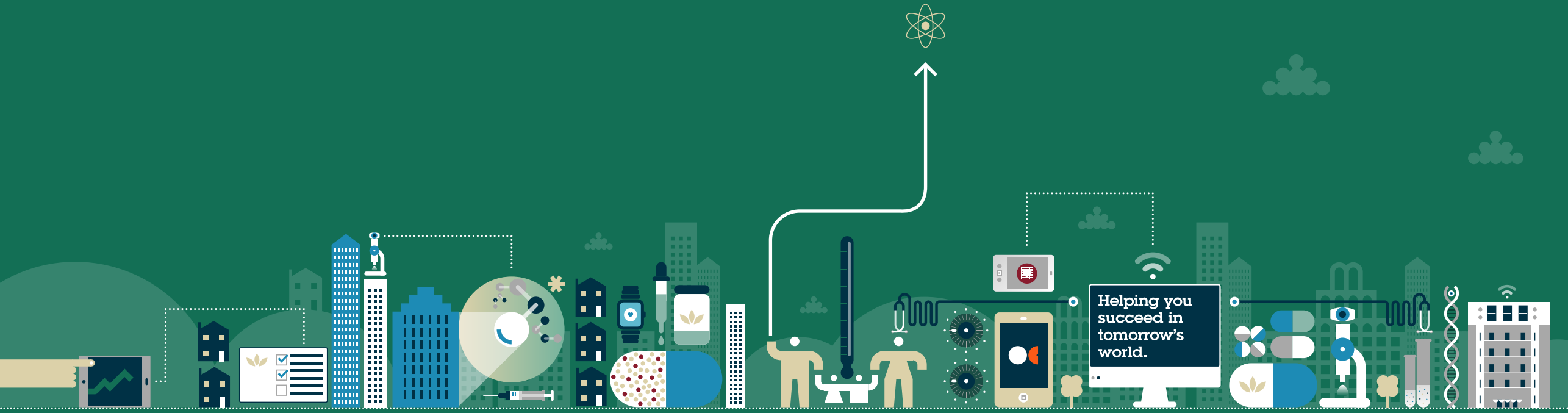
From Hemp to Highs:

An overview of cannabis and CBD legislation across Europe

June 2024

Start



Introduction

Debate and controversy around cannabis and its derivatives are nothing new, with a wide array of legal frameworks and restrictions on its use in place around the world. In Europe, moves to change the legal status of cannabis and cannabidiol (CBD) have been gaining momentum in recent years, leading to several countries implementing changes to their legal frameworks.

In particular, through increasing research and positive outcomes in the fields of life sciences and healthcare, an increasing number of patients have had access to medical cannabis and there is a greater acceptance in society of the potential positive benefits of cannabis for medicinal purposes. Parallel to this, in the consumer market, a rising number of European countries are now considering the legalisation of cannabis for recreational use. Change is also afoot in the cosmetic and food industries, with the use of cannabis plants being explored, which offers the potential for even more widespread applications in the future.

The coming years will undoubtedly be an interesting time from a legislative perspective, with implications on the production, trade and use of cannabis. With different jurisdictions opting for different approaches at different speeds, considerable confusion understandably remains about the existing and future legal status of cannabis across Europe.

Through this report, which draws on the expertise of our teams across Europe, we hope to inform readers interested in current or future opportunities in this space by offering a high-level overview of the status of cannabis and CBD across Europe.

In these pages, you'll discover the key differences and overlaps across legal frameworks, in addition to potential implications for the future - with a special focus on regulations surrounding cannabis for medical and recreational use, as well as CBD.

If you are a business:

- with existing materials/products containing CBD/cannabis looking to expand across Europe,
- looking to develop CBD/cannabis materials or products, or
- looking to invest in a business that does,

and you require expert legal advice, we'd be delighted to hear from you.

Dr Fabian Christoph
Partner, Germany
T +49 40 55436 4076
fabian.christoph
@osborneclarke.com

Larissa Moessmer
Senior Associate, Germany
T +49 89 5434 8100
larissa.moessmer
@osborneclarke.com

Please note, this report reflects the legal situation as of June 2024 and may not include any subsequent changes or updates.

General introduction – International and European law

General regulatory landscape

Before we dive into individual countries' approaches to cannabis and CBD legislation, it's interesting to first examine the current international and EU landscape.

1. Cannabis

The majority of EU member states and the UK are part of the UN Single Convention on Narcotic Drugs which, was established on 30 March 1961 (the "**1961 Convention**"), and the Vienna Convention on Psychotropic Substances laid down on 21 February, 1971 (the "**VC**").

Within these international conventions, which are aimed at controlling and combating drug abuse, cannabis is described in two ways:

- as a narcotic drug, where it's defined as the flowering or fruiting tops of the plant minus seeds and leaves, and from which the resin has not been extracted. Cannabis plants and cannabis resin (the separated resin, whether crude or purified obtained from the cannabis plant) are also covered in this description; and
- as a psychotropic substance, tetrahydrocannabinol (commonly known as "**THC**").

Rules governing the use of cannabis

Within the conventions, specific rules exist regarding the cultivation, manufacture and distribution of cannabis, its uses, how it's labelled, and of course, criminal implications for supply, possession, and usage.

For example, there are provisions that limit the production, manufacture, export, import, distribution of, trade in, use and possession of cannabis except for medical and scientific purposes. In particular, the 1961 Convention contains specific provisions related to the monitoring of the amount of cannabis cultivated and produced for such purposes in each signatory state. For instance, it's recommended that not only the culture of cannabis, but also its further use and commercialisation be subject to specific licences in each state. The Convention, however, also provides for some limited exceptions applying to medical, industrial (fibre and seed) and horticultural use.

Among regulatory requirements related to labelling, the 1961 Convention recommends that signatory states indicate, on all cannabis materials or products for commercialisation, the name of the substance as used by the World Health Organisation (**WHO**). Under the VC, however, signatory states agree to take the recommendations of the WHO into account and to include instructions for use on any label, including cautions and safety warnings for the user, and to generally prohibit the advertising of substances containing THC.

What's more, as cannabis is of course a controlled substance, the signatory states have pledged to adopt the necessary criminal measures to ensure that the broad production and commercialisation of drugs is prohibited and punished (as further defined under Article 36 of the 1961 Convention). Under article 22 of the VC, it's also stated that similar criminal measures for psychotropic substances should be adopted.

Continues on next page

General introduction – International and European law

General

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) will become the EU Drugs Agency (**EUDA**) on July 2nd 2024 and its mandate has been revised to address the new challenges posed by contemporary drug issues (like the issue of polydrug use including the cannabis products adulterated with synthetic cannabinoids). EUDA will develop a new European drug alert system to extend the current work of Early Warning System on new psychoactive substances and complement this with new health and security threat-assessment capabilities. Moreover, the agency will better support EU-level policy needs in its activities.

The future for cannabis

Europe's response to cannabis underscores the risk of harm associated with cannabis use because of the apparently increasing range of cannabis-based products potentially available to consumers, which can include edibles, various forms of vaping technologies, high-potency products and various derivatives of the drug. Such diversity may have implications for the risk of individuals experiencing problems with their cannabis use, but these are poorly understood. Therefore, greater research and regulatory attention is required. Additionally, the European policy approach to cannabis is still particularly diverse, with some Member States considering or changing their policy approach to recreational use, creating various forms of access to cannabis resin and herb products.

2. CBD

By contrast, the approach to CBD is subject to much less restriction. CBD is a substance extracted from the whole cannabis plant. It can also be synthetised chemically and contains a low level of THC.

In its judgment of 19 November 2020, the Court of Justice of the European Union ("**CJEU**") recognised that CBD should not be classified as a narcotic drug under the international conventions. The court's reasoning was based on scientific evidence confirming that THC content not exceeding 0.2% doesn't appear to have any psychotropic or harmful effect on human health[1].

In the same case, the CJEU held that the regulation of a member state prohibiting its import, commercialisation or marketing would breach the EU freedom of movement from which CBD benefits, unless justified by public health.

Similarly, a report from the WHO found that CBD was a safe substance and recommended that it should not be classified as an internationally controlled substance, as neither presents risks in terms of psychoactive properties, nor for potential abuse or dependence.

1 *CJEU, judgement of 19 November 2020, reference no. C-663/18 – "Kanavape-case".*

Go to previous page

General introduction – International and EU Law:
Sector legislation

1. Medicinal products

While also subject to specific local requirements, products containing cannabis-derived substances that meet the definitions set out in the European pharmaceutical legislation should comply with the relevant rules governing medicinal products in the European Union ("**EudraLex**") and particularly those of Directive 2001/83/EC[2] (the "**Community Code**").

