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Global Practice Guides

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2025

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CONTENTS

INTRODUCTION

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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 that 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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Global Cannabis Reform Reaches Critical Juncture in 2025

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. More recent independent forecasts have notably revised Europe's cannabis-market outlook well beyond the USD7.25 billion by 2029 cited in last year's guide. For the medical segment alone, estimates are that the market will grow from USD2.59 billion in 2024 to USD12.65 billion by 2033, at a compound annual growth rate (CAGR) of 18.33% over 2025–2033. Broader market analyses – including medical, adult-use and cannabidiol (CBD) – project expansion from USD4.48 billion in 2022 to USD18.84 billion by 2032, implying a 14.37% CAGR from 2024 to 2032. In the nearer term, Prohibition Partners forecasts that adult-use sales alone could reach EUR1.5 billion by 2026, contingent on the roll-out of recreational programmes in key markets.

Germany

Since the Bundestag passed the Cannabis Act on 23 February 2024, Germany has established a pioneering framework for both medical and recreational cannabis. Adults may cultivate up to three flowering plants per household, possess up to 50 g at home or 25 g in public, and join non-profit cannabis social clubs (maximum 500 members) that can distribute up to 50 g per member per month.

On the medical side, annual sales are increasing rapidly, driven by patient growth and streamlined regulations, including the removal of the tender requirement for domestic cultivation. Imports jumped from 32 tons in 2023 to over 70 tons in 2024, with Canada and Portugal as leading suppliers; current trends suggest imports could surpass 100 tons in 2025.

Digitalisation continues to reshape patient access: telemedicine platforms record over 150,000 visits per month across the leading providers, vastly expanding remote prescribing and reducing barriers for patients in all federal states.

On the recreational front, adults may legally grow three plants at home and acquire up to seven seeds or five clones each month. Non-profit social clubs began operations in mid-2024 and now operate under strict youth-protection and reporting rules.

Politically, on 9 April 2025 the incoming coalition confirmed that it will maintain the current cannabis framework and not seek repeal, committing instead to an open-ended evaluation of home-grow and club schemes in autumn 2025. This assessment will examine youth protection, market efficacy and supply security, and underpin any future legislative refinements.

Switzerland

Across the border in Switzerland, the pilot trials now encompass over 16,000 participants across seven adult-use projects. In February 2025, the National Council's Health Committee communicated the main elements of a draft federal law by 14 votes to nine, which would permit adults to grow up to three plants, purchase and possess cannabis, and restrict sales to licensed non-profit outlets under a stringent electronic tracking system. Products will have to be neu-

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trally packaged, non-branded and subject to an "incentive" tax, with all proceeds funding prevention and treatment programmes. Should this new legislation pass, Switzerland will lead the pack as the first jurisdiction in Europe to provide a fully commercialised supply chain for the non-medical adult-use cannabis market.

Portugal

Since the 2018 medical-legalisation framework, Portugal has surged ahead as Europe's top medical cannabis exporter – shipping over 32 tons in 2024 – yet local patient access remains constrained by high, unsubsidised prices and limited domestic supply. Recreational use has been decriminalised since 2001, but no government-backed proposals for adult-use regulation, cultivation associations or social clubs have advanced amidst recent political upheaval and the growing influence of the far-right. With the current administration showing little appetite for change and the next elections still over a year away, the prospect of a fully regulated adult-use market in Portugal remains distant.

Spain

In Spain, medical cannabis regulation is on the verge of formalisation: the Ministry of Health's draft Royal Decree – detailing prescription, preparation and dispensing of standardised cannabis-based magistral preparations via hospital pharmacies – was submitted to the European Commission in January 2025 and is expected to be approved before summer 2025, though stakeholders criticise its narrow scope and exclusion of cannabis flower and community pharmacies. Recreational cannabis remains illegal under national law, yet hundreds of non-profit cannabis social clubs continue to operate in a de facto tolerance framework (around 400 in Catalonia and over 600 nationwide); however, intensified enforcement has heightened legal uncertainty for operators and members, and no parliamentary bills to decriminalise or legalise adult use have progressed in 2025.

The Netherlands

In the Netherlands, the long-standing "back-door" system – where coffee shops can legally sell cannabis, but suppliers must procure it illicitly – has entered a transformative experimental phase. Launched in December 2023 in Breda and Tilburg and expanded in June 2024 to ten municipalities, the "Closed Coffee Shop Chain Experiment" now requires, as of 7 April 2025, that all participating shops (around 75 in total) source exclusively from government-licensed cultivators. Initially limited to three licensed growers, the pool has been expanded to seven to meet demand. Under strict quality-control and traceability provisions overseen by an independent Monitoring and Evaluation Committee, this four-year trial will assess impacts on public health, crime, safety and nuisance, while providing data to inform nationwide policy. Early indicators point to more consistent product quality and reduced health risks compared to unregulated markets.

UK

In the UK, the medical cannabis sector has grown rapidly between 2023 and 2025, with both NHS and private prescriptions surging and patient numbers reaching the tens of thousands – making the UK one of Europe's fastest-expanding medical markets. This expansion generated annual sales in excess of GBP200 million, driven by a growing network of private clinics, increasingly diverse product portfolios and streamlined telemedicine platforms that have lowered barriers to access and broadened treatment options. In early 2025, the Midlands-based manufacturer Dalgety shipped the UK's first domestically produced medical-grade cannabis flower

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on prescription, a landmark moment for supply security and future market growth. Recreational cannabis remains illegal under the Misuse of Drugs Act 1971.

France

Medical cannabis in France remains in an extended pilot phase: originally launched in spring 2021, the national trial – serving around 1,800 patients – has been prolonged until 31 July 2025 while authorities finalise the regulatory framework and seek European Commission approval. On 21 March 2025, the government notified three draft regulatory texts to the European Commission:

- a decree integrating cannabis-based medicines into the Public Health Code and pharmacovigilance and distribution frameworks;
- a ministerial order defining product specifications and therapeutic indications; and
- a ministerial order setting technical conditions for cultivation, import-export, transport and storage of medicinal cannabis plants.

Member states and the Commission have a three-month stand-still period to comment, after which the decrees must be signed by the executive to take effect. Recreational cannabis remains fully illegal. The government has shown no appetite for decriminalisation beyond the existing fine-and-educate system, leaving France's adult-use market in legal limbo.

Panama

Since President Laurentino Cortizo signed Panama's medical cannabis law in October 2021 and two executive decrees in 2022 set out prescribing rules, patient registries and regulatory oversight, the country now operates one of Central America's most comprehensive medical programmes. In January 2024, the National Directorate of Pharmacy and Drugs awarded the first seven manufacturing licences, paving the way for domestic production of oils, flower and extracts. Recreational use and cultivation remain illegal, though enforcement is generally lax, and personal possession is widely tolerated; no initiatives to decriminalise or regulate adult use have been proposed, so Panama's recreational market remains closed.

Israel

Israel maintains one of the world's largest medical-cannabis markets, with 135,213 registered patients as of November 2023 and over 140,000 active patients recorded in April 2024, making it the highest per capita globally and on track to exceed 240,000 by 2027. New regulations to expand prescribing criteria, originally slated for early 2024, have been delayed due to regional security concerns. Exports remain tightly controlled under existing frameworks. Recreational use has been decriminalised as an administrative infraction since April 2019, but no substantive Knesset bills to legalise or regulate adult-use markets have advanced in 2025.

Poland

Poland has emerged as one of Europe's most dynamic medical-cannabis markets, with consumption up 224% in 2023; in response, the government doubled import quotas and tightened prescribing rules – shifting focus to oils and extracts and restricting inhalable products. A November 2024 ban on private telemedicine prescriptions limited remote prescribing to national health physicians and saw monthly prescriptions plunge from 68,000 in October to 28,000 by December 2024. Recreational use remains illegal in Poland. CBD products are legal under EU novel-food rules, and industrial hemp cultivation is licensed, while "non-industrial" cannabis remains prohibited outside medical channels.

INTRODUCTION

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USA

In the United States, the promise of federal reform has stalled. A hearing on the DEA's proposed rescheduling of marijuana – initially set for 21 January 2025 – was postponed pending appeal, and as of April 2025 the process remains on hold with no further actions scheduled, underscoring ongoing federal uncertainty.

These mostly positive trends in the global cannabis industry 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.

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 license 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 UN 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 legislation and enforcement regularly subject permissible tetrahydrocannabinol (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.

This guide will highlight these pervasive challenges and structure its review of legislative

INTRODUCTION

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frameworks in four primary sectors of the global cannabis industry:

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

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

Legislative momentum in 2025 has already reshaped the cannabis landscape, setting the stage for substantial industry growth in the years ahead.

The Medical Cannabis & Cannabinoid Regulation 2025 Guide offers a comprehensive overview of cannabis laws across various jurisdictions, featuring articles on trends and developments. Each jurisdiction is reviewed through a question-and-answer format, facilitating easy comparison of specific issues and concerns, and providing a clear, jurisdiction-specific yet globally relevant guide to untangling the complexities of international cannabis laws.

FRANCE

Law and Practice

Contributed by:
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Contents

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 *"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, the International Bar Association (IBA) and the French Regulatory Affairs Association (AFAR). She is also 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 legalisation of medical canna-

bis becomes effective. 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

To date, 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 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 an initial 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 yet, 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 tetrahydrocannabinol (THC) dominant ratio, cannabidiol (CBD) 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 were 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).

The pilot programme ended on 25 March 2024 and medical cannabis (*"cannabis-based medicinal products"*) was expected to be generalised on the French market by 1 January 2025 at the latest. However, the complex political situation in France in 2024 resulted in major delays in the setting-up of the legal and regulatory framework. While the legal framework was set out in December 2023 and transposed in the French public health code, the relevant regulatory decrees and orders whose publication is necessary for the generalisation of cannabis-based medicinal products to become effective remain a work in progress at this date.

More specifically, the legal framework regarding cannabis-based medicinal products was set out in French Law No 2023-1250 of 26 December 2023, on the financing of social security for 2024. The law refers to 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**).

However, the legalisation of medical cannabis can only become effective once the relevant decrees and orders setting out the specifications on cannabis cultivation, the specifications on products, prescription and delivery, as well as the criteria for price-fixing and reimbursement of the products, are published, which is yet to happen.

On 19 March 2025, the French government notified the drafts of a decree and two orders on the European Commission's Technical Regulation Information System (TRIS) database, in order for the Commission to assess their compliance with EU law.

These draft regulatory documents provide specifications notably on the production line, the products that can be authorised for use and the prescription and delivery requirements. According to these documents, the following applies.

- Only companies that are authorised as *"pharmaceutical establishments"* (as defined by the French public health code) can apply for a use authorisation for cannabis-based medicinal products.
- The cultivation of the cannabis plant for medical purposes can only be carried out by growers that have entered into an agreement for that specific purpose with a pharmaceutical establishment holding the use authorisation for cannabis-based medicinal products.
- Only indoor cultivation is allowed and the premises where the cannabis plant is to be cultivated must meet the strict requirements, notably in terms of security set out in the relevant order. Outdoor growing is strictly prohibited.
- The requirements for the use-authorisation dossier to be submitted to the ANSM are the same as those applicable to standard marketing authorisation dossiers for medicines, except for clinical study results that do not apply to cannabis-based medicinal products.

Likewise, the pharmacovigilance requirements are the same as those applicable to medicines holding a marketing authorisation.
- Prescription of cannabis-based medicinal products can only be done as a last line treatment – ie, when other available therapies have failed, and in cases where other existing medicines offer little relief or are not tolerated well by patients, or when no suitable pharmaceutical speciality is available.
- Initial prescription must be hospital prescription only.
- Physicians must complete a specific training prior to being able to prescribe cannabis-based medicinal products. However, specifications on this mandatory training are yet to be defined.
- The five therapeutic indications in which cannabis-based medicinal products can be prescribed are the same as those authorised under the pilot programme (as previously described).
- Cannabis-based medicinal products can only be placed on the market as finished products and in accordance with the following requirements:
  (a) dried or granulated flowering tops are not authorised unless they are presented in secure, tamper-proof primary packaging;
  (b) the pharmaceutical forms of authorised final products are oral or sublingual forms;
  (c) other pharmaceutical forms can be authorised provided that they are authorised by the ANSM;
  (d) smoking use of the cannabis-based medicinal products is prohibited; and
  (e) inhalation is permitted provided it is done by using a specific inhalation device that must hold a CE mark as a medical device.

The status quo period is to end on 20 June 2025, provided that no event will stop the clock in the meantime. If the European Commission does not issue a detailed opinion, one could reasonably expect the decree and orders to be finally published during the fourth quarter of 2025.

In the meantime, in order to ensure that the patients that were enrolled in the pilot programme can still have access to medical cannabis, the French Minister of Health has decided to extend the pilot programme until 31 March 2026. During that extension period:

- 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.

Manufacturers and importers are required to declare each product and its composition to the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) before placing it on the market.

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 30 *"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:

- the maximum THC level they contain remains below 0.3%;
- 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;
- 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
- 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.

