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Medical Cannabis & Cannabinoid Regulation 2024

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Global Practice Guides

Medical Cannabis & Cannabinoid Regulation

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2024

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INTRODUCTION

Contributed by: Daniel Haymann, **MME Legal | Tax | Compliance**

MME Legal | Tax | Compliance is an innovative and fast-growing Swiss firm that offers integrated professional advisory and litigation services in all fields of legal, tax and compliance. MME supports and represents both companies and individuals in business and economic-related private matters. Many of MME's partners are nationally and internationally recognised as leading experts in their areas of practice, and together with their teams provide made-to-measure advice and practical, cost-effective and down-to-earth solutions for improving their clients' businesses or resolving their private economic challenges. MME's clients recognise the firm particularly for its lean organisational structure, its co-operative hands-on approach and its cost-effective workflow. They and MME's peers consider the firm an innovation pioneer which consistently operates at the cutting edge of the industry and the relevant fields of business. With its open-door, hierarchy-free company culture and its consistent innovation policy, MME has also become one of the most attractive employer brands in its field in the Greater Zurich Area, and attracts a considerable number of young high-potential associates and consultants.

Contributing Editor

Daniel Haymann specialises in corporate and commercial law with a focus on investments, venture capital and financing transactions, as well as on regulatory issues in the healthcare and consumer goods sectors, including THC, CBD and other cannabinoids and psychedelic compounds. Daniel is the co-founder and co-chair of the European offshoot of the International Cannabis Bar Association (INCBA Europe).

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INTRODUCTION

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The Fuse Has Been Lit for Growth in the International Cannabis Markets in 2024

Cannabis, once a niche and contentious field, has evolved into a multi-billion-dollar industry, influencing sectors such as textiles, biofuels and critical medical treatments. Historically, cannabis markets thrived in regions such as Amsterdam and China, but the liberalisation of laws in the USA and Canada has ignited global legislative revitalisation.

The cannabis industry is set for substantial growth, driven by the legalisation of recreational cannabis and the expansion of medical use. The European cannabis market is projected to reach USD6.2 billion by 2024 and USD 7.25 billion by 2029 (see the Statista Market Forecast here).

Germany has been at the forefront of cannabis regulatory reform. The "Cannabis as Medicine" Act, effective since March 2017, has permitted the use of cannabis for medical purposes. In December 2021, the new federal government included recreational cannabis legalisation in its coalition agreement. By October 2022, the federal Minister of Health presented a preliminary paper to the European Commission; and by February 2024, the Bundestag adopted the Cannabis Act (CanG), partially legalising cannabis from April 2024. The CanG allows for personal cultivation (up to three plants per adult per household) and possession (up to 50 grams privately and 25 grams publicly). Cannabis clubs can dispense up to 50 grams per month per member. Revised medical cannabis laws now allow easier market access and eliminate the need for a narcotics prescription form, among other changes.

In the Czech Republic, medical cannabis has been legal since 2013, with the first patients accessing it in 2014. While recreational use remains illegal, legalisation trends are growing, with draft laws under review. Malta, a pioneer in European cannabis legislation, legalised medical cannabis in 2018, and introduced personal cultivation and cannabis social clubs for recreational use in 2021.

Portugal decriminalised the possession of small amounts of cannabis in 2018, treating it as a misdemeanor. Current proposals aim to legalise recreational use, though political instability and the COVID-19 pandemic have delayed progress. Spain, known for its cannabis social clubs, operates in a legal gray area. While medical cannabis is not regulated, recent moves suggest Spain is working towards establishing a medical cannabis framework.

Switzerland's pilot trials for adult-use cannabis are expanding, with around 10,000 participants. These trials assess various distribution models, including sales through pharmacies, licensed shops and social clubs, to determine the most effective regulatory framework for legalisation. The Netherlands, meanwhile, tolerates cannabis sales in coffee shops but prohibits large-scale cultivation. Recent experiments with regulated supply chains aim to reconcile these contradictions and ensure a consistent legal market.

The UK remains cautious about cannabis legalisation. Medical cannabis prescriptions are limited, and the black market thrives owing to high costs and regulatory challenges. Political support for reform varies, with some parties advocating for decriminalisation and cannabis social clubs.

Israel's medical cannabis market is projected to grow by 70% by 2027, driven by new reforms. Japan's cannabis market expanded sixfold to USD154 million in 2023, with CBD gaining popularity in medical and wellness sectors. Pana-

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ma has made significant progress by granting licences to seven companies for manufacturing medical cannabis products.

In a ground-breaking development, the US Department of Justice proposed rescheduling cannabis as a controlled narcotic, which would:

- reduce draconian taxation on cannabis businesses;
- create research opportunities for medical cannabis;
- protect public health; and
- normalise cannabis under federal law.

These positive trends present challenges for lawmakers, industry participants and consumers with navigating the fragmented legislation that sometimes supports, but at other times undermines, these fast-paced developments.

The Cannabis Regulation 2024 Guide offers a comprehensive overview of cannabis laws across nine jurisdictions, featuring articles on trends and developments. Each jurisdiction is reviewed through an eleven-question format, facilitating easy comparison of specific issues and concerns, and providing a clear and jurisdiction-specific yet globally relevant guide to untangling the complexities of international cannabis laws.

Legislative Frameworks Struggling to Keep Up With International Developments in the Cannabis Industry

Many legislative frameworks are inadequate for handling the complexities and opportunities presented by the burgeoning global cannabis market. Outdated laws, restrictive policies, uninformed authorities and inconsistent enforcement are widespread challenges.

Legal uncertainty in the cannabis industry stems from outdated laws that are designed to control criminal trade and licence hemp for agriculture, not to regulate a sophisticated medical and wellness sector. Rapidly changing rules create further legal uncertainty as authorities interpret and implement new regulations. Most cannabis laws are unfit for the modern industry's objectives, and consequently the proper application of many legal concepts remains unclear and untested in courts. The fluid regulatory environment complicates product development and business planning.

International developments have positively influenced the cannabis industry and associated legislative efforts, but progress has been slow. In January 2019, the World Health Organization (WHO) recommended several relaxations on cannabis controls to the United Nations Commission on Narcotic Drugs (CND). However, most recommendations were rejected. The CND removed cannabis and cannabis resin from Schedule IV of the main international drug control convention, potentially easing medical and scientific access. The CND also declined to clarify CBD regulations, maintaining legal ambiguity around CBD products. This decision reflects recognition of cannabis's medical benefits but also a reluctance to fully relinquish control over recreational and wellness uses.

The European Union (EU) is moving towards more consistent regulations, demonstrated by the 2020 *Kanavape* case. The Court of Justice of the European Union ruled that EU law supersedes national laws regarding CBD, which cannot be classified as a narcotic based on available evidence. Despite this, the European Commission has paused CBD novel food applications pending further safety evaluations by the European Food Safety Authority. Inconsistent legis-

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lation and enforcement regularly subject permissible THC thresholds to variation, hindering harmonisation and free movement of goods. Most European countries permit 0.3% THC in finished cannabis products; however, the Czech Republic and Switzerland allow 1% THC. The UK allows up to 1 mg of THC in the final product, applying a different metric altogether. These varying thresholds and metrics create significant issues for producers, whose products are often seized at customs, creating barriers to market entry and distribution.

In Germany, where cannabis legalisation made a significant leap forwards on 1 April 2024 with its first legislative "pillar", confusion remains regarding how to implement the CanG. A major point of contention is whether cannabis clubs can consolidate the production of various clubs under one roof. At the time of writing, lawmakers seem poised to specify that this is not allowed, which could undermine the CanG's primary goal of combating the illicit market by enabling cost-effective competition from legal cultivators.

This guide will highlight these pervasive challenges and structure its review of legislative frameworks in four primary sectors of the global cannabis industry:

- medical;
- wellness;
- recreational (or "adult use"); and
- industrial hemp.

Significant Consolidation in the Cannabis Industry in 2023 Presents a Great Opportunity for 2024

The COVID-19 pandemic significantly disrupted business operations worldwide, even affecting robust industries. Overinvestment in cannabis production facilities led to an influx of distressed assets on the market, with lower valuations across the board. Many operators struggled to sell their businesses at reduced prices. Compared to the boom years of 2020 and 2021, the size and number of M&A deals in 2023 were significantly smaller. The anticipated federal legalisation and banking reforms in the USA did not progress as hoped, adding to uncertainty and the cautious investment climate. The industry's struggles were further compounded by rising interest rates, reduced funding availability and ongoing regulatory hurdles.

However, some positive developments emerged. Cannabis-based medicines have gained acceptance as treatment options, though much work remains to ensure broader availability. The COVID-19 pandemic spurred growth in the CBD wellness and cosmetics market, particularly via online sales. Classic cultivation-oriented business models started to give way to more innovative cannabis-based approaches. Private equity companies, looking to capitalise on low valuations, have sparked further consolidation of distressed assets, implementing strategies that have proved successful in other industries such as retail.

Summary and Outlook

The legalisation of cannabis for medical and recreational purposes is gaining momentum. Nonetheless, while over 20 European countries have introduced medical cannabis legislation, recreational legalisation remains mixed. Germany is leading with its partial legalisation, and other countries are exploring non-profit models and pilot programmes for navigating EU and UN regulations.

Political challenges and regulatory clarity remain significant hurdles. Effective regulation that balances safety and commercial interests is cru-

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cial. Despite these challenges, the trend towards legalisation in Europe is expected to continue, driven by potential economic benefits and evolving social attitudes.

2024 has already sparked optimism in the cannabis industry, and with current legislative developments, there is good reason to expect further growth in the industry.

FRANCE

Law and Practice

Contributed by:
Marie Sanchez
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NOOA Avocats is a boutique law firm based in Paris, France that is dedicated to the life sciences sector. Founded in 2020, NOOA Avocats advises and represents the interests of various types of companies in the life sciences sector on regulatory matters (market access, clinical trials, product advertising, vigilance, etc), assists them with drafting and negotiating transactions, and represents them in litigation. NOOA Avocats also has an extensive practice in the cannabis sector, advising clients on regulatory and strategic issues related to both the medical cannabis and wellness hemp markets in France, and representing them in commercial litigations against competitors. Always acting as a business partner, the firm participates in a "best friends" network with other law firms and consulting companies who specialise in the life sciences and cannabis sectors, both in France and globally, to provide clients with worldwide expertise and to support them in their international projects and development.

Author

Marie Sanchez has over 15 years of prior legal experience, and founded NOOA Avocats to better serve clients in the life sciences sector (including clients in the pharmaceuticals, medical devices, nutraceuticals, cosmetics, food supplements and veterinary drugs sectors) by offering bespoke guidance on regulatory issues, litigation and contractual matters. She has also developed in-depth expertise on regulatory and legal issues related to the emerging cannabis industry. Her clients include companies of all sizes, both French and international. She is a member of the Paris and Quebec Bars and the French Regulatory Affairs Association (AFAR), and is a member of the governing board and co-chair of the International Committee of the International Cannabis Bar Association (INCBA).

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1. Regulatory Framework

1.1 Primary Laws & Regulations

In France, cannabis and cannabinoids are regulated by a complex set of rules composed notably of laws, decrees and ministerial orders setting forth a general prohibition of cannabis, which is classified as a narcotic substance.

General Prohibition of Cannabis Under French Law

According to the French public health code, the production, manufacturing, transportation, importation, exportation, possession, sale, purchase and use of plants, substances or preparations classified as poisonous, including narcotic substances and psychotropic substances, are governed by regulatory provisions defined by ministerial orders. For the sake of clarity, ministerial orders (*Arrêté* in French) are administrative acts published by ministers and set forth certain rules regulating (for instance) specific sectors, products or activities.

The French ministerial order of 22 February 1990 (Appendix I) classifies cannabis and cannabis resin as narcotic substances. More specifically, French law strictly prohibits the production, manufacturing, transportation, importation, exportation, storage, supply, distribution, purchase or use of:

- cannabis, and its plant and resin, as well as products that contain it or that are produced from cannabis, its plant or its resin; and
- tetrahydrocannabinols, their esters, ethers and salts, and the products containing them.

Exceptions to the General Prohibition Rule

Nevertheless, French law provides for several exceptions to the general prohibition.

The manufacturing, transportation, importation, exportation, possession, sale, purchase or use of medicines containing cannabis or one of the cannabis plant components is allowed if the product has been granted a marketing authorisation either from the French Medicines Agency (*Agence nationale de sécurité du médicament et des produits de santé* (ANSM)) or from the European Medicines Agency (EMA).

Other cannabis-based medicinal products that satisfy specific criteria (notably characteristics, composition, pharmaceutical forms, therapeutic indications) but do not hold a marketing authorisation are accessible as described below.

The ANSM can grant specific authorisations for the production, manufacturing, transportation, importation, exportation, storage, supply, distribution, purchase or use of cannabis and/or its components for research and development purposes.

Cultivation, importation, exportation and industrial and commercial use of hemp plants that do not have any narcotic properties, or of products containing or made out of such hemp strains, can be allowed by ministerial order upon proposition from the General Director of the ANSM.

To date, cannabis regulation remains a work in progress, since there is no fully established legal framework in France. Adult-use cannabis is not legal, and legalisation thereof is unlikely to happen any time soon. Medical cannabis (other than medicines containing cannabis and holding a marketing authorisation) was authorised and therefore accessible to a very limited number of patients through a pilot programme until 25 March 2024, and is currently only accessible to patients that were enrolled in the pilot programme until the effective legalisation of medical

cannabis, expected in January 2025 at the latest. Regulation on wellness hemp remains subject to grey areas that could benefit from numerous clarifications for the sake of a safe market, both for consumers and for operators.

Medical Cannabis

Medical cannabis is only allowed in France if:

- the product is a medicine holding a marketing authorisation or is accessible through early-access programmes (eg, Sativex, Epidyolex, Marinol) issued by the French or the European competent health authority ("medicines containing cannabis"); or
- the cannabis-based product is supplied, prescribed and administered to patients under the conditions of a pilot programme that started in March 2021, until the legalisation of medical cannabis (to be understood as cannabis-based medicinal products subject to a use authorisation) enters into force in January 2025 at the latest.

In other words, any activities related to the cultivation, production, manufacture, transportation, importation, exportation, detention, supply, transfer, acquisition or use of cannabis for exclusively therapeutic purposes outside one of the above-mentioned frameworks are considered criminal offences related to drug trafficking, and are therefore prohibited in France.

The pilot programme on therapeutic cannabis, which began in March 2021, was designed to enrol up to 3,000 patients over a two-year period to assess the feasibility of the supply, prescription and delivery of medical cannabis to patients for whom no other therapeutic alternative is available. Because there is no domestic production line in France, supply was performed exclusively by foreign companies who were selected through a tender, and who were initially required to supply the products free of charge and at their own costs for the entire duration of the pilot programme.

The requirements related to the products, the supply chain, physician training, prescription and delivery as part of the pilot programme were set out in a statement of work published on 19 October 2020, as summarised below.

- Medical cannabis is allowed for five therapeutic indications:
  - (a) neuropathic pain that cannot be treated with available therapies (medicines and non-medicines);
  - (b) certain serious and pharmaco-resistant forms of epilepsy;
  - (c) as part of supportive care in oncology (eg, nausea, vomiting, anorexia);
  - (d) palliative situations; and
  - (e) painful spasticity related to multiple sclerosis or other central-nervous-system-related diseases.
- The products must be supplied as finished products only in their final packaging ready to be delivered to the patient.
- The authorised forms of medical cannabis were initially dried flowers for inhalation by vaporisation (smoking use was excluded from the allowed uses) and oil and capsules for oral use.
- The products use different ratios – the THC dominant ratio, CBD (cannabidiol) dominant ratio, or balanced THC and CBD ratio.
- The production of medical cannabis must comply with a certain number of industry standards, such as good agricultural and collection practices (GACP) for starting materials of herbal origin (EMEA/HMPC/246816/2005) and good manufacturing practices (GMP) set forth in the French public health code or

any equivalent guidelines recognised at the international level, in addition to several other guidelines, including:
(a) the Guidelines on Quality of HMPs/THMPs (CPMP/QWP/2819/00 Rev 2);
(b) the Reflection Paper on Microbiological Aspects of HMPs and THMPs (EMA/HMPC/95714/2013); and
(c) the ICH Q2 Guidelines for Validation.

- The plants used to make the products must meet the specifications of the monograph "Plant Drugs" (1433) of the European Pharmacopoeia.
- Suppliers need to obtain both an importation authorisation for narcotic substances from the ANSM and an exportation authorisation for narcotic substances from the country of origin.
- Selected suppliers are required to enter into a partnership agreement with a pharmaceutical establishment located in France for the distribution of medical cannabis to pharmacies and hospital pharmacies that participate in the pilot programme.
- The pharmaceutical establishment located in France in charge of the distribution of the medical cannabis on the territory must have the status of operator and importer, if applicable, and must hold a narcotics authorisation relating to medical cannabis in the context of the pilot programme.
- The initial prescription of the products was reserved to physicians working at multidisciplinary reference centres specialised in the five indications for which treatment with medical cannabis was allowed. However, once the patient was stabilised, general practitioners were allowed to prescribe medical cannabis to them, upon agreement of both the specialist and the general physician.
- All prescribers involved in the pilot programme must have followed mandatory training (e-learning).
- The dispensing of medical cannabis occurred initially in hospital pharmacies and could later be carried out by retail pharmacies once the stabilisation of the patient had been reached.

While legalisation of medical cannabis was initially expected at the end of the two-year programme, the French authorities decided to extend the pilot programme by one year (Decree No 2023-202 of 25 March 2023). As part of the extension of the programme, the products were no longer supplied for free by the selected suppliers, and some clarification was provided as to the requirements and modalities related to physicians' and pharmacists' participation in the pilot programme, training, remuneration and product specifications by three ministerial orders dated 25 March 2023.

The pilot programme ended on 25 March 2024 and medical cannabis ("cannabis-based medicinal products") is expected to be generalised on the French market by 1 January 2025 at the latest.

French Law No 2023-1250 of 26 December 2023, on the financing of social security for 2024, uses the term "cannabis-based medicinal product" and defines it as "any medicinal product whose active substance is composed of a preparation based on cannabis sativa L (extract), manufactured in accordance with the good manufacturing practices set out in article L 5121-5 [of the French public health code] or any equivalent internationally recognised standard by establishments mentioned in Article L 5124-1 [of the French public health code] and meeting the specifications set by an order of the Minister for Health issued on the recommendation

of the General Director of the French National Agency for the Safety of Medicines and Health Products".

The law also sets out the following conditions for cannabis-based medicinal products to be placed on the French market.

- The cannabis-based medicinal products can only be manufactured and distributed by duly authorised pharmaceutical establishments.
- The cannabis-based medicinal products must obtain a temporary authorisation for use from the ANSM. The use authorisation is delivered for an initial period of five years, renewable for subsequent periods of five years.
- Only companies established in a member state of the European Union (EU) or a country party to the Agreement on the European Economic Area can apply for a use authorisation.
- The use-authorisation holder must collect follow-up data of patients treated at its own costs and provide the ANSM with an annual report.
- The cannabis-based medicinal products can only be prescribed as last-line treatment.
- The information delivered by the use-authorisation holder to healthcare professionals in relation to the use authorisation regarding cannabis-based medicinal products must not be considered promotional. The ANSM is yet to set out the framework for such information (for sanctions in the case of breach of this obligation, please see **1.6 Enforcement & Penalties**).

The details regarding the specifications of the products, prescription and delivery, as well as the criteria for price-fixing and reimbursement of the products, are to be set out in several decrees and orders yet to be published.

Nevertheless, one can reasonably expect that the types of products (except dried flowers, which so far seem to be excluded), their pharmaceutical forms, the therapeutic indications for which the medicines could be prescribed, and the prescription conditions remain very close, if not similar, to those allowed under the pilot programme described above.

During the transition period – which started on 26 March 2024 and should continue until 31 December 2024 at the latest – medical cannabis is only accessible on the following conditions:

- only patients who were enrolled in the pilot programme and were still in it on 25 March 2024 can access medical cannabis;
- the products accessible to those patients are the same as those authorised under the pilot programme (with the exception of dried flowers, which have been removed from the list of authorised products);
- only suppliers elected under the pilot programme can supply the products during the transition period; and
- the conditions of prescription and delivery remain the same as under the pilot programme.

In other words, the transition period does not allow access for new patients, nor does it extend the list of products or suppliers. Therefore, access to medical cannabis remains limited until its effective legalisation.

Industrial Hemp and Cannabinoid-Based Consumer Products

Industrial hemp and hemp extracts are governed by the French ministerial order of 30 December 2021, authorising the cultivation, importation, exportation, and industrial and commercial use of hemp plants that contain up to 0.3% of THC,

and that are duly registered in the Common Catalogue of Varieties of Agricultural Plant Species or the French Catalogue of Plant Varieties and Species.

Hemp extracts and hemp-derived finished products containing extracts can be legally marketed in France if they meet the following requirements:

- hemp extracts (including CBD) must be obtained by using the entire hemp plant, and finished products containing CBD must be extracted from the entire hemp plant; and
- the THC level contained in the hemp extracts and the products containing such extracts must not be more than 0.3%, without prejudice to the provisions of Articles 14 and 15 of Regulation (EC) 178/2002 as regards requirements on the general safety of goods, or to any other more restrictive regulation.

It should be noted that the ministerial order of 30 December 2021 initially set forth a prohibition on the retail sale to consumers and the possession, use and/or consumption by consumers of raw hemp flowers and leaves, regardless of their form (eg, smoking products, potpourri, tea), whether alone or mixed with other ingredients (such as tea preparations), hence limiting the authorised use of the entire hemp flower to industrial use only.

However, the French Council of State (*Conseil d'Etat*) repealed the litigious provision in a ruling of 29 December 2022, notably judging that the French government had failed to bring sufficient proof of an actual risk to public health or public order such as they were using as grounds for the prohibition. Consequently, the retail sale to consumers of raw flowers and leaves – whatever their form, and including prepacked flowers – is now allowed in France.

In addition to the general rules mentioned above, specific rules apply depending on the category of the finished products concerned, as follows.

Rules for Specific Products

CBD smoking products

CBD smoking products (ie, plant-based products that do not contain tobacco and can be consumed by means of a combustion process) are subject to compliance with French rules under application of European Directive 2014/40 of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the member states concerning the manufacture, presentation and sale of tobacco and related products.

The products and their packaging are subject to strict conditions. Applicable law notably prohibits use on the packaging, the product itself and related commercial material of any mention, logo, image or promotional mark that:

- contributes to the promotion or incites the consumption of the product, by giving an erroneous impression of the product's characteristics, health effects, risks or emissions – the labels must not include any information on the product's nicotine, tar or carbon monoxide content, as the case may be;
- suggests that a product is less harmful than others, is intended to reduce the effect of certain harmful components of smoke or has vitalising, energising, healing, rejuvenating, natural, organic, or health or lifestyle benefits;
- indicates that the product is free of additives or flavourings; or
- creates confusion with a food or cosmetic product.

Packaging units and all outer packaging must also bear a health warning in the French language.

CBD smoking products are not currently subject to excise duty in France. In the absence of a dedicated tax category, they are likely classified as other smoking or inhalation tobacco, and are subject to VAT at the standard rate of 20%.

In addition, in the absence of official specific regulation, the producers and distributors of these products are not currently subject to any approval being granted by the General Directorate of Customs and Excise.

CBD in foodstuffs

CBD is considered a novel food and must therefore be authorised prior to it being placed on the market as such or used in a food product as per Regulation (EU) 2015/2283 (the "Novel Food Regulation"). This point is explained in more detail in **3.2 Non-controlled Cannabinoids in Food**.

Animal food products

CBD used as an isolated substance or enriched extracts obtained from extraction processes are considered food additives, and as such must be authorised prior to being placed on the market. To date, CBD, regardless of its processing method, has not been authorised at the EU level as a pet food additive.

CBD-based cosmetic products

CBD-based cosmetic products can be legally placed on the market if they comply with the provisions of Regulation (EC) 1223/2009 on cosmetic products (the "Cosmetics Regulation"), and assuming they do not make any health claim. The use of hemp extracts in cosmetic products is strictly regulated. CBD alone or other hemp extracts must not fall under one of the prohibitions set out in Annex II of the Cosmetics Regulation, notably entry No 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".

Cannabis extracts that can be used in the manufacturing of cosmetic products without restrictions are listed in the European Commission's database for information on cosmetic substances and ingredients (CosIng). Even though CosIng is not legally binding, it is used as a reference by competent authorities, notably in the control of cosmetic products.

E-liquids and vaping products

E-liquids and vaping products can be marketed on the French market, provided that:

(a) the maximum THC level they contain remains below 0.3%;
(b) they comply with Regulation (EC) 1272/2008 (the "CLP Regulation") and Regulation (EC) 1907/2006 (REACH) requiring registration with the European Chemicals Agency (ECHA) of chemical substances that are manufactured or imported in quantities above one ton per year;
(c) vaping products containing nicotine are declared to the French competent authority for the safety of food, environment and work (ANSES) by the manufacturer or the importer six months prior to being placed on the market – the declaration must be made on the EU's common electronic entry gate, and the information and all related documents submitted as part of the declaration must be in French; and
(d) they are not sold to minors.

The regulation of CBD-based consumer products has been subject to many changes over the past few years. Case law has notably played a major role in the evolution of the applicable regulation.

However, there is still some lack of clarity on many aspects related to CBD-based consumer products. The need for clarification in regulation remains critical, to ensure both legal security for operators and consumer safety.

Synthetic Cannabinoids

Lately, new cannabinoids (synthetic cannabinoids and phytocannabinoid derivatives) have emerged on the French market. Alerted by an increase in consumer intoxications, the French authorities have taken measures to classify these new narcotic substances.

Hence, in a decision dated 13 June 2023, the ANSM classified hexahydrocannabinol (HHC) and two derivatives thereof – ie, HHC-acetate (HHCO) and hexahydroxycannabiphorol (HHCP) – as narcotics.

Most recently, by a decision dated 22 May 2024 and published on 24 May 2024, the ANSM classified several new substances as narcotics:

- 5F-CUMYL-PEGACLONE (5F-SGT-151);
- CUMYL-CH-MEGACLONE (SGT-270);
- 7APAICA;
- 5F-7APAICA;
- CUMYL-P7AICA;
- 5F-CUMYL-P7AICA;
- BZO-HEXOXIZID (MDA-19);
- BZO-POXIZID (5C-MDA-19);
- certain cannabinoid derivatives formed from the benzo[c]chromen nucleus, except CBN (cannabinol);
- HHCPO;
- THCA;
- H4-CBD; and
- H2-CBD.

1.2 Regulatory Bodies

The cannabis sector is controlled by several competent authorities, each charged with specific missions.

The ANSM is charged with the control of health products governed by the French public health code. It is the control authority for:

- medicines containing cannabis and holding a marketing authorisation;
- medical cannabis (under the pilot programme and the transition period); and
- cannabis-based medicinal products that will hold a use authorisation after the legalisation of medical cannabis.

Among its powers, the ANSM can:

- provide marketing authorisations;
- authorise pharmaceutical establishments;
- issue importation/exportation authorisations;
- control regulatory compliance of products; and
- allow clinical trials.

Since January 2024, the control of cosmetic products that the ANSM used to share with the DGCCRF (*Direction générale de la concurrence, de la consommation et de la répression des fraudes*) has been fully transferred to the DGCCRF.

The DGCCRF is charged with the control of several types of products – in particular, consumer products such as food and cosmetics. It ensures that these products are compliant in terms of quality, composition and labelling, and that they

are not associated with misleading commercial practices related to their origin or quality. The DGCCRF also controls claims that may be made by distributors on their products.

The DGAL (*Direction générale de l'alimentation*) is charged with the control of food safety. It is competent to control supply chains of vegetal and animal food stuffs. Food safety control was under the DGCCRF's power until 2023; this power has now been transferred to the DGAL.

The ANMV (*Agence nationale du médicament vétérinaire*) is the competent authority for veterinary drugs, and is competent to:

- assess marketing authorisation applications;
- control the risk of side effects;
- control the quality of veterinary medicines and advertising thereof; and
- authorise veterinary medicines, clinical trials and pharmaceutical establishments, and the importation/exportation of products.

1.3 Self-Regulatory Authorities

In France, several trade bodies and organisations are in charge of medical cannabis or industrial hemp-related activities, including:

- *Santé France Cannabis;*
- *L'Union des industriels pour la valorisation des extraits de chanvre* (UIVEC);
- *Le syndicat du chanvre* (SPC); and
- *La Fédération nationale des producteurs de chanvre* (FNPC).

These organisations represent players in the industry, and participate in the setting of legal frameworks related to medical cannabis or industrial hemp.

1.4 Challenges for Market Participants

Medical Cannabis

Until January 2025, when the generalisation of medical cannabis (cannabis-based medicinal products) is expected, market opportunities in France are limited to foreign suppliers and their French distributors who were selected for the implementation of the pilot programme, or to the marketing-authorisation holders of medicines containing cannabis, as the case may be.

While the legal framework is still being developed, and until publication of the relevant decrees and orders in the Official Journal, there is currently a lack of visibility on certain fundamental questions, such as regarding:

- rules on cultivation;
- specifications of cannabis-based medicinal products' use; and
- determination of applicable criteria for price-fixing and reimbursement.

The clock is ticking, and it goes without saying that market players are eagerly waiting for these regulations to be published.

Wellness Hemp

Companies producing and distributing cannabinoid-based consumer products, including CBD products, also face a number of challenges.

While the decision of the Council of State in December 2022 allowed the resumption of distribution and sale to consumers in France of raw hemp flowers and leaves, it should be noted that the French government is still expected to bring much-needed clarification. However, it remains unclear what modifications will be made, whether any new restrictions will be set out and when this will occur.

Another major challenge for operators in the French market relates to novel food. The absence of a clarified position being taken by the French competent authorities creates uncertainty and generates risk for market players, who are still likely to face controls and sanctions.

Finally, litigation has also arisen between economic players, with some companies engaging in lawsuits against competitors on the grounds of unfair competition for selling CBD foodstuffs before the CBD has been given the requested marketing authorisation from the European Food Safety Authority (EFSA).

1.5 Legal Risks

Conducting business in an emerging sector, for which the legal and regulatory framework is not entirely developed, necessarily involves risks.

The most common identified risk is that related to THC levels contained in products. Any product containing more than 0.3% of THC is considered a narcotic if:

- it is not a medicine containing cannabis and holding a marketing authorisation;
- it is not a cannabis product supplied as part of the pilot programme on therapeutic cannabis during said programme and currently the transition period or a cannabis-based medicinal product duly authorised for use by the ANSM after the entry into force of the legalisation; or
- it has not been authorised for research and development purposes.

Any activity related to such product is therefore considered a drug trafficking offence.

In addition, companies distributing hemp-derived products including CBD products to consumers must be aware of the following risks.

Prohibition of Therapeutic Claims and the Risk of Qualification of Foodstuffs/Food Supplements as Medicinal Products

Therapeutic claims are strictly prohibited for food/dietary supplements, as set out in Regulation (EU) 1169/2011 of 25 October 2011 on the provision of food information to consumers. As the line between some product categories (ie, medicinal products, food supplements and foodstuffs) is very thin, making unauthorised health and therapeutic claims in relation to foodstuffs is likely to result in the requalification of the products as medicinal products and to entail criminal sanctions.

Prohibition of Sale of a Medicinal Product Without a Prior Marketing Authorisation

A medicinal product (including a medicine by presentation and a functional medicine) can only be placed on the market if it has been granted a marketing authorisation from the French competent health authority (the ANSM or EMA for human medicines, and the ANMV for veterinary medicines). If a food product may be requalified as a medicinal product due to the prohibited therapeutic claims that were made in relation thereto, the selling of a medicinal product without a prior marketing authorisation would constitute an offence.

Prohibition of Activities Without Mandatory-Use Authorisation From the ANSM

Regarding prohibition of manufacturing, placing on the market, brokering or distribution of cannabis-based medicinal products without having obtained the mandatory-use authorisation from the ANSM, see the definitions in **1.1 Primary Laws & Regulations**.

The Illegal Practice of Pharmacy

Under French law, only pharmacists are allowed to sell medicines. Consequently, operators using therapeutic claims to sell consumer products may face charges for illegal practice of pharmacy should their products be requalified as medicinal products.

Incitement to Use Narcotics

CBD products must not be presented or advertised in a way that could be interpreted as an incitement to use narcotics. In other words, any presentation and/or advertising of a CBD product that is likely to create confusion with recreational cannabis and hence to be considered as inciting the consumer to use recreational cannabis is strictly prohibited.

Breach of the Novel Food Regulation

Applicable enforcement and sanctions are discussed in **3.2 Non-controlled Cannabinoids in Food**.

1.6 Enforcement & Penalties

Various authorities oversee compliance depending on the category of products concerned. Controls and administrative sanctions are applied by the ANSM for medicines and other health products, while the ANMV is the enforcement authority for veterinary products.

For consumer products, the DGCCRF runs frequent controls to verify compliance with the requirements for claims, presentation and labelling of products, as well as to identify any misleading commercial practices in relation to food products, food supplements and cosmetic products. The DGAL oversees enforcement in the case of any breaches of food safety requirements.

The competent authorities can apply administrative sanctions, such as by:

- issuing warnings;
- requiring corrective actions; and
- ordering the withdrawal of non-compliant products from the market.

They can also apply administrative fines to infringing companies.

In addition, several types of criminal penalties can apply. For criminal offences, enforcement is the responsibility of the public prosecutor, who can decide to prosecute either following police investigation or upon transfer of a report from the competent authorities mentioned above.

Key Criminal Sanctions

Of the common criminal sanctions that can apply in relation to the cannabis industry, the following are worth noting.

Drug trafficking

Drug trafficking can result in sanctions of between five years and life in prison (generally subject to a determined period of unconditional imprisonment) and a fine of between EUR75,000 and EUR7.5 million.

Placing on the market without prior authorisation

The placing on the market of a medicinal product without having obtained the requested prior marketing authorisation is a criminal offence punishable by up to five years' imprisonment and a fine of up to EUR375,000.

Activities without use authorisation from the ANSM

Manufacturing, marketing, brokering or distributing, free of charge or against payment,

wholesale or retail, a cannabis-based medicinal product (as defined in **1.1 Primary Laws & Regulations**) without having obtained the required use authorisation from the ANSM is punishable by up to five years' imprisonment and a fine of up to EUR375,000. Moreover, this criminal offence is punishable by up to seven years' imprisonment and a fine of up to EUR750,000 when such offence is likely to:

- entail a serious risk to human health;
- have been committed as part of an organised gang;
- have been committed on a telecommunications network intended for a non-specified public; or
- have been committed by pharmaceutical establishments, brokers, dispensing pharmacists or hospital pharmacies.

These same sanctions also apply to the offence of advertising cannabis-based medicinal products subject to a use authorisation to healthcare professionals, in breach of the framework set out by the ANSM.

The illegal practice of pharmacy

The illegal practice of pharmacy is punishable by up to two years in prison and a fine of up to EUR30,000.

Incitement to use narcotics

Incitement to use narcotics is punishable by up to five years in prison and a fine of up to EUR75,000, even if the incitement does not result in actual use of recreational cannabis by a consumer.

Placing on the market and distribution of non-compliant products

The placing on the market and the distribution of non-compliant products (eg, in breach of requirements relating to product composition, labelling and safety) can result in a fine of up to EUR1,500 multiplied by the number of non-compliant products.

Under French law, the amount of the fine applied to an individual is multiplied by five when applied to a legal person.

2. Cross-Jurisdictional Matters

2.1 Cross-Jurisdictional Issues

The main cross-border issues concern THC levels. The maximum THC level allowed in France is 0.3%.

Consequently, any product containing THC above this maximum level is considered a narcotic and falls under drug trafficking regulation, except where the product is:

- a medicine containing cannabis and holding a marketing authorisation;
- a medical cannabis product duly authorised as part of the pilot programme and after the entry into force of the legalisation, or a cannabis-based medicinal product duly authorised for use by the ANSM after the entry into force of the legalisation; or
- a product holding an importation authorisation from the ANSM.

Issues are likely to arise in the case of importation of products manufactured in other EU member states where allowed THC levels are higher than in France (eg, Italy, the Czech Republic), or of those manufactured in non-EU countries, such as Switzerland, where consumer products can contain up to 1% of THC.

Other issues may arise in relation to importation of finished products manufactured in non-EU countries where the applicable regulation is different from French and/or EU regulation. In practice, issues have been observed in the market in relation to the composition of some products (eg, cosmetic products containing unauthorised ingredients or ingredients subject to limitations on levels above the maximum authorised levels) or in relation to the labelling of products (eg, those missing mandatory information).

Finally, the use of the wrong tariff codes as part of importation/exportation activities would likely constitute tax fraud.

Operators should therefore be extremely cautious when engaging in importation/exportation activities (particularly between EU and non-EU countries) and pay close attention to the type of products they are marketing, in order to ensure compliance with the relevant applicable laws and regulations.

3. Legal and Regulatory Developments

3.1 Access to Medical Cannabis

To date, and until the entry into force of the legalisation of cannabis-based medicinal products in France expected in January 2025, access to medical cannabis remains very limited in the country. Indeed, very few medicines containing cannabis and holding marketing authorisations are available on the market, and they are only prescribed to a limited number of patients for very specific therapeutic indications.

Until the end of the transition period, scheduled for 31 December 2024, medical cannabis (ie, cannabis-based medicinal product) is only accessible to patients who were enrolled in the pilot programme and who were still in it on the date the programme ended in March 2024 (please see **1.1 Primary Laws & Regulations**).

The regulatory framework is still being set up. In particular, decrees and orders setting out the following aspects are yet to be published:

- the requirements related to medical cannabis cultivation and processing;
- the definition of cannabis-based medicinal products' specifications;
- the definition of the criteria for the fixing of product-pricing and reimbursement; and
- conditions and modalities of prescription and dispensing to patients.

Time is of the essence, and France is being watched closely by market players anxious to enter the market once medical cannabis is legalised. In the meantime, most players are trying to navigate the practical and legal uncertainties around the legalisation.

