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Medical Cannabis & Cannabinoid Regulation 2022

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INTRODUCTION

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The Growth of Cannabis Law

A practice area that initially attracted more flippant remarks than serious recognition now facilitates a multibillion-dollar industry, providing for everything from textiles and biofuel to life-saving medicines.

Whereas certain jurisdictions always enjoyed a buoyant but limited cannabis sector – think Amsterdam's historic recreational market, or China's leading industrial hemp industry – it was the relaxation of medical cannabis rules across the USA and Canada that was probably to thank for the astonishing pace of legislative reform that has since swept the globe.

This, together with the helpful discovery that a little-known non-controlled cannabinoid (cannabidiolor CBD) could be widely sold without medicines approval, allowed the plant to shake off its historical associations and be reintroduced to the public in the form of a versatile, innocuous and investable asset, albeit in an industry desperately in need of regulatory reform.

What is clear from many of our authors is that most jurisdictions' legislative frameworks were not ready for the challenges and opportunities that the new global cannabis industry posed. Outdated conventions, uncertain and untested regulations, commercially restrictive policies, ill-informed domestic authorities and inconsistent enforcement are but a few of the barriers faced across the board.

The Medical Cannabis & Cannabinoid Regulation 2022 guide summarises the key principles of cannabis law in six jurisdictions. In addition to several *Trends and Developments* articles, each jurisdiction is reviewed following the same 11-question format, allowing for easy comparisons on specific issues and concerns. It is designed to provide an easy-to-understand guide that is both specific to each jurisdiction whilst also demonstrating how certain areas of practice have reached a near-homogenous position internationally.

The Four Branches of the Industry

Another element that is clear from contributors to this guide is that the global industry is divided into four distinct sectors: medical, wellness, recreational and industrial hemp. As the industrial hemp industry has historically existed without any hindrance, owing to complicated and stringent legal rules, this guide focuses more on the medicinal framework and regulation pertaining to the legally controlled parts of the cannabis plant.

Recreational markets only currently exist in a handful of jurisdictions, including 18 US states and Canada, although it was a recent electoral topic in a number of other jurisdictions, including Germany and Mexico. Within the last year, Malta became the first EU member state to legalise possession (including cultivation) of recreational cannabis within limits, but the country is yet to fully authorise a recreational market, limiting sales to not-for-profit transactions and prohibiting consumption in public.

Medical cannabis has been legalised much more widely (currently including most of North and South America, Canada, much of Europe, and Australia). What is clear from authors in the medical sphere is that legalisation and actual access to medical cannabis are two different things – and that cannabis education, for everyone from politicians through to doctors, is of paramount importance to achieving access for all.

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On the wellness side, one theme that is evident across the jurisdictions is the inconsistency with regard to applicable THC thresholds. These inconsistencies are preventing the harmonisation and free movement of products. For instance, in the UK the level of THC permissible is 1 mg in the end product (regardless of the size of the product), in some European countries the accepted level is 0.2% (with a 0.3% limit at EU level from 2023), in Switzerland it is 1%, while in Germany and certain US states it is 3%. It is clear to see why producers of wellness products are wrong-footed when products are seized at customs.

International Developments

Developments on the international stage have meant a number of beneficial ramifications for the global industry, although these have not gone as far as hoped. In January 2019, the World Health Organization (WHO) made eight recommendations on cannabis and cannabis-related substances to the United Nations' Commission on Narcotic Drugs (CND). These included recommendations for relaxing controls on THC, and extracts from the plant (including CBD).

On 2 December 2020, the CND held a vote that rejected most of the WHO's recommendations, but resulted in the removal of "cannabis and cannabis resin" from Schedule IV (reserved for the most harmful narcotic substances) of the main international convention controlling the plant. This is expected to alleviate issues with access and availability of cannabis for medical and scientific purposes at national levels. However, this will not affect the CBD industry greatly, as "extracts [...] of cannabis" were left in Schedule 1, allowing legal controversy around CBD extracts to continue.

Furthermore, the CND rejected a proposal on the clarification of CBD – which would have provided for an additional note to accompany the Schedules elucidating that preparations that contain predominantly CBD and less than 0.2% THC should not fall under international control. Summarily, these two decisions demonstrate that the CND recognises cannabis as having a beneficial medical application. However, as far as recreational and wellness use is concerned, there remains reluctance to relinquish full control.

At a continental level, the EU is progressing towards a more harmonised set of laws to establish consistency in the industry, and this was demonstrated in the recent Kanavape case (the Court of Justice of the European Union (CJEU) case number C-663/18), where the CJEU clarified that, subject to narrow exemptions, the principles of EU law supersede those at member state/national level, regardless of the product or interest in question.

The CJEU went one step further in its decision by announcing that, based on the available safety and scientific evidence, CBD cannot be classified as a narcotic, especially in light of the recent UN decision – in particular noting that controlling a substance with no apparent psychotropic effect, nor any harmful effect on human health, goes against the spirit of the Convention, which was drafted for protection against harmful and damaging drugs.

As a result, the European Commission has publicly announced that CBD should not be treated or regulated as a narcotic.

International Impacts

COVID-19

The COVID-19 pandemic has disrupted businesses in ways that were unthinkable at the beginning of 2020. Global lockdowns put the brakes on everyday business life, affecting even the most profitable sectors and plunging even the strongest economies around the world into

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deep debt and recession, the likes of which have not been seen since the last world war.

However, there were many notable developments during the height of the pandemic which can only be seen as positives. As discussed in this guide, cannabis-based medicines (CBMs) are not always freely available as a prescribed medicine, yet CBMs are becoming an acceptable method of treatment. Plainly, a lot more can be done in this area – as demonstrated by initiatives such as Carly Barton's Cancard, designed to protect medical cannabis users from prosecution (as described in more detail below).

In the CBD wellness sector, we saw established companies able to push on and continue productivity, and there was a considerable increase in online sales for products such as oils, tinctures and cosmetics. It appears that during the pandemic those businesses which marketed successfully online, or whose brands were sufficiently recognisable, flourished as these products become an essential item for those stockpiling for quarantine at home, some of these products being perceived to help alleviate anxiety and sleep disturbances caused by the intense lockdown periods that people have had to endure.

Brexit

Brexit disruption saw goods being affected by additional import/export checks and paperwork that were now required, when previously there was free movement.

For the medicinal cannabis sector, Brexit caused another dilemma: during the Christmas week of 2020, the UK Department of Health announced that medicinal cannabis prescriptions issued in the UK would no longer be lawfully dispensed in EU member states, due to the end of the Brexit transition period. Delivered to the prescribing doctors of over 40 medicinal cannabis patients, the news came as a bombshell to the families affected, who were effectively given just two weeks' notice before losing access to the life-saving medicine, Bedrocan, from Holland. As a consequence, the UK government agreed with the Dutch government to allow such prescriptions to take place for a further six months to 1 July 2021; it is understood that this has now been extended further until 1 July 2022. This issue has highlighted the need for greater regulation to allow for development of CBMs so that they are readily accessible to patients.

Licensing Systems

A number of jurisdictions note that problems lie with the national cannabis licensing systems, which are the frameworks in place to permit the cultivation or possession of plants for legitimate commercial or research purposes.

Across the globe, contributors report that licensing authorities are taking a conservative approach. Relatively few licences are granted and licensing requirements are notably high (sometimes prohibitively so). Licensing regimes are reportedly not transparent, with little guidance, and are particularly expensive, ultimately pushing product prices up and discouraging competition.

Certain jurisdictions have, however, reformed their licensing frameworks in the last year to improve such issues, including the Isle of Man, which passed new regulations to create a comprehensive regulatory framework governing the issue of licences for the island.

Lack of Legal Certainty

A lack of legal certainty tends to arise in two forms. Firstly, most of the laws and regulations that govern cannabis are unfit for the objectives of the modern cannabis industry. This is because the laws were originally put in place to control the criminal trade of the plant, and license hemp

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for agricultural use, rather than to regulate a sophisticated medical and wellness sector. What we see across the board is reliance on international law to some degree, law that dates back to the early 1960s and the 1970s.

For these reasons, many of the legal concepts are not only unclear, given the modern context, but they are also untested in the courts.

This situation creates a second type of legal uncertainty, in that the rules are frequently changing. This is both because existing rules are in the process of being interpreted by various authorities, and because new rules are being put in place to govern the rapidly changing commercial landscape. Naturally, it is difficult to achieve legal certainty when rules and regulations may change over the life cycle of product development or business plans.

Industry Bodies

One common theme noted by contributors is the absence of a unified, authoritative body to orchestrate sensible regulation for the industry.

In a seminal discussion paper, the authors of the UK *Law and Practice* article recommended to the government that a UK Office for Medicinal Cannabis should be established to bring together the various regulatory responsibilities and oversee the implementation of policy recommendations.

Our Spanish authors note that the incorporation of an association or a similar body will be critical for pushing through a sensible regulatory framework; essentially this would open the local market and ensure patient access to cannabis-based products with high standards of quality, safety and consistency. Increasing awareness and education for politicians, legislators and clinicians is identified as key and needs to be effectively channelled.

Criminal Sanctions and Decriminalisation

There is still disparity around the world with regard to the criminal aspect of dealing with cannabis and its trade. Global in nature, owing to the initial harmonisation of its illegality (through the UN Single Convention on Narcotic Drugs 1961), in recent decades the divergent paths adopted by jurisdictions around the world have reflected the development of a greater understanding of the plant, and its potential medical benefits. As more information surfaces, and social and scientific studies grow more robust and frequent, the changing attitudes towards cannabis can be seen in the context of its treatment in criminal law.

The recurrent theme in those countries that are on the path to legalisation is a gradual relaxation towards the penalties or sanctions for those who are breaking the laws in their jurisdiction by carrying on activities with cannabis. Mexico, a jurisdiction on the precipice of full legalisation of cannabis, has legislation that permits possession of up to 5 g of cannabis per person of legal age, as set out in the General Health Law, a piece of primary legislation. This “blind-eye” approach could be seen as a first step towards the recreational or commercial regulation of cannabis in a jurisdiction.

In England and Wales, the Cancard initiative is a programme where those who are eligible for a private medical cannabis prescription may pay an annual fee to the organisation and receive a holographic ID card. The initiative, supported by members of the UK Parliament and the police, provides a validated indication that the holder of the Cancard is consuming cannabis for medical reasons. This development in the UK, a country with historical social and political aversions to cannabis, is indicative of the global trend of decriminalisation and de-stigmatisation of the plant, providing for autonomous use by those who benefit the most from its properties.

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It can be postulated that this is a stepping stone along the way to full legalisation, a trend that we have seen in those countries where recreational and medical cannabis regulations now sit side-by-side.

INTRODUCTION

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Mackrell.Solicitors is an award-winning, full-service law firm, with a truly global reach. Headquartered in Central London, with offices in the heart of Birmingham, the firm has been providing high-quality legal advice and services since 1845. Mackrell.Solicitors was also one of the founders of Mackrell International, the 33-year-old global network made up of 104 firms across 60 countries, enabling it to offer the added value of immediate international legal advice and assistance in any jurisdiction worldwide. Mackrell. Solicitors set up the first dedicated cannabis legal team three years ago, so in terms of sector-specific knowledge it is at the cutting edge of the current regulatory regime in the UK and Europe. The firm provides regulatory advice and services for the medicinal cannabis and CBD industry, from cultivation licence applications, product and labelling reviews to advice on import/export best practice. In addition, via Mackrell International, it provides multi-jurisdictional advice for all EU countries and beyond.

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Ricardo Geada is a partner of Mackrell.Solicitors and heads up the cannabis and regulatory team. A solicitor with more than 13 years' legal experience – both in private practice and in-house – Ricardo has genuine interest in drug policy reform and regulation, particularly the legal developments and regulatory regimes governing CBD wellness products and medicinal-based cannabis products. He is regularly instructed by global cannabis companies, handling their legal and strategic requirements both in the UK and abroad. Ricardo's in-house and international coverage makes him commercially incisive and an invaluable solicitor to his clients, being described as a pragmatic, strategic and solution-focused business partner.

CO-AUTHOR

Elliott Rolfe was one of the UK's first cannabis lawyers and heads the psychoactive medicines law team at Mackrell. Solicitors. Having studied medical cannabis and other psychoactive medicines across a variety of fields, he has been able to assist some of the world's leading cannabis companies, and has worked with all corners of the industry, including policy institutes, patients, regulators, trade bodies and academics. He is keenly interested in drug policy reform, and is a longstanding supporter of national initiatives promoting these related fields.

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COLOMBIA

Law and Practice

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1. LEGAL/REGULATORY FRAMEWORK

1.1 Source of Regulations

Regulation in the cannabis industry in Colombia is highly complex and results from the establishment of several legal instruments, including the Colombian Constitution, laws, decrees and resolutions issued by different state authorities. In this sense, companies must navigate through several regulatory frameworks, with different rules and procedures, in order to legally participate in the growing market.

While operating within the broad spectrum of cannabis regulation, businesses must also satisfy the legal and technical requirements established for each category of final products derived from cannabis (food, medicines, veterinary products, dietary supplements, cosmetics, among others).

Main Legal and Regulatory Framework for the Cannabis Industry

The central laws in this area are Law 13 of 1974 and Law 1787 of 2016, decreed by the Congress of the Republic.

Law 13 of 1974 approved the Single Convention on Narcotic Drugs of 30 March 1961, and its Amendments Protocol of 25 March 1972.

Within the framework of this Convention, Colombia undertook the obligation to adopt legislative and administrative measures to limit and control the production, manufacture, export, import, distribution and use of narcotic drugs for medical and scientific purposes. Furthermore, the national government covenanted to:

- forecast narcotic drug needs;
- annually report such needs to the International Narcotics Control Board (INCB); and
- adopt a licensing system to trade and distribute narcotic drugs.

In a general sense, the Convention intended that the state had particular control over the use of narcotic drugs, among which certain cannabis components were included.

On the other hand, Law 1787 of 2016 created the main legal framework that formed the true cannabis industry in Colombia, allowing and implementing secure access to medical and scientific uses of cannabis. Law 1787 also established a governmental control for cultivation, production, acquisition, import, export, marketing and additional activities involving to possession of the cannabis plant, its seeds and its by-products.

For such purposes, the Congress of the Republic delegated to different ministries the task of developing the necessary regulations on the matter. Accordingly, the Ministry of Health and Social Protection, the Ministry of Law and Justice and the Ministry of Agriculture and Rural Development were assigned to prepare and set out the first decree ruling the cannabis industry from 2017 until 2021.

Additional Regulation for the Cannabis Industry

Based on the central regulatory legislation for the cannabis industry in Colombia, the national government has issued the following decrees.

Decree 613 of 2017

As a first approach to comply with the provisions set forth in Laws 13 and 1787, Decree 613 of 2017 established a regime of licences to be obtained by companies within the cannabis industry according to their manufacturing and trading activities. While defining manufacturing obligations and prohibitions, Decree 613, generally speaking, created a set of complex rules and requirements to carry out commercial activities

with cannabis and derived products. Nevertheless, since this was a new regulatory framework and it is a young industry in Colombia, the decree included several legal gaps, mainly related to delays when requesting the corresponding approvals, which ultimately led to a general sense of uncertainty in the field.

Decree 811 of 2021

After a four-year process of gathering lessons from the experience with Decree 613, the government issued Decree 811 of 2021, establishing the new main regulatory framework to be considered within the cannabis industry. This Decree sought to solve many of the gaps existing under Decree 613 by expanding the regulatory requirements to obtain cannabis licences in Colombia and acting as a compendium for companies wishing to participate in the market. In this sense, the government provided the main rules and dispositions for industrial and commercial activities using cannabis, its plant and derivatives.

Definitions

Decree 811 of 2021 introduced an important differentiation between the use of cannabis and its by-products. Accordingly, it was established that:

- sowing seeds, vegetable components, cannabis plants, grains, psychoactive and non-psychoactive cannabis, and psychoactive and non-psychoactive derivatives may only be used for medical and scientific purposes; and
- sowing seeds, vegetable components, grains and non-psychoactive derivatives of cannabis may be used for industrial, horticultural and food purposes.

Decree 811 of 2021 provided specific definitions for each cannabis component, helping to reduce confusion when interpreting legislation and regulatory scopes among different authorities.

Please note that, for controlling and licensing matters, the Decree established the technical difference between psychoactive and non-psychoactive cannabis is based on THC (tetrahydrocannabinol) content. Under local legislation, psychoactive cannabis refers to any component or product whose THC content is equal to or greater than 1% by dry weight; anything below that threshold is be considered non-psychoactive cannabis.

This differentiation resulted in the establishment of different set of rules for each product category and, thus, justified the complexity of the regulatory requirements depending on the manufacturing or industrial purpose.

Cannabis licences

To carry out activities with cannabis and its by-products, Decree 811 confirmed that it is necessary to obtain a licence. These licences vary depending on the activity to be carried out and the point in the manufacturing chain where companies will be operating. As such, these are the existing licences:

- licence for using cannabis seeds and grains;
- licence for cultivation of psychoactive cannabis plants;
- licence for cultivation of non-psychoactive cannabis plants;
- extraordinary licence for cultivation of cannabis plants;
- licence for manufacturing psychoactive cannabis derivatives;
- licence for manufacturing non-psychoactive cannabis derivatives;
- extraordinary licence for manufacturing cannabis derivatives.

The licences are valid for ten years and can be renewed as many times as needed, as long as the requirements supporting their granting are not transgressed.

Regarding the approval and granting processes, the regulation establishes that licences must be issued within 30 working days counted from the moment the applicant meets all the requirements set forth for each licence. Nonetheless, current practice results in authorities usually taking more than a year to evaluate and grant licence applications.

It is pertinent to point out that each licence has different modalities that must be selected at the moment of requesting the licence, as listed below.

- Licence for using cannabis seeds and grains:
  (a) commercialisation or delivery;
  (b) research;
  (c) grain processing or production.
- Licence for cultivation of psychoactive cannabis plants:
  (a) production of sowing seeds;
  (b) grain processing or production;
  (c) derivatives manufacturing;
  (d) research;
  (e) export.
- Licence for cultivation of non-psychoactive cannabis plants:
  (a) production of sowing seeds;
  (b) grain processing or production;
  (c) derivatives manufacturing;
  (d) research.
- Extraordinary licence for cultivation of cannabis plants:
  (a) granted to deplete cannabis stock when the original licence is about to expire (it is granted for a single time for a period of up to six months);
  (b) granted for non-commercial research (it is granted for a single time and for up to 12 months with the possibility of extending the validity for an additional 12 months).
- Licence for manufacturing psychoactive cannabis derivatives:
  (a) national use;
  (b) research;
  (c) export.
- Licence for manufacturing non-psychoactive cannabis derivatives:
  (a) granted in a single modality that includes the possibility of carrying out research activities, national use and/or export.
- Extraordinary licence for manufacturing cannabis derivatives:
  (a) granted to deplete cannabis stock when the original licence is about to expire (it is granted for a single time for a period of up to six months);
  (b) granted for non-commercial research (it is granted for a single time and for up to 12 months with the possibility of extending the validity for an additional 12 months).

Accordingly, each modality limits the allowed activities to be carried out by the company under each licence. For their approval, the authorities will require that the applicant demonstrates its capabilities to perform each of the requested modalities. As result, it is not advisable to request all the licences with all the modalities at the same time.

Requirements for obtaining a licence

As previously mentioned, cannabis regulation in Colombia is intricate, meaning that complying with the framework to obtain a manufacturing or commercial licence can be a daunting process.

For this reason, Decree 811 sought to give greater transparency and clarity on the main requirements by incorporating them into general requisites, which apply to any type of requested licence, and specific requisites, which vary

depending on the type and modalities of each licence.

Among the general requirements, applicants must provide documentation describing the shareholding composition of the company, identifications of the legal representatives and statements on the origin of the company's resources, together with an anti-corruption declaration.

Cannabis licences, as set forth in the decree, are tightly linked to the property where the growing activities will be carried out. Therefore, it is also necessary to submit documents demonstrating ownership over the property or a lease agreement thereon. Furthermore, applicants must provide evidence of environmental certificates required for carrying out their industrial activities.

Concerning the specific requirements of each licence, companies must prove that they have the capabilities to develop their activities within the selected modality(ies) and framework of the requested licence. This is usually a challenging task since documentation will vary depending on the type of licence or approving authority. In terms of compliance, the application must include an organisational chart depicting each employee's duties, photographic records of such activities, process flow diagrams of the company, technical descriptions of the involved equipment, and so forth.

Obligations and prohibitions on cannabis licence-holders

The regulation established in Decree 811 contemplates an important number of obligations and prohibitions that must be considered by cannabis licence-holders. Within these, we highlight the following.

- Companies must implement security protocols as established in Resolution 227 of 2022.
- Licensees must report every movement or action related to cannabis manufacturing/processing. To comply with this obligation the government implemented an internet platform, called Information Mechanism for Cannabis Control (*Mecanismo de Información para el Control de Cannabis*, MICC), where related information can be submitted.
- Companies must physically separate psychoactive cannabis plant crops from non-psychoactive cannabis plant crops and delimit their cultivation areas.
- Companies may not market, distribute or deliver cannabis to third parties who are not authorised or who do not have the corresponding licence.
- It is forbidden to carry out cultivation activities of psychoactive cannabis or manufacturing processes of psychoactive cannabis derivatives without having the permission (quota) for it, as described next.
- It is not allowed to carry out activities in buildings or spaces other than those authorised and specified within the granted licence.

Outsourcing licensing activities

Decree 811 also introduced more flexible rules for companies that seek to cover several activities but do not have all the resources or knowledge to do so. Hence, it is now possible to outsource all the activities allowed within the framework of a cannabis licence. This opens the possibility for a company to both cultivate cannabis directly and outsource cannabis research to another company without requiring another licence for the outsourced company. Several inquiries on this matter were raised in the past, and the resulting interpretation and resolution was even more confusing. Therefore, this change solves a longstanding problem in the field.

Quotas

As previously mentioned, activities with psychoactive cannabis under local legislation require

the obtaining of a quota for THC uses, besides compliance with the other requisites. In general terms, a quota is the allowable amount of psychoactive cannabis, authorised by the local authorities, to be cultivated or manufactured into cannabis derivatives. There are two main types of quotas: (i) quotas for the cultivation of psychoactive cannabis; and (ii) quotas for the manufacture of cannabis derivatives.

Resolution 227 of 2022 provides more details on the specific requirements related to the obtaining and approval of cannabis quotas.

Magistral preparations based on cannabis products

Decree 811 also introduced the possibility to prepare cannabis products in a pharmacy, based on a medical prescription for a patient, as long as these activities are carried out in authorised establishments. Also, the decree established that the distribution and sale of magistral preparations/products in pharmacies and drugstores are allowed.

Foreign trade/import and export activities

Regarding the import and export of cannabis and all its by-products, companies are required to comply with all the cannabis licence requirements, plus the submission of a set of approvals from different authorities, which vary according to the by-product to be traded.

Before Decree 811, the export of the dry flower was restricted exclusively to research and scientific purposes. However, the new Decree modified this situation by allowing cannabis growers to export the dry flowers for both research and medical uses.

Due to the government control that exists over cannabis and its by-products in Colombia, any activity involving cannabis cannot be taken lightly. It is therefore advisable to approach the business with a clear understanding of the market, the regulatory framework, and the legal restrictions on the cannabis industry as established by Decree 811 of 2021.

Other Regulatory Provisions to Be Considered

Resolution 227 of 2022

This resolution, issued by the Ministries of Law and Justice, Agriculture and Rural Development, and Health and Social Protection, provides additional provisions related to cannabis licences, modifications, outsourcing activities, security protocols, research projects, advertising, quota systems, and finished products based on cannabis (food, beverages, dietary supplements, etc). The main topics of this legislation are listed below.

- The renewal of a licence must be submitted at least three months before its validity expires. If a company does not comply with this deadline, it will be necessary to submit a new licence application and all activities must stop until the application is approved.
- If the conditions that served as the basis for granting the licence are modified, it will be necessary to apply for a modification of the licence. Depending on the nature of the change, the licence will not be effective until authorisation is obtained for such modification.
- In the event that there are changes in the share composition of the shareholders with a stake greater than or equal to 20%, it is necessary to submit this information to the authorities as a novelty.
- If the licence-holder will outsource the activities of the licence, it will be necessary to notify the authorities about this situation. The licensee will be held responsible if the outsourcing company infringes any of the cannabis regulation provisions.

- The security protocol(s) in each licence must list the security pre-conditions of the property where the cannabis activities will be carried out. This protocol shall also include any plans to implement integrated security and transport systems guaranteeing control over the logistics and supply chain from the point of origin to the point of destination of the cannabis products.
- Concerning cannabis quotas, as pointed out earlier, these must be requested when the intended activities are related to cultivation of psychoactive cannabis or manufacture of cannabis derivatives. These permissions are issued by the Technical Quota Group, which is a body composed of several state entities.