Most recently, the ANSES has proposed that CBD be classified as *"presumed human reproductive toxicant"*. On 17 March 2025, the dossier associated with such proposal was submitted for public consultation on the ECHA's website The consultation should last until 16 May 2025. The aim of this consultation is to give all stakeholders the opportunity to comment on this proposal, by providing any additional scientific arguments and information they may have on the substance's hazard properties. Following this consultation, the initial proposal, comments received and ANSES's responses to them will be analysed by the ECHA's Committee for Risk Assessment, which is to then issue an opinion on the harmonised classification of CBD.

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.

Subsequently, 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.

However, the ANSM modified its decision by a new decision of 3 June 2024, by which it excluded from classification substances that may be contained in very low concentrations in products derived from industrial, textile or agricultural hemp – ie:

- CBNA (cannabinolic acid), a precursor of CBN which is already excluded from classification;
- THCVA (tetrahydrocannabivaric acid) and THCV (tetrahydrocannabivarin), provided that

their content does not exceed 0.3% respectively; and
- THCA (tetrahydrocannabinolic acid), provided that their THC content complies with the 0.3% threshold.

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.

It must be noted that since January 2024 the control of cosmetic products that the ANSM used to share with the *Direction générale de la concurrence, de la consommation et de la répression des fraudes* (DGCCRF) 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 *Direction générale de l'alimentation* (DGAL) is charged with the control of food safety. It is competent to control supply chains of vegetal and animal food stuffs.

The *Agence nationale du médicament vétérinaire* (ANMV) 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 but not limited to:

- *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 the generalisation of medical cannabis (cannabis-based medicinal products) becomes effective – ie, once all the relevant application decrees and orders are published and have entered into force – 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 actual publication of the relevant decrees and orders in the Official Journal, there is and will be a lack of visibility on certain fundamental questions, notably regarding the determination of applicable criteria for price-fixing and reimbursement of cannabis-based medicinal products.

Likewise, uncertainty remains as to the exact requirements applicable to the cultivation and production of cannabis for medical purposes as well as product specifications until the official publication of the relevant decree and orders.

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.

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 to occur in the coming months or early 2026 at the latest), 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 extended transition period, now scheduled for 31 March 2026, medical can-

nabis (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 market access conditions and prices that satisfies all the parties concerned, especially considering the major investments required from industry players to meet the legal requirements regarding cannabis-based medicinal products and production thereof. 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 to place 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 EU member states, 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, and its decision to prohibit the use of dried raw flowers as cannabis-based medicines in order to (according to the French Ministry of Health) avoid any risk of confusion with recreational cannabis, 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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Contents

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 2024, 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 under 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 the aforementioned date, 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 (so-called *"first pillar of the legalisation"*). They are managed in accordance with the principles of association law.

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).

Model Regions

The second pillar of the legislation related to the controlled distribution of cannabis are so-called *"cannabis model regions"*. These provide for the trialling of distribution by professional providers as part of regional pilot projects with commercial supply chains. The aim is to give companies 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.

In December 2024, the Federal Ministry of Food and Agriculture (BMEL) announced the enactment of the Scientific Competence Regulation for Recreational Cannabis. This transfers responsibility for reviewing applications for cannabis model regions to the Federal Office for Agriculture and Food (BLE). The BLE is now reviewing applications from several German cities.

However, Germany must co-ordinate the implementation of the second pillar with the European Commission.

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%.

The last government introduced a so-called *"Industrial Hemp Liberalisation Act"*, which would have removed the abuse clause and allowed indoor cultivation of industrial hemp. However, the act was not passed. It is currently unclear whether the new government intends to pursue the act. Furthermore, hemp falls within the classification of industrial hemp in the case of the following.

- If it is grown by agricultural undertakings that:
  - (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 that 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.

The competent authority for applications for so-called *"cannabis model regions"* is the BLE.

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.

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. It remains unclear how the new German government (in office since May 2025) will handle the cannabis legislation. One of the governing parties, the Christian Democratic Union (CDU),

had campaigned in the election with overturning the legalisation of cannabis. The coalition agreement between the governing parties now only says: *"In autumn 2025, we will conduct an open-ended evaluation of the law on the legalisation of cannabis."*

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.

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.

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. In particular for Germany, it is not clear whether the new government (in office since May 2025) will revoke the recent legalisation and – in the worst case – will classify cannabis as a narcotic again.

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 that 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 successful completion of the equivalence assessment or preparatory phase provided for in some MRAs, during which the parties evaluate each other's GMP inspection systems, inspections are considered mutually recognised. Even if an MRA is in place, it needs to be carefully evaluated for each country 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.

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. Currently, many patients get their prescriptions from so-called *"telemedicine platforms"* without physical treatment from a physician in Germany.

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 datasets 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 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

Partial Legalisation

As outlined before (see **1.1 Primary Laws & Regulations**), the recreational use of cannabis is no longer prohibited. Also, the possession of 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) is not prohibited.

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.

ITALY

Law and Practice

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Contents

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 subject of cannabis is governed by a complex system of regulations according to its field of application and intended use (pharmaceutical, cosmetic, food, technical, industrial, etc).

For the sake of linearity and systematic exposition, it seems appropriate to divide the various topics into:

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

Medical Cannabis

The law of reference is Presidential Decree No 309/1990, the Italian Narcotics Act (*Testo Unico Stupefacenti*). Its Article 14, paragraph 1 (b), in laying down the criteria for the formation of the tables of narcotic substances subject to supervision, stipulates that Table II must include *"cannabis and the products obtained from it"*, and specifies that cannabis is prohibited in its various forms of presentation: 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 (as set out above).

Cultivation, extraction of active ingredients, distribution, importation and exportation are in fact subject to authorisation by the Ministry of Health – Central Narcotics Office (UCS), as the state agency for cannabis for essentially scientific or research purposes.

The Ministry of Health Decree of 9 November 2015 adopted the collaboration agreement between the Ministry of Health and the Ministry of Defence for the launching 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* (SCFM) based in Firenze, which has developed the cannabis varieties FM2 (with tetrahydrocannabinol (THC) content of 5–8% and cannabidiol (CBD) 7.5–12%) and FM1 (with THC content of 13–20% and CBD less than 1%) produced in accordance with EU Good Manufacturing Practices (GMP) in a pharmaceutical workshop authorised by the Italian Drug Agency (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, and will be discussed in **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 a 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 (SSN)

Law No 172/2017 provides that medical cannabis is reimbursable at the expense of the SSN, and limited to the following pathologies:

- pain therapy (potentially any type);
- pain and spasms from multiple sclerosis;
- cachexia (in anorexia, HIV, chemotherapy);
- vomiting and inappetence from chemotherapy;
- glaucoma; and
- Tourette syndrome.

Unfortunately, there are still disparities in access to medical cannabis between patients from different regions of Italy – the law is effective when each region has established the technical modalities for reimbursement.

On the other hand, paid-for medical cannabis can also be purchased in pharmacies outside one's region of residence.

Extracts

As set out above, extracts are included in Table II of the *Testo Unico Stupefacenti*.

Legislative Decree No 219/2006 establishes the principle of prevalence of the regulation on medicinal products over other regulations, whereby, in the case of doubt as to whether a product (taking into account its characteristics) may fall within the definition of a medicinal product and another product, the regulation on medicinal products applies in any case.

By virtue of this provision, following the registration with the European Medicines Agency (EMA) of the medicinal product Epydiolex (ie, an MCT oil with CBD isolated and extracted from the cannabis plant)) – and thus following the presence of CBD as an active pharmaceutical ingredient (API) in the European Pharmacopoeia – a product containing isolated CBD will have to be considered a medicinal product (with the exception of the cosmetic use referred to below).

Therefore, in June 2021, the Ministry of Health published guidelines for obtaining authorisations for the cultivation of cannabis intended for CBD extraction for medical use.

These guidelines provide for a double authorisation:

- the pharmaceutical company (which is authorised by AIFA to produce API) must be authorised by the UCS and for the manufacture of cannabis extracts containing cannabinoids for the production of API; and
- the supply of starting plant material (hemp) and the destruction of the narcotic substances (THC) must also be authorised.

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 of 7 August 2023, the Ministry of Health lifted the suspension of the so-called *"Speranza Decree"* of 2020, which included CBD-containing preparations for oral use in the table of narcotic drugs annexed to the Narcotics Act.

The validity of this decree was confirmed by the Administrative Court, which rejected the appeal brought by the sector's operators.

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 *"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 that 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, and 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 of up to 0.6%.

Only if, following controls by the police, the limit is found to be higher than 0.6% may the seizure and destruction of the cultivation be ordered.

However, the law provides that in any case no criminal liability can be attributed to a farmer who has complied with the provisions of Article 3 (keeping the card and seed purchase invoice).

Checks must be carried out by the *Carabinieri Forestali* according to the method of sampling and analysis foreseen in Annex I of Regulation (EU) No 1155/2017, but may also be carried out by any police force in the exercise of investigative activity (see also **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 fibre, hemp, powders, wood chips, oils or fuels, for supplies to industries and craft activities in various sectors, including the energy sector;
- material intended for the practice of green manure;
- organic material intended for bioengineering work or products useful for bio-construction;
- material intended for phyto-purification for the reclamation of polluted sites;
- cultivations dedicated to educational and demonstrative activities as well as research by public or private institutes; and
- crops intended for floriculture.

This list is to be considered exhaustive and presupposes being connected with sector regulations.

Foods

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

- the only permitted hemp-based foods are 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.

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

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

Indeed, the Ministerial Decree in question envisages the possibility of supplementation with other foodstuffs upon presentation of new scientific evidence.

For further details, please refer to the accompanying Trends and Developments 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"*.

They are regulated by Regulation (EC) No 1170/2009 (which amended Directive 2002/46/EC), and at national level by Legislative Decree No 169 of 21 May 2004 implementing Directive 2002/46/EC, as well as by the Ministerial Decree of 9 July 2012 on the *"Regulation of the use of plant substances and preparations in food supplements"*.

According to the attached tables, and also by virtue of the BELFRIT agreement signed between Belgium and France, only supplements based on hemp seeds or hemp seed oil are permitted in Italy.

Therefore, to date, products based on parts other than seeds or extracts cannot be considered food or food supplements at the regulatory level.

Other issues such as novel food and expected developments will be dealt with in **3.2 Non-Controlled Cannabinoids in Food** and in the accompanying Trends and Developments article.

Cosmetics

Cosmetic products are regulated by Regulation (EC) No 1223/09, with the specifications indicated by the Cosmetic Ingredient Database (the so-called *"CosIng"* list), which, although not legally binding, represents a reference for all advisers in the sector in order to standardise labelling in the EU (and therefore also in Italy).

Thus, as of today, in Italy CBD and cannabigerol (CBG) in isolated form are to be considered ingredients that can be used for the formulation of cosmetic products, provided that 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 they state on the label the intended purpose (topical/external use) and present functionalities and commercial claims in accordance with the cosmetic purpose.

This category is arguably the only product category in which CBD oils can be considered compliant with the regulations.

Floriculture

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

In particular, Article 2 of Legislative Decree No 214/2005 clarifies definitions and establishes that *"plants"* means 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 parts of them for ornamental purposes.

The Ministry of Agriculture, through Circular No 5059 of 5 May 2018, has specified (with reference to hemp) that the production of hemp plants and parts thereof – 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 and not intended to be used for further floricultural production, though still subject to the legal limits for THC content.

Therefore, in Italy the production and sale of ornamental hemp plants can certainly be considered lawful, provided they are germinated from certified seeds.

Plant parts (flowers, leaves, fronds and cuttings) are lawful provided they are intended for an *"end"* use of an ornamental nature, with the exclusion of further floricultural activity.

The same ornamental use would also seem to rule out questions of psychotropic efficacy at root, since this is not intended for human consumption.

By way of analogy, one example is oleander, a plant known to be toxic and which is freely sold without any special precautions being taken.

The regulation of flowers is complex however, and is intrinsically linked to the issues dealt with in **CBD Flowers (*"Cannabis-Light"*)** below.

Fibres

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

Related problems concern the supply chain, as there are critical production issues due to the scarcity of processing plants.

CBD Flowers ("Cannabis Light")

Following the spread in 2017 of the phenomenon of so-called *"cannabis light"* that is, the sale of dried inflorescences of hemp from varieties certified for *"technical use"* or *"collecting"* the first seizures related thereto began, and case law was divided between one side which held that the flowers were covered by Law 242/2016 and another side which instead held that they were covered by the narcotics legislation, as the flowers (like the leaves) were in any case included in the narcotics table.

The matter was referred to the United Sections of the Supreme Court of Cassation, which (while calling on the legislature to provide for clarity) ruled 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
- the marketing of flowers, leaves, oil and resins integrates the offence of dealing unless they are capable of producing psychotropic efficacy in concreto, according to the principle of offensiveness.

This judgment, in the absence of a clarifying intervention by the legislature, has led to the current situation in which the sale of CBD flowers is a widespread practice throughout the country, with various cases of seizures (and consequent criminal proceedings) that are dealt with discretionally by the authorities from case to case and area to area.