These may be deemed medicinal products, active substances, herbal medicinal products, herbal substances, or herbal preparations. In each case, relevant licenses, certificates and/or authorisations should be obtained, and authorised European pharmaceutical standards should be taken into account. This includes, where applicable, complying with the European Pharmacopoeia, which provides for methods and monographs on the quality control of single substances, including herbal substances and herbal preparations.

One specific exception within the Community Code, as clarified by the CJEU relates to synthetic cannabinoid substances that produce effects that modify physiological functions but that:

- do not have any beneficial effects, either immediately or in the long term, on human health; and
- are consumed solely to induce a state of intoxication and are, as such, harmful to human health[3].

On those grounds, the Court (Fourth Chamber) hereby rules:

Article 1(2)(b) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, must be interpreted as not covering substances, such as those at issue in the main proceedings, which produce effects that merely modify physiological functions but which are not such as to have any beneficial effects, either immediately or in the long term, on human health, are consumed solely to induce a state of intoxication and are, as such, harmful to human health.

The European Medicines Agency (the "**EMA**") has further summarised relevant scientific and legislative terminology in the context of evaluating cannabis-derived medicinal products in a 2021 glossary. This glossary, however, doesn't address or have a bearing on the use, classification nor the legal status of cannabis-derived substances or products in the different EU member states – as described later in this report in the respective country sections.

2 *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.*

3 *CJEU, judgement of 10 July 2014, joined cases C-358/13 and C-181/14.*

Continues on next page

General introduction – International and EU Law:
Specific legislation at EU Level

2. Medical devices

If a manufacturer can demonstrate that a cannabis-containing product achieves a medical purpose through a mechanical mode of action (i.e. the product doesn't achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but may be assisted in its function by such means), the medical device route and conformity assessment leading to CE marking could be an option under EU laws. In that case, the relevant safety and performance requirements set out in Regulation (EU) 2017/745 on medical devices[4] and other pre-marketing requirements for placing medical devices on the market should be considered.

3. Food

Considering the status of cannabis as a narcotic drug or psychoactive substance, it would appear logical for it not to be considered a food substance. Since CBD is not considered a narcotic drug, however, the European Commission has considered that it could qualify as a food, provided that the conditions laid down under Regulation (EC) 178/2002[5] are met.

Under EU food law, since CBD was not demonstrated to be used for human consumption to a significant degree prior to 15 May 1997, it must be considered as a "novel food" under the Regulation (EU) 2015/2283[6] (the "**Novel Food Regulation**"). As a food safety measure, novel food is subject to a prior authorisation from the European Commission, after having been assessed by the European Food Safety Agency (the "**EFSA**"), which performs scientific risk assessments on foods when requested by the Commission.

That said, in its latest report published in June 2022, the EFSA concluded that the safety of CBD cannot be established with sufficient certainty as more scientific data is needed in certain areas.

This means that, as of today, CBD is not authorised on the EU market as a novel food, and can therefore not be commercialised as a food.

4 *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.*

5 *Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.*

6 *Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.*

Go to previous page

National laws: Belgium

Part 1 – Cannabis for medical use

4. Cosmetics

The use of cannabis is not authorised in cosmetics. Cannabis is a prohibited substance in cosmetics according to article 14 and Annex II of the Regulation (EC) 1223/2009[7] (the "**Cosmetics Regulation**").

The use of CBD in cosmetics is not specifically regulated under the Cosmetics Regulation. In the European Commission Database for Cosmetics, CBD is listed as a cosmetics ingredient in some categories (such as skin-protecting, antioxidant, and sebum-fighting products), however cosmetic products containing CBD remain subject to a case-by-case assessment before being commercialised.

1. Is the use of cannabis allowed:

a. in OTC pharmaceuticals?

The Belgian Pharmacist Association has issued an opinion in June 2024 on the emergency kit and any narcotics and psychotropic substances dispensed which must be recorded in the pharmacy's computerised register. During the following month, at the end of each quarter, the pharmacist must send the FAMHP by email a quarterly overview of supplies of narcotics and psychotropic substances for the establishment of an emergency kit.

b. in prescribed pharmaceuticals?

The use of cannabis as an active substance in finished medicinal products on prescriptions that have a valid marketing authorisation ("**MA**") may be permitted.

For the time being, however, only one THC-based medicinal product is currently authorised in Belgium and available on the market with a valid prescription: Sativex® (which contains cannabis sativa L., leaf, flower, soil extract – Eq. CBD 2,5 mg/dose and Eq. delta-9-tetrahydrocannabinol ("**Δ9-THC**") 2,7 mg/dose).

Another prescription medicine containing only CBD (i.e., without THC or Δ9-THC) is authorised, on which see more below.

2. What's the legal framework and what are the restrictions for the advertising of medical cannabis-containing products?

Presenting a cannabis-containing product as having properties for treating or preventing disease in human beings without an appropriate MA for a medicinal product is forbidden by law. Only medicinal products that have been granted an MA and are lawfully placed on the market in Belgium may be promoted locally, and only to the appropriate audience.

Any advertising intended for the public for medicines that contain psychotropic or narcotic substances within the meaning of the international conventions is prohibited.

7 *Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast).*

Continues on next page

National laws: Belgium

Part 1 – Cannabis for medical use

Other general rules and principles on advertising of medicinal products can be found in the Medicines Act of 25 March 1964, the Royal Decree of 7 April 1995 on information and advertising, the Compulsory Insurance Act of 14 July 1994, FAMHP guidelines, ministerial circulars and the case law enacted by the Belgian courts and the CJEU on the advertising of medicinal products.

If a cannabis-containing product qualifies as a medical device, the restrictions for the promotion are those applicable under the Belgian medical devices legislation.

3. What laws govern the sourcing of medical cannabis as raw materials from producers?

The Belgian regulatory framework governing the sourcing of raw materials intended for medicinal products is largely based on the principles set out in EudraLex. These were implemented in the Royal Decree of 14 December 2006 on medicinal products for human use, which is based on the aforementioned Medicines Act of 25 March 1964.

In Belgium, the general EudraLex-derived requirements apply to the sourcing of cannabis-containing raw materials.

Of note is that the manufacturing of medicinal products is subject to a licence granted by the FAMHP. Licence holders must comply with good manufacturing practices ("**GMP**") for medicinal products and only use active substances that are:

- manufactured in accordance with GMP for active substance; and
- distributed in accordance with good distribution practices ("**GDP**") for active substances. Belgian law also places a requirement on licence holders to check that manufacturers and distributors of their active substance(s) comply themselves with GMP and GDP by carrying out audits on the relevant manufacturing and distribution sites.

Furthermore, in the case of medicinal products containing chemical and/or biological active substances, the applicant for an MA must be able to provide details on the manufacturing process of the active substance(s) in Module 3 (Quality) of the MA application file. For example, raw materials must be listed, their quality and controls must be documented, and the name, address, and responsibility of each manufacturer (including contractors) and each proposed production site or facility involved in manufacturing and testing must be provided.

4. Through which distribution channels may medical cannabis be distributed (e.g., pharmacies only etc.)?

Medicinal products containing cannabis that have been granted an MA can only be procured in Belgium through pharmacies in accordance with the supply conditions set out in the MA documentation and the Royal Decree of 21 January 2009 regulating the pharmaceutical profession.

Continues on next page

National laws: Belgium

Part 1 – Cannabis for medical use

Outside of this arrangement, "medical cannabis" cannot be distributed anywhere in Belgium.

Belgium enforces a legal ban on the supply by pharmacists of the following preparations intended for human use if they contain THC:

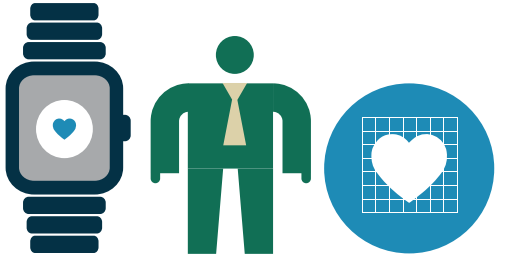
- magistral formulae (i.e., medicinal products prepared in a pharmacy in accordance with a medical prescription for an individual patient); and
- officinal formulae (i.e., medicinal products that are prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and are intended to be supplied directly to the patients served by that pharmacy).