If psychoactive cannabis cultivation will be carried out, the quota will determine the maximum number of plants to be grown, the minimum number of plants to be established on a cultivation site, and the maximum amount of psychoactive cannabis to be obtained.

If cannabis derivatives are manufactured, the quota will determine the maximum amount of cannabis or plant component authorised to be acquired, received and transformed, and the maximum amount of raw material to be extracted.

The quotas have a validity of two years. For their application, companies must comply with a set of requirements varying from the type of quota that will be requested (cultivation or derivatives manufacture) to the different modalities defined for each licence.

Companies must also provide a proper forecast or estimate of the required quota since, otherwise, they are exposed to reductions in future applications or even to a possible denial thereof. In such case, it will be impossible to carry out any related cultivation or manufacturing activity.

The production of food, beverages and dietary supplements is only allowed using the vegetable component, grains and non-psychoactive derivatives of cannabis as raw material. In no case can these products be made with a THC amount equal to or greater than the control threshold (1% by dry weight).

Companies wishing to manufacture this type of finished product with cannabis must take into account the applicable provisions for manufacturing any type of food, beverage and dietary supplement. In any case, it is pertinent to point out that the national government is expected to issue additional provisions concerning the production of food and beverages based on cannabis.

Resolution 539 of 2022

This Resolution, also issued by the Ministries of Law and Justice, Agriculture and Rural Development, and Health and Social Protection, regulates the foreign trade operations of cannabis and its derivatives in Colombia.

In general, those interested in importing or exporting cannabis must submit a request before the Single Foreign Trade Window (*Ventanilla Única de Comercio Exterior*, VUCE), through which: (i) authorities will verify compliance with the requirements established according to the export or import modality; and (ii) the competent entities will endorse the foreign trade process by means of an approval.

Based on the specific product that will be imported or exported, different approvals and requirements must be met. Therefore, it is advisable – before starting commercial operations with cannabis – to project any foreign trade activities so that the fulfilment of the import/export requirements is estimated beforehand.

Lastly, and as previously stated, Decree 811 of 2021 opened the possibility for companies to export cannabis and its by-products (including dry flowers) for research and medical purposes. However, these provisions would come into force once the national government issued special rules on the matter. Resolution 539 of 2022 sets out the specific requirement allowing such trades and, thus, provides a new scope on regulatory matters for the cannabis industry.

Resolution 578 of 2017
This resolution establishes the fees for some of the licence applications that are processed before the Ministry of Justice and Law. While its provision are not yet currently applicable, it is expected that this Resolution will be updated in the upcoming months.

Resolution 2022001026 of 2022
This resolution implements the fees for all the procedures carried out by the National Institute for Drug and Food Surveillance (INVIMA), including procedures related to the manufacture of cannabis derivatives.

Resolution 3168 of 2015
This resolution regulates the activities related to the production, import, and export of cannabis seeds, as well as the registration of agronomic evaluation units and/or research units in plant breeding. The framed legislation is essential for all companies wishing to cultivate cannabis since it contains the requirements for the production and cultivation of seeds in Colombia.

Resolution 67516 of 2020
Finally, this Resolution establishes the requirements for the registration of cultivars within the National Register of Commercial Cultivars. This registration is necessary for cases when the company intends to apply for certain types of licences related to seed sowing in Colombia.

1.2 Regulatory Authorities

The Colombian Regulatory Authorities charged with enforcing the laws and regulations governing the cannabis industry are distributed per their legal duties.

Ministry of Justice and Law

Through its Control of Chemical Substances and Narcotic Drugs Branch, the Ministry is responsible for reviewing and issuing:

- licences for using cannabis seeds and grain;
- licences for cultivation of psychoactive cannabis plants;
- licences for cultivation of non-psychoactive cannabis plants; and
- evaluations and quotas for cultivation of psychoactive cannabis plants.

This entity is also in charge of constantly monitoring the fulfilment of the obligations of the licensees and, in the event of finding irregularities, it may initiate administrative proceedings that can result in the licence revocation.

Ministry of Health and Social Protection

This Ministry oversees the granting of quotas for the manufacture of cannabis derivatives. Likewise, as the entity responsible for formulating all health-related policies, plans and programmes in Colombia, it is in charge of providing the regulation for the use of cannabis in food, beverages and dietary supplements for humans.

The Colombian Agricultural Institute (Instituto Colombiano Agropecuario, ICA)

The ICA is the entity responsible for ensuring the quality of agricultural inputs, seeds and the protection of plant health in Colombia. This office issues multiple permits that are needed to cultivate any vegetable product, including those containing or deriving from cannabis. The main permits issued by ICA are the following:

- registry as a seed producer;
- registry as seed importer or exporter;
- registry as a unit of agronomic evaluation;
- registry as a research unit in plant breeding; and
- registry of cultivars in the national register of commercial cultivars.

In addition, the ICA is responsible for granting the authorisation for finished products for veterinary use, including those comprised of cannabis.

National Institute for Drug and Food Surveillance (Instituto Nacional de Vigilancia de Medicamentos y Alimentos, INVIMA)

Since 2019, INVIMA has been designated as the authority in charge of issuing the licences for manufacturing cannabis derivatives that were previously the responsibility of the Ministry of Health and Social Protection. As the principal Colombian health and marketing authorisation authority, it is also in charge of regulatory compliance for medicines, medical devices, food, beverages, dietary supplements and phytosanitary products, among others.

National Narcotics Fund

Its main objective is the surveillance and control over the import, export, distribution and sale of medicines or materials of special control, including products containing cannabis. Due to its competency, it is responsible for an important component of the authorisations required for the import and export of cannabis and its by-products (including dry flowers).

Technical Quota Group

This is an intersectoral commission, consisting of several ministries and state entities, in charge of evaluating and assigning (ie, granting or denying) quota applications. The entities that comprise the Technical Quota Group are:

- the Ministry of Health and Social Protection;
- the Ministry of Justice and Law;
- the Ministry of Agriculture and Rural Development;
- the National Narcotics Fund;
- INVIMA;
- ICA.

1.3 Self-Regulation

In Colombia, there are no self-regulatory authorities that apply in a generalised way to the entire cannabis industry. Notwithstanding, there have been many initiatives by various organisations to contribute to the growth of the cannabis market in the country.

The most well-known association at the moment is the Colombian Association of Cannabis Industries (Asocolcanna), which was established in 2017 to promote the development of the cannabis industry within the Colombian legal framework.

As it is a private organisation, its guidelines and codes apply exclusively to its members and are not extended to the rest of the cannabis industry. Asocolcanna adopted a conduct code for all of its affiliates through which it seeks to regulate the interrelation between the different agents of the cannabis industry by establishing a series of guidelines and prohibitions.

An external committee is in charge of evaluating the potential complaints and, after due process, imposing the corresponding sanctions in the event of finding any violations. Among these, there are fines ranging from USD2,500 to USD37,500, written warnings and expulsions from the association.

1.4 Key Challenges

Considering that the cannabis industry in Colombia has been developing for more than five years, many of the initial challenges of any

starting industry have been already overcome. Nevertheless, there are still important issues that must be considered within the cannabis market.

One of the most important issues is the access to the Colombian financial system. Due to the historical link between cannabis and drug trafficking, as well as the prohibition of cannabis in the USA at the federal level, many Colombian banks have refused to provide financial services to companies involved with cannabis cultivation and processing. Although the national government has taken measures through state financial institutions, such as the *Banco Agrario,* to overcome these barriers, the reality is that there is still a long way to go for companies to have unrestricted access to financial support.

Another important challenge within the industry is the existing limitation in the domestic market due to the lack of by-products where cannabis can be used. Many companies have adapted to high regulatory standards without finding many outlets for their raw material, partly due to the limitations on exports of dry flowers (existing before 2022) and the lack of regulation on production of food, beverages and other products containing cannabis. On this point, the national government has sought to give different alternatives to the industry by expanding the possibilities for the export of dry flowers (eg, for medical purposes), as well as allowing the usage of certain cannabis derivatives for industrial purposes in the food sector.

Finally, it is important to mention that there are still external agents that do not adhere to regulation of marketed products by claiming miraculous and unverified properties associated with cannabis usage. Unfortunately, these actors are contributing to a widespread distrust about cannabis and misleading the customers as to the true uses it can have.

1.5 Level of Regulation

The Colombian government and local cannabis industry have invested considerable efforts to implement the above-described regulatory regime since 2017. Their goal has been to provide confidence to investors and international agents on the origin and administration of cannabis in the country. With constant modifications to the regulation, the competent authorities have clearly differentiated the cannabis components and the activities that can be done with these components in order to provide different options and solutions to the companies' needs.

In this sense, the Colombian regulatory regime is quite sophisticated and provides solid tools, such as Decree 811 of 2021, for expanding and legally securing the growing market. We observe that the government has been truly interested in helping cannabis companies with their needs and is constantly seeking to improve current legislations to cope with the industry's challenges. As of this date, for example, the Ministry of Health and Social Protection is working on issuing special provisions to regulate the production of food, beverages and dietary supplements with cannabis for human use.

1.6 Legal Risks

As previously mentioned, the regulation of cannabis in Colombia is highly complex and involves constant interaction with different authorities, each of which contemplates several requirements. Accordingly, companies must consider all the obligations and prohibitions they have to comply with to avoid legal risks.

In this context, the most common scenario is that companies cannot perform activities outside the scope of their granted licence or attempt commercial endeavours with individuals lacking the respective cultivation or manufacturing licence.

It is also important to correctly forecast the scope of the quotas scopes required for cultivation of psychoactive cannabis or manufacture of cannabis derivatives. If the company does not use a specific percentage of the quota requested and granted during a term, authorities can – and will – reduce the future quota allocation or, in a worst-case scenario, deny altogether the requested quotas.

Finally, under local legislation, companies are held responsible not only for their activities but also for the actions carried out with third parties. Therefore, it is recommended to implement controls when reaching agreements with other companies to guarantee that the involved parties have the necessary licences and permits to legally cultivate or manufacture cannabis and its by-products.

1.7 Enforcement

As previously explained, compliance of cannabis regulation is overseen by several authorities. However, the specific entities that govern and control cannabis licences are the Ministry of Justice and the INVIMA.

Among the penalties that these entities can impose for non-compliance with the regulation are:

- suspension of the licence for a period of one to six months, including suspension of the activities covered under the licence; and
- total cancellation of the licence and, consequently, revocation of the possibility to carry out industrial and commercial activities with cannabis.

2. CROSS-JURISDICTIONAL ISSUES

2.1 Cross-Jurisdictional Standards

Cross-jurisdictional issues are mainly related to the export of cannabis, which is restricted to scientific and/or medical purposes. For this matter, it is necessary to consider the legal definition of cannabis, based for example in the provisions of Decree 811 of 2021, which corresponds to the flowering or fruiting components of the cannabis plant, with the exception of the seeds and leaves not attached to the parts from which the resin has not been extracted.

On the other hand, sowing seeds, vegetable components, grains, and non-psychoactive derivatives of cannabis can be exported for industrial, horticultural and food purposes. In any case, companies that seek to export their products must also review the regulations and restrictions of the destination country.

3. FUTURE DEVELOPMENTS

3.1 Legal Elements Affecting Access to Medical Cannabis

In order to use cannabis as a medicine or to prepare pharmaceutical products, it is necessary to demonstrate the safety, efficacy and quality of these products. To accomplish this, companies must have sufficient scientific evidence to demonstrate that cannabis, as an active ingredient, has a favourable risk-benefit balance for the desired indication. Likewise, its manufacturing process must be carried out in plants that have certified good manufacturing practices.

In that sense, one of the main obstacles affecting the cannabis industry in terms of accessing the medical market is the elevated cost associated with drug effectiveness and safety research, this

last factor being affected by the lack of sufficient scientific evidence supporting certain therapeutic properties of cannabis.

Additional challenging barriers include the lack of knowledge of health professionals on the potential benefits of cannabis for patients and, thus, the corresponding absence of prescription of pharmaceuticals with cannabis through magistral preparations/products.

3.2 Use of Non-controlled Cannabinoids in Food

Regarding the usage of non-controlled cannabinoids in food products, Decree 811 of 2021 expressly established that it would be possible to use grains, plant components and non-psychoactive derivatives of cannabis as raw materials for the manufacture of food for human and veterinary consumption.

That being said, and in terms of food for human consumption, we are waiting for the Ministry of Health and Social Protection to enact the specific regulation in the matter, allowing the registration of food and beverages that include cannabis as a raw material.

In the case of veterinary nourishment, there is an official ICA ruling, pointing out that the necessary rules for the registration of cannabis-based food products already exists and is currently applicable.

3.3 Decriminalisation or Recreational Regulation

There have been several projects that seek to modify the Political Constitution of Colombia to allow the recreational use of cannabis. These initiatives are in constant evolution, always emphasising the associated economic benefit (eg, increase of industry profit and expansion of the market) and promoting the debate around the social effects related to its legalisation.

However, none of the initiatives have been successful. Considering the current political environment in Colombia, we see it as unlikely that a legal project of this nature will prosper in the near future.

Contributed by: *Ana María Castro, Daniel Cardona, Sebastian Rubiano and Juan Carlos Orjuela,* ***Lloreda Camacho & Co***

Lloreda Camacho & Co is widely recognised as a leading Colombian full-service law firm that provides integral legal services especially to multinational companies doing business in the country. With 80 years' legal experience, the firm places an emphasis on the preventative practice of law, helping its clients to achieve their goals by assessing their legal risks and building innovative, effective and winning strategies. The firm is comprised of a strong team of 60-plus lawyers, who are recognised for their specialised expertise, business-oriented and value-added advice, full commitment geared towards clients' needs and the highest ethical standards. Lloreda Camacho & Co has extensive life sciences experience in all aspects related to the drug cycle, both human and veterinary, as well as in the regulation of drugs, medical devices, commercial and risk aspects, industrial property, access, pricing, and other challenges that the pharmaceutical industry faces during the development of its activities in Colombia. It also has extensive knowledge in the health and safety system.

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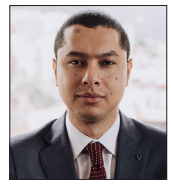

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1. LEGAL/REGULATORY FRAMEWORK

1.1 Source of Regulations

There are several primary laws and regulations that govern practices regarding cannabis in Germany. In the following, the authors will summarise the main legislation that is applicable for the different product types.

General

In relation to all cannabis products, the regulations of the German Narcotics Act (*Betäubungsmittelgesetz,* BtMG) must be observed.

Cannabis, defined in the BtMG as "marijuana, plants and parts of plants belonging to the genus cannabis", is listed in two annexes in the BtMG.

First, cannabis is listed in Annex I that includes narcotics that are generally not marketable and cannot be prescribed (Annex I BtMG); excluded are:

- cannabis seeds, provided that they are not intended for unauthorised cultivation;
- cannabis that originates from cultivation in the EU with certified seed varieties that are listed in Article 9 of Commission Delegated Regulation (EU) No 639/2014 of 11 March 2014 supplementing Regulation (EU) No 1307/2013 of the European Parliament and of the Council establishing rules for direct support schemes for farmers under common agricultural policy support schemes and amending Annex X to that Regulation (OJ L 181, 20.6.2014, p 1, L 181, 20.6.2014, p 1), or:
  - (a) whose tetrahydrocannabinol content does not exceed 0.2%;
  - (b) their marketing (other than cultivation) is exclusively for commercial or scientific purposes;
  - (c) their misuse for intoxication purposes can be precluded;
- if they are planted as protective strips in beet cultivation and destroyed before flowering.

The exemptions also apply to preparations made from these plants and parts of plants if the above conditions are fulfilled.

Second, cannabis for medical purposes is listed in Annex III that includes narcotics which are marketable and can be prescribed.

The only cannabinoid included separately in the BtMG is tetrahydrocannabinol (THC), which is listed several times in Annex I and once in Annex II, depending on its exact composition. On the other hand, pure cannabidiol (CBD) is currently not included in the BtMG.

Medicinal Cannabis

German Narcotics Act

Up until a major legislative reform in 2017, cannabis was only listed in Annex I BtMG and was therefore not marketable and could not be prescribed. Patients could get cannabis only in exceptional cases and could not receive any reimbursement by health insurers. Since 2017, the BtMG also lists cannabis in its Annex III (see above) which contains those narcotics that can be marketed and prescribed in Germany.

Only physicians can prescribe narcotics listed in Annex III (see Section 13 BtMG).

According to Annex III BtMG, medicinal cannabis is only admissible if it stems from a cultivation under state control in accordance with the UN Single Convention on Narcotic Drugs and in preparations that are authorised as finished medicinal products.

Anyone who cultivates, manufactures, trades, imports, exports, delivers, sells, otherwise places on the market, acquires or sells narcotics without trading in them requires a general

licence according to Section 3 BtMG. In the case of an import to Germany according to Section 11 (1) BtMG, a further permission must be obtained for each individual delivery.

Social Security Code

Pursuant to Section 31 paragraph 6 of the German Social Security Code Vol 5 (*Sozialgesetzbuch Fünftes Buch,* SGB V), patients can receive reimbursement from public health insurers under certain circumstances.

Section 31 paragraph 6 SGB V regulates that patients with a serious illness (eg, chronic pain, multiple sclerosis, epilepsy, nausea and vomiting after chemotherapy, and appetite enhancement for HIV/AIDS patients) who are insured with a public health insurer have the right to receive (i) cannabis in the form of dried blossoms or extracts, (ii) finished medicinal products with cannabis, and (iii) medicinal products with the active ingredient Dronabinol or Nabilon, if:

- a generally accepted standard therapy:
  (a) does not exist; or
  (b) in particular cases does not apply according to the justified assessment of the treating doctor, considering expected side-effects and the disease status of the insured patient;
- there is a reasonable possibility that the cannabis will have a positive effect on the disease process or on serious symptoms.

German Medicinal Products Act

Besides the BtMG, the most important statute for medicinal cannabis is the German Medicinal Products Act (*Arzneimittelgesetz,* AMG) which governs the movement of medicinal products in the interest of the proper and safe supply of medicinal products to humans and animals. The AMG covers the manufacturing and trade of medicinal cannabis within Germany and imports from EU countries, as well as third countries, including the requirements of the manufacturing practice in accordance with the EU GMP ("Good Manufacturing Practice") rules.

The following licences are relevant for the handling of medicinal cannabis:

- manufacturing authorisation – every manufacturer of medicinal products needs to apply for such authorisation, pursuant to Section 13 AMG;
- marketing authorisation – finished medicinal products may only be placed on the German market if they have been authorised by the competent German authority or if they are authorised centrally by the EU, pursuant to Section 21 AMG;
- wholesale authorisation – any person who engages in the wholesale trading of medicinal products requires an authorisation to do so, pursuant to Section 52a AMG;
- import authorisation – in case medicinal cannabis will be imported from outside the EU, an import authorisation, pursuant to Section 72 AMG, is required.

Ionising radiation

In the case of cannabis that has been treated with ionising radiation to reduce germ count, the Ordinance on Radioactive Medicinal Products or Medicinal Products Treated with Ionising Radiation (AMRadV) must also be observed.

Lifestyle Products

Besides the general rules of the BtMG, for so-called "lifestyle products" (often containing CBD), a distinction must be made between different categories such as:

- food and animal feed;
- cosmetics; and
- smoking/vaping products (not containing THC).

Food, animal feed and cosmetics law is largely harmonised European law and therefore applies in all EU countries as a matter of priority. The most relevant legislation in this field are:

- German Food and Feed Code (*Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch,* LFGB);
- General Food Law Regulation (EC) 178/2002;
- Novel Food Regulation (EC) 2015/2283;
- Regulation (EC) 767/2009 on marketing feed;
- Regulation (EC) 1831/2003 on feed additives for use in animal nutrition;
- Catalogue of Feed Materials (EU) 68/2013 and (EU) 2017/2017;
- EU Cosmetics Regulation (EC) 1223/2009.

CBD smoking/vaping products that do not contain tobacco or nicotine are considered "herbal products for smoking" and fall within the "tobacco-related products" regulated within the German Tobacco Products Act (*Tabakerzeugnisgesetz, TabakerzG)*.

1.2 Regulatory Authorities

Various regulatory authorities are involved in the cannabis sector. The main authorities responsible for enforcing the laws and regulations for medicinal cannabis and general cannabis (industrial hemp, CBD, etc) are listed as follows.

Medicinal Cannabis

German Federal Institute for Drugs and Medical Devices (BfArM)

The BfArM is an independent federal higher authority within the portfolio of the Federal Ministry of Health and is responsible for medicinal products and devices. In relation to cannabis, the following two agencies of BfArM are of most importance.

The Federal Opium Agency (*Bundesopiumstelle*) was established in 1952 as a result of the International Opium Convention of 1912. It is responsible for the issuing of licences in the traffic of narcotics and/or precursors.

Following the BtMG reform and in line with the UN Single Convention on Narcotic Drugs, the German Federal Institute for Drugs and Medical Devices (BfArM) created a Cannabis Agency (*Cannabisagentur*) that is responsible for the control and monitoring of the cultivation of cannabis for medicinal purposes in Germany. All authorised cultivators have to sell all of their crops of cannabis to the Cannabis Agency. The Cannabis Agency will purchase and take possession of the produced cannabis. Further, the Cannabis Agency will sell the medical cannabis to producers of medicinal products, pharmaceutical wholesalers or pharmacists and will therefore define a sales price.

State authorities responsible for medicinal products

The individual state authorities are responsible for the general enforcement of the German Medicinal Products Act. This concerns, in particular, the granting of wholesale and import licences.

Lifestyle Products

German Federal Office of Consumer Protection and Food Safety (BVL) and respective state authorities

The BVL is involved in the co-ordination of official food, animal feed, cosmetics and smoking products monitoring between the federal states.

The state authorities enforce the respective law within their own states.

German Federal Office for Agriculture and Food (BLE)

The BLE is responsible for the import regulations from third countries, the cultivation notification for industrial hemp and the implementation of THC controls in hemp cultivation.

Decisions by the German authorities can be reviewed by administrative courts upon application.

1.3 Self-Regulation

There are several German and European industry associations which cover cannabis-related topics, for example:

- the German Hemp Association (DHV);
- the Branch Association Cannabis Economy (BvCW);
- the Working Group on Cannabis as Medicinal Product e.V. (ACM);
- the Federal Association of Pharmaceutical Cannabinoid Companies (BpC);
- the International Association for Cannabinoid Medicines (IACM);
- Medical Cannabis Europe;
- the Federal Association of the Pharmaceutical Industry (BpI); and
- the European Industrial Hemp Association (EIHA).

These industry associations are directed to different companies and interest groups and pursue different objectives, such as the legalisation of recreational cannabis or setting standards for cannabis quality.

1.4 Key Challenges

There are several challenges that market participants in the cannabis sector face and have to consider when establishing their business models. The key challenges may be summarised as follows.

Lengthy and Complex Approval Processes

- Licences for the cultivation of medicinal cannabis are only issued via a lengthy tender process.
- The timeline of the approval process for licences on state level can differ in every German state. Certifying manufacturing sites under the EU GMP rules, in particular in third countries, is a very lengthy process.
- The regulations for the distribution of CBD products are quite unclear and violations of the law are prosecuted with varying degrees of severity in the different German states.

Changing Legal Environment and Lack of Experience

Since 2017, the cannabis sector has undergone a huge transformation and has taken on enormous importance in the market. The regulations for some product categories remain unclear, or simply missing, making it difficult for the authorities to issue clear recommendations and thus create legal certainty for market participants.

Due to the still relatively new subject matter, many of the involved authorities on the state level have not yet fully established a reliable administrative practice and are often hesitant to issue statements or make clear decisions.

Enforcement Differs from State to State

The interpretation and enforcement of cannabis-related legislation and regulations may differ widely from state to state, depending on experience and political priorities. For example, medicinal cannabis is classified differently in various German states – either as medicinal product or active ingredient. It is therefore essential to choose the right location for a cannabis business.

High Requirements for Cultivation in Germany

Companies that would like to cultivate cannabis in Germany face different challenges, making it hard for German cultivators to compete with foreign cultivators. Three of the key challenges are listed below.

- Only companies that were authorised by the German Cannabis Agency in a bidding process are allowed to cultivate cannabis in Germany. In April and May 2019, the Canna-

bis Agency awarded the contract for the cultivation, harvesting and processing of cannabis for medical purposes for a total of 10,400 kg for four years. The winners were Aphria (now Tilray Medical), Aurora (both Canadian companies) and Demecan (a German company).
- The cultivation premises must be highly secured so that unauthorised access can be excluded.
- Due to the unfavourable weather conditions in the country, the cultivation of cannabis indoors needs a lot of energy which makes the production costly.

Difficulties in Establishing Brand Recognition for Medicinal Cannabis

In Germany, with the exception of very few authorised finished medicinal products, medicinal cannabis is mainly dispensed by pharmacies as a so-called magistral formulation – ie, the flowers and extracts must be "prepared" for the patient in the pharmacy in accordance with the prescription presented and made available to the patient in the correct dosage form.

As a result, the product packaging originally branded by the manufacturer does not reach the end consumer, which poses challenges to building recognition in the market.