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 a drugging effect in practice.

In practice, CBD flowers are mostly sold for ornamental purposes as end products of the floricultural supply chain, with a THC content of less than 0.5% to avoid presenting psychotropic efficacy.

Worthy of note is the entry into force of Decree Law No 48/2025 on 11 April 2025, which amended Law 242/2016 and excluded all forms of use of inflorescences (production, possession, processing, transport and marketing) in any form (including semi-processed, crushed and dried), as well as derivatives consisting of or containing inflorescences (resins, extracts and oils) from the scope of this law, and brought them under the narcotics legislation. This topic is dealt with in more detail in the Italy Trends and Developments article in this guide.

Psychotropic Efficacy

The concept of drugging efficacy deserves its own space, as there is no unambiguous definition covering it and it is left to the judge's evaluation on a case-by-case basis.

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

In other cases, some public prosecutors' offices have instead sustained a radical thesis according to which flowers are always narcotics regardless of the 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.

In the authors' opinion, the issue may be resolved in the criminal trial still pending against Luca Marola (founder of Easy Joint, a pioneer company in the sector), who is accused in Parma of drug-dealing for having possessed about 700 kg of hemp sativa with a THC content of less than 0.2% – which, according to the prosecutor's office, would translate to about 200,000 doses.

This situation continues to represent a major problem of the Italian system characterised by chronic legal uncertainty, and which thus essentially stems from territorial business based on risk management, as discussed later.

CBD Oils

A large number of products are also sold on the Italian market as CBD oils, 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 for violation of the Narcotics Act and sometimes for violation of the Medicines Decree.

CBD oils present the same problems as CBD flowers with regard to relations with narcotics legislation, which are resolved in the assessment of psychotropic efficacy (however, they are more easily resolved as they are hardly ever marketed with a THC content of more 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, as the specific offence would not be typified and therefore the principle of the taxability of criminal offences would be violated.

These products are to be considered illegal on the Italian market following the Ministry of Health Decree of 23 August 2023 and the Lazio Regional Administrative Court ruling No 8818/2024 of 16 Aptil 2025, which rejected the appeal of the operators in the sector and confirmed the Decree.

Recreational Cannabis

The recreational use of cannabis is prohibited in Italy by the *Testo Unico Stupacenti* (Consolidated Text on Narcotic Drugs), even though the possession of cannabis for personal use is only administratively sanctioned (albeit with important repercussions in the personal sphere: limitations on driving licences, gun permits, documents for expatriation, residence 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 relates to the pending bills referred to in **3.3 Decriminalisation**.

1.2 Regulatory Bodies

The regulatory bodies that oversee the system for the production of cannabis and cannabinoids (pharmaceutical grade) 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;
- issues authorisations for pharmaceutical workshops to procure hemp and for the extraction of CBD as an API for the preparation of medicines;
- issues authorisations for cannabis cultivation for research purposes; and
- annually determines 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. It is the competent agency for the recognition of pharmaceutical workshop quality.

Furthermore, to date the SCFM is the only institution in Italy authorised to cultivate cannabis for medical use.

The regions are responsible for the reimbursability of cannabis as a medicine to citizens, and must annually communicate to the Ministry of Health data on cannabis prescribed in the 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

There are many associations that deal in the field of medical cannabis, especially from the point of view of patients' rights, issues of cannabis shortages, reimbursability by the SSN, and training and information activities for medical personnel.

Mention should be made of scientific societies such as the Italian Cannabis Research Society (SIRCA) and the Italian Medical Hemp Society (SICAM). Additionally, the Luca Coscioni Association has been active since 2002 in the area of the protection of civil liberties and human rights throughout the country, with particular attention paid 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.

The associations Federcanapa, Canapa Sativa Italia and Resilienza Italia are also active in the national territory, and deal with the promotion and protection of the supply chain.

Self-regulation documents have also been adopted by operators, such as:

- the protocols for production of hemp flowers adopted by Federcanapa, CIA - Agricoltori Italiani and Confagricoltura in 2018; and
- guidelines on hemp extraction adopted by Federcanapa and Agrinsieme in 2021.

Many associations also operate at a regional level – for instance, the activity carried out in Tuscany by the Ente Tutela Innovazione Canapa Toscana (ETICA), 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 and Cannabinoids

For years, participants in the cannabis sector in Italy have found themselves operating in a grey area, particular regarding flowers and extracts. The United Sections of the Court of Cassation had already highlighted the need for clarifying legislative intervention in 2019.

Despite various amendment proposals, the law has not been supplemented, and a situation of general uncertainty remains with differences in interpretation and application by the competent authorities varying from case to case and area to area.

A key challenge for the sector's operators has long been to obtain legal and regulatory clarity for the production and sale of flowers and extracts.

For this reason, the lobbying activity carried out both through dialogue with the competent authorities and by challenging decrees that are detrimental to the sector (see the adjacent Italy Trends and Developments article) is one of the keystones for the development and regulation of the sector.

The main challenge is to delineate a field of application in the category of nutraceuticals, phytotherapeutic products and food supplements, which represent an 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 just the exclusive domain of pharmaceutical companies but also of the industry in the sector, which in recent years has shown that it knows how to make the most of research results when 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.

In fact, to increase national production, it is necessary for the regions to transmit annual data on medical cannabis prescriptions to the Ministry of Health. Hence, 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.

The current situation is well summarised by the *Istituto Superiore di Sanità* report of June 2024, according to which, *"[t]he data collected confirm that medical cannabis in Italy is mainly used as adjuvant therapy for chronic pain, with a good safety profile and a low incidence of adverse reactions. However, the variability in prescribed*

dosages and the regions' failure to fully adhere to the ISS platform suggest the need for further standardisation and more widespread monitoring. The growing acceptance of cannabis as a therapeutic option underlines the importance of continuous regulatory and scientific updates to ensure safe, effective and accessible treatments for patients".

It is clear that proper medical and professional training is key to the growth and development of the medical cannabis sector in Italy.

1.5 Legal Risks

The risks are mainly concentrated in the industrial hemp sector following the entry into force of the Security Decree (referred to in the Trends and Developments article), since the medical cannabis sector has rather well-delineated regulations.

For the patient, there are no legal risks regarding the possession of cannabis as long as they have a valid medical certificate and the cannabis is regularly purchased in a pharmacy.

The biggest problems concern driving vehicles in the event of police checks. In January 2025, the new Highway Code came into force, which reformed Article 187, changing the offence of *"driving under the influence of drugs"* to *"driving after taking drugs"*.

The reform has caused great concern among patients undergoing medical cannabis treatment since, in the case of *"control"*, cannabinoids remain in the blood fluids for several days after consumption.

Despite calls for the rule to be corrected, to date the approach by the police is discretionary and is still based on subjective criteria at the time of the check-up inherent in the driver's behaviour. However, after several months of the new Highway Code being in force, there have been no significant cases in which ascertaining officers have sanctioned patients under the new Article 187 offence when involving medical cannabis and possession of a valid certificate.

It should be noted that some associations have mobilised preparing operational vademecums and free legal protection and assistance services for patients (eg, www.clinn.com).

For penalties, please refer to **1.6 Enforcement & Penalties**.

1.6 Enforcement & Penalties

As outlined in previous sections, in Italy cannabis is considered a narcotic in its flower, leaf, oil and resin manifestations. Hence, controls and related sanctions – irrespective of the considerations and legal disputes previously outlined – stem from the violation of the narcotics legislation.

All Italian police forces therefore have authority, in the performance of judicial police activity, to carry out controls on cannabis and derivatives.

In particular, Law No 242/2016 provides that controls on industrial hemp crops be carried out by the *Carabinieri Forestali* according to the protocol provided for in Regulation (EU) No 1155/2017, All I.

If the police detect a potential offence at a stage of the supply chain, they can proceed to contest the violation of the Consolidated Narcotics Act, and consequently criminal proceedings can be opened at the competent public prosecutor's office.

Most of these proceedings end with dismissal following laboratory analyses showing that the THC content is below the threshold of psychotropic efficacy (discussed previously).

In addition to the controls and sanctions arising from the Consolidated 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), from which penal or administrative sanctions (fines, suspension of activity, adoption of prescriptions, etc) may result.

Since many cannabis products and derivatives do not have a clear product classification (especially CBD flowers and CBD oils), it is clear that the objections that may arise from possible controls are manifold and depend on the types of controls performed and on the authorities that carried them out.

For all these reasons, given the complexity of the regulations on the subject, the figure of the adviser becomes pre-eminent for operators in the sector of hemp and its derivatives.

2. Cross-Jurisdictional Matters

2.1 Cross-Jurisdictional Issues

The biggest problems concern the industrial hemp and cannabnoid sector, which, as previously outlined, still presents grey areas and legal risks common to many other EU countries. Arguably, the general position of the authorities with regard to the hemp plant is substantially similar to that of Spain and Portugal, where in fact only hemp seeds and fibre are upheld as legal.

The entry into force of Article 18 of the Security Law Decree and the recent ruling of the Lazio Regional Administrative Court No 8818/2025 that legitimised the inclusion of oral compositions containing CBD among narcotic medicinal products (which are discussed further in the Trends and Developments article) imposes a very restrictive model with enormous problems in relations with other member states.

In any case, it can be said that the evolution of the sector (particularly with reference to the food and supplement sector) will depend on the decisions at the European level taken by the European Food Safety Authority (EFSA) (see **3.2 Non-Controlled Cannabinoids in Food**).

In general, in view of the differences in interpretation on certain product categories between the various member states, the EU has begun a process of acquiring data from operators in the sector, in order to define a single European regulation 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

In Italy, there are no particular issues regarding medical cannabis. The problems are political and opportunity-related, and relate to access procedures. This requires more training for prescribing medical personnel.

The limitation of the Italian system is the political choice inherent in the production of medical cannabis, which on the one hand is left to the Ministry of Defence through the SCFM and on the other hand to the purchase of cannabis from abroad.

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 remains suspended while awaiting the administrative authority's ruling on the appeals of certain participants.

It is evident how the entire system is held back in terms of competition and competitiveness (and consequently quality, quantity and efficacy of medical cannabis) by the exclusive concession to the Ministry of Defence (through the SCFM) of the national production of medical cannabis.

A change of course would be desirable that would allow (subject to acquisition of the relevant authorisation) the opening to private companies which should, by submitting their requirements, be free to produce medical cannabis and distribute it directly to pharmacies in a free market system.

The path in this direction seems extremely long and not easy to implement.

At the same time, space has opened up for the importation of cannabis and API-based medicines produced in other EU member states, as the Ministry of Health has authorised the importation of such products to certain pharmaceutical companies or distributors.

The main legal issues relate to driving and the reform of the Highway Code; see **1.5 Legal Risks**. On 11 April 2025, the Ministries of Health and the Interior issued a circular with some operational instructions for ascertainers, including the need to ascertain that the intake took place in the hours before driving (traces in blood and urine are therefore not relevant for this purpose) and recognising the necessary assessment at both the control and analysis stage for patients undergoing treatment with narcotic drugs.

These indications affect the discretion of ascertaining officers; in practice, there are no reported cases of patients undergoing treatment with cannabis with a regular medical certificate being sanctioned under the new Article 187 offence of the Road Traffic Act.

3.2 Non-Controlled Cannabinoids in Food

Italy considers cannabinoids and all parts of the cannabis plant, with the exception of seeds and derivatives, as novel foods, and does not recognise their traditional use prior to 15 May 1997. Prior authorisation by the EFSA is therefore required for their production and marketing.

To date, several Italian companies have begun the process of obtaining this authorisation from the EFSA, either individually or through participation in the so-called *"Novel Food Consortium"* promoted by the EIHA. At present, an application for CBD isolate extracted from the plant has been submitted and the relative risk assessment is pending (which, except for suspensions due to the request for further clarifications, will end in October 2024).

An 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 Developments article.

3.3 Decriminalisation

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

In December 2023, the Meglio Legale platform filed the text of a popular initiative bill with the Court of Cassation to make domestic cannabis cultivation legal in Italy. This bill provides for the lawfulness of the cultivation of cannabis plants both individually and in association. In the first case, cultivation of up to four plants and consequent possession of the proceeds is permitted, while the associated form 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 is set at 30 grams/month.

By spring 2024, the phase of collecting the 50,000 subscriptions will be completed and the bill will be handed over to one of the two branches of parliament (Chamber of Deputies or Senate of the Republic) for scheduling in the Chamber of Deputies and subsequent discussion.

The two branches of parliament have different regulations: in the Senate, there is an obligation to include citizens' initiative bills in the work programme, while in the House of Representatives this is only an option for the President and the 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 on.

Nevertheless, according to the organisers, the function of this initiative 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

In recent months, the cannabis and cannabinoid sector has undergone heavy restrictive legislative interventions, which have mainly affected the areas of cannabidiol (CBD) flowers and CBD oil.

These reforms have reversed the previous trend that was also gaining ground in case law in the wake of the Court of Justice of the European Union (CJEU) rulings in the *Kanavape* case.