A major challenge will be for the relevant players and the French government to find agreement on product specifications, market access conditions and prices that satisfies all the parties concerned. Otherwise, this may discourage new players from venturing into the French market, and may eventually frustrate the purpose of facilitating access to these new medicines for patients in need.

3.2 Non-controlled Cannabinoids in Food

Broadly speaking, food products can be placed on the market provided they meet the general safety requirements set out by applicable laws and regulations, notably Articles 14 and 15 of Regulation (EC) 178/2002.

The Novel Food Regulation

However, as in other EU member states, cannabinoids (including CBD) and food products containing cannabinoids are considered a novel food as per the Novel Food Regulation (see also **1.1 Primary Laws & Regulations**) and are registered as such in the Novel Food Catalogue.

Novel foods are products for which the history of safe consumption before 1997 has not been demonstrated. These products must therefore obtain an authorisation from the EFSA prior to being placed on the market. The prior authorisation requirement applies both to cannabinoid extracts and to finished products containing cannabinoid extracts as an ingredient, regardless of whether the extract is natural or synthetic.

Consequently, some food products that are derived from the hemp plant (eg, hemp seed oils, hemp seed flour and hemp seeds) are not considered novel food and can legally be placed on the market.

However, hemp extracts and any products to which hemp extracts have been added as an ingredient (eg, hemp seed oil, drinks, waters and chewing gum enriched with CBD) are considered novel food, and as such may not be placed on the market until a risk assessment has proved that they are safe for consumption and a novel food authorisation has been granted for CBD or another cannabinoid, as the case may be.

In addition, it should be noted that French Decree No 2006-352 of 20 March 2006 on food supplements expressly prohibits the use of novel food in the manufacturing of food supplements. Consequently, according to this regulation, only hemp seeds can be used in the manufacturing of food supplements (eg, cold-pressed hemp seed oil, grounded hemp seeds).

Enforcement of the Novel Food Regulation in France

In recent years, the enforcement of the Novel Food Regulation regarding CBD has apparently been handled very differently from one member state to another.

More specifically, while some countries' competent authorities have adopted a clear position on the implementation of the Novel Food Regulation and are taking restrictive measures accordingly, it appears that enforcement in France has been quite different. Indeed, it remained quite limited until 2023, with frequency of controls varying depending on region.

This has resulted in a very large number of CBD food products being placed on the French market. These products can be found at CBD stores, pharmacies, supermarkets and online.

Although it appears that the number of controls has increased since 2023, the French competent authorities have not taken any official position.

The apparent tolerance of French controlling authorities, combined with the lack of a clear and official position regarding the placing on the market of CBD food products and dietary supplements, creates an insecure environment where operators distribute their products while still being exposed to controls and potential sanctions, notably including:

- products' withdrawal from the market and prohibition from selling the products;
- destruction of products at the cost of a non-compliant company; and
- a fine of up to EUR1,500 per non-compliant product.

Several novel food authorisations have been applied for before the EFSA. However, to date no authorisation has been given for CBD.

Another issue resulting from the lack of regulatory clarity relates to the CBD levels contained in products. While some medicinal products containing high doses of CBD have obtained marketing authorisation, other consumer products available on the French market (and, in particular, at pharmacies) are also marketed with a very high CBD content, often along with therapeutic claims, and are largely used by consumers for self-medication, which is not without risk for the consumers.

To date, while observations in the field may lead one to think that products containing high levels of CBD may be removed from the market in the case of controls, there is no legal provision or official position from the competent authorities establishing a maximum level of CBD permitted to be used in consumer products – this, again, causes confusion and puts operators that venture placing their products on the French market at risk.

3.3 Decriminalisation

While France is often described as Europe's largest consumer of cannabis, it also has some of the toughest laws against drugs. Although the conversation regarding whether cannabis should be legalised has arisen several times over the past few years, with lobbying actions being engaged or public consultation being launched, cannabis remains a major stigma in France.

To date, and despite the change in position of some neighbouring member states (notably Luxembourg and Germany), there has been no discussion as to whether or not cannabis for recreational purposes should be legalised in France. Based on the current government's firm position on narcotics (particularly cannabis) which suggests even more enforcement of narcotic laws, it is very unlikely that any change will occur until at least the next Presidential elections, which will take place in 2027.

GERMANY

Law and Practice

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CMS Germany is one of the largest German law firms and forms a part of CMS Legal, a global firm with 77 offices in 43 countries and over 4,800 lawyers. CMS Germany is recognised as having a strong focus on the life sciences and healthcare sectors, with teams in Hamburg, Cologne and Düsseldorf. The life sciences team in the Hamburg office consists of 23 lawyers, with specialists in the areas of regulatory, product liability, drug advertising, co-operation agreements, IP, compliance and reimbursement. The Hamburg team has had a strong focus on cannabis law since the legalisation of medicinal cannabis in 2017. This expertise includes providing advice on regulatory and strategic issues in connection with German/EU market entry as a supplier of medicinal cannabis, and the setting-up of prescription (RX) cannabis businesses in Germany. CMS offers full-coverage advice for cannabis clients, including on structuring and negotiating transactions and on co-operations in the field. The team regularly advises on regulatory issues regarding food, animal feed, smoking/vaping products and cosmetics containing CBD.

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1. Regulatory Framework

1.1 Primary Laws & Regulations

Several primary laws and regulations govern practices regarding cannabis in Germany. The main legislation applicable for the different product types is as follows.

General

In 2024, there was a major legal reform in Germany that removed cannabis from the Narcotics Act (*Betäubungsmittelgesetz*, BtMG) and legalised it for personal use. As part of this reform, two new laws were created: the Medical Cannabis Act (*Medizinal-Cannabis Gesetz*, MedCanG) and the Consumer Cannabis Act. In addition, numerous regulations in existing laws were amended.

The amendment to the BtMG is a major change as, up until now, the regulations of the BtMG had to be observed in relation to all cannabis products (with the exception of cannabidiol (CBD) without trace tetrahydrocannabinol (THC)).

Medicinal Cannabis

The Medical Cannabis Act

The first legislative reform took place in 2017, when cannabis was moved to the list of narcotics that can be marketed and prescribed in Germany.

With the exclusion of cannabis from the BtMG in the current reform, a new law was created for the handling of medicinal cannabis – the MedCanG. The existing regulations on medicinal cannabis remain essentially unchanged.

Only physicians can prescribe cannabis (see Section 3 MedCanG). In contrast to the previous provisions, a special narcotics prescription is no longer required for this, as now a regular prescription from a doctor is sufficient to obtain medicinal cannabis from a pharmacy. Only the active ingredient nabilone (synthetic cannabinoid) must still be prescribed on a narcotics prescription (see Annex I to Section 1I BtMG).

According to Section 2(1) MedCanG, medicinal cannabis is defined as plants, flowers and other parts of plants belonging to the genus cannabis, which originate from cultivation for medical purposes under state control in accordance with the UN Single Convention on Narcotic Drugs, 1961.

Anyone who cultivates, manufactures, trades, imports, exports, delivers, sells, otherwise places on the market, obtains or acquires medicinal cannabis, or uses it for medical scientific purposes, requires a general licence from the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*

– BfArM) according to Section 4(1) MedCanG. Unlike in the past, however, a Europe-wide tender procedure is no longer required for the cultivation of medicinal cannabis in Germany. Holders of a valid licence in accordance with Section 3 BtMG are initially still entitled to handle cannabis products in accordance with the scope of the permit issued in accordance with Section 3 BtMG, even after the entry into force of the MedCanG. A written application must be submitted by post for the transfer of the contents of a valid licence pursuant to Section 3 BtMG to a licence pursuant to Section 4 MedCanG, in which any deletions of items that are no longer required in the future can also be listed.

In the case of an import into Germany according to Section 12 MedCanG, a further permission must be obtained.

Furthermore, companies cultivating medicinal cannabis can now also market and distribute their harvest themselves. They will be subject to monitoring by the BfArM and the relevant state authorities.

The transit of medicinal cannabis or cannabis for medical-scientific purposes through Germany is only permitted under customs supervision (see Section 12 MedCanG).

The 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 in 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 cannabis in the form of dried blossoms or extracts, finished medicinal products with cannabis and medicinal products with the active ingredient Dronabinol or Nabilon, if:

- a generally accepted standard therapy does not exist, or 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; and
- there is a reasonable possibility that the cannabis will have a positive effect on the disease process or on serious symptoms.

The German Medicinal Products Act

Besides the MedCanG, 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 trading of medicinal cannabis within Germany and imports from EU countries, as well as third countries, including the requirements of manufacturing practice in accordance with the EU's "Good Manufacturing Practice" (GMP) 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; and
- import authorisation – where medicinal cannabis will be imported from outside the EU, an import authorisation is required, pursuant to Section 72 AMG.

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.

Recreational Cannabis

The German Consumer Cannabis Act

The most drastic change of the 2024 reform is the creation of the Consumer Cannabis Act (*Konsum-Cannabis Gesetz*, KCanG), which contains regulations on private home cultivation, cultivation associations and the handling of industrial hemp. The regulations have been in force since 1 April 2024.

Private consumption

Since then, it is legal for persons who have reached the age of 18 to possess up to 25 grams of cannabis, in the case of flowers, leaves close to the flower or other plant material of the cannabis plant based on the weight after drying, for personal consumption (Section 3(1) KCanG). Adults may grow a total of up to three cannabis plants at a time for personal consumption and may possess a total of 50 grams of dried cannabis for personal consumption at their place of residence (Section 3(2) KCanG). Cannabis from private home cultivation may not be passed on to third parties. For private cultivation, it must be ensured that the plants are protected from access by third parties, especially children and adolescents (Section 10 KCanG).

Cultivation associations

Furthermore, the new legislation allows for so-called cultivation associations (*Anbauvereinigungen*), also named "Cannabis Social Clubs", which are registered, non-commercial associations or registered co-operatives whose purpose is the joint, non-commercial cultivation and distribution of cannabis and propagation material (seeds and cuttings of cannabis plants) for personal consumption. They are managed in accordance with the principles of association law.

A cultivation association can start operating in Germany from 1 July 2024. Such cultivation association requires a licence from the competent authority (Section 11 KCanG). Cultivation associations can have up to 500 adult members that are German residents (Section 16 KCanG). Requirements for the community cultivation of cannabis are stipulated in Section 17 KCanG. Members of a cultivation association receive a maximum of 25 grams of cannabis per day and a maximum of 50 grams of cannabis per month for personal use. For adolescent members (ie, persons who have reached the age of 18 but not yet the age of 21), the maximum monthly amount of cannabis to be distributed is 30 grams and may not exceed a THC content of 10% (Section 19(3) KCanG).

Advertising and any form of sponsorship for cannabis and for cultivation associations are prohibited (Section 6 KCanG). The provision will be in force from 1 July 2024 onwards.

Industrial hemp

Industrial hemp falls under the definition of cannabis in Section 1(8) KCanG, but is legally privileged as it does not pose any health risks. The cultivation of industrial hemp is regulated in Sections 31 et seq of the KCanG. For the distinction between cannabis within the meaning of Section 1(8) KCanG and industrial hemp within the meaning of Section 1(9) KCanG, the factual feature of the exclusion of "abuse for intoxication purposes" is still relevant. This distinction requirement was previously included in the BtMG. Accordingly, a plant is not subject to the regulations of the KCanG if the handling of it (apart from cultivation) serves exclusively commercial or scientific purposes that exclude abuse for intoxication purposes, and provided the other requirements for industrial hemp are met – namely, as follows:

- the industrial hemp originates from cultivation in member states of the EU with certified seed of hemp varieties, which are listed in the common catalogue of varieties of agricultural plant species on March 15th of the year of cultivation and which are certified in accordance with Article 17 of Council Directive 2002/53/EC of 13 June 2002 in the common catalogue of varieties of agricultural plant species (OJ L 193, 20 July 2002, p 1) as amended by Regulation (EC) No 1829/2003 (OJ L 268, 18 October 2003, p 1), in its current version, published by the European Commission in the Official Journal of the European Union, C series; or
- its THC content does not exceed 0.3%.

Furthermore, hemp falls within the classification of industrial hemp in the case of the following.

- If it is grown by agricultural undertakings which:
  - (a) meet the requirements of Section 1(4) of the Act on Old-Age Insurance for Farmers, with the exception of enterprises in forestry, horticulture and viticulture, fish-farming, pond-farming, beekeeping, inland fishing and transhumance; or
  - (b) are eligible for a direct payment in accordance with the provisions on direct payments under the Common Agricultural Policy of the European Union.
- Additionally, if the cultivation is carried out exclusively from certified seed of hemp varieties which are listed in the common catalogue of varieties of agricultural plant species on March 15th of the year of cultivation, and which are published by the European Commission in the C series of the Official Journal of the European Union in accordance with Article 17 of Directive 2002/53/EC, as amended.

Lifestyle Products

Besides the general rules of the MedCanG and KCanG, 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 EU law, and therefore applies in all

EU countries as a matter of priority. The most relevant legislation in this field includes:

- the German Food and Feed Code (*Lebensmittel-*, *Bedarfsgegenstände- und Futtermittelgesetzbuch*, LFGB);
- the General Food Law Regulation (EC) 178/2002;
- the 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;
- the Catalogue of Feed Materials (EU) 68/2013 and (EU) 2017/2017; and
- the 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 Bodies

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 as follows.

Medicinal Cannabis

The 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. As cannabis has been removed from the scope of application of the BtMG, it is now regulated in the MedCanG. The competent authority for the application of the MedCanG is the BfArM. The BfArM is not responsible for any tasks in connection with the KCanG.

Following the BtMG's reform in 2017, and in line with the UN Single Convention on Narcotic Drugs, the BfArM created a Cannabis Agency (*Cannabisagentur*) that is responsible for issuing licences for the cultivation of cannabis for medical purposes and for medical-scientific purposes in Germany. The requirements for the pharmaceutical quality of herbal medicinal products must be met for permission to cultivate for medicinal purposes. This primarily concerns the quality-determining process steps of cultivation, harvesting, trimming, drying and storage.

State authorities responsible for medicinal products

The sale of medicinal cannabis by doctors and in pharmacies is subject to supervision by the respective state authorities.

Also, the individual state authorities are responsible for the general enforcement of the German Medicinal Products Act (*Arzneimittelgesetz*, AMG). This concerns, in particular, the granting of wholesale and import licences.

Recreational Cannabis

The competent authority for the supervision of cultivation associations is determined by the relevant states.

Lifestyle Products

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

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

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

The German Federal Office for Agriculture and Food (BLE)

The BLE is responsible for the import regulations regarding 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-Regulatory Authorities

Several German and European industry associations cover cannabis-related topics – for example:

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

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

In relation to the founding of cultivation associations ("Cannabis Social Clubs"), Cannabis Cultivation Associations Germany (CAD) was founded to represent the interests and concerns of cannabis cultivation associations and to promote the sustainable, responsible development of legal cannabis cultivation and consumption for recreational purposes in Germany. In addition, numerous Cannabis Social Clubs have already been founded in the 16 federal states, and will be allowed to operate from 1 July 2024.

1.4 Challenges for Market Participants

There are several challenges that market participants in the cannabis sector face and must 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 process.

The timeline of the approval process for licences at state level can differ in every German state. Certifying manufacturing sites under the EU GMP rules, particularly 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.

The 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 further reform in 2024 with the legalisation of cannabis for private consumption (including the establishment of Cannabis Social Clubs) has brought further change in the legal landscape. The second pillar of the legislative reform, which envisages the

testing of distribution by professional providers as part of regional pilot projects with commercial supply chains, has not yet been implemented but is on the government's agenda.

The regulations for certain product categories (cosmetics, food, feed, etc) remain unclear, or simply missing, making it difficult for the authorities to issue clear recommendations and thus to create legal certainty for market participants.

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

Many planning uncertainties persist for the industry – owing to the current uncertainties on how the full legislative plans will proceed – particularly for the medical cannabis sector. For example, newcomers to the business are faced with the question of how much they must comply with the strict safety requirements that currently apply, when the measures – which are often cost-intensive – may be overdue in just a few months/years and violations that have occurred by then may be granted amnesty.

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 a medicinal product or an active ingredient. It is therefore essential to choose the right location for a cannabis business.

High Requirements for Cultivation in Germany

Companies wishing 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.

- If a company wishes to cultivate medicinal cannabis, it requires a licence from the BfArM, Section 4l MedCanG, which can take time. (Note: prior to the 2024 reform, only companies authorised by the German Cannabis Agency were allowed to cultivate cannabis in Germany. In April and May 2019, the Cannabis 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 cultivation premises must be highly secured so that unauthorised access can be excluded.
- Due to the unfavourable weather conditions in the country, the indoor cultivation of cannabis requires a lot of energy, which makes production costly.

Difficulties in Establishing Brand Recognition for Medicinal Cannabis and Recreational Cannabis

In Germany, except for 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 presented prescription and be 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. However,

some participants in the market have – so far successfully – experimented with collaborations with pharmacies, whereby cannabis flowers or extracts have been dispensed to pharmacy customers as magistral formulations in branded packaging as part of this collaboration.

With respect to recreational cannabis, advertising and any form of sponsorship for cannabis and for cultivation associations are prohibited (Section 6 KCanG), which makes it very difficult for companies operating in that area to achieve brand recognition.

1.5 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 wishing to engage in the cannabis business, including the following.

Lack of Legal Certainty

The legal landscape, both in Germany and at the EU level, is constantly changing, so a current major legal risk is a lack of long-term certainty. It may very well be that an assessment of a certain product's legality changes during 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 food law? Also, the classification of a product (eg, as a cosmetic, general commodity or food) is essential for the marketability of such a product.

Criminal and Administrative Liability

Cannabis and non-synthetic THC are no longer legally classified as narcotics within the meaning of the BtMG; as such, criminal liability is no longer the focus. However, violations of official licensing requirements and record-keeping obligations, unauthorised advertising or sponsorship constitute administrative offences and are punishable by a fine. Permission for the cultivation association may also be revoked.

Particularly in the CBD sector, companies too often run the risk that their product will not be classified under the exemption of KCanG for industrial hemp, as authorities/courts rule that misuse for intoxication purposes cannot be ruled out for many products. Based on that determination, such product will fall within the scope of the KCanG and cannot be marketed, and the involved persons would face criminal charges for illegal trade with cannabis (see Section 34 et seq KCanG). Even though some German and EU case law on the subject now exists, there is still a degree of legal uncertainty when abuse for intoxication purposes is affirmed.

When marketing medicinal cannabis, a risk exists under criminal law when the provisions of the MedCanG are not adhered to – eg, when medicinal cannabis is not marketed with the respective licence (see Section 25 et seq MedCanG). Furthermore, the prohibition of lay advertising under the German Drug Advertising Act (*Heilmittelwerbegesetz*, HWG) has to be observed.

Seizure of Revenues

Where 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 include the turnover of the company.

1.6 Enforcement & Penalties

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

Prosecution Authorities and Regulatory Authorities

Currently, several criminal law and administrative law regulations apply in connection with cannabis, such as the following.

KCanG

As mentioned previously, cannabis is no longer a prohibited substance under the BtMG. The criminal provisions of the BtMG are therefore no longer applicable to cannabis. Instead, the KCanG itself regulates criminal offences in Section 34; such offences are based on the previous regulations. Anyone who possesses, cultivates, produces, traffics in, imports, exports, sells, dispenses, otherwise puts into circulation, acquires or otherwise obtains cannabis contrary to the exemption provisions in the KCanG can be punished with imprisonment of up to three years or with a monetary penalty. In particularly serious cases, the penalty is a prison sentence of three months to five years. According to Section 36(5) KCanG, the advertising/sponsoring of cannabis, directly or indirectly, constitutes an administrative offence which is subject to a fine of up to EUR30,000.

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 with a monetary penalty.

The Medicinal Products Act

According to Section 95, paragraph 1, No 4 and Section 45, paragraph 1, sentence 2 AMG, it is forbidden to trade with prescription medicinal products outside pharmacies. This can particularly apply where CBD lifestyle products are advertised as medicinal products.

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

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 for competitors or consumer associations to 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 Matters

2.1 Cross-Jurisdictional Issues

There is no fully harmonised legal landscape within the EU in relation to medicinal cannabis, which leads to different rules across EU member states and can also lead to various cross-jurisdictional issues. In Germany, this is particularly noticeable in connection with the importation of medicinal cannabis from third countries outside the EU – the biggest challenge for manufacturers in third countries is obtaining EU GMP certification to make importation to the EU possible.

Some countries have concluded mutual recognition agreements (MRAs) with the EU. Upon suc-

cessful 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 regarding whether the MRA also includes cannabis, as the scopes of agreements vary.

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 must travel to the relevant manufacturing sites. Third-country inspections were significantly stalled due to the ongoing COVID-19 pandemic.

However, the strict EU GMP rules are not applicable where the cannabis product is classified as an active pharmaceutical ingredient (API) instead of as a medicinal product. This classification needs to be confirmed by the authority of the country of origin (with a written confirmation), and the German authority must also have the same classification for the product to be imported. As the import licence falls within the competence of the individual states, such classification also differs across 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 a medicinal product and prohibit importation until the manufacturing site has been EU GMP-certified.

So far, German authorities have allowed imports of cannabis from numerous jurisdictions, including Australia, Denmark, Israel, Jamaica, Canada, Columbia, Lesotho, Malta, New Zealand, the Netherlands, North Macedonia, Austria, Poland, Portugal, Spain, Uganda and Uruguay.

3. Legal and Regulatory Developments

3.1 Access to Medical Cannabis

Several legal elements that affect access to medical cannabis must be considered.

Untrained Physicians

Only a physician can prescribe cannabis or finished medicinal products with cannabis (see Article 3 MedCanG). However, many physicians are still reluctant to prescribe cannabis. This is, inter alia, caused by the persistent stigma of cannabis as a recreational substance. Furthermore, physicians often have a lack of knowledge about prescribable cannabis products and possible effects.

Few Medical Studies

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

However, where a therapy with medicinal cannabis has been approved by the statutory health insurers (see **1.1 Primary Laws & Regulations**), participation in an accompanying survey conducted by the BfArM was obligatory. This survey was completed by 31 March 2022 and the results were released on 6 July 2022. Although the survey has been partly criticised in professional circles (especially as the data sets were insufficient), it did provide information on the scope of application of medicinal cannabis, the average user and the average effectiveness of the treatment as perceived by patients – which,

for example, in the case of cannabis flowers was rated as positive by over 90% of those treated.

Reimbursement Depends on the Health Insurer

As outlined in **1.1 Primary Laws & 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 must 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 this bureaucratic burden, a health insurance company has – for the first time – already signed a contract with the German Society for Pain Medicine (DGS) to facilitate the provision of medicinal cannabis, especially in pain therapy. Rebate contracts between pharmaceutical wholesalers of medicinal cannabis and public health insurers are also in place.

3.2 Non-controlled Cannabinoids in Food

Foods containing cannabinoids have been trending in recent years and are still of interest, with the topic being much discussed. However, foods containing cannabinoids are currently not marketable in Germany for the following reasons.

Food Containing Cannabinoids Is Considered "Novel Food"

In Germany, food and food supplements with cannabinoids are currently classified as "novel foods" 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 to 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 as an addition to the so-called Union List, in accordance with Article 10 ff Novel Food Regulation. To date, the European Commission has not authorised any food or food supplements containing CBD. Foodstuffs containing CBD are therefore not yet marketable in light of the requirements of the novel food regime.

- Many local authorities have acted forcefully against companies selling food and food additives containing CBD. In some cases, products have had to be taken off shelves and administrative proceedings started. However, as previously discussed, 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.

Currently, the European Food Safety Authority (EFSA) has 19 applications for approving CBD as a novel food. In June 2022, EFSA indicated in a statement that the assessments on CBD will be suspended until new data on safety is available. So far, there have been no new developments in this regard.

Food Containing Cannabinoids Can Fall Under the KCanG

Food and food supplements are not marketable in Germany if they fall outside the definition of industrial hemp (see **1.1 Primary Laws & Regulations**).

Many products containing CBD include CBD extracts that derive from the whole cannabis plant, and may therefore contain THC residues. As such, the following needs to be observed.

Low THC content

The THC content of the food product may not exceed 0.3%.

No misuse for intoxication purposes

Another hurdle was and still is the question of misuse of the CBD product for intoxication purposes. This requirement was previously included in the BtMG and is now included in the definition of industrial hemp in the KCanG. This means that if industrial hemp is concerned the provisions in the KCanG (except regarding cultivation) do not apply.

With respect to "misuse for intoxication purposes" under the old provisions, the BGH has, in a recent decision, confirmed that an abuse of the food product derived from the cannabis plant for intoxication purposes must be excluded for all possible uses of 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% could 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, with a skilful baking process it is possible to make the THC usable for intoxication purposes.

It remains to be seen how the very strict interpretation will develop in the new legislative landscape.

3.3 Decriminalisation

Two-Pillar Legalisation

As planned by the German government (elected in September 2021), the legalisation of cannabis was to take place in a two-pillar model. The first pillar, which envisaged provisions for the controlled distribution of cannabis to adults for recreational purposes, has now been implemented (see **1.1 Primary Laws & Regulations**). Therefore, recreational use of cannabis is no longer prohibited in Germany.

The second pillar of the draft legislation related to the controlled distribution of cannabis in licensed stores. It provides for the trialling of distribution by professional providers as part of regional pilot projects with commercial supply chains. However, this second pillar has not yet been implemented. The aim is to give compa-

nies the opportunity to produce and distribute cannabis for recreational use and to sell it to adults in specialised shops within a licensed and state-controlled framework. The trial is to be locally limited, and comprehensively monitored and analysed.

However, Germany must co-ordinate the implementation of the second pillar with the European Commission. The government has until autumn 2025 to implement it during the current legislative period.

The Effect of the Legalisation on Past Convictions

As stated previously, Cannabis is no longer a prohibited substance under the BtMG. The criminal provisions of the BtMG are therefore no longer applicable to cannabis; instead, the KCanG itself regulates criminal offences in Section 34, and these are based on the previous regulations.

Previous convictions can be erased from the Federal Central Criminal Register upon application, if the conduct at the time is no longer punishable under the new law – in particular, for possession of up to 30 grams or personal cultivation of up to three plants (Section 40 et seq KCanG). When the legislation comes into force, investigations and criminal proceedings that no longer have a basis under the new law will be discontinued.

Furthermore, an amnesty provision has been introduced (which was a controversial aspect of the legislative process). According to this provision, sentences imposed before 1 April 2024 for offences that are no longer punishable under the new law and that are no longer subject to fines will be remitted when the new law comes into force.

Trends and Developments

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CMS Germany is one of the largest German law firms and forms a part of CMS Legal, a global firm with 77 offices in 43 countries and over 4,800 lawyers. CMS Germany is recognised as having a strong focus on the life sciences and healthcare sectors, with teams in Hamburg, Cologne and Düsseldorf. The life sciences team in the Hamburg office consists of 23 lawyers, with specialists in the areas of regulatory, product liability, drug advertising, co-operation agreements, IP, compliance and reimbursement. The Hamburg team has had a strong focus on cannabis law since the legalisation of medicinal cannabis in 2017. This expertise includes providing advice on regulatory and strategic issues in connection with German/EU market entry as a supplier of medicinal cannabis, and the setting-up of prescription (RX) cannabis businesses in Germany. CMS offers full-coverage advice for cannabis clients, including on structuring and negotiating transactions and on co-operations in the field. The team regularly advises on regulatory issues regarding food, animal feed, smoking/vaping products and cosmetics containing CBD.

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From Prohibition to Permission: Germany's Journey Towards Cannabis Legalisation

The further legalisation of cannabis – which has been planned for some time – took another major step this year. Since 1 April 2024, the first steps towards legalisation of cannabis for private consumption have been implemented. Cannabis for medical use had already been legalised in 2017.

A first (short) overview

The first step towards legalising cannabis was taken in 2017 by amending the Narcotics Act and accordingly the German Social Code, Book V, thereby legalising cannabis for medical use. These amendments to the law enabled (for the first time) seriously ill patients to obtain dried cannabis flowers and cannabis extracts on a doctor's prescription with a so-called narcotics prescription. While this legal reform has, to a large degree, been a success both for patients and for the cannabis industry, increasingly more companies have been jumping on the bandwagon of dispensing medicinal cannabis in Germany, while the market of purchasers has been growing steadily. Thus, over time, a stable set of rules and good practice for dispensing medicinal cannabis has been established.

However, the legalisation of medicinal cannabis has not silenced calls for further reforms. The socio-political discussion has also increasingly focused on the legalisation of cannabis for recreational purposes. This debate has now come to a preliminary conclusion with the Cannabis Act (*Cannabisgesetz*, CanG). As of April 2024, Cannabis is no longer qualified as a narcotic and no longer falls within the scope of the Narcotics Act (*Betäubungsmittelgesetz*, BtMG).

Furthermore, two new laws were enacted by the German Parliament on 27 March 2024: the Medicinal Cannabis Act (*Medizinal-Cannabis Gesetz*, MedCanG) and the Consumer Cannabis Act (*Konsum-Cannabis Gesetz*, KCanG). At the same time, several other laws have also been amended.

This is the result of a lengthy political initiative that is not yet completed.

A decisive driving force behind the legalisation-reform efforts in Germany was and still is the ambitious approach of the current German federal government, consisting of the Social Democratic Party (SPD), the Free Democratic Party (FDP) and Alliance 90/the Greens (*Bündnis 90/Die Grünen*) elected in Germany in 2021. In their election manifestos, all three parties had already announced their support for the legalisation of cannabis for recreational purposes, and aimed towards such legalisation within their legislative period.

These endeavours were then laid down in a first White Paper of the federal government for a comprehensive draft of a cannabis law in October 2022. After further consultation, this was developed in a second White Paper published in April 2023, leading to the first submission of a draft bill on the controlled use of cannabis and the amendment of other regulations (the Cannabis Act) by the responsible German Ministry of Health.

For medicinal cannabis, the MedCanG came into force on 1 April 2024, bundling the regulations on medical cannabis into one law.

On the same day, the KCanG also came into effect as regards cannabis for recreational purposes. According to the KCanG, non-commercial, private consumption and cultivation of cannabis has been decriminalised. The regulations on self-cultivation in cultivation associations will

enter into force on 1 July 2024. In addition, further legalisation on a commercial supply chain for recreational cannabis is planned (the so-called second pillar of the reform). Germany will co-ordinate the implementation of the second pillar with the European Commission – the government has until autumn 2025 if it still wishes to implement this within the current legislative period.

Medicinal Cannabis as the Starting Point for Legalisation

The "Cannabis as Medicine" provisions (Law on the Amendment of Narcotics Law and Other Provisions) entered into force on 10 March 2017 and changed patient care in Germany, particularly in the areas of pain and palliative treatment. From that point onwards, the prescription of medicinal cannabis is subject to the condition that, in the assessment of the attending physician, the drug may noticeably improve or influence the course of the disease or its symptoms.

In this context, the amendment to the German Social Code, Book V was also ground-breaking, as it allowed for an extended coverage of costs by the statutory health insurance, not only for finished cannabis-based medicinal products but also for dried cannabis flowers, provided these were necessary for therapeutic purposes.

As a further novelty, a dedicated Cannabis Agency was formed as part of the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*, BfArM) to steer and control the cultivation of cannabis for medicinal purposes in Germany. First licences for the cultivation of medicinal cannabis in Germany were granted to three companies: the Canadian companies Aphria (now Tilray Medical) and Aurora, as well as the German company Demecan. Furthermore, import licences for medicinal cannabis have been granted to many companies from numerous countries, including Australia, Denmark, Israel, Jamaica, Canada, Columbia, Lesotho, Malta, New Zealand, the Netherlands, North Macedonia, Austria, Poland, Portugal, Spain, Uganda and Colombia.

With the new MedCanG coming into force on 1 April 2024, the existing regulations on medicinal cannabis are bundled into one law. The major change is that cannabis is no longer classified as a narcotic, and thus the strict requirements regarding the prescription of narcotics are not relevant anymore (except for the active ingredient nabilone, a synthetic cannabinoid). If a company wishes to cultivate medicinal cannabis, it requires a licence from the BfArM. Unlike previously, however, a Europe-wide tender procedure is no longer required.

Legalisation for Recreational Purposes

The starting point

The positive developments regarding medicinal cannabis have contributed to the increasing popularity of cannabis as an active ingredient, and have attracted more interest and attention in society as well as in various industries and sectors. Accordingly, this success has not gone unnoticed at the political level either.

As the subject of cannabis for recreational purposes already received considerable attention in the coalition negotiations of the current German federal government, the steps towards further expansion of legalisation hardly came as a surprise after the federal election in 2021.

Initially, a consensus was reached within the federal government to introduce controlled dispensing of cannabis to adults for consumption purposes in licensed shops. In this regard, the Federal Minister of Health, Prof Dr Karl Lauter-

bach, stated that the primary objective of the legislative process must be to ensure the best possible health protection for consumers, as well as the protection of children and adolescents. According to the federal government, the advantages of legalising recreational cannabis outweigh the potential disadvantages. The existing risks were mainly seen in the large black market for cannabis, which lacked quality standards and controls, and which led to contaminated cannabis products entering the illegal market.

The legalisation of cannabis was also based on the intention to encourage consumers to use cannabis responsibly. Controlled dispensing to adults, combined with comprehensive health risk education, was intended to reduce the potential health risks of cannabis and to encourage regulated and responsible use, aiming (along with appropriate education) at the reduction of drug abuse, especially among young adults.

Due to legal concerns regarding compatibility of a *nationwide* licensed-shop model with international and European law, the initial plans were amended and the legalisation transformed into a so-called two-pillar model.

While the first pillar concerns the private, collective and non-profit self-cultivation of cannabis, the second pillar envisages the testing of distribution by professional providers as part of *regional* pilot projects with commercial supply chains.

First pillar: legalisation of private, collective and non-profit self-cultivation of cannabis

The first pillar was implemented with the Consumer Cannabis Act (KCanG), passed on 27 March 2024. Numerous parts of the law have already been in force since 1 April 2024.

The main provisions of the new KCanG are as follows.

- Persons who have reached the age of 18 are allowed to possess and carry up to 25 grams of cannabis.
- Persons who have reached the age of 18 and who have been permanently or ordinarily resident in Germany for at least six months may grow up to three cannabis plants at the same time for the purpose of personal consumption at their place of residence or habitual abode. The number of three cannabis plants applies per adult person in a household.
- Cannabis may only be cultivated and possessed for personal use. Distribution between private individuals is generally prohibited. Distribution to minors is a criminal offence and is punishable by a custodial sentence.
- Storage and consumption are restricted by various regulations – for example, cannabis may not be consumed in the vicinity of playgrounds and sports facilities or in the immediate presence of minors.

Further provisions of the KCanG will come into force from 1 June 2024. In particular, regulations are planned concerning the communal, non-profit cultivation of cannabis and the controlled distribution of cannabis and propagation material in cultivation associations for personal consumption (*Anbauvereinigungen*), also called "Cannabis Social Clubs".

The following provisions (among others) will apply regarding these associations.

- The number of members should be limited to a maximum of 500 persons.
- The association must be established as a registered association or co-operative, and must be registered with the competent court.

There must be at least seven members at the time of formation.
- The established association can only apply for a cultivation licence if it fulfils all local and personal requirements. The licence is limited to seven years, and can be reapplied for after five years. The competent authority still has to be determined by ordinance in the individual federal states.
- The persons authorised to represent the association must be reliable. The associations must also appoint a prevention officer, and must draw up a health protection and youth protection concept.
- The facilities of the association must be at least 200 metres away from the sites of schools, kindergartens, youth facilities and sports fields. The cultivation area must not be visible to the public and must be secured against unauthorised access. Furthermore, the cultivation area must not be located in a private flat or house.
- Only members may cultivate. They may only be employed and paid for cultivation as part of marginal employment (currently EUR538 per month). Employees may be hired without wage limits for activities outside cultivation, such as cleaning, security, accounting or laboratory services.
- Membership should require a minimum age of 18 years and residence in Germany.
- Members of a cultivation association receive a maximum of 25 grams of cannabis per day and a maximum of 50 grams of cannabis per month for personal use. For adolescent members (ie, persons who have reached the age of 18 but not yet the age of 21), the maximum monthly amount of cannabis to be distributed is 30 grams and may not exceed a THC content of 10%.
- The transfer should take place at the location of the club. Consumption on the site is prohibited.
- Dispensing should only take place in pure form (flowers or resin). Information on the product, dosage, application and risks of consumption, as well as on counselling centres, must be included. The packaging must be neutral in design.
- The costs for the acquisition of cannabis should be covered by membership fees. There is no upper limit for membership fees.

The approach of this first pillar and its legal implementation are to be evaluated after four years.

Second pillar: legalisation of commercial supply chains

Perhaps the most significant deviation from the originally planned approach of legalising cannabis for recreational purposes is the fact that no licensed specialist shops are to be installed. Instead, scientifically monitored model projects in the form of commercial supply chains are intended to be implemented in districts and cities of several federal states. This is to implement the planned dispensing in specialised shops, albeit in a different manner than originally envisaged.

These projects aim to enable companies to produce, distribute and sell to residents of the model regions in specialised shops. The project duration is limited to five years as of the establishment of the supply chain. At the end of this period, the project shall be evaluated regarding health and youth protection as well as the effects on the black market.

However, the German federal government already stated in the White Paper that no time

perspective can currently be given for this second pillar. This pillar of the legalisation project is still subject to notification, meaning that a final decision can only be expected after consultation with the European Commission.

Further Updating of Cannabis Legislation

In addition to the legal changes already mentioned, other laws were amended as part of the legalisation efforts, including the following:

- the Medicinal Products Act (*Arzneimittelgesetz*, AMG);
- the Federal Non-Smoker Protection Act (*Bundesnichtraucherschutzgesetzes*, BNichtrSchG);
- the Workplace Ordinance (*Arbeitsstättenverordnung*, ArbStättV);
- the Road Traffic Act (*Straßenverkehrsgesetz*, StVG);
- the Criminal Code and the Code for the Federal Register of Criminal Offences (*Strafgesetzbuch*, StGB and *Bundeszentralregistergesetz*, BZRG); and
- cannabis and non-synthetic THC are no longer legally classified as narcotics under the Narcotics Act (BtMG).