1.5 Level of Regulation

The current regulatory regime has been developed and refined substantially since 2017. Major aspects of the cannabis business are now covered by legislation and/or regulations. However, some relevant questions still need to be further addressed and a respective administrative practice needs to be established. Court decisions allow for more and more guidance, in particular in the growing CBD business.

1.6 Legal Risks

Due to the cannabis industry still being relatively new in Germany, there are several legal risks that need to be considered by companies who would like to engage in the cannabis business, including the following.

Lack of Legal Certainty

The legal landscape, both in Germany but also on the EU level, is constantly changing, so one of the major legal risks at the current time is a lack of long-time certainty. It may very well happen that an assessment of the legality of a certain products changes in the course of only a few months. This is of particular relevance to "newer" product categories that do not fall within the clearly defined traditional product categories – for example, do CBD chew pouches fall within the food law? However, the classification of a product (eg, as a cosmetic, a general commodity or food) is essential for the marketability of such a product.

Criminal Liability

Particularly in the CBD sector, companies too often run the risk that their product will not be classified under the exemption of Annex I BtMG, since authorities/courts rule that misuse for intoxication purposes cannot be ruled out. Based on that determination, the product will be classified as a narcotic that cannot be marketed and the involved persons face significant criminal charges for illegal trade with narcotics. Even though there is now some German and EU case law on the subject, there is still a degree of legal uncertainty when abuse for intoxication purposes is affirmed.

Seizure of Revenues

In case authorities consider that a criminal offence has been committed in connection with the cannabis business of a company, it is possible that revenues from such cannabis business will be seized – in some cases, this may be the turnover of this company.

1.7 Enforcement

In relation to the enforcement of the legislation, it is important to distinguish between criminal and administrative offences, as well as violations of unfair competition law.

Prosecution Authorities

There are several criminal law regulations in connection with cannabis, such as the following.

- The Narcotics Act: according to Section 29 BtMG, anyone who cultivates, produces, traffics in, imports, exports, sells, dispenses, otherwise puts into circulation, acquires or otherwise obtains narcotics without permission can be punished with imprisonment up to five years or a monetary penalty. This also applies for the advertising for narcotics.
- The Food Law: pursuant to Section 1a (1) NLV in conjunction with Section 59 (3) No 2 of the German Food, Commodities and Feed Act (*Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch,* LFGB), anyone who, contrary to the Novel Food Regulation ((EU) 2015/2283) places a novel food on the market without having the corresponding authorisation can be punished with imprisonment of up to one year or a monetary penalty.
- The Medicinal Products Act: according to Sections 95 paragraph 1 No 4, 45 paragraph 1 sentence 2 AMG, it is forbidden to trade with prescription medicinal products outside pharmacies. These can, in particular, apply in case CBD lifestyle products are advertised as medicinal products.

The competent authorities for enforcement of criminal offences are the public prosecutors.

Regulatory Authorities

The competent local authorities verify whether cannabis products are in compliance with regulatory legal requirements. If not, the authorities can order a sales stop. They can also order administrative penalties in many cases.

Competitors and Consumer Associations

In Germany, complaints about products that are not compliant with the legal requirements or about unfair advertising claims are often brought by competitors and consumer associations. It is common that competitors or consumer associations apply for a court injunction, which includes a cease-and-desist obligation. This means, for example, that products can no longer be marketed and may even have to be recalled.

2. CROSS-JURISDICTIONAL ISSUES

2.1 Cross-Jurisdictional Standards

There is no fully harmonised legal landscape within the EU in relation to medicinal cannabis, which leads to different rules within the EU member states. This can lead to various cross-jurisdictional issues. In Germany, this is particularly noticeable in connection with the import of medicinal cannabis from third countries outside of the EU.

In relation to the import of medicinal cannabis from third countries, the biggest challenge for the manufacturers in third countries is to obtain an EU GMP certification so that an import to the EU would be possible.

Some countries have concluded Mutual Recognition Agreements (MRAs) with the EU. Upon successful completion of the equivalence assessment or preparatory phase provided for in some MRAs, during which the parties evaluate each other's GMP inspection systems, inspections are considered mutually recognised. Even if an MRA is in place, it needs to be carefully evaluated for each country whether the MRA also includes cannabis because the scope of the agreements varies.

In all other cases, third-country inspections must be carried out by an authority authorised in Europe. In Germany, the third-country inspection is a quite lengthy process as the GMP inspectors have to travel to the manufacturing sites for a third-country inspection. In addition, the third-country inspections are currently significantly stalled due to the ongoing COVID-19 pandemic.

However, the strict EU GMP rules are not applicable in the case the cannabis products are classified as an API instead of a medicinal product. This classification needs to be confirmed by the authority of the country of origin with a written confirmation and, in addition, the German authority needs to have the same classification for the product to be imported. As the import licence falls within the competence of the individual states, the classification also differs within Germany. Some state authorities allow for cannabis flowers to be imported as an API (ie, no EU GMP certification is necessary), while others classify cannabis as medicinal products and prohibit the import until the manufacturing site has been EU GMP-certified.

So far, German authorities have allowed imports of cannabis from the following jurisdictions: the Netherlands, Portugal, Uruguay, Australia, Spain, Israel and Colombia.

3. FUTURE DEVELOPMENTS

3.1 Legal Elements Affecting Access to Medical Cannabis

In relation to medicinal cannabis, several legal elements have to be considered that affect the access to it.

Untrained Physicians

Only a physician can prescribe cannabis or finished medicinal products with cannabis (see Article 13 paragraph 1 sentence 1 BtMG). However, many physicians are still reluctant to prescribe cannabis. This is, inter alia, caused by the persistent stigma of cannabis as a recreational narcotic. Furthermore, physicians often have a lack of knowledge about the prescribable cannabis products and possible effects.

Few Medical Studies

Apart from authorised finished medicinal products containing cannabis, such as Sativex®, there are few serious medical studies about the effects of cannabis products on serious diseases.

However, in case a therapy with medicinal cannabis was approved by the statutory health insurers (see under **1.1 Source of Regulations**), the participation in an accompanying survey conducted by the German Federal Institute for Drugs and Medical Devices (BfArM) was obligatory. This survey was completed by 31 March 2022, so that further data – including the efficacy of therapy – is to be expected.

Reimbursement Depends on Health Insurer

As outlined under **1.1 Source of Regulations**, patients with a serious illness can, under certain circumstances, be reimbursed by their public health insurer. However, when medicinal cannabis is prescribed for the first time, the patient has to ask for the public health insurer's approval. Although this approval can only be refused in justified exceptional cases, it is still a bureaucratic burden that often leads to a delay for patients.

To reduce the bureaucratic burden, the first health insurance company is currently negotiating a contract with the German Society for Pain Medicine (DGS) to facilitate the provision of medical cannabis, especially in pain therapy.

3.2 Use of Non-controlled Cannabinoids in Food

Foods containing CBD are still on the rise, and therefore the subject is much discussed. However, foods containing cannabinoids are currently not marketable in Germany due to the following reasons.

Food Containing Cannabinoids Is Considered "Novel Food"

In Germany, food and food supplements with CBD are currently classified as "novel food" and therefore are not marketable without a corresponding authorisation.

Pursuant to the Novel Food Catalogue of the European Commission, extracts of *Cannabis sativa L.* and derived products containing cannabinoids are considered novel foods as a history of consumption (before 1997) has not been demonstrated. This applies to both the extracts themselves and any products to which they are added as an ingredient (such as hemp seed oil). It further applies to extracts of other plants containing cannabinoids and synthetically obtained cannabinoids.

German case law and authorities have often confirmed the classification of food and food supplements that contain the cannabinoid cannabidiol (CBD) as novel food, as briefly summarised below.

- Several administrative court decisions considered CBD-based food as novel food.
- The Federal Government of Germany and the Federal Office of Consumer Protection and Food Safety (BVL) have both stated that they are currently not aware of any cases in which CBD products would be marketable as food. From the BVL's point of view, either an application for authorisation of a medicinal product or an application for authorisation of a novel food must be submitted for ingestible products containing CBD before they are placed on the market. Within the framework of these procedures, the safety of the product must be proven by the applicant.
- Novel foods are only marketable after prior authorisation by the European Commission and an addition to the so-called Union List, in accordance with Article 10 ff. Novel Food Regulation. So far, the European Commission has not authorised any food or food supplements containing cannabinoid. Foodstuffs containing cannabinoid are therefore not yet marketable in the light of the requirements of the novel food regime.
- Many local authorities have recently acted forcefully against companies that are selling food and food additives containing CBD. Products in some cases had to be taken off the shelves and administrative proceedings have been started. However, as pointed out above, enforcement priorities often differ from state to state.
- Some consumer or trading organisations have successfully brought claims for cease-and-desist against CBD food businesses in civil courts.

Food Containing Cannabinoids Can Fall under the BtMG

Food and food supplements are not marketable in Germany in case they are considered narcotics pursuant to the BtMG.

CBD itself is not listed as a narcotic in the BtMG. However, many products containing CBD include CBD extracts that derive from the whole cannabis plant and may therefore contain THC residues.

The European Court of Justice ruled in its decision from 19 November 2020 (C-663/18) that CBD is not a narcotic, even if a CBD preparation is contaminated with THC but the THC content does not exceed 0.2%. However, according to

many German authorities, CBD products with a THC content of less than 0.2% are only not to be classified as a narcotic drug if the additional requirements of the exception of Schedule I of the BtMG for cannabis apply (see **1.1 Source of Regulations**).

Low THC content

The THC content of the food product may not exceed 0.2%.

Commercial purpose

For a long time, a major hurdle for CBD products containing trace THC has been that CBD is only exempt from narcotics law if the CBD product has a mere commercial purpose. German legal literature, many authorities and almost all lower criminal courts in Germany have argued that such commercial purpose must also be present with the end user (ie, the consumer). According to this view, products derived from the cannabis plant that can be ingested by the end user can never pursue a commercial use.

In a landmark decision in 2021, the German Federal Court of Justice (*Bundesgerichtshof,* BGH) has ruled that this interpretation is too narrow and not compatible with the intention of the legislator. Rather, it is sufficient that only one of the participants in the commercial transaction sells a product to an end user with a commercial purpose (decision of 21 April 2021, 6 StR 240/20). According to the BGH, no other rules apply to food.

No misuse for intoxication purposes

However, another hurdle is the question of misuse of the CBD product for intoxication purposes. The BGH has confirmed in its recent decision that an abuse of the food product derived from the cannabis plant for intoxication purposes must be excluded for all possible uses for the product. Therefore, the BGH confirmed the previous decision of the regional court according to which hemp tea with a THC content under 0.2% can be a classified as a narcotic if the dried plant parts could also be used for baking cannabis cookies. According to the expert opinions issued in the court proceedings, it is possible with a skilful baking process to make the THC usable for intoxication purposes.

3.3 Decriminalisation or Recreational Regulation

The recreational use of cannabis is not permitted yet in Germany, but the new German government, elected in September 2021, is planning a liberalisation of cannabis for recreational use. According to the coalition treaty between the governing parties, the government will initiate the controlled distribution of cannabis to adults for recreational purposes in licensed stores.

However, many questions regarding the liberalisation are still open – for example, which shops will be licensed to sell and the future handling of medicinal cannabis. Furthermore, it is unclear how the (increasing) demand will be met. Experts estimate that the amount of cannabis grown in Germany will be far from sufficient to meet the demand. However, the import and export of cannabis for recreational cannabis is against the UN Single Convention on Narcotic Drugs.

Therefore it remains to be seen how and when the legalisation of cannabis for recreational use will be implemented in German law.

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Trends and Developments

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Marketability Requirements for CBD Products in Germany

In Germany, there is a rising demand for lifestyle products containing cannabis. Whether hemp oil, hemp tea or skincare products and shampoos containing cannabidiol, a great number of different products can be found on the shelves of supermarkets and drugstores.

The current discussion in Germany focuses in particular on products containing the cannabinoid CBD. The abbreviation CBD stands for cannabidiol. CBD is extracted from the female cannabis plant, but – unlike the cannabinoid tetrahydrocannabinol (THC) – CBD has no psychoactive (intoxicating) effect. Instead, CBD is supposed to have anti-inflammatory, pain-relieving and relaxing effects, according to the manufacturers.

Depending on the specific type of product (medicinal product, medical device, food/food supplement, cosmetics, animal feed, vaping products, etc), there are different challenges in placing the products on the market in a legally secure manner.

Legal requirements of the German Narcotics Act

For all categories of products, the requirements of the German Narcotics Act (*Betäubungsmittelgesetz,* BtMG) must be observed. Trading in narcotics is subject to authorisation (Section 3 (1) BtMG). If listed in Schedule I to Section 1 (1), BtMG narcotics are prohibited in Germany and are thus generally not marketable. While cannabis is listed in Schedule I (along with THC), this does not apply for CBD. Therefore, CBD per se does not fall under the general marketing prohibition of the German Narcotics Act.

"Cannabis" as defined in the German Narcotics Act means marijuana, plants and parts of plants that originate from plants which belong to the genus Cannabis. However, it does not fall under the Act if the cannabis plants used either originate from cultivations with certified EU seeds or the THC content does not exceed 0.2%. In addition, for both alternatives, an exclusively commercial or scientific purpose must be pursued, which excludes abuse for intoxication purposes. According to the German Narcotic Act, hemp seeds that do not contain cannabinoids do not fall under the mentioned prohibition. There shall also be no risk of abuse if the seeds are pressed, roasted or ground. Products made exclusively from hemp seeds, such as hemp seed oil and defatted hemp seeds, are therefore permitted in Germany.

Depending on the classification of the products, further national regulations beyond the requirements of the Narcotics Act must be observed.

CBD in food and food supplements

Currently, food and food supplements containing CBD are generally not marketable in Germany as food and food supplements containing CBD are classified as "novel food" by German authorities and courts, according to Regulation (EU) 2015/2282 and are therefore only marketable in cases where they are authorised by the European Commission.

Food and food supplements containing CBD may not be considered narcotics

According to the German Food Law, a product that contains cannabis in the sense of the UN Single Convention on narcotic drugs (1961) may not be placed on the market as food or a food supplement. CBD itself is also not listed as a narcotic in the UN Single Convention, but "cannabis" is. According to Article 1 (1) (b) of the UN Single Convention (1961), "cannabis" means the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated. In regard to CBD, it is currently uncertain whether German courts will adapt their case law in light of the ruling by the European Court of Justice (ECJ) on 19 November 2020 (C-663/18), according to which CBD extracts obtained from the whole *Cannabis sativa L.* plant are not considered narcotics.

In view of the Federal Institute for Drugs and Medical Devices (BfArM), what matters for food is whether certain THC limits are complied with. However, these limits are currently in revision. Until recently, the limit of the Federal Institute for Risk Assessment (BfR) had been based on 0.005 mg/kg for beverages, 5 mg/kg for edible oils and 0.15 mg/kg for all other food. In future, however, the BfR will base its assessment on the toxicological assessment of the European Food Safety Authority (EFSA), which is based on an acute reference dose (ARfD) of 0.001 mg delta-9-THC/kg body weight (2015).

Products containing CBD, especially food and food supplements containing CBD, have often been considered as illegal by prosecutors and criminal courts in the same way as industrial hemp. This holds true in particular if they contain more than 0.2% THC, but often also below that threshold as it is claimed that CBD products at the end point (ie, the consumer level) are not used for scientific or commercial purposes and may lead to abuse for intoxication purposes. For example, German courts have considered hemp tea with a THC content under 0.2% as a narcotic, because the dried plant parts could also be used for baking cookies. According to the court, it is possible with a skilful baking process to make the THC usable for intoxication purposes.

However, the German Federal Court of Justice (*Bundesgerichtshof,* BGH) ruled on 21 April 2021 that the German Narcotics Act does not require that the end-user of a cannabis product such as hemp tea must also use the product for commercial purposes themself. With its decision, the Federal Court of Justice ruled that food containing cannabis can also be marketable in principle without infringing the German Narcotics Act. In doing so, the court clearly rejected the previously prevailing opinion in case law and literature that selling CBD products to end-users for consumption purposes could never constitute a commercial purpose. The court now opens up new perspectives for food containing cannabis by clarifying a long-running national dispute about the interpretation of the Narcotics Act. Nevertheless, the CBD product in question must still exclude the opportunity for abuse for intoxication purposes.

CBD-based products are considered "novel food" in Germany

After the European Commission included cannabinoids in the EU catalogue of "novel foods" in January 2019, there was a great uncertainty on the German market as to how German authorities would assess foods and food supplements containing CBD. According to this catalogue, only certain products or plant parts obtained from *Cannabis sativa L.* are not to be classified as "novel" – namely, hemp seeds, hemp seed oil, hemp seed flour and defatted hemp seeds. On the other hand, extracts from *Cannabis sativa*

L. and products derived from them that contain CBD are considered novel foods.

Over the last year, based on the EU Novel Food Catalogue, several administrative courts classified food and food supplements containing CBD predominantly as "novel foods", which may not be placed on the market without approval by the EU Commission.

According to a recent administrative court decision (cf VG Cologne, 20 March 2022, 7 K 954/20), CBD drops, marketed as food supplements, are to be classified as medicinal products, irrespective of health claims ("*Funktionsarzneimittel*"), since the court alleges CBD to have a pharmacological effect. However, it is yet to be seen whether other courts will follow this reasoning.

The German authorities' practice has been correspondingly strict to date, leading to numerous local bans. The following should be noted.

- In a statement of 6 March 2020, the Federal Office of Consumer Protection and Food Safety (BVL) repeatedly stated that it was sticking to its previous view that there is currently no case where CBD in food and food supplements would be marketable. From the BVL's point of view, either an application for authorisation of a medicinal product or an application for authorisation of a novel food must be submitted for products containing CBD before they are placed on the market.
- Lately, local authorities have been increasingly issuing general orders prohibiting the marketing/sale of products containing cannabidiol (as "CBD isolates" or "CBD-enriched hemp extracts"). The prohibitions include both shop-based as well as mail-order trade and sale on the internet.

Novel foods are only marketable after prior authorisation by the European Commission and an addition to the so-called "Union List" in accordance with Article 10 ff. Regulation (EU) 2015/2283 on Novel Foods. Following the ECJ's decision of 19 November 2020, the EU Commission already resumed several provisionally suspended authorisation applications for the inclusion of CBD in the Union List in December 2020. So far, however, the European Commission has not authorised any food or food supplements containing CBD. Food and food supplements with CBD are therefore not yet marketable in the light of the requirements of the novel food regime.

Requirements of the Health Claims Regulation

Provided that the food containing CBD is approved, the Regulation (EC) No 1924/2006 (the "Health Claims Regulation") must also be observed when advertising the products. Health claims are only permitted if the presence, absence or reduced content in a food or category of food in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific data (Article 5 (1) (a), 13 (1) (a) of the Health Claims Regulation). Currently, there is no approved health claim for either THC or CBD as herbal substances in the positive list of the Health Claims Regulation.

CBD in cosmetics

CBD can be used as an active ingredient in cosmetics. However, CBD cosmetics have to comply with the restrictions that originate from the German Narcotics Act and the EU Cosmetics Regulation (EC) No 1223/2009.

In accordance with Regulation (EC) No 1223/2009, the cosmetic product may not contain narcotics as listed in Table I and II of the UN Single Convention on narcotic drugs (1961). Until February 2021, only synthetically obtained CBD was a permitted ingredient in cosmetics in the (legally non-binding) Cosmetic Ingredients

(CosIng) database. Following the ruling by the ECJ in November 2020, the EU Commission included a corresponding entry for "cannabidiol from cannabis extract, tincture or resin" as an antioxidant and skin-protectant, amongst other things.

Cosmetics containing CBD must also comply with the above-stated requirements of the German Narcotics Law. Provided the cosmetic product cannot easily be ingested, German authorities generally agree that cosmetics that contain less than 0.2% THC are "harmless" products, that cannot be misused for intoxicating purposes. A case-by-case assessment is necessary.

CBD cosmetics do not require an authorisation under German law, but only a notification of the competent local authorities. This makes the cosmetic market particularly interesting for manufacturers of CBD products. Nonetheless, a notification at the CPNP (Cosmetic product notification portal of the EU) is necessary, too. In Germany, the place of manufacture or import must also be notified.

However, there are also obstacles to avoid when using cosmetics containing CBD. For example, cosmetics with an intended oral use must be differentiated from foods on a case-by-case basis, since (as mentioned above) food containing CBD requires approval as a novel food. Based on the intended use, it must be differentiated whether the product is intended for cosmetic purposes or for consumption. In the product design of the cosmetic item and the cosmetic claims, it is also essential to prevent the product from becoming a so-called "presentation drug" ("*Präsentationsarzneimittel"*), with the consequence that the product would fall under the German Medicines Act (*Arzneimittelgesetz,* AMG) and require a licence for manufacturing and for placing the medicinal product on the market.

When advertising the cosmetic product, Regulation (EC) 1223/2009 and (EC) No 655/2013 and the related guidelines must also be observed. According to these, advertising claims for cosmetic products should particularly be truthful, substantiable and fair. Unlike health claims, there is no exhaustive list of permissible cosmetic claims. If the advertising claim refers to the recognition, elimination or alleviation of diseases, ailments or pathological complaints, a prohibition of misleading advertising also applies according to Section 3 of the German Drug Advertising Act (*Heilmittelwerbegesetz,* HWG).

CBD in animal feed and pet products

Animal feed and complementary feed containing CBD are marketable if in accordance with the provision of the European Feed Law. Besides the above-stated requirements according to the German Narcotics Act, the CBD content in the product may only derive from hemp and by specific manufacturing processes as listed in the catalogue of feed material (Commission Regulation (EU) 2017/1017).

As the respective manufacturing processes are explicitly listed, CBD in pet food only falls within the definition in the feed catalogue if the CBD product contains the amount of CBD that naturally occurs in the plants or parts of plants. If CBD is concentrated – for example, by way of extraction – it does not fall within the feed catalogue but is classified as a feed additive and so currently would not be marketable within the EU as CBD has not yet been approved as a feed additive. In addition to the general admissibility of cannabis in feed, it must be ensured that the product is safe for pets (Article 4 of the Regulation (EC) 767/2009 and Article 15 of the Regulation (EC) 178/2002).

According to a new draft amending Commission Regulation (EU) 2017/1017, the current entry for "hemp oil" in Chapter 2 of the Catalogue of feed

material, "Hemp oil: oil obtained by pressing hemp plants and seeds" (cf feed material entry number 2.22.3 of Commission Regulation (EU) 2017/1017), is to be deleted and replaced by a new (rather generic) entry for "Hemp [Cannabis]; hemp [Cannabis] products" in a new feed material entry, number 6.7.4. The new entry covers products derived from varieties of *Cannabis sativa L.*, other than those listed in Chapters 2 and 6, excluding their flowering tops, buds and blossoms (flowers), with a THC content under 0.2%. The draft regulation could affect the classification of hemp oil obtained by pressing hemp plants.

However, it is currently not fully clear whether, according to the draft, it is irrelevant how the "hemp product" is obtained and whether therefore also hemp products obtained by extraction instead of pressing fall under the draft feed material entry number 6.7.4. It also remains unclear whether the new entry, for example, also covers CO_2 extraction. In the event that the draft amendment to the Commission Regulation (EU) 2017/1017 is adopted, it would in any case remain to be seen how the national regulatory authorities will interpret the new feed catalogue once it has become binding.

Animal feed containing CBD has been the subject of regulatory and judicial reviews in Germany over the past year, in particular with regard to the question of whether (i) the CBD amount contained in the feed corresponds with the natural amount occurring in the plants or parts of plants that have been used in the production of the feed, or (ii) some form of extraction process has been carried out by the manufacturer.

Feed must be clearly distinguished from veterinary drugs that are governed by the German Medicines Act (*Arzneimittelgesetz,* AMG). Therefore, it is important that no advertising statements are used on the packaging or in other promotional materials that could give the consumer the impression that the product has properties to cure or prevent animal diseases.

For all CBD products, a case-by-case assessment is decisive

There are many other products containing CBD available on the market – for example, CBD vaping products, CBD pouches and CBD aroma oils. All such products have in common that a case-by-case assessment of the specific product under national law is necessary. Especially in cases of borderline products, the classification under national law is of decisive importance in determining whether a product is marketable, whether it requires approval/authorisation or whether there is an obligation to notify the competent authorities. Violations of national law can lead to marketing prohibitions by local authorities, fines, and even – in the worst-case scenario – criminal prosecution. The legal classification of the products also determines the advertising claims that are permissible for the products and can contribute to the avoidance of infringements of unfair competition law and advertising rules.

From an overall perspective, the current state of affairs regarding CBD products can be summarised as follows: so far, although there have been significant positive developments for manufacturers of products containing CBD at the European Union level over the past year, these have not yet had a significant influence on the restrictive practice of German authorities. Therefore, a decision by the EU Commission on the current novel food applications concerning CBD is still awaited with great anticipation.