By way of exception, the FAMHP tolerates pharmacists supplying magistral and officinal formulae that contain CBD with traces of THC, subject to conditions explained below (see part III, question 4).

What's more, while physicians can theoretically prescribe "medicinal cannabis," which is not available in Belgium based on the principle of therapeutic freedom, and the import of it from abroad is not permitted i.e., the purchase of "medical cannabis" from a foreign pharmacy is legal, but its import into Belgian territory is subject to compliance with a specific declaration by the country where the patient is registered. In practice, however, the FAMHP doesn't accept any such declaration. The rationale behind this approach is that imported cannabis may be confiscated by police forces under the Act of 24 February 1921 on drug traffic, which is explained below (see part II, question 1 a).

This position may evolve over time, as the FAMHP and other national competent authorities are studying the possibility to supply "medical cannabis" in the future.

"Vladimir Murovec [adds] significant regulatory and compliance expertise in the medical device and digital health sectors, as well as traditional pharma and life sciences."
EU Regulatory: Pharma, Medical Devices And Biotech, Legal 500



Go to previous page

National laws: Belgium

Part 2 – Cannabis for recreational use

1. Is the use of cannabis allowed:

a. for recreational purposes?

The sum of concentrations for these cannabis products (all parts of the cannabis plant are concerned) has been upped to > 0.3% (it was 0.2% before) of Δ9-THC (delta-9-tetrahydrocannabinol) and THCA (delta-9-tetrahydrocannabinolic acid).

b. in food and beverages?

The use of cannabis is forbidden in foods and beverages, regardless of whether it is a standalone food product or incorporated in other food products. It's considered as a "dangerous food" under the Royal Decree of 31 August 2021 on the manufacture and trade in foodstuffs composed of or containing plants or plant preparations.

A derogation can nonetheless be requested from the regulator (in Belgium, the FPS Health) provided that the producer of the food product containing cannabis can demonstrate that all toxic substances (i.e., THC) have been removed. According to the regulator, such derogations can never be granted for:

- cannabis leaves and flowers in the form of tea or infusion; and
- food products containing CBD as these qualify as a "novel food" under European legislation (see above: International and EU law, Sector legislation, point 3).

c. in cosmetics?

The Belgian legislation doesn't add anything specific to the Cosmetic Regulation (see above: International and EU law, Sector legislation, point 4).

2. What is the legal framework and what are the restrictions for the advertising of recreational cannabis-containing products?

Subject to the 1961 Convention and the VC prohibiting the advertising of cannabis, there's no specific regulation of the promotion of recreational cannabis-containing products under Belgian law. However, doing so would normally be forbidden under several local laws.

Continues on next page

National laws: Belgium

Part 2 – Cannabis for recreational use

First, the Act of 24 February 1921 on drug trafficking prohibits any action facilitating the use of cannabis, by encouraging its use, which can be interpreted as including its commercialisation and promotion. Any breach of this legislation can be subject to criminal sanctions.

Second, Article VI.100, 9° of the Code of Economic Law considers it to be an unfair commercial practice in all circumstances should a professional state or otherwise create the impression that a product can be legally sold when it cannot. This would also cover advertising of cannabis-containing products, which are generally forbidden under Belgian law.

In addition, the Belgian Ethical Board for Advertising JEP also takes the position that the promotion of the product itself, or even mentioning it as component of an advertising, could be contrary to Article 2 (Social Responsibility) of the ICC Advertising and Marketing Communications Code.

3. What laws govern the sourcing of recreational cannabis as raw materials from producers?

The culture of cannabis is forbidden under several provisions of the decree of 6 September 2017 implementing the Act of 24 February 1921 on drug traffic.

The only exception to this rule is the culture of cannabis complying with the conditions set out under Regulation (EU) 1307/2013[8], which establishes rules for direct payments to farmers under support schemes within the framework of the common agricultural policy, and its local regional implementations. Such an exception is subject to a permit delivered by the regulator in advance. If permitted by the legislation, the culture of cannabis should be granted strictly for medical, scientific or educational purposes.

4. Through which distribution channels may cannabis be distributed for recreational purposes (e.g., pharmacies only etc.)?

The holder of the authorisation mentioned above can only sell cannabis to one of the following categories of buyers:

- other authorisation holders, provided that their authorisation allows the purchase of cannabis;
- pharmacies (without prejudice to the restrictions that come into play downstream, as regards what pharmacies may or may not supply - see more under A. General Introduction);
- authorised warehouses, provided that the cannabis-containing product qualifies as a medicine.

8 *Regulation (EU) 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) 637/2008 and Council Regulation (EC) 73/2009.*

Go to previous page

National laws: Belgium

Part 3 – CBD

1. Is the use of CBD allowed:

a. in food and beverages?

No. At an EU level, CBD qualifies as a "novel food" under the Novel Food Regulation, and its placement on the market is not currently authorised (see General Introduction on page 3). The Belgian food regulator, the Federal Agency for the Safety on the Food Chain ("**FASFC**"), repeated this in its joint opinion with the FPS Health, and Belgian law doesn't add anything specific in this respect.

b. in cosmetics?

Yes, the general answer under EU law would remain applicable for Belgium and there's no specific complementary legislation.

c. in OTC pharmaceuticals?

See part 1, question 1a. This is generally applicable to any use of cannabis sativa L. (leaf, flower) in medicinal products.

d. in prescribed pharmaceuticals?

The use of CBD as an active substance in finished medicinal products on prescription bearing a valid MA may be permitted.

The only prescription medicine containing only CBD (i.e., without THC or Δ9-THC) that's currently authorised in Belgium is *Epidyolex*®. The medicine, which was authorised through the centralised procedure in September 2019, is not yet available on the market in Belgium.

2. What is the legal framework and what are the restrictions for the advertising of CBD-containing products?

Promotional activities and advertising around CBD should first comply with the local restrictions on B2B and B2C commercial practices (including misleading advertising, comparative advertising or other consumer rights principles set out under the Belgian Code of Economic Law).

Any regulated product (e.g., a medicinal product or a cosmetic product) containing CBD should also follow the restrictions on the advertising of such products in Belgium.

CBD for smoking may also be subject to specific labelling, advertising requirements and sales restrictions to minors, depending on composition.

3. What laws govern the sourcing of CBD as raw materials from producers?

Depending on the location of hemp or CBD production, this activity may be subject to urban or environmental permits.

The production and commercialisation of CBD as a raw material in smoking products is regulated by the Royal Decree of 5 February 2016 on manufacturing and commercialisation of tobacco-based products and plant-based smoking products. Any producer must therefore communicate annually to the regulator information such as the type of goods produced, their ingredients, the intended packaging and labelling.

For more information about the sourcing of CBD as a raw material intended for medicinal products, please see part I, question 3.

Continues on next page

National laws: Belgium

Part 3 – CBD

If CBD is sourced by pharmacists to prepare a magistral or officinal formula – for more information about which see part III, question 4 – they are bound by a requirement to only use authorised raw materials or, if a raw material is not authorised, to only use such raw material in magistral formulae (i.e., only on prescription) and subject to a certificate of analysis issued by an approved laboratory.

4. Through which distribution channels may CBD be distributed (e.g., pharmacies only etc.)?

In Belgium, the appropriate distribution channel(s) are required to be assessed on a case-by-case basis, taking into account the nature and the regulatory qualification of the CBD-containing product.

CBD-containing medicinal products that have been granted an MA can only be procured through pharmacies in accordance with the supply conditions set out in the MA documentation and the Royal Decree of 21 January 2009 regulating the pharmaceutical profession. The FAMHP also tolerates pharmacists supplying magistral and officinal formulae that contain CBD + limited traces of THC subject to conditions laid down in a specific administrative circular. Such conditions include, but are not limited to, an exposition to THC limited to a maximum of 1 microgram of Δ9-THC per kilogram of body weight per day.

The distribution of CBD products is further regulated in the event that the product qualifies as a tobacco product. Online sales of this type of CBD products are forbidden. As a reseller of CBD products, a retailer (in any capacity) may need to apply for a prior authorisation before starting their commercialisation, and any new CBD product placed on the market should be notified to the regulator before being sold.

“What makes Osborne Clarke unique – unlike many international law firm – is the ability to combine different fields of expertise while keeping advice on a very practical and hands-on way considering the specificity of the client.”
Industry Focus: Healthcare & Life Sciences, Legal 500

Go to previous page

National laws: France

Part 1 – Cannabis for medical use

1. Is the use of cannabis allowed:

a. in OTC pharmaceuticals?