The Security Decree

With Decree Law No 48/2025, published in the Official Gazette on 11 April 2025 and in force the following day, the government introduced amendments to Law No 242/2016, excluding from the scope of that law any use of industrial hemp inflorescences (production, possession, transport, processing and sale) in any form (including dried, shredded or semi-processed), as well as derivatives containing or consisting of them (resins, oils and extracts), and bringing these products under the narcotics regulation.

In essence, CBD flowers are being equated with cannabis flowers with tetrahydrocannabinol (THC).

Trade associations have brought proceedings before the ordinary courts for incompatibility with EU law and the Constitution.

For now, the proceedings are awaiting a hearing, in which the judge will have to decide on the plaintiffs' requests – ie, whether to disapply the national rule that is in conflict with EU law or to refer the preliminary question to the CJEU or the question of constitutionality to the Constitutional Court.

Judgment No 8818/2025 of the Lazio Regional Administrative Court, Third Section Quater

The TAR Lazio (Italian Administrative Court), through ruling No 8818/2025 published on 16 April 2025, rejected the appeal of sector operators against the Ministry of Health Decree of 27 June 2024 concerning the inclusion in the table of narcotic medicinal products of compositions for oral use containing CBD extracted from the hemp plant.

The Court held this inclusion to be valid, deeming the application of the precautionary principle to be lawful in this case on the basis of the scientific evidence presented by the Ministry with the opinions of the *Istituto Superiore di Sanità* and

the *Consiglio Superiore di Sanità*, which highlighted, in summary:

- health risks due to interaction between CBD and THC, as the extraction process from the plant always results in residue percentages of various cannabinoids in addition to CBD; and
- unsafe risks of marketed CBD-containing products.

This judgment will be appealed by the industry before the Council of State, with the aim of requesting an independent technical verification; at the European level, the matter may also be referred to the CJEU for a preliminary ruling on the grounds of conflict with EU law.

The Possible Scenario

The Security Decree has provoked many protests from trade associations and national agricultural associations, and there have been calls for the Decree's text to be changed when the Decree is converted into law, in order to protect and safeguard the agricultural production of the hemp plant (which the current wording of the Decree undermines).

Sector operators have brought an action before a civil judge to ascertain incompatibility with EU law and/or the Constitution and thus to request the disapplication of the incompatible national rule, or to request referral of the preliminary question to the CJEU or of the question of constitutionality to the Constitutional Court. At present, the procedure is awaiting a hearing, in which a judge can assess the foregoing.

A scenario of considerable uncertainty therefore looms for operators in the hemp sector in Italy.

It is clear that, in order to also avoid different interpretations and applications between member states, intervention by the EU is needed with a binding regulation clarifying that industrial hemp is the whole plant in all its parts as far as agricultural production is concerned.

The assessment of product safety (and possible restrictions) can be applied to individual uses on the basis of the specific sector regulations.

PANAMA

Law and Practice

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Contents

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1. Regulatory Framework

1.1 Primary Laws & Regulations

This time last year, Panama was on track to legally sell its first medical cannabis product before the end of 2024 and – as in all new markets – the frenzy of preparations was hectically underway. New laws and lengthy regulations had private investors spending in a hurry to ensure compliance with all the legal requirements.

There was doubt regarding which route Panama would explore. Would it take the wait-and-see approach that had permitted Panama to incorporate concepts from neighbouring countries while remaining faithful to its strategic geographical advantages when carefully considering and regulating the use of medical cannabis in, and from, Panama? Or would it take a direct-action approach and accept the growing pains that accompany such an approach?

The next 24 months were to be critical in determining whether Panama embraces or squanders this opportunity. Now that the first 12 months have passed, the author can confirm two things: much has changed yet nothing has.

The approach Panama took has been unexpected. The government decided to:

- completely stop, without any justification, everything related to medical cannabis;
- keep patients waiting while the regulations are completely and unilaterally rewritten by the local authorities, with no feedback from the government to patients or licensees; and
- suddenly, without much preview and on a Friday afternoon, publish the new regulations.

In the midst of all this, Panama opted to legalise hemp – although it remains unregulated. Panama also chose to eliminate the prohibition of the use of synthetic tetrahydrocannabinol (THC) in medical cannabis. One can look to more mature markets to investigate the effects of allowing synthetic THC in medical products; it has resulted in a flood of litigation.

The most recent update to the regulation of medical cannabis in Panama – Decree 6 of 4 April 2025 (*"Decree 6"*) – appears intent on committing the same mistakes as were made in the US and Canadian markets, including delving into all the confusion and litigation currently being waged between the medical cannabis industry and the hemp industry. Before exploring this further, it is worth providing updated responses to two important questions: *"How does Panama define medical cannabis?"* and *"How did Panama reach this point?"*.

Definition of Medical Cannabis in Panama

Panama considers cannabis to be *"controlled substance"*. Panama defines a controlled substance as any substance mentioned in one of the two international conventions – namely, the United Nations' 1961 Single Convention on Narcotic Drugs (in which cannabis is specified) and its 1971 Convention on Psychotropic Substances.

The main laws and regulations governing this subject in Panama define medical cannabis as any product that is derived from the cannabis plant and contains at least 1% THC. Products containing cannabidiol (CBD) but maintaining THC below 1% levels are not considered to be controlled substances. Products containing synthetic THC of any type, as of April 2025, are not prohibited.

The Story So Far in Panama

On 4 April 2025, with no prior notice or consultation with the medical cannabis industry in

Panama, the rules regarding medical cannabis use, sale, production and so forth - in or through Panama - were completely rewritten. How did Panama reach this point? After much pressure from local patients' associations and doctors, Panama took the following steps, leading up to Decree 6.

- October 13 2021 - Law 242 of 13 October 2021 (*"Law 242"*) is passed by Panama's legislative branch. Law 242 declares that its purpose is *"to regulate the medicinal and therapeutical use of cannabis and its derived products"*.
- 1 September 2022 - Executive Decree 121 of 1 September 2022 (*"Executive Decree 121"*), which regulates Law 242, is published by the Health Ministry of Panama (*Ministerio de Salud de la República de Panamá*, or *"MINSA"*).
- 25 September 2023 - a total of 14 companies presented their application to obtain one of the seven available medical cannabis licences in Panama.
- 17 January 2024 - MINSA published Resolution 008, listing the seven companies that were approved for the first seven licences.
- 29 January 2024 - MINSA announced that three out of the seven companies not granted approval for a licence in Panama have presented their first legal recourse, *"reconsideration"* of the 17 January 2024 resolution.
- 12 March 2024 - MINSA announced that it was maintaining its previous decision as detailed in its 17 January 2024 communication.
- 28 March 2024 - MINSA announced that all three companies that had presented their unsuccessful reconsideration had presented their second and final executive recourse, an appeal to the Health Minister himself.
- 2 May 2024 - MINSA resolved the appeals presented on 28 March 2024 and declared that Resolution 008 of 17 January 2024 is valid.
- 24 March 2025 - Law 464 of 24 March 2025 (*"Law 464-2025"*) is passed by Panama's legislative branch. This law is aimed at *"regulating the production, commerce and export of hemp in the Republic of Panama"* (see **1.4 Challenges for Market Participants** (Legal Uncertainty) for further details).
- 4 April 2025 - Decree 6, which regulates Law 242, overturned Executive Decree 121, Executive Decree 61 and Resolution 925. Decree 6 was published by MINSA.

Current Legislative and Regulatory Landscape

As the foregoing list of developments chronicles, at the beginning of 2024, there were two main bodies of law regulating medical cannabis in Panama (ie, Law 242 and Executive Decree 121). Currently, in 2025, there are four main legal documents that govern this yet-to-operate industry in - namely, Law 242, Decree 6 (overturning Executive Decree 121), Law 464-2025, and Law 419 of 1 February 2024 (*"Law 419-2024"*) that *"regulates medicines and medical devices intended for human use"*.

Law 419-2024 was regulated by Executive Decree 27 of 10 May 2024 and reformed all previous laws that regulated medicine for human consumption and the public procurement of medicines, including medical equipment, consumables and devices. Law 419-2024 indicates that medicine that has a valid registration from the pharmacopoeiae of Germany, Argentina, Spain, Greece, Japan, Mexico, China, the EU, the USA and several other territories can expect to receive a Panama Sanitary Registration within ten days of presenting the complete forms and

documents to MINSA. Law 419-2024 should, in theory, reduce the waiting time to obtain a sanitary registration from years to days and - in so doing - also reduce the retail cost of drugs and favour patients.

There are multiple other legal documents that can be applied to medical cannabis, such as:

- Law 28 of 28 October 2014 (*"Law 28-2014"*) and its modifications, also known as the *"Rare Diseases Law"*, which entails a guarantee of treatment to patients of rare or infrequent illness;
- 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' 1961 Single Convention on Narcotic Drugs and the 1971 Convention of Psychotropic Substances; and
- Law 203 of 18 March 2021 (*"Law 203-2021"*), which regulates telehealth.

Although there are many other decrees, resolutions and the like related to this industry in Panama, this section will only concentrate on the most important laws and regulations that relate to medical cannabis: Law 242 and Decree 6. Navigating through newly installed laws that have zero jurisprudence may seem complicated, so it is worth trying to break them down as much as possible to simply matters, as follows.

- Law 242 dictates the four *"W"*s when it comes to medical cannabis in Panama – ie, *"What?"* (products can be sold or purchased), *"When?"* (can it be sold and purchased and for how long), *"Where?"* (can it be sold and purchased and where can it not), and *"Who?"* (can sell or purchase medical cannabis).
- Decree 6 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 be under the impression that the regulation of this industry is lax in Panama. On the contrary, the regulations are aimed at making sure medical cannabis is not used recreationally.

Law 242 – "What?"

The government of 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 of its current forms, with some prohibitions (such as vapes). Further information regarding vapes in **1.4 Challenges for Market Participants** (Product Uncertainty).

Law 242 stipulates that there will be two types of licences: fabrication licences and investigation licences. For the first five years, a maximum of seven fabrication licences will be issued.

Current regulations authorise those with fabrication licences to produce, grow, transform, import, export, re-export and commercialise flowers, edibles, pills, beverages and topically used products containing 1% or more THC - all of which are permissible for medicinal use. The list of illnesses for which they can be prescribed has been eliminated via Decree 6, allowing the final decision to be taken by the medic while treating the patient. Consumption of medical cannabis is limited to patients that hold a valid prescription issued by a trained medic.

It is prohibited to produce or sell:

- beverages that combine alcohol and cannabis - the only exclusion to this regulation applies to beverages that use alcohol as a solvent;
- medical cannabis produced in attention-grabbing shapes – no cannabis products in the shapes of animals, people, fruits, or any other shape that may draw the attention of minors;
- promotion/marketing - none is allowed (neither online, nor via traditional channels), with the only exception being educational material that does not directly promote the sale of any specific product, brand or strain; and
- vapes containing medical cannabis.

Growing and transforming cannabis in Panama has been regulated bearing 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 require Good Manufacturing Practice (GMP) standards and all fabrication licensees must ensure their operations are compliant with modern GMP guidelines.

Several regulatory bodies are entrusted with powers to inspect and verify strict compliance to quality standards. As one government official recently told the author: *"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 and pills.

Executive Decree 121 prohibited the use of any sort of synthetic THC in medical cannabis produced, used or sold in Panama. Decree 6 eliminated the prohibition of using synthetic THC in Panama, paving the way for litigation similar to that found in the USA, Canada and other mature markets concerning the use of Delta-9 and other synthetic psychoactive THC products.

Control

There is plenty of control in Panama. Every plant will be traced from seed to harvest and every product will be inventoried per piece or weight. CCTV systems with face recognition software are an obligation in every room that produces, processes, stores, transports or sells a medical cannabis product, including dispensaries. Under the new regulations, dispensaries are considered as a standard pharmacy and must obtain the same permits and government authorisations as any other pharmacy.

Transporting medical cannabis in Panama will require closed and tagged parcels. Each parcel must have a Global Positioning System (GPS) tracking device and each car that transports the parcels must have a GPS tracking device. A manifesto must accompany each transportation of medical cannabis in Panama and all of the foregoing is subject to review and inspections by the regulatory authorities.

Decree 6 presents minor yet cost-increasing changes in the transportation of medical cannabis. By way of example, prior to Decree 6, containers containing medical cannabis concentrates such as oil could only weigh 4.5 kg at most; Decree 6 changes the maximum weight of each container to 0.5 kg.

Industry employees must be vetted prior to being incorporated on a licensee's payroll.

One of the main benefits of Panama's regulations is the authorisation of licensees to import, export and re-export medical cannabis products. Keeping true to its historical nature as the tax-free crossroads of the world, Panama has the potential to develop – in the short term – into the world's premier tax-free medical cannabis hub, which in turn should facilitate an increase in the amount of products international clients can offer their patients.

International commerce of medical cannabis is tightly controlled and is only approved to be B2B. This means 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 cannabis strains permitted for medical use.

Law 242 – "Who?"