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1. LEGAL/REGULATORY FRAMEWORK

1.1 Source of Regulations

The main rules on the activities regarding controlled substances in Portugal are set forth by the following laws and regulations:

- Decree Law No 176/2006 of 30 August ("Medicines for Human Use"), which establishes the general legal framework for the obtaining of a marketing authorisation (MA) for medicines for human use, including medicines based on the cannabis plant;
- Decree Law No 15/93 of 22 January (DL 15/93), which establishes the Anti-Drug Law and contains the main rules regarding all the activities related to drugs and controlled substances, including for medicinal purposes;
- Regulatory Decree No 61/94 of 12 October (RD 61/94), which develops the legal regime of the DL 15/93 regulating the practical aspects of the activities related to controlled substances, such as the procedures to obtain the relevant authorisations to develop activities related to these substances, including cannabis for medicinal purposes;
- Law No 33/2018 of 18 July ("Medical Cannabis Law"), which allows the use of medicines, preparations and substances based on the cannabis plant for medicinal purposes, and establishes that such medicines, substances and preparations can only be dispensed in pharmacies;
- Decree Law No 8/2019, of 15 January (DL 8/2019), regulating and developing the applicable legal regime established by the Medical Cannabis Law and clarifying some aspects that were not provided by the Medical Cannabis Law, including the terms and conditions under which the Authorisation for Placement in the Market (ACM) can be issued to a preparation or substance based on the cannabis plant;
- Ordinance No 83/2021 of 15 April ("Ordinance 83/2021"), which set forth the requirements and procedures on the granting and maintenance of authorisations for the exercise of activities related to the cultivation, manufacture, wholesale trade, transport, circulation, import and export of medicines, preparations and substances based on the cannabis plant;
- Ordinance No 44-A/2019 of 31 January ("Ordinance 44-A/2019"), which establishes the price regime for cannabis-derived preparations and substances for medicinal purposes;
- Decree Law No 97/2015 of 1 June 2015 (DL 97/2015) establishing the National Evaluation System of Health Technologies (SiNATS), which is subsidiary, applicable to the price aspects not provided by Ordinance 44-A/2019 and also applicable to the price aspects for medicines based on the cannabis plant;
- Resolution No 11/CD/2019 of 31 January 2019 of the Board of Directors of INFARMED, which establishes the therapeutical indications which can be treated with cannabis-derived products;
- Resolution No 010/CD/2019,of 31 January 2019 of the Board of Directors of INFARMED, which establishes the Regulation for monitoring the safety of preparations and substances on the cannabis plant.

The Portuguese legal framework regarding controlled substances has as its basis the Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances signed in Vienna in 1971, ratified by the Portuguese state.

As mentioned, the cannabis plant as used for medical purposes has a specific legal regime in Portugal, establishing the rules applicable to the cultivation, manufacture, import, export, wholesale and sale of medicines, preparations

and substances based on the cannabis plant as used for medical purposes. The existence of such a specific framework for cannabis-related products for medical purposes implies that both DL 15/93 and RD 61/94 became only applicable as subsidiary regulation to those matters which are not expressly foreseen in the Medical Cannabis Law, DL 8/2019 and Ordinance 83/2021.

1.2 Regulatory Authorities

The regulatory body enforcing the laws and regulations on cannabis and cannabinoids for medical purposes in Portugal is INFARMED – National Authority of Medicines and Health Products, I.P. – *Autoridade Nacional do Medicamento e Produtos de Saúde,* I.P.

INFARMED is part of the state's indirect administration and is endowed with administrative and financial autonomy. It is responsible for carrying out the responsibilities of the Ministry of Health under the supervision and guidance of the Minister of Health.

In what concerns cannabinoids, for other than medicinal purposes, the competent authority is the General Directorate of Agriculture and Veterinary – *Direção Geral de Alimentação e Veterinár* ia (DGAV). DGAV is responsible for issuing the authorisations for the commercialisation of food supplements and for the surveillance of this market. DGAV is part of the state's direct administration and operates under the Ministry of Agriculture. DGAV is responsible for the definition, implementation and evaluation of food safety, animal protection, animal health, plant protection and plant health policies, and for the functions of national veterinary and phytosanitary health authority, veterinary medicines and the management of the food safety system. For further products involving non-psychotic cannabinoids, please see **1.4 Key Challenges**.

1.3 Self-Regulation

Under the Portuguese legal framework, INFARMED is the sole competent authority for the authorisation and surveillance of the activities related to controlled substances. In what concerns cannabinoids used in general consumer products, such as food supplements with cannabis-derived ingredients, the competent authority is DGAV. In the exercise of their surveillance powers, both INFARMED and DGAV can be assisted by the Food and Economic Safety Authority – *Autoridade de Segurança Alimentar e Económica* (ASAE).

1.4 Key Challenges

Although Portugal has a sympathetic approach to medical cannabis and its regulatory framework is very well established, the use of medical cannabis is still residual, namely due to the following motives.

Availability of Cannabis-Derived Products in the Market

The market does not have a significant number of options. At this moment, only one medicine is sold in Portugal, and it is sold at a relatively high price, even though it is subject to co-payment by the state. In regard to substances and preparations, there are some applications pending before INFARMED, but only one preparation is currently being marketed and it is not subject to any co-payment.

Price

Another problematic aspect is the price. Even with co-payment by the state, the patient still must bear a significant part of the price of these products, which makes access to therapy difficult for a significant proportion of patients. There are certainly situations where the doctors has proposed prescribing medical cannabis products to a patient, but the possibility is refused by the patient since they do not have the necessary financial capacity to cover such treatment.

In this regard, we believe that it is essential to treat products based on the cannabis plant for medical cannabis as "common" medicines and to grant to those products the same level of co-payment granted to other medicines for the same or similar pathologies.

It should also be highlighted that Portuguese law allows the co-payment by the state of medicines, substances and preparations based on the cannabis plant for medicinal purposes. This can be a vicious circle, since if the price is not supportable by patients then the industry has no motivation to invest in R&D and place new products in the market, thus worsening the lack of availability of products in the market, as described above.

Providing the Medical Class with Scientific Evidence

There are also big challenges with the medical class. Indeed, doctors have been expressing some reservations, mainly due to the lack of evidence on the use of medical cannabis in the treatment of pathologies. As the use of cannabis-derived products is dependent on prescription by doctors – in Portugal, a special medical prescription is essential for the acquisition of medicinal cannabis products – it is essential to provide doctors with scientific evidence giving them comfort and confidence when prescribing cannabis products to their patients.

The final decision on the prescription of a medical cannabis product belongs to the doctor and they will only prescribe such a product – either a medicine, a substance or a preparation – if they trust the product. On the other hand, it is also important to provide health education on cannabis treatments to patients, eliminating the stigma that still exists about treatments based on these substances. We strongly believe that this aspect needs broad industry co-operation, both from the classical pharmaceutical industry and the medical cannabis industry.

Thus, there is still some work to be done to have medical cannabis accepted and used by doctors. It should be based in two main vectors: (i) R&D, and (ii) the production or release of scientific evidence on the benefits and efficacy of medical cannabis products in human health.

Limitation on Doctors' Prescriptions of Medicines, Substances and Preparations Based on the Cannabis Plant

As referred in **1.1 Source of Regulations**, through the issuance of Resolution No 11/CD/2019 of 31 January 2019, INFARMED has clearly established the therapeutical indications whereby medical cannabis products can be prescribed by doctors to their patients.

The Resolution also prescribes that substances and preparations based on the cannabis plant can only be prescribed when it is clear that conventional treatments with authorised medicines are not producing the expected effects or are causing significant adverse effects to patients. This restriction means that doctors are obliged to start the treatment with common medicines, relegating medical cannabis to the last part of the treatment possibilities' chain. This, combined with the lack of options available in the market and the price of such alternatives, is preventing access to these treatment technologies by patients and limiting the growth of the medical cannabis market.

Use of Cannabinoids in Cosmetics, Food and Food Supplements and Veterinary Foods

The use of cannabinoids (CBD) in cosmetics, food and food supplements and veterinary foods is also a key challenge that the market players are facing right now. EU member states have different approaches, with some of them allowing its use (ensuring that it comes from *Can-*

nabis Sativa L. and contains less than 0,2% of THC), some of them are ignoring its use, and the remaining jurisdictions banning its use in cosmetics, food and food supplements and veterinary foods.

Portugal is currently in the last group, restricting the use of CBD in these products. In what concerns cosmetics, INFARMED – which is also the competent authority for cosmetic products – have recently issued an informative letter highlighting that the use of CBD is not allowed in cosmetics as it is a substance coming from the cannabis plant, being a controlled substance under the Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances signed in Vienna in 1971.

In what concerns food supplements, CBD is considered a "novel food" as per Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015, and DGAV does not allow the use of CBD in food supplements based on this aspect. The same applies to food and veterinary foods. Until CBD is considered an authorised novel food – and there are applications currently ongoing for such purpose – it is not expected that DGAV will change its position in the short term.

Effects of the COVID-19 Pandemic

As in the majority of sectors, the COVID-19 pandemic highly impacted the Portuguese medical cannabis market, taking the industry by surprise. During the height of the pandemic, stakeholders were waiting to see to what extent it would impact the medicinal cannabis market and considering how to overcome the new circumstances it caused. Several projects were suspended and a lot of applications for obtaining cultivation and manufacture authorisations were dropped by their promoters. Notwithstanding, Portugal has continued to attract a lot of world players, who maintained and strengthened their investments in the country.

Fortunately, the market has begun to show clear signs of recovery and there are a significant number of projects starting to resume their course, with several companies still investing in Portugal – including some of the biggest global companies in this sector. This is quite clear if we look at the number of investment rounds in cannabis companies and the number of M&A transactions in this sector since the beginning of 2022.

Without prejudice of the above-mentioned challenges, which we are confident will be overcome, we strongly believe that Portugal is the place to be in terms of the cannabis industry, and that prosperous times are ahead for this sector in Portugal.

1.5 Level of Regulation

The regulation of controlled substances in Portugal started in 1993, with the publication of DL 15/93, followed in 1994 by RD 61/94, which established the general framework applicable to controlled substances and, specifically, the rules in regard to the legal market of these substances.

Subsequently, in 2001, Portugal became the first European country to abolish all criminal penalties for drug consumption, under Law No 30/2000 of 29 November. Consuming drugs is now treated as an administrative offence, as long as the possessed quantity does not exceeds the average for individual consumption for a ten-day period. If the quantity is above this ten-day limit, it is deemed to be for drug trafficking, being punishable with (i) four to 12 years, (ii) five to 15 and (iii) one to five years of imprisonment, depending on the concrete crime and the type of controlled substances.

In 2018, Law 33/2018 was published; it was specifically intended to frame the activities related to the cannabis plant for medicinal purposes, and subsequently settled by DL 8/2019. Finally, Ordinance 83/2021, regulated the practical aspects of the applications for authorisations for cultivation, manufacture, import, export and wholesale of medicines, preparations and substances based on the cannabis plant for medicinal purposes.

As described, the regulatory regime for medical cannabis is comprehensive, covering all the stages of the value chain. Despite being a very demanding framework – which is to be expected, considering the nature of this industry – the Portuguese medical cannabis framework is clear and reasonable in what concerns the legal requirements applicable to these activities, allowing stakeholders to be very well-informed about the requirements to ensure a successful application to obtain authorisation for the exercise of such activities.

In addition, Portuguese law has developed creative solutions to allow the growth of the medicinal cannabis market, ensuring at the same time safety in the use of the products and the protection of public health.

The Portuguese law distinguishes: (i) MA, which is the authorisation for marketing a medicine, whether based on the cannabis plant or not, and ruled by DL 176/2006; and (ii) the authorisation for placement in the market – *Autorização de Colocação no Mercado* (ACM) – which is applicable only to preparations and substances based on the cannabis plant. Considering that preparations and substances are less complex than common medicines, Portuguese law establishes a less demanding procedure to apply for an authorisation for marketing of such a preparation or substance. As opposed to medicines, to apply to obtain an ACM, further to the information of the applicant, the applicant shall provide the following information:

- proof of compliance by the grower with the Good Agriculture and Collection Practices (GACP);
- proof of compliance by the supplier of the plant with the applicable local laws of the country of origin for the cultivation of the cannabis plant for medical purposes;
- proof of compliance by the manufacturer of the substance or preparation with the Good Manufacturing Practices (GMP), as well as the copy of the manufacture authorisation;
- proof that the manufacture preparation or substance is in compliance with the applicable laws of the country of origin, in case of imported preparations or substances;
- a dossier able to ensure the quality of the preparation or substance in accordance with the specific guiding standards to medicines and preparations based on plants which was published by the European Medicines Agency and is available in its website.

This is probably the most innovative solution created by Portuguese law to allow the access to cannabis-derived treatments. Although there are some challenges to ensuring full access by the patients who need these kinds of therapies, we believe that the legal and regulatory framework is suitable to such purpose. For further developments on the access issues, please see **3.1 Legal Elements Affecting Access to Medical Cannabis**.

1.6 Legal Risks

The activities related to medical cannabis are highly regulated in Portugal, with very restrictive and concrete, applicable rules. Stakeholders' compliance with the relevant provisions is closely monitored by INFARMED. The stakeholders shall ensure at all time their compliance with all requirements established by law for the activities

of cultivation, manufacture, import, export and wholesale of medicines, substances and preparations based on the cannabis plant for medical purposes. Any breach of compliance with such provisions can result in severe fines and, in the worst-case scenario, withdrawal of the authorisation to exercise the activity.

In what concerns non-psychoactive cannabinoids, there are also several challenges, which are perhaps more difficult to overcome. As the use of these substances are not subject to a European common regulation, the room for different interpretations is significant and is able to cause considerable damage to the stakeholders. For further development on non-psychoactive cannabinoids, please see **3.2 Use of Non-controlled Cannabinoids in Food**.

1.7 Enforcement

The authorities responsible for enforcement of compliance are: INFARMED for medical cannabis; and DGAV for foods and food supplements. INFARMED's and DGAV's decisions regarding medical cannabis and non-psychoactive cannabinoids may be challenged through administrative and/or judicial channels, within a given period.

Individuals and entities who are affected by these decisions can appeal against them, namely on the grounds of breach of the law.

In what concerns criminal enforcement, it is the competence of the Public Prosecutor's Office, assisted by the Judiciary Police (*Polícia Judiciária*), the National Republican Guard (*Guarda Nacional Republicana*) and the Public Safety Police (*Polícia de Segurança Pública*) and is judged in the general criminal courts.

Regarding administrative offences, the applicable penalties vary according to the concrete violations. As for infringements to DL 15/93 and RD 61/94, the main sanction for non-compliance is an economic sanction, which may be minor, severe or very severe, punishable as per Decree Law No 9/2021 of 29 January, which establishes the Legal Framework for Economic Offences – *Regime Jurídico das Contraordenações Económicas* (RJCE).

In what specifically concerns DL 8/2019, the violation of its provisions is considered an administrative offence, punished with a fine between EUR1,500 and EUR3,740.98 in the case of natural persons and EUR3,000 to EUR44,891.81 in the case of legal persons. It is important to underline that both negligence and attempt are punishable, with the minimum and maximum amounts of the fine being reduced to half of the amounts set out if negligence is proven (rather than intent).

The violation of the rules applicable to the activities of cultivation, production, manufacture, import, export, transport, transit, distribution, commercialisation and possession, and parallel regulation such as production quotas, exceeding crop, entities allowed to acquire cannabis plants, substances and preparations, registration obligations, delivery conditions, communications, reports, packaging and labelling set forth in DL 15/93, as well as the provisions of DR 61/94, are considered severe administrative offences, punishable as per RJCE.

Under Article 18 of RJCE, the fines for administrative offences are as follows.

In the case of minor administrative offences:

- between EUR150 and EUR500 in the case of single persons;
- between EUR250 and EUR1,500 in the case of micro companies (ie, companies with less than ten employees);

- between EUR600 and EUR4,000 in the case of small companies (ie, companies with between ten and 49 employees);
- between EUR1,250 and EUR8,000 in the case of medium companies (ie, companies with between 50 and 249 employees);
- between EUR1,500 and EUR12,000 in the case of big companies (ie, companies with 250 or more employees).

In the case of severe administrative offences:

- between EUR650 and EUR1,500 in the case of single persons;
- between EUR1,700 and EUR3,000 in the ase of micro companies (ie, companies with less than ten employees);
- between EUR4,000 and EUR8,000 in the case of small companies (ie, companies with between ten and 49 employees);
- between EUR8,000 and EUR16,000 in the case of medium companies (ie, companies with between 50 and 249 employees);
- between EUR12,000 and EUR24,000 in the case of big companies (ie, companies with 250 or more employees).

In the case of very severe administrative offences:

- between EUR2,000 and EUR7,500 in the case of single persons;
- between EUR3,000 and EUR11,500 in the case of micro companies (ie, companies with less than ten employees);
- between EUR8,000 and EUR30,000 in the case of small companies (ie, companies with between ten and 49 employees);
- between EUR16,000 and EUR60,000 in the case of medium companies (ie, companies with between 50 and 249 employees);
- between EUR24,000 and EUR90,000 in the case of big companies (ie, companies with 250 or more employees).

Moreover, in addition to the economic sanctions, INFARMED may decide to apply ancillary actions, such as the interdiction of the exercise of an activity for a period of time, the suspension of authorisations, licences, permits or the loss of objects and deprivation of the right to participate in public tenders.

2. CROSS-JURISDICTIONAL ISSUES

2.1 Cross-Jurisdictional Standards

As an EU member state, Portugal is subject to EU law and regulations. Considering that medical cannabis and cannabinoids are a recent field of activity, the member states have still not established a common basis for legislation in this area (as is the case with mainstream medicines, for example).

In the absence of a common EU legislation, there have been some recent examples of different interpretations between member states on cannabis and cannabinoids regulation. Some of these conflicts have arrived at the ECJ as there were different interpretations regarding the free movement of goods and the internal market. Case C-663-18 (the Kanavape case) is currently the textbook case in which these matters were discussed in the European Court of Justice. Given the current inconsistencies on cannabis and cannabinoids regulation across the EU, it is likely that cross-jurisdictional issues may arise in near future.

3. FUTURE DEVELOPMENTS

3.1 Legal Elements Affecting Access to Medical Cannabis

The Portuguese medical cannabis market is very well-regulated and well-established, being sym-

pathetic to stakeholders interested in investing in this activity. Despite being in the regulatory vanguard, there are still some obstacles to overcome to allow access to medical cannabis products by those patients who need such products to treat their pathologies.

As referred to in **1.4 Key Challenges**, there are some aspects which need to be worked out to make medical cannabis accessible to patients.

The first is the products available on the market. Portugal currently has on the market only one preparation based on the cannabis plant (dry flower) and one medicine, which is a very limited range on offer for patients. In fact, scientifically and medically, different pathologies need different solutions and the only way to allow this to be properly addressed is to increase the range of products available for prescription by doctors.

The second aspect is the price. The products currently available in the market are very expensive and not economically accessible to a significant number of patients. Being a last resort solution, as per the therapeutical indications approved by INFARMED, medical cannabis should be co-paid by the state in the same terms as other last-resort medicines used – oncology treatments, for example, which are fully supported by the state. Portuguese law already provides this possibility, and it is now for the stakeholders to give evidence of a positive cost-benefit relationship of medical cannabis, thus allowing the increase of its co-payment by the Portuguese state.

For further details, please see **1.4 Key Challenges**.

3.2 Use of Non-controlled Cannabinoids in Food

The interpretation of the Portuguese authorities is very restrictive on the use of cannabinoids in foods.

In what concerns food supplements, DGAV – Portugal's competent authority for food supplements – is very restrictive on the use of cannabinoids in food supplements. As CBD is considered a novel food under the Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015, DGAV does not allow use of CBD in any food supplements. The only exception to this rule is the use of *Cannabis Sativa L.* usually referred to as hemp, provided it is registered in the EU's Common Catalogue of Varieties of Agricultural Plant Species and its tetrahydrocannabinol (THC) content does not exceed 0.2%.

In addition, it should be noted that Portuguese authorities understand CBD to be a controlled substance, as per the United Nations Convention on Narcotics, and do not allow the use of CBD in any consumer products. The competent authority for general market surveillance is ASAE.

The changing of this approach by the Portuguese authorities will largely depend on the path followed by European authorities in this field. Portugal usually closely follows European standards and positions in regulatory matters, and it is not expected that there will be an exception regarding this particular matter.

From an EU law perspective, there are also several aspects that need to be clarified. The harmonisation of the inconsistent medicinal cannabis and cannabinoids regulations across EU member states is essential to allow the growth of this market in Europe.

As per the scientific evidence already in place, it is now more or less clear that non-psychoactive cannabinoids, such as CBD, are safe and have several beneficial effects. This should be enough to make European authorities objectively face reality and create a reasonable framework for all

stakeholders, thereby ensuring that all the people who need this substance have access to it, guaranteeing the quality of the products placed in the market and preventing the flourishing of a black market as a consequence of legal "grey zones".

3.3 Decriminalisation or Recreational Regulation

As referred to in **1.5 Level of Regulation**, Portugal became the first European country to abolish all criminal penalties for drug consumption, under Law No 30/2000, of 29 November; since then, Portugal has faced drug dependence as a public health problem and not as a legal or criminal problem.

Beyond the decriminalisation, Portugal has put in place several programmes in order to help drug-dependent individuals to overcome their dependence through alternative drug programmes managed by public health authorities, such as the provision of methadone to heroin dependents who are in the process of recovery.

Indeed, the decriminalisation of drug consumption was a further step forward in regard to Portuguese drug politics. In 1977, Portugal started to treat drug addicts with methadone as substitute for heroin. This programme has had a significant success, with an appreciable number of recuperations of drug-addicted persons.

Another initiative, back in 1993, was the syringe-exchange programme, through which drug dependents could replace used syringes for sterilised new ones. This exchange was made in community pharmacies, which entered a protocol with the Ministry of Health and the National AIDS Commission. As a consequence, Portugal achieved a massive reduction of infections by HIV, whose main transition vehicle was precisely the sharing of syringes between drug dependents. Considering the close connection of drug dependents with other social issues, such as prostitution and homelessness, this was the perfect environment for the spreading of the virus.

In what concerns "recreational" cannabis regulation, the Portuguese Parliament has started discussions on the liberalisation of cannabis for personal use. The bills were submitted by the party *Bloco de Esquerda* (Left Block) and *Iniciativa Liberal* (Liberal Initiative) in 2021, and aim to allow the consumption of recreational cannabis, without prescription, under certain circumstances. Although the bills were submitted, they have not yet been voted on, mainly due to the political crisis in Portugal in the last months of 2021.

Portuguese society is currently having a wide-ranging discussion on the allowance of recreational cannabis for personal use. The discussions are now, in our opinion, clearly moving towards a relative consensus around the allowance of use of cannabis for recreational purposes. Considering the composition of the Parliament arising from the general election held in January 2022, it is likely that recreational cannabis for personal use will be allowed and regulated in the short-to-medium term.

As it is highly likely that recreational use of cannabis will be allowed in the not-too-distant future, it is essential to develop a reasonable framework for this new reality and to avoid mixing it with the framework for medical cannabis. Medical cannabis and recreational cannabis have totally different targets and functions, and it is essential to define and clearly distinguish the two fields of activity.

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Trends and Developments

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The Cannabis Industry in Spain

The definitions of "cannabis" and "cannabis derivatives" used in this article follow those set out in the UN Single Convention on Narcotic Drugs 1961 and by international drug control authorities. "Cannabis and its derivatives" mean all products that derive from the cannabis plant, including flowering or fruiting tops, resin, oils, tinctures, extracts and preparations (capsules, oils, infusions, etc).

Spain ratified the 1961 UN Convention and the 1971 UN Convention on Psychotropic Substances and, thus, the general law regulating controlled substances was passed in 1967 (*Ley 17/1967, de 8 de abril por la que se actualizan las normas vigentes sobre estupefacientes y adaptándolas a lo establecido en el convenio de 1961 de las Naciones Unidas*). To date, there are no developments or amendments to this piece of legislation, nor are there clear guidelines or secondary legislation providing a clear view on some of the more pressing aspects of regulation around the cannabis industry.

Hence, in terms of regulatory activity, Spain can be described as both a conservative and "follower" jurisdiction regarding cannabis. This notwithstanding, as of this date – based on the expanded social and media coverage and spurred by the pressing need to tackle the growing illegal market – the Spanish Congress of Deputies has created a specific sub-commission to start gathering up (yet again) evidence and analysis to reflect on the possibility of legislating further on the medical aspects of cannabis. Any further regulation that would address recreational use is still far away, notwithstanding the popularity of the drug in Spain.

Spain, to date, lacks a structured industry lobby. The authors believe that the incorporation of an association or a similar body is critical for pushing a sensible regulatory framework, which would open the local market and ensure patient access to cannabis-based products with high standards of quality, safety and consistency. Increasing awareness of politicians, legislators and key opinion leaders (doctors, etc) is key and needs to be channelled.

Spain has a thriving "cannabis culture" and, hence, a huge commercial potential that remains untapped due to stagnant regulation and insufficient advocacy.