In France, cannabis, cannabis resin and THC are classified as narcotics by decree (Order of 22 February 1990 establishing the list of substances classified as narcotics – *Arrêté du 22 février 1990 fixant la liste des substances classées comme stupéfiants*).

The use of:

- cannabis, its plant and resin, products containing them or those obtained from cannabis, its plant or resin; and
- THC, natural or synthetic, its esters, ethers, salts as well as the salts of the aforementioned derivatives and the products containing them,

is allowed in pharmaceuticals according to Article R5132-86 of the French Public Health Code (*Code de la santé publique* – "**CSP**").

Unless otherwise foreseen by order of the Ministry of Health (Article R5132-2 CSP), a prescription is mandatory for drugs classified as narcotics to be delivered to patients (Article R5121-36 CSP).

As no decree regarding pharmaceuticals containing cannabis has been published yet, cannabis is not allowed in OTC pharmaceuticals.

b. in prescribed pharmaceuticals?

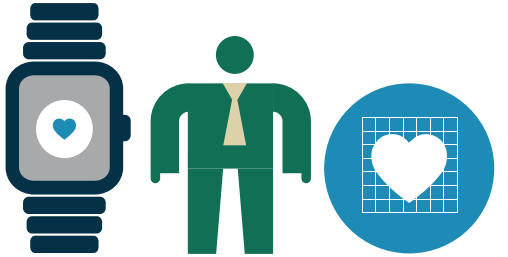
The use of cannabis in pharmaceuticals is allowed (Article R5132-86 CSP).

Prescription of narcotics is subject to 'a secure prescription meeting precise technical specifications (CSP).

In France, Sativex (nabiximols) is the only medicine with cannabis as an active substance (active substances: delta-9-tetrahydrocannabinol and cannabidiol) to have obtained MA. Nonetheless, the drug is yet to be marketed due to a lack of agreement regarding its price.

Other medicines such as Marinol (dronabinol) are only available through derogatory access to medicinal products, i.e., compassionate use authorisation given by the French National Agency for Medicines and Health Products Safety (*Agence nationale de sécurité du médicament et des produits de santé* – "**ANSM**").

In addition, a national experiment (Article 43 of the law on the financing of the Social Security Financing Act for 2020 ("**LFSS**") on the medical use of cannabis, provided for by the "LFSS", began in March 2021 and is due to end in 2024. This experiment has been validated by the working group created by the ANSM on the proposal of the High Authority of Health (*Haute Autorité de santé* – "**HAS**"), at the request of the Minister of Health, following requests from patient associations and parliamentarians.



Continues on next page

National laws: France

Part 1 – Cannabis for medical use

For the purpose of the experiment[9]:

The prescription is limited to five therapeutic indications:

- neuropathic pain refractory to accessible therapies (medicinal or not);
- certain forms of severe and pharmaco-resistant epilepsy;
- certain intractable symptoms in oncology-related to cancer or its treatments;
- palliative situations; and
- painful spasticity in multiple sclerosis or other central nervous system pathologies.

The drugs are available in different ratios of THC to CBD: dominant THC; a balanced ratio of THC and CBD; and dominant CBD.

The forms of medicines made available are cannabis flowering tops to be vaporised for inhalation, oils administered orally, and sublingual tablets.

The experiment is being carried out exclusively by physicians in voluntary reference health structures.

2. What is the legal framework and what are the restrictions for the advertising of medical cannabis-containing products?

Pharmaceuticals containing cannabis fall under the legal framework of any other prescribed pharmaceutical reimbursed through the social security system.

For this reason advertising:

- is only allowed if the pharmaceutical has obtained a MA;
- can only be directed to healthcare professionals (Article L5122-6 CSP);
- is subject to prior control of the ANSM: a request must be sent to resulting in the grant of a prior authorisation, valid for two years (Article L5122-9 CSP); and
- must indicate:
  - the date on which it was last drawn up;
  - the name of the medicinal product;
  - the name and address of the company exploiting the medicinal product;
  - the pharmaceutical form of the medicinal product;
  - the qualitative and quantitative composition in active ingredients, with the common name, and in constituents of the excipient, knowledge of which is necessary for the correct administration of the medicinal product;
  - the MA or registration numbers;
  - the essential pharmacological properties with regard to the therapeutic indications;

9 *Order of 16 October 2020 setting the specifications of cannabis-based medicinal products used during the experiment provided for in art. 43 of Law No. 2019-1446 of 24 December 2019 on the financing of social security for 2020, the conditions under which they will be made available and the therapeutic indications or clinical situations in which they will be used (Arrêté du 16 Octobre 2020 fixant les spécifications des médicaments à base de cannabis utilisés pendant l'expérimentation prévue à l'article 43 de la loi n° 2019-1446 du 24 Décembre 2019 de financement de la sécurité sociale pour 2020, les conditions de leur mise à disposition ainsi que les indications thérapeutiques ou situations cliniques dans lesquelles ils seront utilisés).*

Continues on next page

National laws: France

Part 1 – Cannabis for medical use

- the therapeutic indications and contraindications;
- the method of administration and, if necessary, the route of administration;
- the dosage;
- adverse events;
- special warnings and precautions for use;
- drug and other interactions;
- the classification of the medicinal product with regard to prescription and delivery mentioned in the MA;
- the limit of sale price to the public when such a price is fixed in application of the laws and regulations in force, accompanied, in this case, by the cost of the daily treatment; and
- the situation with regard to reimbursement by health insurance bodies.

3. What laws govern the sourcing of medical cannabis as raw materials from producers?

The possession and the cultivation of cannabis for the purpose of manufacturing medicines are submitted to authorisation by the ANSM and are limited to farmers who entered into a contract with a pharmaceutical company, or a company authorised to manufacture active substances (Article R5132-86 CSP).

4. Through which distribution channels may medical cannabis be distributed (e.g., pharmacies only etc.)?

In France, pharmaceuticals can only be distributed through pharmacies. Pharmaceuticals containing narcotics, including cannabis, are subject to the same regulation.

For the purpose of the aforementioned experiment, six pharmaceutical companies supply the medicines directly to the referenced health structures.

"Very pleasant collaboration with the France team which has gained a lot of expertise – France team is always available and relevant in its analyses."
Industry Focus: Healthcare & Life Sciences, Legal 500

Thomas Devred nominated by peers in Biotechnology and Life Sciences Practice in the 13th edition of Best Lawyers in France 2023.

Go to previous page

National laws: France

Part 2 – Cannabis for recreational use

1. Is the use of cannabis allowed?

In France, cannabis, cannabis resin, and THC are classified as narcotics by decree, and the use of cannabis is limited to medicines. For this reason, the use of cannabis in any other product is banned for recreational purposes, in food and beverages and in cosmetics.

2. What is the legal framework and what are the restrictions for the advertising of recreational cannabis-containing products?

Promotion of unlawful use of plants classified as narcotics is sanctioned by a maximum of 5 years imprisonment and a fine of 75,000 euros (Article L3421-4 CSP).

2. What laws govern the sourcing of recreational cannabis as raw materials from producers?

Given that the recreational use of cannabis is not allowed, there are no additional frameworks governing this area.

3. Through which distribution channels may cannabis be distributed for recreational purposes (e.g., pharmacies only etc.)?

Given that the recreational use of cannabis is not allowed, there are no additional frameworks governing this area.

Continues on next page

National laws: France

Part 3 – CBD

1. Is the use of CBD allowed?

French law (Article R5132-86 CSP). prohibits the production, manufacture, transport, import, export, possession, offer, transfer, acquisition or use of cannabis (plant, resin, and derivatives) other than in pharmaceuticals.

The cultivation, import, export, and industrial and commercial use of varieties of hemp, cannabis sativa L., without narcotic properties are, however, authorised by order of the Ministers of Agriculture, Customs, Industry and Health (Article R5132-86-1 CSP).

A ministerial order of 30 December 2021 authorised the cultivation, import, export, and industrial and commercial use of varieties of hemp, with a THC content of no more than 0.3%. This threshold of THC is therefore the one below which hemp varieties are considered devoid of narcotic properties.

For this reason, unless otherwise stated in a stricter regulation, the use of CBD in products is authorised if the products contain 0.3% of THC or less. This has been recently confirmed by a ruling of the High Administrative Court (Conseil d'Etat): the marketing of raw flowers and leaves of cannabis varieties with a THC content lower than 0.3% is authorised according to a decision of 29 December 2022 of the High Administrative Court.

a. in food and beverages?