This section will concentrate on three *"Who"*s – namely, who can purchase, who can participate in the industry, and who can sell.

Who can purchase medical cannabis?

In a nutshell, patients and medical establishments (including pharmacies) are permitted to purchase medical cannabis products. 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 (the *"National Registry"*) and validate their prescriptions. Inclusion in the National Registry has been doubled through Decree 6 and, under the new regulations, membership must be renewed every two years. The National Registry will be synchronised and updated constantly. This will guarantee that a patient cannot purchase more medical cannabis than has been prescribed to them.

Prescriptions may be filled by any pharmacy. Pharmacies, hospitals and dispensaries must retain on file a copy of each prescription they fulfilled, either completely or partially. They are obligated to hold the copy on file for five years.

Who can participate in the medical cannabis industry?

i) Doctors

Doctors have been among main benefactors of Decree 6, for the following reasons.

- Training – previously, all licensed doctors were obligated to take an extensive, and yet to be determined, training course before they could be authorised to prescribe cannabis to patients. Decree 6 eliminates this training completely and transfers the decision and responsibility of prescribing medical cannabis to the doctor. Keeping medical decisions within the doctor–patient relationship is something many in the medical industry will applaud.
- Limitations of prescriptions – previously, Executive Decree 121 listed 23 specific illnesses and *"other illnesses that the Medical Cannabis Technical Board will recommend"* as candidates for medical cannabis. Decree 6 simplifies this by stipulating that any doctor or veterinarian may prescribe medical cannabis and eliminates the need for the approval of any medical board.
- Patients' clinical file – Decree 6 simplifies the clinical file doctors keeps for each medical cannabis patient, placing minimums of

what information must be held by the doctor instead of burdening doctor with requirement's that previously only existed for Medical Cannabis.

ii) Licensees

As previously mentioned, holders of fabrication licences are authorised to produce, transform, import, export, re-export, and domestically sell medical cannabis. Meanwhile, holders of investigation licences cannot commercialise medical cannabis in any of its forms; these licensees can only use cannabis for investigative purposes. The investigation licence is aimed at universities and regional investigation centres and laboratories located in Panama. They will certify the quality, THC and CBD content, and other requirements regarding medical cannabis produced in Panama.

Decree 6 now stipulates that to obtain a fabrication licence one must first obtain an *"operations licence"* from MINSA. After obtaining an operations licence, the licensee must obtain *"pharmacy licence"* for retail distribution of medical cannabis. If the licensee intends to proceed with international distribution, a third *"distribution agency licence"* might be necessary. If a licencee intends on growing any medical cannabis plants, several Ministry of Agriculture (*Ministerio de Desarollo Agropecuario*, or *"MIDA"*) licences will be required.

Decree 6 simplifies and deregulates some aspects of the medical cannabis industry in Panama, but manages to cause confusion regarding others. What was previously one *"all inclusive"* licence has transformed into an array of options and licences.

iii) Industry associates

Until recently and irrespective of which type of licence a licensee had, all industry employees were obligated to obtain a special Labour Code Identification Number prior to being employed. Decree 6 eliminates the need for this registration of all employees, thereby lowering onboarding costs.

Complete disclosure of every licensee's corporate structure, shareholders, strategic international partners, and financial capacities - including any changes to these – remains a licensee obligation.

iv) Training entities

Decree 6 eliminates the need for training and education regarding this industry for employees prior to being hired. Whereas Executive Decree 121 mandated the implementation of *"Suppliers Training Registry"* and the obligation for all industry employees to pass lengthy training, Decree 6 takes a more logical approach by eliminating the need to train employees that do not have contact with medical cannabis. No more lengthy medical cannabis training for licensee accountants, auditors, tech support or administrative employees in general.

Who can sell medical cannabis?

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 on 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, once the seven licence winners have been chosen, each of them would have 60 days within which to comply with Executive Decree 121 in respect of security, hygiene, legal paperwork, and GMPs regulating the production, storage and transportation of medicinal products, as well as to request an inspection that will be headed jointly by MINSA and Panama's Ministry of Security (*Ministerio de Seguridad Pública de Panama*, or *"MINSEG"*). Those 60 days have long since passed and, even though the licence winners have passed all inspections, still no licences have been granted.

During the first 24 months of each licence, the licensee will be permitted to import any medical cannabis product from any international supplier, provided the supplier is an authorised medical cannabis seller in their home country. This 24-month period is permitted so that the licensees can promptly attain 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 importing and re-exporting cannabis products through Panama's tax-free commerce zones.

If, after the initial ten years, a fabrication licensee is interested in extending their licence, they must request an extension of their licence.

It is worth mentioning that many of the licensees invested hastily and heavily in complying with the allotted 60-day window in order to comply with the now overturned Executive Decree 121. Most of the licensees have passed multiple inspections by MINSA and MINSEg, and still have not received their license. Decree 6 does not stipulate this 60-day window for the licensee to be ready for inspection; it would be useless, as all inspections have been completed.

Currently, there is no confirmed date for when medical cannabis will be available for sale in Panama, as no licences have been emitted. Based on previous current local trends, in 2024 the author dared to forecast that the first licensees would be operational before the end of that year. As of spring 2025, the author's forecast has not materialised. For further details, please refer to **1.4 Challenges for Market Participants**.

Law 242 – "Where?"

As regards where medical cannabis can be sold in Panama, the answer is simple: anywhere controlled substances can be sold either B2B or by retail.

Pharmacies, hospitals and licensees are approved for selling medical cannabis. Doctors can neither 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.

As regards where cannabis may be grown in Panama, only controlled and pre-approved areas such as greenhouses or warehouses will be authorised to grow cannabis. Cultivation sites must be approved by MIDA and MINSEG.

If a fabrication licensee intends on re-exporting medical cannabis, they must be located in a tax-free zone. The fabrication licensee must also re-export from a pre-approved location.

As for the consumption of medical cannabis in Panama, use is intended to be private. Consumption in public spaces such as roads, parks, restaurants, theatres, clubs and the like are prohibited. At work, if an employer approves the use of medical cannabis on their property and has a designated area in which to do so, then the patient may consume their medical cannabis at work.

Decree 6 – "How?"

Decree 6 mandates the *"How?"*s in terms of Law 242. Most importantly for the local government, Decree 6 determines how to control. In simple terms, Panama's path to control is through software and technology.

Decree 6 regulates how every medical cannabis product will be grown, imported, produced, exported, sold or investigated in Panama. It regulates the operation of the software and subjects licensees to supervision by the relevant regulatory bodies and to a surveillance system. This system is known as the Tracking and Traceability System (the *"System"*). The complexities of those regulatory bodies - as well as how they interact with the System, among themselves, and with licensees - are discussed in **1.2 Regulatory Bodies**.

One major difference between Executive Decree 121 and Decree 6 is that the previous regulations ordered the entire medical cannabis industry in Panama to operate under one System. Which System was a point of contention, producing dozens of options and valid candidates; Decree 6 changes this. As of April 2025, each licensee can contract the System of their preference, provided the System abides by the regulations of Panama and is approved by the Ministry of Health.

1.2 Regulatory Bodies

Law 242 and Decree 6 mandate six regulatory bodies to directly and actively oversee the medical cannabis industry. An additional three regulatory bodies will be involved, albeit in a more passive form.

The six active regulatory bodies are:

- MINSA;
- MIDA;
- MINSEG;
- the Ministry of Commerce (*Ministerio de Comercio e Industrias*, or *"MICI"*)
- the Customs Authority (*Autoridad Nacional de Aduanas*, or *"ADUANA"*) and
- the National Innovation Authority (*Autoridad Nacional de Innovacion Gubernamental*, or *"AIG"*).

The three passive regulatory bodies are:

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

These responsibilities of these regulatory bodies sometimes overlap, as follows.

MINSA

MINSA is the legal governing body supervising and regulating all health-related issues involving humans, including controlled substances. Hospitals, protocols, vaccines, medicines, nurses, pharmacies, medicine approval and Medical Competency Certificates are all encompassed under MINSA's jurisdiction.

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

With regard to medical cannabis, MINSA will specifically be responsible for:

- educating doctors and the general public about the positive and negative effects of medical cannabis;
- issuing the licences;
- supervising all stages of medical cannabis in Panama, including growth, production, importation and sale;
- approving the criteria for 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 exports estimate from each fabrication licensee – under Executive Decree 121, the estimates were yearly, whereas Decree 6 now requires estimates to be done on a three-year basis;
- receiving the quarterly reports from each investigation licensee;
- developing a national programme for investigating medical cannabis and its uses;
- approvals of the National Registry, including the requisites a patient must complete before being added to the National Registry, as well as the issuance of the special identification all patients must have in order to fulfil their prescriptions;
- establishing criteria regarding which patients can apply for inclusion in the National Registry, as well as how to proceed if a patient is not a Panamanian citizen;
- regulating the prescriptions required for the purchase of medical cannabis – prescriptions are only valid for 90 days;
- 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.

Under Executive Decree 121, there were several offices in MINSA that would attend to the medical cannabis industry. The new Decree 6 streamlines the vast majority of MINSA's responsibilities into the remit of two main offices: the office of the Director General of the Ministry of Health and the office of the DGFD.

MINSA, through Decree 6, eliminated the additional burden imposed on the labelling of medical cannabis products. Previously, there were multiple special requirements for labels of medical cannabis products, whereas now these products must abide by the same labelling requirements as all other medical products.

MINSEG

MINSEg, is the legal governing body supervising and regulating all security-related issues such as the police force, the border patrol, the naval services, immigration, illegal drugs, and all things related to firearms. Due to Panama not having an army, navy or air force, MINSEg, fills in those voids on a national level.

In terms of medical cannabis, MINSEg, will specifically be responsible for:

- supervising the correct implementation of the System;
- approving and ensuring that licensees comply with the security standards described in the regulation;
- approving the security protocols that will be 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 will store medical cannabis;
- assisting MINSA and MIDA in their (notified or not) inspections of fabrication licensee's cultivation and storage areas;
- reviewing industry-wide employee background checks, including employees related to the international strategic partner;
- conducting any necessary criminal record checks on industry employees and, in the case of bedridden patients, the person the patient sends to a dispensary or pharmacy to fulfil their prescription;
- validating the approval of the importation of any cannabis seeds or plants into Panama, provided they have already been pre-approved by MIDA;
- approving every exportation of any medical cannabis product produced in Panama, prior to the shipment leaving the country; and
- receiving reports from licensees in the event they become aware of any plans or actions by third parties aimed at the theft, misuse or illegal sale of medical cannabis products.

The security standards imposed on every licensee are stringent and include the following.

- All entries and exits of places where medical 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 specifically monitor the entrance to secure areas of buildings where medical cannabis is stored.
- All cameras must be high resolution so employees, as well as the products they manipulate, can be easily identifiable.
- Cameras must be able to record the facial features of all (eg, patients, visitors, employees) who enter a place where medical cannabis is stored.
- GPS tracking must be in place for all medical cannabis products, including plants.
- All industry security protocols must be updated.
- Legal action must be taken in the event that protocol violations by licensees or patients merit criminal investigations.

When necessary, the coercive enforcement of the Law 242 and Decree 6 will be one of the responsibilities MINSEg, has assumed.

MIDA

MIDA is the legal governing body supervising and regulating all issues related to the national food supply, national agriculture and farm animals. This includes veterinarians and the products they use.

MIDA can and does offer local producers tax incentives, reduced interest rates on farm related loans, and other financial policies aimed at incrementing Panama's consumption of locally grown products, as well as the exportation of locally produced agricultural products.

In terms of medical cannabis, MIDA's main responsibilities will be:

- 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 medical cannabis for veterinarian use;
- authorising each fabrication licensee's cultivation plan (including location), 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;
- executing inspections of medical cannabis production sites to ensure phytosanitary protocols are followed and that licensees have proved MIDA with correct information;
- supervising the quarantine of cannabis plants or seeds, in case it is deemed necessary;
- including cannabis seeds in the National Seed Commission database, which registers all seeds (and their importers) in Panama;
- verifying that the licensees comply with the technical sheet for imported plants or seeds, as well as ensuring no harmful pesticides or chemicals are used by licensees;
- supervising the cultivation of medical cannabis in Panama and ensuring GMP standards are upheld;
- supervising the System;
- approving any products containing cannabis 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.

MICI

MICI is the legal governing body that administers Panama's commercial and overall industrial aspects, including the national and international promotion of Panama-based commerce. It also supervises, approves and regulates all the tax-free commercial zones in the country; these tax-free commercial zones should be thought of as huge bounded warehouses (some of which are the size of smaller cities). The Colón Free Zone, the largest such zone on Panama's Atlantic coast, is the world's second-largest tax-free zone. In 2024, it boasted commercial transactions totalling more than USD25 billion dollars.

MICI now has two specific roles to play in this industry:

- approving the incorporation of a licensee into a tax-free commercial zone; and
- promoting medical cannabis products that originate in Panama or take advantage of Panama's strategic geographic position and tax incentives, using the country as the logistical hub it is.