Outlook

The present German federal government still has until the end of the term in 2025 to finalise its plans for cannabis legalisation, and to implement them according to the political agenda. To date, the legislation shows the relevance and willingness with which the issue of cannabis is being addressed on a political level.

With the recently implemented law, a first step has been taken. Even if there might be some disappointment for the industry and consumers regarding the divergence from the initial far-reaching approach, the quick implementation of the first pillar shows that the federal government has treated cannabis legalisation as a priority. It remains to be seen to what extent the second pillar will be implemented, and within what timeframe. Ultimately, the decision for this lies first and foremost with the European Commission, on whose approval the project partly depends.

However, the current fast-moving developments show that Germany is trying to set an example and to take a measured approach on the matter of cannabis legalisation. Only time will tell where the developments lead in the coming weeks and months, not only for Germany but for all of Europe.

ISRAEL

Law and Practice

Contributed by:
Adi Rozenfeld, Yoni Ahrend and Shira Gutman
Herzog Fox & Neeman

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Herzog Fox & Neeman combines an interdisciplinary approach with its extensive team of hundreds of legal personnel. The firm's expertise allows it to provide businesses with tailored solutions to legal issues, promoting both organic and M&A-based growth. Services include approval and licensing; representation before regulators; local and international M&A; corporate law; investment transactions; commercial agreements; IPOs; dual listings; mass financing; ongoing consultation to public and private companies; tax consultation; medical patents and trade marks; employment agreements; and general financing matters. Herzog Fox & Neeman's cannabis desk offers a range of strategic and legal services, both locally and internationally. The firm advises clients on all stages of the supply chain – from cultivation, manufacturing, marketing and distribution to sale. The office maintains direct contact with regulatory cannabis bodies in Israel and overseas, leading foreign firms servicing the cannabis industry, and research and pharma entities at the forefront of cannabis technology.

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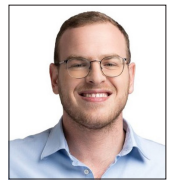

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1. Regulatory Framework

1.1 Primary Laws & Regulations

The State of Israel signed the 1961 Single Convention on Narcotic Drugs ("the Convention") aimed at stepping up comprehensive measures and international co-operation against drug trafficking. In particular, the Convention establishes unique supervision and controls of cannabis, including the existence of a government agency responsible for regulating its use.

In addition to the Convention, local laws, an ordinance, government resolutions, and official procedures regulate Israel's medical cannabis industry. The 1977 Penal Law sits at the heart of criminal law in Israel, and addresses the matter of drugs, including cannabis, although mainly within the context of convictions. The Dangerous Drugs Ordinance (New Version) enacted in 1973 (the "Ordinance") and the Dangerous Drugs Regulations of 1979 (the "Regulations"), as amended from time to time, regulate the use of cannabis in the country. The Ordinance is divided into two additions, with the first further separated into two parts that distinguish between substances, the lawful possession of which requires a licence from the Director as defined in the Ordinance – "the Director General of the Ministry of Health or a person authorised by the Director" ("The Director" or "IMCA", respectively), and those that only require a prescription. Currently, cannabis is listed under the first part of the first addition, and therefore a licence from the IMCA is required for lawful possession.

In April 2022, the Knesset, or Israeli parliament, officially approved the Administrative Offences Regulations (Administrative Fine – Possession of Cannabis and its Use for Personal Consumption), 5772–2022 ("Administrative Offences Regulations") that completely rescind the possession of up to 15 grammes of cannabis for personal use as a criminal offence, and stipulate that such possession will constitute an administrative offence only.

In 2011, as part of Government Resolution 3609, the government committed to a programme that included policy development, enforcement, and supply for cannabis patients and researchers in the field. The development of this programme has made the state of Israel one of the first countries in the world to allow a quality supply source for medical cannabis patients similar to that of other medicines. Following this Resolution, in 2011, the Israeli Medical Cannabis Agency at the Ministry of Health (IMCA) was established.

Additionally, in 2013, Government Resolution 1050 was approved to regulate the area of cannabis for medical use, creating a proper cannabis supply source according to predetermined and established standards, as committed to by Resolution 3609.

In 2016, Government Resolution 1587 introduced regulation for the field of cannabis for medical use and research. The IMCA published the procedures, instructions and standards for handling the high-grade medical cannabis required for medication. The aim was to position cannabis closer to medicine by applying as many similar standards as possible, ensuring that the products produced from the plant are of high quality, and also to make the process of obtaining a medical cannabis licence/prescription easier for patients.

In 2016, the IMCA published procedures ("IMCA Procedures") for the medical cannabis industry that are still continuously updated to this day and include the following.

- Procedure 106 specifies the indications and medical conditions alongside the criteria for obtaining licences and/or prescriptions for the use of cannabis products.
- Procedure 107 specifies the guidelines for the operation, licensing, and manufacturing process applicable to cannabis and its derivatives for medical use (the "Road Map").
- Procedure 108 specifies the guidelines for submitting applications for licensing research and approving new forms of administration in the field of cannabis.
- Procedure 109 outlines the guidelines for the approval process for applications to import cannabis as a dangerous drug for medical use and research.
- Procedure 110 specifies the approval process of applications for the export of cannabis as a dangerous drug.
- Procedure 151 (GAP–IMC) stipulates the proper growing conditions for medical cannabis.
- Procedure 152 (GMP–IMC) specifies the quality requirements in manufacturing cannabis products for medical use.
- Procedure 153 (GDP–IMC) stipulates the specifications needed for storage, distribution and delivery of medical cannabis products.
- Procedure 155 (GWDP–IMC) mandates the correct elimination process for cannabis intended for destruction.

In August 2023, the Ministry of Health published an "Enabling Reform Outline" ("the Reform"), in light of which, on 1 April 2024, the IMCA's Regulations and Procedures were amended. In accordance with the Reform, it is now possible for doctors to prescribe cannabis for medical purposes within the framework of public medicine, according to the Regulation's guidelines, as opposed to the previous licence model. Subject to Procedure 106, the prescriptions may be given to patients under certain indications set down by the IMCA. The Reform also eliminated cannabis as a "last resort treatment" for some indications, as detailed in **3.1 Access to Medical Cannabis**.

In addition, the Reform has made cannabis research simpler. The research approval process now includes a structured research licence for farms or factory owners and a standardised method of proving the safety and efficacy of new delivery systems. It also facilitates research on new products in various fields including cosmetics, nutritional supplements and animal products, etc.

Moreover, the Reform calls for several easements, as follows:

- significant alleviation of the export process;
- changes to product packaging; and
- the approval of new delivery systems due to the significant health risks associated with smoking, resulting in vast public interest in enabling new ways of cannabis consumption, etc.

Furthermore, some cannabinoids are expected to be exempt from the Ordinance (see **3.2 Non-Controlled Cannabinoids in Food**).

1.2 Regulatory Bodies

As the Convention required the establishment of the IMCA, it was set up in 2011 under the Ministry of Health, according to Government Resolution 3609. Subject to the Ordinance, the IMCA grants patients who meet the criteria licences or prescriptions to use medical cannabis. Procedure 106 laid down the indications, conditions, and situations in which a medical cannabis licence can be issued to a patient. As mentioned, according to the Ordinance, cannabis is defined as a dangerous drug, and prohibited for use without a licence or prescription.

The IMCA is the responsible regulatory entity for all regulation regarding the issuance of licences to operators in the field of medical cannabis, and thus constitutes a significant and almost exclusive regulatory body in the field. Any entity interested in engaging in the medical cannabis market that meets the threshold conditions specified by the IMCA will be able to engage in commercial cannabis activity, such as propagation, cultivation, manufacturing, transportation, warehousing, distribution, pharmacies, R&D, destruction, etc.

That said, there are several other regulatory bodies involved in the medical cannabis industry, as follows.

The Israeli Police

Once the initial application has been made for a licence to operate/use cannabis, the police are responsible for checking whether any information about the applicant could disqualify them from receiving a licence. If such information exists, the request will be denied. If no disqualifying information comes to light, it is possible to obtain an initial approval/licence, assuming the applicant satisfies all remaining conditions. In addition, the police examine and issue security approval for the location of a cannabis business every time a licence is renewed.

The Ministry of Agriculture

Applications for a cultivation licence require preliminary approval for the location of a cannabis farm from the Rural Planning and Development Division of the Ministry of Agriculture. In certain cases, approval from the Ministry of Agriculture will also be required in order to perform pesticide residue tests with respect to the agricultural produce of the farm.

The Israel Land Authority

The Land Authority restricts the use of agricultural land for commercial purposes (see **1.4 Challenges for Market Participants**).

The Planning Administration

To obtain a licence to operate facilities, one must meet the requirements of planning and building laws. Additionally, for some applications, a certificate proving that the applicant has lawful rights in legally constructed buildings may be required; or, in the case of building plans, a building permit must be attached.

1.3 Self-Regulatory Authorities

While in Israel regulation and supervision of the activities of patients and operators in the cannabis market is carried out exclusively by the government and the competent authorities, there are entities and associations that act for the benefit of patients and the public. The main associations are as follows.

- The Medical Cannabis Association, established by medical cannabis patients in 2016 with the aim of promoting their public activities and patient rights. The association promotes its goals, inter alia, by filing petitions to the High Court of Justice and providing voluntary accompaniment in the approval process for individual patients. In addition, the association advises and guides hundreds of cannabis patients annually through bureaucratic and legal channels.
- The medical cannabis lobby in the Knesset, which assists in the promotion of legislation and protection of patient rights, and carries out parliamentary, legal and media activities to raise awareness and promote solutions to issues within the cannabis field.

1.4 Challenges for Market Participants

Market participants face several notable challenges in Israel, the main one being frequent regulatory fluctuations arising from the fact that the cannabis market is still new and cultivating a body of knowledge via research. As such, regulations are constantly adapting to catch up with a rapidly developing industry, and local industry players that are developing new products must take this impaired reliability into account in making business decisions.

Also, it should be noted that, according to the Ordinance, cannabis, and that includes any part of the plant, is still defined as a dangerous drug. This has resulted in the adoption of a slightly negative attitude towards the local market and the entrepreneurs who wish to operate within the related legal framework provided. However, the market's public image is steadily improving.

In addition, considering the political instability that the State of Israel has been experiencing, various arrangements and laws regarding some areas of the cannabis field remain unclear, increasing uncertainty and reducing confidence in the norms currently in force.

Finally, as of the time of this publication (May 2024), the Israeli market is limited in several areas as compared to other markets around the world, due to the existing legal prohibition on the following products/components:

- cannabis oil for vaping and smoking; and
- cannabis or hemp in consumer products/goods such as food, supplements, and cosmetics.

Agricultural Settlement Law

In accordance with Section 8.12.1 of the Israel Land Council Resolution 2024, the use of agricultural land for commercial purposes is restricted such that cannabis companies operating on agricultural land owned by the government (which represents over 90% of land) are limited in their share capital. This introduces a built-in restriction on operators, forcing them to make do with low holdings.

Cultivation in Greenhouses and Climatic Conditions

In Israel, most cannabis cultivation is carried out in greenhouses, and is subject to seasonal conditions and the variables of nature. In fact, some farms can grow only during certain months of the year, and mainly during the winter. The scorch-

ing heat of the Israeli summer forces growers to use expensive cooling mechanisms in cultivation rooms, which often forces breaks until the end of the warm season to avoid heavy electricity costs.

Both in Israel and around the world, raising capital for cannabis companies under current market conditions is challenging, and is compounded by the significant price declines that cannabis has endured across the globe, which have also affected the local market. Additionally, cannabis patients' preferences often fluctuate according to personal taste and participation in forums and groups on various media, which is particularly significant in the very small Israeli market. Rapid changes in patients' tastes and preferences often require companies to adapt quickly, sometimes leaving them with unsold inventory.

Lack of Personalised Treatment

Despite global and ongoing research, it is difficult to adapt cannabis strains to patients based on their individual needs, which is a challenge for both cannabis companies and patients alike. However, it is important to emphasise that the field remains determined to continue research and eventually bridge this gap.

1.5 Legal Risks

As stated, the Israeli cannabis industry is still considered new, and has not yet stabilised. Against this normative backdrop, companies face the following legal risks:

Legislation Changes

As detailed in **1.1 Primary Laws & Regulations**, Israeli legislation regarding cannabis consists of a hierarchy of many legislative documents. These include the Ordinance, regulations and government decisions that change and are updated from time to time. Government resolutions and the legal landscape are constantly changing, meaning that one of the current major legal risks is long-standing uncertainty, particularly considering the frequent turnover of governments and lack of governmental stability.

Liability and Criminal Record

As part of the process of obtaining approval to operate in the medical cannabis field, the operator is required to present a list of all those involved in their company. This list includes all interested parties, signatories, and managers/office holders, as well as any employees or subcontractors working in the field on behalf of the operator. The list is forwarded to the Israeli police, who examine the involved parties and their registration as well as any information available in the police systems. If disqualifying information arises, the operator will receive notice that their application has been rejected. As part of the application review process, the IMCA and the police are not required to disclose to the operator the reason for disqualification.

The IMCA's Extensive Enforcement Power

There are many guidelines that operators must meet across all the links of the value chain, including cultivation, manufacturing, storage, distribution, marketing, and dispensaries. The frequent regulatory changes, introduced at the discretion of the IMCA and the Ministry of Health, have led companies to cease their activities due to non-compliance with new restrictions and demands.

This reality of swift changes creates a certain risk for operators and constitutes a major consideration in entering the cannabis arena, since, if they do not meet new mandatory requirements, they may be required to destroy their goods and sometimes even cease activities.

Cannabis and Driving

In Israel, the legal status of medical cannabis patients behind the wheel is complicated. From a legal standpoint, it is strictly forbidden to drive while under the influence of cannabis or cannabis metabolites. That said, the prohibition comes with no clear provisions regarding the time that a driver should wait from the moment they consume medical cannabis until driving is permitted again. The issue has not yet been regulated by legislation. However, the Ministry of Health is set to publish regulations that will allow patients to drive under certain conditions, depending on the length of time that has passed since the cannabis was consumed and the amount of cannabis present in the patient's body. As long as such regulations have not come into effect, driving is prohibited for any person (including licensed patients) under the influence of cannabis or its metabolites.

Advertising Medical Cannabis Products

Under the law, it is illegal to advertise medical cannabis products without the written approval of the IMCA and outside of non-medical mediums. But it should be clarified that, in some cases, and at the discretion of the IMCA, certain content can be considered for advertising. The rationale behind this prohibition is to protect public safety by avoiding the creation of a recreational retail atmosphere that encourages the use of cannabis for non-medical purposes.

This makes the operation of cannabis-based business challenging, as one must retain a competitive advantage without the aids of advertisement and marketing materials. However, it should be noted that while specific products may not be advertised, there are no limitations on advertising the cannabis companies themselves.

Importing Medical Cannabis

Under the current regulatory framework, importing cannabis into Israel is permitted, and imported products constitutes a high percentage of the products on the shelves. However, to import cannabis into Israel, one must meet the requirements of Procedure 109, which defines the import procedures in all aspects required. Under this framework, the import of cannabis end products is permitted only if they were manufactured under GMP IMC or EU–GMP standards, provided that they were transported, stored and maintained in proper transportation and storage conditions as defined by the IMCA. Compliance with these rules poses an additional challenge for those working in importation.

These risks are in addition to the hurdles presented in **1.4 Challenges for Market Participants**.

1.6 Enforcement & Penalties

Since cannabis is defined as a dangerous drug in the state of Israel, any unlicenced or unapproved operation with cannabis constitutes a violation of the criminal law and carries a criminal punishment in accordance with the Penal Law, 5737–1977.

Accordingly, both companies and prospective patients must comply with the Ordinance, the Regulations and IMCA Procedures. Failure to comply with the aforementioned constitutes a criminal offence that may lead to sanctions.

Enforcement and Penalties for Individuals

The entities tasked with enforcing compliance are mentioned in **1.2 Regulatory Bodies** above.

The Administrative Offences Regulations mentioned in **1.1 Primary Laws & Regulations** impose a monetary fine of ILS500 on individu-

als found with up to 15 grammes for personal use. Additionally, using cannabis in a public place will result in a fine of ILS1,000. Soldiers, prison guards and police officers were excluded from the Regulations, meaning that, for them, any amount of cannabis possession constitutes a criminal offence. In addition, following the Regulations, President Herzog and the Minister of Justice called on citizens who were convicted of using or possessing cannabis for personal consumption to appeal to the authorities to have their criminal records expunged. The Administrative Offences Regulations also stipulate that possessing a quantity larger than 15 grammes for personal use may hold a penalty of up to three years in prison. Additionally, a penalty of up to 20 years in prison applies for importing, trafficking, supplying or any other transaction involving cannabis.

Enforcement and Penalties for Operators

In accordance with the provisions of Procedure107, all interested parties, signatories, managers/office holders, employees and any subcontractors engaging in the field on behalf of the operator must comply with the Ordinance, Regulations and Procedures and their licence, as mentioned in **1.1 Primary Laws & Regulations**.

The operator is required to detail any changes to the details of the involved parties indicated above to the IMCA.

2. Cross-Jurisdictional Matters

2.1 Cross-Jurisdictional Issues

There are no common cross-jurisdictional applicable.

3. Legal and Regulatory Developments

3.1 Access to Medical Cannabis

There are several elements that affect access to obtaining a licence to operate or use medical cannabis, as follows.

Lack of Authorised Doctors to Issue Medical Cannabis Licences

There are over 140,000 medical cannabis patients in the State of Israel today. However, there are only 65 doctors who are authorised to issue and renew licences for these patients, of whom a much smaller number do so in practice. This situation causes many delays and difficulties in obtaining and renewing licences.

Lack of Insurance Reimbursement

Currently, medical cannabis is not defined as a registered medication in the Israeli Medication Registry. Therefore, most insurance companies will not reimburse expenses for the purchase of medical cannabis and its ancillary products. The few insurance companies that do reimburse patients do so only for oncology patients.

Likelihood of Increasing Patient Access

There is high likelihood that patient access to medical cannabis will increase as regulations become more favourable. As mentioned in **1.1 Primary Laws & Regulations**, the Reform eased and simplified all regulatory and licensing processes for patients.

The most significant change brought on by the Reform was the introduction of a prescription-based model rather than the previous licence-based model for the following:

- cancer;
- Crohn's disease;

- AIDS;
- multiple sclerosis;
- Parkinson's disease;
- Tourette's syndrome;
- epilepsy;
- autism;
- dementia; and
- those given the prognosis of less than six months to live.

Additionally, the Reform eliminated cannabis as a "last-resort treatment" for the following indications:

- cancer;
- stomach illnesses;
- AIDS;
- multiple sclerosis;
- Parkinson's disease;
- epilepsy; and
- dementia.

Previously, patients had to demonstrate that other conventional forms of treatment were ineffective over long periods of time although now, for some indications, the period required for demonstration is shorter.

Both milestones show a trend in broadening patient access to medical cannabis, and there is a high likelihood that this trend will continue.

3.2 Non-controlled Cannabinoids in Food

Currently, cannabis is defined in the Ordinance as "Any plant or part of a plant of the cannabis family and any part thereof, including its roots but excluding oil produced from its seeds" (the first addition to the Ordinance).

Thus, all parts of the cannabis plant are considered dangerous drugs, and are completely prohibited for use or consumption in any way, including in food and cosmetics. Despite the above, according to publications by the Ministry of Health regarding the Reform, it is possible that, as of early June 2024, only cannabis with psychoactive components with a concentration of more than 0.2% THC (and the rest of its family of cannabinoids) will remain in the Ordinance. Thus, cannabinoids with less than 0.2% of psychoactive components will no longer be covered under the IMCA regulation, but rather under the food and cosmetics regulation.

3.3 Decriminalisation

In Israel, the recreational use of cannabis is strictly prohibited. The legislative source of the criminal prohibition is the Ordinance, which defines the rules regarding the various types of offences (possession, cultivation, commerce, etc) and determines the various penalties for these offences.

"Decriminalisation" Regulations

The prohibition notwithstanding, in recent years there has been a change in attitudes in state institutions regarding minor drug offences (personal use of cannabis). Thus, in April 2019, the Dangerous Drugs Law (Special Fine Offence – Temporary Order), 5778–2018, came into effect, which states that an offence of consuming or possessing cannabis for personal use will result in an administrative monetary fine only. If another offence is committed within five years from the date of the first offence, the fine will be higher. These fines will be considered a special fine offence under the Criminal Procedure Law (Combined Version), 5742–1982.

After three years, with the expiration of the order, the Knesset officially approved the Administrative Offences Regulations, which stated that possession of cannabis for personal use (up

to 15 grammes) will result in an administrative offence only (see **1.6 Enforcement & Penalties**).

Export to Non-medical Markets

The Reform includes easements in cannabis exports. Prior to the Reform's entry into effect, cannabis could be exported only in accordance with Israeli rules and standards and only for medical purposes. In accordance with the Reform, the words "for medical use and research" were deleted from Procedure 110, which defines the guidelines for the approval process of applications for export of a dangerous cannabis drug.

This change marks a significant and positive milestone for exporters, as it dramatically expands their market reach. Additionally, exporters are no longer bound by stringent regulations, as there is no longer a need to comply specifically with Israeli standards, although they still require an import permit from the receiving country.

In conclusion, over the years, many bills have been and continue to be submitted, aimed at regulating recreational use. This increase in legislative pressure demonstrates an upward trend in favour of legalisation.

Disclaimer: While the above discusses legal issues, and is grounded in expert legal knowledge, it does not constitute legal advice or act in replacement of it. Moreover, it is only applicable at the time of publication of this guide (May 2024), as the legal landscape is constantly evolving.

Trends and Developments

Contributed by:
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Herzog Fox & Neeman combines an interdisciplinary approach with its extensive team of hundreds of legal personnel. The firm's expertise allows it to provide businesses with tailored solutions to legal issues, promoting both organic and M&A-based growth. Services include approval and licensing; representation before regulators; local and international M&A; corporate law; investment transactions; commercial agreements; IPOs; dual listings; mass financing; ongoing consultation to public and private companies; tax consultation; medical patents and trade marks; employment agreements; and general financing matters. Herzog Fox & Neeman's cannabis desk offers a range of strategic and legal services, both locally and internationally. The firm advises clients on all stages of the supply chain – from cultivation, manufacturing, marketing and distribution to sale. The office maintains direct contact with regulatory cannabis bodies in Israel and overseas, leading foreign firms servicing the cannabis industry, and research and pharma entities at the forefront of cannabis technology.

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Introduction – Pathway to Legalisation?

For years, the legalisation of cannabis has been gaining traction gradually in Israeli discourse. However, despite winning support both in the court of public opinion and among many lawmakers over the years, various efforts towards full legalisation have stalled in parliament. While Israel's medico-regulatory approach to cannabis has driven imperative research and development, it has challenged broad access to those in need and limited commercial opportunities for local industry as its regulation remains very tight. However, reforms implemented this year, bi-partisan support and increased demand all point to a major shift, offering the potential for easements for patients as well as commercial opportunities across the entire value chain.

Short Overview – History of Regulation and Status Quo

Under the 1961 Single Convention on Narcotic Drugs (the "Convention"), of which Israel is a signatory, and its Dangerous Drugs Ordinance (DDO), cannabis is classified as a "dangerous drug" in Israel. Nonetheless, both allow for the medical or scientific use of cannabis under strict supervision and regulation.

In 2011, Government Res. No 3069 established a regulatory authority in Israel responsible for all aspects pertaining to the supervision, control, and regulation of cannabis with respect to its propagation, cultivation, post-harvest processing, distribution, delivery, possession, transportation, destruction, consumption, and research, under the Ministry of Health. In 2013, these responsibilities and associated powers were transferred to the newly established Israel Medical Cannabis Authority (IMCA).

In terms of patient reimbursement in Israel, cannabis patients are entitled to partial or full reimbursement under the discretion of the Ministry of Defence and the National Insurance Institute (social security).

Although the Ministry of Health has granted patients licences to use cannabis for medical purposes under certain conditions, it maintains that cannabis is not a medicine, and that its efficacy and safety as a medicine have not yet been sufficiently demonstrated. It also contends that cannabis should be handled like any other complementary medical product that is subject to regulation in order to protect public health and welfare.

However, Procedure 106 of the IMCA, which sets out a list of medical conditions that merit treatment with medical cannabis products, and was published along with its inception, states that there is evidence that cannabis could aid patients afflicted with certain medical conditions and alleviate their suffering. Medical disorders are periodically reviewed and updated for inclusion. They currently include Tourette's syndrome, multiple sclerosis, cancer, pain, nausea, seizures, muscular spasms, epilepsy and post-traumatic stress disorder.

Pursuant to Procedure 106, medical cannabis licences were granted to patients by a select number of IMCA-approved doctors which, at times, presented a complex bureaucratic situation as bottlenecks were created due to high demand and the limited number of authorised doctors.

A framework for regulating the cannabis industry for medical purposes and establishing a reliable source of cannabis supply in accordance with agreed-upon standards was adopted in 2013 with Government Res No 1050 ("Resolution 1050").

The "Road Map," also known as Government Res. No 1587 ("Resolution 1587"), was enacted by the Israeli government in 2016, establishing a uniform licensing procedure for all cannabis-related activity. Based on the Road Map, each operation in the medical cannabis field, including propagation, cultivation, manufacturing, storage, distribution, and pharmaceutical services, must comply with the provisions of applicable laws and have IMCA approval.

The aim of the resolution was to regulate the use of cannabis for medical purposes and establish professional authorisation criteria for its use in treating medical conditions. The "Road Map" resulted in the following:

- it gave cannabis medical status;
- it ensured medical-grade product quality through proper supervision;
- inessential barriers for patients were removed and accessibility eased;
- the number of authorised doctors was increased;
- the number of operators engaged in cultivation and supply was extended; and
- it introduced supervision of proper medical practice and use labels.

Of special note is the fact that, for some medical conditions, the resolution examined the transition from a licensing regime to a prescription regime.

In April 2019, the Ministry of Health's Medicalisation Reform entered into force enacting a new reform regarding the issuance of licences and the use of medical cannabis. The reform created a shift away from the grower-to-patient distribution model in favour of a comprehensive value-chain model that covers not only the growing of medical cannabis but also manufacturing, storage, distribution, transportation, and exclusive pharmaceutical services. The new model nevertheless retained the licence-for-use requirement.

The Medicalisation Reform also defined new procedures and standards of quality and security, resulting in many farmers suddenly finding themselves no longer compliant. This led to their closure by the IMCA and to the destruction of much of their produce, resulting in a noticeable deficit in medical cannabis supply, negatively affecting patients and their therapeutic continuity. The result was the approval of a cannabis importation procedure and the easing of gov-

ernmental controls relating to the importation of medical cannabis products. As part of the Medicalisation Reform, the Israeli government also approved the export of medical cannabis.

Following the full implementation of the Medicalisation Reform, patient numbers climbed and eventually doubled, hitting 59,431 by February 2020.

Additionally in 2019, a three-year provisional ruling decriminalised adult usage of non-medical cannabis. The order stipulated that the private possession of cannabis would now be punishable by a specific fine offence, according to the procedures of Criminal Procedure Law, of ILS1,000 in total for the first infraction and roughly ILS2,000 for the second. If an adult repeatedly breaks the law, authorities may, at their discretion, launch criminal proceedings.

After the interim order came to an end in 2022, the Administrative Offences Regulations (Administrative Fine-Possession and Use of Cannabis for Self-Consumption) were formally passed by the Israeli parliament. These regulations completely abolished the criminal record for the offence of cannabis possession for personal use (in an amount of up to 15 grammes) and state that such possession will result in an administrative offence with imposition of a fine of ILS500, and that using cannabis in a public place will result in a fine of ILS1,000.

Furthermore, the regulations eliminated the distinction between the first infraction and subsequent offences (resulting in a greater punishment). The proposed laws also impose an administrative fine on those with criminal records; however, juveniles, inmates, and military personnel were left out of these decriminalised measures.

In accordance with the Administrative Offences Regulations, the President and the Minister of Justice invited those who had been found guilty of using or possessing cannabis for personal use to contact the authorities and request that their criminal records be expunged.

This shift from criminal to merely administrative punishment was perceived by the public as a significant step toward a less stringent regime.

Currently, CBD is regulated by the DDO, and is still perceived as a dangerous drug. In 2024, Israel intends to remove CBD and other non-THC cannabinoids, such as THCV and HHC, from the DDO. This initiative was also seen as encouraging by the public.

It is widely accepted that 2024 will be a year of significant cannabis reforms as the Ministry of Health published a draft for public comments entitled “Enabling Reform Outline” in August 2023, in which regulations and IMCA procedures were amended to ease and simplify all regulatory and licensing processes for practitioners, patients, entrepreneurs and operators.

The Enabling Reform is the broadest medical cannabis regulation to date. Perhaps the most anticipated change was the shift away from the licence model. Medical cannabis will become available through prescription for some medical conditions, like any other medicine, and will not be limited to a small number of IMCA-approved doctors, which is expected to eliminate the previous bottlenecks.

On 1 April 2024, the move away from licences to prescriptions came into force for cancer, Crohn’s disease, AIDS, multiple sclerosis, Parkinson’s diseases, Tourette’s syndrome, epilepsy, autism, dementia, and for those with terminal illnesses

and a prognosis of less than six months to live. All these patients are now able to obtain prescriptions from their doctors without a licence. Opponents contend that ignoring the needs of patients left outside the scope of this stipulation, eg, those suffering from PTSD, fibromyalgia, and chronic pain, could spur the use of substitutes from the opiate family of drugs.

As of April 2024, there are above 140,000 registered cannabis patients in Israel. As seen with the introduction of previous cannabis reforms, a further drastic increase in patients is expected as additional parts of the Enabling Reform enter into force incrementally.

Key Players and Characteristics

Israel boasts one of the world's most extensive and well-organised medical cannabis markets, with one of the highest patient per capita ratios.

The value chain in Israel is divided into the building blocks of cultivation, production, storage and distribution, transportation, and dispensation (pharmacies).

In addition to the various stakeholders described above, a number of government entities are involved in the ecosystem, as follows.

- The Ministry of Defence, the Ministry of Health, and the National Insurance Institute (social security) handle patient reimbursement, financing, and serve as recommending bodies;
- The Ministry of Agriculture preliminarily handles applications for a cannabis growing/breeding farm licence; the Israel Land Authority restricts the use of agricultural land for commercial purposes; and the Planning Administration ensures that licence applicants meet planning and building law requirements.

After the initial stages of an application for an occupation licence are cleared, the Israeli police are tasked with assuring that an applicant's record, including their criminal record, does not contain information that disqualifies them from receiving the licence.

The relatively large and growing quantity of cannabis patients in Israel has also boosted stakeholders in pharmatech, agritech and startups, attracted domestic and foreign investors, and driven further medical research in academia and hospitals.

The characteristics of the market are substantially influenced by Israel's:

- well-established clinical trial system;
- early foothold in cannabis research;
- advanced R&D capabilities;
- very significant concentration of startups; and
- universal healthcare system that continues to offer the market as it expands.

The Israeli medical cannabis market is supplied through local production as well as imports from, among other countries, Canada, Portugal, Lesotho, Uganda and South Africa. The market is undoubtedly a significant player in terms of import volumes, despite the small size of the country. Israel also exports cannabis, a trend that is expected to continue as the Israeli government eases exports for medical cannabis and allows for the export of non-medical cannabis, as per theEnabling Reform.

Future Developments and Trends

The local market is set to respond to the aforementioned top-to-bottom Enabling Reform and encourage several trends pertaining to both patients and the local industry.

In terms of patient trends, significant growth is expected, as the market will become more accessibility to many given the transition to a prescription model, as the pre-reform licensing mechanism created bottlenecks and required patients to navigate heavy bureaucracy.

The Enabling Reform is set to allow cannabis as a first-line treatment for some, as opposed to merely a treatment of last resort, offering better access, as the period required to demonstrate that other conventional forms of treatment were ineffective is shortened. Additionally, the Enabling Reform will expand the pool of those eligible for treatment, eliminating some age limits, including children with certain chronic conditions.

As of April 2024, the number of registered cannabis patients stood at just over 140,000. The regulatory changes, as well as the outcomes of the war, which led to an increase in PTSD cases and patients with chronic pain, are expected to significantly increase an already growing number of patients by approximately 70%.

In terms of easements for the local industry, significant simplifications for market participants in medical cannabis are underway. These include cannabis exportation, which is set to significantly increase as the Enabling Reform will approve outbound cannabis for both recreational and medical markets, and will align with EU-GMP standards (without needing to comply with Israel's standards) which will further extend the global reach of market participants, as mentioned in **3.3 Decriminalisation** of Law and Practice for Israel's Medical Cannabis & Cannabinoid Regulation 2024. Furthermore, the reform is also set to encourage cannabis innovation and research through the simplification of the entire process.

These promising steps forward in the local industry are expected to boost the number of local cannabis companies, and their specialties, value, and quality, whether their focus be on products, medical devices, delivery systems, agritech, or R&D.

Experts also foresee that the Enabling Reform will reduce the demand for illicit cannabis, which has been seen worldwide.

Additionally, the ongoing ambiguity surrounding CBD regulation is set to be addressed. The country's CBD industry is subject to significantly harsher regulations than North America and Europe, which is why many view this as a major step forward.

Commercial Opportunities and Challenges

The current and prospective regulatory environment presents both opportunities and challenges in the local market.

In alignment with Israel's mature and robust technological infrastructure, commercial opportunities in medical cannabis largely surround the areas of R&D, medical devices, delivery systems, agritech, genetics, and cannabinoid development. These opportunities have attracted myriad local and international players in pharmatech, hospitals, academia, tech startups, and among investors.

Additionally, as Israel offers comfortable regulatory conditions for clinical research, many countries, including the US, Canada, Australia, and Germany, among others, have outsourced their research to Israel, meaning that clinical trials are underway in this promising field where there is still much to discover.

The current regulatory environment does, however, continue to pose challenges for entrepreneurs and patients alike, as regulation tries to catch up and adapt to a global and fast-developing industry. The local industry is eager to perform, and is outpacing sluggish or outdated regulation, while political instability serves as an additional hurdle. However, as mentioned, the Enabling Reform is set to propel commercial activity as restrictions ease.

In line with the rest of the world, local market participants are also being tested by a tightened investment environment as we witness a slowdown in capital markets, private equity, and venture capital investments hurting the entire cannabis sector. Moreover, cannabis companies around the world are struggling as product oversupply has led to a significant decline in both wholesale and retail cannabis prices, which also affects local industry. However, many view this current lull as a sign of market correction, echoing trends in other young industries.

Conclusion – Market Outlook and Expert Opinion on Legalisation

The changes seen in the medical cannabis industry in recent years, as well as the maturity of the market, which, once volatile and unpredictable, has now stabilised, offer an optimistic outlook for patients and market participants alike.

The Enabling Reform is widely viewed as a transformative measure due to its extensive reach, aimed at enhancing accessibility for those in need while simplifying the previously complex regulatory landscape, once characterised by convoluted bureaucracy and supervision under numerous authorities, leading many market participants to endure hardship or financial strain.

Local experts are divided on the subject of legalisation. Several of them endorse it, considering it a positive, unavoidable step that could lead to the creation of a globally recognised domestic industry. Proponents cite the trends of increased job creation, increased investments for a sector in need, and a decline in use among youths and in overall crime that has been linked to legalisation elsewhere. They also note the developments seen in states that have since legalised cannabis due to tax revenues generated that are then redirected towards various public services and infrastructure projects.

On the other hand, critics point out public health concerns due to misuse, overconsumption, and over-accessibility to young people that only regulation can curb, since cannabis can impair or harm if abused or consumed in an uninformed manner.

In light of the above, the question arises as to the path Israel will take if legalisation can happen, which would certainly constitute a major milestone in the timeline of the country's cannabis programme.

In conclusion, Israel's regulatory shifts and market response will be interesting to follow in the coming months as patients and market participants alike anticipate much awaited change.

Disclaimer: While the above discusses legal issues, and is grounded in expert legal knowledge, it does not constitute legal advice or act in replacement of it. Moreover, it is only applicable at the time of publication of this guide (May 2024), as the legal landscape is constantly evolving.

ITALY

Law and Practice

Contributed by:
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Studio Legale Bulleri offers assistance and legal solutions in the field of civil law, with a particular focus on the areas of corporate and commercial law. The firm strives to pre-empt and resolve conflicts in a transactional manner, aiming to avoid litigation wherever possible. It deals with all facets of corporate life, including shareholders' meetings, potential dissolutions, liquidations, challenges to resolutions, and the interpretation of articles of association, while also handling relations between shareholders. A key objective is safeguarding the business interests of companies and resolving any disputes that may arise between shareholders or between companies and third parties. Finally, it takes care of all aspects concerning the economic and financial restructuring of companies in crisis due to over-indebtedness, and debt collection procedures with banks and various corporate creditors. The firm's expertise extends to real estate law, overseeing property transfers and transactions, including the management of judicial auctions. Studio Legale Bulleri also provides advisory and advocacy services in the cannabis and industrial hemp sector for the strategic business development of start-ups and companies in Italy and the EU.

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1. Regulatory Framework

1.1 Primary Laws & Regulations

The regulatory landscape surrounding cannabis is intricate, varying significantly based on its intended use, ranging from pharmaceutical to cosmetic, food, technical, and industrial applications. To navigate these complexities with clarity, it is practical to categorise the discussion into three distinct sections:

- medical cannabis;
- industrial hemp (from certified varieties); and
- recreational cannabis.

Medical Cannabis

In Italy, the primary legislative framework governing medical cannabis is Presidential Decree No 309/1990, the Italian Narcotics Act (*Testo Unico Stupefacenti*). Article 14, paragraph 1, letter b) of this Act stipulates the inclusion of cannabis and its derivatives in Table II of narcotic substances subject to supervision, prohibiting cannabis in its various forms, including flowers and leaves, oil and resin.

In Italy, cannabis is, as a rule, a narcotic substance, subject to exceptions based on its scope and intended use.

Cultivation, extraction of active ingredients, distribution, import and export are in fact subject to authorisation by the Ministry of Health – Central Narcotics Office (*l'Ufficio Centrale Stupefacenti*, UCS), which is the state agency for cannabis intended for scientific or research purposes.