CBD, synthetic or not, qualifies as a "novel food" according to European food regulations.[10]

As such, CBD products must first be authorised by the European Commission prior to being put on the market. While applications have been made, including for food supplements, the European Commission has yet to make a decision.

b. in cosmetics?

The use of CBD is permitted as an ingredient in cosmetic products, as well as cannabis derivatives that comply with the prohibitions listed in Annex II of the Cosmetics Regulation.

The THC content of these products must not exceed 0.3%.

10 *Novel Food Regulation – EFSA Catalogue: "The hemp plant (cannabis sativa L.) contains a number of cannabinoids and the most common ones are as follows: delta-9-tetrahydrocannabinol (Δ9-THC), its precursor in hemp, delta-9-tetrahydrocannabinolic acid A (Δ9-THCA-A), delta-9-tetrahydrocannabinolic acid B (Δ9-THCA-B), delta-8-tetrahydrocannabinol (Δ8-THC), cannabidiol (CBD), its precursor in hemp cannabidiolic acid (CBDA), cannabigerol (CBG), cannabinol (CBN), cannabichromene (CBC), and delta-9-tetrahydrocannabivarin (Δ9-THCV).*

Without prejudice to the information provided in the novel food catalogue for the entry relating to cannabis sativa L., extracts of cannabis sativa L. and derived products containing cannabinoids are considered novel foods as a history of consumption has yet to be demonstrated.

This applies to both the extracts themselves and 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 considered as novel."

Continues on next page

National laws: France

Part 3 – CBD

c. in OTC pharmaceuticals?

CBD is not classified as a narcotic (Kanavape-case).

The use of CBD in OTC pharmaceuticals is authorised if the products contain 0.3% of THC or less.

If the percentage of THC is higher, the regulation regarding narcotics applies, thereby forbidding the use of cannabis in OTC pharmaceuticals unless otherwise stated in a ministerial order.

d. in prescribed pharmaceuticals?

The use of CBD is allowed in prescribed pharmaceuticals.

Only one prescribed pharmaceutical containing cannabidiol without THC is marketed in France: *Epidyolex* (cannabidiol).

2. What is the legal framework and what are the restrictions for the advertising of CBD-containing products?

Unless approved as a drug, no claim implying the therapeutic effect of the consumption of a product containing CBD, and no less than 0.3 % THC, can be made.

Claims creating confusion between CBD and narcotics are forbidden.

3. What laws govern the sourcing of CBD as raw materials from producers?

Pursuant to Article 1 of the Order of 30 December 2021 implementing Article R5132-86 CSP). (*Arrêté du 30 Décembre 2021 portant application de l'article R. 5132-86 du code de la santé publique*) only varieties of cannabis sativa L., whose THC content is not greater than 0.3% and that are registered in the Common Catalogue of Varieties of Agricultural Plant Species or in the Official Catalogue of Species and Varieties of Plants grown in France can be cultivated, imported, exported, or used in industrial or commercial products in France.

The products derived from hemp may be imported to France from countries outside the European Union or exported from France to countries outside the European Union, only if they are accompanied by documents attesting their compliance with French regulations.

Only farmers, qualifying as active farmers within the definition of Article 9 Regulation (EU) 1307/2013, may cultivate hemp flowers and leaves.

The purchase of hemp flowers and leaves produced on French territory is subject to a written contract between the producer and the buyer. The contract includes information regarding the volume and price of the products. The contract may include information on the expected quality of the products. The contract is concluded before the start of the production campaign.

4. Through which distribution channels may CBD be distributed (e.g., pharmacies only etc.)?

Unless approved as a drug and containing tobacco, a CBD product can be sold in any kind of shop.

Go to previous page

National laws: Germany

Update on the (partial) legalisation of cannabis in Germany:

On 1 April 2024, a new Cannabis Act (*Cannabisgesetz* – "**CanG**") came into force in Germany, which provides for the partial legalisation/decriminalisation of cannabis for recreational purposes:

- For adults (over the age of 18), the private cultivation and possession for personal use of cannabis for recreational purposes in certain quantities will now be decriminalised, but the commercial trade in cannabis for recreational use remains illegal.
- Communal cultivation for personal consumption in non-commercial cultivation associations ("cannabis clubs") and the controlled distribution of the grown cannabis to their members are allowed in certain quantities. These clubs may not make any profit from distribution or charge members any fees apart from the statutory contributions to cover their own costs. Licences to operate a cultivation association can be applied for from 1 July 2024.
- It still is illegal to trade or place cannabis for recreational use on the market, or to possess or cultivate cannabis in excess of the permitted quantities.
- Cannabis is now no longer considered a narcotic within the meaning of the German Narcotics Act (*Betäubungsmittelgesetz* – "**BtmG**").

In addition to the provisions on the controlled use of cannabis for recreational purposes in the Consume Cannabis Act (*Konsumcannabisgestz* – "**KCanG**"), the CanG, which is designed as a comprehensive framework law, contains further amendments to existing laws in connection with decriminalisation, such as amendments to the German Criminal Code (*Strafgesetzbuch* – "**StGB**").

Besides, the new CanG contains provisions on cannabis for medical and medical-scientific purposes, which are regulated in a separate law, the Medical Cannabis Act (*Medizinal-Cannabisgesetz* – "**MedCanG**").

The implementation of the new CanG is the **first pillar** of the German government's two-part legalisation plan. As a **second pillar**, regionally limited pilot projects are planned in which cannabis shall be available in licensed specialist shops under scientific supervision.

National laws: Germany

Part 1 – Cannabis for medical use

1. Is the use of cannabis allowed:

a. in OTC pharmaceuticals?

While the use of cannabis for medical purposes has been legal in Germany since 2017 (see part I, question 1b. below), it is only available on prescription and through pharmacies. It is not available as OTC medication in Germany.

b. in prescribed pharmaceuticals?

Yes, the use of cannabis in/as prescribed pharmaceuticals is already legal since 2017 in Germany.

On 1 April 2024, a new Medical Cannabis Act (*Medizinal-Cannabisgesetz* – "**MedCanG**") came into force, which contains specific provisions on cannabis for medical and medical-scientific purposes. According to Section 3 paragraph 1 sentence 1 of the MedCanG, cannabis for medical purposes may be prescribed by doctors or administered as part of a medical treatment.

Whereas previously doctors could only prescribe medicinal cannabis flowers or pharmaceutical-grade cannabis extract on the basis of a specific narcotic prescription, under the new legislation any doctor can now issue a regular prescription for cannabis.

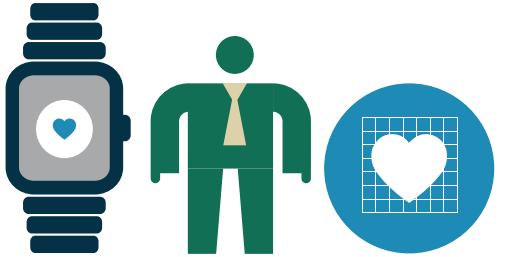
2. What is the legal framework and what are the restrictions for the advertising of medical cannabis-containing products?

The advertising of medical cannabis products in Germany is heavily restricted and mainly regulated by the German Act on the Advertising of Medical Products (*Heilmittelwerbegesetz* – "**HWG**").

Respectively, the HWG stipulates (among other regulations) that advertising for prescription-only medicines is only permitted to healthcare professionals, not to the general public. This means that advertising for cannabis-based drugs cannot be directed to patients.

3. What laws govern the sourcing of medical cannabis as raw materials from producers?

The sourcing of medical cannabis as raw material from producers is mainly regulated by the new Medical Cannabis Act (*Medizinal-Cannabisgesetz* – "**MedCanG**") and the German Medicinal Products Act (*Arzneimittelgesetz* – "**AMG**").



Continues on next page

National laws: Germany

Part 1 – Cannabis for medical use

Section 4 paragraph 1 of the MedCanG stipulates that anyone wishing to cultivate, produce, trade, import, export, dispense, sell, otherwise place on the market, obtain or acquire cannabis for medical purposes or cannabis for medical-scientific purposes requires a licence from the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte* – "**BfArM**").

The AMG regulates the production and distribution of medicines, including cannabis-based drugs. This means that companies producing medical cannabis-containing products must comply with the requirements of the AMG, including obtaining a manufacturing or import licence or a wholesale permit (Großhandelserlaubnis), and adhering to GMP and GDP standards.