Decree 6 specifically indicates that only fabrication licensees that are established in a tax-free zone can re-export medical cannabis products.

AIG

The AIG has one specific role to play in the medical cannabis industry: ensuring the System and the National Registry is secure and online. This

includes data security related to patient confidentiality and rights, System and National Registry access, and maintenance.

During the reign of Executive Decree 121, the AIG had a much more *"hands on"* approach. It was in charge of creating or contracting the System and working on its smooth implementation in Panama. In the three years between the publication of Executive Decree 121 and the publication of its replacement, Decree 6, the AIG failed to accomplish its specified goals.

By 2025, three years after the publication of Executive Decree 121, no System had been created, purchased or contracted. Nor was there any sign of the AIG moving forward on anything related to the System. Decree 6 took all control over decisions related to the System from the AIG and transferred it to the licensees - all of which have declared their intent to use established software that is currently in use in other countries.

SUPERBANCOS, SUPERSEGUROS and SSNF

These three more passive governing bodies will oversee the medical cannabis industry just as they oversee almost all national industries. There is one exception, however; fabrication licensees can expect additional scrutiny, at least initially.

SUPERBANCOS will be influential in deciding how much access the medical cannabis industry will have to the banking industry, including national accounts, international accounts, financing, and payroll and credit card processing. Even though a year has passed since the previous instalment of this guide, SUPERBANCOS has yet to clarify its policy on the medical cannabis industry. As such, licensees have been left guessing as to how they will charge patients and pay employees and suppliers once they start operations.

SUPERSEGUROS will be important in the regulating of private medical insurance companies and their coverage of medical cannabis. The latter is currently unclear.

The SSNF will oversee the adherence of fabrication licensees to local compliance and KYC norms. However, the SSNF will not play a specific role with regard to medical cannabis.

1.3 Self-Regulatory Authorities

Given that Panama's medical cannabis industry is still on paper and not yet operational, self-regulatory bodies as such are yet to take on any active powers in the industry. The closest thing to self-regulatory bodies in Panama are several organisations that have supported patients' claims to access medical cannabis, assisted in the creation and implementation of Law 242 and Executive Decree 121, and remain active in promoting medical cannabis in Panama.

Involvement of these groups in the creation of Decree 6 was neither requested nor permitted; Decree 6 was an executive decision that consulted none of these or other patient- or industry-related groups. 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 (Lights Foundation)

Founded by Panamanian-born epilepsy specialists renowned as worldwide 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 Lights 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 successful outcomes for their patients.

The Lights Foundation was the pioneer in medical cannabis legislation in Panama and instrumental in getting legislation finally approved. It donated doctors' time to meet with governmental authorities, elected officials, lawyers, and - of course - patients.

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

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

ANPEMUFA

A few years after the Lights Foundation started pressuring local authorities to approve legislation related to medical cannabis, the National Association of Multiple Sclerosis and Neuromyelitis Optica Patients (*Asociación Nacional de Personas con Esclerosis Múltiple, Familiares y Amigos*, or *"ANPEMUFA"*) joined the cause and has been an active player ever since. As a non-profit organisation, ANPEMUFA states its primary goal as *"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 the need for regulating medical cannabis to uninformed doctors, lawyers and government officials. More importantly, ANPEMUFA provides living proof that many patients report better and faster results using cannabis than using certain pharmaceutical products.

If the Lights Foundation is constituted mainly by renowned medics looking at options to help their patients, ANPEMUFA is - on the contrary - constituted mainly by vocal patients looking at options to help their medics legally prescribe medical cannabis. ANPEMUFA is expected to remain involved in the industry once it is operational with regard to verifying quality, supply and pricing.

National Lawyers Union

Panama does not have a Bar Association as in other countries; the closest thing is the National Lawyers Union (*Colegio Nacional de Abogados*, or CNA), which is a non-profit union of lawyers. The CNA is commonly called on for advice by law-makers and private citizens and assists in fine-tuning legislations and forecasting difficulties in applying laws. Any work done by a lawyer for the CNA is pro bono, non-political, and should have altruistic intentions. The CNA operates through commissions and each commission has its own board of directors that report directly to 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 - namely, to assist patients in legally

obtaining access to the medicines that their doctors prescribe (especially medicines that are controlled substances) and to ensure local laws that assist patients' rights are duly enforced.

The CNA's Commission for Medicinal Controlled Substances has held multiple meetings with patients, doctors, law-makers and industry leaders. In doing so, it serves as a neutral meeting ground to present contrary opinions, discuss each perspective and reach common ground.

The CNA should remain active in their support for patients, patient rights, and doctors throughout the next few years. It is also expected to propose potential beneficial modifications to the current regulations.

Medical Cannabis Guild

This organisation is agreed upon, but yet to be formed. The seven fabrication licensees have agreed on forming a guild that aims to guarantee three things: quality, supply and compliance.

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

Licensees cannot market their products in Panama and are only allowed to promote medical cannabis through the education of the population, including the doctors. For this reason, a particular effort is being placed on promptly training local doctors and reducing the historical stigma that exists in Panama in relation to cannabis.

If negative media is constantly circulating in Panama regarding the misuse of medical cannabis, or mistakes by the newly allotted licensees, then doctors will shy away from prescribing it. The licensees' plan to mitigate these risks is to create a guild that shares administrative responsibilities, meets regularly, and ensures and verifies that quality standards are not lowered and that all seven licensees adhere to all laws and regulations.

1.4 Challenges for Market Participants

The most notable challenges that market participants currently face, and will remain facing in 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 about 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. That meant that no vapes can be legally sold in Panama, nor can they be used in public spaces.

Law 315 did not differentiate between nicotine-containing products and products that do not contain nicotine. No distinction was made between a vape device designed for tobacco and one designed for cannabis.

On 11 June 2024, the Supreme Court of Panama declared Law 315 to be unconstitutional. By doing so, the law was nullified. Since June 2024, one can find nicotine and non-nicotine vapes quite easily at gas stations, supermarkets and convenience stores, as well as through delivery services; they all offer a wide array of vape options. Vapes are available at low prices in many flavours and even more colours.

Even though vapes that do not contain cannabis or CBD are available everywhere in Panama, Decree 6 strictly prohibits the sale of medical cannabis vapes. Indeed, it does so twice. The legal basis for permitting the sale of recreational nicotine vapes in Panama, while at the same time prohibiting the sale of medical cannabis vapes in Panama, will be surely challenged in the Supreme Court using similar arguments as the 11 June 2024 ruling.

All of the foregoing is important when considering two things:

- Panama boasts one of the lowest rates of tobacco consumption worldwide, hovering at around 7% of the population; and
- any smoking, especially 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% and dropping fast. Smoking is prohibited in restaurants, casinos, concerts and public spaces in Panama. All this means one can visit Panama for a full week and probably only see one or two people per day smoking cigarettes.

Panamanians are 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 in any place, will immediately draw the attention of passers-by. Given that patients have enough to deal with, adding more stigma to their treatment is not beneficial.

The solution for many patients is medical cannabis vapes. They enable immediate discreet dosage of medical cannabis, with practically no smell, and thereby help to maintain patient privacy.

So, what happens if a specialist prescribes that medical cannabis should be consumed via vape pen instead of in edible or smokable form? This uncertainty is probably going to make its way through the court system in the next few months.

Banking Uncertainty

Panama's currency is the balboa, which is pegged at par (1:1) to the US dollar. The Constitution of Panama 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, it is done in US currency.

Panama has 4 *"general licence"* banks/first-tier 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 Panama's banks depend on their banking correspondents in the USA for access to international markets and the SWIFT (Society for Worldwide Interbank Financial Telecommunication) wire system. If the correspondent bank in the USA is unwilling to open an account for a dispensary in California or Bos-

ton, it is far less willing to allow a Panamanian bank to use it 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; therefore, the same government that charges the licensees for their licence fee is the same government that owns these two banks. That being said, the uncertainty here concerns 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 will do so.

Running a cash-only medical cannabis enterprise in Panama would be 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 less than 1.5% THC) 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 approximately only USD600 per month, one can understand the need for public or private medical insurance to cover this medication cost.

Although Law 28-2014 mandates that *"public and private insurance companies have the responsibility to attend"* to patients who have rare diseases, 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, while Decree 121 allows the donation of medical cannabis to patients via hospitals, Decree 6 specifically prohibits this.

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 but cannot sustain the monthly costs of medication.

Bureaucratic Uncertainty

Yet another year has passed and the bureaucratic uncertainty has increased. As noted in **1.1 Primary Laws & Regulations**, the medical cannabis legislation in Panama comprises multiple laws and regulations – many of which overlap on occasion. This causes uncertainty and creates the risk of incompliance due to error rather than through ill will.

Even though the medical cannabis legislation comprises hundreds of pages of laws and regulations and dates back to October 2021 (and its former regulations, dating back to September 2022, were in force for almost three years before being overruled and completely modified in April 2025 by Decree 6), not a single medical cannabis licence has been issued and not a single prescription has been filled. During multiple meetings with MINSA, licensees have been left wondering what the future holds and what will happen to their multimillion-dollar investments.

The previous government of Panama, the Cortizo government, passed Law 242 and Executive Decree 121 but did not implement either. The current government of Panama, the Mulino government, has been in power for 11 months, has held multiple meetings with the licensees and has created new regulations via Decree 6 - yet

still has not permitted a single patient to fulfil a single prescription.

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

The training of the police force in respect of medical cannabis has not been completed, prompting questions as to what would happen were a patient stopped during a routine traffic stop and medical cannabis found in their possession. Panama has a very strict policy regarding narcotics and leniency is seldom shown. Educating the police force and changing their perspective to one of understanding that a patient is not the same as a recreational user will be paramount to eliminating the current stigma and preventing discomfort among patients.

Calendar Uncertainty

Based on previous uncertainties, it seems that – even if all seven licences were 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); and
- lease commercial space for dispensaries.

All the foregoing activities 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. Even if licensees were to face no other issues regarding banking in Panama, SUPERBANCOS and the SSNF require a formal business plan to be delivered to the bank before the licensee's bank account can be opened. Although local authorities are working diligently to cut delay times, no business can plan without a calendar and clear dates on hand.

Panama's Law 242 obligated every licence applicant to include a reputable and experienced international partner in their corporate structure. The vast majority of these international partners are US- or Canada-based companies - some of which are listed on the US stock market. Panama has bilateral treaties with the USA regarding protecting American investments in Panama. Those multimillion-dollar investments appear at risk and far from protected.

Panama would be wise to prevent further adverse situations with the U.S.A. and other international partners, by reading daily news one can notice that, under the current Mulino and Trump administrations, Panama -U.S.A. relations are not at their prime.

Legal Uncertainty

On 24 May 2025, Panama passed its *"Hemp Law"*, Law 464-2025 – a short, seven-page law that is still unregulated but has caused much uncertainty in the market. Medical cannabis licensees in Panama fear their investments are at risk based on the current ongoing litigation concerning hemp and medical cannabis in other markets. Adding yet more governmental confusion to a hyper-regulated market that has yet to launch after years of private investments and modified regulations is far from the ideal situation in which to attract further investments into Panama.

1.5 Legal Risks

It said that a smooth sea never made a skilled sailor. In that case, Panama may need some life jackets, as the water ahead appears turbulent.

Administrative Compliance

Panama's multiple and overlapping cannabis regulations are reminiscent of when the Foreign Account Tax Compliance Act (FATCA) regulations passed in the USA in 2010 were imposed on Panama and its banking sector a few years later. Overnight, the overwhelming majority of Panamanian banks decided to unilaterally stop working with American citizens. Accounts were closed and new accounts were rejected. 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.

The reason was not based on anti-American sentiment nor 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, despite wanting to comply, did not know how to and feared that an omission due to lack of clarity would entail fines or – even worse – accusations that the bank was assisting US citizens to evade US laws.

A simple solution was swiftly devised. The solution was to cease all work with American citizens unless the transactions were financially large enough to merit such a risk.

Today, the cannabis industry in Panama is very similar. There is a common fear among all licence holders. Although they all claim to be investing heavily in compliance and want to ensure complete adherence to the local norms and regulations, licensees all fear that - owing to the volume, overlap and complexity of the laws – they will falter on some technicality and get fined or even prosecuted. Law 242 and Decree 6 describe a long list of monetary sanctions that can be imposed on licensees in the event they falter – although this also leaves the door open for criminal investigations.

Changing regulations without any prior notice does not help eliminate the compliance risk.

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, whereas now you they are presumed innocent until proven guilty.

The system may have changed but not necessarily the people in it. Many prosecutors come from the old system, have been trained in that system, worked inside that system for 20 years, and today still hold positions of importance in the new system. One of the downfalls of the current criminal system is that prosecutors and/or district attorneys bear no responsibility for their actions, meaning that a prosecutor can present frivolous charges against a person, start an investigation that takes years, take an undocumented case to court and lose that case in an overwhelming manner, then go to work the next day as though nothing happened.

This is because there are no ramifications for the prosecutor, which is worrisome because 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 the medical cannabis industry because, 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 the licensee triumphs in court. Training prosecutors should be as important as training industry employees, as both can have an adverse effect on the industry.