The latest news

During 2020, two events took place that might have an impact on cannabis regulations in Spain. However, their effects remain to be seen.

The first is the ruling of the Court of Justice of the European Union (CJEU) dated 19 November 2020 (C-66318, the Kanavape case).

Briefly, the CJEU found that:

- cannabidiol (CBD) is not expressly included in the list of international and EU psychotropic substances;
- the CBD upon which the main dispute was based – produced in the Czech Republic,

extracted from a cannabis plant that was used in its entirety – "does not appear to have psychotropic or harmful effects on human health on the basis of the available scientific data"; and
- the prohibition on CBD would not affect the marketing of synthetic CBD that had the same properties as CBD extracted from the *Cannabis sativa* plant in its entirety.

In light of the above, the CJEU concluded that any national legislation which prohibits the marketing of CBD lawfully produced in another member state, when extracted from the *Cannabis sativa* plant in its entirety and not just from fibre and seeds, would contravene the Treaty on the Functioning of the European Union, unless such legislation can be deemed as appropriate to secure the aim of protecting public health and does not reach beyond what is strictly necessary for such purpose, which is something to be assessed by national courts.

As per the considerations of the CJEU, the prohibition on CBD obtained from the plant as a whole is neither consistent nor systematic in accordance with the ultimate target of protecting public health. The ruling is binding and sets a relevant precedent for all EU member states and institutions.

The second event was the vote, on 2 December 2020, by the United Nations (UN) on the recognition of the medicinal and therapeutic potential of cannabis. The UN urged to remove cannabis and cannabis resin from Schedule IV of the Single Convention on Narcotic Drugs, which includes the most dangerous substances with limited or no medical value, such as heroin. Thus, from now on, cannabis and cannabis resin should only be classified under Schedule I of the aforementioned Convention, which includes substances that, despite their addictive potential, are not deemed harmful to health and have a therapeutic value.

As stated, the authors cannot anticipate any tangible influence of these two events in terms of future cannabis regulations in Spain, although they consider themselves as optimists in this regard. This article aims to forecast the potential consequences, in particular of the Kanavape sentence, and their impact on the Spanish market, as well as a general overview of the cannabis industry from a legal point of view.

Summary of main economic indicators and political trends

Spain's population is just over 47 million and, according to the Spanish Health Ministry, total healthcare expenditure was 7.9% of GDP during 2020, whereas before the COVID-19 pandemic it was stabilised around 6.5%; in 2021, it was 6.6%.

According to the latest CIS barometer survey, published in April 2021, 90.1% of the population surveyed argue that medical "marijuana" (the word used in the questionnaire) should be legalised, and 49.7% would support legalising its recreational use. The CIS is an independent entity assigned to the Ministry of the Presidency whose main remit is to contribute scientific knowledge on Spanish society.

Spain is home to well-known seed companies and is said to have nurtured a skilled workforce. Users and activists have managed to establish a relevant network of stakeholders (associations, patient groups, seed banks, shops, researchers, etc) and several companies seem to be making significant revenues out of the sale of hemp-related products.

As evidenced by increased media presence, industry events and publication of research, Spain's know-how is growing. Associations and

organisations are flourishing and becoming more vocal, but, unfortunately, in a very unstructured way, lacking a real "industry lobby" that would advocate for regulation of the medical market.

Political trends

A few years ago, in 2017, cannabis came back on to the political agenda in the wake of a changing international and European attitude towards regulation of the industry. Since then, several political initiatives around cannabis have been put forward in the Spanish Congress.

To summarise, the position of Spanish political parties on cannabis is as follows. At the end of 2021, *Mas País* and *Esquerra Republicana de Cataluña* (ERC), on the one hand, and Podemos, on the other hand, all left-wing political parties, submitted two proposals of bills to regulate cannabis. They understood that cannabis must be regulated in Spain to ensure its safe use and avoid illegal traffic. However, neither of these bills passed.

Partido Socialista Obrero Español (PSOE), currently the governing party, has been pleading for the opening of a comprehensive and in-depth debate on the matter. *Ciudadanos* (Cs) suggests the opening of a study paper, in the Health Commission, about the regulation of the medicinal cannabis market. On the other hand, the *Partido Popular* (PP) seem to oppose what they call the "legalisation" of cannabis, but have been less vocal lately.

These political initiatives have consolidated on the creation of a sub-commission within the Spanish Congress of Deputies that is currently studying the future regulation of medical cannabis, having started its work analysing the regulatory experience of other countries.

Lack of a Concrete Regulatory Framework

General overview

Unlike Germany, Italy or other EU countries, Spain lacks a specific approach to the regulation of cannabis, other than under international drug control treaties, Law 17/1967 and criminal and administrative legislations, covering controlled substances and licensing for medicinal or scientific purposes, which is currently causing both social/political alarm and legal insecurity.

The *Agencia Española de Medicamentos y Productos Sanitarios* (AEMPS) is the state agency within the Spanish Ministry of Health that guarantees quality, safety, efficacy and accurate information on medicines and medical devices marketed in Spain. AEMPS protects public health by means of authorisations, registration and controls of manufacturing and marketing carried out on medicines for human use, veterinary medicines, medical devices, cosmetics and personal care products, and support of clinical research. Regarding cannabis, the AEMPS is in charge of issuing the relevant licences – and their supervision and control – to cultivate cannabis for medical or research purposes, as well as the authorisation of medicines containing cannabis derivatives and supervision of cosmetics.

In compliance with its mission, the AEMPS strictly follows the EU framework for cannabis. The AEMPS, as a regulatory body, is characterised by being very low-profile and conservative. In the authors' experience, any approach to this agency should be made prudently and in a co-ordinated manner, as the regulator is under constant pressure from both the industry and politicians.

Market access – licensing

Cultivation licences under Law 17/1967

In Spain, the cultivation of cannabis that is not aimed at producing fibres, grains or seeds and with a high content of tetrahydrocannabinol

(THC) (above 0.2%, pending an update to 0.3%) may only have two different purposes, which are relevant for the grant of licences and authorisations:

- the licence for cultivation of cannabis plants for research purposes, such as the creation of cannabis varieties or seeds for therapeutic use or research of the physical and pharmacological properties of cannabis and its products, will be granted for a year, renewable (for subsequent one-year periods) upon request until the end of the research project;
- the licence for cultivation of cannabis plants for medicinal and scientific purposes is designed in applicable regulations as a "two-step process" – ie, a general licence is needed, which authorises concrete activities, which is subsequently complemented by specific authorisations regarding each concrete plot of land or cultivation site.

The grant of licences and authorisations is subject to the fulfilment by the applicant of certain requirements. Licences and authorisations of the AEMPS are specific to the persons or entities, plots of land, timing and products for which they have been issued and, consequently, do not confer any rights to otherwise dispose of the products or plants out of the scope of the licence granted.

Number of licences issued and rejected so far

As stated above, the grant of research and medical and scientific licences in Spain has been increasing in the last years, although the AEMPS still maintains a conservative approach. It must be considered that, even though laws and regulations do indeed lay down a set of principles and requirements for the grant of licences and authorisations, the AEMPS has been following its own procedures to assess applications, particularly in regard to the concrete order and requests of information, the depth and detail thereof and other relevant aspects. A transparent approach in compliance with applicable laws is key to obtain and maintain licences and authorisations.

In this respect, the AEMPS regularly publishes a list of granted licences on its website. Hundreds of applications have been rejected by the AEMPS, which is very selective and makes a thorough assessment of the commercial plans, solvency and reliability of applicants in order to preserve the legal cannabis market in Spain.

Cultivation of hemp

Cannabis for strict industrial uses (hemp) is excluded from the licensing regime, provided it "lacks the narcotic active principle", as stated in Law 17/1967.

In the European Union (EU), the cultivation of *Cannabis sativa L.* varieties is permitted provided they are registered in the EU's Common Catalogue of Varieties of Agricultural Plant Species and the THC content does not exceed 0.2%. Although hemp cultivation is not subject to authorisation, it must comply with some requirements, including: use of certified seeds; cultivation aimed exclusively to obtain fibres, seed or grains; and farmers must be registered as a producer of seed and nursery plants.

Use of cannabis in medicines

Medicines are regulated throughout their entire life cycle. All medicines used in Spain must obtain a previous marketing authorisation, which AEMPS will grant, after assessing their quality, safety and efficacy. Likewise, any variation of the medicine must be authorised or reported to the AEMPS. These assessments are intended to ensure a positive balance between the benefit and risk of the medicine throughout its progress on the market.

To date, the AEMPS has authorised Sativex and Epidyolexas pharmaceutical medicines containing Delta-9-THC and CBD.

Cosmetics

Regulation 1223/2009 defines "any substance or mixture intended to be placed in contact with the external parts of the human body [...] or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours".

EU regulation is binding and enforceable for each of the member states (including Spain) through their local authorities, which have powers to oversee and regulate in compliance with the EU standards regulatory framework – in Spain, it is the AEMPS. Products meeting the provisions of said Regulation have access to the EU market and may circulate freely within the EU, subject to compliance with certain local law requirements. No pre-market approval is needed (although certain exceptions apply) as the system is based on an internal market control and alert scheme.

The pivotal principles of the EU cosmetics regulation are:

- safe assessment prior to product placement on the market (carried out by manufacturers under high standards);
- appointment of a "responsible person", without which cosmetics cannot be placed on the market;
- cosmetics need to be included in the Cosmetic Products Notification Portal (CPNP) centralised database; and
- reporting of serious undesirable effects (SUE) by responsible persons to local authorities, who will share them with the EU.

Use of CBD in cosmetics

Annex II of Regulation 1223/2009 lists the substances that are prohibited from use in cosmetics. This list includes: "306 – Narcotics, natural and synthetic: All substances listed in Tables I and II of the Single Convention on narcotic drugs signed in New York on 30 March 1961".

CosIng (ie, Cosmetic Ingredients) is the EU Commission's database for information on cosmetics substances and ingredients. However, the CosIng glossary does not constitute a list of ingredients that are to be deemed as authorised for use, is not exhaustive and does not provide proof of a regulatory status. The use of substances in any cosmetic product must always be supported by an assessment of its safety.

Spanish authorities still follow the former entry related to CBD in the CosIng, according to which: "Cannabidiol (CBD) as such, irrespective of its source, is not listed in the Schedules of the 1961 Single Convention on Drugs. However, it shall be prohibited from use in cosmetic products if it is prepared as an extract or tincture or resin of cannabis in accordance with the Single Convention." In other words, natural CBD obtained from non-audited parts of the plant or of synthetic origin is allowed, while CBD obtained from audited parts of the plant is forbidden as a cosmetic ingredient. In this regard, the AEMPS has taken what seems an even more conservative approach, supporting a very strict interpretation around the sources and uses of CBD.

Food

Some products derived from hemp (under 0.2% THC) – such as seeds, seed oil, hemp seed flour and defatted hemp seed – have a history of consumption in the EU and, therefore, are not novel and can be consumed in Spain, according to the Spanish food agency. Regarding CBD, the EU authorities understand that, according to the

information available, this product was not used as a food ingredient before 15 May 1997.

Foods or food supplements that have not been consumed to a significant degree in the EU before 15 May 1997 are classified as "novel foods" and subject to the Novel Food Regulation.

"Novel foods" are (i) recently developed or innovative types of food or food supplements that have been created using technology, and (ii) any food that may have been traditionally eaten outside of the EU. Manufacturers and distributors of such foods can only place them on the market once the EU has granted authorisation following an application.

The routes to be able to market food or food supplements in the EU (or Spain, specifically) are:

- proving a significant history of use in the EU prior to 1997 (there is an official consultation procedure laid down in Article 4);
- as traditional food from a third country with a history of over 25 years of safe usage (Article 15); and
- obtaining a novel food authorisation.

The last-named route requires a safety assessment and a pre-market authorisation before placing the product on the EU market. Such authorisation requires the filing and processing of an application and the implementing act of placing the product on the market, by means of which the novel food will be included in the EU list.

Cannabis as an ingredient of food

Extracts derived from *Cannabis Sativa L.* and derived products containing cannabinoids, such as CBD, according to the Novel Food Catalogue, fall into the novel foods category, both as extracts and as products to which they are added as an ingredient. The status of novel food further applies to extracts of other plants containing cannabinoids and to synthetically obtained cannabinoids.

At the beginning of 2022, EU regulators resumed their review of novel food authorisation applications for CBD products, after abandoning their preliminary stance that CBD should be treated as a narcotic, a change that seems to have come after the Kanavape sentence. Lately, the European Food Safety Authority (EFSA) has stated that it had validated novel food applications from a "number of companies", which means that these applications are now in the final stage of the novel food authorisation process.

Animal feed

EU regulations set out provisions regarding animal feed on:

- safety and marketing requirements;
- responsibilities and obligations of feed businesses;
- restriction and prohibition;
- types of feed;
- labelling and packaging; and
- claims (ie, messages that state, suggest or imply that a feed has particular characteristics).

Feed regulation follows the same principles already analysed regarding food. Feed cannot contain or consist of materials whose placing on the market or use for animal nutritional purposes is prohibited.

While for foods intended for human consumption there is a so-called "positive list" in which ingredients that are approved for human consumption are listed, there is no such list for feed products (only a list of prohibited or restricted materials). The regulations on animal feed are

more open and the use of any natural plant extract is allowed as long as the extracts are made from plants that can be legally cultivated in the EU and do not include any prohibited materials listed in the regulation.

As of today, registrations before the Feed Materials Register of feed containing CBD have been rejected under the consideration that CBD is a non-authorised feed addictive.

Conclusion

With 11 licensed cultivators and two licensed manufacturers currently active, commercial medical cannabis exports began in the second half of 2020 with sales to three countries. This distinguishes Spain as a production powerhouse in European cannabis cultivation, but may be only the beginning. While the opportunities proliferate for producers and Spain is leading the way in developing commercial supply, the country faces the challenge of having to adapt and increase its flexibility to fully accommodate the pressing market reality.

To reiterate: the lack of structured lobbying makes it difficult for the industry to advance and take an evidence-based approach. While the authors believe that the Kanavape case will trigger regulatory reflection, the industry will still have to push very hard in order for Spanish authorities to open their eyes and address the situation.

Contributed by: *Cristina Romero de Alba and Fernando A. Martín Martín,* ***Loyra Abogados***

Loyra Abogados was founded 39 years ago. It specialises in business advisory and public law, creating a full-service boutique for operators, suppliers, governments and investors acting in highly regulated industries. As a result, Loyra is broadly known for its extensive experience in regulated sectors such as cannabis, media, gaming and betting regulations and compliance across jurisdictions. The firm has advised on regulatory efforts and transactions in the cannabis industry (both domestic and cross-border). In addition, the corporate department (M&A, tax, IP/IT, labour and public law) has continued to provide day-to-day advice to both investors and industry companies who are looking to grow their business and rely on a close and top-of-the-range team of experts as an extension of their internal teams. Loyra has worked both on the preparation and structuring, as well as on the execution, of transactions and investments.

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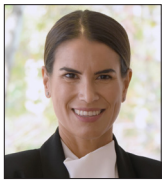

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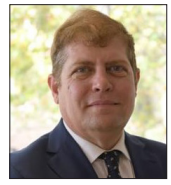

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1. LEGAL/REGULATORY FRAMEWORK

1.1 Source of Regulations

In Switzerland, products containing hemp, or *Cannabis sativa L.* (cannabis), are regulated by a set of laws and regulations that are intertwined, complex, and create a level of legal uncertainty that lawmakers have realised needs to be addressed. The main tenets surrounding cannabis are regulated in the narcotics, therapeutic products, health insurance, foodstuff, chemical, cosmetic, utility articles, tobacco substitutes as well as plant varieties and seeds laws and regulations.

To facilitate matters, this chapter will provide an overview of only the most important aspects of cannabis laws and regulations, and draw a distinction between (i) cannabis products containing a tetrahydrocannabinol (THC) content of above 1%, which are considered prohibited narcotics under the Federal Act on Narcotics and Psychotropic Substances (Narcotics Act, NarcA), and (ii) products with a THC content below 1%, which have been popularised and aggregated in a somewhat untechnical jargon as "CBD products", which stands for products containing cannabidiol, and which are not subject to the NarcA so are more freely marketable.

Due to recent developments, also regarding the use of other cannabinoids (CBG, for example), the following statements, insofar as they relate exclusively to CBD, can in principle also be applied to other – non-psychotropic – cannabinoids. Both THC and CBD have garnered notoriety as the most prominent cannabinoids over the last years; however, research has shown that well over 140 cannabinoids, which are naturally occurring compounds found in the cannabis plant, can be identified (THC, THCV, CBD, CBG, CBT, CBN, CBL, CBE, etc).

Cannabis Products with a THC content of Above 1%

Narcotics Act, NarcA

The use of narcotics is primarily regulated by the NarcA. The implementation of the NarcA is today governed by four ordinances on the control of narcotics (BetmKV), the addiction to narcotics (BetmSV), the register of narcotics, psychotropic substances, precursors and auxiliary chemicals (BetmVV-EDI), and the Ordinance on Pilot Trials under the NarcA (BetmPV).

The BetmKV governs the activities of the Swiss Agency for Therapeutic Products (Swissmedic) in the area of granting authorisations for the legally permitted handling of controlled substances and the associated controls, and is of importance for the industrial use of these substances.

The BetmSV regulates the measures for prevention, therapy and harm reduction as well as the exemptions for the restricted medical use of cannabis-containing medical products and the corresponding controls. The BetmVV-EDI lists all controlled narcotics and psychotropic substances and determines to which control measures they are subjected. Lastly, the BetmPV regulates the requirements for conducting scientific pilot trials with narcotics of the cannabis type in accordance with Article 8a NarcA.

Cannabis is classified as a prohibited narcotic if its THC content exceeds 1%. An amendment to the NarcA in force since 1 July 2011 provides for a restricted decriminalisation of the preparation of a negligible quantity of cannabis for one's own consumption (10 g). Cannabis products with a THC content lower than 1%, on the other hand, can be legally produced and marketed. This holds true for all cannabis products except for cannabis resin.

Cannabis resin is separately listed in the BetmVV-EDI and is considered a controlled narcotic

independent of its THC content. This classification of cannabis resin as a narcotic drug, which was confirmed by the Swiss Federal Tribunal in 2019, is considered rather unfortunate by the local cannabis industry as it limits the commercial exploitation of the most cannabinoid-dense part of the cannabis plant, drives a wedge of unequal treatment between cannabis extracts, which are legal if their total THC content remains below 1%, and cannabis resin, and creates a whole range of other legal issues (eg, in cosmetics regulation).

However, in its statement of 16 February 2022 on a respective motion, the Federal Council announced the amendment of the ordinance so that the THC-threshold of 1% will also be applicable for cannabis resin in the future. Therefore, in the future, the regulation of cannabis as a narcotic drug will commonly be connected (no matter what part or form of the plant) to the threshold of 1% THC content. Hence, the aforementioned issues with regard to cannabis resin (and the currently missing limitation of 1% THC content) will soon be resolved.

Pursuant to the NarcA, the Federal Office of Public Health (FOPH) may issue exceptional licences for cultivating, importing, producing and placing on the market narcotics containing an effective concentration of cannabinoids, where this is not prohibited by an international agreement and these narcotics are needed for scientific research, the development of medical products or for restricted medical use. The prescription for medical purposes of unauthorised cannabis-based medical products which contain a THC level of above 1% is permitted under certain circumstances. Such an exemption permit from the FOPH is required:

- to develop medical products with prohibited narcotics;
- to use prohibited narcotics for limited medical purposes; and
- to use an authorised medical product with prohibited narcotics for any purpose other than the approved indication.

An exceptional licence for restricted medical use is issued to the attending physician. The physician then goes on to prescribe the medical cannabis product (in the form of oils and tinctures for ingestion). Based on this prescription, the corresponding medical product may be dispensed to the patient within the framework of the Therapeutic Products Law. The granting of a licence for the restricted medical use of prohibited narcotics also requires a prior written declaration by the patient stating that they consent to the use. An exceptional licence for restricted medical use may only be granted if the following conditions are cumulatively fulfilled:

- the patient suffers from a generally incurable disease;
- the suffering can be alleviated by taking the prohibited narcotic;
- the existing treatment options have been exhausted or there are no alternative treatment options; and
- the administration of the prohibited narcotic enables the patient to live more independently (eg, in case inpatient treatment can be avoided).

Applying for a special permit at the FOPH is therefore quite cumbersome, and a revision to the NarcA, which was adopted on 19 March 2021, will provide long-sought relief, as will be described in detail in the adjacent Trends & Developments article.

On 24 June 2020, the Federal Council submitted to Parliament a dispatch on the amendment of the Narcotics Act (BetmG), which provides for the facilitation of the handling of cannabis for

medical purposes. The bill was largely uncontroversial in parliamentary deliberations and was adopted by both Chambers of Parliament on 19 March 2021. The adopted amendment to the law facilitates access to cannabis medicines for thousands of patients as part of their treatment. This mainly affects cases of cancer or multiple sclerosis, where cannabis-containing medicines can alleviate chronic pain.

According to the new legal situation, which is expected to come into force in the autumn of 2022, special authorisation from the Federal Office of Public Health will no longer be required. In other words, doctors will be able to prescribe cannabis to their patients in the future as part of their regular treatment – ie, without the requirement of a special licence.

Therapeutic Products Law

Legal basis

The regulations on the use of medical products and medical devices are mainly set forth in:

- the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA);
- the Ordinance on Pharmaceutical Products (VAM);
- the Ordinance on Advertising of Pharmaceutical Products (AWV);
- the Ordinance on the Approval of Medicinal Products (AMZV);
- the Products Licensing Ordinance (MPLO); and
- the Medical Devices Ordinance (MedDO).

These laws and regulations apply to therapeutic products according to the TPA, which include medical cannabis products.

Authorisation

Ready-to-use medical products may be placed on the market only if authorised by Swissmedic. The application for obtaining a market authorisation for medical cannabis products with indication must include, for example, detailed documentation on the results of physical, chemical, galenic and biological or microbiological tests, as well as the results of pharmacological and toxicological tests and clinical trials. The applicant must also prove that the medical products are of high quality, safe and effective and that the medical product in question does not pose a risk to the safety of consumers.

Only one ready-to-use medical product with a THC content above 1%, Sativex®, is fully approved in Switzerland. Sativex can be prescribed without special permit for spastic convulsions in multiple sclerosis patients only (ie, its application is very limited in scope).

In the context of cannabis-based medicinal products, reference can also be made to Epidyolex®, a ready-to-use medicinal product without THC but including cannabidiol. Epidyolex® was approved by Swissmedic on 10 February 2021, and is used as adjunctive therapy for seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients two years of age and older.

The manufacture of medical products and pharmaceutical excipients whose manufacture requires a licence must conform to the recognised rules of Good Manufacturing Practice (GMP). The Medicinal Products Licensing Ordinance (MPLO) refers to the GMP guidelines of the EU (Annex 1). Thus, in Switzerland the GMP guidelines of the EU are applicable.

The GMP guidelines provide the minimum requirements that a manufacturer of medical products must meet to ensure that their products are consistently of sufficiently high quality for their intended use. This includes risk management, documentation, continuing improve-

ment processes as well as internal and external audit requirements. Each manufacturer must determine and document in writing how it complies with and implements the GMP guidelines.

An audit must verify whether all the required boxes of the GMP standard were ticked and thus the products meet the safety and quality standards. Swiss-domiciled companies with a valid establishment licence for the manufacture of medical products may apply to Swissmedic to obtain a GMP certificate through its eGov GMP-GDP online portal.

Exemption from authorisation

The Therapeutic Products Act also provides for the market placement of medicinal products that are exempt from authorisation. These include medical cannabis products manufactured as an extemporaneous preparation ("magistral formula") – that is, medicinal products prepared according to a doctor's prescription by a public pharmacy or a hospital pharmacy for a given person or group of persons. The conditions for the use of medicinal products that are exempt from authorisation are restrictive. Such use is mainly considered in order to ensure the supply if no authorised drug is available for this purpose. Due to these requirements, extemporaneous preparations can and may only be produced in small quantities. Their prior authorisation is impossible for time reasons and also not necessary, because the protection of public health is ensured by the fact that the prescribing physician and the pharmacist preparing the drug (or the manufacturer) have appropriate training and are controlled by the authorities.

Medical cannabis products as a formula magistralis, produced by a pharmacy based on a medical prescription, require an exceptional authorisation from the FOPH under the NarcA. An exceptional authorisation is also required for an approved drug (ie, Sativex®) that is dispensed for an indication other than the one for which it has been approved. However, as mentioned above, this legal situation will change in autumn 2022, when cannabis-prescribing doctors will no longer require a special authorisation from the FOPH.

The reason for this exemption from authorisation is, according to the legislator, that the training of the physician and the cantonal supervision of the professional licences guarantee that the physician issues the prescriptions correctly and the pharmacist prepares the prescriptions according to the law.

