings in federal court to enjoin the behaviour and seek penalties.

Competitors and consumers may also challenge unlawful promotion and advertising. The FDCA and FTCA do not provide a right of action to competitors or consumers; however, the submission of trade complaints to the FDA and/or FTC may prompt the agencies to act. HCPs, consumers and competitors can also notify the FDA of unlawful pharmaceutical marketing through the FDA's "Bad Ad Program" hotline. In addition, competitors and/or consumers may seek to challenge advertising directly through state and/or other federal laws.

Companies may also challenge competitors' "false and misleading" advertising in court under the Lanham Act and before the self-regulatory body of the NAD of the Better Business Bureau (BBB), which is a voluntary process and not enforceable under law.

## 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

### FDA and FTC Enforcement

Penalties for unlawful pharmaceutical marketing and advertising vary depending on the statute used to challenge the activity. If the FDA or FTC pursue enforcement in federal courts, injunctions are common penalties; the FDA may also seize products. In more extreme cases, the FDA may co-ordinate with the DOJ to bring criminal charges. Misdemeanour convictions of "misbranding" a drug can result in a fine of USD1,000 and a year in prison. A felony conviction could result in a USD10,000 fine and three years in prison.

In a typical challenge under the Lanham Act, the court may award injunctive and/or monetary remedies, based on lost profits or loss of goodwill due to false advertising, or to reimburse the costs of corrective advertising. In extraordinary cases and in some jurisdictions, courts may also consider granting a preliminary injunction, disgorgement of profits, treble damages, and/or an award of attorney's fees.

### AKS

Under the AKS, criminal sanctions include a fine not to exceed USD250,000 or imprisonment for up to five years, or both, for each offence. In addition, monetary penalties for each offence may be increased to USD500,000 for organisations. Civil penalties include fines of up to USD50,000 for each violation, and monetary damages of up to three times the amount paid for referrals and/or exclusion from the Medicare programme. Furthermore, any claims submitted to Medicare or Medicaid as a result of an illegal kickback now automatically constitute false or fraudulent claims under the federal False Claims Act.

### False Claims Act

Penalties for violating the False Claims Act can be civil and/or criminal, with statutory civil penalties between USD5,000 and USD10,000 (which can be increased to up to USD23,607) per false claim and triple the amount of the damage to the government. The criminal False Claims Act can be enforced with imprisonment and/or criminal fines.

## 11.4 Relationship between Regulatory Authorities and Courts

Regulatory authorities such as the FDA and FTC may pursue enforcement against unlawful advertising and promotion in federal court, while state enforcement occurs in a state court. Self-regulation through the NAD is a voluntary process. Although NAD decisions are not binding in court; some cases may be referred to the FTC for potential enforcement.

## 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

Based on OPDP enforcement letters issued over the past few years, the FDA is focusing on a range of digital and broadcast advertising and promotional activities, including DTC television advertisements, consumer videos, websites, emails, sponsored links, and social media. Consistent with past enforcement letters, the most cited violation continues to be false or misleading presentation of risk information; however, there is also a strong focus on false or misleading efficacy claims. Products with boxed warnings in their labelling are a frequent target of OPDP letters.

For both the FDA and FTC, marketing by physicians, celebrity spokespeople and influencers is

a key focus area for both prescription and OTC drugs. Recent enforcement related to influencer and spokesperson marketing has cited omission or minimisation of risk information, overstatement of efficacy, and lack of adequate disclosure of the relationship between the influencer and the sponsoring company. Finally, due to the COVID-19 pandemic, both agencies have regularly issued enforcement letters against products marketed with fraudulent claims for the treatment or prevention of COVID-19.

**King & Spalding LLP** has more than 1,200 lawyers in its 22 global offices and helps companies advance business interests in more than 160 countries. The firm's FDA and life sciences practice plays a critical role within this context. With over 40 lawyers and professionals in the US and Europe, the group counsels more than 250 large, mid-cap and start-up drug, biotech and medical device companies, food manufacturers, distributors, healthcare providers and technology ventures. The EU team focuses on EU and national (French, Belgian and German) issues associated with the legal requirements for pharmaceuticals/biologics, medical devices, cosmetics and foods. The firm's clients receive tremendous synergy from the interaction of the FDA/regulatory and healthcare teams with the product liability, government investigations, discovery, appellate, intellectual property, corporate and litigation teams. More than 400 lawyers and professionals in 17 areas devote all or a substantial portion of their practices to the life sciences industry.

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KING & SPALDING

# Trends and Developments

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## Relevant Laws or Codes Governing Pharmaceutical Advertising in the USA

In the US, prescription drug advertising is primarily regulated by the US Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act (FD&C Act) and its implementing regulations, as well as through FDA guidance documents (see 21 USC § 352(n); 21 CFR § 202.1). Other federal and state government entities that enforce various false and/or deceptive advertising claims (pertaining to prescription drugs) include the US Federal Trade Commission (FTC) and individual state attorneys general. Pharmaceutical company product-related statements have also drawn enforcement scrutiny from the US Securities and Exchange Commission (SEC) where investors have somehow been misled.

Over-the-counter (OTC)/non-prescription drug advertising is primarily regulated by the FTC under 15 USC §§ 52–57, where false or deceptive OTC drug advertising (likely to induce the product's purchase) is unlawful and enforceable by the FTC. The National Advertising Division (NAD) of the Better Business Bureau (BBB), the advertising industry's self-regulatory body, independently reviews and monitors national advertising for accuracy and truthfulness, and offers a voluntary dispute resolution process for advertisers. Many challenges to OTC drug advertising are brought before the NAD for review and adjudication.

## Pre-approval Product Communications

As a general matter, promotion of a prescription drug prior to FDA approval of that drug is not allowed (see 21 CFR § 312.7(a)). Over the last several years, the FDA has taken increased interest in pharmaceutical company prescription drug product communications that cross over into promotional territory (as opposed to pure scientific discourse), issuing enforcement letters to a number of companies. The letters consistently highlight communications that tend to make conclusive statements or representations regarding the safety and efficacy of an investigational new drug (a drug being studied in clinical trials) where the safety and efficacy have not yet been established and the product lacks FDA approval. The FDA's focus on these types of communications has shown no signs of waning.