The Ministry of Health Decree dated 9 November 2015 adopted the Collaboration Agreement between the Ministry of Health and the Ministry of Defence for the launch of the Pilot Project for the national production of cannabis-based substances and preparations of plant origin.

The purpose of this project was to develop national production in order to supplement the imports of cannabis that had hitherto been exported to Italy by the Office for Medicinal Cannabis of the Dutch Ministry of Health, Welfare and Sport (Bedrocan, Bediol, Bedrobinol and Bedica).

According to this agreement, the only national entity authorised to produce medical cannabis is

the *Stabilimento Chimico Farmaceutico Militare* based in Firenze (SCFM), which has developed the cannabis varieties FM2 (with THC content 5/8% and CBD 7.5/12%) and FM1 (with THC content 13/20% and CBD less than 1%) produced in accordance with EU Good Manufacturing Practice (GMP) in a pharmaceutical workshop authorised by the Italian Drug Agency (*Agenzia Italiana del Farmaco*, AIFA) and whose distribution is authorised by the UCS.

Recently, a public call for tenders was launched for the cultivation of cannabis for therapeutic use to be contracted to the SCFM. The selection and award process is still pending (see **3.1 Access to Medical Cannabis**).

Cannabis prescription and magistral preparations

Law No 94/1998 (the so-called Di Bella Law), which regulates "off-label" drugs, is the reference law for the prescription and administration of therapeutic cannabis.

Physicians may prescribe magistral preparations to be prepared by a pharmacist upon presentation of a non-repeatable medical prescription using Dronabinol or cannabis-based plant active substance for medical use.

Physicians must supplement the prescriptions with anonymous patient data on age, sex, dosage by weight of cannabis and treatment requirements according to the relevant form, which must then be transmitted to the competent region for statistical purposes. All physicians may prescribe cannabis regardless of their specialisation. Magistral preparations can be used in two different ways: orally or by inhalation.

Reimbursability of drugs charged to the National Health System (Il Servizio Sanitario Nazionale, SSN)

Law No 172/2017 provides that medical cannabis is reimbursable through the SSN, but this reimbursement is confined to treatments for specific pathologies:

- pain therapy (potentially any type);
- pain and spasms from multiple sclerosis;
- cachexia (in anorexia, HIV, chemotherapy);
- nausea and lack of appetite induced by chemotherapy;
- glaucoma; and
- Tourette's syndrome.

Despite the national provision for reimbursement, the practical application of this law varies significantly across different Italian regions. Each region is responsible for establishing its own technical modalities for the reimbursement process. Paid medical cannabis, on the other hand, can be bought in pharmacies outside one's region of residence.

Extracts

As set out above, extracts are included in Table II of the Narcotics Act.

However, a key principle exists: Legislative Decree No 219/2006 prioritises regulations for medicinal products. This means if a product with specific characteristics could be classified as both a medicine and another type of product it will be treated as a medicine.

This principle became relevant with the registration of the medicinal product Epydiolex (a CBD isolate with MCT oil) with the European Medical Agency (EMA). Since CBD is now an official active pharmaceutical ingredient (API) in

the European Pharmacopoeia, CBD isolates are considered medical products.

In June 2021, the Ministry of Health published guidelines for obtaining authorisations for the cultivation of cannabis intended for CBD extraction for medical use. This process requires a double authorisation:

- The pharmaceutical company, already authorised by AIFA to produce APIs, must obtain additional authorisation from the UCS. This authorisation allows them to manufacture cannabis extracts containing cannabinoids for API production.
- Separate authorisation is needed for the supply of starting plant material (hemp) and the destruction of any narcotic substances (THC).

In essence, a prior agreement is required between the farm (which is authorised to grow and supply the product to the pharmaceutical company) and the pharmaceutical company (which is authorised to supply the hemp produced by the farm, as well as the extraction of API). To date, only two extraction licences have been issued.

Finally, it should be mentioned that by Ministerial Decree dated 7 August 2023, the Ministry of Health lifted the suspension of the so-called 2020 Speranza Decree, which included CBD-containing preparations for oral use in the table of narcotic drugs annexed to the Narcotics Act.

This decree has been challenged and is currently suspended by the competent Administrative Court, with the next hearing set for September 2024.

Hemp and Cannabinoids

Hemp is defined as cannabis sativa L. from certified varieties registered in the Common Catalogue of Varieties of Agricultural Plant Species, pursuant to Article 17 of Council Directive 2002/53/EC of 13 June 2002, which do not fall under the scope of the Italian Narcotics Act.

The reference law is Law No 242/2016, which consists of a framework law for the support and promotion of the agro-industrial hemp production chain.

This law incentivises:

- cultivation and processing;
- use and final consumption of semi-finished hemp products from priority local supply chains;
- development of integrated territorial supply chains that enhance the results of research and pursue local integration and real economic and environmental sustainability;
- production of foodstuffs, cosmetics, biodegradable raw materials and innovative semi-finished products for industries in various sectors; and
- implementation of bioengineering, land reclamation, educational and research activities.

The cultivation of hemp can be carried out by the farmer without the need for prior authorisation. The farmer is only obliged to keep the seed card for one year and the purchase invoice for the period required by tax regulations (ten years).

Crop controls and THC limits

Article 4 of Law 242/2016 sets the THC limits in the field at 0.2% (from 1 January 2023 the limit was raised at the European level to 0.3% following the CAP reform) with a margin of tolerance up to 0.6%.

If police controls detect THC levels exceeding 0.6%, the law mandates the seizure and destruction of the crop. However, it is critical to note that the farmer is shielded from criminal liability provided they have adhered to the stipulations of Article 3 of the same law. This includes maintaining proper documentation such as the card and seed purchase invoices, which serve as proof of compliance with regulatory requirements.

Checks must be carried out by the Carabinieri Forestali according to the method of sampling and analysis foreseen in Annex I of Reg. (EU) no. 1155/2017, but may also be carried out by any police force in the exercise of investigative activity (see **1.6 Enforcement & Penalties**).

Destinations of use

According to Article 2(2) of Law 242/2016, hemp crops can be used to produce:

- foodstuffs and cosmetics produced exclusively in accordance with the regulations of the respective sectors;
- semi-finished products, such as fibres, hemp, powders, wood chips, oils or fuels, for supplies to industries and craft activities in various sectors, including the energy sector;
- material intended for green manure;
- organic material intended for bio-engineering works or products useful for bio-construction;
- material intended for phyto-purification for the reclamation of polluted sites;
- cultivations for educational and demonstrative purposes, as well as for research by public or private institutes; and
- crops intended for floriculture.

This list is considered exhaustive and requires compliance with regulations specific to each application.

Foods

Hemp-based foods in Italy are regulated by the Ministerial Decree of the Ministry of Health dated 4 November 2019, which states:

- permitted hemp-based foods are only seeds and derivatives (oil and flour); and
- the THC limits allowed are 5 ppm for oil and supplements and 2 ppm for seeds and flour.

Importantly, these limits are to be considered modified due to the effect of Regulation (EU) No 1393/2022, which sets the THC limits at the European level to 7.5 ppm for hemp seed oil and 3 ppm for seeds and flours.

THC in foodstuffs is, in fact, considered a contaminant and therefore regulated by Regulation (EU) No 915/2023, which modified the previous Regulation (EC) No 1881/2006.

The Ministerial Decree in question provides for the possibility of introducing additional foodstuffs containing hemp, but this would require presenting new scientific evidence to support such inclusion. For further details, please see the Trends and Development article.

Food supplements

Food supplements are: “foodstuffs intended to supplement the common diet and which constitute a concentrated source of nutrients, such as vitamins and minerals, or other substances with a nutritional or physiological effect, in particular, but not exclusively, amino acids, essential fatty acids, fibres and extracts of plant origin, whether mono- or multi-compound, in pre-dosed forms”.

Food supplements are regulated by Regulation (EC) No 1170/2009 (which amended Directive 2002/46/EC) and at the national level by Legislative Decree No 169 of 21 May 2004 implement-

ing Directive 2002/46/EC and by the Ministerial Decree dated 9 July 2012 on the "Regulation of the use of plant substances and preparations in food supplements". According to the tables attached thereto, and also by virtue of the BELFRIT agreement signed with Belgium and France, only supplements based on hemp seeds or hemp seed oil are permitted in Italy.

To date, products based on parts other than seeds or extracts cannot therefore be considered food or food supplements at the regulatory level. For other issues, such as novel food and expected developments, see **3.2 Non-controlled Cannabinoids in Food** and the Trends and Development article.

Cosmetics

Cosmetic products are regulated by Regulation (EC) No 1223/09. This regulation is supplemented by the Cosmetic Ingredient Database (CosIng List), which, while not legally binding, is widely regarded as a key reference point for industry professionals. The CosIng List helps standardise labelling practices across the EU, and therefore also in Italy.

In Italy, CBD and CBG in their isolated forms are recognised as permissible ingredients for use in cosmetic formulations provided they are produced synthetically or obtained from non-prohibited parts of the cannabis sativa L. plant (ie, leaves, roots, shoots and seeds), as well as extracts of such parts.

These products are therefore marketable as long as the label states the intended purpose (topical/external use), and the functionalities and commercial claims align with the cosmetic purpose. This category can be considered the only product category in which CBD oils can be considered compliant with regulations.

Floriculture

The field of floriculture is regulated by a multitude of EU-derived regulations, which outline the scope of application of the legislation with important terminological and definitional specifications, as well as indicating the authorisation system and the requirements for conducting floricultural activities.

In particular, Article 2 of Legislative Decree No 214/2005 clarifies the definitions by establishing that "plants" refer to live plants and parts of plants, including cut flowers and leaves.

It is therefore clear that Article 2(2)(g), having included cultivation for floricultural purposes among the (mandatory) legal uses of hemp, makes it lawful to also produce these plants and their parts for ornamental purposes.

The Ministry of Agriculture, in Circular No 5059 dated 5 May 2018, has specified with reference to hemp that the production of hemp plants and their parts, such as leaves, fronds, inflorescences and ornamental cuttings, according to the sector's regulations in force, falls within lawful activities, provided that it is a final product, not intended for further floricultural production, subject to the legal limits for THC content. It can therefore be considered that in Italy the production and sale of ornamental hemp plants is lawful provided they are germinated from certified seeds.

This guidance explicitly states that ornamental hemp, including its various plant parts like flowers, leaves, fronds, and cuttings, is lawful as long as it is intended for end-use in an ornamental

capacity only. This use excludes any possibility of further floricultural activities. Since ornamental hemp is not intended for human consumption, concerns regarding its psychotropic effects are largely irrelevant. By way of analogy, one may cite the example of oleander, a plant known to be toxic, which is freely sold without any special precautions being taken. However, the regulation of flowers is complex and intrinsically linked to the issues dealt with in the appropriate section below.

Fibres

Fibres do not present any particular legal or interpretative problems as they are unquestionably lawful.

The problems, on the other hand, concern the supply chain as there are critical production issues due to the scarcity of processing plants.

CBD flowers (so-called cannabis light)

The spread in 2017 of so-called cannabis light – ie, the sale of dried inflorescences of hemp from varieties certified for "technical use" or "collecting", sparked immediate seizures, and case law was divided between one side that held that the flowers were case covered by Law 242/2016 and another that held that they were covered by the narcotics legislation because the flowers (like the leaves) were included in the narcotics table.

The matter was referred to the United Sections of the Supreme Court of Cassation, which ruled, while also calling on the legislature to provide clarity on the matter, that:

- the marketing of flowers, leaves, oil and resins is not covered by Law 242/2016;
- Law 242/2016 is only concerned with the taxable destinations referred to in Article 2 (see above); and
- trading flowers, leaves, oil and resins generally constitutes drug dealing; however, an exception exists if these products lack the potential to induce psychoactive effects (following the principle of offensiveness).

In the absence of legislative clarification, the sale of CBD flowers has become a widespread but legally precarious practice across Italy. Enforcement varies significantly, with authorities handling cases discretionally, leading to a patchwork of legal interpretations and enforcement practices. This has resulted in numerous seizures and criminal proceedings, each treated differently depending on the region and specific circumstances.

In essence, a paradoxical situation has arisen in which industrial hemp flowers and resins are not covered by the law (at least for retail sale), but their sale does not involve criminal offences since they do not have an intoxicating effect in practice.

CBD flowers are in any case mostly sold for ornamental purposes as end products of the floricultural supply chain with a THC content of less than 0.5% to avoid psychotropic effects.

Psychotropic efficacy

The concept of "intoxicating efficacy" lacks a clear, universally accepted definition and is subject to interpretation by individual judges on a case-by-case basis.

In some cases, the limit of 0.5% THC (sum of THC and THCA) is applied as an absolute weighted figure borrowed from forensic toxicology. Thus, in many cases, if the CBD flower limit is below this threshold, many proceedings end in dismissal or acquittal.

In other cases, some public prosecutors' offices have taken a radical stance that flowers are always considered narcotics regardless of THC content. In such proceedings, the total active ingredient present in the seized goods is multiplied and divided by the average single dose with the consequence that the defendant is charged with dealing "doses" of narcotics.

The issue may be resolved in the pending criminal trial against Luca Marola, founder of Easy Joint, a pioneer company in the sector. He is accused in Parma of drug dealing for possessing 700 kg of hemp sativa with a THC content of less than 0.2% but which, according to the Prosecutor's Office, translates to about 200,000 doses.

This situation exemplifies the major problem plaguing the Italian system: chronic legal uncertainty. The lack of clear regulations forces businesses to navigate this uncertainty, often basing their operations on risk management strategies that vary by region.

CBD oils

A large number of products are also sold on the Italian market as CBD oil, which, except for a few that are registered in accordance with the cosmetic regulations referred to above, are sold for an unspecified use as "technical" oils.

Such oils are often seized by the authorities, sometimes citing a violation of the Narcotics Act and sometimes a violation of Legislative Decree No 219/06 on medicinal products.

CBD oils present the same problems as CBD flowers with regard to the narcotics legislation, which are resolved by assessing psychotropic efficacy (however, this is more straightforward as they are rarely marketed with a THC content higher than 0.2%).

At the same time, they present greater problems in relation to the regulation of medicinal products for the reasons set out above.

In fact, in many cases the criminal proceedings instituted following an allegation of infringement of Legislative Decree No 219/06 end with the acquittal of the accused. This stems from the lack of a clearly defined offence, violating the principle that criminal offences require a clear taxonomical definition.

In any case, the fate of these products is intrinsically linked to the appeal pending before the Administrative Court and the developments discussed in the Trends and Development article.

Recreational Cannabis

The recreational use of cannabis is prohibited in Italy by the Narcotics Act. Possessing cannabis for personal use is not criminally prosecuted but is subject to administrative sanctions. These sanctions can have significant personal consequences, affecting one's eligibility for driving licenses, firearm permits, passports for international travel, and various types of work permits.

It should be noted that the Supreme Court recently affirmed the principle that the cultivation of cannabis for personal use with rudimentary means does not constitute criminally relevant conduct.

This orientation of the Supreme Court is instrumental in shaping the pending bills referred to in **3.3 Decriminalisation**.

1.2 Regulatory Bodies

The regulatory bodies that oversee the system for the production of pharmaceutical-grade cannabis and cannabinoids are essentially the UCS in its capacity as the State Cannabis Board

established under the Single Convention and AIFA.

- The UCS issues authorisations for the cultivation and supply of hemp to pharmaceutical workshops.
- The UCS issues authorisations for pharmaceutical workshops to procure hemp and for the extraction of CBD as an API for the preparation of medicines.
- The UCS issues authorisations for cannabis cultivation for research purposes.
- The UCS determines annually the quantities of medical cannabis needed on the basis of data communicated by the regions.
- AIFA is the national public body that regulates medicines for human use in Italy.
- AIFA is the competent agency for the recognition of pharmaceutical workshop quality.

The following should also be noted:

- To date, the SCFM is the only institute in Italy authorised to cultivate cannabis for medical use.
- The regions are responsible for the reimbursability of cannabis as a medicine to citizens, and on an annual basis must communicate to the Ministry of Health the data regarding the amount of cannabis prescribed in the relevant regional territory for medical use.
- The regions are also competent for the issuance of certain authorisations for medical companies provided for by Legislative Decree No 219/06 on medicinal products.

1.3 Self-Regulatory Authorities

In Italy, the field of medical cannabis is supported by a diverse and active network of associations that advocate for patient rights, address issues related to cannabis availability, reimbursement by the SSN, and the education of medical personnel. They include SIRCA (the Italian Cannabis Research Society), SICAM (the Italian Medical Hemp Society), and the Luca Coscioni Association, which has been active since 2002 in the area of the protection of civil liberties and human rights throughout the country with particular attention to the freedom of scientific research and the freedom of self-determination.

In the hemp sector, the Ministry of Agriculture has set up the Hemp Sector Table, in which stakeholders in the sector at the regulatory, scientific and association levels participate, and which is working on the new hemp sector plan.

Active nationally are the associations Federcanapa, Canapa Sativa Italia, and Resilienza Italia, which deal with the promotion and protection of the supply chain.

Self-regulation documents have also been adopted by operators:

- Protocols for Production of Hemp Flowers, adopted by Federcanapa, CIA – Agricoltori Italiani and Confagricoltura in 2018; and
- Extraction Hemp Guidelines adopted by Federcanapa and Agrinsieme in 2021.

There are also many associations operating at a regional level, such as the Ente Tutela Innovazione Canapa Toscana (E.T.I.CA.) in Tuscany, which signed a memorandum of understanding with the Regional Command of the Carabinieri Forestry Department to standardise the control and analysis procedures of hemp cultivation in Tuscany.

1.4 Challenges for Market Participants

Hemp

For years, operators in the sector in Italy have found themselves operating in a grey area, par-

ticularly regarding flowers and extracts. The United Sections of the Court of Cassation had already highlighted the need for clarifying legislation in 2019. Despite various amendment proposals, the law has not been supplemented and there is still a situation of general uncertainty, with differences in interpretation and application by the competent authorities from case to case and from area to area.

The long-standing challenge for operators in the sector has been to obtain legal and regulatory clarity for the production and sale of flowers and extracts. For this reason, the lobbying activities carried out both through dialogue with the competent authorities and by challenging decrees detrimental to the sector (see the Trends and Development article) are cornerstones for the development and regulation of the industry.

The main challenge is to delineate a field of application in the category of nutraceuticals, phytotherapeutic products and food supplements, which represent that intermediate band between foodstuffs and pharmaceuticals. In essence, it is a matter of carving out a legal and regulated sector for the production and sale of health products that are not the exclusive domain of pharmaceutical companies, but also of the industry in the sector, which in recent years has demonstrated its ability to capitalise on research results applied to the realisation of industrial products.

Medical Cannabis

In the medical cannabis sector, the fundamental challenge is to implement and develop national production by opening it up to private companies with production know-how superior to that of the SCFM. In essence, it is a matter of overcoming the current "monopolist" approach by contracting out cannabis production to private companies capable of guaranteeing suitable quality standards. This objective presupposes a series of synergetic and strategic actions throughout the supply chain, starting with the training of medical personnel.

To increase national production, it is necessary for the regions to transmit annual data on medical cannabis prescriptions to the Ministry of Health. Therefore, it is necessary for doctors to be adequately trained and informed about the potential of medical cannabis, as medical prescriptions are an essential element of the supply chain.

1.5 Legal Risks

The risks in the hemp industry are more pronounced compared to the medical cannabis sector, which benefits from clearer legislation. There remain numerous interpretative and application-related grey areas, creating an uncertain framework for industry operators. This is especially true for those dealing with CBD flowers and CBD oil, where legal uncertainties compel operators to make decisions based on risk management. Essentially, operating in this sector involves entrepreneurs consciously accepting a level of risk.

Understanding the local culture and legal landscape is crucial for developing and managing business operations effectively. Given the complexity of the regulations and legal interpretations involved, it is vital for operators to engage with professionals who specialise in this area.

Legal risks vary significantly across different production segments. The marketing of products, whether business-to-business (B2B) or business-to-consumer (B2C), such as CBD flowers and CBD oil, often encounters significant legal challenges, including frequent product seizures.

Additionally, the extraction of cannabinoids presents its own set of issues, stemming from the overlapping jurisdictions of narcotics and industrial hemp legislation.

A thorough understanding of the specific legislation applicable to each sector, whether industrial, cosmetics, or others, is essential. Such knowledge enables proper activity framing and the effective management and profiling of associated risks. Regrettably, the industrial hemp sector still faces widespread risks, both criminal and administrative, which stem not only from narcotics legislation but also from the sector-specific regulations governing various uses.

For penalties, see **1.6 Enforcement & Penalties**.

1.6 Enforcement & Penalties

In Italy, cannabis in its forms such as flowers, leaves, oils, and resins is classified as a narcotic, subjecting it to strict controls and sanctions under narcotics legislation, despite ongoing legal disputes and differing interpretations. Consequently, all Italian police forces are authorised to conduct checks on cannabis and its derivatives as part of their judicial police duties.

Law No 242/2016 stipulates, in particular, that controls on industrial hemp crops are carried out by the Carabinieri Forestali according to the protocol provided for in Reg. (EU) No. 1155/2017, All. I. If a potential offence is detected at any stage of the supply chain, the police can initiate legal action under the Consolidated Narcotics Act, leading to possible criminal proceedings by the competent Public Prosecutor's Office. Most of these proceedings are concluded with dismissal if laboratory analyses confirm that the THC content is below the level that can produce psychotropic effects.

In addition to the controls and sanctions arising from the Narcotics Act, it is also necessary to check compliance with the sector regulations relating to the individual uses of the products (food, cosmetics, pharmaceuticals, etc). Non-compliance can lead to penal or administrative sanctions, including fines, suspension of activities, or other regulatory measures.

Given the ambiguity in product classification, especially with CBD flowers and CBD oils, the potential issues arising from regulatory controls are varied and heavily dependent on the type of enforcement and the authority conducting it.

Given the complexity of the regulations in this field, it is imperative for operators in the sector of hemp and its derivatives to seek legal advice.

2. Cross-Jurisdictional Matters

2.1 Cross-Jurisdictional Issues

The industrial hemp and cannabinoid sector in Italy, much like in many other EU countries, continues to navigate through significant legal grey areas and risks. The stance of Italian authorities towards the hemp plant broadly aligns with that of Spain and Portugal, where currently only hemp seeds and fibres are recognised as legal.

At the same time, recent rulings by the Administrative Court (discussed in more detail in the Trends and Development article) have affirmed the same principles established by the French Conseil d'Etat and even earlier by the European Court of Justice on the lawfulness of using the entire hemp plant from certified varieties.

In any case, it is possible to say that the evolution of the sector, with particular reference to the food and supplement sector, will depend on the

decisions at European level that will be taken by the EFSA (see **3.2 Non-controlled Cannabinoids in Food**).

In general, in view of the differences in interpretation of certain product categories between the various member states, the EU has started a process of acquiring data from operators in the sector in order to define a single European regulation in order to avoid alterations to the common market.

Within the general European framework, an extremely important role will also be played by developments in the UK and Switzerland, countries which, although not part of the EU, nevertheless play a very important role in both regulatory and commercial terms.

3. Legal and Regulatory Developments

3.1 Access to Medical Cannabis

While access to medical cannabis in Italy is not hampered by major legal hurdles, the system suffers from limitations rooted in political choices. The production of medical cannabis is tightly controlled by the Ministry of Defence through the SCFM, alongside a reliance on imports, which underscores a major limitation in the current Italian system.

A call for tenders was issued in 2022 to allow private companies to grow medical cannabis for supply to the SCFM. Companies were selected but to date the procedure is suspended while waiting for the Administrative Authority to rule on the appeals of some participants.

The SCFM's monopoly stifles competition, hindering advancements in the quality, quantity, and efficacy of medical cannabis. The ideal solution would involve a significant policy shift, allowing private enterprises, once they have obtained the necessary authorisations, to cultivate and directly distribute medical cannabis to pharmacies in a free market system. However, such changes are complex and challenging to implement, suggesting a lengthy and difficult road ahead.

At the same time, there has been an opening for the importation of cannabis and API-based medicines from other EU member states, as the Ministry of Health has authorised the importation of such products to certain pharmaceutical companies or distributors. While this approach broadens access to medical cannabis and could serve as a model for replication, it inadvertently places domestic producers at a disadvantage.

3.2 Non-controlled Cannabinoids in Food

Italy considers cannabinoids and all parts of the plant with the exception of seeds and derivatives as novel foods by not recognising their traditional use prior to 15 May 1997.

Prior authorisation by the EFSA is therefore required for their production and marketing.

At the moment, several Italian companies have started the process of obtaining this authorisation from the EFSA either individually or through participation in the Novel Food Consortium promoted by the EIHA. At present, the application for CBD isolates extracted from the plant has been submitted and the relative risk assessment is pending, which, except for suspensions due to the further request for clarifications, will end in October 2024.

The application for authorisation of full-spectrum extracts will also be submitted shortly.

Pending issues related to the use of parts other than seeds in food, also with reference to the use of hemp as a medicinal plant, are dealt with in the Trends and Development article.

3.3 Decriminalisation

For a long time, there have been periodic initiatives to regulate the recreational use of cannabis.

In December 2023, the platform "Meglio Legale" submitted a proposal for a popular initiative bill to the Court of Cassation aimed at legalising domestic cannabis cultivation. This proposal outlines specific provisions for both individual and collective cultivation. In the first case, cultivation of up to four plants and consequent possession of the proceeds is permitted, while collective cultivation consists of the opening of so-called cannabis social clubs, private associations with a maximum of 200 members each, in which it is possible to cultivate a maximum of four plants per member. In this case, the sale of the finished product to members would be capped at 30 grams per month.

The process of collecting the required 50,000 signatures to move the bill forward is expected to be completed by spring 2024. Following this, the bill will be submitted to either the Chamber of Deputies or the Senate of the Republic, where it will be scheduled for discussion. The legislative procedures differ between the two branches: the Senate is mandated to include citizens' initiative bills in its agenda, whereas in the Chamber of Deputies, inclusion is at the discretion of the president and parliamentary groups.

Given the precedents and the quality of the majority in parliament, which is composed of parties ideologically opposed to any form of cannabis regulation, it seems predictable that this initiative will not be followed up.

The function of this initiative, however, according to the organisers, is to keep the political and social debate on narcotics alive, to create an even wider network of activists in view of future initiatives, and to demonstrate how Italian society is ready for the regulation of cannabis.

Trends and Developments

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Studio Legale Bulleri offers assistance and legal solutions in the field of civil law, with a particular focus on the areas of corporate and commercial law. The firm strives to pre-empt and resolve conflicts in a transactional manner, aiming to avoid litigation wherever possible. It deals with all facets of corporate life, including shareholders' meetings, potential dissolutions, liquidations, challenges to resolutions, and the interpretation of articles of association, while also handling relations between shareholders. A key objective is safeguarding the business interests of companies and resolving any disputes that may arise between shareholders or between companies and third parties. Finally, it takes care of all aspects concerning the economic and financial restructuring of companies in crisis due to over-indebtedness, and debt collection procedures with banks and various corporate creditors. The firm's expertise extends to real estate law, overseeing property transfers and transactions, including the management of judicial auctions. Studio Legale Bulleri also provides advisory and advocacy services in the cannabis and industrial hemp sector for the strategic business development of start-ups and companies in Italy and the EU.

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Introduction

The cannabis and cannabinoid sector in Italy is currently mired in significant legal uncertainty, largely due to how authorities interpret the nexus between narcotics laws, medicinal regulations, and legislation concerning industrial and European hemp. Despite global trends indicating a growing acceptance and interest in cannabis and its derivatives, Italian regulatory bodies maintain a stringent adherence to the strict letter of narcotics laws. This approach starkly overlooks recent updates in EU and national regulations specifically addressing cannabis from certified varieties.

This rigid interpretation stands at odds with the original intent of narcotics legislation, which aims to prevent the consumption of substances that are toxic and harmful to humans. This foundational principle seems hardly applicable to cannabis products that, in practical terms, lack psychotropic effects.

Such restrictive views have not only fostered a repressive regulatory stance towards emerging cannabis products, particularly flowers and extracts but have also given rise to many court cases in both criminal and administrative courts.

The Status Quo

Even after the European Court of Justice's ruling in the Kanavape case, the Italian authorities have continued to ignore the demands of the sector by enforcing outdated prohibitions. Under their current interpretation, only hemp seeds and fibres are considered permissible, creating a stark contrast with both EU directives and national laws that are more inclusive.

This inconsistency is particularly glaring when considering Law No 242/2016, the framework legislation for the sector. This law explicitly exempts certified hemp varieties from narcotics legislation. It defies logic that a plant classified as an agricultural product (further reinforced by EU regulations) can morph into a narcotic based solely on the harvested part.

This restrictive interpretation has ignited strong opposition from legal scholars and courts. They point to the lack of psychoactive effects in industrial hemp and the contradiction with EU law as insurmountable obstacles to this theory.

These opposing arguments culminated in an appeal filed by hemp trade associations before the Lazio Regional Administrative Court ("TAR

Lazio") against an Interministerial Decree on medicinal plants.

Judgments No 2313 and 2316 of 14 February 2023 of TAR Lazio

The Italian state issued an Interministerial Decree on 7 August 2023 that was supposed to contain the list of officinal plants as part of a reform initiated by Legislative Decree No 75/2018, which recognised all cultivation and initial processing activities of these plants as agricultural.

However, the decree controversially noted that while the cultivation of hemp seeds and fibres was governed by the national law on industrial hemp, the production of flowers and leaves would be governed by the Narcotics Act. The associations of the sector (Canapa Sativa Italia, Resilienza Italia onlus, Sardinia Cannabis and Federcanapa) challenged the decree, claiming that it was contradictory and in contrast with EU and constitutional law. The applicants pointed out that the supranational legislation and, in particular, the EU legislation did not distinguish between the parts of the hemp sativa plant coming from certified varieties classified as a whole as an agricultural product.

Moreover, Regulation No 1307/2013 and No 1308/2013 delineate sativa hemp by establishing the limit of THC in the field allowed (0.3% from 1 January 2023) andintroduced a common market organisation for flax and hemp.

Consequently, the contested decree resulted in an infringement of EU law in that it imposed a de facto quantitative restriction on the common market that was not justified by scientifically relevant public health protection requirements.

The TAR Lazio examined this complex regulatory framework, drawing on both the principles expressed by the Court of Justice of the European Union in the Kanavape case and the judgment of the French Conseil d'Etat No 444487 of 30 December 2023 stating that the "[e]xamination of these rules, however, does not reveal any distinction between the parts of the hemp plant that are freely cultivated, within the meaning of the aforementioned Law No 242/2016, which can be used for the purposes established by that law. The sectoral discipline of international and EU matrix clarifies, in fact, that the discretional criterion for establishing the free cultivation of hemp lies in the type of plant, considered in its entirety".

In essence, the distinction between cannabis drugs, governed by Presidential Decree No 309/1990, and industrial hemp governed by Law No 242/2016, lies in the origin of certified varieties registered in the Common Catalogue of Agricultural Plant Species.

Judgments No 2313 and No 2316 dated 14 February 2023 set a fundamental precedent for Italy in that they recognise the prevalence of EU law over national law and, as a result, sanction the lawfulness of the use of the entire hemp sativa plant as a medicinal plant, thus adding a very important use to the "agricultural" uses provided for by Law No 242/2016.

These rulings have been challenged by the competent Ministries before the Council of State. Although a hearing has not yet been set for discussion, one is expected later in 2024.

The Possible Scenario

If the Italian Council of State confirms the judgments of the TAR Lazio, it could indeed herald a transformative period for the hemp industry in Italy. This would affirm the full legality of cultivating, processing, and using the entire hemp

plant, recognising it both as an agricultural product under Law No 242/2016 and as a medicinal plant.

Under this new legal framework, farmers would be permitted to cultivate the entire Cannabis sativa plant, with the only requirement being compliance with Good Agricultural Collecting Practice (GACP). Farmers may also carry out all the initial processing operations of the cultivated hemp that are indispensable for production needs. These consist of washing, defoliation, sorting, grading, hulling, drying, cutting and selection, pulverisation of the dried herbs, and obtaining essential oils from fresh plants directly on the farm, if the latter activity needs to be done with freshly harvested plants and plant parts. Also included in the initial processing stage, which is indispensable for production needs, is any activity aimed at stabilising and preserving the product intended for the subsequent stages of the supply chain.

The hemp thus obtained and processed may therefore be utilised both for the purposes envisioned by Article 2(2) of Law No 242/2016, and supplied to qualified entities for the handling and sale of medicinal plants according to the intended use.

Particularly noteworthy is the possibility of using hemp as a medicinal plant. Pharmacists and herbalists could potentially prepare non-prepackaged, loose, extemporaneous food preparations containing whole hemp plants, extracts, or mixtures thereof.

This could lead to the possibility of using the hemp plant for human consumption as an officinal plant, thus introducing a subject that inevitably intersects with pending cases concerning food hemp: the relationship with novel foods legislation on one hand, and the limits of THC in foodstuffs as a contaminant on the other. In this writer's opinion, this represents the main challenge the sector must face in the near future in order to obtain full legitimacy and mainstream affirmation, also from a social and mass-market perspective.

The safety of the product must, in fact, be assessed on the finished product itself based on the applicable regulations in the sector, not prejudged by preemptively prohibiting the use of certain plant parts. As affirmed by judgments from the CJEU, the French Council of State, and the Italian Administrative Court, such blanket bans contravene EU law by undermining the common market organisation without grounding in proven scientific requirements, relying solely on a generic precautionary principle and public health protection rationale.

Under Regulation (EU) No 915/2023, which updates and replaces Regulation (EC) No 1881/2006, THC is categorised as a contaminant. However, current regulations specify THC limits only for seeds and their derivatives, leaving a regulatory gap for other plant parts and extracts. In this regard, the application proposed by the EIHA Project (the consortium promoted by the EIHA) for the recognition of full-spectrum hemp extracts as novel foods represents a potential breakthrough.

This application, based on an innovative scientific study, could be a valid tool to demonstrate that, like many herbal preparations (eg, alcoholic tinctures or extracts of various medicinal plants) or food supplements, what matters is not the absolute threshold of the presence of the contaminant, but rather the daily intake dosage.

Another extremely pertinent issue among the potential scenarios relates to the free movement of goods within the European common market.

The aforementioned judgments have, in fact, reaffirmed that national laws restricting the use of whole plants or the sale of CBD products legally produced in a member state constitute a quantitative restriction on the common market, and are therefore unlawful unless grounded in proven scientific necessity. However, when scrutinised, the evidence put forth by member states that had adopted restrictive regulations proved only to rely on generic, unproven public health protection rationales and a broad precautionary principle.

These measures, together with the political choice of some member states (eg, the Czech Republic and Poland) have led to a scenario in which CBD products are lawfully produced in certain countries while banned in others. This has precipitated a clear distortion of the common market and competitive landscape, as many member states cannot produce certain products or cultivate and utilise the whole plant, yet must contend with imports of those very same products from states where they are legally produced.

This creates a risk of a two-speed Europe that must be averted. To remedy this, the relevant Directorates General of the EU Commission (DG AGRI, DG SANTE and DG GROWTH) are working on their respective dossiers on food, cosmetics and animal feed in order to find a unified solution at the European level and avoid the above-mentioned risk.

The aim is to reinforce the European common market and safeguard it from imports of goods from non-EU countries, which possess vast resources posing a formidable threat to the European market at the detriment of producers within the member states.

It is therefore imperative that the sector operates by harmonising the legal sphere with scientific research in order to uphold a new conception of sustainability, yielding innovative products for consumers characterised by superior quality and an inextricable link to their territory of origin.

It would be desirable for hemp to follow in the footsteps of wine by cultivating production specifications intrinsically tied to geographical provenance, developing genetics tailored to various latitudes, and establishing self-regulatory standards adeptly integrating and interpreting existing regulations. This would mirror the path forged by organic products in 1980s Italy, where self-regulation initially compensated for regulatory deficiencies before being enshrined into law.

In parallel, it is also prudent to explore further applications. The experience of some member states, such as Belgium and Luxembourg, demonstrates that hemp can also be included in inhalation products.

After all, this supplementary use appears to be one of the primary consumer demands (especially regarding CBD flowers), which, irrespective of the stated intended use (technical, collector's, horticultural or ornamental), are in fact also utilised for inhalation as tobacco substitutes.

In Italy, adding inhalation as a recognised use for hemp could align with consumer preferences and expand the market. However, this should not become the sole recognised use for hemp but rather a complementary option alongside existing applications.

The inclusion of hemp as an inhalation product requires careful consideration of tax regulations. The Italian Customs and Monopolies Agency (ADM) would play a crucial role in overseeing the production and distribution chain. This oversight is essential not only to protect consumers but also to ensure that the state collects appropriate revenues from this new market segment. Moreover, tax regulations need to be fair and effective, reflecting the unique characteristics of the hemp sector, which is predominantly made up of small and medium-sized enterprises and features craftsmanship akin to that found in the wine or craft beer industries.

One potential solution could be to envisage a flat-rate system for artisanal hemp products intended for inhalation and, as far as marketing is concerned, apply by analogy the provisions for liquid inhalation products.

These proposals are still under discussion and evaluation within the supply chain committee established at the Ministry of Agriculture.

JAPAN

Trends and Developments

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Mori Hamada & Matsumoto is one of the largest full-service Tokyo-headquartered international law firms. MHM has over 750 lawyers and over 600 support staff (including patent attorneys, licensed tax accountants, judicial scriveners, legal assistants and translators). The firm is highly recognised by both clients and legal professionals in the following practice areas: M&A, joint ventures, finance, international capital markets (including JREITS), asset management, loans and securitisations, private equity, infrastructure and energy, PFI and PPP, insolvency and restructuring, healthcare and life science, intellectual property, antitrust and competition, and fintech. Other core practice areas include tax and labour law. MHM has a strong presence in Asia with offices in Beijing, Shanghai, Singapore, Bangkok, Ho Chi Minh City, Hanoi and Jakarta. The leading law firm in Thailand, Chandler & Thong-ek Law Offices Limited, integrated its operations with the firm's Bangkok office on 1 January 2017 under the name Chandler MHM Limited. MHM also has domestic offices in Osaka, Nagoya, Fukuoka, Takamatsu and Sapporo.