The provisions of the TPA apply to narcotics used as therapeutic products even if they are placed on the market with an exceptional authorisation under the NarcA. The provisions of the NarcA are applicable to these narcotics insofar as the TPA does not provide any regulation or provides a less far-reaching regulation than the NarcA. In other words, narcotics used as medicinal products that are exempt from an exceptional authorisation by Swissmedic must also comply with the minimum standards of the TPA.

Health Insurance Law

The reimbursement of costs for medicinal products by the compulsory health insurance (OKP) generally requires that the medicinal product is included in the list of specialties (SL) of the FOPH. To be included in that list, the medicinal product requires both a licence from Swissmedic and proof of its efficacy, usefulness and cost-effectiveness (WZW).

In Switzerland, it is considered that there is limited evidence for the efficacy of cannabis in the treatment of chronic pain, nausea in chemotherapy and spasms in multiple sclerosis, etc. Accordingly, no medicinal product, not even Sativex®, is on the FOPH's list of specialties for

reimbursement by the compulsory health insurance.

Only in cases of hardship, and upon request for a cost approval by a physician, is reimbursement by the OKP of a medicinal product not listed in the SL possible. It is considered a case of hardship if the use of the product is expected to provide a major therapeutic benefit against a disease that may be fatal for the insured person or result in severe and chronic health impairments, and no other effective and approved treatment method is available due to a lack of therapeutic alternatives. It remains to be seen whether an amendment to the NarcA, which was adopted by the Swiss Parliament on 19 March 2021, will provide relief in terms of reimbursement by the OKP. Unfortunately, the adopted amendment does not envisage an adjustment to the reimbursement requirements.

A Health Technology Assessment report (HTA) that was published on 30 April 2021, on behalf of the FOPH, was prepared to clarify the scientific evidence regarding the efficacy and cost-effectiveness of medical cannabis products and to differentiate between the various patient groups. Unfortunately, the HTA ultimately decided that the efficacy data on medical cannabis use for chronic pain and spasticity was inconsistent (ie, studies with comparable patient populations and similar type of medical cannabis did not show consistent results pointing in the same direction) and inconclusive (ie, none of the studies was able to draw a definitive conclusion on the efficacy of medical cannabis). As a result, the WZW criteria for medical cannabis have not been confirmed.

Cannabis Products with a THC content of Below 1%

Cannabis products with a THC content below 1% are not captured by the scope of the NarcA. Of all the known cannabinoids in the cannabis plant, CBD stands out as the most prominently marketed cannabinoid in the cannabis market. On 21 April 2021, Swissmedic, the FOPH, the Federal Food Safety and Veterinary Office (FSVO) and the Federal Office for Agriculture (FOAG) jointly released an updated version of Products containing cannabidiol (CBD): Overview and implementation guide, the main elements of which are set out below.

CBD products can only be marketed legally if they comply with the Swiss legislation that is applicable to their respective classification. The range of CBD-containing products is extensive and includes raw materials such as cannabis buds or flowers with a high CBD content, extracts in the form of oils or pastes, ready-to-use products such as capsules, food supplements, liquids for e-cigarettes, tobacco substitutes, scented oils, chewing gums and ointments, some of which are offered as personal care products.

In order to determine the applicable legislation, the product must be assigned to the corresponding product category based on the relevant factors such as composition, intended use and dosage.

As an initial step, however, it must be determined whether the CBD product is a raw material or ready-to-use product. CBD products considered as raw materials are governed by the Chemicals Act and the Chemicals Ordinance. If no intended use can be determined for a cannabis-based raw material, it should be placed on the market in accordance with the legislation governing chemicals. Lastly, the Federal Act on Product Safety (PrSG) acts as a fallback catch-all legislation for products for which there is no other specific applicable law.

CBD offered as chemicals

CBD-containing products may be marketed legally as scented oils. Manufacturers must clas-

sify, package and label the product in accordance with the provisions of the Chemicals Ordinance (ChemO) after having assessed that substances or preparations they intend to place in the market do not endanger human life, health or the environment.

However, if the presentation of the products indicates, or suggests, other uses that are covered by other legal provisions, their marketability must be assessed according to these provisions. This may be the case, for example, if a "scented oil" is sold in a cartridge for e-cigarettes, in which case foodstuffs/utility articles legislation applies for the assessment of marketability. The same would apply if cannabis oils containing full spectrum hemp extracts would be labelled as having a specific nutritional value, for example.

The requirements of the general ruling issued by the Swiss Chemicals Notification Authority on 24 March 2022, must also be taken into account. According to this general ruling, CBD-containing scented oils (ie, ready-to-use products) may now only be placed on the market or sold to consumers if they contain a denaturant in a suitable concentration to prevent misuse (ie, oral application).

CBD sold as medicinal products

Ready-to-use CBD-containing products with a medical intended use are regarded as medicinal products under the TPA, which require authorisation by Swissmedic to be placed on the market. Companies that manufacture, distribute or dispense medicinal products containing CBD always require a corresponding authorisation from Swissmedic or the respective canton.

Epidiolex®, a ready-to-use CBD monopreparation prescribed for the adjuvant treatment of two rare forms of epilepsy, was approved by the United States Federal Drug Administration (FDA) on 28 June 2018. This was the first time a ready-to-use CBD medicinal product has been approved anywhere in the world. Recently, on 10 February 2021, the same preparation was approved in Switzerland under the name of Epidyolex®.

Pharmacies can also prepare and dispense CBD containing medicinal products as extemporaneous preparations (ie, as a magistral formula), based on a prescription of a specialised physician in Lennox-Gastaut syndrome and Dravet syndrome or other treatment-resistant forms of epilepsy. The medicinal product must be prepared with CBD that has been produced in compliance with GMP to a quality standard that, as a minimum, satisfies the requirements of monograph C-052 cannabidiol of the current German Drug Codex DAC/NRF and the preparation itself at the pharmacy level must comply with the GMP requirements of the current Pharmacopoea Helvetica (Ph. Helv.).

CBD sold as cosmetics

According to the Ordinance on Foodstuffs and Consumer Products (LGV), cosmetic products are broadly defined as "substances or preparations intended to come into external contact with certain parts of the human body, such as the skin, the hair system, the nails, the lips or external intimate regions, or with the teeth and the mucous membranes of the oral cavity, for the sole or predominant purpose of cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or influencing body odour" (unofficial translation).

Cosmetic products must be safe, and the safety of the individual ingredients must be documented in a safety report. References of any kind to disease-curing, disease-soothing or disease-preventing effects of cosmetics (eg, medicinal or therapeutic properties) are prohibited.

CBD has gained widespread popularity as an ingredient in cosmetic products in recent years (skin care oil, skin cream, lip care oil, mouthwash, toothpaste, bath capsules, mouth spray, dental gum, etc). The use of synthetic CBD is not specifically regulated and can be used in the formulation of cosmetic products if the requirements set forth in the LGV are met.

Regarding the use of naturally derived CBD in cosmetics – ie, CBD derived from the cannabis plant – the Implementation Guide provides as follows.

Article 54 (1) LGV refers to the list of substances prohibited in cosmetic products in Annex II of Regulation (EC) No 1223/2009 on Cosmetic Products, Entry No 306, which reads: "Narcotics, natural and synthetic: All substances listed in Tables I and II of the single Convention on narcotic drugs signed in New York on 30 March 1961".

Schedule I of the signed Single Convention on Narcotic Drugs of 1961 (the Single Convention) lists cannabis, cannabis resin, cannabis extracts and cannabis tinctures. According to the definition in Article 1 of the Single Convention, "cannabis" means "the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated". "Cannabis resin" is further defined in the Single Convention as "the separated resin, whether crude or purified, obtained from the cannabis plant".

The Implementation Guide goes on to conclude that, therefore, the use of "cannabis" or non-deresinated flowering or fruiting tops of the cannabis plant and products made from them (eg, hemp extracts, CBD) are prohibited in cosmetic products. Cannabis resin obtained from any part of the cannabis plant can also not be used to introduce CBD into cosmetics. Seeds and leaves not accompanied by the flowering or fruiting tops, however, can be used to produce cosmetics.

On 19 November 2020, the European Court of Justice (ECJ) concluded in its judgment C-663-/18 (the Kanavape case) that CBD extracted from the fruiting or flowering tops of the cannabis plant, and not only from the seeds and leaves, "is not a drug within the meaning of the Single Convention". The ECJ clarified that "since CBD does not contain a psychoactive ingredient in the current state of scientific knowledge […] it would be contrary to the purpose and general spirit of the Single Convention to include it under the definition of 'drugs' within the meaning of that convention as a cannabis extract". It is to be expected that a similar/analogous decision will also be made by the Federal Supreme Court of Switzerland in the near future.

Cosmetic ingredients have an international designation, an INCI term (International Nomenclature for Cosmetic Ingredients). Each ingredient is also listed in the Central European Register of Cosmetic Ingredients (CosIng) either with or without restriction. Following the publication of the decision in the Kanavape case and upon request of the European Industrial Hemp Association (EIHA) to lift the existing restriction on the use of cannabis extracts in cosmetic products, the European Commission has lifted the restriction on CBD and has revised the entry as follows: "Cannabidiol – derived from extract or tincture or resin of cannabis". It recently did the same for cannabigerol, or CBG, which is another known minor constituent of cannabis. While the CosIng database is not legally binding, the listing of ingredients is regarded by authorities and courts in the EU member states as a strong indication of their legality in cosmetic products.

While cannabis resin is clearly defined as a narcotic under Swiss law, cannabis extracts are exempt from the NarcA if their THC content is 1% or above. (However, this qualification will change due to the approved interpellation of Ms Léonore Porchet, a member of the Swiss Parliament, and so cannabis resin will also follow the typical limitation requirement of 1% THC content.)

In view of a harmonisation with recent practice in the EU, as well as the ECJ's conclusion that "it would be contrary to the purpose and general spirit of the Single Convention to include CBD under the definition of 'drugs' within the meaning of that convention as a cannabis extract", it would be desirable and, in the authors' view, in line with current legislation to reconsider the described practice in the Implementation Guide to the effect that CBD derived from cannabis extracts from the flowering and fruiting tops should also be allowed in cosmetic products.

CBD sold as utility articles

CBD-containing liquids for e-cigarettes are classified as utility articles that come into contact with mucous membranes under the Federal Act on Foodstuffs and Utility Articles (Foodstuffs Act, FSA) as well as the LGV, may be sold unless they release substances in quantities that pose a risk to health. It is further not permitted, in principle, to add CBD to liquids for e-cigarettes in pharmacologically effective doses.

However, this rule is superseded by the requirements of the Cassis De Dijon principle, according to which CBD-containing liquids may be sold in Switzerland if they have been lawfully placed on the market in an EEA or EU state. In addition, since the regulations on technical barriers to trade aim to prevent discrimination against domestic suppliers compared to internationally operating suppliers, CBD-containing liquids may currently be lawfully marketed in Switzerland (and, at the latest, after the new Tobacco Products Act enters into force in summer 2023).

Refill containers for e-cigarettes containing CBD are subjected to the provisions of the chemicals legislation. Distributors must carry out self-regulation and implement labelling and reporting obligations (product registration for chemicals).

On a side note, it may be added that paraphernalia and smoking accessories such as bongs, vaporisers, grinders (without CBD) may be sold without restriction if they comply with the FSA, the LGV and the PrSG.

CBD sold as tobacco substitutes

Hemp with a total THC content of less than 1% does not fall under the NarcA and can be sold as a tobacco substitute for smoking. Tobacco substitutes are a part of Swiss food legislation and are subject to the Tobacco Ordinance (TabV), independent of the Swiss Federal Tribunal's decision that hemp containing CBD is not considered a tobacco substitute according to the Tobacco Tax Act (TStG).

Therefore, it is lawful to sell tobacco substitutes containing CBD or other cannabinoids as dried flower, buds, or as cigarettes/cigars, for example. However, existing food legislation must be observed, which includes the obligation to self-regulate and to notify the FOPH before placing products on the market.

According to the TabV, tobacco substitutes must satisfy the prerequisites applicable to the smoked tobacco products they replace (eg, herbal cigarette packaging must contain photographic warnings). The substitutes must not pose a direct or unexpected threat to health.

In summer 2023, the new Tobacco Products Act (TobPA) will enter into force. Under the TobPA, all tobacco-based and similar products (ie, with

a similar purpose) will therefore be regulated under the TobPA and Swiss food law (according to the LMG, LGV, etc) will no longer apply to such products.

CBD sold as foodstuffs

The use of non-controlled cannabinoids in foodstuffs will be discussed in **3.2 Use of Non-controlled Cannabinoids in Food**, which will also include some comments on the consumption of THC.

Reform of Switzerland's hemp seed legislation

As of 1 January 2021, all provisions of the seed legislation relating to the production and sale of hemp seed and seedlings, which includes cannabis with a THC content of below 1%, were repealed. Previously, only approved varieties of hemp grown for oil and fibre that were listed in the Federal Office of Agriculture's (FOAG) varieties ordinance or the EU's Common Catalogue of Varieties, which is still in force, could be placed on the market for commercial use in agriculture. This is a significant competitive advantage for Switzerland as an innovation hub for the development of hemp seeds and varieties as compared to the EU.

For the agricultural production of hemp, the provisions of the plant health legislation and the direct payments legislation must be respected; for the use of hemp as animal feed, the provisions of the Animal Feed Law must be observed.

1.2 Regulatory Authorities

Switzerland is a federal state, which means that powers are divided between the Confederation, the cantons, and the communes, according to the principle of subsidiarity. The Confederation, in principle, only undertakes tasks that the cantons are unable to perform, or which are expressly allocated to the Confederation by the Federal Constitution.

As discussed in **1.1 Source of Regulations**, regulations affecting the cannabis market span a very wide spectrum of the law. It would go beyond the scope of this guide to describe the authorities responsible for enforcement on both a federal and cantonal level for each area of law. However, a short overview will be provided of the enforcement authorities in the laws related to narcotics, therapeutic products, foodstuffs and utility articles (which includes cosmetics) and chemicals.

Enforcement of the NarcA

As a result of Switzerland's federal political system, the cantonal law enforcement agencies (ie, the public prosecutor's office) are principally charged with enforcing the NarcA, with the help of the police.

The clear statement of the law that the enforcement of the NarcA lies within the competence of the cantonal law enforcement agencies was relativised by the fact that it had always been assumed that the narcotics sector was subject to special supervision by the Confederation. Consequently, the Office of the Attorney General of Switzerland could, under certain circumstances, order investigations itself if the criminal acts were committed in whole or in part abroad or in several cantons. This competence continues to exist. Thus, there is a parallel investigative competence of the Confederation in this area.

The Confederation exercises oversight over the implementation of the NarcA. It conducts controls at the border (import, transit and export) and in customs warehouses and bonded warehouses. The Confederation and the cantons work together to fulfil their tasks under the NarcA and co-ordinate their work; they may call on the assistance of other organisations concerned.

Non-compliance with the NarcA is a criminal offence. Under the NarcA any person who

without authorisation, among others, cultivates, produces, stores, sends, transports, imports, exports, or carries in transit narcotic substances, possesses, keeps, buys, acquires or otherwise obtains narcotic substances, etc, is liable to a custodial sentence not exceeding three years or to a monetary penalty.

As mentioned in **1.1 Source of Regulations**, medicinal cannabis products with a THC content of 1% and above may be prescribed with a special authorisation by the FOPH, which develops Switzerland's health policy and works to ensure that the country has an efficient and affordable healthcare system in the long term.

Enforcement of the TPA

Swissmedic is responsible for the duties assigned to it by the TPA. It is involved in the entire life cycle of a medicinal product through its duties in the areas of authorisation, approval and monitoring of medicinal products. Swissmedic is run by the Confederation with the co-operation of the cantons, as an institution under public law with its own legal personality.

It is important to note that Swissmedic's areas of responsibility are closely related to those of other authorities or implementing bodies. For example, when it comes to the delimitation between medicinal products and cosmetics or between medicinal products and foods, where the FOPH and the Federal Food Safety and Veterinary Office (FSVO) are involved – all areas relevant for the emerging cannabis market.

Furthermore, Swissmedic has, among others, the competence to authorise ready-to-use medicinal cannabis products and to grant a licence for imports of therapeutic products (including medicinal cannabis) if the applicant complies with the requirements of the Medicinal Products Licensing Ordinance.

In simplified terms and on a cantonal level, the Cantonal Office for the Control of Therapeutic Products (*Kantonale Heilmittelbehörde*) in Zurich for example is divided in three operative units: the inspectorate, the laboratory and the administration. The *Kantonale Heilmittelbehörde* in Zurich is responsible for the control of the production, wholesale trade and dispensing of therapeutic products, the market surveillance of therapeutic products (which includes marketability reviews and conformity tests in accordance with recognised pharmacopeias), the granting of cantonal licences for the dispensing of medicinal products (pharmacies, drugstores etc), the issuance of professional and narcotic licences and other tasks. The cantonal pharmacy is mandated to secure a high quality and economical supply of therapeutic products to hospitals, a wide range of institutes and the general population. In the Canton of Zurich, the cantonal pharmacy is also responsible for the production of a wide range of pharmaceutical products. Other cantons have similar structures.

In terms of enforcement, non-compliance with the TPA may lead to a series of administrative (including disciplinary) and penal actions on both the federal and cantonal level.

Enforcement of the FSA

According to the LGV, business operators who manufacture, process, treat, distribute, import, or export food, food additives or utility articles must exercise self-control and designate a responsible person who appropriately documents compliance with the requirements of the FSA/LGV. This includes the obligation to secure good manufacturing procedures, the implementation of quality management systems as well as the obligation to withdraw or recall unsafe food, if applicable.

On its website, the Swiss Association of Cantonal Chemists (ACCS) published a useful list

of local law enforcement authorities for food and utility articles in Switzerland. In Zurich, for example, the Cantonal Laboratory is responsible for the implementation of food safety regulation, including the control of reporting and permitting obligations, as well as the implementation of special protective regulations of non-food or utility articles such as cosmetics.

Authorities charged with the implementation of the FSA and its many ordinances have a wide range of administrative measures they can impose on non-compliant market participants.

1.3 Self-Regulation

While there are numerous organisations that act as self-regulatory bodies to the cannabis industry in Switzerland, three groups stand out in particular.

The Interest Group Hemp (IG Hanf)

Interest Group Hemp (IG Hanf) is an association representing the Swiss hemp industry and its members in politics, before authorities and in public. It is by far the largest interest group of market participants in the cannabis industry in the country. The association's goal is to promote exchange and co-operation among its members and thus strengthen the hemp industry in Switzerland. Its mission is to establish cannabis in society in a sustainable manner and to create a regulated cannabis market in order to ensure that Switzerland plays a leading role in the global cannabis industry.

To secure quality control among its members, the IG Hanf established the quality label "Swiss Certified Cannabis". The label guarantees products and consumer safety and determines quality standards (in accordance with ISO 9001). Specifically, the goals of the label as stipulated in the guidelines of Swiss Certified Cannabis are:

- to guarantee absolute traceability throughout the production chain;
- to ensure highest security for consumers and customers;
- to build trust with consumers, customers and authorities;
- to protect against economic damage or loss of reputation.

The Swiss Certified Cannabis label can only be used by certified companies. The application process includes:

- training by a qualified auditor;
- a certification audit on site by an independent and qualified auditor;
- a decision on the granting of the certificate based on the audit report by the board of directors of IG Hanf.

The guidelines of Swiss Certified Cannabis set standards on quality policy, production, packaging, storage, safety, control, work safety and hygiene, labour, environment and infrastructure.

Swiss Society of Cannabis Medicine

The Swiss Society of Cannabis in Medicine's (SGCM-SSCM) goal is to promote the acceptance of cannabis as a therapeutic product, its legal regulation, as well as its clinical implementation in close co-operation with the FOPH. As an umbrella organisation for professionals from medicine, pharmacy, pharmacology, research and industry, its declared goal is to foster the scientific, rational and destigmatised use of medicinal cannabis as well as the simplified, unbureaucratic access to therapies with medicinal cannabis.

Its task is to serve as the Swiss interdisciplinary knowledge and information platform for the medical use of cannabis and cannabinoids and as a networking platform for a wide range of professionals, care-givers, interest groups, etc. The

organisation further promotes basic and clinical research and collects valuable data, based on which it elaborates medical recommendations for the most relevant treatment principles. SGCM-SSCM is the Swiss ambassador of the IACM (International Association for Cannabinoid Medicines).

Medcan

Medcan advocates for the interests of patients in Switzerland who take cannabis as a medicine, and provides information on the use and effects of the medicinal plant. The association pursues the goal of ensuring that patients in Switzerland have legal access to cannabis without a great deal of bureaucracy and can use it medically in tested quality and at reasonable prices. Moreover, it demands from the FOPH to further educate physicians regarding possible indications and dosages and to minimise the bureaucratic effort to obtain medicinal cannabis. Medcan advocates on a political and on a public level for people who use cannabis for medical purposes.

1.4 Key Challenges

The cannabis market faces tremendous challenges such as inconsistent cannabis and cannabinoids terminology, significant differences in enforcement between cantons as well as a constantly changing regulatory environment.

The most obvious challenge market participants face is that cannabis is considered a narcotic drug if the THC content exceeds 1%. Consequently, all efforts by market participants to legally bring products to market are biased by the default assumption that cannabis is an illicit drug. This negative bias leads to heightened scrutiny by enforcement agencies and is not particularly conducive to the success of an emerging new industry.

A practical example of a wide-spread confusion in the market is the classification of "CBD pollinate". As mentioned in **1.1 Source of Regulations**, cannabis resin is defined in the Single Convention as "the separated resin, whether crude or purified, obtained from the cannabis plant". Cannabis resin is further separately listed in the BetmVV-EDI and is considered a controlled narcotic independent of its THC content. (However, this will be adjusted in 2022 and aligned with the overall limitation of 1% THC content.)

In contrast to cannabis resin, however, pollinate (hemp flower pollinate) consists of fine CBD hemp flower components that fall off when the biomass is shaken into drums (known as pollinators). The production of hemp flower pollinate is based exclusively on a process where the flower components of the cannabis plant, which are freely marketable, are intensively refined and extracted, resulting in a powder called hemp flower pollinate. At no point in this process is the resin content explicitly increased. The resin content (consisting of trichomes) of these products is the same as in CBD flowers. The resin is thus not secreted from the flower but is still in the very small flower components. Yet, many market participants had significant quantities of their pollinate production confiscated and destroyed, which has caused widespread legal insecurity and economic damage.

The classification of pollinate as cannabis resin is debatable and remains to be clarified by higher instance courts or, ideally, by lawmakers. CBD pollinate is often exported into the EU and, in most cases, has a THC content of less than 0.2%. This is just one example of how confusing it can potentially be to bring cannabis products to market.

Furthermore, some of the most challenging aspects of the cannabis market come to the surface where various areas of the law overlap. The development of a new product can be very challenging when it is unclear, for example, whether

it is governed by therapeutics or cosmetics law. A chewing gum containing CBD could be many things – for example, a therapeutic product, a cosmetic product or a foodstuff. Defining the product category and abiding by all regulatory requirements while considering pertinent case law can only be managed with a detailed technical and legal assessment.

Reference can be made to two very useful guides that can help, to some extent, navigate these complexities. Firstly, the guide on Demarcation criteria therapeutic products – foodstuffs with regard to products to be taken orally published jointly by Swissmedic and the FSVO; secondly, the guide on Criteria for the demarcation of cosmetic products from therapeutic products and biocidal products, jointly issued by Swissmedic, the FOPH and the FSVO.

Another main challenge in the CBD market is the classification of cannabis extracts or tinctures (CBD oils). They can be qualified as raw materials or as ready-to-use products. While in practice, most consumers are ingesting CBD oils, such oils cannot be marketed as foodstuff or nutritional supplements without authorisation of its components as novel food by the FSVO or the European Commission (EC). No company in Switzerland, or in the EU, has obtained such authorisation to date.

Another key challenge for participants in the medical cannabis industry is to place a medicinal cannabis product on the market. In view of the revision of the NarcA, which is thoroughly described in the Trends & Developments article, and the lifting of the export ban for cannabis for medicinal purposes, the market for medicinal cannabis should be more accessible for companies in the future.

The above examples of key challenges do not touch on the many complexities surrounding international trade of medicinal and recreational cannabis products, and a whole range of other issues and uncertainties that participants in the cannabis market must deal with.

1.5 Level of Regulation

Cannabis-specific regulations in Switzerland are, with few exceptions, limited to narcotics and criminal law. Legal uncertainty is still prevalent in production, trade and consumption of cannabis products of all kinds (cosmetics, foodstuffs, medicines, recreational use), as is inconsistent cantonal enforcement.

In other jurisdictions – such as in many US states where medical and recreational cannabis has been legalised – the cannabis market is meticulously regulated. Other countries are following suit with various regulatory models (eg, Canada, Uruguay).