## Product Safety

One area of pharmaceutical company advertising that consistently garners FDA scrutiny is communications involving product safety. Tracing back through decades of enforcement letters from the FDA's Office of Prescription Drug Promotion (OPDP) and its predecessor, the Division of Drug Marketing, Advertising and Communications (DDMAC), the Agency routinely objected to various promotional statements and tactics viewed as minimising or omitting important risk information. Embedded in the OPDP's mission is the aim to protect public health by helping ensure that prescription drug promotion is truthful, balanced and accurately communicated. Downplaying or completely omitting risk information from product advertising and promotion will continue to capture the OPDP's enforcement interest, as these misrepresentations work to throw off balanced promotional presentations.

Over the years, prescription drug product safety communications have also caught the attention of the US Department of Justice (DOJ), particularly when false statements relating to product

safety were made in order to increase the sales of prescription drugs.

### Federal Trade Commission

The Federal Trade Commission (FTC) is the primary federal government agency enforcing unfair and deceptive trade practices, including false advertising. The FTC's primary authority stems from the FTC Act, 15 USC §§ 41–58, as to which the Commission has exclusive enforcement authority. The FTC shares primary responsibility with the FDA in the agencies' concurrent jurisdiction over pharmaceutical advertising, marketing and promotion, according to a memorandum of understanding pursuant to which the FDA regulates all aspects of prescription drugs and the mandated labelling of all other FDA-regulated products, while the FTC has primary responsibility over "the truth or falsity of all advertising (other than labe[l]ling) of foods, [non-prescription] drugs, devices, and cosmetics". The two agencies advise each other on matters within the other's turf; the FTC defers to the FDA's judgment where the subject matter of OTC drug advertising mirrors FDA-regulated labelling, for example, whereas the FTC has advised the FDA on potential deception in direct-to-consumer advertising of prescription drugs. The FTC actively enforces what it deems unfair or deceptive practices in the advertising of OTC drugs, devices and cosmetics, including such things as the efficacy of analgesics. The FTC, sometimes jointly with the FDA, also enforces disease prevention or treatment claims by foods, dietary supplements and other products that the agencies contend render these products unapproved or misbranded drugs or medical devices.

### Social Media Marketing and Influencers

Given that we are predominantly living in a digital age, it is no surprise that pharmaceutical company advertising and promotion has increasingly explored digital delivery methods. Through the use of various social media platforms, companies are finding new and innovative ways to deliver tailored messaging to consumers as well as healthcare professionals. Although these platforms may present new ways of delivering content, the rubric of FDA rules and policies governing prescription advertising has not really changed that much – as evidenced from OPDP enforcement letters implicating various social media platforms. At the end of the day, prescription drug advertising must be truthful, non-misleading, and balanced, no matter the medium.

The FDA has also continued taking interest in influencer advertising – where pharmaceutical companies use various celebrities and/or influencers to market to their large social media following. Influencer marketing of prescription drugs is overseen by the FDA, while that for non-prescription drugs and other products is overseen by the FTC. Sometimes the agencies act jointly, as they did in a late 2021 series of letters to companies and influencers promoting the nicotine-containing liquids used in vaping devices. These letters and other actions by the FDA and FTC stress the dual requirements associated with influencer marketing: (1) the advertising must be truthful, non-misleading and contain all disclosures that would be required in any other advertising; and (2) any material connection between the influencer and the advertiser must be disclosed, as the FTC considers the failure to disclose such connections to be a distinct deceptive practice.

### Competitor Activities

Over the last several years, the FDA has taken a pretty inactive stance on competitor superiority claims. Remarks made in 2018 by the FDA's former director of the Center for Drug Evaluation and Research (CDER), Dr Janet Woodcock, at a discussion hosted by the Alliance for a Stronger FDA, signalled that the Agency was more inclined to let competitors "duke it out" when it came to

disputes not involving threats to human health or safety. Although under different leadership, not much has changed at CDER on this topic. In 2021, the FDA issued no-enforcement letters to pharmaceutical companies for unsubstantiated or misleading comparative claims, and 2022 will most likely continue to see the same level of inaction. Pharmaceutical companies wishing to stop competitors from making inaccurate or misleading product comparative claims should expect to continue seeking redress under the false/misleading advertising provisions of the Lanham Act and/or submitting complaints to the FTC and individual state attorneys general. Competitors may also lodge a self-regulatory challenge before the National Advertising Division (NAD), although participation in this forum is voluntary, and compliance with the NAD's decision is not legally enforceable.

Since FTC and state attorneys general are not always responsive to competitor complaints that primarily affect the commercial positions of the parties rather than consumer welfare, the federal Lanham Act litigation may be the only effective option to shut down a competitor's offending marketing claims. Such litigation has drawbacks, however:

- the complaining plaintiff carries the burden to prove the advertiser's claims false, whereas a regulator could require the advertiser to substantiate them;
- Lanham Act litigation permits counterclaims against the original plaintiff for any of its own allegedly false advertising that the sued party can dig up; and
- like any federal litigation, the process can be lengthy, invasive and expensive.

### Off-Label Promotion

Although not at a level seen in the early to mid-2000s, OPDP has not stopped issuing enforcement letters for off-label promotion. The wording and the charges, however, do differ as they are carefully crafted to focus more on misbranding, as opposed to vilifying speech. For example, recent letters cite off-label communications as providing evidence of a new, intended use for which the products' labelling did not provide adequate information for use, rendering the products misbranded. The last couple of letters honed in on sales representatives' oral statements and emailed communications. In an effort to continue asserting its presence in this space, continued but measured FDA enforcement against off-label promotion should be expected going forward.