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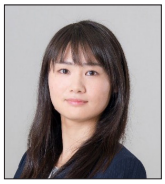

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Overview of Cannabis and Cannabinoid Regulations in Japan

Under the current Cannabis Control Act in Japan, the possession, transfer, acceptance, importation and exportation of cannabis plants and their products are prohibited, except for possession by a person with a licence to cultivate or research cannabis plants. No one is allowed to engage in any medical or recreational use of cannabis plants and their products, or to cultivate cannabis plants except by a person with a cultivation or research licence. As the Japanese government has been very reluctant to issue cultivation licences, there were only 27 licensed cultivators as of 31 December 2022. In other words, the market for cannabis plants and their products is virtually non-existent in Japan.

However, the seeds and mature stems of cannabis plants and their products are exempt from regulations under the Cannabis Control Act. Therefore, there is a market for products of cannabis seeds such as animal feed, essential oil materials, and spices, as well as for products of mature cannabis stems such as textile products and traditional products used in Shinto rituals.

In recent years, CBD products or CBD as a raw material said to be made from mature stems are being imported from foreign countries and distributed in Japan. However, there have been several cases where Delta-9-THC was detected in CBD products being distributed in the Japanese market, and the regulatory authorities have issued warnings to distributors and requested them to conduct voluntary recalls.

It is worth noting that the Japanese government designates many controlled substances as having harmful effects and likely to be abused as narcotics. The possession, use, transfer, acceptance, manufacture, importation and exportation of narcotics are prohibited and penalised under the Narcotics and Psychotropics Control Act. The Cannabis Control Act regulates cannabis and cannabis products, and prohibits, with penalty, the possession, transfer, acceptance, importation and exportation of these substances and products.

The rate of drug use among Japanese citizens is remarkably low compared to that of other countries. According to one study, the lifetime experience rate of cannabis use in Japan is only 1.4% of the population, compared to 20–40% in the United States and Europe. As can be seen from these experience rates of drug use, the Japanese government is generally very strict in its enforcement against drug crimes, including those related to cannabis.

Recent Regulatory Change

In recent years, pharmaceutical products made from cannabis are gradually being approved and marketed in the United States and Europe. In addition, given the recognition of the medical usefulness of pharmaceutical products made from cannabis, the regulatory category of cannabis in the Single Convention on Narcotic Drugs, 1961 was reclassified from Schedule IV (that is, selected drugs from Schedule I that are considered to have particularly dangerous properties and limited or no therapeutic benefit) to Schedule I (that is, drugs the control provisions of which constitute the standard regime under the 1961 Convention), a category that includes substances that may also have medical usage.

In response to these developments, the Japanese government had been considering changes to the cannabis and cannabinoid regulation. Thus, in December 2023, a bill (the “Amending Law”) was passed to amend the regulatory framework on cannabis, including fundamentally

amending the Cannabis Control Act as well as revising the Narcotics and Psychotropics Control Act. Although the Amending Law has not yet come into effect and will be implemented in two phases, in 2024 and 2025, it will allow the use of pharmaceutical products manufactured from cannabis and facilitate the distribution of THC-free cannabis-derived products, particularly CBD products.

This chapter of the guide sets out the regulatory landscape as it will appear after the Amending Law comes into effect.

Drastic Regulatory Framework Reform

The Amending Law will drastically change the regulatory framework for cannabis.

Before the Amending Law, the Cannabis Control Act regulated cannabis plants, with the exclusion of mature stems and seeds, and products made from these plants. In other words, the cannabis and cannabinoid regulation focused on certain parts of cannabis plants (eg, leaves, flowers, flower heads, resin and immature stems).

In contrast, the Amending Law changes the approach in regulating THC derived from cannabis by classifying it as a narcotic under the Narcotics and Psychotropics Control Act, based on the understanding that the essential harm of cannabis is caused by THC, the toxic component of cannabis.

As a result, products containing THC will be regulated by the Narcotics and Psychotropics Control Act similar to other narcotics, regardless of whether or not the THC is derived from cannabis. The Cannabis Control Act, on the other hand, will primarily regulate the cultivation of cannabis plants, and has been renamed the Cannabis Plant Cultivation Regulation Act.

Medical Cannabis and Cannabinoid

The Amending Law removes the prohibition under the Cannabis Control Act on the use of pharmaceutical products manufactured from cannabis, thus lifting the ban on the use of those products, such as Epidiolex®, which is one of the main objectives of the regulatory reform.

As a result of the aforementioned revision, pharmaceutical companies can manufacture and sell pharmaceutical products derived from cannabis, subject to approval for the pharmaceutical products themselves under the Pharmaceuticals and Medical Devices Act, and doctors and patients will, therefore, be allowed to use those pharmaceutical products.

However, pharmaceutical products containing THC as an ingredient, including THC derived from cannabis, will fall under the category of narcotic drugs. Therefore, pharmaceutical products derived from cannabis will be controlled under strict distribution regulations under the Narcotics and Psychotropics Control Act, similar to other pharmaceutical products containing narcotics as an ingredient. This means that pharmaceutical companies and distributors involved in manufacturing and distribution of those products will be required to obtain a licence under both the Narcotics and Psychotropics Control Act and the Pharmaceuticals and Medical Devices Act.

Please note that the use of cannabis plants that have not been approved as a pharmaceutical product for medicinal purposes, the so-called medical cannabis, will remain prohibited.

Permitted Products/CBD Products

Products derived from cannabis, other than approved pharmaceutical products, that can be legally distributed include:

- fibre products made from the mature stems of cannabis and products made from the seeds such as animal feed, essential oil materials, and spices; and
- products made from CBD extracted from cannabis.

Under the Amending Law, CBD products made from CBD extracted from cannabis leaves or flower heads will be allowed to be distributed as long as they do not contain the above-mentioned THC, which is a narcotic. Although very small amounts of THC may remain in CBD products, THC residues in products must remain below certain threshold concentrations, which will be set by government ordinance. On 30 May 2024, a draft of the government ordinance was published for public comments. Under the draft, the concentration limits of Δ9-THC are as follows:

- 10 ppm for oil, that is a food or beverage product;
- 0.1 ppm for beverage products excluding oil products; and
- 1 ppm for other products.

The proposed thresholds are those at which the health effects of THC are not likely to occur.

Under the current Cannabis Control Act, CBD products containing even very small amounts of THC are banned from distribution; therefore, many businesses are hesitant to enter the CBD product market because it has been difficult to clearly check the legality of CBD products. The recent revision that ensures the legality of CBD products by controlling the allowable concentration limits of THC residues would be a big step forward in the development of CBD product businesses.

Hemp Regulation

Under the newly renamed Cannabis Plant Cultivation Regulation Act, in order to cultivate cannabis plants, it is necessary to obtain a Class I or a Class II cannabis plant cultivator licence, depending on the purpose of cultivation. Class I cannabis plant cultivators are those who cultivate cannabis plants for the purpose of harvesting mature stems, seeds or raw materials for other permitted products, such as CBD products. Class II cannabis plant cultivators, on the other hand, are those who cultivate cannabis plants for the purpose of harvesting raw materials for pharmaceutical products.

Class I cannabis plant cultivators are permitted to cultivate cannabis plants containing only THC in concentrations below a certain standard, which will be set by government ordinance. On 30 May 2024, a draft of the government ordinance was published for public comments. Under the draft, the weight of Δ9-THC must not exceed 0.3% of the weight of the cannabis plant. Class I cannabis plant cultivators must obtain a licence from the prefectural governor and renew their licence every three years.

Additionally, Class I cannabis plant cultivators are permitted to extract CBD from cultivated cannabis plants if they have separate permission from the Minister of Health, Labour and Welfare. This is expected to facilitate the cultivation of cannabis plants for the purpose of extracting raw materials for CBD products, as it will allow cannabis plant cultivators to engage in various activities such as cultivating cannabis plants, extracting CBD, and selling CBD to businesses that manufacture CBD products.

By contrast, Class II cannabis plant cultivators are permitted to cultivate cannabis plants containing high concentrations of THC. However,

a Class II cannabis plant cultivator licence will be granted by the Minister of Health, Labour and Welfare only for the cultivation of cannabis plants for the purpose of extracting raw materials for pharmaceutical products. Class II cannabis plant cultivators are required to have their licence renewed every year.

International Trading of Cannabis Products

Under the Amending Law, licensed narcotic importers can import pharmaceutical products derived from cannabis if they have separate permission to import those pharmaceutical products. They are treated in the same way as importers of other pharmaceutical products with narcotic ingredients.

Provided the THC is below the residue limit concentration, CBD products can be imported without any specific licence. However, when importing a CBD product, the importer is required to obtain an import confirmation from the Regional Bureau of Health and Welfare that the CBD product does not contain THC above the residue concentration limit, by submitting a THC component analysis report. At the time writing this guide, details of the import confirmation procedure have not yet been published.

Future Outlook of Cannabis and Cannabinoid Regulation in Japan

The Amending Law passed in December 2023 will significantly reform the current regulatory environment of cannabis and cannabinoid. The introduction of new cannabis plant cultivator licences, as discussed in "Hemp Regulation" above, is expected to come into effect in 2025, while the other amendments are expected to come into effect in 2024. In particular, the provisions of the Amending Law that will come into effect in 2024 have great significance in encouraging the expansion of businesses of cannabis-derived products, including the lifting of the ban on cannabis-derived pharmaceutical products and the deregulation of CBD products. Important regulatory details on the implementation of the Amending Law in 2024 are expected to be disclosed soon. Thus, interested players must continue to closely monitor legislative and policy developments.

PANAMA

Law and Practice

Contributed by:
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1. Regulatory Framework

1.1 Primary Laws & Regulations

Panama is on track to legally sell its first medical cannabis product before the end of 2024, and as with all new markets, a frenzy of preparation is hectically underway.

Taking the wait-and-see approach has permitted Panama to incorporate concepts from neighboring countries while staying faithful to its strategic geographical advantages, carefully considering and regulating the use of medical cannabis in and from Panama.

The next 24 months will be critical in determining whether Panama embraces or squanders this opportunity.

Before delving further, the reader should be brought up to date on two important subjects:

- how Panama defines "medical cannabis"; and
- how Panama got here.

How Does Panama Define "Medical Cannabis"?

Panama considers cannabis to be a "controlled substance", which it defines as any substance mentioned in one of the following two international conventions:

- the Single Convention on Narcotic Drugs, 1961, in which cannabis is specified; and
- the Convention on Psychotropic Substances, 1971.

The main laws and regulations governing this subject in Panama define medical cannabis as any product derived from the cannabis plant that contains at least 1% tetrahydrocannabinol (THC).

Products containing cannabidiol (CBD) while maintaining THC levels below 1% are not considered to be controlled substances.

Products containing synthetic THC of any type are not considered medical cannabis, and are prohibited.

How Did Panama Get Here?

After much pressure from local patients' associations and doctors, the following occurred in Panama:

- 13 October 2021 – Law 242 of 13 October 2021 was passed by Panama's legislative branch;
- 1 September 2022 – Decree 121 of 1 September 2022, which regulates Law 242, was publicised by the Health Ministry of Panama (MINSA);
- 25 September 2023 – a total of 14 companies presented their applications to obtain one of the seven available medical cannabis licences in Panama;
- 17 January 2024 – MINSA published Resolution 008, with a list of the seven companies that were approved for the first seven licences;
- 29 January 2024 – MINSA announced that three of the seven companies not granted approval for a licence in Panama had presented their first legal recourse, a "reconsideration" of the resolution of 17 January 2024;
- 12 March 2024 – MINSA announced that it was maintaining its previous decision, as detailed in its communication of 17 January 2024;
- 28 March 2024 – MINSA announced that all three of the companies that had presented their unsuccessful reconsideration had presented their second and final executive

recourse, an appeal to Panama's Health Minister himself; and
- 2 May 2024 – Panama's Health Minister resolved the appeals presented on 28 March 2024, and declared that the resolution of 17 January 2024 was valid.

Primary Laws and Regulations

Two main legal documents govern the medical cannabis industry in Panama:

- Law 242 of 13 October 2021, which declares its purpose as being "to regulate the medicinal and therapeutical use of cannabis and its derived products" (Law 242-2021); and
- Executive Decree 121 of 1 September 2022, released by the Ministry of Health, in turn "regulates Law 242 of 13 October 2021" (Decree 121).

Multiple other legal documents can apply to medical cannabis, such as:

- Law 28 of 28 October 2014 (Law 28-2014) and its modifications (known as the "Rare Diseases Law"), which entails a guarantee of treatment to patients of rare or infrequent illnesses;
- Law 14 of 19 May 2016 (Law 14-2016), which regulates the production, transportation and usage of controlled substances as described in the products included in the United Nations Single Convention on Narcotic Drugs, 1961 and the Convention on Psychotropic Substances, 1971;
- Law 203 of 18 March 2021, which regulates telehealth; and
- Law 419 of 1 February 2024, which reformed all previous laws that regulated medicine for human consumption and the public procurement of medicines, including medical equipment, consumables and devices.

Although many other decrees, resolutions and similar relate to this industry, this article will only concentrate on the most important laws and regulations – namely, Law 242 and Decree 121.

Navigating through new laws that have zero jurisprudence can seem complicated – the following is therefore a simplified breakdown:

- Law 242 dictates the "W's" regarding medical cannabis in Panama – ie, "what" (what products), "when" (and for how long), "where" (and where not) and "who" (who can sell, purchase); and
- Decree 121 dictates the "How's" of Law 242 – ie, how to control, report, grow, produce, import, export, deliver, transport, secure, prescribe, dispense and so forth.

The reader should not think that this industry is lax in Panama; on the contrary, the regulations are aimed at ensuring that medical cannabis is not used recreationally.

Understanding Law 242

Law 242 – "What?"

Panama has approved the investigation, production, transformation, importation, exportation, re-exportation and domestic sale of medical cannabis for consumption in Panama and internationally, in all its current forms, with one gray area: vapes. See more regarding vapes in **1.4 Challenges for Market Participants**.

Law 242 stipulates two types of licence – a "fabrication licence" and an "investigation licence" – and that for the first five years a maximum of seven fabrication licences will be issued.

Current regulations authorise fabrication licence holders to produce, grow, transform, import, export, re-export and commercialise flowers,

edibles, pills and beverages; topical use of products containing THC of 1% or higher is all permissible for medicinal use, and the list of illnesses for which they can be prescribed is extensive, permitting the final decision to be taken by the medic while treating the patient. Consumption of medical cannabis is limited to patients who hold a valid prescription issued by a trained medic.

The following are prohibited.

- Beverages that combine alcohol and cannabis. The only exception to this applies to beverages that use alcohol as a solvent.
- Medical cannabis produced in attention-grabbing shapes – ie, no cannabis products in the shapes of animals, people, fruits or any other shape that may draw the attention of minors.
- Using cannabis in food destined for human consumption. The only exception to this applies to medical cannabis edibles.
- Promotion/marketing. None is allowed – ie, not online nor on traditional channels. The only exception to this is educational material that does not directly promote the sale of any specific product, brand or strain.

The growing and transforming of cannabis in Panama has been regulated with two main objectives in mind: quality and control.

Quality

Panama will only permit the growth and consumption of medical cannabis that is free of harmful chemical products, such as pesticides, fungicides, herbicides and/or chemical solvents or products that may harm public health. Any medical cannabis produced in Panama will need to meet good manufacturing practice (GMP) standards, and all fabrication licensees must ensure that their operations are compliant with modern GMP guidelines.

Several regulatory bodies are entrusted with powers to inspect and verify strict compliance with quality standards. As one government official recently stated, “Panama has the world’s best coffee; now we aim to have the world’s best medical cannabis”.

Similar GMP guidelines apply for the transformation of flower cannabis into other products, such as edibles, creams, pills and so forth.

Control

Control in Panama’s cannabis industry is widespread. Every plant is traced from seed to harvest, and every product inventoried per piece or weight. CCTV systems with face-recognition software are a requirement in every room that produces, processes, stores, transports or sells a medical cannabis product, including dispensaries.

Transporting medical cannabis in Panama requires closed and tagged parcels; each parcel must have a GPS tracking device, as must each car that transports the parcel(s). A manifesto must accompany each transportation of medical cannabis in Panama. All the forgoing is subject to review and inspection by the regulatory authorities.

Industry employees must be vetted and preapproved by regulatory bodies prior to being put on a licensee’s payroll.

A main benefit of Panama’s regulations is the authorisation to licensees to import, export and re-export medical cannabis products. Staying true to its historical nature as the tax-free crossroad of the world, Panama has the potential to develop (in the short-term) into the world’s premier tax-free medical cannabis hub, which

should help to increase the number of products international clients can offer their patients.

International commerce of medical cannabis is tightly controlled, and is only approved as business-to-business – meaning that a licensee from Panama can only purchase from, or sell to, a licensee from another country.

There is no limit on THC or CBD percentages, nor regarding cannabis strains.

Law 242 – "Who?"

Three "Who?" matters are worth focusing on: who can purchase, who can participate in the industry and who can sell.

Who can purchase?

In brief, patients and medical establishments (including pharmacies) can purchase.

Wholesale medical cannabis can only be purchased in Panama by fabrication licence holders (selling among licensees) and pharmacies that have a licence to sell controlled substances.

The retail purchase of medical cannabis is limited to patients with a valid prescription.

The prescription can be valid for a maximum period of 90 days, and patients will need to register in the National Medical Cannabis Registry and validate their prescriptions. Inclusion in the Registry must be renewed yearly. When prescriptions are fulfilled in a pharmacy or dispensary, the purchase must be registered in the Registry prior to handing the medical cannabis to the patient.

The National Medical Cannabis Registry is constantly synchronised and updated, meaning it will guarantee that a patient cannot purchase more medical cannabis than has been prescribed to them.

Pharmacies, hospitals and dispensaries must retain a copy on file of each prescription they fulfilled, either completely or partially, and are obligated to hold the copy on file for five years.

Who can participate?

Doctors can participate after they have undertaken the mandatory training course offered by a MINSA-approved training entity.

Licensees can also participate. Law 242 specifies two types of available licence for medical cannabis in Panama, as follows.

- Fabrication licence: holders of this licence are authorised to produce, transform, import, export, re-export and domestically sell medical cannabis.
- Investigation licence: holders of this licence cannot commercialise medical cannabis in any of its forms; such licensees can only use cannabis for investigative purposes. This licence is aimed at universities, regional investigation centres and laboratories located in Panama, and that will certify the quality, THC and CBD content, and other requirements regarding medical cannabis produced in Panama.

Regarding industry associates, whatever type of licence a licensee holds, *all* industry employees must obtain a Labour Code identification number ("Labour Code ID") prior to being employed. This is free and is given after the employment candidate provides the following:

- a clean criminal record as relates to multiple criminal offences;

- proof of having undertaken a GMP/training course;
- valid identification;
- a curriculum vitae; and
- a certificate of competence in the case of pharmacists.

This Labour Code ID must be renewed every two years, and a similar approval process is imposed for other industries, such as casinos.

As a requisite of the MINSA licence-awarding process, all 16 fabrication licence applicants had to:

- fully disclose their corporate structure, shareholders and financial capacities;
- list their board of directors; and
- list their strategic international partner.

Every person involved in an application for a fabrication licence had to provide a clean criminal record and proof of identity, and pass an extensive background check under the scrutiny of the Ministry of Security.

Regarding the strategic international partner, each fabrication licensee must have an experienced partner from a country that legally sells medical cannabis. This partner oversees supplying the know-how, and in some cases the financial backing, of the Panamanian fabrication licensee.

Panama is serious about training and education regarding this industry, and used Decree 121 to mandate the implementation of a "Suppliers Training Registry". Some consider this a third type of licence, while others see it as more of a database of approved suppliers. Training entities can be any public or private, natural or legal person. There is currently no limit regarding a specific number of entities, and such entities are entrusted with training:

- doctors on the use of medical cannabis for patients;
- pharmacists and dispensary personnel; and
- licensee employees.

Every course is different; each complete course must be at least six hours, and no course can be held virtually.

Who can sell?

Fabrication licensees can sell wholesale to pharmacies, hospitals and other licensees. They can also distribute on a retail level through their own dispensaries.

Pharmacies, hospitals and dispensaries can only sell medical cannabis at a retail level.

Any other sales channels are considered illegal and may constitute an administrative and/or criminal offence.

Law 242 – "When?"

Law 242 stipulated that, after the seven licence winners were chosen, each of them had 60 days to comply with Decree 121 in regard to security, hygiene, legal paperwork, and GMP regulating production, storage and transportation of medicinal products, and to request an inspection headed jointly by MINSA and Panama's Ministry of Security.

If all boxes are checked during the inspection and following full compliance, the licensee will be permitted to pay the governmental licensee fee of USD150,000 – after which, the government will issue their licence, valid for ten years.

During the first 24 months of each licence, the licensee will be permitted to import any medical cannabis product from any international supplier, conditional on the supplier being an authorised medical cannabis seller in their home country. This 24-month period is permitted so that licensees can promptly accomplish local supply of medical cannabis and satisfy the local medical cannabis market in Panama.

After these initial 24 months, all medical cannabis products that are sold in Panama must be produced in Panama. This limitation does not apply to importation and re-exportation of cannabis products through Panama's tax-free commerce zones.

After the initial ten years, if a fabrication licensee is interested in extending their licence, they must request such an extension.

Currently, there is no confirmed date for when medical cannabis will be available for sale in Panama, as no licences have yet been issued. Based on current local trends, the authors estimate that the first licensees will be operational before the end of 2024. For more detail on this, see **1.4 Challenges for Market Participants**.

Law 242 – "Where?"

The matter of where medical cannabis can be sold in Panama is simple – ie, anywhere where controlled substances can be sold, either business-to-business or retail.

Pharmacies, hospitals and licensees are approved for selling medical cannabis. Doctors cannot sell medical cannabis nor prescribe a specific brand.

Delivery via commercial couriers is strictly forbidden; however, patients that cannot fulfil their prescription personally may empower one person at a time to do so on their behalf.

Only controlled and pre-approved areas (such as greenhouses or warehouses) are authorised to grow cannabis in Panama. Cultivation sites must be approved by the Ministry of Agriculture and the Ministry of Security.

If a fabrication licensee intends to re-export medical cannabis, they must be located in a tax-free zone and in a pre-approved location.

Regarding consumption of medical cannabis in Panama, use is intended to be private. Consumption in public spaces (such as roads, parks, restaurants, theatres, clubs and similar) is prohibited. In the workplace, if an employer approves the use of medical cannabis on their property and has a designated area for such use, the patient may consume their medical cannabis at work.

Decree 121

Decree 121 applies most importantly to local government – ie, concerning how to control. In simple terms, Panama's path to control is through software and technology.

Decree 121 regulates how every medical cannabis product is grown, imported, produced, exported, sold or investigated in Panama. It regulates:

- how software systems operate and who administers them; and
- how licensees are subject to a surveillance system and to supervision by regulatory bodies.

This system is known as the Tracking and Traceability System (the "System"). The complexities

of these regulatory bodies and how they interact with the System, both among themselves and among licensees, is discussed in **1.2 Regulatory Bodies**.

1.2 Regulatory Bodies

Law 242 and Decree 121 mandate six regulatory bodies to directly and actively oversee the medical cannabis industry; an additional three regulatory bodies are involved, but in a more passive form.

The six active regulatory bodies are:

- *Ministerio de Salud* (Ministry of Health, or MINSA);
- *Ministerio de Desarollo Agropecuario* (Ministry of Agriculture, or MIDA);
- *Ministerio de Seguridad* (Ministry of Security, or MINSEG);
- *Ministerio de Comercio e Industrias* (Ministry of Commerce, or MICI);
- *Autoridad Nacional de Aduanas* (Customs Authority, or ADUANA); and
- *Autoridad Nacional de Innovacion Gubernamental* (National Innovation Authority, or AIG).

The three passive regulatory bodies are:

- *Superintendencia de Bancos* (Bank Superintendency, or SUPERBANCOS);
- *Superintendencia de Seguros* (Insurance Superintendency, or SUPERSEGUROS); and
- *Superintendencia de Sujetos No Financieros* (Superintendency of Non-Financial Regulated Subjects, or SSNF).

These sometimes-overlapping regulatory bodies are discussed further below.

Ministry of Health (MINSA)

MINSA is the governing body that supervises and regulates all health-related issues involving humans, including for hospitals, protocols, vaccines, medicines, nurses and pharmacies. Approval of medicine, and medical competency certificates, also falls under MINSA's jurisdiction, including for controlled substances.

MINSA executes its responsibilities relating to medicine for human consumption through the *Direccion General de Farmacias y Drogas* (General Directorate of Drugs and Pharmacies, or DGFD), which has been designated by MINSA to oversee the complete medical cannabis commercial cycle in Panama. It is DGFD's responsibility to oversee the importation, production, transformation, transportation, commerce and local dispensing of medical cannabis for human consumption.

As relates to medical cannabis, MINSA is specifically responsible for the following:

- educating doctors and the general public about the positive and negative effects of medical cannabis;
- evaluating all 16 fabrication licence applications, and choosing the first seven licensees;
- issuing licences;
- supervising all stages of medical cannabis in Panama, including growth, production, importation, sale, etc;
- approving the criteria for, and suppliers of, the System;
- supervising the correct implementation of the System;
- establishing criteria for laboratory tests that will be applied to medical cannabis products sold in Panama;
- receiving the yearly exports estimate from each fabrication licensee;

- receiving the quarterly reports from each investigation licensee;
- developing a national programme for investigating medical cannabis and its uses;
- approving the National Registry of Medical Cannabis Users (the "National Registry"), including the requisites a patient must fulfil before being included in the National Registry and the issuance of the special identification all patients must have to obtain their prescriptions;
- establishing criteria regarding which patients can apply for inclusion in the National Registry, and how to proceed if a patient is not a Panamanian citizen;
- regulating the prescriptions required for the purchasing of medical cannabis – prescriptions are only valid for 90 days;
- choosing and supervising the training entities;
- approving or denying the applications for a Labour Code ID, obligatory for all industry employees;
- approving the importation of any medical cannabis requested by an investigation licensee; and
- approving every exportation of any medical cannabis product produced in Panama, prior to the shipment leaving the country.

Ministry of Security (MINSEG)

MINSEG is the governing body that supervises and regulates all security-related issues, such as regarding the police, border patrol, naval services, immigration, illegal drugs and all things related to firearms. As Panama does not have an army, navy or air force, MINSEG fills in those voids on a national level.

As relates to medical cannabis, MINSEG is specifically responsible for the following:

- supervising the correct implementation of the System;
- approving licensees and ensuring that they comply with the security standards described in the regulations;
- approving the security protocols implemented in any establishment that stores medical cannabis;
- verifying that medical cannabis residues or expired products are weighed before they leave storage, and are correctly disposed of;
- inspection of the private, in-house version of the System that each licensee must operate, basically validating that all inventory is accounted for;
- approving the external security measures of establishments that store medical cannabis;
- assisting MINSA and MIDA in their inspections (notified or not) of fabrication licensee's cultivation and storage areas;
- reviewing industry-wide employee background checks, including for employees related to international strategic partners;
- if a patient is bedridden, pre-approving the person the patient sends to a dispensary or pharmacy to obtain their prescription;
- validating the approval of the importation of any cannabis seeds or plants into Panama, on the condition that they have previously been pre-approved by MIDA; and
- approving every exportation of any medical cannabis product produced in Panama, prior to the shipment leaving the country.

The security standards imposed on every licensee are stringent, and include the following (among others):

- all entries and exits of places where cannabis is stored must have interior and exterior cameras;
- all areas where medical cannabis is weighed, packed, transported or labelled must have cameras;
- one camera must be in place specifically for the entry into secure areas of buildings where medical cannabis is stored;
- all cameras must be high-resolution, so that employees and the products they manipulate can be easily identifiable;
- cameras must be able to record the facial features of all that enter a place where medical cannabis is stored – this includes patients, visitors, employees, etc;
- industry employees must be vetted prior to being hired; and
- GPS tracking of all medical cannabis products must be in place, including for plants.

In cases of necessity, coercive enforcement of Law 242 and Decree 121 is among MINSEG's responsibilities.

Ministry of Agriculture (MIDA)

MIDA is the governing body that supervises and regulates all issues related to the national food supply, national agriculture and farm animals, including veterinaries and the products they use.

MIDA offers local producers tax incentives, reduced interest rates for farm-related loans, and other financial policies aimed at managing Panama's consumption of locally grown products and the exportation of locally produced agricultural products.

As relates to medical cannabis, MIDA's main responsibilities include the following:

- approving all cannabis seeds and plants prior to their arrival in Panama;
- developing procedures and approving protocols for the use and investigation of cannabis seeds and plants, as well as of medical cannabis for veterinarian use;
- authorising each fabrication licensee's cultivation plan, as each licensee must present a yearly estimate of their expected cultivation yield, per strain, prior to planting a seed;
- analysing, preventing and mitigating the risk of plagues arriving in Panama through the importation of cannabis seeds and plants;
- establishing the phytosanitary protocols that will be followed by the fabrication licensees;
- conducting inspections of medical cannabis production sites, to ensure that phytosanitary protocols are followed and that licensees have provided MIDA with correct information;
- supervising the quarantining of cannabis plants or seeds, if deemed necessary;
- including cannabis seeds in the National Seed Commission's database, which registers all seeds and their importers in Panama;
- verifying licensees' compliance with the technical sheet of imported plants or seeds, as well as ensuring that no harmful pesticides or chemicals are used by licensees;
- supervising the cultivation of medical cannabis in Panama, ensuring that GMP standards are upheld;
- supervising the System;
- approving any products that contain cannabis and that are intended for veterinary use; and
- issuing a certificate of agricultural exports for any medical cannabis product produced in Panama, prior to the shipment leaving the country.

Ministry of Economy and Finance (MEF)

MEF is the governing body that administers Panama's treasury. It also supervises, approves and regulates all the tax-free commercial zones in the country; these tax-free commercial zones are similar to huge, bounded warehouses, with some the size of small cities. The Colon Tax Free Zone, the largest such zone on Panama's Atlantic coast, is the world's second largest tax-free zone, and in 2023 boasted commercial transactions totalling over USD25 billion.

MEF has one specific role to play in this industry: approving the incorporation of a licensee into a tax-free commercial zone.

Decree 121 specifically indicates that only fabrication licensees that are established in a tax-free zone can re-export medical cannabis products.

National Innovation Authority (AIG)

AIG, like MEF, has one specific role to play in this industry: ensuring that the System and the National Patient Registry are secure and online. This includes data security related to patient confidentiality and rights, System and Registry availability, maintenance and so forth.

SUPERBANCOS, SUPERSEGUROS and the SSNF

These three more passive governing bodies oversee the medical cannabis industry, similar to how they oversee almost all national industries, with one exception: fabrication licensees can expect additional scrutiny (at least initially).

SUPERBANCOS is influential in deciding how much access the medical cannabis industry will have to the banking industry, including for national accounts, international accounts, financing, payroll and credit card processing, etc.

SUPERSEGUROS is important in the regulation of private medical insurance companies and their coverage of medical cannabis, an area which is currently unclear.

The SSNF oversees fabrication licensees' adherence to local compliance and know-your-client (KYC) norms, but has no specific role related to medical cannabis.

1.3 Self-Regulatory Authorities

As Panama's medical cannabis industry still only exists on paper and is not yet operational, self-regulatory bodies as such are yet to take on any active powers in the industry. The closest things to self-regulatory bodies in Panama are organisations that have supported patients' claims for access to medical cannabis (assisted by Law 242 and Decree 121), and that remain active in promoting medical cannabis in Panama. Four groups, including the industry guild, deserve special mention and are listed in the chronological order in which they became active in promoting medical cannabis.

Fundación Luces (the Lights Foundation)

Founded by Panamanian-born epilepsy specialists, renowned worldwide as leaders in their field, this non-profit foundation has one aim: to assist epilepsy patients in overcoming their illness through education and innovative treatments.

Several of the Foundation's members are or were practising medics in the USA's best hospitals, and had been prescribing medical cannabis to their patients for several years, reporting extraordinary success in their patients' outcomes.

The Foundation was the pioneer in medical cannabis legislation in Panama, and was instrumental in finally obtaining approval for legislation. It

provided doctors with time to meet with governmental authorities, elected officials, lawyers and (of course) patients.

The reputable board of directors of this Foundation was key in capturing the attention of three different Panamanian Presidents, three distinct legislative branches and hundreds of doubtful local doctors. The Foundation has the support of several patient associations, local celebrities and a wide array of doctors, and, through continuous educational efforts combined with real case success, has even managed to apply enough pressure for cannabis to be considered as a viable alternative medicine for patients.

The Foundation has now been actively involved in the medical cannabis legislative process in Panama for almost ten years, and is expected to remain involved once the industry starts operating.

National Association of Multiple Sclerosis and Neuromyelitis Optica Patients (ANPEMUFA)

A few years after Fundación Luces started pressuring local authorities to approve legislation related to medical cannabis, ANPEMUFA joined the cause, and has been an active player ever since. As a non-profit organisation, ANPEMUFA states that their primary goal is "ensuring that people who suffer from the illness have access to alternative treatments and solutions to the challenges of living with multiple sclerosis".

ANPEMUFA, composed mainly of patients and their families with the support of national and international doctors, has also invested time and effort in explaining to uninformed doctors, lawyers and government officials the need for regulating medical cannabis. More importantly, it has shown that many patients report better and faster results from using cannabis than from using certain pharmaceutical products.

While Fundación Luces is comprised mainly of renowned medics looking at options for helping their patients, ANPEMUFA is, in contrast, constituted mainly by vocal patients looking at options for helping their medics prescribe medical cannabis legally. ANPEMUFA can be expected to remain involved in the industry once it is operational, as regards verifying quality, supply and pricing.

Colegio Nacional de Abogados (National Lawyers Union, or CNA)

Panama does not have a Bar Association as in other countries – the closest thing is the CNA, which is a non-profit union of lawyers. The CNA is commonly called on for advice by lawmakers and private citizens, and assists with fine-tuning legislation and forecasting difficulties in applying laws. Any work done by a lawyer for the CNA is pro bono. The CNA operates through commissions; each commission has its own board of directors that reports directly to the CNA's President.

In early 2024, for the first time in its history, the CNA formed the Commission for Medicinal Controlled Substances. This Commission has two main goals:

- assisting patients in legally obtaining access to medicines that their doctors prescribe, especially medicines that are controlled substances; and
- ensuring that local laws which assist patients' rights are duly enforced.

The CNA's Commission has held multiple meetings with patients, doctors, lawmakers and industry leaders, and has served as a neutral

meeting ground for presenting contrary opinions, discussing perspectives and reaching common ground.

The CNA can be expected to remain active in its support for patients, patients' rights and doctors throughout the next few years, and to propose potential, beneficial modifications to the current regulations.

Medical Cannabis Guild

This organisation is agreed upon but not yet formed. The seven fabrication licensees have agreed on forming a guild that aims to guarantee three things: quality, supply and compliance.

A common worry among the seven licensees is that one (or more) of them will commit an offence by design or by mistake (such as faltering in compliance, erring in reporting, supplying low-quality products, or worse). As medical cannabis is new and heavily regulated in Panama, the potential mistakes of one licensee undoubtedly affect the other six.

Licensees cannot market their products in Panama and are only allowed to promote medical cannabis through education of the population, including doctors. For this reason, particular effort is being put into promptly training local doctors and reducing the historical stigma that exists in Panama related to cannabis. Doctors may shy from prescribing cannabis if negative media constantly circulates in Panama regarding the misuse of medical cannabis, or regarding mistakes by the new licensees.

The licensees' answer for mitigating these risks is the creation of a guild that:

- shares administrative responsibilities;
- meets regularly;
- verifies that quality standards are not lowered; and
- ensures that all seven licensees adhere to all laws and regulations.

1.4 Challenges for Market Participants

The most notable challenge that market participants currently face – and will continue to face for the near future – is uncertainty.

Product Uncertainty

Cannabis vape pens represent a significant percentage of the industry's market share, with numbers varying widely between 15% and 40%, depending on the country or state, market age composition and several other factors. What is agreed upon by most international industry participants is that medical cannabis vape pens are here to stay.

On 30 June 2022, Panama published Law 315, which aims at educating the general population on the hazards of e-cigs and similar products. At the same time, Law 315 prohibits the use or sale of electronic equipment such e-cigs, vaporisers, tobacco heating systems and similar products in Panama.

This means that no vapes can be legally sold in Panama, nor can they be used in public spaces.

Law 315 does not differentiate between nicotine-containing products and non-nicotine-containing products – no distinction is made between a vape device designed for tobacco and one for cannabis.

Importing, producing and/or exporting vapes from Panamanian territory is permitted provided the products are not sold or consumed in Panama.

All the above is important when considering two things – ie, that:

- Panama boasts one of the lowest rates of tobacco consumption worldwide, at around 7% of the population; and
- any smoking (especially of cannabis) is considered harmful and entails a strong, historical social stigma.

Approximately 30% of Spaniards and Germans smoke cigarettes, as do almost 20% of Americans and Canadians. Panama is at 7% in this regard, and dropping fast. Smoking is prohibited in restaurants, casinos, concerts or public spaces in Panama. This means that, in a visit to Panama lasting a full week, one would probably only see one or two people per day smoking a cigarette.

Panamanians are thus not accustomed to seeing people smoke in public, nor are they used to the smell of burnt tobacco in their midst. Smelling cannabis smoke, or seeing a patient smoke cannabis anywhere, would immediately draw the attention of passersby. As patients have enough difficulties to deal with, adding further stigma to their treatment is not beneficial.

The solution for many patients is medical cannabis vapes. The immediate discrete dosage thereof, with practically no accompanying smell, helps to maintain patient privacy.

The legality of the use of medical cannabis vapes in Panama is controversial. Those against vapes point to Law 315 of 2022, which is very clear regarding the prohibitions of vapes in Panama. Those in favour of vapes point to Law 28-2014, which states that the commencement or interruption of a medicine for patients of rare diseases will be determined solely by the patient's specialist. However, what happens if a specialist prescribes that medical cannabis should be delivered by vape pen instead of by an edible or smokable? This uncertainty will likely reveal itself in the court system over the next few months.