In addition to that, the requirements of the Ordinance on the Trade with Medicinal Products (*Arzneimittelhandelsverordnung* – "**AM-HandelsV**") must be complied with.

4. Through which distribution channels may medical cannabis be distributed (e.g., pharmacies only etc.)?

As medical cannabis products are prescription-only drugs, Section 3 paragraph 2 Sentence 1 of the Medical Cannabis Act (*Medizinal-Cannabisgesetz* – "**MedCanG**") states, that it may only be dispensed by a pharmacy on presentation of the prescription. This is also required by the German Medicinal Products Act (*Arzneimittelgesetz* – "**AMG**").

Go to previous page

National laws: Germany

Part 2 – Cannabis for recreational use

1. Is the use of cannabis allowed:

a. for recreational purposes, i.e., as a drug?

The legal situation regarding cannabis for recreational use has recently changed in Germany. The new Cannabis Act (*Cannabisgesetz* – "**CanG**"), which came into force on 1 April 2024, contains among other laws the law on the use of cannabis for recreational purposes, called "Consume Cannabis Act" (*Konsumcannabisgesetz* – "**KCanG**"), which brought a partial legalisation/ decriminalisation of cannabis for recreational use in Germany:

- Cannabis (marijuana, plants and plant parts of plants belonging to the genus cannabis) is no longer listed in Annex I to Section 1, paragraph 1 of the German Narcotics Act (*Betäubungsmittelgesetz* – "**BtMG**") as a narcotic drug.
- Adults (over age 18) are now permitted to possess up to 25 grams of dried cannabis for personal use in public places and up to 50 grams of dried cannabis at their place of residence or habitual abode.
- The private cultivation of up to three cannabis plants at their place of residence or habitual abode for personal consumption is allowed. Non-commercial community cultivation for personal consumption in cultivation associations, so-called "cannabis clubs", is also authorised.

Nevertheless, there are also restrictions to be observed in that regard, among others:

- The consumption of cannabis in the immediate presence of persons under the age of 18 is prohibited as well as the consumption "within sight" of children's playgrounds, children's and youth facilities, publicly accessible sports facilities, pedestrian zones between 7 a.m. and 8 p.m. and within the pacified property of cultivation associations.
- Trafficking and trading with cannabis as well as the acquisition, possession and cultivation above the permitted quantities remains illegal.

b. in food and beverages?

The use of cannabis (containing THC) in food and beverages is currently not permitted in Germany.

There are limited exceptions for hemp foods, that are made from authorised varieties of industrial hemp and that do not contain any relevant amounts of THC. In the EU, hemp plants grown for food production may currently contain a maximum of 0.3% THC in the raw material. Under these conditions, hemp seeds and food products made from them are allowed, provided that a misuse for intoxication purposes is excluded.

Examples are hemp seeds, hemp seed oil and hemp protein, which have a long history of consumption in the EU and are therefore not "novel" under to the European Novel Food Regulation and allowed in food and beverages.

Continues on next page

National laws: Germany

Part 2 – Cannabis for recreational use

c. in cosmetics?

The use of cannabis in cosmetics is not specifically addressed in German law but pursuant to European law, only the cannabis plant's leaves and seeds (e.g., hemp seed oil and hemp seed extract) are allowed as ingredients in cosmetics as long as they are produced in compliance with EU regulations.

According to Article 14 no. 1 lit. a, in conjunction with Annex II of the Cosmetics Regulation, which lists substances that are prohibited to use in cosmetics, an unrestricted prohibition applies to narcotics within the meaning of Tables I and II of the 1961 Convention. Table I of the UN Single Convention on Narcotic Drugs of 30 March 1961 ("**1961 Convention**") lists cannabis, cannabis resin, extracts, and cannabis structures, whereby the seeds and leaves are not covered by the Single Convention insofar as they are not combined with the blossoms.

2. What is the legal framework and what are the restrictions for the advertising of recreational cannabis-containing products?

Section 6 of the Consume Cannabis Act (*Konsumcannabisgesetz* – "**KCanG**") contains a general advertising ban for cannabis and prohibits any advertising and any form of sponsorship for cannabis and for cannabis cultivation associations.

Furthermore, the Health Claims Regulation (*Health Claims-Verordnung* – "**HCVO**") must be observed when advertising cannabis/hemp products for which approval as a food ingredient is obtained. The HCVO standardises permitted advertising with health-related claims for certain substances.

3. What laws govern the sourcing of recreational cannabis as raw materials from producers?

The sourcing of recreational cannabis as raw materials from producers is now regulated in the new Consume Cannabis Act (*Konsumcannabisgesetz* – "**KCanG**").

4. Through which distribution channels may cannabis be distributed for recreational purposes (e.g., pharmacies only etc.)?

According to the new cannabis law in Germany, cannabis for recreational use is only available through private home cultivation or community cultivation in members-only cultivation associations in certain quantities.

These cultivation associations are allowed to distribute the cannabis they grow in a controlled manner to their members for personal use but must operate non-commercial. Apart from the statutory contributions to cover their own costs, these clubs may not charge members any fees or make any profit from distribution. Licences to operate a cultivation association can be applied for from 1 July 2024.

The commercial sale of cannabis for recreational use therefore remains illegal in Germany for the time being. In the future, however, as a second pillar of the legalisation, regionally limited pilot projects are planned in which cannabis will be available in licensed specialist shops under scientific supervision.

Go to previous page

National laws: Germany

Part 3 – CBD

1. Is the use of CBD allowed:

a. in food and beverages?

As of today, the use of CBD in food and beverages is not allowed in Germany.

CBD is considered as a "novel food" under the Novel Food Regulation, which means that any food product containing CBD must go through a rigorous safety assessment and be authorised by the EFSA before it can be sold in the EU.

To date, no CBD-containing novel food has been authorised by the EFSA.

b. in cosmetics?

Cosmetics with CBD are marketable in Germany if they are in accordance with the requirements of the Cosmetics Regulation.

According to Article 14 paragraph 1 lit. a) in conclusion with Annex II of the Cosmetics Regulation, cosmetic products may not contain "prohibited substances" like narcotics as listed in Table I and II of the UN Single Convention on Narcotic Drugs of 30 March 1961 ("**1961 Convention**").

Synthetically produced CBD (which is not extracted from the cannabis plant), and the cannabis plant's leaves and seeds and products derived from them are not qualified as narcotics under the 1961 Convention and are therefore allowed as additives for cosmetics.

Naturally derived CBD extracted from the entire cannabis plant (i.e., not only from the leaves and stems), is - according to the wording of the 1961 Convention - considered a substance that is not permitted in a cosmetic product.

However, the Court of Justice of the European Union ("**CJEU**") ruled in its Kanavape-case that even naturally derived CBD obtained from the hemp plant as a pure substance is not to be classified as a narcotic. Following the ruling of the CJEU, the EU Commission added naturally derived CBD to its Cosmetic Ingredients Database ("**CosIng**"), which until then only listed synthetically derived CBD as an admissible ingredient in cosmetics. Although the CosIng database is not legally binding, it serves as a guideline for EU member states.

Provided the cosmetic product usually cannot be ingested, German authorities generally agree that cosmetics containing less than 0.2% THC are "harmless" products that cannot be misused for intoxicating purposes.

Whether CBD-containing products may be marketed as cosmetics thus depends on a precise case-by-case assessment of the respective product prior to being commercialised.

Continues on next page

National laws: Germany

Part 3 – CBD

c. in OTC pharmaceuticals?

The use of CBD in OTC pharmaceuticals is currently not allowed in Germany.

While CBD is not considered a controlled substance and is legal to possess and use, it has been included in the drug prescription regulation (*Arzneimittelverschreibungs-Verordnung* – "**AMVV**"). Therefore, medicinal products containing CBD, regardless of the dose or route of administration, are subject to the prescription requirement under pharmaceutical law according to section 48 of the German Medicinal Products Act (*Arzneimittelgesetz* – "**AMG**"). By implication, this means that CBD is not allowed as an OTC pharmaceutical.

Since the hurdle for the approval of products as medicinal products is high, suppliers of CBD-containing products currently frequently aim for the classification as cosmetic product.

However, it should be noted that, in some cases of CBD products which have been marketed as dietary supplements or cosmetics and declared to have health-promoting effects, the courts considered them as pharmaceuticals which require an approval and compliance with the regulatory standards as pharmaceuticals.