AML Regulations

Panama has an abundance of AML regulations. Anyone who considers they can walk into a bank in Panama with USD20,000 in cash and open a bank account in less than a month has obviously not been to Panama and is uninformed.

Most of Panama's AML regulations are aimed at controlling the flow of cash in and through Panama. The Criminal Code describes 37 different criminal offences that can lead to money laundering – all of which carry a prison sentence of between five and 12 years.

Every company in Panama that receives more than 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 be reported to the same entity.

Obligating the cannabis industry to operate without banks will be counterproductive. How can Panama enforce all the positive and well-intended AML regulations while obligating the licensees to operate using only 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.

AML regulations and their compliance will be difficult if licensees cannot use digital cash services, credit cards and banks in general. Non-compliance with AML 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

There are three regulatory bodies that are entrusted with enforcing compliance and applying penalties 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 - namely, penalties for minor infractions, penalties for major infractions, and penalties for severe infractions.

Minor infractions

MINSA may fine a licensee anywhere between USD500 and USD5,000 per each minor infraction. There are currently 12 minor infractions, including:

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

Major infractions

MINSA may fine a licensee anywhere between USD5,001and USD15,000 per 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 prescription information being fed into the System;
- transporting medical cannabis without completing the established protocols;
- failure to inform 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 USD$25,000 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 in reports or in the System;
- repeating major infractions; and
- interfering with MINSA's inspections.

The final penalty amount to be imposed is decided by MINSA after considering:

- the damage caused by the infraction;
- the benefits obtained by the infraction;
- whether the infraction was intentional or negligence-based; and
- whether or not the licensee has previously committed the same infraction.

MIDA

MIDA can impose penalties on licensees - specifically, with regard to the cultivation division of their operation. MIDA's powers only encompass the agricultural aspect of medical cannabis, however. As such, MIDA is in charge of ensuring that:

- no harmful chemicals are used;
- only approved seeds are used;
- agricultural GMPs are strictly followed; and
- the complete cultivation process – from seed to flower – is supervised.

Penalties can be imposed by MIDA but there is no distinction between the penalties MIDA applies to fruits and vegetables grown in Panama and the penalties it applies to medical cannabis.

MINSEG/Public Prosecutor

While MINSA and MIDA are entrusted with applying monetary penalties (and possibly licence suspensions) in the case of lax compliance by licensees, MINSEg, will oversee 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 but, given that this is also a criminal offence in Panama,

the offender may incur potential personal liberty restrictions in addition to a monetary fine.

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, with the sole condition that supplier is licensed to sell medical cannabis in their home country. The same applies with regard to selling medical cannabis from Panama to other countries – local licensees are free to sell to any country in the world, as long as 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 concerns how the responsibilities of MINSA, MIDA, MINSEg, and the System overlap in some cases. This overlap can lead to repetitive reporting, an increase in paperwork, and confusion over to whom a licensee must report. By way of example, when an industry employee is hired at any level, the potential employee must first obtain a Labour Code Identification Number from the Ministry of Labour 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 to MINSA in the System. 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 continue to affect access to medical cannabis in Panama, as follows. All should have been resolved prior to - or, at the latest, during - 2024.

The System Is Not Operational

The System is not yet operational. In 2024, the System was going to be implemented by the AIG; however, this recently changed, sending all licensees hunting for a System that they believe would be approved by MINSA and MINSEg, (even though the exact standards of the System have yet to be established).

The National Registry, a module of the System that will log all patients' use of medical cannabisis, is also not yet operational – meaning there are no approved medical cannabis patients. This indicates that, even if the product were available, it would still be illegal to dispense.

In 2025, the National Registry was renamed - through Decree 6 – as *Programa Nacional para el Estudio y Uso Medicinal del Cannabis y sus Derivados* (PNEUCAM), which translates as *"National Programme for the Study and Medicinal Use of Cannabis and Its Derivatives"*. New name, same situation: still not online.

Insurance Coverage

A significant number of patients will receive a prescription that will be too expensive for them

to fulfill 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. In theory, national and private insurance companies must both cover medical cannabis; however, it is unclear how they will do so while cannabis remains under Schedule I.

Prescription Fulfilment by Third Parties

In case of bedridden patients, patients with limited mobility, or patients in palliative care, if a doctor prescribes medical cannabis, the patient cannot go to a pharmacy or dispensary to get the prescription fulfilled. The patient can send a person to do this for them, but that person has to be registered in the National Registry and must have been approved by MINSEg, after presenting a clean criminal record, which can all be troublesome.

Decree 6 specifies how patients who are under professional care – or those who are still minors - can obtain their prescriptions. Decree 6 leaves a gap when it comes to situations in which the patient is an elderly person who is not under professional care but instead lives at home with their family. Their family members must obtain a court order to be authorised to fulfil a medical cannabis prescription. This complicates an already complicated situation.

3.2 Non-Controlled Cannabinoids in Food

Until April 2025, Panama's regulations only mentioned one non-controlled cannabinoid – namely, CBD. There was no limitation on edibles containing CBD, as long the final product did not contain 1% or more THC. All other medical cannabis products were strictly prohibited from being used in food intended for human consumption.

Decree 6 presents a major shift in this policy. It has completely eliminated the prohibition of using medical cannabis as an ingredient in products registered as food for human consumption.

3.3 Decriminalisation

There is no current legal action or legislative appetite to decriminalise cannabis in Panama, much less promote its recreational use. If and when a rescheduling in the classification of cannabis is approved by the US Drug Enforcement Agency, then Panama may perhaps feel enticed to follow suit. At the moment, nothing indicates any intention on Panama's part to decriminalise the use of cannabis products containing more than 1% THC.

POLAND

Law and Practice

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Contents

Monika Duszyńska Law for Lifesciences is a boutique law firm focusing on the life sciences sector, providing services for pharmaceuticals companies and manufacturers of medical devices. Three senior lawyers offer daily support in commercial and regulatory matters, advising on intellectual property (licences and purchases of registration dossiers, R&D agreements), contracts with healthcare professionals, patient organisations, contract manufacturers, suppliers, grants and donations. The firm assesses permitted relationships with HCPs, and provides advice on or audits marketing studies and activities. It counsels on regulatory affairs, pharmaceuticals advertising, clinical trials and reimbursement, as well as on the distribution and manufacturing of medicines and medical devices, including the drafting of contracts.

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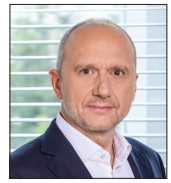

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1. Regulatory Framework

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 medical cannabis typically contains higher levels of THC, whereas CBD is primarily derived from hemp. Both medical cannabis and hemp are different varieties of the same species — 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 LPNA 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 varieties 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 cannabis. 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 at present 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**). However, the Ministry of Health has prepared a draft amendment to the LPNA which provides for the explicit prohibition of the sale of CBD products for smoking or inhalation. According to the amendment, fibre hemp may only be used for food, cosmetic and industrial purposes. The proposed changes triggered strong criticism from Poland's hemp industry, which is concerned about the prohibition – and related criminalisation – of selling products with CBD for smoking or inhalation. The LPNA amendment has also been widely criticised for its alleged lack of compliance with The Single Convention on Narcotic Drugs of 1961.

The amendment is currently in the early stages of Polish legislative procedure, with first round of public consultations concluded.

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 Manu-

facturing 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 Manufacturing 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, only varieties of cannabis other than hemp could be cultivated for research purposes, and 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 PLN60 and PLN80 (EUR14-EUR18) 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 (however, according to the draft amendment to the LPNA, these might become prohibited).

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 (Microsoft Word – EstMar25). These requirements are regularly updated, and in Poland they also set thresholds for annual imports of the narcotic drugs listed there.

In general, the ChPI will issue one-off import licences for certain narcotic drugs on condition that the annual limit for Poland for the drug is not exceeded. The annual limit in 2025 for importing medical cannabis is 20 million grams (50 grams for cannabis resin). The limit for cannabis for Poland has been significantly increased from 6 million grams in 2024.

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.

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 associa-

tion 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 (12 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.
- The pending amendment to the LPNA which will exclude CBD products intended for smoking or inhalation from legal trade, if adopted, may adversely affect the profitability of businesses operating in this sector.

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 can-

nabis 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), subject, nevertheless, to special regulatory permits. 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. The considered amendment to the LPNA aimed at prohibiting the sale of CBD products for smoking and inhalation should also be noted.

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, pharmaceutical inspectors, etc) sometimes extend the procedures or cause previously unforeseen legal complications.
- Changing legislation, which is still in the early stages of development 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 (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 activi-

ties, 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 (note, however, the amendment to the LPNA under consideration), 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 at which dosages. Each physician should decide individually on whether to prescribe medical cannabis in given circumstances, bearing personal liability. However, 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. The regulations were tightened again by the MoH on 29 October 2024, with access to prescriptions for medical cannabis restricted. Since 7 November 2024, prescriptions for certain controlled substances – such as medical cannabis, fentanyl, morphine, and oxycodone – can only be issued after an in-person examination by a physician. This change effectively ends the practice of prescribing these medications via teleconsultation, particularly impacting private medical facilities. An exception exists for patients under primary healthcare (POZ) within the public system, where follow-up prescriptions can still be issued remotely, provided the initial consultation was conducted in person. The regulation aims to enhance oversight of controlled-substance prescriptions and mitigate risks associated with their misuse.

In 2024, more than 7.8 tonnes of medical cannabis were dispensed from Polish pharmacies. This is a huge increase compared to previous years. Compared to 2023, pharmacists dispensed as much as 4.6 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 – 33,219 grams;
- 2020 – 94,038 grams;
- 2021 – 427,017 grams;
- 2022 – 1,167,752 grams;
- 2023 – 4,658,759 grams; and
- 2024 – 7,800,000 grams.

The amendment to the LPNA of May 2022 (see **1.4 Challenges for Market Participants**) 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. Currently, the parliamentary panel is leaning towards the solution to decriminalise the possession of 15 grams of dried or one bush of cannabis. However, it is still difficult to predict when and if a bill to this effect will be presented and subject to legislative process.

SWITZERLAND

Law and Practice

Contributed by:
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Contents

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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, plant-based smoking products and electronic cigarettes, 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 will 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 (CBD), and which are not subject to the NarcA and so are more freely marketable.

Owing 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 subject.

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 Switzerland Trends and Developmentsarticle in this guide.

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 pro-

vide 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 1 May 2025, 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, plant-based smoking products, electronic cigarettes, 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.

Products offered as chemicals

Cannabinoid-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 *"scented oil"* is sold in a cartridge for e-cigarettes, in which case the TapPA and the TapPO apply 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).

Products 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.

Products 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 document-

ed 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.

Products sold as utility articles (eg, tobacco- and nicotine-free substitutes for snus)

Some specialty retailers offer non-smokable tobacco substitutes infused with CBD and other cannabinoids (for example, snus replacements). These products 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 or other cannabinoids to such products in pharmacologically effective doses. This also applies to any claims that imply it is a therapeutic product. However, this rule is superseded by the requirements of the Cassis De Dijon principle, according to which cannabinoid-containing utility articles 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, cannabinoid-containing utility articles may currently be lawfully marketed in Switzerland.

Refill containers for e-cigarettes containing cannabinoids 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.

Products offered as plant-based smoking products, as well as electronic cigarettes and their refill materials (liquids)

A new Tobacco Products Act (TabPA) and its Ordinance (TabPO) came into force on 1 October 2024, replacing the old food-law requirements for tobacco. Under this framework, both smoked plant-based goods and e-cigarettes (plus their refill liquids) fall squarely under tobacco-product regulation. Notably, hemp containing less than 1% total THC is now classified as non-psychoactive and may be marketed as a plant-based

smoking product; adding CBD to e-liquids is likewise permitted.

Manufacturers and importers must continue to perform self-checks and are required to file digital product notifications – along with supporting documentation – with the FOPH within one year of market placement via an online platform, www.tabacinfo.ch (Tabacinfo).

E-liquid refill containers must satisfy both the TabPO's labelling and safety provisions and the Chemicals Ordinance's requirements, including automatic registration in the Chemicals Register through Tabacinfo. Any promotional claims that mislead consumers about health effects are expressly forbidden, with enforcement handled by cantonal authorities.

Because even low-THC hemp products can impair driving, a specific warning requirement has been introduced. Consumers may also face legal risks abroad due to stricter THC limits elsewhere. The FOPH therefore encourages suppliers to inform users of these potential repercussions.

Products 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 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 at 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 for 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

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"*, issued jointly 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 (TPA);
- the Foodstuffs Act (FSA);
- the Ordinance on Foodstuffs and Utility Articles;
- the Chemicals Ordinance (ChemO); 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, the cannabis trials for recreational purposes, as well as a soon-to-be-published draft legislation for full legalisation of cannabis 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 Switzerland Trends and Developments article.

Importers of cannabis products with a THC content of 1% and below must be able to provide proof in the form of a batch-specific analytical certificate for the delivery in question, issued by

a laboratory accredited to ISO/IEC 17025 or by a GMP laboratory.