Banking Uncertainty

Panama's currency is the balboa, which is pegged one-to-one to the US dollar. The local Constitution prohibits a central bank or the issuance of paper currency. In short, using bills in Panama means using US dollar bills. When one transfers money into or out of Panama, this is done in US currency.

Panama has 41 "general licence" banks, or "first-floor" banks. Most are Panamanian or regional banks, six are international banks and two are national, government-owned banks.

The exact same issues that are affecting the cannabis industry in the USA are affecting the industry in Panama. All of Panama's banks depend on their banking correspondents in the USA for access to international markets and the swift wire system. If a correspondent bank in the USA is unwilling to open an account for a dispensary in California or Boston, they are much less willing to allow a Panamanian bank to use them to transfer proceeds from medical cannabis to or from Panama.

The two government-owned banks, *Banco Nacional* and *Caja del Ahorro*, are in a complicated position; Panama has no federal system, so the government that charges licensees for their licence fee is the same government that owns the banks. That said, the uncertainty here pertains to why a government-owned bank would not open a bank account for a company that holds a government-issued medical cannabis licence, and whether private banks would do so.

Running a cash-only medical cannabis enterprise in Panama is complicated, costly, risky and a compliance nightmare for all involved.

Insurance Uncertainty

Similar to banks, insurance companies are very cautious when considering medical cannabis. Patients that require very specific strains of medical cannabis (normally with THC under 1.5%) have complained that the monthly cost of medicines (which they are forced to smuggle into Panama) can exceed USD500 per month. In a country where the monthly minimum salary is around USD600 per month, the need for public or private medical insurance to cover this medication cost is understandable.

Although Law 28-2014 mandates that "public and private insurance companies have the responsibility to attend" rare-disease patients, there is no obligation to do so regarding other patients. Law 28-2014 also allows pharmaceutical companies that donate their products directly to patients to deduct the cost of these products from their income tax; however, Decree 121 prohibits the donation of medical cannabis.

Will public or private insurance companies cover medical cannabis prescriptions? Will local suppliers be permitted to donate part of their production to patients in need? Eliminating these uncertainties will help patients who require medical cannabis and who cannot sustain the monthly costs of medication.

Bureaucratic Uncertainty

As noted in **1.1 Primary Laws & Regulations**, multiple laws and regulations form Panama's medical cannabis legislation, and on many occasions they overlap. This causes uncertainty, and creates the risk of non-compliance due to error rather than ill will.

The System – which is fundamental – has not yet been acquired by the Panamanian government, much less installed, tested or taught to regulators or to those being regulated.

The laboratories meant to verify the quality of products produced in or sold in Panama have yet to receive their operating licences.

The training entities meant to train medics, industry employees and the police have yet to be chosen or contracted for, and the course material has not been circulated in the industry.

MIDA has not yet established a protocol for the importation of cannabis seeds, nor for the growing of cannabis in Panama.

MINSA has yet to circulate the protocols to be followed in cases of visitors or expats in Panama – ie, can visitors purchase medical cannabis, if prescribed?

Training of the police force has not been completed, leading to the question of what would happen were a first patient to be stopped during a routine traffic stop and medical cannabis found in their possession. Panama has a very strict, non-lenient policy regarding narcotics; educating police and changing their perspective – ie, in understanding that a patient is not the same as a recreational user – will be paramount for eliminating the current stigma and preventing discomfort among patients.

Calendar Uncertainty

Based on previous uncertainties, it must be concluded that, even if all seven licences were to be issued tomorrow, Panama would still not be able to supply its patients for several more months (or possibly even years).

Currently, local industry participants cannot:

- plan their cultivation cycles;
- reserve ready-to-ship products from overseas suppliers;
- import machinery needed in the industry;
- hire employees (as they are not yet trained); or
- lease commercial space for dispensaries.

All the above should, under normal circumstances, be part of a well-developed business plan; however, this is impossible owing to uncertainty regarding when sales will be available. Regarding banking issues, SUPERBANCOS and the SSNF require that a formal business plan be delivered to the bank prior to opening a licensee's bank account. Although local authorities are working diligently to cut delay times, no business can plan without a calendar and clear dates on hand. This is a big risk since, as is well known, "those who fail to plan, plan to fail".

1.5 Legal Risks

A smooth sea never made a skilled sailor – Panama may require some life jackets as the water ahead appears turbulent.

Administrative Compliance

Panama's multiple and overlapping cannabis regulations are reminiscent of when FATCA regulations were passed in the USA in 2010 – a few years later, they were imposed on Panama and its banking sector. Overnight, the overwhelming majority of Panamanian banks decided to unilaterally stop working with American citizens.

Accounts were closed and new accounts were rejected. Getting an American to sign on their Panamanian spouse's Panamanian checking account, in a Panamanian bank, was near impossible.

However, the reasons for this were not based on anti-American sentiment or anything similar. On the contrary, Panamanian banks wanted American clients, and wanted to comply with FATCA. The issue was fear on the part of Panamanian banks; the FATCA regulations were long, complex and hard to understand. The banks, although wanting to comply, did not know how to, and feared that an omission due to lack of clarity would entail fines (or worse) and accusations that they were assisting US citizens in evading US laws.

Overnight, a simple solution was devised: to cease all work with American citizens unless the transactions were financially large enough to merit such risk.

Today, the cannabis industry in Panama is very similar. There is a common fear among all licence holders; they all claim to be investing heavily in compliance, and want to ensure complete adherence to local norms and regulations. They all fear that, due to the volume, overlapping nature and complexity of laws, they will falter in some technicality and be fined or even prosecuted. Law 242 and Decree 121 both provide a long list of monetary sanctions that can be imposed on licensees if they falter, though this also leaves the door open for criminal investigations.

Criminal System

Panama switched criminal systems in late-2016, eliminating the previous inquisitorial criminal system and implementing a new accusatory criminal system. Previously, defendants had the right to try and prove their innocence; now they are presumed innocent until proven guilty.

The system changed, but not necessarily the people in it. Many prosecutors hail from the old system, were trained in that system, worked

inside that system for 20 years and today still hold positions of importance in the new system. A downside to the current criminal system is that prosecutors and/or district attorneys bear no responsibility for their actions, meaning that they can:

- present frivolous charges against a person;
- start an investigation that takes years;
- take an undocumented case to court;
- lose that case in an overwhelming manner; and
- go to work the next day as though nothing happened.

This is because there are no ramifications for the prosecutor, which is worrisome since, in Panama, simply having one's name mentioned in a criminal investigation can swiftly lead to bank accounts being closed, commercial ties being suspended and assets being frozen. This is relevant to medical cannabis as, if one uninformed and uneducated prosecutor decides to open an investigation into a licensee with zero evidence of wrongdoing, that licensee will be under a microscope until the investigation is closed due to lack of evidence, or until victory in court. Training prosecutors should be as important as training industry employees, as both can have an adverse effect on the industry.

Anti-money Laundering Regulations

Panama has an abundance of anti-money laundering regulations. Anyone who believes that they can walk into a Panamanian bank with USD20,000 in cash and open a bank account in under a month's time has obviously not been to Panama, and is uninformed.

Most of Panama's anti-money laundering regulations are aimed at controlling the flow of cash in and through Panama; the Criminal Code lists 37 criminal offences that can be considered money laundering, all carrying a prison sentence of five to 12 years.

Every company in Panama that receives over USD10,000 in cash in a transaction needs to report that transaction to a specialised government agency. Every real estate transaction, even if it is 100% purchased through a mortgage, must report the transaction to the same entity.

Requiring the cannabis industry to operate without banks is counterproductive. How can Panama enforce all the positive and well-intended anti-money laundering regulations while requiring licensees to work only in cash? Panama's medical cannabis industry is estimated to rake in anywhere between USD300 million and USD600 million domestically per year. Such amounts of cash pose a security risk – licensees would not wish to have such amounts on hand or face the problem of its secure storage.

Compliance with anti-money laundering regulations is difficult if licensees cannot use digital cash services, credit cards and banks in general. Non-compliance with anti-money laundering laws is a criminal offence that leads to a money laundering investigation. It is a vicious cycle with no proposed exit route.

1.6 Enforcement & Penalties

Three regulatory bodies are entrusted with enforcing compliance and applying penalties in Panama's medical cannabis industry: MINSA, MIDA and MINSEG.

MINSA

MINSA is the main regulatory body and, as such, the institution with the most oversight and penalty-imposing powers. MINSA can impose three

types of penalties, for minor infractions, major infractions and severe infractions.

Minor infractions

MINSA may fine a licensee anywhere between USD500 and USD5,000 per each minor infraction. There are currently a dozen minor infractions, including:

- non-compliance with monthly, on-time reports to MINSA;
- presenting incomplete reports;
- minor sanitary violations;
- failure to notify MINSA of a licensee's administrative changes, such as licensee operating hours and location; and
- storing medical cannabis outside the licensee's secure areas.

Major infractions

MINSA may fine a licensee anywhere between USD5,001 and USD15,000 per each major infraction. There are currently 29 major infractions, including:

- fulfilling incomplete or altered prescriptions;
- presenting inventory discrepancies between what the licensee has in stock and what they should have in stock;
- impeding MINSA investigations;
- presenting import or export documents that differ from the actual products being imported or exported;
- altering information being fed into the System;
- transporting medical cannabis without completing the established protocols;
- not informing MINSA of the theft or loss of any products;
- purchasing medical cannabis from unauthorised sources; and
- failure to inform MINSA of changes to the licensee's corporate structure.

Severe infractions

MINSA may fine a licensee anywhere between USD15,001 and USD25,000 per each severe infraction. There are currently eight severe infractions, including:

- producing or selling contaminated, altered or expired products;
- dispensing medical cannabis without a prescription;
- falsifying information on reports or in the System;
- repeating major infractions; and
- interfering with MINSA's inspections.

A final penalty amount to be imposed is decided by MINSA, after considering:

- the damage done by the infraction;
- the benefits obtained from the infraction;
- whether the infraction was intentional or negligent; and
- whether the licensee had previously committed the same infraction.

MIDA

MIDA can apply penalties on a licensee, and specifically as regards the cultivation division of their operation. MIDA's powers only encompass the agricultural aspect of medical cannabis. Hence, MIDA is in charge of ensuring that:

- no harmful chemicals are used;
- only approved seeds are used; and
- agricultural GMPs are strictly followed.

MIDA also supervises the complete cultivation process from seed to flower. MIDA can impose penalties, but no distinction is made between

penalties applied to fruits and vegetables grown in Panama and those applied to medical cannabis.

MINSEG/Public Prosecutor

MINSA and MIDA are entrusted with compliance and with applying monetary penalties (and possibly licence suspensions) in the case of lax compliance by licensees.

MINSEG oversees the security compliance of each medical cannabis product sold in Panama, including verifying traceability.

The public prosecutor's office is responsible for interpreting whether these infractions are of a criminal nature or not. MINSA may impose a fine on a licensee for dispensing medical cannabis to a person without a prescription – this is also a criminal offence in Panama, so the offender may incur a monetary fine as well as potential personal liberty restrictions.

2. Cross-Jurisdictional Matters

2.1 Cross-Jurisdictional Issues

The main international cross-jurisdictional issues currently faced by Panama concern assurance of international compliance and respect for other countries' authority. Panama requires that all local licensees work only with valid licensees from other countries. A licensee in Panama can purchase products from a supplier anywhere in the world, solely conditional on the supplier being licensed to sell medical cannabis in their home country. The same applies as regards selling medical cannabis from Panama to other countries; local licensees are free to sell to any country in the world provided their client is authorised by their home country to purchase medical cannabis.

Any transaction involving Panama and the importation or exportation of medical cannabis will need to be declared and validated by Panama and the partner country, prior to any products arriving in or leaving Panama.

Regarding national cross-jurisdictional issues, the main issue is the overlapping responsibilities that sometimes occur between MINSA, MIDA, MINSEG and the System. These overlapping responsibilities can lead to repetitive reporting, an increase in paperwork and confusion regarding to whom a licensee must report.

For example, when hiring an industry employee at any level, the potential employee must first obtain a Labour Code ID from the Labour Ministry, before completing a course with a certified training entity. The employee must then be submitted to scrutiny by MINSEG, and the employer must be declared in the System to MINSA. If the employee works in the cultivation section of the business, they must also be registered with MIDA.

3. Legal and Regulatory Developments

3.1 Access to Medical Cannabis

Several legal elements affect access to medical cannabis in Panama, all of which should be resolved during 2024.

The System Is Not Operational

The System, including the National Patient Registry, is not yet operational. Even if a licensee had the products to supply the market today, they would be unable to due to inability to register their inventory; and it would be unclear how they would register prescriptions or present their monthly reports.

The National Patient Registry, a module of the System, is also not yet operational – meaning that there are no approved patients for medical cannabis, and indicating that even if the product were available it would still be illegal to dispense.

Training Entities Are Not Themselves Trained

Doctors must undertake a course prior to being certified to prescribe medical cannabis.

Pharmacists must complete a training course prior to being approved to fulfil a medical cannabis prescription.

A licensee's employees, including their administrative staff, must complete a training course prior to working for the licensee.

To date, MINSA has yet to inform the public of the content of these training courses, their duration, and whether they will be virtual or not. Currently, there is also lack of clarity regarding which companies will undergo such training.

With the content of the training courses yet to be determined, and with those companies that will train local experts and employees still not decided on, completing obligatory training is not an achievable goal.

Insurance Coverage

An important number of patients will receive prescriptions that will be too expensive for them to fulfil without making use of medical insurance.

Will the public healthcare system supply cannabis? Will private medical insurance companies cover medical cannabis? There are simply no answers yet. While certain laws do specifically mandate both public and private medical insurance companies to cover all expenses of patients suffering from rare diseases, there is still lack of clarity regarding what happens in the case of patients suffering from other illnesses that are more frequent than for one in 2,000 people.

Another question concerns who decides whether cannabis is the correct medicine for a patient. The answer, according to MINSA, is the patient's doctor. This means that, in theory, private insurance companies should cover medical cannabis – though in practice this remains to be seen.

Prescription Fulfilment by Third Parties

In the case of bedridden patients, limited-mobility patients or patients in palliative care, if a doctor prescribes medical cannabis, the patient cannot go to a pharmacy or dispensary to fulfil the prescription. The patient can send a person to do this for them; however, that person must be registered in the National Patient Registry and be approved by MINSEG after presenting a clean criminal record, which can prove troublesome.

3.2 Non-controlled Cannabinoids in Food

Panama's regulations only mention one non-controlled cannabinoid: CBD. No limitation applies to edibles containing CBD, provided that the cannabinoids are not synthetic, and that the final product does not contain 1% or more THC. Nonetheless, this does not mean an open season for CBD in Panama. Each product must arrive in Panama with documentation proving that it has been laboratory-tested in its country of origin and contains under 1% THC – after which, each product will need to apply for and obtain a sanitary registration prior to being sold in Panama.

3.3 Decriminalisation

Currently, there is no legal move or legislative appetite for decriminalising cannabis in Panama, much less for promoting its recreational use. If

and when a rescheduling of the classification of cannabis is approved by the US Drug Enforcement Agency, Panama may feel persuaded to follow suit.

For now, nothing indicates any intention by Panama to decriminalise the use of cannabis with THC of over 1%.

POLAND

Law and Practice

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Law for Lifesciences

1. Regulatory Framework

1.1 Primary Laws & Regulations

There are a number of laws in Poland that govern the production, distribution and use of medical cannabis and cannabinoids. The principal law regulating medical cannabis and cannabis in general is the Law on Preventing Narcotics Addiction (LPNA), and corresponding regulations of the Minister of Health (MoH). The most popular cannabinoids are tetrahydrocannabinol (THC) and cannabidiol (CBD); therefore, this article will focus on regulations concerning these two.

It should be noted that the cannabis species (referred to as medical cannabis) contains higher doses of THC, while CBD comes first from hemp. Medical cannabis and hemp are different strains of the same species, which is cannabis sativa.

The Law on Preventing Narcotics Addiction (LPNA) (Ustawa o przeciwdziałaniu narkomanii)

The LPNA addresses numerous aspects concerning medical cannabis and hemp, including their classification, holding and permitted use, placing on the market, cultivation and harvest. It also imposes the obligation to obtain various authorisations or permits before engaging in any of these activities.

Classification

The LPN A splits the cannabis genus (cannabis L) into two categories:

- hemp (literally, fibrous cannabis); and
- non-fibrous cannabis.

These terms are used throughout Polish regulations applicable to cannabis. Non-fibrous cannabis is, in practice, equivalent to medical cannabis; other strains are considered hemp.

Fibrous cannabis (hemp) is defined in the LPNA as a plant belonging to the cannabis species (cannabis sativa L), in which the content of the delta-9-tetrahydrocannabinol and tetrahydrocannabinolic acid (delta-9-THC-2-carboxylic acid) in flowering or fruiting tops of the plant from which the resin has not been removed does not exceed 0.3% (until May 2022, this was 0.2%) of its dry weight. In contrast, any other cannabis containing higher content than the above THC combination will be considered non-fibrous can-

nabis. This is a very important differentiation, because cannabis (and its derivatives listed in the LPNA) containing THC of up to 0.3% will not be considered a narcotic drug and, therefore, many activities concerning it will be allowed (or merely limited) in contrast to those concerning cannabis where concentration of THC is higher than 0.3%.

The LPNA refers to the following:

- herb – defined as any terrestrial part of a cannabis plant (alone or in a mixture) of non-fibrous cannabis, excluding seeds, containing over 0.3% of THC; and
- cannabis resin – defined as resin and other cannabis products containing THC (delta-9-tetrahydrocannabinol or delta-9-tetrahydrocannabinolic acid) (please note that resin may come from either regular hemp or non-fibrous cannabis, and the key difference is in THC content).

All herbs and extracts, pharmaceutical tinctures and all other extracts of non-fibrous cannabis (that is, containing THC of over 0.3%) and cannabis resin are considered narcotic drugs (I-N group); they are listed as narcotic drugs in Annex 2 (Part 1) to the MoH Regulation regarding the list of psychotropic substances, narcotics and new psychoactive substances. Manufacturing, use and distribution of such narcotic drugs is either prohibited or strictly limited, while the same activities regarding hemp are considerably less regulated.

CBD is not listed as a narcotic drug or other regulated substance under the LPNA.

Possession

According to the LPNA, possession of any narcotic drugs is authorised only for entities or individuals who are allowed to possess them under binding statutory provisions. The police or customs authorities may seize and secure any possessed narcotic drugs in the absence of such entitlement.

The LPNA authorises the following entities to possess narcotic drugs:

- pharmacies;
- healthcare institutions and physicians, provided they obtained a special permit issued by the regional pharmaceutical inspector; and
- certain other entities.

Medicinal products containing narcotic drugs (such as those defined above regarding derivatives of medical cannabis) for individuals are available in pharmacies, on special medical prescription. Otherwise, possessing medical cannabis, which is in principle qualified as a narcotic drug, is subject to criminal liability (though in the case of small quantities, held for one's own use, criminal proceedings may be dismissed). For details, please see **1.6 Enforcement & Penalties** and **3.3 Decriminalisation**.

Possession of products including just CBD is not regulated under the LPNA.

Permitted use

According to the LPNA, all narcotic drugs (I-N and II-N) – including, therefore, herbs and extracts, pharmaceutical tinctures and all other extracts of medical cannabis, as well as cannabis resin, as defined in the LPNA – may be used only for medical, industrial or research purposes (upon meeting other applicable requirements).

For medical purposes, such derivatives and resin may be considered pharmaceutical raw materials that might serve for the preparation

of pharmaceutical materials in pharmacies, and which are available on medical prescription (and subject to special marketing authorisation).

It should be noted that recreational use of medical cannabis is currently not allowed in Poland and is subject to criminal liability (please see above, under Possession).

Use of products including only CBD is not regulated under the LPNA; however, limitations on such use may result from other legal regulations, in particular those concerning novel food (for details, please see under Other Regulations below, and see also **3.2 Non-controlled Cannabinoids in Food**).

Marketing medical cannabis

Most of the terms applicable for marketing medical cannabis are included in the LPNA. Marketing medical cannabis requires a special marketing authorisation, designed specifically for medical cannabis (that is, herbs of non-fibrous cannabis and cannabis resin – please see the definitions discussed above), and referred to in the LPNA and a corresponding MoH Regulation. This concerns the application form for the marketing authorisation of pharmaceutical raw material for the preparation of prescription medicines in the form of non-fibrous cannabis herbs and extracts, pharmaceutical tinctures, and other extracts of non-fibrous cannabis and resin, as well as a detailed range of data and a list of documents covered by this application. Also provided are details of specific proceedings, in which the marketing authorisation specifically for medical cannabis is issued, such as concerning the content of the application and the required documents (including, in particular, the manufacturing authorisation). The marketing authorisation, in the case of medical cannabis, is issued for a pharmaceutical raw material (and not a medicinal product); specifically, no summary of product characteristics is issued.

Other general requirements on marketing authorisations that would also apply to medical cannabis are included in the Pharmaceutical Law (see below under The Pharmaceutical Law); and the LPNA refers to a number of specific provisions regarding renewals, fees and refusals to grant.

Manufacturing

The LPNA regulates two basic stages of manufacturing of medicines, including narcotic substances, such as the derivatives from medical cannabis.

The first stage consists of manufacturing the active pharmaceutical ingredient for the further manufacturing of a pharmaceutical raw material containing medical cannabis, and, as is explicitly defined in the LPNA, of grinding dried parts of plants and carrying out physicochemical operations (as a result of which the substance is produced) including extraction, and packaging in bulk packaging. The requirements of Good Manufacturing Practice for active pharmaceutical ingredients, included in the Pharmaceutical Law and in the corresponding MoH Regulation concerning the requirements of Good Manufacturing Practice, apply to such operations. One such requirement is the obligation for the manufacturer to be registered in the register of manufacturers of active substances.

The second stage is manufacturing the pharmaceutical raw material, and consists of repackaging from bulk into packaging in which the raw material will be delivered to pharmacies. These operations should observe the requirements of the manufacturing of medicinal products, contained in the Pharmaceutical Law and in the corresponding MoH Regulation on Good Manufac-

turing Practice. The key requirement is holding a regular manufacturing authorisation.

The LPNA also requires a separate specific authorisation for the manufacturing, processing, importation and distribution of narcotic drugs, including medical cannabis. For details, please see **1.2 Regulatory Bodies**.

Cultivation and harvest

Cultivation of hemp (fibrous cannabis) is allowed only for explicitly listed purposes; however, their scope is quite large and covers numerous industrial purposes. Both cultivation and buying hemp from its manufacturer require prior registration in a special register run by the National Support Centre for Agriculture.

The LPNA provides for numerous requirements applicable to manufacturers and buyers of hemp, and determines the required content of applications and the documents that should be submitted with them in order to be registered. It also provides for the right to inspect manufacturers and buyers to ensure they are compliant with applicable requirements.

Cultivation of medical cannabis (non-fibrous cannabis) is strictly regulated. Until 2022, it was only permitted to cultivate strains of cannabis other than hemp for research purposes, by very limited categories of research institutions, upon special authorisation issued by the Chief Pharmaceutical Inspector.

Since May 2022, in Poland it is permitted to cultivate non-fibrous cannabis (medical cannabis), as well as to harvest herbs and resin from it, for the purpose of the manufacturing of pharmaceutical raw material, with a special permit issued by the Chief Pharmaceutical Inspector. Such permit may be issued only to research institutions, supervised by the Minister of Agriculture. In practice, domestic authorised cultivation of medical cannabis has not yet begun, to the best of the authors' knowledge; therefore, all requirements for medical cannabis on the Polish market are satisfied by imported medical cannabis only.

Distribution

Wholesale of medical cannabis is also strictly regulated by the LPNA and requires special authorisation (for details, please see **1.2 Regulatory Bodies**).

The Pharmaceutical Law

The second major legal act applying to medical cannabis (only) is the Pharmaceutical Law (*Ustawa prawo farmaceutyczne*), which establishes legal requirements for the manufacturing, importation, wholesale and retail distribution of medicinal products in general.

The following provisions of the Pharmaceutical Law apply to medicinal products containing derivatives of medical cannabis:

- on the marketing authorisation, including those on special proceedings concerning market approvals for raw pharmaceutical materials;
- on the manufacturing and importation of medicinal products, and Good Manufacturing Practice;
- on the manufacturing of active pharmaceutical ingredients, including Good Manufacturing Practice of active pharmaceutical ingredients;
- on wholesale distribution of medicines;
- on retail sale of medicines; and
- on prescriptions.

Other Regulations

Reimbursement

In Poland, medicinal products containing medical cannabis are not currently reimbursed; therefore, a person wishing to buy such product and holding a medical prescription will have to bear its entire cost. In May 2024, the pharmacy price for such products ranges between PLN50 and PLN70 (EUR12-EUR16) per gram.

Lifestyle products

Various products (other than medicinal products) containing cannabinoids (especially CBD) are available on the Polish market. These products may be divided into the following categories (among others):

- cosmetic products;
- food; and
- smoking accessories.

It should be noted that food and cosmetics laws and regulations are often EU-wide and, therefore, are directly applicable throughout the entire EU. However, it must be emphasised that in Poland there are no regulations dedicated specifically to non-controlled cannabinoids (especially CBD). There is a wide variety of such products on the market, in terms of both their ingredients and their quality.

1.2 Regulatory Bodies

There are numerous authorities responsible for enforcing laws regarding cannabis in Poland.

The President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (ORMP) (Prezes Urzędu Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych)

The President of the ORMP is responsible for issuing marketing authorisations for human and veterinary medicines.

The President of the ORMP issues marketing authorisations specifically concerning medicinal cannabis (coming from a determined supplier), as a pharmaceutical raw material from which a medicine available in pharmacies can be manufactured. Such marketing authorisation is issued for five years, in special proceedings regulated by the LPNA, an MoH Regulation and the Pharmaceutical Law (for details, please see **1.1 Primary Laws & Regulations**).

The Chief Pharmaceutical Inspector (ChPhI) (Główny Inspektor Farmaceutyczny)

The ChPhI is the governmental authority for supervision of manufacturing, importation, wholesale distribution and advertising of medicinal products, and is a major governmental agency dealing with medical cannabis, whose determined derivatives (please see the definition in **1.1 Primary Laws & Regulations**) are considered narcotic drugs. The various authorisations and permits issued by this authority are listed below.

Regular manufacturing authorisation

The ChPhI issues regular manufacturing authorisation required to manufacture any medicinal product, including medical cannabis, as the raw pharmaceutical material. Also, importation of medical cannabis (ie, from countries outside the EEA) and its testing and distribution would require an import authorisation issued by the ChPhI.

Specific manufacturing authorisation for narcotic drugs

The ChPhI is also responsible for issuing specific authorisation required to manufacture, process, import or distribute narcotic drugs, such as medical cannabis. This is issued for an undefined time period (ie, unlimited in time). To obtain this authorisation, the applicant should first have obtained a regular manufacturing authorisation.

Regular wholesale distribution authorisation

Wholesale distribution of any medicinal product, including medical cannabis, would also require a regular wholesale authorisation granted by the ChPhI.

Specific wholesale distribution authorisation for narcotic drugs

A separate authorisation is also necessary for wholesale distribution of narcotic drugs.

Import and export licences

The ChPhI is also responsible for issuing special licences required for the importation, exportation or intra-community supply of narcotic drugs. These licences should be obtained for each such specific import, export or supply, and should determine the volume and the term in which these can be performed (eg, one-off licences). It should be noted that there are annual limits in force that determine the maximum volume of all medical cannabis imports into Poland. Estimated world requirements for determined narcotic drugs (including medical cannabis and separately cannabis resin) for all the countries are available on the International Narcotics Control Board website. These requirements are regularly updated, and in Poland they also set thresholds for annual imports of the narcotic drugs listed there.

In general, ChPI will issue one-off import licences for the import of certain narcotic drugs in accordance with the application, provided however that the annual limit for Poland for this particular narcotic drug is not exceeded. The annual limit in 2024 for import of medical cannabis is 6,000,000g and 50g for cannabis resin.

Permits for cultivation and harvesting of non-fibrous cannabis

Cultivation and harvesting of medical cannabis require a special permit issued by the ChPhI. As stated above, to the best of the authors' knowledge, no such permits have been issued yet and all local requirements need to be met with imported cannabis, and only one application for the cultivation permit has been submitted (currently the proceedings are suspended for undisclosed reasons).

The National Support Centre for Agriculture (Krajowy Ośrodek Wsparcia Rolnictwa)

The Director of the National Support Centre for Agriculture maintains a register of poppy and hemp, in which producers (cultivators) of hemp and entities purchasing hemp from them should already be registered before cultivation begins. In other words, the producer must have all production contracted before they start cultivation.

1.3 Self-Regulatory Authorities

In Poland, there are no self-regulatory authorities, but there are a number of industry associations that promote use of cannabis for various purposes.

One such organisation is Free Cannabis (*Wolne Konopie*), which describes itself as an association acting for the reasonable and effective use of cannabis, established in 2006.

Examples of other organisations active in the market include the following.

The Polish Association of Hemp Producers and Processors – headquartered in Warsaw – was founded in early 2019. The Association's goals include disseminating knowledge about hemp and developing a concept for the development of the hemp market in Poland.

The Polish Federation of Patients is an organisation that represents the interests of patients in Poland. The Federation's goals include fighting for the legalisation of medical cannabis in Poland and providing patients with easier access to this form of treatment.

CannabiMed Foundation is an organisation dedicated to promoting knowledge about the uses of medical cannabis in the treatment of various diseases and conditions. The Foundation is also working to change Polish law regarding the legalisation of medical cannabis.

TRUSTT is one of two companies in Europe that have emerged to track the manufacturing processes of medical cannabis products and verify regulatory compliance. The company implements solutions based on advanced technology such as blockchain, ensuring the security and immutability of the data obtained. The solution proposed by TRUSTT can be an element of market self-regulation, but above all it can be a tool used by the regulator to control the market.

The list of the organisations involved in the topic of hemp in Poland continues to grow, as interest in the subject has grown in recent years. Most such organisations are focused on spreading awareness of the use of medical cannabis and on providing access to it for those who need it.

None of these organisations has a dominant position in the market, nor have they managed to develop and introduce any significant documents, rules or principles that would already significantly affect the market. There are no commonly accepted "Good Market Practices" relating to the production, importation, distribution, or labelling of the composition of products containing cannabinoids which would be followed by market participants. Each of these players is trying to attain a significant position, but so far it is not possible to point to any entity considered to be shaping or significantly influencing market behaviour. The market is still in the early stages of development, where there is a high degree of discretion in the areas not strictly regulated by national law. This causes confidence in this market and its participants to remain quite low.

1.4 Challenges for Market Participants

Key market challenges include the following.

- The lack of quality standards for cannabidiol products. The vast majority of the market operates without any certification or quality monitoring. The market for cannabidiol products is growing rapidly, which causes many operators to try to achieve the best possible sales results at a low cost. Hence, for most products, there is no certainty that the product complies with the declared composition.
- The attitude of the State administration is still highly distrustful, and lack of education of forces responsible for law enforcement (police, customs, etc) causes cannabis to continue being associated mainly with narcotics. This means that the cultivation of hemp with an acceptable THC content (ie, below 0.3%) is still subject to numerous difficulties.
- The lack of uniform nationwide laboratory methods for determining THC levels to

exclude the risk of erroneous or contradictory results, which can have serious consequences, including the risk of criminal liability. There are no standards and scopes for laboratory testing. There is no practice of testing for more cannabinoids, for terpenes or for contaminants such as heavy metals. Of course, standards are in place with pharmaceutical standard laboratories taking into account EU Good Manufacturing Practice, but unfortunately most testing is done in non-standardised units. This also (and perhaps especially) applies to forensic laboratories and customs. Due to the wide disparity in standards and testing methods used, there is large discrepancy with final laboratory results.

- The cultivation of medical cannabis is basically subject to the Ministry of Agriculture, since research institutes (which are the only ones that can apply for a permit for the cultivation of medical cannabis) are supervised by the Ministry of Agriculture and have no experience in the drug manufacturing market, which in the authors' opinion is a systemic error – a farmer will not produce a pharmaceutical product. This creates a great deal of problems and controversy, given the limited number of entities that can cultivate (13 State research institutes), which do not have adequate funds or ways to obtain them from the market, and which do not have the knowledge or competence regarding how to put into practice the provisions of the law and to start growing medical cannabis, not for research but for commercial purposes, and on an appropriate scale.
- After the parliamentary elections in the autumn of 2023, the liberalisation of the cultivation of medical cannabis laws is not on the new government's agenda for the time being. In spite of this fact, the situation with regard to liberalisation of law in respect of not only medical but also recreational cannabis appears to be much better than under the previous conservative government. Moreover, according to one recent public survey, 73.4% of Poles are against punishing individuals for possessing recreational cannabis. Therefore, future changes of the law seem to have only one direction – liberalisation. Of course, the frequently changing regulations are a challenge for those planning to operate in this market.
- The need for improving knowledge of medical cannabis therapy, especially among doctors. Numerous doctors complain about unavailability of adequate training on how and in which indications to prescribe medical cannabis.
- The absence of medical cannabis on the list of reimbursed medicines. Therapy with medical cannabis should be financed entirely by patients; due to relatively high costs of medical cannabis, certainly many patients who could benefit from using it cannot afford it.
- Restrictions on agricultural land trading constitute a barrier for entities that would like to enter the market of industrial hemp cultivation and that do not have the status of a farmer in the understanding of Polish law.

Poland's current regulatory system for medical cannabis is still in the process of development, following the initial amendments allowing, to a limited extent, for the cultivation of medical cannabis in Poland. In the authors' opinion, further significant changes are necessary and expected by the market.

A major legal change occurred in 2017, when use of medical cannabis, including THC, became legally allowed for medical purposes (under defined terms). In another recent significant legislative change, since May 2022, cultivation and

harvesting of non-fibrous cannabis with THC content over 0.3% became permitted for purposes other than research, and in particular for medicinal purposes (both changes concerned the LPNA). However, this change should only be seen as a prelude to a true opening of the market for medical cannabis cultivation in Poland, since this option is available only to a limited number of State research institutes, which should meet numerous and extremely strict requirements. In practice, this significantly reduces, if not eliminates, any chance for domestic cultivation of medical cannabis.

Given the lack of any experience in this field, the typically excessive formalisation of the State's institutions, and the decision-making process, it is hard to be optimistic about the quick effects of the regulation concerning cultivation of medical cannabis. Therefore, in the coming months, and perhaps even in the longer term of one or two years, it is difficult to expect significant changes and the emergence of marketable volumes of medical cannabis from domestic cultivation.

At the same time, the permitted concentration of THC in cannabis derivatives was increased from 0.2% to 0.3%, which is reported as having a potential to boost crops and general use of cannabis, and to decrease the legal risk connected with the use or handling of cannabis in general.

As regards lifestyle products, including CBD from hemp, the regulations are very widespread and sometimes difficult to identify. It is widely discussed that with respect to lifestyle products, quality criteria and certification proceedings are missing, which can adversely affect their quality. For certain categories of popular lifestyle products, supervision by regulatory authorities is rather weak or ineffective.

1.5 Legal Risks

The Polish cannabis market is still in the early stages of development both in terms of legislation and market practices. Legal risks include the following.

- Numerous laws (no single act comprehensively regulating the cannabis market) – ie, for medical cannabis, cannabinoids and industrial hemp – makes it difficult for start-ups to know all their rights and obligations.
- It should be remembered that hemp and cannabis are still widely and strongly perceived as narcotics in Poland, which is why the cannabis business still faces a certain amount of suspicion and mistrust, especially towards newcomers to the business. However, the awareness of state authorities is increasing and medical cannabis is already seen as a drug used in many therapies. Recently, the Polish Police, when queried by the Ombudsman, confirmed that persons with a prescription for the use of medical cannabis are treated like any other patient in the event of an inspection. Of course, this does not apply to the situation of driving under the influence of medical cannabis.
- Polish authorities are significantly focusing on even small discrepancies of the legalised THC percentage, which has resulted in bans on product importation, penalties for businesses and delays in delivery, and even exposure to criminal liability.
- The lack of standards and methods for determining THC that are uniform for all domestic laboratories may mean an increased risk of violating norms regarding permissible THC levels.
- Compliance procedures can be quite complicated and time-consuming, and differences in the interpretation of the law between State control services (police, customs, pharma-

ceutical inspectors, etc) sometimes extend the procedures or cause previously unforeseen legal complications.
- Changing legislation, which is still in the early stages of development, and annual limits on medical cannabis imports introduced at the national level (in the context of estimated domestic demand), make long-term business development planning difficult.
- There is also limited access to the agricultural land enabling the cultivation of hemp, due to the restrictions of Polish law on agricultural land trading and leasing.

1.6 Enforcement & Penalties

Certain derivatives of medical cannabis are considered narcotic drugs (please see **1.1 Primary Laws & Regulations**), and activities concerning them are penalised. In Polish law, sanctions – both criminal and administrative – are included in the Criminal Code and legal regulations regarding specific categories of products (ie, narcotics, medicinal products and food).

Criminal Sanctions and the Authorities Enforcing Them

The LPNA

As referred to in **1.1 Primary Laws & Regulations**, the LPNA classifies non-fibrous hemp as a narcotic drug, which results in the application of severe criminal sanctions for various activities related to it. Polish law also penalises certain activities involving fibrous hemp.

Penalties for individual offences vary depending on the type of offence and the amounts of narcotic drug involved, as follows.

- Placing narcotic drugs on the market or taking part in such activities: imprisonment for six months to eight years. In the case of significant amounts: imprisonment for two to 12 years, and a fine.
- Importation, exportation, transportation, intra-community acquisition or intra-community supply of drugs: imprisonment of up to five years, and a fine. In the case of significant amounts, or where the perpetrator acts for their own financial or personal advantage: imprisonment from three years to 20 years, and a fine.
- Manufacturing and reprocessing of narcotic drugs: imprisonment for up to three years. In the case of significant amounts, or where the perpetrator acts for their own financial or personal advantage: imprisonment from three years to 20 years.
- Unauthorised possession of a narcotic drug: imprisonment for up to three years. In the case of significant amounts: imprisonment for one to ten years.
- Advertising or promoting narcotics drugs: a fine, restriction of liberty or imprisonment for up to one year.