### Investor Lawsuits/SEC Scrutiny

Investor lawsuits against pharmaceutical companies for misleading statements made in public-required and investor-related disclosures are becoming more and more commonplace. Often, these statements also appear in company-issued press releases, which have the potential to be viewed as promotional – depending on what is stated and how it is stated. When crafting press releases concerning product performance, potential, or a candidate product's likelihood of FDA filing success, not only should pharmaceutical companies be aware of the various FDA promotional requirements that apply, but companies should also think about SEC implications. Many investor lawsuits allege that the company at issue made misleading statements about its product's safety or efficacy that turned out to be not as rosy as depicted, or somehow actually resulted in a negative FDA action, usually somehow causing injury to investors due to a decrease in stock prices.

### Consistent with Labelling Communications

As the FDA has expressed an increased interest in real-world evidence (ie, clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of real-world data – which is data relating

to patient health status and/or the delivery of healthcare routinely collected from a variety of sources), many pharmaceutical companies have started incorporating or, at least, considering how and whether to include information in advertising and promotional materials that is supported by real-world evidence. Often, the information supported by the real-world evidence is not included in FDA-approved labelling for the product at issue. As companies continue to navigate this new area of information, the FDA's guidance for the industry, "Medical Product Communications That Are Consistent With the FDA-Required Labelling – Questions and Answers", in combination with lessons learned from various enforcement letters citing the use of real-world evidence, will continue to be of interest to companies.

### Healthcare Fraud and Abuse Considerations

In recent years, pharmaceutical company speakers' programmes (a practice where pharmaceutical companies pay healthcare practitioners (HCPs), who often prescribe the companies' products, to promote these products to other HCPs) and speaker training meetings have faced intense government scrutiny where the allegations have been that these events induced HCPs to prescribe prescription drug products in violation of the Anti-Kickback Statute (AKS) and False Claims Act (FCA). These programmes tend to be the highest-risk marketing practice in the pharmaceutical industry and most likely will retain that designation for some time going forward.

### Conclusion

Navigating US rules and policies governing pharmaceutical advertising requires focused attention on several sources of oversight – both official and unofficial – each with unique requirements. Violations of official government-imposed requirements can land companies into significant trouble. However, industry self-regulatory activities are unlikely to yield the same level of enforcement consequences. Nonetheless, one thing is for sure – care should be taken to avoid false, misleading and/or deceptive promotional claims and practices, as these tend to be at the heart of many challenges to pharmaceutical product advertising.

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**Foley Hoag LLP** is a nationally recognised, full-service life sciences practice that draws on the talents of a wide variety of professionals – many of whom have had previous careers as scientists, medical doctors and high-ranking government officials – to advise clients across the industry ranging from start-ups to Fortune Future 50 companies. The firm's advertising and marketing legal team provides a broad range of regulatory, advisory and disputes-oriented representation around the promotion of goods and services, and brings considerable experience to all the legal issues affecting a business's ability to promote its offerings. From offices in Boston, New York, Paris and Washington, DC, the team helps clients achieve their business goals while minimising risk, as they navigate the complex waters associated with the development, approval, commercialisation, reimbursement and coverage of innovative medical products and services.

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# VIETNAM

## Law and Practice

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## 1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

### 1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The advertising of medicines in Vietnam is mainly governed by the following regulations:

- the Law on Advertising No 16/2012/QH13;
- the Law on Pharmacy No 105/2016/QH13; and
- Decree No 54/2017/ND-CP (as amended).

In addition, regulations on drug advertising are also mentioned in two professional pharmaceutical trade association guidelines:

- the Code of Ethical Practices issued by Pharma Group under the European Chamber of Commerce in Vietnam ("PG Code"); and
- the Voluntary Codes on Business Ethics in the Vietnam Pharmaceutical & Biopharmaceutical Sector, issued by the Vietnam Pharmaceutical Companies Association ("VNPCA Code").

### 1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The PG Code applies to all Pharma Group members and all of their employees (whether on indefinite term, definite term, or seasonal labour contracts) as well as third-party agencies representing the interests of Pharma Group member companies. The VNPCA Code applies to all VNPCA members and related organisations and individuals.

Neither of these codes has legal value.

## 2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

### 2.1 Definition of Advertising

"Advertising" is defined as the implementation of various means to present to the public products, goods and services for profit; products and services not for profit; and organisations and individuals which are trading and providing the presented products, goods and services, except for news, social policies and personal information.

There is no specific definition of drug advertising under current regulations in Vietnam – only the general definition of advertising.

### 2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

"Drug information", under regulations in the law on the collection and provision of such information, means information about a drug, including indications, contraindications, dosage, administration, adverse effects, and information relevant to the quality, safety and efficacy of the drug provided by responsible facilities on behalf of pharmaceutical authorities, healthcare professionals and those using the medication.

The current regulations are silent on the provision of drug information to authorities and those using the medication; only regulations on the provision of drug information to medical and healthcare professionals are available. Specifically, drug information can be provided to healthcare professionals through one of three forms:

- drug introducers (medical representatives);
- drug information documents; and
- drug introduction seminars.

The biggest difference between drug information provision and drug advertising is the main targeted subjects – healthcare professionals for drug information and users/consumers of the medication for drug advertising. In addition, drug advertising is only allowed for drugs satisfying all of the following conditions, ie, they must:

- be non-prescription;
- not be subject to limited use or subject to use under the supervision of a physician; and
- have valid marketing authorisation (MA).

Under the Law on Advertising, print products and events are means of advertising; and any materials (such as patient leaflets) or programmes aiming to provide patients with information about drugs are subject to regulations on drug advertising.

### 2.3 Restrictions on Press Releases regarding Medicines

There are no specific regulations on press releases for medicinal products in Vietnam.

### 2.4 Comparative Advertising for Medicines

Under the Law on Advertising, it is prohibited to use advertising that directly compares the prices, quality or efficiency of the advertiser's products with those of other products of the same kind (including medication).

## 3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

### 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

It is only permissible to provide drug information for drugs that have been granted MA or import licences. For drugs with import licences, the only form of drug introduction allowed is seminars. Thus, it is not possible to provide information on unauthorised medication.

In addition, the grounds to create drug information to be provided to healthcare professionals include only:

- the Vietnamese National Drug Formulary;
- the medicine package insert approved by the Ministry of Health (MOH); and
- professional documents/instructions relating to the medicine, either issued or accepted by the MOH.