3. Legal and Regulatory Developments

3.1 Access to Medical Cannabis

The main elements affecting medical cannabis in Switzerland are described in the accompanying Switzerland Trends and Developments article, 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 EC is required. This applies to extracts of Cannabis sativa L that contain cannabinoids such as 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 EC. If the application is granted, foodstuff containing CBD can also be placed on the Swiss market. Hence, the authorisation from the EC 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 EC 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 EC, 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 Switzerland Trends and Developments article.

Trends and Developments

Contributed by:
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Introduction

The current regulatory environment for cannabinoid-based products in Switzerland remains uncertain due to vague legislative requirements and heterogeneous, sometimes arbitrary, enforcement. However, the recent cannabidiol (CBD) boom and the growing medical-cannabis market – fuelled by liberalised recreational examples from Canada, Uruguay and certain US states – have raised public awareness of the cannabis plant's benefits. Together with new legislative proposals, this creates an opportunity for Switzerland to become a role model for an innovative, pragmatic, safe and comprehensively regulated cannabis market.

Medical Cannabis Reform

A new status quo is emerging

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 special permit for spastic convulsions in multiple sclerosis patients. For any other indication, an exception permit by the Federal Office of Public Health (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 which 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, *"formula magistralis"* which is how most cannabis is prescribed in Switzerland today.

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. Every doctor in Switzerland can prescribe medical cannabis.

- For the first few years after the coming into force of the amendment in August 2022, doctors must regularly report to the FOPH a whole range of data regarding the relevant therapies. The data collection should serve as a basis for the scientific evaluation of the revision as well as guidance for the responsible cantonal enforcement authorities and the 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.

A study conducted by the Institute for Addiction and Health Research on behalf of the FOPH, the findings of which were published in February 2020, concluded that, for over 96% of the participants questioned, the consumption of medical cannabis has led to an improvement of their symptoms. Half of the participants reported an *"extreme improvement"*. Many participants with cannabinoid prescriptions reported reducing or stopping other medications.

The number of patients who are legally prescribed medical cannabis in Switzerland is growing rapidly. The FOPH estimates that over 110,000 patients are consuming *"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. As more doctors receive training in medical cannabis and an increasing number of pharmacies are authorised to dispense it, demand for a fully regulated supply chain continues to accelerate.

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 studies was able to draw a definitive conclusion on the efficacy of medical cannabis). As a result, the efficacy, usefulness and cost-effectiveness

(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, first and foremost, is facilitated access to medical cannabis for patients – will hinge on whether these patients will be able to obtain reliable, quality-controlled, safe and affordable, ideally reimbursed medical cannabis products.

Cannabis Legalisation: the Recreational Pilot Trials

Cannabis is the most frequently consumed illegal substance in Switzerland. Around one third of people aged 15 years and over have already had experience with the drug. According to the FOPH, 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 15–64 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 a 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.
- The 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 if 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 were published in a report titled *"Analysis and Results from Cannabis Pilot Trials in Swiss Cities – Part I, 2023 to Mid-2024"* on the FOPH's website. By June 2024, the seven trials mentioned above enrolled about 7,000 adults. Preliminary findings show non-profit models focus on prevention and a neutral atmosphere, while for-profit outlets use vibrant branding and active social media to promote products.

All trials have run smoothly so far, with strong collaboration among authorities, police and sales partners, and no public order issues or leakage to the illegal market. Early observations suggest a modest shift towards lower-risk consumption methods such as vaporisers, and a destigmatising effect in health-oriented settings. In the Basel-Stadt *"Weed Care"* trial, 94% of participants were satisfied with pharmacy service; however, over 30% were unhappy with product quality and 49% also sought illegal sources, while nearly 70% requested edibles, 59% THC oil and 43% e-liquids. Participant samples were more educated than the general population and predominantly male, with recruitment and health-screening practices varying between trials. Sales-staff training – delivered via two-day face-to-face workshops or combined online modules – was universally provided and well received, though pharmacy models emphasised clinical advice and speciality shops prioritised product knowledge.

Packaging ranged from discreet, unbranded formats in pharmacy settings to colourful, logo-driven designs in some speciality shops, reflecting divergent approaches to complying with advertising bans. Economic tensions emerged between consumer protection imperatives and for-profit models, as some private trials pressured for broader recruitment to meet sales targets, potentially conflicting with safety protocols. Further user-centred data collection and longer-term analysis will be essential to align consumer preferences – such as broader product selection and quality improvements – with governance and youth-protection objectives as Switzerland develops its evidence-based cannabis regulation.

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 will incorporate the above-mentioned initial feedback from the published report and that provide a wide product range and reliably supply high-quality products will be successful and 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 publicised in most mainstream media. First experiences by the public as well as 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 that was signed by a total of 40 members of the Swiss National Council, in an attempt to force a new and comprehensive regulation for the cultivation, production, trade and consumption of cannabis containing THC in line with the recommendations of the Federal Commission on Narcotic Drugs (EKSF). The main objectives of the initiative are:

- the control of production and trade by governmental bodies;
- the separation of the medical and the non-medical markets;
- the drying up of the 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 has 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, 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 that 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. On 14 February 2025, the Commission issued a press release presenting the principal provisions of a preliminary draft federal law on cannabis products – adopted by a vote of 14 to nine, with two abstentions – with the following key elements.

- Adults residing in Switzerland shall be permitted to cultivate, purchase, possess and consume cannabis. The rules on protection against passive smoking shall apply.
- Any supply or sale of cannabis to minors is prohibited.
- For personal supply, a maximum of three female plants in flowering stage may be cultivated. Maximum quantities for possession in private and public spaces shall apply.
- Profit-oriented, commercial production shall be permitted. Producers and manufacturers must meet strict requirements to receive a federal licence. Importation or exportation may also be authorised for specific purposes.
- Strict product-quality requirements shall apply. Cannabis products must be neutral, be without branding elements, carry health warnings and package leaflets, and be packaged in child-resistant containers.
- Sales shall be subject to a state monopoly. Cannabis products may be purchased at a limited number of licensed retail outlets and online from a single licensed distributor. Sales must not be profit-oriented; any profits are to be invested in prevention, harm reduction and addiction support. The cantons will grant retail licences; the Federal Government may grant the licence for online trade. The range must also include non-smokable products and those with low THC content to enable lower-risk consumption.
- In accordance with the ban on vertical integration, organisations shall not be allowed to produce and sell cannabis simultaneously.
- The entire supply chain shall be monitored by a digital tracking system.
- A comprehensive advertising ban shall apply to cannabis products, as well as to seeds, cuttings and related accessories.
- Cannabis products shall be subject to a steering levy to restrict consumption and steer it towards lower-risk forms. The levy shall depend on THC content and the form of consumption. The revenues from the steering levy shall be redistributed via health insurance, after deducting the Confederation's general enforcement costs. Cantons may impose a supervisory levy and fees.
- Cantons shall continue to play a key role in enforcement, in line with current practice, with a particular focus on youth in education, counselling and prevention. They shall control product quality and sales and carry out test purchases.
- Persons who evade the legal market shall face tougher penalties than at present.
- Zero tolerance in road traffic remains unchanged: anyone proven to have consumed cannabis shall be considered unfit to drive.

Switzerland is now poised to become the first European country to legalise recreational cannabis. The proposed framework set out above centres on a tightly regulated, pilot-based approach: sales would be channelled through a single government-run online portal alongside non-profit retail outlets, and all cultivation, testing and distribution must meet strict quality standards. This approach guarantees product

purity, strengthens consumer protections, and allows authorities to monitor health and social impacts.

However, the proposed model with a single online provider poses certain challenges in terms of competitiveness. To effectively curb the illegal market, price, availability and product selection must be attractive enough to offer consumers real added value – something the initial results of the pilot projects already suggest. Experience from other countries shows that overly restrictive regulations, excessive taxation and the lack of flexible pricing policies cannot eliminate the illicit market. A single online provider could lack the competitive pressure that encourages an attractive offering. In particular, the requirement that retail outlets must not be profit-oriented poses the risk of losing market pressure and incentives for innovation. Without the opportunity to generate economic profits, operators will find it difficult to invest in the necessary infrastructure and distribution – leaving all profits to the upper levels of the value chain. An example from Canada illustrates that state monopolies that do not allow market-standard profit margins are often not competitive enough to effectively combat the black market, as they lead to limited availability.

Nevertheless, the latest political developments surrounding cannabis legislation are proof that the urgency to comprehensively regulate this growing market has manifested itself in the general public consciousness. The limited view of cannabis as an allegedly harmful narcotic drug and the stigmatisation of its consumers is making way for the recognition of its significant medical potential, as well as the promising economic growth that 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, the liberalisation of cannabis for medical purposes and a soon-to-be-published draft bill for full legalisation of cannabis for recreational purposes, Switzerland is in the pole position to expand its leading role in Europe as an innovative, responsible and attractive hub for cannabis entrepreneurs all along the value chain.

UK

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 specialisms 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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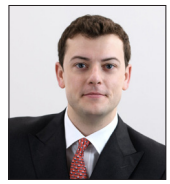
Cameron Crowe KC is recognised as a leading barrister in the fields of consumer law, health and safety, life sciences, and business and regulatory crime by the independent legal directories. He advises and represents national regulators in the fields of product safety, health and safety, and food safety, as well as businesses facing regulatory investigation or criminal proceedings in those areas. He regularly lectures enforcers on their powers and was a member of List A on the Unified List of Specialist Regulatory Advocates until his recent appointment to King's Counsel. He is also a Recorder of the Crown Court.



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Introduction

Despite increased market awareness of medical cannabis and cannabidiol (CBD) products, the UK remains restrictive in its approach to their 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 (the *"MDR 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 specific 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 taken steps in recent years 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 Regulation 2 of the MDR 2001 to introduce a new category of product known as *"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 attributed 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.

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 with-

in 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 *"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 April 2025 no CBD product has received full authorisation. The Food Standards Agency has previously indicated that it is waiting to progress any applications to full authorisation

until legislative amendments have been 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 suffered from significant unexplained delays, which have been further complicated by the election of a new government in July 2024.

Nonetheless, the industry has reason to be hopeful. As discussed further below, in November 2024 the Food Standards Agency released a roadmap for future regulation of CBD products. There is good reason to think that, once the regulatory structure has been finalised (and expectations are communicated to manufacturers), 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 which has garnered significant government interest and discussion but as yet remains unresolved.

The most often cited legislation in this context is Regulation 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 *"component part"*? Does it depend on the way in which the product is packaged? If so, would a blister pack of ten tablets be counted as a single component part or ten 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 indicated that the definition of *"exempt product"* would be further tightened to exclude products which were 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.

When the government accepted this recommendation, two things appeared likely. First, the definition of *"exempt product"* in Regulation 2 of the MDR 2001 would be amended so as to exclude consumer CBD products. Second, a specific 50 microgram limit for THC would be placed on consumer CBD products (which it was assumed must be by way of separate legislation).

However, the election of a new Labour government in July 2024 introduced uncertainty, as it was unclear whether the commitments made by the precious Conservative government would be adopted. Whilst no formal statement has been made by the new government, in October 2024 the Home Office updated its drug licensing factsheet regarding CBD. The amended guidance makes no reference to amending legislation and refers only to the existing wording of Regulation 2 (1) of the MDR 2001 but suggests that CBD products will benefit from the exemption. In particular, the guidance states: *"It is the Home Office view that the applicable unit of measure (ie, the component part of the product or preparation) for the 1mg 'threshold' referred to in Limb (c) is that of the container (such as a bottle of oil) and not (for example) the supposed typical dose (of any product)."* It remains unclear whether the new government intends to introduce any amending legislation to give effect to this interpretation, or whether it hopes that the courts will simply apply the government's interpretation of the existing legislation by applying the gloss in the Home Office guidance. As matters stand, the latter seems likely.

Shortly thereafter, in November 2024 the Food Standards Agency announced that it would be making recommendations regarding CBD to the government in spring/summer 2025. In December 2024, it was reported that the Food Standards Agency board had discussed the future of CBD regulation. There appeared to be some disagreement among board members as to the framing of maximum THC content in CBD products. In particular, whilst the board accepted the Home Office's amended guidance regarding the Regulation 2 MDR 2001 exemption, some members suggested that the Food Standards Agency should push manufacturers to achieve zero detectable THC. If this proposal is adopted, it could lead to a distinction being drawn between the regulation of CBD as a controlled drug and its regulation as a novel food. In other words, it is possible that a CBD product containing trace amounts of THC might benefit from the controlled drug exemption in the MDR 2001 but nevertheless fall foul of novel foods law (for example, if the Food Standards Agency imposed a condition that novel foods applications for CBD products would only be approved where the product contained zero detectable THC).

As such, the CBD industry once again faces regulatory uncertainty. Bespoke legislation, as envisaged by the previous government, would have been welcomed by industry and regulators alike. It can only be hoped that the government will make the legal position clear after the Food

Standards Agency's recommendations are published in spring/summer 2025.

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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