There is a separate offence specifically concerning non-fibrous hemp (and certain other plants), as follows.

- Cultivation and harvesting of non-fibrous hemp (unauthorised): imprisonment for up to three years. Where the crops may produce significant amounts of non-fibrous hemp: imprisonment for six months to eight years.

It should be noted that according to the general provisions of the Polish Criminal Code, a fine can always be inflicted by the court upon a perpetrator condemned to imprisonment, where this perpetrator committed the offence to obtain financial advantage, or where they obtained financial advantage. The maximum fine under the Polish

Criminal Code is PLN1.08 million, which corresponds to roughly EUR235,000.

Certain practical aspects concerning possession of medical cannabis are presented below.

Possession of medical cannabis

According to the LPNA, narcotic drugs (including medical cannabis) may only be possessed by an entrepreneur, organisational unit or individual authorised to possess them under the provisions of the LPNA, Regulation 273/2004 or Regulation 111/2005. An individual who does not have a medical cannabis treatment certificate commits a criminal offence.

Responsibilities of a person in possession of medical cannabis

A person in possession of medical cannabis should:

- keep it in its original packaging (unless a smaller amount has been measured at the pharmacy, in which case in an airtight package from the pharmacy);
- carry a medical cannabis treatment certificate;
- carry an identity card; and
- carry documents that confirm the purchase of medical cannabis in accordance with the law – eg, a scan of a prescription from a pharmacy with a receipt.

Prohibition on processing medical cannabis

A patient who has legally acquired medical cannabis with a doctor's recommendation cannot process the acquired dried product (in theory, even shredding may be considered such processing).

Driving after consuming medical cannabis

When determining a case for an offence against safety in communication committed under the influence of an intoxicant, the court must determine in each case whether the drug had a real effect on the psychomotor performance of the driver of the vehicle to a degree similar to that of being under the influence of alcohol.

The LPNA also penalises:

- manufacturing, storing, purchasing, selling or adapting equipment which may be used for the unauthorised manufacturing or reprocessing of narcotic drugs;
- preparations to commit offences penalised by the LPNA;
- inducing other persons to use narcotic drugs, and providing them with, or making it possible or easier to use, such drugs; and
- certain other activities regarding use of narcotic drugs.

The law also penalises the following activities in relation to fibrous hemp:

- illegal cultivation or buying of hemp – punishable with a fine; and
- providing inaccurate information about the surface of crops – also punishable with a fine.

The Food Law

The Polish Law on Food and Nutrition Safety (*Ustawa o bezpieczeństwie żywności i żywienia*) (the "Food Law") penalises the following activities, which may concern food products containing cannabinoids:

- manufacturing or placing on the market a food supplement or novel food harmful to health or life – subject to a fine, restriction of

liberty or imprisonment of up to three years; and
- placing on the market novel foods without authorisation to be obtained in accordance with EU law – subject to a fine, restriction of liberty or imprisonment of up to two years.

The Act also provides for fines for non-compliance with the labelling requirements applicable to foodstuffs, including presentation, advertising and promotion.

The Polish Criminal Code

Bringing danger to the life or health of many people by manufacturing or marketing substances, foodstuffs or pharmaceuticals that are harmful to health and that do not meet the applicable quality conditions is a crime listed in the Polish Criminal Code. Such an act is punishable by the basic penalty of imprisonment for six months to eight years.

Enforcement authorities

In enforcing criminal law provisions, the key role is played by the authorities conducting criminal proceedings – ie, the police, public prosecutors and common courts. The police and public prosecutors conduct criminal investigations, which may result in bringing charges to a common criminal court, which conducts judicial proceedings that may result in conviction and determined penalties.

Enforcement by Administrative Authorities

The Pharmaceutical Law

The Pharmaceutical Law applies to narcotic drugs within the meaning of the provisions on preventing narcotics addiction and which are considered medicinal products. The enforcement authorities for medicinal products are the Chief Pharmaceutical Inspector (*Główny Inspektor Farmaceutyczny*) and the regional pharmaceutical inspectors.

Pharmaceutical inspectors may issue decisions:

- on suspension or withdrawal from the market or of use of medicinal products in the event of suspicion or finding that a given product is not authorised in Poland;
- prohibiting placing on the market, or on the withdrawal of an active substance from the market; or
- on suspension or withdrawal of prohibited products from public pharmacies and pharmaceutical wholesalers.

Importantly, in the event of violation of the conditions for the manufacturing or importation of medicinal products, which are very restrictive in relation to drugs containing cannabinoids, the Chief Pharmaceutical Inspector may issue a decision prohibiting the placing of a medicinal product on the market or on withdrawing a medicinal product from the market.

Medicinal products containing narcotic substances may be dispensed only upon a medical prescription. Conducting wholesale trade in narcotic drugs requires an additional permit, whereas brokering in narcotic drugs is prohibited.

In addition, it is prohibited to advertise medicinal products containing narcotic drugs to the public. In accordance with the Pharmaceutical Law, breaking this prohibition is punishable by a fine (ie, it is a criminal offence).

Under the Food Law

The State Sanitary Inspection is the Polish authority responsible for supervision over the health conditions of food. The Chief Sanitary Inspector (*Główny Inspektor Sanitarny*) as the

central government administration authority, may, after receiving a notification about the first time a food has been placed on the market, conduct explanatory proceedings regarding this product (eg, a food supplement). The investigation procedure is aimed at clarifying whether the product covered by the notification is a foodstuff in accordance with the qualification proposed by the food business operator and whether it meets the requirements for a given type of foodstuff (eg, for a food supplement). In addition, the procedure determines whether or not the food meets the requirements of a product of another category (eg, a medicinal product).

In the event of suspicion that a food product not meeting the specified requirements is on the market, the regional sanitary inspector may decide to temporarily suspend the marketing of this food product or to withdraw it from the market until the end of the procedure.

2. Cross-Jurisdictional Matters

2.1 Cross-Jurisdictional Issues

Given the lack of uniform regulation of hemp and medical cannabis at the level of EU legislation, players in the European market must take into account and analyse national regulations.

The problem is even more significant in the case of cross-border trade with non-EU countries. Although there is a common trend across the EU towards liberalisation of THC levels in cannabis products and availability of medical cannabis, differences remain. Therefore, any market player which intends to engage in cross-border transactions must carefully examine the legal environment of the country in question before entering into such transactions. There is a lack of organisations, platforms or other initiatives at the international level that would transparently present the differences in regulations from one country to another. This is even more important given the fact that national laws are constantly being amended, and although they are usually aimed at liberalising regulations, these constant changes make it difficult to operate across borders.

3. Legal and Regulatory Developments

3.1 Access to Medical Cannabis

Use of medical cannabis for medical purposes is allowed, under strictly defined terms. These terms are included in the LPNA and in the Pharmaceutical Law. At present, access to medical cannabis requires a special medical prescription for narcotic substances. This can be issued by any physician; however, many do not have appropriate training and expertise for treating patients with medical cannabis. There are no official guidelines on indications in which medical cannabis may be used, and in which dosages. Each physician should decide individually on whether to prescribe medical cannabis in given circumstances, bearing personal liability. Notwithstanding, at least several dozen thousands of prescriptions are issued in Poland for medical cannabis, what makes Poland a country where the medical cannabis market grows quickly.

During the COVID-19 pandemic, medical consultations and online prescriptions were permitted on a large scale. As a result, internet portals specialising in medical consultations related to medical cannabis treatment were established. This resulted in a certain market pathology, in which a prescription for medical cannabis could have been obtained online literally within minutes. The problem has already been recognised

by the MoH and in consequence, a regulation was adopted, which became binding in August 2023. The regulation introduced an obligation on each doctor prescribing medical cannabis to a patient to verify the number and kinds of other medicines which were prescribed to this patient, and to examine the patient, on an on-site or online consultation, if the time since the last examination exceeded three months.

In 2023, more than 4.6 tonnes of medical cannabis were dispensed from Polish pharmacies. This is a huge increase compared to previous years. Compared to 2022, pharmacists dispensed as much as 3.5 tonnes more medical cannabis. This indicates a growing interest in medical cannabis in Poland.

The values of medical cannabis dispensed in Poland between 2019 and 2023 are as follows:

- 2019 – 33,219g;
- 2020 – 94,038g;
- 2021 – 427,017g;
- 2022 – 1,167,752g; and
- 2023 – 4,658,759g.

The above-mentioned amendment to the LPNA has established a framework for the cultivation, production and distribution of medical cannabis in Poland. Some key aspects of this amendment include the following.

- The amendment requires entities that want to cultivate medical cannabis to obtain a licence from the Polish Pharmaceutical Inspectorate. The licence is granted for a period of five years and is subject to renewal.
- The amendment sets out quality control standards for medical cannabis, including testing for contaminants and ensuring consistency of the active ingredients.
- The amendment regulates the supply chain for medical cannabis, from cultivation to distribution for patients. It requires that all entities involved in the supply chain be licensed and comply with relevant regulations.
- The amendment aims to improve patient access to medical cannabis by allowing licensed entities to produce and distribute medical cannabis products. Patients will still need a valid prescription from a licensed physician to obtain medical cannabis, but the amendment may help to ensure a more reliable and consistent supply of medical cannabis products.

As a result of current unavailability of domestic cultivation of medical cannabis, all the requirements for it have so far been met by imports from other countries (mostly the EU). This certainly affects access to it, since imported medical cannabis is expensive. Considering that medical cannabis is not reimbursed in Poland, patients wishing to purchase it must pay for it with their own resources. Where dosages prescribed by treating physicians are high, the monthly costs of treatment (which may be close to the minimum monthly salary in Poland) may be unaffordable for some patients.

There have been discussions about expanding the list of medical conditions for which medical cannabis can be used, but no significant changes have yet been made. The Polish government has been generally cautious about cannabis legalisation, so any changes to the legal elements affecting access to medical cannabis may take time. However, with the growing awareness of the potential benefits of medical cannabis, it is possible that the legal landscape may evolve in the future.

3.2 Non-controlled Cannabinoids in Food

Under the current legislation in force in Poland, non-controlled cannabinoids cannot be used in food due to the application of Regulation (EU) 2015/2283 on novel foods. This Regulation is applied directly in Poland. The Polish Food Law refers to EU law as regards novel foods.

EU Regulation 2015/2283 defines novel food as a product that was not used to a significant degree as a food or food ingredient before 15 May 1997. To place such food on the market in the EU (including in the Polish market), a safety assessment and an EU authorisation under Regulation 2015/2283 is required. The list of novel foods requiring authorisation is included in Commission Implementing Regulation (EU) 2017/2470. The European Commission determined that cannabidiol (CBD) can be considered as a novel food. No such authorisation has yet been granted for non-controlled cannabinoids; therefore, they cannot be used in food.

An important issue should be emphasised in this context. Some cannabis sativa L products (such as seeds, seed oil, hemp seed flour and defatted hemp seeds) are widely used in the EU, have a long history of use and are not considered novel foods. In contrast, extracts from cannabis sativa L that contain cannabinoids (such as cannabidiol (CBD), and foods enriched with extracts from cannabis sativa L or with cannabinoids such as CBD (eg, hemp seed oil with CBD or dietary supplements with CBD)) are considered novel foods, as history of consumption has not been demonstrated. This applies to both the extracts themselves and to any products to which they are added as an ingredient (such as hemp seed oil). This also applies to extracts of other plants containing cannabinoids. Synthetically obtained cannabinoids are also considered novel foods.

The safety of products with CBD as a novel food is currently being investigated by the European Food Safety Authority (EFSA). According to the official information provided by EFSA, its scientists cannot currently establish the safety of cannabidiol (CBD) as a novel food due to data gaps and uncertainties about potential hazards related to CBD intake. According to EFSA, there is insufficient data on the effect of CBD on the liver, gastrointestinal tract, endocrine system, nervous system and people's psychological well-being. Therefore, as long as the scientific assessment of CBD in terms of its safety remains incomplete, and foodstuffs containing CBD remain not authorised by the European Commission, products containing CBD cannot be placed on the Polish market as food.

Jurisprudence of Courts and Positions of State Authorities

In one of the more interesting court cases concerning cannabis sativa L in the context of novel foods, the Voivodeship Administrative Court in Warsaw held that only the following are novel foods:

- cannabis sativa L plant extracts containing cannabinoids;
- products derived from these extracts – ie, any products to which these extracts have been added (such as seed oil);
- extracts from plants, other than cannabis sativa L, containing cannabinoids; and
- synthetically obtained cannabinoids.

The court explained that the cannabis sativa L herb is not a novel food, because it has a long history of use and does not constitute a novel food according to catalogues published by the EU. In the opinion of the court, the EU list of novel foods does not by definition list all food products and ingredients that can be used in

food production. The fact that a food or ingredient is not explicitly mentioned does not automatically mean that it is a novel food. The list of novel foods includes only those products and ingredients for which the European Commission has received a request for an opinion on whether a given product or ingredient should undergo the authorisation procedure. On this basis, the court concluded that cannabis sativa L (the herb) is not a novel food.

The court's reasoning has led to some belief that this might be a step towards wider acceptance of hemp products as food; however, it seems that the court has only made it clear that, in assessing the novel status of a given food, a case-by-case approach is appropriate, and made a clear indication that certain products containing cannabinoids are novel foods, so their placing on the market requires European Commission authorisation (judgment of the Voivodeship Administrative Court in Warsaw of 17 February 2022, Case No V SA/Wa 5258/21).

The position on the use of hemp in food was also analysed by the sanitary authorities. For example, the Voivodeship Sanitary Inspector in Białystok stated that some products derived from the cannabis sativa L plant (seeds, seed oil, hemp seed flour and defatted seeds) are not considered novel foods. Nevertheless, when placing food containing the above-mentioned raw materials on the market in Poland, the supplier should have current and reliable results of the analysis of the finished food, confirming the absence of psychotropic substances (ie, tetrahydrocannabinol (THC) above acceptable levels).

Issues related to hemp are also within the scope of the Polish tax authorities. Although the decisions of these authorities are not generally applicable law and do not determine whether a given commodity can be legally traded as food, they indirectly (by reference to the circumstances of a given case) show the industry practice and the variety of problems and issues related to the marketing of the products in question. For example, in one of the decisions clarifying the combined nomenclature (CN) classification for the purpose of taxation, dried hemp inflorescences were presented to the tax authorities as a product not intended for human consumption, and such classification was accepted (Director of the National Tax Information 0115-KDST1-1.440.16.2022.3.ANJ).

Market practice

Despite the aforementioned, products containing CBD are available on the market in Poland. However, they are not promoted as food, and their labels do not contain information suggesting that the products are edible. Such information can sometimes be obtained from the sellers. Interestingly, manufacturers or sellers provide information on the characteristics of a product, without stating explicitly that the described effects require its consumption as food. However, this conclusion can quite easily be drawn from the context of the product's presentation.

Some CBD-containing products are also presented as food supplements; however, due to the lack of authorisation under novel food regulations, this is not legally allowed. Such controversial practices are partly a result of inefficient market supervision. The Polish supervisory authorities for compliance with food law and that are responsible for performance of official food inspections are the State Sanitary Inspection and the Chief Sanitary Inspector, which is the relevant central government administration authority.

Each food business operator is obliged to make a notification regarding the first placement on the market of a food supplement, and the Chief Sanitary Inspector may conduct explanatory proceedings regarding the product to clarify it is a foodstuff in accordance with the qualification proposed by the food business operator, and whether it meets the requirements for a given type of foodstuff. In addition, the procedure may aim to determine whether the food is not in fact a different category of a product (eg, a medicinal product). Despite the broad competences of the Sanitary Inspection, the great number of notifications (roughly 25,000 in 2020) makes it difficult to control the market.

3.3 Decriminalisation

In Poland, until 2000, possession for personal use of small amounts of substances covered by the regime of the LPNA was not punishable. The situation changed when the provisions of Article 62 were adopted, stipulating that possession of any type of drug is punishable, regardless of the quantity and purpose of possession. The rationale behind this step was to increase the effectiveness of police operations. Among other things, the idea was that a dealer arrested with a prohibited substance should not escape responsibility by declaring possession for personal use. The 2000 amendment caused the number of detected drug possession offences to rapidly increase – from nearly 1,900 in 1999 to over 31,200 in 2007 (data from the Polish Drug Policy Network).

Prosecutors have the option to discontinue prosecution for possession of insignificant amounts of psychoactive substances. Today, one in three cases for possession is dropped.

In recent years, a growing number of countries around the world have begun to liberalise their cannabis policies, which has led to increasingly more debate about legalising recreational cannabis in Poland.

In Poland, a parliamentary panel on the legalisation of recreational cannabis was established in 2019. However, until 2023, the output of this panel's work was very modest; there have only been a few meetings, leading to the conclusion that legalisation of recreational cannabis in Poland should not be expected in the near future.

SPAIN

Law and Practice

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Faus Moliner is a modern boutique law firm, specialised in dealing with legal matters typical of the pharmaceutical industry and companies that operate in the life sciences sector. Founded in 1997, Faus Moliner focuses on pharmaceutical law, commercial contracts, corporate transactions, corporate governance, compliance, competition law, public procurement, product liability, advertising, litigation and arbitration. The firm advises pharmaceutical and healthcare clients, acts on behalf of large companies and smaller biotech start-ups and is frequently called upon to advise public authorities on matters such as draft legislation.

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1. Regulatory Framework

1.1 Primary Laws & Regulations

The main regulations on cannabinoids or affecting medicinal cannabis are as follows:

- Law 17/1967, on the updating of narcotic and psychotropic regulations to the provisions of the Single Convention of Narcotic Drugs of 1961 ("Law 17/1967"); and
- the Single Convention of Narcotic Drugs of 1961 on narcotic drugs, signed and ratified by Spain on February 3, 1966 (the "Single Convention").

According to the aforementioned regulations, cannabis is included in List I of the Single Convention, and is therefore considered a narcotic. According to the Spanish Agency of Medicinal Products and Medical Devices (AEMPS), its production, manufacture, export, import, distribution, trade, use and possession must be limited to medical and scientific purposes. Cannabis is also included in List IV of the Single Convention, and is therefore considered a prohibited article or genre.

Other than the above, there is no specific regulation addressing the use of medicinal cannabis in Spain. However, in October 2021, the Subcommittee of the Congress of Deputies on the regulation of cannabis was formed. This Subcommittee, dependent on the Spanish Committee on Health and Consumer affairs, was composed of experts in the field of medicinal cannabis from universities, healthcare centres, European authorities and research centres. The purpose of this Subcommittee was to study and submit to the Congress of Deputies clinical and scientific evidence in connection with the uses of medicinal cannabis. The Subcommittee issued its final report on 27 June 2022, including several conclusions and recommendations. The most relevant are as follows:

- the AEMPS is encouraged to define the most appropriate mechanisms, within the current regulations, to permit the prescription and use of medical cannabis (ie, through magistral formulas or standardised preparations);
- the therapeutic areas for which medical cannabis can be prescribed and used are limited to those supported by scientific evidence (and listed in the final report);
- patients treated with medical cannabis must be inscribed in a central registry with the purpose of further evaluation of the treatments;
- dispensation of medical cannabis should be limited to the pharmacists of the National Health System (NHS), with preference for hospital pharmacy services;
- the Spanish regions and the inter-territorial health council are encouraged to draw up clinical guidelines for the use of medicinal cannabis; and
- measures should be taken to ensure that this medicinal use of cannabis favours the consumption of cannabis outside the healthcare sphere.

Additionally, the republican parliamentary group *Esquerra Republicana de Catalunya* (ERC) submitted before the Spanish Congress of Deputies a proposal for a law on the comprehensive regulation of cannabis, including regulation for therapeutic and medical use, in February 2023. This proposition was rejected by 78 votes in favour, 261 against and two abstentions.

As a consequence of the recommendations made by the Subcommittee of the Congress of Deputies on the regulation of cannabis, the Spanish Minister of Health (MoH) worked with the AEMPS to define the best regulatory frame-

work for medicinal cannabis. In February 2024, the MoH released the prior public consultation for the Royal Decree project on the conditions for the production and dispensing of cannabis-derived products. This is the only regulatory proposal for medicinal cannabis at this time. The project establishes that medicinal cannabis preparations can only take the form of "magistral formula" and solely for a specific set of therapeutic indications. The proposal also intends to limit the preparation of magistral formulas derived from cannabis to those that have a monograph in the National Formulary. Note that the National Formulary is a list that contains the typified magistral formulas, their categories, indications and raw materials involved in their composition or preparation, as well as the standards for correct preparation and control.

There are no regulations on the use of cannabinoids in other products, except for the informative note issued by the Spanish Food Security Agency (AESAN) in March 2019 (confirmed in December 2022) on the use of cannabinoids such as THC, CBD, CBG and others in food products. According to this informative note, adding these cannabinoids to other food products (for example, to an oil or a beverage), regardless of their having a natural or synthetic origin, leads to their being considered novel foods and thus subject to the relevant EU regulations.

1.2 Regulatory Bodies

The main regulatory authorities will depend on the purpose of use of the medical cannabis or cannabinoid.

- AEMPS – this agency has been appointed to further regulate the use of medical cannabis according to the final report of the Subcommittee for the study of medical cannabis mentioned in **1.1 Primary Laws & Regulations**. The AEMPS oversees the use of cannabinoids in cosmetics and personal care products and is responsible for the authorisation of medicinal products (including those containing cannabis derivatives). It also grants authorisations for the cultivation of cannabis plants for research purposes, and for the production and/or manufacture of cannabis-derived products for medical and scientific purposes according to Law 17/1967.
- AESAN – this agency oversees the production and commercialisation of food products containing cannabinoids, such as food supplements with CBD.

1.3 Self-Regulatory Authorities

There are no self-regulatory authorities governing or overseeing the industry in Spain, apart from the national associations for medicinal products, medical devices and self-care products.

In addition, the Spanish Observatory on Medical Cannabis (OECM), composed of researchers, doctors and patient associations involved in the use of medical cannabis, has been very active in demanding a proper regulatory framework for medical cannabis, but to date is not acting as a self-regulatory body. Other than this entity, Spain lacks a structured industry lobby.

1.4 Challenges for Market Participants

The main challenge faced by market players will be the ability to truly participate in the medicinal cannabis industry by manufacturing and selling cannabis-derived products. If the proposal for the Royal Decree on the conditions for cannabis production and dispensing moves forward, cannabis products will only be authorised under the format of "magistral formulas". These can only be prepared and dispensed by pharmacy offices and will require an individualised patient medical

prescription. According to Spanish regulations, pharmacy offices can only be owned by a single natural person holding a degree in pharmacy, thus excluding the possibility of companies holding ownership of pharmacy offices. Therefore, industrial manufacturing and commercialisation of cannabis derivatives may encounter a significant barrier to entering the Spanish market.

1.5 Legal Risks

The legal risks that companies should consider in this industry would depend on the qualification that may be given to a particular product. These risks may include:

- product recalls (ie, a food supplement containing a non-authorised cannabinoid that does not pose a health risk);
- administrative sanctions (ie, cannabis-derived products that may qualify as a medicinal product but without the pertinent marketing authorisation); and
- criminal offences (ie, use of medical cannabis if the final product qualifies as a narcotic, or offences against public health).

At present, while cannabis-derived products containing cannabinoids (except THC) are not actively prosecuted, the promotion of medical uses of cannabis (including THC-containing products) by means that do not fit into the current regulatory framework for medicinal products would be a risky activity. Notably, Spain can be described as a conservative jurisdiction with regard to cannabis, as several bills for the comprehensive regulation of cannabis (including medicinal cannabis) submitted before the Spanish Congress of Deputies have all been rejected (October 2021, May 2022 and February 2023).

1.6 Enforcement & Penalties

See **1.2 Regulatory Bodies**. In the event that a particular product qualifies as a narcotic drug, it would fall within the scope of criminal offences.

2. Cross-Jurisdictional Matters

2.1 Cross-Jurisdictional Issues

The differences in patient access programmes regarding medical cannabis between European countries may give rise to cross-border problems. However, Spain has not addressed this issue.

3. Legal and Regulatory Developments

3.1 Access to Medical Cannabis

The absence of a regulatory framework and the conservative approach to cannabis and its derivatives by the Spanish political class are the main legal elements affecting access to medical cannabis by Spanish patients.

See **1.1 Primary Laws & Regulations** in connection with the final report, dated 27 June 2022, of the Subcommittee of the Congress of Deputies on the regulation of cannabis, encouraging the AEMPS to define mechanisms within the medicinal products regulatory framework and to guarantee patient access to medical cannabis. This is in connection with the draft bill for a Royal Decree on the conditions for the production and dispensing of cannabis-derived products, which limits the use of these products to certain and predefined therapeutic indications, and only under the format of “magistral formulas”.

3.2 Non-controlled Cannabinoids in Food

According to the informative note issued by the AESAN in March 2019 and confirmed on December 2022 (see **1.1 Primary Laws & Regulations**), on the use of hemp and cannabinoids in food products, hemp-derived foods – including beverages – are authorised in the European Union only regarding those products originating exclusively from hemp seeds (for example oil, hemp protein or hemp flour) as long as they are Cannabis sativa L varieties with THC content below 0.2%.

However, cannabinoids (THC, CBD, CBG and others) used as such or to be added to other food products (for example, to an oil or a beverage) are considered novel foods under the informative note of the AESAN, regardless of them having a natural or synthetic origin, since it has not been possible to demonstrate a history of significant or safe consumption in the European Union before 15 May 1997. The above is also applicable to other extracts and other parts of the Cannabis sativa L plant (such as flowers, leaves and stems).

Therefore, any company wishing to commercialise these parts of the Cannabis sativa L plant (flowers, leaves and stems) extracts and cannabinoids in the food field must submit an application to the European Commission in accordance with the provisions of the Novel Food Regulation (EU) 2015/2283; once the risk has been assessed by the European Food Safety Authority (EFSA), the pertinent authorisation will be granted.

The AESAN informative note also states that the marketing of a product with these ingredients (cannabinoids) is not authorised in the European Union (unless covered by a novel food authorisation), and therefore the principle of mutual recognition cannot be applied to market products containing cannabinoids or extracts of the Cannabis sativa L plant in Spain.

3.3 Decriminalisation

See **1.1 Primary Laws & Regulations** and **1.5 Legal Risks** on the bills for comprehensive regulation of cannabis presented by the ERC before the Congress of Deputies, which have been rejected. Reasons for the rejection always revolve around the fact that cannabis is a dangerous drug and that it poses a risk to public health.

Additionally, the final report of the Subcommittee of the Congress of Deputies on the regulation of cannabis (dated June 2022) concluded that "the availability of cannabis for therapeutic use must be prevented from leading to increased availability and use of cannabis outside the healthcare context".

In Catalunya only, a law on cannabis clubs was passed in June 2017 (promoted by popular legislative initiative, which obtained 67,500 signatures) and was practically unanimous, with 118 votes in favour and only 8 votes against (from the Popular Party). This law was subsequently annulled by the Spanish Constitutional Court in 2018.

In light of the above, it is understood that Spain is far from having legislation decriminalising recreational cannabis.

SWITZERLAND

Law and Practice

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1. Regulatory Framework

1.1 Primary Laws & Regulations

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

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:

- cannabis products containing a tetrahydrocannabinol (THC) content of 1% and above, which are considered prohibited narcotics under the Federal Act on Narcotics and Psychotropic Substances (the "Narcotics Act", NarcA); and
- products with a THC content below 1%, which have been popularised and aggregated into a somewhat untechnical jargon as "CBD products" – this refers to products containing cannabidiol, and which are not subject to the NarcA and so are more freely marketable.

Due to recent developments, also regarding the use of other cannabinoids (CBG, for example), the following statements, in so far 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 recent 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 THC of 1% and Above

The Narcotics Act, NarcA

The use of narcotics is primarily regulated by the NarcA. Today, the implementation of the NarcA is governed by four ordinances:

- on the control of narcotics (BetmKV);
- on the addiction to narcotics (BetmSV);
- on the register of narcotics, psychotropic substances, precursors and auxiliary chemicals (BetmVV-EDI); and
- 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%, unless it is used

for medical purposes. 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 of lower than 1%, on the other hand, can be legally produced and marketed.

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.

Since 1 August 2022, an exceptional authorisation from the FOPH is no longer required for cannabis with a THC content of 1% and above, if it is used for medical purposes. In other words, doctors are free to prescribe cannabis to their patients as part of their regular treatment.

The long-sought relief of the recent medical cannabis reform is still, almost two years after its introduction, considerably new and will be described in further detail in the adjacent Trends and Developments article here.

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 (the "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 Medicinal Products Licensing Ordinance (MPLO); and
- the Medical Devices Ordinance (MedDO).

These laws and regulations apply to therapeutic products according to the TPA, including 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 a 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 MPLO refers to the EU's GMP guidelines (Annex 1). Thus, in Switzerland the EU's GMP guidelines 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 improvement 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 that 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 supply if no authorised drug is available for this purpose. The prescribing physician and the pharmacist preparing the drug (or the manufacturer), who are controlled by the authorities, are protecting public health by having appropriate training.

As mentioned above, medical cannabis products as magistral formulas, produced by a pharmacy based on a medical prescription, no longer require exceptional authorisation from the FOPH under the NarcA. The same applies to an approved drug containing cannabis (eg, Sativex) that is dispensed "off-label" for an indication other than the one for which it has been approved.

Health insurance law

The reimbursement of costs for medicinal products by the compulsory health insurance (OKP) generally requires that the medicinal product be 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, there is considered to be 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 if no other effective and approved treatment

method is available due to a lack of therapeutic alternatives. Unfortunately, the medical cannabis reform did not provide relief in terms of reimbursement by the OKP, and no adjustments were made to the reimbursement requirements.

A Health Technology Assessment (HTA) report 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. 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 types 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 THC Content of Below 1%

Cannabis products with 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 12 April 2024, Swissmedic, the FOPH, the Federal Food Safety and Veterinary Office (FSVO), the Cantonal Pharmacists' Association and the Association of Swiss Cantonal Chemists jointly released an updated version of "Products containing cannabidiol (CBD) and other cannabinoids which do not fall under narcotics regulation: 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 high CBD content;
- extracts in the form of oils or pastes; and
- 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 (ChemO). 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 classify, package and label the product in accordance with the provisions of the 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, where 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, for example, where cannabis oils containing full-spectrum hemp extracts are labelled as having a specific nutritional value.

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 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, and 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 was 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 for 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 on 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). Furthermore, the position papers of the Association of Cantonal Pharmacists regarding "Cannabis medicinal products" and "Formula medicinal products, manufacture and placing on the market" should be consulted in the current versions.

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 in its previous version went on to conclude that, therefore, cannabis resin obtained from any part of the cannabis plant may not be used to introduce CBD into cosmetics. Seeds and leaves not accompanied by the flowering or fruiting tops, however, may be used to produce cosmetics.

In a remarkable update, the latest version of the Implementation Guide finally corrects this previously held conclusion, clarifying that the Single Convention is not "self-executing" and that it is up to the signatories to the Single Convention to define how it should be implemented (no harmonised interpretation).

The Implementation Guide further notes that in Switzerland "the Single Convention is implemented accordingly in national narcotics legislation". "Cannabis" is defined in Annex 1 of the BetmVV-EDI. The total THC content of at least 1.0% is decisive, regardless of whether CBD or other cannabinoids were extracted from the flowers or leaves of the hemp plant. For the production of CBD or other cannabinoids for use in cosmetic products, it does not matter which part of the hemp plant is used. The decisive factor is rather that none of the intermediate products has THC content of more than 1.0% during the entire manufacturing process.

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". Swiss authorities have now adopted the same interpretation as in the Kanavape case, and further extended it to apply to all cannabinoids, if

the THC content remains below 1%. This latest update in the Implementation Guide finally clarifies a long-contested issue regarding the use of cannabinoids in cosmetic products, and paves the way for easier market access.

It is worthwhile to note that a recent decision by the High Court of the Canton of Fribourg confirmed that the ECJ's findings in the Kanavape case need to be considered when interpreting EU Regulations, thus setting a precedent in Switzerland that CBD, regardless of how it was derived from the cannabis plant, does not constitute a prohibited narcotic and can, in general, be introduced into cosmetic products.

Lastly, the Implementation Guide mentions for the first time that "CBD and other cannabinoids, regardless of their origin, may only be used in cosmetic products if their safety to health has been scientifically proven in a safety assessment" in accordance with the LGV. CBD oils with a CBD content of up to 12% sold as cosmetic skin care oils and proper documentation (including a product information file containing toxicological data) have further been accepted by various cantonal enforcement agencies.

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 (the "Foodstuffs Act", FSA) and under the LGV, and 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 2024).

Refill containers for e-cigarettes containing CBD are subject to the provisions of 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 and 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 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 2024, the new Tobacco Products Act (TobPA) will enter into force. Under the TobPA, all tobacco-based and similar products (ie, with a similar purpose such as pouches) 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 Non-controlled Cannabinoids in Food**, which also includes 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 compared to the EU.

For the agricultural production of hemp, the provisions of plant health legislation and 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 Bodies

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 Primary Laws & 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 for the laws related to narcotics, therapeutic products, foodstuffs and utility articles (which include 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 (importation, transit and exportation) 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, or possesses, keeps, buys, acquires or otherwise obtains narcotic substances, is liable to a custodial sentence not exceeding three years or to a monetary penalty.

As mentioned in **1.1 Primary Laws & 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, regarding 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 instance, is divided into three operative units: the inspectorate, the laboratory and the administration. The *Kantonale Heilmittelbehörde* in Zurich is responsible for:

- the control of the production, wholesale trading 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 and the obligation to withdraw or recall unsafe food, if applicable.

On its website, the Swiss Association of Cantonal Chemists (ACCS) has 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 that they can impose on non-compliant market participants.

1.3 Self-Regulatory Authorities

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

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 to 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, 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; and
- 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; and
- 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.

The Swiss Society of Cannabis in 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, and 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 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 International Association for Cannabinoid Medicines (IACM).

Medcan

Medcan advocates 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 that they can use it medically in tested quality and at reasonable prices. Moreover, it demands from the FOPH the further education of physicians regarding possible indications and dosages, and minimisation of the bureaucratic effort involved for obtaining medicinal cannabis. Medcan advocates on both a political and public level for people who use cannabis for medical purposes.

1.4 Challenges for Market Participants

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

The most obvious challenge faced by market participants 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.

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, in navigating these complexities:

- the guide on "Demarcation criteria therapeutic products – foodstuffs with regard to products to be taken orally", published jointly by Swissmedic and the FSVO; and
- 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, a lot of consumers ingest CBD oils, such oils cannot be marketed as foodstuff or nutritional supplements without authorisation of their 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. Meanwhile, CBD oils have gained wide popularity as cosmetic skin care or as oral care (mouth spray) products.

Further challenges for participants in the medical cannabis industry are described in the accompanying Trends and Developments article here.

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

1.5 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 included, 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 compliance with the NarcA. Cannabis resin is illegal, independent of its THC content. Furthermore, depending on the classification of the product placed on the market, cannabis products with a total THC content of below 1% must meet the specific requirements of (among others):

- the Therapeutic Products Act;
- the Foodstuffs Act;
- the Ordinance on Foodstuffs and Utility Articles;
- the Chemicals Ordinance; and
- the Tobacco Ordinance.

It should be noted that, in addition to the NarcA, other acts such as the TPA also provide for penal provisions.

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 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 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 US states 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 Enforcement & Penalties

Please refer to **1.4 Challenges for Market Participants** and **1.5 Legal Risks**.

2. Cross-Jurisdictional Matters

2.1 Cross-Jurisdictional Issues

In Switzerland, only cannabis with a THC content of 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 0.3% and above are considered narcotic drugs and thus cannot be imported, except for medical purposes with a special permit from local authorities.

Since the revision of the NarcA in August 2022, medical cannabis independent of its THC content can be traded cross-border under an authorisation process by Swissmedic. Further details can be found in the accompanying Trends and Developments article here.

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. Legal and Regulatory Developments

3.1 Access to Medical Cannabis

The main elements affecting medical cannabis in Switzerland are described in the accompanying Trends and Developments article here, along

with an overview of impending changes to the current regulatory framework.

3.2 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, or vice versa.

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 (described below), cannabis products may also be used in foodstuffs. The main principle 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, importation 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). Placing 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 also be placed on the Swiss market. Hence, the authorisation from the European Commission entails the advantage 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 that 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 representing 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 and to the European Food Safety Authority (EFSA) for the EU market (which, as mentioned previously, would include Switzerland), the costs of which are 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 cannabinoid-containing ingredients have already been tested to ensure that 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 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.

EFSA has already conducted preliminary assessments on applications forwarded by the EU Commission, and its experts panel identified numerous gaps in the data on the health effects associated with the consumption of CBD. Until these data gaps have been closed by the applicants, the assessment of CBD as a novel food is currently suspended in the EU. There are safety concerns in Switzerland too, and the safety of CBD or other cannabinoids as a foodstuff cannot be conclusively assessed at present due to data gaps.

3.3 Decriminalisation

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

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 to heterogenous, sometimes arbitrary, enforcement. However, with the rise in 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 a whole range of other cannabinoids during the last few years (and growing anecdotal evidence from liberalised recreational markets such as Canada, Uruguay and certain US states), recent legislative developments present 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 questioned participants the consumption of medical cannabis has led to an improvement of their symptoms. Half the participants reported an "extreme improvement". A large number 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 to 4,000 patients are legally prescribed medical cannabis in Switzerland today. The FOPH estimates that over 110,000 patients consume "medical" cannabis illegally – that is, sourced from the illicit 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, three times the FOPH figure.

Since 1 August 2022, cannabis with a tetrahydrocannabinol (THC) content of 1% and above is no longer considered a prohibited narcotic if it is used for medical purposes. The adopted amendment to the law facilitates access to cannabis medicines for thousands of patients as part of their treatment. This affects cases of cancer, multiple sclerosis and many other indications 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 for 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 a 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, and 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 that is exempt from approval by Swissmedic. 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.

The amendment to the Narcotics Act

The main features of the legislative amendment to the Narcotics Act (NarcA) were as follows.