Thus, it can be interpreted that it is not permitted to provide information about indications that have not yet been approved by the authority.

#### Pre-information Procedure

Before releasing drug information documents or conducting drug introduction seminars, it is necessary to obtain a certificate of drug information content (approval) from the Drug Administration of Vietnam (DAV) for drug information documents, or from the provincial Department of Health for drug introduction seminars.

It is not required to obtain approval from the authorities before conducting drug information provision via drug introducers (medical representatives), provided they have been granted

specific medical representative cards for such activity.

### 3.2 Provision of Information during a Scientific Conference

As mentioned in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, it is not possible to provide information on unauthorised medication or indications, regardless of the form of information provision.

#### Pre-information procedure

Before conducting a scientific conference directed at healthcare professionals, it is necessary to obtain a certificate of drug information content from the provincial Department of Health.

In addition, at least three working days before holding the conference, the establishment that has been granted the certificate of drug information content must send the provincial Department of Health written notification of the time and place of the conference, accompanied by a copy of the granted certification of drug information content.

Furthermore, if there is a change to the time or place mentioned in the certificate of drug information content, the establishment must notify the local Department of Health where the conference is being organised at least one working day before the conference date.

### 3.3 Provision of Information to Healthcare Professionals

Companies are not allowed to provide healthcare professionals with information about medicines/indications that have not yet been approved by the authority. Thus, it is not possible for companies to send information on unauthorised medicines or unauthorised indications to healthcare professionals.

Information on unapproved indications (off-label use) of an active ingredient, or unapproved active pharmaceutical ingredients may be discussed in a non-promotional scientific exchange, if approved by the Vietnamese authorities in charge.

### 3.4 Provision of Information to Healthcare Institutions

Information on unauthorised medicines or unauthorised indications may be sent to healthcare institutions in the context of clinical trials. Such communications will not be considered as drug advertising or promotion; rather, the communication would be stipulated in the clinical trial agreements or related documents.

### 3.5 Publication of Compassionate Use Programmes

The regulations are silent on the publication of compassionate use programmes. In practice, such programmes may be published. For example, the MOH announced a programme on early access to unapproved Molnupiravir for the treatment of COVID-19.

## 4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

### 4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

It is strictly prohibited to advertise prescription medicines. Advertising is allowed only for over-the-counter (OTC) medication which is not subject to restrictions on use and does not need to be given under the supervision of a physician as recommended by a relevant state agency, and which has valid MA licences in Vietnam.

An approval (in the form of a certificate) on drug advertising content must be obtained from the DAV before conducting the advertising activity

relating to the advertising content. The advertising activity must comply with the approval.

## 4.2 Information Contained in Pharmaceutical Advertising to the General Public

### Requirements for Drug Advertising Content

Drug advertising content must include the following:

- name of the medicine;
- active ingredients or herbs;
- administration;
- dosage;
- contraindications, recommendations for particular sectors of the population (pregnant or breastfeeding women, etc);
- cautions and warnings;
- undesirable effects;
- name and address of manufacturer;
- the sentence "*Đọc kỹ hướng dẫn sử dụng trước khi dùng*" ("Read instructions carefully before use");
- at the bottom of the first page of drug advertising content, the serial number of the certificate of drug advertising content of the MOH and the date of issue must be clearly stated;
- for multi-page advertising content, the pages must be numbered and the number of pages and the page on which readers can obtain details on the product must be stated on the first page; and
- a note on supporting documents specifying the information cited in the documents (the citation must ensure accurate communication of information, without presenting the information in a way that causes misunderstanding about the safety and efficacy of the medicine).

If the advertisement has audio, it must be presented with the following content:

- name of the medicine;
- active ingredients or herbs;
- administration;
- contraindications, recommendations for particular sectors of the population (pregnant or breastfeeding women, etc);
- name and address of manufacturer; and
- the sentence "*Đọc kỹ hướng dẫn sử dụng trước khi dùng*" ("Read instructions carefully before use").

### Prohibited Content

The information and images below may *not* be used in drug advertising content.

- Information and images specified in the Law on Advertising, such as unfair competition; the words "best", "the best", "only", "number one" or words with similar meaning without legitimate documents proving such, as prescribed by the Ministry of Culture, Sports and Tourism (such as the results of a market survey or certificate obtained from a competition, etc); and another person's image, words or text without obtaining that person's consent.
- Misleading contents about the ingredients, effects, indications or origin of the drug.
- Content creating the following understanding: this drug is number one; this drug is better than all others; using this medicine is the best measure; use this medicine without consulting a doctor; this drug is completely harmless; this drug has no contraindications; this drug has no undesirable effects; this drug has no harmful effects.
- Sentences, words and images that are overly deductive, leading to misunderstandings as to the effects, indications and effectiveness of the drug, or exaggerating the effects, indications and effectiveness of the approved drugs.
- The effect of each ingredient of the drug to advertise the effects of the drug itself, or con-

fusing the effect of each ingredient with the effect of the finished drug.
- Words and phrases, such as: "root treatment", "elimination", "special treatment", "top", "top of list", "first-time", "selection", "high quality", "100% guarantee", "safety", "stop", "immediate reduction", "quit immediately", "completely cured", "assured", "don't worry", "recommended", "hotline", "consultation phone", and words and phrases with similar meanings.
- Indications for treatment of tuberculosis and leprosy, sexually transmitted diseases, insomnia, cancers and tumours, diabetes or other similar metabolic disorders, viral hepatitis and emerging dangerous diseases; indications for sexual arousal; and indications for drug addiction cessation treatment.
- Clinical research results, non-clinical research results, testing results, or bioequivalence results which have not yet been approved by the MOH to advertise as drug information.
- The name, position, prestige, testimonials, or thank-you letters of organisations and individuals to advertise the drugs.
- The origin of drugs or medicinal ingredients to advertise the drugs.
- Pictures, names and symbols of medical staff.
- Images of animals and plants on the list of endangered, precious and rare species prioritised for protection.
- Sentences and words of advice to recommend a medicine.
- Images of patients to describe the medical condition or use of the drug, which are inconsistent with the drug-related documents and professional guidelines issued or recognised by the MOH.