Considering these developments, a revision of Switzerland's approach to cannabis regulation appears warranted, as was recently proposed in a postulate submitted to the Council of States on 18 March 2021 by Thomas Minder, a member of the Council of States. Specific cannabis-related legislation could bring legal certainty throughout the value chain and secure efficient quality control measures. An allocated taxation of cannabis products could generate state revenues and secure the financing of already necessary prevention and health measures, particularly for the protection of youth.

At the same time, cannabis legislation concerning THC limits in Switzerland is considered rather progressive if compared to the EU and the USA, where the threshold from legal cannabis (or hemp in the USA) to a narcotic drug (which in some states in the USA is legalised) is passed when the THC levels surpass 0.2% or 0.3%, respectively. Also, the Ordinance on the Maximum Levels of Contaminants (VHK) allows

for significantly higher values of THC intake from food than the THC values in the EU. Switzerland has further repealed all provisions of the seed legislation relating to the production and sale of hemp seed and seedlings and is no longer bound by the EU's Common Catalogue of Varieties.

In view of the latest developments in legislative reform of the NarcA regarding medicinal cannabis, as well as cannabis trials for recreational purposes, Switzerland is well positioned to further expand its regulatory edge in the emerging European cannabis industry.

1.6 Legal Risks

Companies and individuals in the cannabis market must navigate a complex web of interrelated, constantly changing areas of law. Non-compliance with existing laws and regulations may lead to indictments for criminal offences, to administrative penalties and potentially to civil damage claims.

Recent enforcement measures by authorities were, for example, the shutdown of a retailer's website for publishing health claims in connection with CBD products, and the imposition of a marketing ban for specific CBD oils.

However, special attention must be paid to the compliance with the NarcA. Cannabis resin is illegal independent of its THC content. Furthermore, cannabis products with a total THC content below 1% must meet the specific requirements of the Therapeutic Products Act, the Foodstuffs Act, the Ordinance on Foodstuffs and Utility Articles, the Chemicals Ordinance and the Tobacco Ordinance, among others, depending on the classification of the product placed on the market. It should be noted that not only the NarcA but also other acts such as the TPA provide for penal provisions.

1.7 Enforcement

Please refer to **1.4 Key Challenges**.

2. CROSS-JURISDICTIONAL ISSUES

2.1 Cross-Jurisdictional Standards

In Switzerland, only cannabis with a THC content below 1% can be exported. The cannabis legislation of the importing country must therefore be complied with. Generally, in the EU, cannabis-products with a THC content of 0.2% and above are considered narcotic drugs and thus cannot be imported, except for medical purposes with a special permit from local authorities.

A revision of the NarcA which was adopted on 19 March 2021 will allow for exports of medical cannabis with a THC content of 1% and above. It is estimated that the revised law will be enacted in the autumn of 2022. Further details can be found in the Trends & Developments article.

Importers of cannabis products with a THC content of 1% and below must be able to provide proof in the form of a batch-specific analytical certificate for the delivery in question issued by a laboratory accredited to ISO/IEC 17025 or by a GMP laboratory.

3. FUTURE DEVELOPMENTS

3.1 Legal Elements Affecting Access to Medical Cannabis

The main elements affecting medical cannabis in Switzerland are described in the Trends and Developments article, along with an overview of impending changes to the current regulatory framework.

3.2 Use of Non-controlled Cannabinoids in Food

The FSA sets forth the rules on the safety and transparency of foodstuffs and utility articles. According to the FSA, foodstuffs are all substances or products that are intended (or may reasonably be expected) to be consumed by human beings in a processed, partly processed, or unprocessed state. Medical products, narcotics and psychotropic substances do not fall under the definition of foodstuffs, and the other way around.

Except for a few reservations (eg, novel foods), non-described foods without an authorisation can be placed on the market, provided they meet all the requirements of food law.

Under certain circumstances, which will be described below, cannabis products may also be used in foodstuffs. The main tenet in foodstuffs law is that foodstuffs must be safe – in other words, they must neither be harmful to health nor unsuitable for human consumption.

Novel Foods

For foodstuffs that have not been used for human consumption to any significant extent, either in Switzerland or in an EU member state before 15 May 1997 – so-called "novel foods" – an authorisation by the Federal FSVO or an approval by the European Commission (EC) is required. This applies to extracts of *Cannabis sativa L.* that contain cannabinoids such as cannabidiol (CBD) and food products enriched with extracts of *Cannabis sativa L.* or with cannabinoids such as CBD (eg, hemp seed oil with added CBD, food supplements with CBD), which are classified as novel foods and therefore require an authorisation.

Products of *Cannabis sativa L.* or parts of plants that had a safe and documented significant use as food in the EU before 15 May 1997, are not considered novel foods in Switzerland provided they originate from an approved plant of *Cannabis sativa L.* This is particularly the case for hemp seeds, hemp seed oil, hemp seed flour and defatted hemp seeds.

Furthermore, in Switzerland, herbal tea made from leaves of the hemp plant *Cannabis sativa L.* is also not considered a novel food. However, the production, import or market placement of herbal teas obtained from the herb of the cannabis plant is possible if one furnishes proof that the herbal tea was already consumed as a foodstuff to a significant degree prior to 15 May 1997, and is therefore not classified as a novel food. Novel foods that do not require an authorisation are listed in the FDHA Ordinance on Novel Foods.

Authorisation

As part of the authorisation procedure for novel foods, the FSVO examines whether the product is safe and not deceptive. The basic prerequisite for approval is that the product is classified as a foodstuff and is not covered by the legislation on medicinal products. In the case of foodstuffs containing cannabis, the Ordinance on the Maximum Levels of Contaminants (VHK) is relevant. It regulates the maximum permissible levels of delta 9-tetrahydrocannabinol in foodstuffs (which are generally higher than in the EU).

It is important to note that all foods which, in accordance with the Novel Food Regulations (EC) No 258/97 and (EU) 2015/2283, may be placed on the market in the EU are fundamentally also marketable in Switzerland (except for genetically modified foods). To place foodstuff with CBD on the European market presupposes the application for authorisation to the European Commission. If the application is granted, foodstuff containing CBD can be also placed on the Swiss market. Hence, the authorisation from the European Commission entails the advan-

tage that the foodstuff can be placed on both the European and the Swiss markets. However, the reverse situation does not apply. Foodstuffs that are not novel foods in Switzerland or have been authorised as such in Switzerland and are classified as a novel food in the EU require an authorisation from the European Commission for market placement in the EU.

Lastly, authorisations are generally not issued for composite foods. The authorisation requirement always relates to a substance, not to a composite product containing a novel food as an ingredient.

The EIHA Consortium

The European Industrial Hemp Association (EIHA) is Europe's largest association that represents the common interests of hemp farmers, producers, and traders working with hemp fibres, shives, seeds, leaves and cannabinoids.

In 2019, EIHA created a Novel Food Consortium with the aim of submitting a joint novel food application both to the UK Food Safety Authority for the British market as well as to the European Food Safety Authority (EFSA) for the EU market (which, as mentioned above, would include Switzerland), the costs of which will be shared among its members. It is estimated that the consortium will invest up to EUR3.5 million for financing all relevant and unprecedented toxicological studies on CBD and THC with the help of a qualified service provider (ChemSafe).

A whole range of cannabinoids containing ingredients will be tested to ensure all food products using these ingredients will be covered by the joint application. For the purpose of the application, a corporation under German law was founded (EIHA projects GmbH), which collects the special contributions to finance the project and ultimately acquires the rights for the distribution of the approved products. EIHA projects GmbH will manage these rights and transfer them to EIHA members, with an established sublicensing system for white label (retail) trading companies.

Swiss companies aspiring to develop and bring cannabis-based food products to market are advised to evaluate a participation in the EIHA Consortium.

3.3 Decriminalisation or Recreational Regulation

The latest developments regarding a potential legalisation of cannabis use for recreational purposes can be found in the Trends and Developments article.

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Trends and Developments

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Introduction

The current regulatory environment surrounding cannabinoid-based products in Switzerland is still marked by a high degree of uncertainty, due both to vague legislative requirements and heterogenous, sometimes arbitrary, enforcement. However, with the rise of public awareness of the general benefits of the cannabis plant as a result of the cannabidiol (CBD) boom, as well as the increasing use of cannabigerol (CBG) during the last few years – plus growing anecdotal evidence from liberalised recreational markets such as Canada, Uruguay and certain US states – recent legislative developments are presenting an opportunity for Switzerland to establish itself as a role model for an innovative, pragmatic, safe and comprehensively regulated cannabis market.

Medical Cannabis Reform

The status quo

A study conducted by the Institute for Addiction and Health Research on behalf of the Federal Office of Public Health (FOPH), the findings of which were published in February 2020, concluded that for over 96% of the participants questioned, the consumption of medical cannabis has led to an improvement of their symptoms. Half of the participants reported an "extreme improvement". A large part of the participants who already had prescriptions for cannabinoid-based medicines reported that they were able to either completely abandon other prescribed drugs, or at least strongly reduce their consumption.

Around 3,000 patients are legally prescribed medical cannabis in Switzerland today. The FOPH estimates that over 110,000 patients are consuming "medical" cannabis illegally – that is, sourced from the black market – which exposes them to significant health risks due to the lack of quality control and a growing number of cut and contaminated products in circulation. This number does not include the number of recreational cannabis consumers, which is, by a conservative estimate, a threefold of the FOPH figure.

Cannabis with a THC (tetrahydrocannabinol) content of 1% and above is considered a prohibited narcotic in Switzerland. Under very restrictive circumstances, cannabis with a THC content above 1% may be prescribed for medical purposes, but it requires an exceptional permit from the FOPH. However, the Swiss Parliament approved an amendment to the law to facilitate access to cannabis medicines on 19 March 2021, which essentially states that in the future (ie, from autumn 2022, as expected) cannabis for medical purposes will be possible without any exceptional permit from the FOPH. The adopted amendment to the law facilitates access to cannabis medicines for thousands of patients as part of their treatment. This mainly affects cases of cancer or multiple sclerosis, where cannabis-containing medicines can alleviate chronic pain.

As the currently most-researched cannabinoid, THC is predominantly used for chronic pain conditions, spasticity and spasms, as well nausea and loss of appetite (mostly in the context of chemotherapy). Ready-to-use medicinal products may only be marketed in Switzerland if they are approved by Swissmedic, the Swiss Agency for Therapeutic Products.

At present, in Switzerland, only two ready-to-use medicinal products based on cannabis have

been approved by Swissmedic, one of which is Sativex®, with a THC content of above 1%. Sativex can be prescribed without special permit for spastic convulsions in multiple sclerosis patients. For any other indication, an exception permit by the FOPH must be obtained (ie, for "off-label-use").

The second medicinal product is Epidyolex, a CBD-based drug that was approved by Swissmedic on 10 February 2021. Epidyolex contains the active substance cannabidiol, which can be used for the treatment of seizures (epilepsy). Epidyolex is an oral solution. It is used in combination with other medicines in patients aged two years and older with Lennox-Gastaut syndrome or Dravet syndrome; both syndromes are rare diseases associated with seizures and fits (epilepsy).

If an approved preparation is unsuitable, physicians can prescribe cannabis as a drug which is exempt from approval by Swissmedic, but which still requires a special permit by the FOPH. The drug is then usually produced by a pharmacy on a doctor's prescription as a so-called "extemporaneous preparation" – ie, a "formula magistralis" – which is how most cannabis is prescribed in Switzerland today.

Applying for a special permit at the FOPH is burdensome, both for the physician and the patient. Although most applications are granted, the surge of applications in the last few years no longer justifies the special treatment of medical cannabis as a prohibited narcotic. This realisation has led to a revision of the current regime and the required amendments to the Federal Act on Narcotics and Psychotropic Substances (NarcA), which the Swiss Parliament recently adopted (on 19 March 2021).

The amendment of the NarcA

The main features of the legislative amendment are as follows.

- The ban on marketability of medical cannabis will be lifted. Medical cannabis will be reclassified as a controlled narcotic with restricted marketability. Cultivation, processing, production and trade will be subject to the authorisation and control system of Swissmedic, in the same way as other narcotics that are used in a medical context, (eg, morphine).
- A special permit by the FOPH will no longer be required to prescribe medical cannabis. In other words, every doctor in Switzerland will be able to prescribe medical cannabis.
- During the first few years after the coming into force of the amendment, doctors will have to regularly report to the FOPH a whole range of data regarding the therapies. The data collection will serve as a basis for the scientific evaluation of the revision as well as guidance to the responsible cantonal enforcement authorities and the prescribing physicians.
- Commercial exports of medical cannabis will be made possible.

Apart from the Narcotics Act, executive ordinances will also be amended. According to the current wording of Swiss law, cannabis resin (hashish) is considered a narcotic drug that is subjected to the Narcotics Act independent of its THC content, (ie, even if the THC content is below 1%). However, in its statement of 16 February 2022 on a respective motion, the Federal Council announced the amendment of the ordinance so that the THC threshold of 1% will also be applicable for cannabis resin in the future.

Reimbursement by compulsory health insurance

Unfortunately, treatment with medical cannabis products is not covered by the compul-

sory health insurance (OKP) due to insufficient scientific evidence regarding the efficacy and cost-effectiveness of these medicines (and this will not change after the entry into force of the aforementioned revision), especially for extemporaneous preparations. Such medicines are reimbursed by the health insurance providers in consultation with the physician on an exception basis only.

The major challenge regarding the adopted amendment is that the law does not envisage adjusting the current requirements for reimbursement by the OKP. According to Medcan, Switzerland's largest medical cannabis patient's association, the costs of treatment with medical cannabis can range from CHF450 to over CHF10,000 per month.

A Health Technology Assessment report (HTA) that was published on 30 April 2021, on behalf of the FOPH, was prepared to clarify the scientific evidence regarding the efficacy and cost-effectiveness of medical cannabis products and to differentiate between the various patient groups. Unfortunately, the HTA ultimately decided that the efficacy data on medical cannabis use for chronic pain and spasticity was inconsistent (ie, studies with comparable patient populations and similar type of medical cannabis did not show consistent results pointing in the same direction) and inconclusive (ie, none of the studies was able to draw a definitive conclusion on the efficacy of medical cannabis). As a result, the WZW criteria for medical cannabis have not been confirmed, which leaves the issue of reimbursement by healthcare insurance unresolved.

Commercial opportunities

The amendment to the NarcA presents entrepreneurs with a range of new and exciting commercial opportunities, such as:

- cultivation of medical cannabis in Switzerland (with a special permit by Swissmedic when the amendment has been enacted);
- further research into new plant varieties and traits as well as cannabinoid development;
- innovative research and development of cannabinoid-based drugs;
- development of new delivery methods, including vaporisers, dry powder inhalers, slow-release tablets, etc;
- establishment of a cross-border medical cannabis marketplace with a surge in imports as well as exports;
- development of software tools for quality assurance, seed-to-sale traceability solutions as well as documentation standards (GACP, GMP, etc);
- education platforms for physicians, patients and the general public.

Many more opportunities will arise in this growing and fast-moving industry. The success of the adopted amendment, the purpose of which is first and foremost a facilitated access to medical cannabis for patients, will hinge on whether these patients will be able to obtain reliable, quality-controlled, safe and affordable medical cannabis products.

Tiptoeing in Cannabis Legalisation: the Recreational Pilot Trials

Cannabis is the most frequently consumed illegal substance in Switzerland. Around one-third of people aged 15 years and over have already had experience with the drug. According to the FOPH and Addiction Monitoring Switzerland, approximately 7.7% of the population used cannabis at least once during the last 12 months, and 4% in the last 30 days.

Repression has never been effective in curbing cannabis consumption or in eliminating the black market. Legislators in Switzerland arrived at the conclusion that alternative regulatory

options must be examined. At its meeting on 31 March 2021, the Federal Council adopted the Ordinance on Pilot Trials as per the NarcA, which sets a detailed framework for the dispensing of cannabis products for non-medical use. On 15 May 2021, the amendment to the NarcA has come into effect. It now allows pilot testing of the controlled dispensing of cannabis for recreational purposes. From that point onwards, applications to conduct such trials can be submitted to the Federal Office of Public Health.

The amendment to the NarcA, which will remain in effect for ten years (ie, until 14 May 2031), provides the legal basis for the implementation of local and time-limited scientific pilot trials with cannabis. The pilot trials will allow consumers to legally purchase a wide range of cannabis-based products. The cannabis offered must meet high quality standards, with strict seed-to-sale transparency, and must originate from organic cultivation.

The aim of the studies is to expand knowledge on the advantages and disadvantages of controlled access to cannabis. They should facilitate the examination and documentation of the consequences on health and consumption habits of users in a scientific framework and provide data on the effects on the local illicit drug market, as well as on the protection of minors and public safety.

In more detail, the pilot trials must meet the following main requirements.

- Pilot trials are limited in time (five years, with an option to extend by another two years), location (one or several municipalities), as well as number of participants (maximum 5,000 participants per trial).
- Cannabis supplied to the pilot trials has to originate in Switzerland, be in line with the Guideline on good agricultural and collection practice (GACP) of the European Medicines Agency (EMA), and be, in principle, organically produced according to the Organic Farming Ordinance of 22 September 1997; only outdoor or greenhouse production that is soil-bound is permitted (ie, indoor-grown cannabis is excluded).
- Regarding product quality, the total THC content may not exceed 20%; in products for oral intake, the THC content may not exceed 10 mg per serving. Cannabis products must not contain levels of contaminants that give rise to health concerns and must be limited to specified amounts of foreign components, microbial contaminants, mycotoxins, heavy metals, pesticides and solvent residues from extraction. Notably, the maximum levels of delta-9-THC content, as per Annex 6 of the Contaminants Ordinance of 16 December 2016, do not apply to edibles.
- Cannabis products must abide by a whole set of safe packaging and labelling requirements.
- Advertising for cannabis products remains prohibited.
- Minors under the age of 18 are excluded from the pilot trials and participants must already be consumers of cannabis products.
- The maximum amount of dispensed cannabis per participant per month may not exceed 10 g of total THC.
- Cannabis products may only be dispensed at points of sale with trained staff and adequate infrastructure, and at a price that is in line with the black market. Distribution will therefore be made possible in both pharmacies and social clubs, for example.
- Both public and private organisations can apply to the FOPH to conduct cannabis trials.
- Outside of the pilot trials, the existing cannabis prohibition with the associated penal provisions for violations of the law will continue to apply.

A long list of further requirements is detailed in the Ordinance on Pilot Trials as per the NarcA of 31 March 2021.

While the adoption of the pilot trial legislation has been positively received by the cannabis industry and is recognised as a possible further step towards a controlled liberalisation, the requirements for the cannabis products to be used in the trials poses some major challenges of which law-makers may not have been fully aware.

Most of the cannabis from the black market that is consumed today is produced indoors. In general, the indoor cannabis flower grown in a controlled environment tends to be denser, contain a higher trichome count and provide a more potent high than cannabis grown outdoors or in greenhouses, although this point is subject to repeated debate within the cannabis community. Concerns have been raised that the requirements set with regard to organic farming, which limits suppliers of the cannabis trials to soil-bound outdoor production or greenhouse operations, may thwart obtaining reliable data from the trials by failing to attract enough participants willing to try a new avenue with products to which they are not accustomed.

Other challenges may be to abide by a precise THC limit of 20% when growing outdoors where weather conditions cannot be controlled, as well as the use of clones only, as opposed to "feminised" seeds which are not compliant with the Organic Farming Ordinance but have grown popular as they can be relied on to produce female plants only and increase yield. It should be noted that no such restrictions have been imposed on cultivation of cannabis for medical purposes.

Commercial opportunities

The high bar set regarding the application process, cultivation, production, distribution and data gathering of recreational cannabis products in the context of the trials as well as the black-market pricing ceiling will leave very limited room for extracting meaningful margins for suppliers or distributors of the pilot programme. While the pilot trials allow for up to 5,000 participants, the first impressions obtained by universities and cities planning to conduct such trials is that the actual number of participants will be significantly lower – ie, in the hundreds at best – mostly for funding reasons.

However, the trials may well be a first step towards a trend in further liberalisation of the recreational cannabis market. Companies with a reliable, quality-controlled supply chain may be well-positioned to use the pilot trials to establish brand equity, create innovative new products and gather valuable experiences in a new and developing market.

Further Political Developments

Parliamentary Initiative: "Siegenthaler"

On 25 September 2020, Heinz Siegenthaler, a member of the Swiss National Council, filed a parliamentary initiative which was signed by a total of 40 members of the Swiss National Council, in an attempt to force a new and comprehensive regulation for the cultivation, production, trade and consumption of cannabis containing THC in line with the recommendations of the Federal Commission on Narcotic Drugs (EKSF). The main objectives of the initiative are the control of production and trade by governmental bodies, the separation of the medical and the non-medical markets, the drying up of the black market by lifting the prohibition, the regulation of taxation and advertising as well as cultivation for personal use.

The reasoning accompanying the original text of the initiative describes a general moral and legal inconsistency in cannabis prohibition, based on current scientific research, especially if contrast-

ed with other harmful substances such as tobacco and alcohol. The Federal Council, in a statement made on 23 May 2018, candidly admitted that the NarcA has failed to fulfil its purpose of protecting the population, considering the more than 300,000 regular cannabis consumers in Switzerland. A flourishing black market, the lack of quality controls, effective protection of youth and reliable information, as well as a growing risk of "cut" cannabis products containing artificial and toxic substances, warrant the replacement of the current prohibition with a fully regulated cannabis market that meets the requirements of Swiss addiction policy, according to the initiative.

On 28 April 2021, Switzerland's Health Commission of the National Council voted in favour of a controlled legalisation of cannabis. This was a first important political hurdle the Siegenthaler parliamentary initiative has passed. On 19 October 2021, the equivalent commission in the Council of States with an overwhelming majority of nine to two followed suit and gave the Health Commission of the National Council the green light to prepare draft legislation as proposed by the initiative.

Postulate: "Minder"

On 18 March 2021, Thomas Minder, a member of the Swiss Council of States, filed a postulate mandating the Federal Council to evaluate in a report how the various forms of cannabis could be made more economically usable and how a contemporary and comprehensive cannabis regulation could be enacted (including health, food, cosmetics, medicinal products, reasonable thresholds for driving, tobacco products and customs regulations). The goal would be to achieve more legal certainty and a more uniform enforcement throughout Switzerland regarding the production, trade and use of cannabis products. In doing so, the experience of other countries, such as the USA or Canada, which have liberalised the use of cannabis, ought to be considered.

According to the text of the postulate, there is still a great deal of legal uncertainty in the area of production, trade and consumption of hemp products of all kinds (cosmetics, foodstuffs, medicines, recreational use), as well as extremely inconsistent cantonal enforcement, and even arbitrariness.

The postulate refers to the findings in a comprehensive report issued by the Federal Commission on Narcotic Drugs (EKSF) in 2019, according to which a revision of the NarcA regarding cannabis is warranted, as is a general reorganisation of the approach towards cannabis. The EKSF highlights familiar argumentation, such as the assumption that market control with a regulated supply chain is likely to reduce health risks for consumers and that taxation would unlock much-needed capital to increase preventative measures in vulnerable populations (eg, minors and persons under guardianship).

The text concludes that it is the right time for a political discussion on a comprehensive cannabis reform, also in view of the significant economic potential of hemp in general. On 17 June 2021, the Council of States concurred with this view, and passed the motion.

The latest political developments surrounding cannabis legislation are proof that the urgency to comprehensively regulate this growing market has manifested itself in the general public consciousness. The limited view of cannabis as an allegedly harmful narcotic drug and the stigmatisation of its consumers is making way for the recognition of its significant medical potential, as well as the promising economic growth it could generate in terms of recreational and industrial use.

Contributed by: *Daniel Haymann and Daniel Donauer,* ***MLL Meyerlustenberger Lachenal Froriep Ltd***

With an already progressive regulatory framework regarding THC thresholds compared to the rest of Europe and the liberalisation of cannabis for medical purposes, Switzerland is in an excellent position to expand its leading role in Europe as an innovative, responsible and attractive hub for cannabis entrepreneurs all along the value chain.

Contributed by: *Daniel Haymann and Daniel Donauer,* ***MLL Meyerlustenberger Lachenal Froriep Ltd***

MLL Meyerlustenberger Lachenal Froriep Ltd is a leading Swiss law firm with a history dating back to 1885. The firm has grown both organically and through strategic mergers, the most recent of which was completed on 1 July 2021 between Meyerlustenberger Lachenal and Froriep. Through this merger, MLL has become one of the largest commercial law firms in Switzerland, with over 150 lawyers in four offices in the country. Two offices abroad, in London and Madrid, also provide local contact points for clients seeking advice on Swiss commercial law. Today, the firm has a strong international profile and a long-established global network. MLL combines recognised leadership and notable expertise in all areas of Swiss and international business law.

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1. LEGAL/REGULATORY FRAMEWORK

1.1 Source of Regulations

The cannabis industry is broadly split into two halves: the partially regulated CBD wellness sector, and the fully regulated medical cannabis sector.

There is no single piece of legislation that directly governs cannabis in the UK; the laws and regulations that currently govern the practices in this jurisdiction are spread across numerous statutes.