- The ban on marketability of medical cannabis was lifted. Medical cannabis was reclassified as a controlled narcotic with restricted marketability. Cultivation, processing, production and trade are now 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 is no longer required to prescribe medical cannabis. In other words, every doctor in Switzerland is able to prescribe medical cannabis.
- For the first few years after the coming into force of the amendment in August 2022, doctors must regularly report a whole range of data to the FOPH regarding the relevant therapies. The data collection should serve as a basis for the scientific evaluation of the revision, and as guidance for the responsible cantonal enforcement authorities and prescribing physicians. Note that failure to report such data is not penalised, which weakens its purpose and effect.
- Commercial exports of medical cannabis have been made possible.

Apart from the NarcA, executive ordinances have also been amended, and a two-tiered licensing system with Swissmedic has been introduced for cultivation of medical cannabis.

Reimbursement by compulsory health insurance

Unfortunately, treatment with medical cannabis products is not covered by the compulsory health insurance (OKP) due to insufficient scientific evidence regarding the efficacy and cost-effectiveness of these medicines, 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 patients' association, the costs of treatment with medical cannabis can range from CHF450 to over CHF10,000 per month.

A Health Technology Assessment (HTA) report 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 types of medical cannabis did not show consistent results pointing in the same direction) and inconclusive (ie, none of the stud-

ies 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 the required permits by Swissmedic);
- 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 and documentation standards (GACP, GMP, etc);
- acquisition of pharmacies and development of specialised know-how in the field of medical cannabis; and
- 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, facilitated access to medical cannabis for patients – will hinge on whether these patients are able to obtain reliable, quality-controlled, safe, affordable and ideally reimbursed medical cannabis products.

Cannabis Legalisation: Recreational Pilot Trials

Cannabis is the most frequently consumed illegal substance in Switzerland. According to the FOPH, more than a third of the population aged 15 and over in Switzerland has tried cannabis at some point in their lives. In 2017, 7.7% of Swiss people aged 15 to 64 had used cannabis.

Repression has never been effective in curbing cannabis consumption or in eliminating the illicit 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 out a detailed framework for the dispensing of cannabis products for non-medical use. On 15 May 2021, the amendment to the NarcA came into effect. It now allows pilot testing of the controlled dispensing of cannabis for recreational purposes.

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 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) and 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 in principle be 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 illicit market. Distribution can be organised through pharmacies, cannabis social clubs and non-profit stores, as well as via other distribution channels. This will allow for a comparison of the different distribution systems and show which regulatory models are accepted by consumers.
- Both public and private organisations can apply to the FOPH to conduct cannabis trials.
- Outside 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 implementation of the first pilot trials has been positively received by the cannabis industry and is recognised as an important further step towards controlled liberalisation, the quality requirements for the cannabis products to be used in the trials still pose some challenges.

Various pilot trials have already been authorised and successfully launched. They are listed on a dedicated website of the FOPH. The purposes of these trials are diverse.

- In Lausanne, the Cann-L project intends to assess the feasibility and the potential impact of a model for regulating the consumption of cannabis through its sale on a non-profit basis.

- In the Canton of Basel-Stadt, the WeedCare pilot studies the regulated sale of cannabis in pharmacies and its public health impact.
- La Cannabinothèque trial examines whether regulated access to cannabis may improve knowledge of the substance and its associated issues, and thus reduce the health and social risks that drug consumption usually entails.
- ZüriCan in Zurich investigates the extent to which regulated sale, supplemented by advice, can enhance both knowledge and behaviour in respect of the lower-risk forms of cannabis, and whether this can be implemented.
- SCRIPT, a pilot trial in Berne, Bienne and Lucerne, tries to evaluate what impact a regulated not-for-profit sale of cannabis in pharmacies combined with related advisory services may have on cannabis consumption.
- Grashaus Projects BL, in Basel-Country, examines whether the structured, controlled sale of cannabis can bring about a change in consumption and a higher quality of life.
- The Cannabis Research Zürich trial in the canton of Zurich aims to investigate the social and economic consequences of legalising recreational cannabis use in Switzerland.

First results from the WeedCare trial in Basel-City were presented by the local health authorities on 25 March 2024. While satisfaction with the pharmacy as a source of supply (94%) was reported as very high, satisfaction with the product range (57%) and quality (69%) was significantly lower. 67% of participants requested other products in addition to the available flower and hash products. 70% of participants requested so-called edibles (gummy bears, chocolates, etc), 59% requested THC oil and 43% requested e-liquids. In addition, some of the participants also requested stronger products with a THC content above the maximum threshold of 20% that is allowed in the pilot trials. This explains why almost half the participants also consumed cannabis from illegal sources in addition to the study cannabis.

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 illicit-market pricing ceiling, certainly limits the profitability of running a pilot trial and adds considerable cost to the value chain. At the point of sale, which can be a social club, a pharmacy or a dispensary, the sales price must cover costs and leave no profit margin. However, upstream margin opportunities present themselves to cultivators, manufacturers of specialised products such as edibles or vaporisers, and distributors, with some being able to secure their sales prices in long-term offtake agreements. The FOPH regularly receives additional applications for new pilot trials. Trials that incorporate the above-mentioned initial feedback from the WeedCare project, provide a wide product range and reliably supply high quality products will be successful and will secure reasonable returns for producers, manufacturers of specialised products, and distributors.

The pilot trials are a first and important step towards a trend in further liberalisation of the recreational cannabis market. The trials are usually announced with considerable media fanfare and are publicised in most mainstream media. First experiences by the public and the authorities have been rather well received and have not led to wide-ranging criticism. 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 were:

- the control of production and trade by governmental bodies;
- the separation of the medical and non-medical markets;
- the drying up of the illicit market by lifting the prohibition;
- the regulation of taxation and advertising; and
- 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 when contrasted 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 had failed to fulfil its purpose of protecting the population, considering the more than 300,000 regular cannabis consumers in Switzerland. A flourishing illicit market, the lack of quality controls and effective protection of youth and reliable information, as well as a growing risk of "cut" cannabis products containing artificial and toxic substances, warranted 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 the first important political hurdle the Siegenthaler parliamentary initiative had passed. On 19 October 2021, the equivalent commission in the Council of States followed suit, with an overwhelming majority of nine to two, and gave the Health Commission of the National Council the green light to prepare draft legislation as proposed by the initiative. The initial deadline to present draft legislation for a controlled legalisation of cannabis was extended by two years to the National Council's autumn session of 2025.

In the meantime, the Commission is considering in its deliberations the conclusions of the report in the Minder postulate, as set out below, closely eyeing the results from the pilot trials and monitoring the developments in Germany, where cannabis was partially legalised on 1 April 2024.

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 areas 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.

On 1 November 2023, the Federal Council presented its findings in a comprehensive report, acknowledging the requirement to regulate cannabis for recreational purposes in a new specialised law. New legislation should be evidenced-based and in the best interest of public health. Furthermore, it is recognised that a new law would be a great opportunity to reduce the negative effects of cannabis prohibition on consumers and society, as well as to harness the social, health and economic benefits of a legalised cannabis market.

The Federal Council summarised its findings with a list of recommendations for a legalisation framework, a few of which are as follows.

- Start with a strictly limited, low-risk regulation that can be expanded and relaxed at a later date if necessary (eg, additional products or a more liberal market regulation).
- Refrain from a profit-oriented retail trade and excessive commercialisation of cannabis.
- Access to cannabis should be restricted to adults, and strict measures should be taken to protect minors.
- As proven measures of structural prevention, adopt high incentive levies or incentive taxes on cannabis products (depending on the THC content and the health risk of the products), a comprehensive ban on advertising and promotion, clear restrictions on availability (opening hours, sales outlet density) and warnings on product packaging. The report reasonably specifies that the final sales price, including taxes, must not be so high that the illicit market remains attractive.
- To protect third parties, introduce passive smoking protection rules (similar to those for tobacco) and strict measures for traffic safety.
- To protect consumers, set product safety standards, contaminant limits and declaration requirements for ingredients.
- Provide for the monitoring of indicators on the effects of the new law and evaluate them regularly in the first few years.

The latest political developments surrounding cannabis legislation are proof that the urgent need to comprehensively regulate this growing market has manifested itself in the general pub-

lic's 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.

With an already progressive regulatory framework regarding THC thresholds compared to the rest of Europe, the implementation of pilot trials 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.

UK

Law and Practice

Contributed by:
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Mackrell.Solicitors is an award-winning, full-service law firm, with a global reach. Headquartered in Central London, and with offices in Birmingham, the firm has provided high-quality legal advice and services since 1845. Mackrell.Solicitors is also one of the founders of Mackrell International, the 35-year-old global network made up of 90 firms across 60 countries, enabling it to offer immediate international legal advice and assistance in any jurisdiction worldwide. Mackrell.Solicitors set up the first dedicated cannabis legal team in the UK five years ago, to provide regulatory advice and services for the medicinal cannabis and CBD industry. The team has market-leading sector knowledge and is at the cutting edge of the current regulatory regime in the UK and Europe. It deals with the whole life cycle of medical cannabis businesses from start-up to exit, advising on cultivation licence applications, wellness and medicinal product manufacture and distribution, importation and exportation best practice, product compliance, labelling and promotion, and regulatory issues and agreements for clinics, pharmacies and other parts of the supply chain.

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1. Regulatory Framework

1.1 Primary Laws & Regulations

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

There is no consolidated 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 the following categories.

- Controlled drugs legislation.
- Product class-specific legislation, applicable to the cannabinoid wellness sector (ie, food, vape and cosmetics laws).
- The Medicines and Healthcare products Regulatory Agency's (MHRA) regime for medicinal products in relation to:
  - (a) unlicensed medicines (namely "cannabis-based products for medicinal use" or CBPMs), which primarily relate to issues with prescribing, importation, manufacture, distribution and dispensing of CBPMs, and other regulatory bodies' rules that interplay such as of the Care Quality Commission (CQC) and General Pharmaceutical Council (GPhC); and
  - (b) general licensed medicine laws relating to elements such as clinical trials, regulatory approvals and pharmacovigilance.
- Ancillary legislation – for example, advertising rules (from the ASA and MHRA) relating to promotion of medicines, money laundering legislation that applies to UK professional services firms and investors in relation to (non-medical) cannabis markets, or jurisdictions with substantially different licensing regimes.

Controlled Drugs Legislation

The two primary pieces of legislation from which the controlled drugs 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 criminal 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, almost exclusively, "unlicensed" as they have not been tested in clinical trials and therefore do not have a marketing authorisation or "product licence". They are referred to in the legislation as "cannabis-based products for medicinal use in humans" (CBPMs), and this has meant that from 1 November 2018 there was a legal route for medical cannabis to be prescribed by doctors on the General Medical Council (GMC) Specialist Register for a variety of indications.

The result of the 2018 change in law was, however, somewhat of an anti-climax in practice. 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 unlicensed CBPMs have been issued on the NHS to date.

Private prescription of CBPMs has shown far greater overall numbers and growth, with 4,469 prescriptions reported to have been written in 2020, increasing to 42,393 in 2021 and to 46,846 in the first six months of 2022, with some reports suggesting that the figure for the first nine months of 2022 was 182,010.

CBD Wellness Products: Class-Specific Legislation

Consumables

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

Marketing of 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; this therefore applies to wellness products containing CBD, or other cannabinoids.

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 Foods Regulation ((EU) 2015/2283) (NFR) defines a "novel food" as a 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 require authorisation before it can be sold. Only hemp seed oil extracted using traditional cold compression methods have the potential to be considered not novel by the FSA

and, consequently, authorisation may not be required for all hemp seed products.

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

In England and Wales, CBD products had 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. Those businesses that had a novel foods application submitted by 31 March 2021 and that were duly "validated" were allowed to continue to sell their products while awaiting full authorisation. No other products are allowed to be sold 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 just "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 that were on sale at the time of the FSA's announcement (13 February 2020) and that 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 43 CBD food products on sale in England and Wales that were allowed to stay on the market until a decision on their authorisation had been made (as they had met the requisite validation threshold). The list produced by the FSA is split into two sections, which comprise 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 who have set out robust plans to complete the risk assessment but who are yet to supply all the information needed to continue in the process.

The list saw several updates from early 2022, with around 6,000 products showing by the end of April. At this stage, the FSA also began striking products from the list, and to date 409 have been removed following further review of their applications, as they did not pass the pre-validation stage. On 30 June 2022, it was confirmed that no more products would be added to the list on the basis of the forbearance position, and new products would need to be fully authorised before they can be added to the list.

As of early-2024, there are 12,115 products on the list, and all are either showing a validated status or are on hold awaiting evidence. The FSA recently noted that the first of these applications is not expected to be fully authorised until Summer 2024 at the earliest.

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 regulations do not prohibit CBD ingredients in cosmetic products other than CBD that is extracted from the buds or "flowering tops".

Following the European Court of Justice (ECJ) decision in *Kanavape* (which ruled that precluding a product from a market based on the part of the cannabis plant used for extraction was unlawful) the cosmetic ingredients database (CosIng) was updated, and as of 2 February 2021 CBD had been added. CosIng is the EU's official database for cosmetic ingredients – it is not applicable to the UK following Brexit, but the *Kanavape* ruling is binding on UK courts and, as such, companies extracting CBD from the buds of cannabis plants should no longer face enforcement.

Again, as with food products, since the Brexit transition came to an end, the Office for Product Safety and Standards (OPSS) handles 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 the 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), 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 – remain classified as Class B controlled substances 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 Bodies**). 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 growing 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.

The MHRA Regime for Medicinal Products

Licensed cannabis medicines

Prior to the change in law in 2018, only three cannabis medicines could be prescribed in the UK: Sativex, Epidyolex and Nabilone. The reason that these products could be prescribed despite the criminalisation and "Schedule 1" restriction of cannabis in the UK was because they are *licensed* medicines. This is to say that these medicines had been through clinical trials, received marketing authorisations from the MHRA and been individually rescheduled out of Schedule 1 of the MDR 2001 into less restrictive schedules as part of their MHRA licences.

In addition to controlled drugs legislation, the laws applicable to these types of cannabis medicines are those that apply to general pharmaceuticals – ie, the MHRA's regime for licensed medicinal products, encompassing everything from investigational medicinal product rules and clinical trials legislation to marketing authorisa-

tion requirements and the pharmacovigilance regime.

Treatment with these licenced cannabis medicines can be funded by the NHS, but only for a very small number of indications. For individuals suffering from indications other than those for which the three licensed cannabis medicines were approved, there was no option in the UK in terms of cannabis medicine pre-2018.

Unlicensed cannabis medicines (CBPMs)

The change in law in 2018, however, meant that CBPMs – cannabis medicines that did not have a marketing authorisation (or "licence") – could now be prescribed by specialist doctors. With an estimated 1.4 million citizens in the UK obtaining cannabis for medical use from the legacy market, private companies flocked to the industry to meet the anticipated demand for CBPMs. 20 to 30 private clinics regulated by the Care Quality Commission have since set up operations in the UK and started prescribing, which, as noted above, has allowed private prescription of CBPMs to increase tenfold from 2020 to 2021, and then to double from 2021 to 2022. The law relating to CBPMs stems from:

- regulatory rules and guidance that apply to unlicensed medicines (for example, the Human Medicines Regulations 2012, and MHRA guidance that stipulates particulars around the manufacture, distribution, labelling, storage, marketing, importation and exportation of CBPMs);
- regulated participants in the medicine or patient care chain (for example, CQC rules for clinics and GPhC rules for pharmacies); and
- licensing rules and quality guidelines applicable to the supply chain (for example, cultivation (GACP), distribution (GDP) and manufacture (GMP)).

Curiously, the MHRA has not yet allowed exports of CBPMs to countries outside the UK – a restriction that is puzzling to many considering the enormous potential investment, tax and domestic cost-efficiency benefits (not to mention the fact that the UK has been hailed as the world's largest exporter of (non-CBPM) cannabis).

1.2 Regulatory Bodies

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 is the relevant regulatory authority for each sector, and its scope.

The Care Quality Commission (CQC)

The CQC regulates health and social care in England.

Private clinics prescribing CBPMs and licensed cannabis medicines must undergo monitoring and inspection by the CQC.

While there are no cannabis-specific elements of CQC regulation that apply to clinics prescribing cannabis medicines, it is necessary to be aware of the requirements of the inspection regime.

The Food Standards Agency (FSA)

The FSA regulates and oversees the food industry in the UK. It is 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 holds the opinion that CBD is a novel food and therefore requires that

producers of CBD and the resulting ingestible products be subject to an application procedure to ensure safety and standardisation.

The Medicines and Healthcare products Regulatory Agency (MHRA)

The MHRA is responsible for overseeing medicines and certain healthcare products in the UK market.

The MHRA is 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.

The National Institute for Health and Care Excellence (NICE)

NICE publishes guidance on the use of new and existing medicines, treatments and procedures, as well as on clinical practice.

NICE's guidance dictates whether, and how, particular medicines are prescribed through the NHS, particularly with regard to cost justification and the indications that a drug should be used to treat.

NICE's guidelines on the use of cannabis medicines currently restrict the indications that it can be used for, and this is one of the key reasons why their prescription is not more widespread in the NHS.

The Home Office

The Home Office operates as the UK National Cannabis Agency (pursuant to the UN Single Convention on Narcotic Drugs 1961).

The Home Office acts in a regulatory capacity with respect to cultivation licensing and other cannabis-related activities, and oversees the issuance and maintenance of both hemp and high-THC controlled drugs licences.

The Home Office also acts through Border Force with respect to inspecting imports and exports, and will seize cannabis and CBD-related products that it suspects do not comply with national legal requirements.

The Veterinary Medicines Directorate (VMD)

The VMD is primarily responsible for protecting animal (and pet) health.

The VMD views CBD as a medicine when given to animals, thus requiring a rigid scientific assessment and application procedure (plus approval) for a CBD product for pets to be placed on the UK market.

The VMD has restricted access to the UK market for CBD treats or products for pets without proper authorisation, and can enforce its decisions.

Advisory Authorities

The Advisory Council on the Misuse of Drugs (ACMD)

The ACMD is an advisory, rather than regulatory, body and makes recommendations to the government on the control of drugs that may be dangerous or otherwise harmful, including classification and scheduling under the MDA 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 the government. The four recommendations were as follows.

- The total dose of trans-delta-9-tetrahydrocannabinol-C5 (delta-9-THC) and all other controlled phytocannabinoids in consumer CBD products should be controlled. The dose of each controlled phytocannabinoid should not exceed 50 micrograms per unit of consumption.
- Regulatory authorities should ensure compliance with the above – this recommendation infers regulatory co-operation (for example, between the Home Office, FSA, OPSS, DHSC and DEFRA, the report notes).
- 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.

The government responded to the ACMD's recommendations on 21 January 2022, agreeing with the purpose of each of the four recommendations, though noting that it believed some of the proposed outcomes could be delivered in a different way.

1.3 Self-Regulatory Authorities

A number of trade bodies at the UK and EU level 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 and efficacy, and to ensure that they are of a high standard and not misrepresenting the cannabinoid content.

1.4 Challenges for Market Participants

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 and the lack of education for clinicians or support by medical bodies such as NICE, the MHRA and the NHS.

Part of the confusion may lie in the unique and complex properties of the cannabis plant itself: a historically well-known but poorly understood plant comprising a blend of hundreds of different extractable components – some psychoactive and others not, some expressly controlled and others controlled to varying degrees, some with applications for wellness or for medicine depending on the precise dose and form, and many unstudied altogether.

The non-criminally controlled 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 non-licensed CBD products as having medicinal properties. The challenges here are inherent to the plant and to the law, and it is no surprise that educational difficulties are at the top of that list.

Pace of Change

Legal change in relation to the cannabis plant is happening at two different levels:

- at the macro-level (major national change, generally implemented through amendments to primary legislation); and
- 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 is an onerous task involving many different working parts, but also due to politics. A further complication arises as UK and EU legislation in this area is 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 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. These changes are more numerous and less red tape is involved in the amendment process, so changes can be realised more quickly. Changes might include:

- changes to the percentage of THC allowed in a cultivar;
- changes to novel food rules; or
- updates to the CosIng database.

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 manufacturers cannot import or possess the bulk CBD distillate required to create their products (without an expensive and difficult-to-obtain licence), even though no controlled drugs licence is needed for the possession or sale of the CBD products themselves. Even this permissible threshold was, for a long time, untested regarding its applicability to the commercial CBD market, and it was only in early-2024 that the judicial review of a decision to ban the exportation of CBD products from Jersey to the UK confirmed that a permitted de minimis amount of THC is allowed in CBD products provided they meet certain criteria.

Another example is the outdated controlled drugs licensing system itself. Both the licence required to cultivate cannabis and the licence 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 money in meeting Home Office licence requirements. The administrative difficulties of achieving approval have also come under criticism: the protracted application process can take two years, even when unsuccessful.

Without a licence, extraction of CBD is also only permitted from the CBD-sparse stalks and seeds of the plant, making commercial extraction almost impossible and creating yet another CBD-sourcing issue; and the MHRA does not allow exportation of UK-produced CBPMs, substantially restricting investment into the UK market.

Resolving these systemic licensing issues would increase the efficiency and profitability of the

UK's commercial sector, and alleviate barriers to medical research.

Regulatory Uncertainty

The current regulatory regime is underdeveloped, fragmented and product-dependent.

No overarching regulatory regime has been developed for the plant and its component parts. For this reason, a legal grey area exists over many aspects of cannabis use. The patchwork of regulations across various sectors is open to misinterpretation and confusion – for example, the common misunderstanding that it is legal to sell and consume hemp flower/buds in the UK. Unexpected interpretations of existing legislation and regulations have also led to serious legal consequences for producers and commercial enterprises, particularly in the CBD sector.

The one area where there is relative simplicity and clarity is licensed cannabis medicines, where the regulatory regime is the same as for other medicines in the UK.

1.5 Legal Risks

Changing Regulations

One major risk area for companies is the unstable regulatory regimes governing cannabis and cannabinoids in the UK. This has never been more relevant than in the 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.

The FSA has already shown a willingness to take a different view to the EU (for example, on the topic of CBD being classified as a narcotic or a food – to which the ECJ eventually decided in favour of 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.

Given the rapid public adoption of legal cannabis-derived products, particularly CBPMs and CBD, there may come a time when the government introduces cannabis-specific legislation. Participants in the cannabis sector should closely follow industry developments.

Unclear, Unpublished, Untested and Generic 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 trading 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 was rife in the industry for years, with many participants relying on inapplicable thresholds and a general lack of consensus as to many of the rules. The situation has broadly improved following regulatory guidance, a handful of rulings and growing industry awareness of the law, but there is still a long way to go.

Another example of underdeveloped regulation is the current rules on which the CBPM market relies – these are the generic rules that apply to all unlicensed medicines. Participants in the medical cannabis industry note that these rules are not sufficiently bespoke, particularly around importation and distribution, to cater for the current needs of patients and the industry participants that support them. The industry reports a range of issues as a result, including products constantly going out of stock, products expiring

before reaching patients and other continuity-of-care issues.

Another challenge is the haze that sits between the industry and regulators owing to the body of internal expectations, rules and processes that remain largely unpublished. Regulators are regularly asked to confirm their expectations with regard to licensing requirements, operational procedure, quality requirements and which particular guidelines apply to certain parts of the seed-to-shelf process. Some regulators have been praised for their understanding and co-operative approach with current and prospective licence holders in light of these difficulties.

Proximity to Criminal Liability

Lawful activity in the cannabis industry sits close to the national criminal law regime. The only element separating lawful business and illegal activity is either an appropriate licence (covering manufacture, possession, supply, importation or exportation, for example) or adequate legal advice (covering which parts of the plant are lawful to use or extract from without a licence, for example).

The Proceeds of Crime Act

Part 7 of the Proceeds of Crime Act 2002 (PoCA) criminalises dealing with or entering into arrangements in respect of the proceeds of "criminal conduct". The definition of criminal conduct in the PoCA captures conduct which is lawful overseas but which 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 that have generated their revenues from sources that are not yet lawful in the UK (recreational cannabis, for example). Best practice should always be followed. This issue is not a straightforward one, with no clear authority on certain matters that arise.

1.6 Enforcement & Penalties

UK Criminal Law

In terms of the MDA 1971, possession, supply or importation of a Class B controlled substance are "either-way offences" (ie, criminal offences that can be heard in the Magistrates' Court 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 a Class B substance 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 that 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 the Criminal Law Act 1977.

Packaging and Labelling Law

In general, putting 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.

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

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

The UK's 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 applies to food law and other regulations.

2. Cross-Jurisdictional Matters

2.1 Cross-Jurisdictional Issues

There is no harmonised international regulatory landscape that clearly sets out the rules for the activities of cannabis and cannabinoids. This has left 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 maintain consistency in the industry, and this was demonstrated in the *Kanavape* case of November 2020 (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 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 2020 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 Single Convention on Narcotic Drugs 1961, 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: a consistent approach to treatment of cannabinoids and their production will go a long way towards easing cross-border trade. At present, however, it is worth noting that CBD novel food applications in the EU were placed on hold as the European Commission consults the European Food Safety Authority (EFSA) to give its opinion on the safety of CBD consumption for humans. In June 2022, the EFSA issued a statement identifying a number of data gaps with the health effects of CBD intake, requiring evaluation before it can make a determination. See *Cannabidiol novel*

food evaluations on hold pending new data – EFSA (europa.eu).

The German government's decision to create an adult-use market in the country will also have further ramifications for the development of cannabis regulation on the continent, and by extension in the UK, although it is hard to predict whether there will be the political will in the UK to align with any developments in the regulatory regime in the EU and mainland Europe. Watch this space carefully.

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 is not expected to affect the CBD industry, as "extracts […] of cannabis" were left in Schedule 1, allowing the legal controversy around CBD extracts to continue.

Furthermore, the CND rejected a proposal for a note to accompany the Schedules clarifying that preparations that contain predominantly CBD and less than 0.2% THC should not fall under international control. While the CND recognises cannabis as having a beneficial medical application, as far as recreational and wellness use is concerned, reluctance to relinquish full control remains.

3. Legal and Regulatory Developments

3.1 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. There is a prospect of the prescription bottleneck being eased somewhat, with the UK Home Office acknowledging that e-prescribing should be made possible for CBPMs, but no changes to the rules have yet been made.

A second element affecting access to medical cannabis is guidance issued by NICE. This guidance, which ultimately affects state-funded access to medical cannabis, recommends the medicine for only four indications:

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

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 Non-controlled Cannabinoids in Food

As described in **1.1 Primary Law & Regulations**, cannabinoids are caught by the Novel Foods Regulation, 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. However, in the UK companies may continue to market their products in England and Wales if they were on sale on or before 13 February 2021 and if a novel foods application was submitted by 31 March 2021 and was subsequently validated.

3.3 Decriminalisation

There is no doubt that "decriminalisation" and "recreational regulation" are words constantly on the lips of everyone in every level of this sector. 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 by the government to decriminalise, regulate or legalise cannabis for recreational purposes. 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 to experience how a legal and regulated cannabis market operates. 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. Khan subsequently launched the London Drugs Commission to examine the effects of drug policies, announcing it in May 2022. The hostile reception from the Labour Party to the idea of a relaxation of cannabis laws suggests that political appetite for following Germany in exploring an adult-use market is limited, and at the end of 2023 Khan announced that the Commission had been put on the back-burner.

As far as 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 card 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 confirming 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.

Trends and Developments

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Gough Square Chambers has been a market leader in the life sciences sector for over 30 years, and was a founding member of the Food Law Group in 1990. Its members regularly act in contentious matters involving food (including novel foods and dietary supplements), cosmetics, cosmeceuticals (medical cosmetics), tobacco, vapes, novel psychoactive substances, medical devices, and borderline medicinal products. Gough Square is one of the few sets to maintain specialism in enforcement, advertising, importation, and licensing in this field. Members of Chambers write a number of the leading practitioner texts, including Butterworths Law of Food and Drugs, the authoritative loose-leaf in the field. Members also edit "Consumer and Trading Standards: Law and Practice" (now in its twelfth edition), including chapters on food law, novel foods, food supplements, medicines, medical devices, cosmetics, tobacco, and novel psychoactive substances.

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Despite increased market awareness of medical cannabis and CBD products, the UK remains restrictive in its approach to regulation. UK legislators and regulators have been slower than their international counterparts to accept the legitimacy of medical cannabis and CBD products.

That said, progress has been made in recent years in relation to the licensing of medical cannabis. That trend is set to continue, particularly as overseas investors look to the underdeveloped medical cannabis market in the UK for new opportunities.

The state of CBD product regulation has remained murky in recent years. Having initially determined that the UK would adopt the EU's novel foods approach to CBD, the Food Standards Agency introduced a regulatory amnesty to protect existing retailers of CBD products from criminal enforcement. However, the amnesty has been the subject of much controversy and legal argument, with its precise scope remaining somewhat unclear. The Food Standards Agency has also struggled with the mammoth task of processing applications for CBD products under the novel foods regime (the first such exercise undertaken by the Agency since Brexit).

The lack of clarity surrounding the CBD amnesty has been made worse by similar ambiguities in the maximum permitted concentrations of THC in CBD products. The definition of "exempt product" under the Misuse of Drugs Regulations 2001 has received much attention and has led to extended correspondence between the Home Office and the Advisory Council on the Misuse of Drugs. In turn, this has delayed the Food Standards Agency in progressing CBD novel foods applications to full authorisation, as the Agency waits for legislative amendments to be made to the 2001 Regulations.

This is a sector that remains in a state of regulatory uncertainty. However, there are positive signs that the government is aware of this issue and is taking meaningful steps to develop a more robust system of regulation with clear rules and guidance for business. Whilst this process will take time, the mere fact that the government has acknowledged the need for better regulation is significant; this acknowledgment serves as a signal to business and regulators that the CBD market is legitimate, and worthy of bespoke regulation.

Cannabis in the UK

By way of brief overview, cannabis remains a Class B controlled drug under Part II, Schedule 2, of the Misuse of Drugs Act 1971. As a result, it is generally a criminal offence to possess, supply, produce, import, or export cannabis without a licence from the Home Office. Similarly, it is an offence to cultivate cannabis plants without a licence from the Home Office.

The penalties for breach of these restrictions remain severe. The maximum penalty for supply and production of unlicensed cannabis is up to 14 years' imprisonment and an unlimited fine (with the risk of any fine being calculated as a percentage of the supplying business's worldwide turnover). In addition to any fine imposed, a business engaged in these activities faces the prospect of confiscation proceedings under the Proceeds of Crime Act 2002, which would result in forfeiture of any profit made by the business through its unlawful trade.

The commentary below must be seen in the context of this stark starting point. From a commercial and regulatory perspective, it is essential that businesses ensure that they possess the relevant licence, fall within an applicable exemption, or benefit from an amnesty from

enforcement. Without such certainty, it is difficult to secure long-term investment for CBD businesses.

It is unsurprising that – given the current lack of legal clarity (particularly in relation to CBD products) – business and investment in the sector in the UK has lagged behind international markets. However, there are a number of reasons to be optimistic. Legislators and regulators have made great strides in recent months towards providing better regulation and greater certainty for businesses. These efforts are to be welcomed, and bode well for the future.

Cannabis for Medicinal Use

In November 2018, amendments were made to reg. 2 of the Misuse of Drugs Regulations 2001 (MDR 2001) to introduce a new category of product known as a "cannabis-based product for medicinal use in humans" or CBPM. Under these new provisions, a specialist doctor may prescribe a CBPM without the need for any licence from the Home Office (although businesses supplying CBPMs still require such a licence).

Whilst these changes were initially welcomed by industry, time has proven them to be less revolutionary than anticipated. This is due to a number of factors, but may be due largely to the lack of available medical evidence to support the use of many CBPMs in a clinical context. In addition, the National Health Service has not supported doctors in prescribing CBPMs to patients in the UK.

That said, from a regulatory perspective (and in contrast to the position in relation to CBD products), the path is clear for this sector to grow in the future.

Cannabidiol (CBD) Products

The current state of CBD regulation in the UK can be broken into two sections: (i) novel foods regulation, and (ii) THC content regulation.

Novel foods regulation

On 1 January 2018, Regulation (EU) 2015/2283 ("the Novel Food Regulation") came into effect. The Novel Food Regulation defined "novel foods" and set out a process requiring authorisation before a novel food could be marketed within the EU. This approval process was managed by the European Food Safety Authority (EFSA). Where products were granted authorisation, they were placed on the "Union List". The European Commission also established the Novel Food Catalogue ("the Catalogue"). Whilst the Catalogue does not have any true legal basis – it is, in essence, a policy statement – it remains highly influential in the determination of whether a food product is a novel food. As such, the Catalogue serves as guidance for Member States in determining whether a particular product requires novel food authorisation in the first place.

Up until mid-January 2019, the Catalogue provided that most CBD products were not considered novel foods. In broad terms, novel foods authorisation was only required to market CBD if the levels of CBD were significantly boosted beyond their natural levels. However, in 2019, and despite concentrated lobbying by the CBD industry, the European Commission decided to change its stance and amend the Catalogue so that all CBD would be considered novel foods.

From a UK perspective, this change in policy stance was rendered all the more complex by the UK's imminent withdrawal from the EU. For some time, it remained unclear whether the Food Standards Agency would adopt the same

approach taken by the European Commission, or whether this was an area that would see regulatory divergence from the EU. Some in the CBD industry saw this as an opportunity to develop a lighter-touch approach to CBD regulation in contrast to the EU stance.

However, in February 2020, the Food Standards Agency announced that it would adopt the European Commission's stance on CBD products, and that it would be implementing a similar novel foods process as had previously been undertaken by EFSA.

Since no manufacturer or supplier of CBD products held novel food authorisation at the time of this announcement (and since the announcement required no underpinning legislation, as it was simply a reinterpretation of the existing novel foods regime), the consequence was to effectively criminalise the entire CBD industry overnight. Recognising that this would be capricious, the Food Standards Agency announced a regulatory amnesty from prosecution for existing CBD retailers. This gave "grandfather rights" to businesses which already had CBD products on the market whilst preventing new CBD products from being introduced.

The response from industry was unsurprisingly negative. Legal challenge was made by way of judicial review, but this ultimately failed due to the time taken before issuing legal proceedings.

To make matters worse, the Food Standards Agency suffered from significant delays in processing applications for authorisation. A register was established to record the details of products which had "validated" applications (ie, valid applications in process), but much time passed before any applications were added to the register. The process of adding applications to the register has remained extremely slow, with businesses facing the risk of criminal enforcement if their products do not appear on the register (regardless of whether a valid application has been submitted).

Despite announcing this process in February 2020, as of May 2024 no CBD product has received full authorisation. The Food Standards Agency has indicated that it is waiting to progress any applications to full authorisation until legislative amendments are made to the Misuse of Drugs Regulations 2001 to stipulate the permitted maximum concentration of THC in CBD products (discussed below). However, that process has also suffered from significant unexplained delays.

Nonetheless, the industry has reason to be hopeful. As discussed further below, in October 2023 the government announced its intention to move forward with the necessary legislative amendments. There is good reason to believe that, once these legislative amendments are made, full authorisations for CBD products will follow quickly. This would be a very welcome development for the UK CBD sector.

THC content regulation

In its purest form, CBD does not contain THC. In reality, however, many production methods will result in small trace amounts of THC being contained in CBD products. From a business certainty perspective, it is essential that manufacturers and suppliers have clear rules about the maximum permitted concentration of trace THC in CBD products. Unfortunately, however, this is not the case. It is a topic that has garnered significant government interest and discussion but as yet remains unresolved.

The most often cited legislation in this context is reg. 2(1) of the MDR 2001, which provides the definition for an "exempt product". Whether this exemption applies to CBD products has been the topic of much debate between the government and industry in recent years. In particular, part of the definition requires that "no one component part of the product or preparation [may contain] more than one milligram of the controlled drug".

The natural question which this definition raises is: what is a "component part"? Does it depend on the way in which the product is packaged? If so, would a blister pack of 10 tablets be counted as a single component part or 10 component parts? By defining a total weight of controlled drug rather than a maximum concentration or ratio, the law remains highly unclear on this point.

As noted above, this has not gone unnoticed by the government. In January 2021, Kit Malthouse (the Minister of State for Crime and Policing) wrote an open letter to the Advisory Council on the Misuse of Drugs (ACMD). The letter indicated that the government was considering amending the MDR 2001 to clarify the legal position and asked the ACMD to recommend a THC limit by weight.

In December 2021, the ACMD reported back and recommended a maximum weight of 0.05mg of THC per "unit of consumption". This has been interpreted as meaning 0.05mg per "dose" or "single serving" in consumer products.

Initially, this suggestion was welcomed by many in industry as providing much-needed clarity to this area of law. Unfortunately, however, almost two years passed without any indication from the government as to whether the ACMD's recommendations would be accepted.

Finally, in October 2023, the government responded, and accepted the ACMD's recommendations. It stated: "The Government accepts this recommendation and intends to bring forward legislation to implement it, subject to Parliamentary approval. The specificity of the terms of legislative provisions setting the Unit of Consumption (or serving) for the permitted dose, which will differ between different products, will require further careful consideration."

The open correspondence between the ACMD and the government indicates that the definition of "exempt product" may be further tightened to exclude products which are intended for administration to humans. However, the ACMD separately recommended that the "50 microgram per unit of consumption" threshold be applied to consumer CBD products.

Since the government has accepted this recommendation, two things appear likely. First, the definition of "exempt product" in reg. 2 of the MDR 2001 will be amended so as to exclude consumer CBD products. Second, a specific 50 microgram limit for THC will be placed on consumer CBD products (which we assume must be by way of separate legislation).

These recent developments have been welcomed wholeheartedly by many in the CBD industry. In particular, the prospect of bespoke legislation for consumer CBD products is both welcome and long overdue. It is hoped that the government will consult with industry and stakeholders in developing this legislation to ensure that care is taken to distinguish between different types of CBD products and different manufacturing methods.

Conclusion

Whilst there remains much work to be done to rationalise the law, the outlook is good for the UK medical cannabis and CBD sector. From a regulatory perspective, the path is clear for the medical cannabis market to grow in the future. As for CBD, it appears that the government is willing to take meaningful steps towards legitimising consumer CBD products and providing much-needed legal certainty in relation to regulation. This cannot come soon enough for the UK CBD industry.

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