In addition, advertising content is required to conform with: (i) the Vietnamese National Drug Formulary; (ii) the medicine package insert and labels approved by the MOH; and (iii) professional documents/instructions relating to the medicine issued or accepted by the MOH. This means, in principle, that it is not permitted to include information in the advertising content that is not included in these documents.

### Drug Prices

The main policy for medicinal product pricing in Vietnam is that drug manufacturers, exporters, importers, MA holders and wholesalers/distributors are free to set the prices of their products, and compete on prices, but are still liable to the law. Pharmaceutical establishments must declare their drug prices to the DAV but no approval for the declared price is issued by the authority.

None of the documents (i), (ii) or (iii) mentioned above include the drug price. Thus, the drug price should not be mentioned in the advertising.

## 4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

### Under Vietnamese Law

It is prohibited for medical representatives of companies selling medication to approach patients, to collect information regarding the medical records or medical prescriptions of patients; or to discuss or require information related to patients.

### Under the PG Code

"PG members must not answer requests from individual members of the public for advice on personal medical matters. Enquirers must be referred to their personal physicians. This includes toll-free information services. Medical representatives must never discuss medical matters with patients in any forum, including health fairs, pharmacies, hospitals, and physicians' waiting rooms, even if approached directly by a patient, nor may they instruct patients on how to use company products. Patients must be advised to seek advice directly from their phy-

sician, who, in turn, may contact PG members for further information. Disease awareness campaigns or patient education program[me]s can be supported by PG members by providing a grant to a competent medical association which is authorised to conduct such campaigns.

PG members may support the work of independent patient associations but must ensure that their involvement has been declared and is transparent, that all of the arrangements comply with this Code and applicable Laws, and that a written agreement is in place. PG members must not influence the operation of the funded patient associations. The independence of this association must be fully kept."

### Under the VNPCA Code

No specific provision is mentioned. In interactions with all relevant parties, a member company is committed to:

- implementing the highest ethical standards;
- implementing fully and responsibly all laws and regulations in force;
- encouraging medical professionals, government officials, and others working with the company, to always respect and apply the appropriate ethical standards that conform to the VNPCA Code; and
- ensuring that the company interacts in a professional manner and aims to bring benefits to the patients, as per the VNPCA Code.

## 5. ADVERTISING TO HEALTHCARE PROFESSIONALS

### 5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Drug information provided to healthcare professionals must include the following: the name of the medicine, its composition, concentration, strength, dosage form, indications, contraindications, dosage and administration, the use of the medicine in specific sectors of the population, information related to warnings and safety, and other necessary information.

Similar to drug advertising to the general public, the grounds to create drug information for provision to healthcare professionals include: (i) the Vietnamese National Drug Formulary; (ii) the medicine package insert approved by the MOH; and (iii) professional documents/instructions relating to the medicine issued or accepted by the MOH. Thus, in principle, information that is not included in the documents above may not be provided. Accordingly, the drug price should not be mentioned in drug information content provided to healthcare professionals.

### 5.2 Reference to Data Not Included in the Summary of Product Characteristics

As mentioned in **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**, drug information provided to healthcare professionals must be included in specific documents, including the approved package insert. The Summary of Product Characteristics ("SmPC") is only required for new drugs under regulations in Vietnam while the package insert will be required for any drugs (new and generic) registered in Vietnam. The content of the package insert is similar to that of the SmPC.

If a piece of information is not mentioned in the documents above, the pharmaceutical entity first needs to register such information with the DAV by submitting a variation dossier (Variation 39: Adding and/or updating information to provide product information and advertising) to obtain the DAV's approval for the use of the document/information for provision of drug information.

### 5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

See **5.2 Reference to Data Not Included in the Summary of Product Characteristics**. Any information not included in the three documents mentioned in **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals** needs to be approved first by the DAV in terms of a variation registration dossier before it can be used in product information and advertising.

### 5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Medical representatives who are in charge of directly providing drug information to healthcare professionals of pharmaceutical establishments are prohibited from providing drug information that is not as accurate as the information submitted to or verified by the regulatory authority, and from publishing drug information or documents that are not verified by the regulatory authority.

Thus, companies are not allowed to provide reprints of journal articles to healthcare professionals referring to medical and scientific information on unapproved new uses for approved drugs.

### 5.5 Medical Science Liaisons

There is no specific definition or requirement for medical science liaisons (MSLs) in Vietnam. However, as with medical representatives, it is presumably not permitted to proactively discuss information on unauthorised medicines or indications with healthcare professionals at an MSL.

## 6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

### 6.1 Requirements for Prior Notification/ Authorisation

Approval must be obtained from the DAV for various aspects of a drug advertisement, such as the content, layout and form, and the applicant must comply with the approval in the course of advertising. The advertising of drugs before obtaining the DAV approval is prohibited.

### 6.2 Compliance with Rules on Medicinal Advertising

There are no specific regulations on what arrangements companies must have in place to ensure compliance with the rules on medicinal advertising. There are only requirements for medical representatives who are in charge of directly providing drug information to healthcare professionals. In particular, medical representatives must meet the following requirements:

- they must have a college degree or higher in medicine or pharmacy; and
- they must be hired and trained by pharmaceutical businesses in professional skills and operations related to drug introduction and legal documents on pharmacy.

Medical representatives must be granted a “medical representative card” by the pharmaceutical business.

## 7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

### 7.1 Regulation of Advertising of Medicinal Products on the Internet

Advertising of medicinal products on websites follows general regulations on drug advertising specified in **4.2 Information Contained in Pharmaceutical Advertising to the General Public**.

If the advertising content has multiple pages or is a sound or video recording with multiple scenes, the pages or scenes of the advertisement must appear consecutively, pausing long enough for viewers to read all the information; plus pages and scenes with product information must be stationary and not moving so that viewers have time to take in the product information. The advertising script included in the application for content approval must describe how the content pages will appear for multi-page advertisements.

The advertising of medicines in this form must be separate and multiple medicines must not be advertised at the same time, to avoid misunderstanding.