Before placing a CBD product on the market, it is therefore important to determine whether, from the consumer's perspective, the medicinal purpose (healing, alleviation, or prevention of diseases) or the cosmetic-specific purpose (wellness or enjoyment) predominates in an overall assessment. Depending on the intended purpose, a CBD product may be classified as a medicinal product, with the consequence that the regulations under pharmaceutical law must be observed in this respect.

d. in prescribed pharmaceuticals?

The use of CBD in prescribed pharmaceuticals is allowed in Germany.

The only FDA approved prescription drug containing CBD which is currently authorised in Germany is Epidiolex, which is used to treat certain rare forms of epilepsy.

Continues on next page

National laws: Germany

Part 3 – CBD

2. What is the legal framework and what are the restrictions for the advertising of CBD-containing products?

The laws and regulations that apply for the advertising of CBD-containing products in Germany depend on the classification of the respective product:

- For medicinal CBD-containing products, the German Act on the Advertising of Medical Products (*Heilmittelwerbegesetz* – "**HWG**") is decisive. It stipulates (among other regulations) that advertising for prescription-only CBD drugs is only permitted to healthcare professionals and not to the general public.
- If approval as a food ingredient is obtained, compliance with the Health Claims Regulation (*Health Claims-Verordnung* – "**HCVO**") must be observed in advertising. For CBD as herbal substances, there are no approved claims so far.
- The German Advertising Act (*Gesetz gegen den unlauteren Wettbewerb* – "**UWG**") generally stipulates that advertising may not be misleading or deceptive.

3. What laws govern the sourcing of CBD as raw materials from producers?

The laws governing the sourcing of CBD as raw materials from producers in Germany depend on the nature and the regulatory classification of the CBD-containing product.

Companies producing medicinal CBD-containing products must comply with the requirements of the German Medicinal Products Act (*Arzneimittelgesetz* – "**AMG**"), including obtaining a manufacturing or import licence or a wholesale permit, and adhering to GMP and GDP standards.

In addition to that, the requirements of the Ordinance on the Trade with Medicinal Products (*Arzneimittelhandelsverordnung* – "**AM-HandelsV**") must be complied with.

4. Through which distribution channels may CBD be distributed (e.g., pharmacies only etc.)?

In Germany, the appropriate distribution channel depends on the nature and the regulatory classification of the CBD-containing product.

Prescription-only CBD pharmaceuticals can only be distributed through authorised pharmacies and with a valid prescription from a licensed physician according to the German Medicinal Products Act (*Arzneimittelgesetz* – "**AMG**").

CBD-containing cosmetics or dietary supplements that fulfil the respective regulatory requirements may be distributed through various channels in Germany, including pharmacies, drug stores, health food stores and online retailers, however, it must comply with regulations set forth by the BfArM and other relevant authorities.

Go to previous page

National laws: Italy

Part 1 – Cannabis for medical use

1. Is the use of cannabis allowed:

a. in OTC pharmaceuticals?

No, OTC pharmaceuticals are not permitted to contain cannabis;

b. in prescribed pharmaceuticals?

Yes, the decree of the Ministry of Health ("**MOH**") of 9 November 2015 and its implementing measures allow qualified physicians to prescribe magistral preparations based on cannabis through a non-repeatable prescription. The prescription is exclusive to the individual and cannot be transferred to others. Article 18 *quater*, par. 6, of Law Decree 148/2017, as converted by Law 172/2017, allows reimbursement of cannabis-based preparations prescribed for the pain therapy (Law 38/2010) and for other uses allowed by MOH decree. The level of reimbursement is fixed at the regional level.

A number of authorised medicinal products contain THC (Tetrahydrocannabinol) or CBD (Cannabidiol) extracted from cannabis sativa L as active ingredients.

2. What is the legal framework and what are the restrictions for the advertising of medical cannabis-containing products?

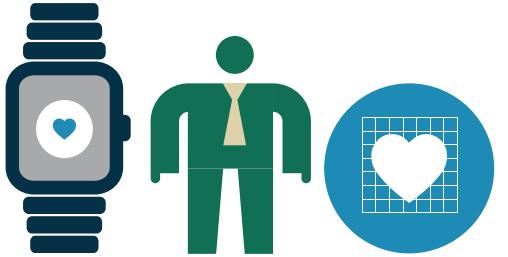
The legal framework consists of two different set of rules:

- Legislative Decree 219/2006 (which implemented Directive 2001/83/EC on the Community code relating to medicinal products for human use), namely art. 113 and following governing the advertising of medicinal products;
- Presidential Decree 309/1990 ("*Consolidated text of laws governing narcotics and psychotropic substances*") ("DPR 309/1990").

In particular, article 115, par. 2 of Legislative Decree 219/2006 prohibits the advertising to the public of prescription medicines and medicines containing psychotropic substances or narcotics. Article 84 of the DPR 309/1990 also prohibits the advertising of substances or preparations included in the tables of article 14 (such as cannabis for therapeutic use), even if it is carried out indirectly.

3. What laws govern the sourcing of medical cannabis as raw materials from producers?

i. MOH Decree of 9 November 2015 established a national production of cannabis. The MOH has identified the Chemical Pharmaceutical Military Plant located in Florence as the facility where the active substance has to be cultivated and produced (Cannabis FM2 THC 5-8 percent, CBD 7.5 – 12 percent and Cannabis FM1 containing THC 13.0-20.0 percent, CBD<1 percent are produced).



Continues on next page

National laws: Italy

Part 1 – Cannabis for medical use

The quantity of cannabis produced by the Chemical Pharmaceutical Military Plant can vary in accordance with the consumption needs of the previous years and the requests of the regions/ provinces. To guarantee the presence of enough cannabis, in December 2021, a collaboration agreement between the MOH and the Ministry of Defence was executed with the aim to expand the national production of cannabis-based medicines, giving to the Chemical Pharmaceutical Military Plant of Florence the possibility to point out to the MOH additional growers deemed suitable for the cultivation of cannabis. It will be then a duty of the MOH, with its own decree, to choose the growers to be authorised. In the case of surplus, the agreement provides for the possibility to export cannabis to other countries that have made a request to the competent authority (in Italy the MOH that acts as the "*State organism for Cannabis*" under the 1961 Convention.

ii. The MOH may also issue, pursuant to DPR 309/1990, authorisation to cultivate cannabis sativa L. from certified seeds of varieties permitted by EU legislation, for the supply of leaves and inflorescences of cannabis sativa L. to pharmaceutical manufacturers (i.e., Officine Farmaceutiche), authorised by the Italian Medicines Agency (AIFA) to enable the production of active pharmaceutical ingredients ("**API**"), according to legislative decree 219/2006.

The MOH also authorise the production of cannabis extract containing cannabinoids for the production of API by authorised pharmaceutical manufacturers. Pursuant to article 31 of DPR 309/1990, each year the MOH is in charge of publishing a decree stating the maximum quantity of cannabis that can be produced by each authorised manufacturer for the following year.

3. Through which distribution channels may medical cannabis be distributed (e.g., pharmacies only etc.)?

Cannabis-based medicines can only be distributed through pharmacies. A specific registration and recording system provided for by DPR 309/1990 applies.

It is a pharmacist's responsibility to prepare magistral preparations in accordance with dosage and method of administration indicated by the doctor's prescription.

Go to previous page

National laws: Italy

Part 2 – Cannabis for recreational use

1. Is the use of cannabis allowed:

a. for recreational purposes, i.e., as a drug?

Pursuant to DPR 309/1990, cannabis and its derived products are considered narcotic or psychotropic substances for which the cultivation, production, sale and marketing is prohibited. Breach of this decree is punished with a fine and imprisonment, in addition to, if applicable, an administrative sanction.

Law 242/2016 ("*Provisions for the promotion of the cultivation and agro-industrial supply chain of hemp*") authorised (i) the cultivation of certain varieties of hemp (cannabis sativa L.), allowed under art. 17 of Directive 2002/53 EC and not falling within the ambit of application of DPR 309/1990; and (ii) the use of such hemp for the specific scopes indicated in article 1 par. 3 and for the production of the products mentioned in art. 2, par. 2 only.

A grey area exists, however, given that there's no explicit mention of the "recreational use" or the possibility to commercialise hemp directly under Law 242/2016. This has led to different interpretations by Italian jurisprudence.

We are aware of two different legislative proposals aimed at clarifying the point.

b. in food and beverages?

Law 242/2016 expressly authorises the use of legally cultivated hemp to obtain food, provided that the maximum levels of THC permitted (as specified by the MOH decree of 5 November 2019 and by EU Regulation 2022/1939 amending Regulation 1881/2006) are not exceeded, and that the applicable requirements of the specific product legislation are complied with.