The primary laws and regulations fall into three categories:

- controlled drugs legislation;
- product class-specific legislation, applicable to the CBD wellness sector (ie, food, vape and cosmetic laws); and
- the Medicines and Healthcare products Regulatory Agency's (MHRA) pharmaceutical medicines regime for medicinal products.

Controlled Drugs Legislation

The two primary pieces of legislation from which the overarching laws stem are the Misuse of Drugs Act 1971 (MDA 1971) and the Misuse of Drugs Regulations 2001 (MDR 2001). These two pieces of legislation classify cannabis and cannabis resin as a Class B, and Schedule 1 controlled substance, respectively – meaning that a licence from the Home Office is required for all activities involving the substance, from research to cultivation.

Aside from controlling the plant itself, these statutes also clarify that certain cannabinoids (compounds contained within the cannabis plant) are controlled. The omission of cannabidiol (CBD), among other minor cannabinoids from this list, has allowed for its use commercially and in the health and wellness space as there are no penalties for using, possessing or selling it.

On 1 November 2018, the UK legalised the use of medical cannabis through the rescheduling of certain types of medical cannabis product from Schedule 1 to Schedule 2. These Schedule 2 cannabis products are referred to as "cannabis-based products for medicinal use in humans" (CBPMs), and this meant that from 1 November 2018 there was a legal route for CBPMs to be prescribed by doctors on the General Medical Council (GMC) Specialist Register.

The result of the 2018 change in law was, however, somewhat of an anti-climax in its effect. Restrictive guidelines, together with the fact that the legislative change did not authorise general practitioners (ie, first port-of-call doctors operating within the UK National Health Service, the NHS) to issue initial prescriptions, has meant that only a handful of prescriptions for CBPMs have been issued on the NHS to date.

CBD Wellness Products: Class-Specific Legislation

Consumables

CBD wellness products are subject to the same legislative framework that applies to consumable products generally.

Marketing the purported medical, nutritional or health benefits of a consumable product in the UK is regulated by transposed EU law, and the MHRA, which issues strict and very prescriptive guidance as to what may and may not be said, and this therefore applies to wellness products containing CBD.

As with other products, general product claims on CBD products are covered by the Consumer Products and Unfair Trading Regulations 2008 (CPUTR 2008).

"Novel food" rules also apply. The Novel Food Regulations ((EU) 2015/2283) (the NFR) defines a "novel food" to mean food that was not consumed by humans to a significant degree within the EU before 15 May 1997.

The NFR requires that novel foods be authorised at European Community level and provides an authorisation procedure by way of keeping a "Union List" (better known as the Novel Foods Catalogue). In January 2019, it was decided that the NFR reference to *Cannabis Sativa L.* should be extended to include the entry of cannabinoids. Therefore, any cannabis extract intended for consumption would be considered a novel food and requires authorisation before it can be sold. Only hemp seed oil extracted using traditional cold compression methods are considered not novel and, consequently, authorisation is not required for these hemp seed products.

In England and Wales, the Food Standards Agency (FSA) regulates the food market. Since the Brexit transition period came to an end, from 1 January 2021 the FSA opened its doors to receiving NFR applications for food products intended for sale in England and Wales.

In England and Wales, CBD products have previously been sold without novel foods authorisation; accordingly, in February 2020 the FSA offered forbearance to businesses that were selling products on or before 13 February 2020, namely that such businesses must have a novel foods application submitted by 31 March 2021 and duly validated if they are to continue to sell while awaiting full authorisation; all other products will be removed from shelves until they obtain full authorisation.

"Validation" is effectively an administrative check, that involves establishing that an application contains all information required by law to allow it to proceed to the authorisation process. The quality of the data is not assessed at this stage, and if any of this information is missing, the application cannot be legally validated.

The forbearance position was made clear by the FSA on 11 March 2021, when it announced that applications no longer needed to be "validated" but "submitted" by 31 March 2021. The FSA press release stated: "The criteria for products which can remain on sale from 1 April 2021 has been updated. Previously, only products which were on sale at the time of the FSA's announcement (13 February 2020) and were linked to an application which had been validated by 31 March 2021 were to be included. To maximise the opportunity to pass validation, this now includes all products on sale on 13 February 2020 and linked to an application submitted before 31 March 2021 that is subsequently validated."

On 19 April 2021, the FSA produced a list of CBD food products on sale in England and Wales. These products were to be allowed to stay on the market until a decision on their authorisation has been made (as they had met the requisite validation threshold). The list produced by the FSA is split into two sections, which are made up of products associated with applications that either:

- have been validated in the initial stage of the process before going on to the safety assessment; or
- are "on hold", with applicants having set out robust plans to complete the risk assessment but yet to supply all the information needed to continue on in the process.

As previously stated, the list was first produced on 19 April 2021 and was intended to be updated weekly. The list, as at 26 April 2021, had only been updated once, and with only 43 products listed (from four manufacturers/suppliers). It is

understood that more than 500-plus applications were received by the FSA by the deadline of 31 March 2021 but it is unclear how many of these applications had been processed as of 26 April 2021.

The list saw a long-awaited update on 31 March 2022, bringing the list total to 3,536 products. Each product, as mentioned above, had the potential to fall within the categories of validated, on hold ("awaiting evidence") or authorised (although no product has been authorised to date).

On 27 April 2022, a further 2,447 products were added to the list and the industry is expecting another important update before 30 June 2022. After this date, no new products will be added to the list. The only changes that will subsequently occur will be to reflect the status of the products in the authorisation process.

We suspect that the position will become extremely contentious for those companies that have not made the final list, as no clear guidance has been given by the FSA (to date) for those wishing to challenge the FSA's decision.

Cosmetics

The primary legislation concerning cosmetics is Regulation (EC) No 1223/2009 (the "EU Cosmetics Regulation") and Schedule 34 of the Product Safety and Metrology, etc (Amendment, etc) (EU Exit) Regulations 2019.

The cosmetic ingredients database (CosIng) is the EU's official database for cosmetic ingredients, and as of 2 February 2021 CBD has been added to the database.

Again, as with food products, since the Brexit transition came to an end, the Office for Product Safety and Standards (OPSS) handle the listing of cosmetic products in the UK.

Vaping products

The vaping sector is regulated by the Tobacco and Related Products Regulations 2016 (TRPR). CBD products are not captured by the definition of "herbal product for smoking" pursuant to Part 5 of TRPR. Part 6 on e-cigarettes will only apply where there is some sort of tobacco-derived material contained within the product. If the proposed CBD products contain no tobacco-derived material (eg, nicotine) then they will not be caught by these regulations.

Industrial hemp

The cultivation of hemp is an augmenting industry in the UK: the leaves and flowers of the hemp plant – cannabis plants with notably low tetrahydrocannabinol (THC) content – remains classified as a Class B controlled substance under the MDA 1971. However, the MDR 2001 permits the cultivation and certain handling of the hemp plant subject to a licence with special conditions attached, obtained through the Home Office (see **1.2 Regulatory Authorities**). As hemp is typically grown for the industrial application of fibres and the nutritional benefit of its seeds, the licences granted for its cultivation usually require the destruction of the leaves and flowering tops on the grow site. A Controlled Drugs Licence would need to be obtained from the Home Office in order to handle the parts of the plant controlled by the MDA 1971.

1.2 Regulatory Authorities

Regulatory Authorities

Medical cannabis and cannabinoids, and their uses, are regulated by a number of authorities, depending on the sector in which they are used. Below are the relevant regulatory authority for each sector and their scope.

Food Standards Agency

- The FSA regulate and oversee the food industry in the UK.

- The FSA are responsible for maintaining food safety and hygiene with power to enforce through local Trading Standards, if needed.
- Ingestible CBD is categorised as a "food supplement" in the UK and therefore these types of products are regulated by the FSA.
- Echoing the view of the EFSA (its European counterpart), the FSA hold the opinion that CBD is a novel food and therefore requires producers of CBD and the resulting ingestible products be subject to an application procedure to ensure safety and standardisation.

Medicines and Healthcare Products Regulatory Agency (MHRA)

- The MHRA are responsible for overseeing medicines and certain health products in the UK market.
- The MHRA are responsible for assessing and ensuring the safety of medicinal products and medical devices that are already on, or are to be placed on, the UK market.
- The MHRA's duties in relation to CBD extend to monitoring the extent that the cannabinoid is not being marketed as a medicinal product without the proper safety, quality and efficacy tests being carried out as part of marketing authorisation approval.

Veterinary Medicines Directorate (VMD)

- The VMD is primarily responsible for protecting animal (and pet) health.
- The VMD view CBD as a medicine when given to animals, thus requiring a rigid scientific assessment and application procedure (plus approval) in order for a CBD product for pets to be placed on the UK market.
- The VMD have restricted access to the UK market for CBD treats or products for pets without proper authorisation and can enforce their decision.

The Home Office

The Home Office operates as the UK National Cannabis Agency (pursuant to the UN Convention on Narcotic Drugs 1961). They act in a regulatory capacity with respect to cultivation licensing and oversee the issue and maintenance of both hemp and high-THC cannabis licences. The Home Office also acts through the Border Force with respect to inspecting imports and exports, and will seize cannabis and CBD-related products that they suspect do not comply with national legal requirements.

Advisory Authorities

The Advisory Council on the Misuse of Drugs (ACMD)

The ACMD makes recommendations to government on the control of drugs that may be dangerous or otherwise harmful, including classification and scheduling under the Misuse of Drugs Act 1971 and its regulations.

In January 2021 the ACMD was commissioned to advise the government on establishing a legal framework for consumer CBD products. On 20 December 2021, the ACMD provided a report that contained conclusions as a result of key research undertaken and four recommendations for government. The four recommendations were as follows.

- The total dose of trans-delta-9-tetrahydrocannabinol-C5 (Δ9-THC) and all other controlled phytocannabinoids in consumer CBD products to be controlled. The dose of each controlled phytocannabinoid should not exceed 50 micrograms per unit of consumption.
- Regulatory authorities should ensure that any consumer CBD product permitted to market has limits on the content of controlled phytocannabinoids, such that the dose of Δ9-THC (including its precursor Δ9-THCA) and of each of the other controlled phytocannabinoids

does not exceed 50 mg per unit of consumption.
- A further inter-laboratory comparison trial ("ring trial") should be commissioned, specifically to support the capability of testing laboratories to detect controlled phytocannabinoids below the recommended maximum levels in a representative range of consumer CBD products.
- The development of more accurate testing for controlled phytocannabinoids should be supported, to allow testing capabilities to develop and be fully regulated.

As at the date of this guide, the government are yet to announce its views on the ACMD's recommendations.

1.3 Self-Regulation

There are a number of trade bodies at the UK and EU level that represent companies in the cannabinoid wellness industry and provide guidance and referrals for those wishing to enter the industry. They usually provide an annual membership, which requires members to have their products routinely tested for safety, efficacy and to ensure they are of a high standard and not misrepresenting the cannabinoid content.

1.4 Key Challenges

Public and Professional Unfamiliarity

By far one of the biggest struggles for market participants in the medical cannabis and cannabinoid wellness sectors is the lack of reliable information for consumers, the lack of education for clinicians or support by medical bodies such as the National Institute of Care and Excellence (NICE), MHRA and the UK National Health Service (NHS).

The confusion may lie in the unique property of the cannabis plant and its cannabinoids. The non-controlled (legal) cannabinoid CBD has been shown to have medicinal properties not dissimilar to licensed medicines already in the market, yet CBD product producers are restricted from marketing the non-licensed CBD products as having medicinal properties due to strict legislation governing medicines in the UK.

Pace of Change

There are two fundamental levels to consider when addressing the pace of legal change relating to activities related to the cannabis plant. One of these is at the macro-level (major national change, generally implemented through amendments to primary legislation), and the other is at the micro-level (more granular, technical changes, usually to regulatory rules or guidance, for example).

The pace of change at the macro-level is slow – for example, making cannabis-based medicines available to the UK public. Any changes at this level are a protracted exercise – not only because amending legislation in and of itself is an onerous task involving many different working parts, but also due to politics – and a further complication arises as UK and EU legislation in this area are interlinked with international law (ie, the UN Conventions), which adds another layer of complexity to the amendment process.

The pace of change at the micro-level, however, is relatively fast. This generally involves targeted tweaks to regulations and guidance that address how specific elements of the cannabis plant are treated in England and Wales. Not only are these changes more numerous, but less red tape is involved in the amendment process and so changes can be realised more quickly. Changes at this level might include the percentage of THC allowed in a cultivar, changes to novel food rules or updates to the CosIng database, for example.

Strict Laws and Expensive/Protracted Licensing

The current rules, particularly around licensing, create substantial bottlenecks that prevent the UK industry from operating at full capacity.

For example, the threshold for permissible THC levels in products or containers is not expressed as a percentage, but instead as a fixed milligram measure. This means that, whereas no controlled drugs licence is needed for the possession or sale of the CBD products themselves, manufacturers cannot import or possess the bulk CBD distillate required to create their products (without an expensive and difficult-to-obtain licence).

Another example is the outdated controlled drugs licensing system itself. Both the licence that is required to cultivate cannabis and the licence that is required to permit the possession of controlled cannabinoids (that may arise as a result of the manufacturing process) require applicants to spend, some would say, disproportionate time and excessive sums of money to try and meet the Home Office licence requirements. The administrative difficulties to achieving approval have also come under criticism. As a result of a protracted application process, approval (or rejection) can occur over two years after the initial application date.

Another example is the fact that extraction of CBD is only permitted from the CBD-sparse stalks and seeds of the plant (without a licence), making extraction inefficient and creating yet another CBD-sourcing issue.

Resolving these systemic licensing issues would not only increase the efficiency and profitability of the UK's commercial sector, but also alleviate barriers to medical research.

1.5 Level of Regulation

The current regulatory regime is substantially underdeveloped. In this regard, with the treatment and status of cannabis in the UK, essentially there is no overarching regulatory regime that has been developed for the plant and its component parts. For this reason there exists a legal grey area over many aspects of cannabis use with the aforementioned patchwork of regulations across various sectors being potentially misinterpreted, which leads to instances of confusion – eg, the common misunderstanding that hemp flower/buds are legal to be sold and consumed in the UK.

Further, it has been the tenuous interpretations of existing legislation and regulations that has led to serious legal consequences for producers and commercial enterprises, particularly in the CBD sector.

As far as medical cannabis is concerned, the regulatory regime for its governance falls squarely under the same regime governing the activities of medicines in the UK.

1.6 Legal Risks

Changing Regulations

One major risk area that companies should be aware of is the constantly shifting regulatory regimes governing the different activities of cannabis and cannabinoids in the UK.

This has never been more relevant than in a post-Brexit landscape. With the opportunity to garner more autonomy in terms of how cannabis is treated – and particularly in relation to CBD – the UK may steer away from the existing regulations to better achieve its own ambitions for the cannabinoid.

We have already seen the Food Standards Agency take a different view to the EU on the topic of CBD being classified as a narcotic or food (to

which the ECJ eventually decided in the latter, as was the FSA's stance). An example such as this – but with a different result – could dramatically shift how enterprises work in the UK.

As we see the prevalence of medical cannabis and cannabinoids grow, there may come a time for legislation to be drafted which directly addresses cannabis and its component parts. Consequently, participants in the cannabis sector must be ever-aware and closely follow the industry developments.

Unclear or Untested Regulations

Some sources of legislation that govern cannabis were drafted in the early-1960s and the 1970s. Aside from considering them outdated in many respects, observers note that these laws are unfit for purpose, as they were put in place to control the criminal trade of the plant, rather than to govern a commercial industry. For this reason, some of the central rules on which the industry relies are unclear and have not been tested in the courts. As a result, confusion is rife in the industry, with many participants relying on inapplicable thresholds and a general lack of consensus as to many of the rules.

Proximity to Criminal Liability

One difficulty with any industry centred around controlled substances is that the lawful activity sits relatively close to the national criminal law regime. In this regard, the only element separating lawful business and illegal activity is either an appropriate licence (covering manufacture, possession, supply, import or export, for example) or adequate legal advice (covering which parts of the plant are lawful to use or extract from without a licence, for example).

Proceeds of Crime Act

The Proceeds of Crime Act 2002 (PoCA) Part 7 criminalises dealing with or entering into arrangements in respect of the proceeds of "criminal conduct". The definition of criminal conduct in PoCA captures conduct which is lawful overseas, but would be a crime if it occurred in the UK.

Certain risks may arise for investors and professional services firms in particular, where funds are received from overseas companies which have generated their revenues from sources that are not yet lawful in the UK (recreational cannabis, for example), and best practice should always be followed. This issue is not a straightforward one, with no clear authority on certain matters that arise.

1.7 Enforcement

UK Criminal Law

In terms of the MDA 1971, possession, supply or importation of a controlled substance of Class B are "either-way offences" (ie, criminal offences that can be heard in the magistrates' or Crown Court). Charges are brought by the police on the advice of the Crown Prosecution Service (CPS), which then conducts the prosecution case in court. The maximum sentence on indictment for possession of Class B is five years' imprisonment (or an unlimited fine). For offences of supplying a drug of Class B, the maximum sentence is ten years' imprisonment (or an unlimited fine).

For an offence of importing (or exporting) a drug of Class B, the maximum sentence is 14 years' imprisonment (or an unlimited fine). The CPS may elect to charge the business which sells the product or the individuals involved in importing, storing or selling the product.

Section 28 of the MDA 1971 provides a defence where the accused neither knew nor suspected that the substance in question was a controlled drug. Per the judgment in R v Lambert [2001] UKHL 37, the burden is on the prosecution to disprove this defence, once raised by the accused, beyond reasonable doubt.

It should be noted that offences of conspiracy to supply or import a controlled substance are not subject to this statutory defence, as they are strictly speaking offences under Criminal Law Act 1977.

Packaging and Labelling Law

Dealing with product claims more generally, misleading claims on products is an offence under Regulation 9 of the CPUTR 2008. It is punishable by either a fine or two years' imprisonment.

In respect of medicinal products, as mentioned above, the MHRA regulates this area. In practice, as long as products do not make the medicinal claims or present themselves as medicines, the MHRA have been reluctant to intervene and require authorisation. Breaches of the marketing authorisation requirement is punishable by either a fine or two years' imprisonment.

When it comes to unauthorised health claims made in marketing materials about food products, the UK Advertising Standards Agency (ASA) will act against businesses breaching any of the rules. Local Trading Standards are empowered to enforce when it comes to food labelling. Breaches here are punishable by either a fine or two years' imprisonment. General or specific health claims about CBD are unauthorised.

The UK Border Force also acts as an enforcement authority and will seize products that are suspected of breaching national laws. This is not limited to criminal law, but also to food law and other regulations.

2. CROSS-JURISDICTIONAL ISSUES

2.1 Cross-Jurisdictional Standards

In the absence of a harmonised regulatory landscape which clearly sets out the rules for the activities of cannabis and cannabinoids, we have been left with a variety of jurisdiction-specific rules – eg, permitted levels of THC in CBD products.

The EU is progressing towards a more harmonised set of laws to keep consistency in the industry, and this was demonstrated in the recent Kanavape case (the Court of Justice of the European Union (CJEU) case number C-663/18), where the CJEU clarified that the principles of EU law supersede those at member state/national level, regardless of the product or interest in question.

The CJEU went one step further in their decision by announcing that, based on the available safety and scientific evidence, CBD cannot be classified as a narcotic, especially in light of the recent UN decision (see below) – in particular noting that CBD's apparent non-psychotropic effect and lack of any harmful effect on human health goes against the spirit of the Convention, which was drafted for protection against harmful and damaging drugs.

As a result, the European Commission has publicly announced that CBD should not be treated or regulated as a narcotic, and that CBD should qualify as a food (albeit a novel food), paving the way for a route to market through novel food authorisation.

This could provide a benefit for the UK: having a semblance of consistency with regard to characteristics of a cannabinoid or its production will go a long way in terms of ease of cross-border trade.

UN CND Decision

On 2 December 2020, the United Nations' Commission on Narcotic Drugs (CND) held a vote that resulted in the removal of "cannabis and cannabis resin" from Schedule IV of the Convention (reserved for the most harmful narcotic substances). This is expected to alleviate issues with access and availability of cannabis for medical and scientific purposes at national level. However, this will not affect the CBD industry greatly, as "extracts [...] of cannabis" were left in Schedule 1, allowing the aforementioned legal controversy around CBD extracts to continue.

Furthermore, the CND rejected a proposal on the clarification of CBD – which would have provided for an additional note to accompany the Schedules elucidating that preparations that contain predominantly CBD and less than 0.2% THC should not fall under international control. Summarily, these two decisions demonstrate that the CND recognises cannabis as having a beneficial medical application. However, as far as recreational and wellness use is concerned, there remains reluctance to relinquish full control.

3. FUTURE DEVELOPMENTS

3.1 Legal Elements Affecting Access to Medical Cannabis

Access to medical cannabis is currently limited by a number of legal and policy factors.

The greatest (legal) access barrier is that medical cannabis in the UK cannot initially be prescribed by general practitioners, per se. The statutory instrument that rescheduled cannabis in the UK included a provision that restricted the prescribing of cannabis-based medicines to those doctors who were specialists in an area of concern (eg, paediatrics, ophthalmology, etc) and listed on the GMC's Specialist Register. Less than 30% of the UK's doctors are on this register and, in practical terms, only a fraction of these specialists could be in a position to prescribe medical cannabis to patients, thereby creating a considerable bottleneck in meeting patient need.

A second element affecting access to medical cannabis is guidance issued by the National Institute for Clinical Excellence (NICE). This guidance, which ultimately affects state-funded access to medical cannabis, recommends the medicine for only three indications:

- chemotherapy-induced nausea and vomiting;
- spasticity in adults with multiple sclerosis; and
- severe treatment-resistant epilepsy.

It has also been suggested that guidance from the British Paediatric Neurology Association (BPNA) is restrictive (whether duly or unduly) and affecting patient access.

As a consequence of Brexit, reduced import and export flexibility has reportedly affected access to some cannabis-based products for medicinal use (CBPMs) in the UK.

3.2 Use of Non-controlled Cannabinoids in Food

As described in **1.1 Source of Regulations**, cannabinoids are caught by the Novel Food Regulations, as there is no evidence of their consumption by humans to a significant degree (as extracted or purified) within the EU before 15 May 1997.

This means that products or foods containing any cannabinoids will require full authorisation prior to being used in foods. We reiterate, however, that in the UK the FSA has given some brands/products a lifeline to be able to continue to market their products in England and Wales

– if said products were on sale on or before 13 February 2021 and a novel foods application was submitted by 31 March 2021 and was subsequently validated.

3.3 Decriminalisation or Recreational Regulation

There is no doubt that both decriminalisation and recreational regulation are words constantly on the lips of everyone in every level of this sector, including the government. The discussion papers that have been presented suggesting the socio-economic benefits of the plant – spanning medicinal, industrial and economic factors – keep the fires of discussion alight.

That said, to date there have been no formal moves to decriminalise, regulate or legalise cannabis for recreational purposes, from a governmental perspective. However, small but significant attitude changes may be observed from politicians and state institutions, involving a number of debates in Parliament (for example, Sir Norman Lamb's December 2018 motion to legalise the possession and consumption of cannabis), and there has been a subtle but profound relaxation in terms of charging those who are in possession of small amounts of cannabis for their own personal use.

In 2019, a cross-party group of MPs went on a fact-finding trip to Canada in order to experience how a legal and regulated cannabis market operates. Recently – in the context of the 2021 London mayoral candidate race – the incumbent Mayor of London, Sadiq Khan, stated that he would consider looking into the partial decriminalisation of cannabis in the capital. It may only be a matter of time before full legalisation and regulation happens in England and Wales, given the socio-economic benefits such a move would bring.

Where users of cannabis for bone fide medical reasons are concerned, there is an initiative in the UK that aims to help these users avoid criminal consequences of cannabis use. The Cancard scheme is a non-government initiative that is publicly supported by Members of Parliament, a number of national and local police associations and other bodies. The initiative provides members with a card showing that the holder has been diagnosed with a condition that cannabis has been shown to treat. It does not provide a defence to possession in law but aims to support a police officer's use of discretion during a search or arrest, with the hope (and, in most cases, result) that the user will not face criminal sanctions for possession.

Mackrell.Solicitors is an award-winning, full-service law firm, with a truly global reach. Headquartered in Central London, with offices in the heart of Birmingham, the firm has been providing high-quality legal advice and services since 1845. Mackrell.Solicitors was also one of the founders of Mackrell International, the 33-year-old global network made up of 104 firms across 60 countries, enabling it to offer the added value of immediate international legal advice and assistance in any jurisdiction worldwide. Mackrell. Solicitors set up the first dedicated cannabis legal team three years ago, so in terms of sector-specific knowledge it is at the cutting edge of the current regulatory regime in the UK and Europe. The firm provides regulatory advice and services for the medicinal cannabis and CBD industry, from cultivation licence applications, product and labelling reviews to advice on import/export best practice. In addition, via Mackrell International, it provides multi-jurisdictional advice for all EU countries and beyond.

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