### 7.2 Advertising of Medicines on Social Media

Advertising medicines on social media is not prohibited, provided that the relevant advertising content has been previously approved by the DAV.

### 7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

In principle, drug information documents can only be provided to the correct (approved) subjects. This means that if information is approved to be provided to healthcare professionals, websites containing the information must include access restriction so that only healthcare professionals can access them.

### 7.4 Provision of Disease Awareness Information to Patients Online

Pharmaceutical businesses may not provide disease awareness information and/or materials to patients online. Companies can only support disease awareness campaigns or patient education programmes by providing support to a competent medical association which is authorised to conduct such campaigns.

### 7.5 Online Scientific Meetings

Regulations on online scientific meetings are similar to those for offline meetings in Vietnam.

Pharmaceutical companies are allowed to sponsor scientific meetings or congresses and/or virtual attendance by healthcare professionals at these events; no special restriction is stipulated under Vietnamese law. However, the sponsorship should be in compliance with corresponding guidelines from relevant pharmaceutical associations, if any.

Under Decision No 06/2020/QD-TTg of the prime minister dated 21 February 2021 on the organisation and management of international conferences and seminars in Vietnam, an "international conference or seminar" is defined to cover any conference or seminar involving foreign elements which is organised in the form of a face-to-face meeting in Vietnamese territory or in the form of an online meeting with at least one location for streaming in Vietnamese territory, including:

- conferences and seminars organised by Vietnamese organisations with foreign participation or sponsorship; and
- conferences and seminars organised by foreign organisations.

"Vietnamese organisations" are those established under Vietnamese law and managed by a Vietnamese authority, such as central state or local administrative agencies. "Foreign organisations" include those permitted by an authority to operate in Vietnamese territory.

Online conferences may be considered "international" events if they meet the definition above.

Before being held, online international meetings must be registered with the authority in Vietnam. This also means that the content of such meetings will be evaluated by the authority, based on Vietnamese law.

There are no specific rules on accessing conference recordings, materials, etc, after the date of the conference. In practice, attendees can typically access such recordings or materials after the conference.

## 8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

### 8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

The key legislation governing anti-bribery and anti-corruption matters in Vietnam is the Anti-corruption Law and Penal Code. Under this law, corruption-related offences, including the giving and promising of bribes, the receiving of bribes, the "brokerage" of bribes, and embezzlement are strictly prohibited and the violators may be subject to criminal liability. Given the broad definitions under the Anti-corruption Law, any persons who have certain positions and authority in both the public and private sectors can be deemed "office holders" liable for offences relating to bribery.

For the act of giving/promising bribes, the law does not distinguish between bribes given to an individual office holder or to an organisation. In theory, giving or promising bribes to healthcare organisations or healthcare professionals, especially those who concurrently hold managerial titles in a healthcare organisation, is strictly prohibited and may be subject to criminal liability.

In practice, corruption or bribery charges are applied to individuals rather than organisations. Depending on the value of the benefits given and the severity of the crime, the penalty for an individual will be a monetary fine ranging from VND20 million to VND200 million (about USD880 to USD8,800) or six months' to 20 years' imprisonment.

### 8.2 Legislative or Self-Regulatory Provisions

It is prohibited for medical representatives to use material benefits to influence healthcare professionals or those using the medication to make them write more prescriptions or purchase more of the medication.

## 9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

### 9.1 Gifts to Healthcare Professionals

#### Vietnamese Law

It is not specified by Vietnamese law under what circumstances pharmaceutical companies may offer gifts to healthcare professionals (HCPs).

#### PG Code

"Gifts (examples include but are not limited to sporting or entertainment tickets, sight-seeing travels including sight-seeing travels in con-

junction with events, electronic items, social courtesy gifts, wreaths, etc) provided to healthcare professionals ("HCPs") (either directly or indirectly) are prohibited. Providing or offering cash, cash equivalents or personal services is also prohibited.

*Items of medical utility*

- Items of medical utility may be offered or provided by PG member companies to HCPs if such items are of modest value (no independent value and not for personal benefit), do not offset routine business practices, are directly beneficial to enhancing the provision of medical services and patient care, and in line with Vietnamese laws.
- Items of medical utility should be given to HCPs on an occasional basis only, even if each individual item is appropriate.
- Items of medical utility can include the company name but must not be product branded, unless the product's name is essential for the correct use of the item by the patient, and in line with Vietnamese laws.

*Educational items that enhance Patient Care*

- Informational and educational items that enhance Patient Care provided to HCPs for their education or for the education of patients on disease and its treatments may be offered by member companies provided that the items are primarily for educational purposes and do not have independent value.
- These informational and educational items can include the company name but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

The total value for items of medical utility, informational and educational items that enhance Patient Care given to HCPs must be less than VND2,000,000 per HCP per year (cumulative).

Items of medical utility, informational and educational items that enhance Patient Care must never be given to HCPs or medical institutions, organisations or associations for the personal benefit of the HCP or to influence the recommendation, prescription, purchase or usage of medicines and must never be formative of a quid pro quo arrangement."

**VNPCA Code**

"Companies should not pay/give cash or gifts to healthcare professionals.

The company may offer gifts that are items that have educational, medical or patient benefit (eg, medical books) to health workers. These gifts must conform to the specialised field of health workers."

The VNPCA Code does not provide a specific threshold limit for such gifts.

## 9.2 Limitations on Providing Samples to Healthcare Professionals

The provision of samples is considered as a type of product promotion. Under the applicable law on product promotion, promoted or promotional products may not include medicines for human use, including those permitted for circulation as regulated by the Ministry of Health (except where the sales promotion is dedicated to traders involved in selling medication). As such, providing medical samples as a product promotion activity to HCPs is prohibited in Vietnam.

The same prohibition is also regulated under the PG Code and VNPCA Code. However, these codes additionally provide three exemptions: (i) samples for tenders as requested by the hospitals; (ii) samples of vaccines and biological products for quality-testing purposes by a relevant authority before circulation in the market; and (iii) samples requested by the health authorities.

## 9.3 Sponsorship of Scientific Meetings

### Vietnamese Laws

It is not specified under Vietnamese law whether pharmaceutical companies may sponsor scientific meetings or congresses and/or attendance by HCPs at these events:

### PG Code

"Sponsorship to individual HCPs to attend events:

- PG members can organise or sponsor HCPs (either directly to HCPs or through their organisation) to attend in-country events or international events, provided that such international events derive participants from many countries. Any sponsorship for HCPs to attend such events must not be conditional upon an obligation to promote, recommend, prescribe or purchase, supply or administer any pharmaceutical product. Such sponsorship must:
  (a) Always be in line with the primary purpose of enhancement of scientific and medical knowledge, through obtaining information that is critical to the improvement of patient care and overall enhancement of healthcare delivery, and such sponsorship must be supported by written documentation;
  (b) Avoid any conflict of interest as stipulated in relevant Vietnamese laws and conform to the internal regulations of the HCP's organisation; and
  (c) Comply with the PG Code and applicable laws.
- A PG member's sponsorship for HCPs to attend events must be subject to the following conditions:
  (a) The sponsorship must have a legitimate scientific and medical knowledge enhancement purpose, and strictly follow applicable Vietnamese laws;
  (b) PG member must inform the HCP's organisation and ensure full transparency about invitations or sponsorship for HCPs to attend events, including details of the sponsorship and the agenda of the event; and
  (c) The event program[me] must not include standalone entertainment, sight-seeing or side trips, or other inappropriate activities or be located at an inappropriate venue.
- A PG member's sponsorship for HCPs to attend events must comply with the following requirements:
  (a) The selection of HCPs must be based on the expected added value of the event for their area of expertise, following a fair selection process and not give any potential appearance of inappropriateness or bias, and avoid any issue of conflict of interest. The PG member must ensure that the HCPs have obtained official permission from their organisation to attend the event;
  (b) Transportation and accommodation should be provided as per reasonable standards considering the nature and venue of the event and the level of involvement of the HCPs. For example, business class tickets for local travel, luxurious or extravagant accommodation must not be provided. Sponsorship to standalone entertainment, sight-seeing or side trips, or other leisure or social activities is not allowed. There must be a reasonable and justified timeframe for the departure and return of the HCPs to and from the event location;
  (c) Hospitality provided to the HCPs must be limited to refreshments and/or meals incidental to the main purpose of the event and its value must be moderate and reasonable as judged by local standards. Alcoholic drinks are not allowed during the event lunch. Refreshment during dinner can have alcoholic drinks, within a

reasonable limit. Applicable laws must be respected;

(d) Companies must not pay any costs associated with individuals accompanying the HCP, except in cases of medical necessity. HCPs can have accompanying individuals with them at their own expense, but PG members will not involve [themselves] in logistical arrangements for accompanying people. Accompanying people (except in cases of medical necessity) should not be allowed to attend any event for HCPs;

(e) All sponsorship arrangements must be appropriately documented before and after the event.

Specifically regarding sponsorship for HCPs to attend international events, there must be commitment from HCPs who attend the event to share the benefit of knowledge gained on their return to Vietnam, such as through presentation to other HCPs (no honorarium shall be provided) or a report to their organisation or other academic/medical institution".

*Events organised in foreign countries*

"PG members must not organise or sponsor HCPs to attend events that take place outside of their home country unless it is appropriate and justified to do so from a logistical or security point of view. PG members can organise or sponsor HCPs to attend international events, as these derive participants from many countries. In this case, the host country regulations and standards can be applied, unless otherwise provided by Vietnamese laws."

### VNPCA Code

"Any financing of companies offered to individual healthcare professionals may not be tied to conditions and/or obligations and/or suggestions to prescribe, recommend use, or promote any medicines."

## 9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

### Vietnamese Laws

It is not specified under Vietnamese law whether pharmaceutical companies may organise or sponsor cultural, sports or other non-scientific events at scientific conferences.

### PG Code

"PG members must not organise or sponsor recreational events such as tours, sports, leisure activities, year-end parties for medical institutions, anniversary events of medical institutions, etc. PG members are prohibited from offering any kind of compensation to HCPs for participation in the events."

### VNPCA Code

It is not specified under the VNPCA Code whether pharmaceutical companies may organise or sponsor cultural, sports or other non-scientific events at scientific conferences.

## 9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

### Vietnamese Law

It is not specified under Vietnamese law whether pharmaceutical companies may provide grants or donations to HCPs or healthcare institutions.

### PG Code

- "No financial benefit or benefit-in-kind (including grants, scholarships, subsidies, supports, consulting contracts or education or practice-related items) may be provided or offered to an HCP that inappropriately influences prescribing, recommending, purchasing, supplying or administering medicines or a commitment to continue to do so (ie, no quid pro quo).
- Donations are prohibited to be given directly to individuals.
- Donations must be in written agreement with examination and treatment establishments,

and public hospitals. It must be clearly stipulated that the donation recipients have to: (i) follow the procedures for the preparation, evaluation and approval of the foreign non-governmental aid amount in compliance with applicable regulations; and must (ii) manage and use the donation only for humanitarian objectives in accordance with its commitments in the agreement and not use the donation for any other purposes."

### VNPCA Code

"Funding, scholarships, subsidies, support, consulting contracts, education, etc, should not be provided to healthcare professionals to exchange, set the conditions of recommended use or drug prescription, or influence the ethics and independence of the related healthcare professionals. Companies should only sponsor, grant scholarships, subsidise, etc, with the purpose of supporting legal education, scientific research and/or medical research."

## 9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Providing rebates or discounts on drugs to HCPs is considered a type of product promotion and is prohibited under Vietnamese law.

The law is silent on providing healthcare institutions with discounts. However, the procurement of any products and services by a public healthcare institution must comply with the Law on Tender, where the tender price must be approved by the relevant authority. Normally, the price listed in such tender contract is the listed price without discount.

## 9.7 Payment for Services Provided by Healthcare Professionals

### Vietnamese Laws

It is not specified under Vietnamese law whether it is possible to pay for services provided by HCPs.

### PG Code

"HCPs may be engaged as consultants and advisors for services such as: speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, translating medical documents, interpretation at medical meetings, writing a medical article and/or giving medical training, and participating in market research, where such participation/services, involves honorariums.

The arrangements covering legitimate provisions of such services must meet the following conditions:

(i) The engagement does not interfere with the interest of the HCP's employer and the employer has no objection against the engagement;
(ii) A written contract with the engaged HCP is put in place which specifies the nature of the services to be provided and the basis for payment of those services;
(iii) Payment to HCP service providers must be based on market criteria and be proportionate to the time devoted, the work done and the responsibilities assumed and must be adequately documented. Payments of service fees must not be made in advance. Cash payment is prohibited;
(iv) Only engage HCP service providers where there is a legitimate need for their services clearly identified and documented in advance, and: the criteria for selecting consultants must be directly related to the identified need; the consultants must have the expertise nec-

essary to provide the service; the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need; the compensation for the services must be reasonable and reflect the fair market value.

The amount of the honorarium for local speakers/moderators at local meetings should be at fair market value. The honorarium for foreign speakers at local meetings or local speakers at international meetings should be at the level of normal practice in the speaker's home country."

**VNPCA Code**

"A healthcare professional who renders counselling services or is a rapporteur should be paid a reasonable remuneration and travel expenses, accommodation and meals to provide services as per market cost."

### 9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

No prior authorisations or notifications (eg, employer consent, regulatory authority approval) are required in relation to any of the activities described in this section.

## 10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

### 10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

Under Vietnamese law, every individual and organisation in the private sector has the right to report acts of corruption and bribery where they are aware of such misconduct.

In terms of transfers of value not subject to anti-corruption and anti-bribery issues, the law is silent on disclosure requirements and reporting obligations towards the health authorities relating to any sponsorship, donation or grant to HCPs and healthcare institutions, or the seminars and events organised by a pharmaceutical company.

However, details of donations, sponsorships and gifts will be assessed and represented as part of the auditing process, and reported as per the request of a relevant authority, on a case-by-case basis.

### 10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

These transparency requirements do not apply to foreign companies and/or companies that do not yet have products on the market.

## 11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

### 11.1 Pharmaceutical Advertising: Enforcement Bodies

The DAV, along with inspectors under the MOH and local Departments of Health, monitors compliance with advertising regulations.

### 11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

The authorities (including DAV or MOH inspectors) may initiate proceedings against entities for drug advertising infringements when the infringements are discovered. Companies may proactively alert the authorities about any infringements. It is not necessary for most pharmaceutical advertising infringements to be handled in court, unless they are related to the

advertising of counterfeit drugs or are instances of repeated false advertising.

### 11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

Violations of regulations on pharmaceutical advertising can be subject to a fine of up to VND80 million (about USD3,400). In addition, the relevant companies may be forced to suspend operations for three to six months, or the material and financial benefits from the acts may be confiscated, depending on the specific case. Furthermore, the violator will be forced to recall and remove infringing elements in some cases; and where the infringing element cannot be removed, the product will have to be destroyed.

### 11.4 Relationship between Regulatory Authorities and Courts

When self-regulatory authorities notice any pharmaceutical advertising infringements, they may apply internal sanctions, such as suspending the violator's membership. The self-regulatory authorities may also alert the authorities about the infringements.

There does not appear to be any other relationship between measures taken by the self-regulatory authority and the procedures before or taken by courts/authorities.

### 11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

In COVID-19 situations, many entities have released false advertisements on anti-COVID-19 products. The MOH and other authorities have proactively conducted inspection activities to handle infringements relating to COVID-19 prevention and treatment.

**Tilleke & Gibbins** is a South-East Asian regional law firm with over 200 lawyers and consultants practising in Cambodia, Indonesia, Laos, Myanmar, Thailand and Vietnam. The firm provides full-service legal assistance to investors and companies that drive economic expansion in Asia. Established in Bangkok in 1890, today Tilleke & Gibbins is a major international firm with offices in six countries that prioritises understanding its clients' businesses and working with them towards their commercial goals. The firm is known for its deep local knowledge and commitment to this fast-developing part of the world, which is especially valuable to global companies needing to navigate unfamiliar markets and regulatory environments in South-East Asia. Clients who engage Tilleke & Gibbins are given a team of advisers who provide clear, practical advice; who are responsive in communications; who represent them with integrity; and who guide their clients through the available options to arrive at the most effective course of action, whether this means following well-established procedures or applying an innovative approach.

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**Hien Thi Thu Vu** heads the Tilleke & Gibbins regulatory affairs team in Vietnam, advising and assisting chemical, pharmaceutical, medical device, and biotechnology companies in the registration of their products with Vietnam's regulatory agencies. She also assists with technical matters and patent infringement cases. In a region where generic drugs are increasingly promoted, Hien advocates for the rights of healthcare companies that devote extensive assets to R&D activities, and helps pharmaceutical companies list their products in the original brand-name lists issued by the Drug Administration of Vietnam. She has a strong background in life sciences, with a pharmacy degree, experience as a medical representative, and 15 years' experience as a patent executive. Hien previously headed the patent unit at a leading local firm in Hanoi.

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**Kien Trung Trinh** is a partner in Tilleke & Gibbins' corporate and commercial group in Vietnam. With more than 20 years' experience in advising multinational companies on a wide range of commercial and corporate law matters, Kien takes an active role in the firm's life sciences practice, where he advises and assists clients with the registration of pharmaceuticals, medical devices, foods, and animal products. Kien is known for providing expert advice across a range of corporate and commercial legal practice areas in Vietnam, such as company work rules, benefit plans, social and health insurance, personal income tax, employment contracts, collective bargaining agreements, confidentiality agreements, and terminations and disciplinary actions.

**Phuong Thi Minh Tran** is an associate in Tilleke & Gibbins' Ho Chi Minh City office. Her practice covers M&A and due diligence, licensing and corporate formation, and contract review, among other corporate and commercial matters. With experience serving corporate clients across a wide spectrum of industries, she provides responsive, reliable advice on issues of vital importance to businesses and investors in Vietnam. Phuong has worked with clients across a wide range of industries and advises many well-known multinationals in the pharmaceutical sector.

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