There are no specific regulations for beverages but, to the extent that they can be considered to fall within the food category, they should be permitted with the same conditions.

c. in cosmetics?

Law 242/2016 expressly authorises the use of legally cultivated hemp to obtain cosmetics, provided that the applicable requirements of the specific product legislation are complied with.

Annex 2 of EU Regulation 1223/2009 indicates that '*any substance listed in Tables I and II of the Single Convention on Narcotic Drugs executed in New York on 30 March 1961*' cannot be used in cosmetic products.

For this reason, only hemp lawfully cultivated pursuant to Law 242/2016 can be used in the production of cosmetics.

Continues on next page

National laws: Italy

Part 2 – Cannabis for recreational use

2. What is the legal framework and what are the restrictions for the advertising of recreational cannabis-containing products?

Article 84, par.1 of the DPR 309/1990 prohibits advertising for substances or preparations included in the tables of art. 14, such as cannabis.

However, given that foods and cosmetics containing the lawfully cultivated cannabis pursuant to Law 242/2016 are permitted, advertising is allowed provided (with a disclaimer) that the amount of THC contained inside such products is made clear, and that it complies with the general principles and regulations on advertising (e.g., those provided for by Legs. Decree 206/2005, the so called Consumer Code).

3. What laws govern the sourcing of recreational cannabis as raw materials from producers?

Article 2, par. 1, of Law 242/2016 allows the production in Italy of cannabis sativa L. in varieties allowed under art. 17 of Directive 2002/53 EC, not falling within the ambit of application of DPR 309/1990, without the need for growers to obtain any kind of authorisation, provided that the cultivation is carried out for the specific scopes indicated in article 1 par. 3 and for the production of the products mentioned in art. 2, par. 2 only (e.g., production of food or cosmetics, with no express mention of recreational use as such, see comment above).

The grower is obliged to keep the tags of the purchased seed for a period of not less than twelve months in addition to the invoices for the period established by law (article 3).

4. Through which distribution channels may cannabis be distributed for recreational purposes (e.g., pharmacies only etc.)?

The distribution of foods or cosmetics containing lawfully cultivated cannabis (with no express mention of recreational use as such, see comment above) can take place either through physical shops or through online shops.

Go to previous page

National laws: Italy

Part 3 – CBD

1. Is the use of CBD allowed?

The MoH issued a Decree on 7 August 2023, which qualifies CBD intended for oral administration as a narcotic substance.

The Decree has been appealed before the Administrative Tribunal of Rome (TAR Roma) challenging the legitimacy of the MOH decision to qualify CBD intended for oral administration as a narcotic substance, pursuant to DPR 309/1990. The Court granted interim orders suspending the efficacy of the Decree of 7 August 2023, so allowing the use of CBD in preparation to be administered orally again.

The suspension is valid until the first instance judgment will be issued on 24 September 2024.

a. in food and beverages?

No, CBD both if extracted from inflorescences or if synthetically produced, is considered as a "novel food" and therefore requires specific authorisation from the European Commission according to EU Regulation 2015/2283, subject to risk assessment by the European Food Safety Agency – EFSA.

b. in cosmetics?

Yes, synthetically produced CBD is included in the 'CosIng' EU database of cosmetics ingredients.

c. in OTC pharmaceuticals?

If the appeal against the MOH of August 2023 (mentioned above) is rejected, it would not be possible to use CBD in OTC pharmaceuticals, only in prescription medicines. Whilst we're not aware of any OTC product authorised in Italy that contains CBD, in principle it could be authorised provided that safety and efficacy, in addition to a positive risk benefit ratio, are proven.

d. in prescribed pharmaceuticals?

Yes, in particular the Italian Medicines Agency (AIFA) has authorised the reimbursement for the CBD-based drug for human use.

2. What is the legal framework and what are the restrictions for the advertising of CBD-containing products?

The type of promotion allowed for products containing CBD depends on the specific product category.

Advertising of cosmetics containing CBD is allowed provided that the general principle and regulation on advertising have been complied with (e.g., those provided for by the Legs. Decree 206/2005, the so called "**Consumer Code**").

For medicinal products, the provisions of art. 113 and following of Legs. Decree 219/2006 apply, which means, among other things, that the advertising of prescription medicines to the public is prohibited.

3. What laws govern the sourcing of CBD as raw materials from producers?

Currently, no specific legislation exists.

4. Through which distribution channels may CBD be distributed (e.g., pharmacies only etc.)?

Medical products containing CBD can be dispensed by pharmacies only following the procedure indicated in Article 45 of the DPR 309/1990 which also provides for a specific registration and recording system (see Art. 62 of the DPR 309/1990).

Cosmetics containing CBD can be distributed through shops.

Continues on next page

National laws: Poland

Part 1 – Cannabis for medical use

1. Is the use of cannabis allowed:

a. in OTC pharmaceuticals?

In Poland, "non-fibrous hemp herb and pharmaceutical extracts, tinctures and all other extracts of non-fibrous hemp" are classified as narcotics (see Act on Counteracting Drug Addiction, OJ.2023.1939, as amended, "Act on Counteracting Drug Addiction" and the implementing regulations), having the I-N (least restricted) category. Non-fibrous hemp is defined as containing more than 0.3% of the sum of Δ9-THC and Δ9-THCA (i.e. as opposed to fibrous hemp, which is not expected to have any psychoactive effect). Narcotics from this category can be used for medical, industrial or scientific purposes. Currently, there are no medicinal products containing cannabis that are OTC available.

b. in prescribed pharmaceuticals?

The only medicinal product containing delta-9-tetrahydrocannabinolum that has been authorized in Poland is Sativex. It is available as an oral spray, in packs containing 3 containers of 10 ml. The drug is not subject to reimbursement. Sativex is dispensed only against prescription from a doctor ("Rpw" availability category for products containing narcotic or psychotropic substances). For information on the other medicinal product, Epidyolex, containing CBD as an active substance – see: Part 3 – CBD.

Cannabis for medical use is also authorized on the market as pharmaceutical raw material and available to patients as prescription drug (*lek recepturowy*) against the Rpw prescription. In practice, such products are in the form of dried hemp, which can be smoked. The use of cannabis in prescription drugs has been explicitly allowed in Poland since 1 November 2017 (see Act amending the Act on Counteracting Drug Addiction and the Act on Reimbursement of Medicines, Foodstuffs for Special Nutritional Purposes and Medical Devices, OJ.2017.1458).

Pursuant to the Pharmaceutical Law (OJ.2024.686, "**Pharmaceutical Law**"), prescriptions for medicinal products containing narcotic or psychtropic substances are issued in electronic format only. Since patients can have their medical consultations online, medical cannabis is relatively easily accessible, in spite of not being OTC-available. Certain restrictions are introduced by implementing regulations enacted by the Ministry of Health and official communications, introducing requirements such as additional examination of patients.

2. What is the legal framework and what are the restrictions for the advertising of medical cannabis-containing products?

Advertising and promoting psychotropic substances, narcotics, substitutes, or new psychoactive substances is prohibited under the Act on Counteracting Drug Addiction. Similarly, the Pharmaceutical law prohibits in particular advertising to the public (as opposed to advertising to persons authorised to prescribe or trade in medicinal products) medicinal products that:

a. are dispensed on prescription only;

b. contain narcotic drugs and psychotropic substances.

Continues on next page

National laws: Poland

Part 1 – Cannabis for medical use

According to the Regulation of the Minister of Health on the advertising of medicinal products (OJ.2023.1648), non-consumer advertising needs to be presented in such a way that it does not reach those for whom it is not intended.

What laws govern the sourcing of medical cannabis as raw materials from producers?

Before May 2022 it was not possible to cultivate non-fibrous hemp in Poland and therefore medical cannabis had to be imported from abroad.

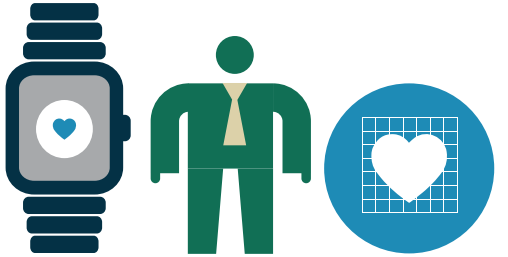
Pursuant to the Act on Counteracting Drug Addiction, cultivation of non-fibrous hemp for pharmaceutical raw materials can be carried out by research institutes. Cultivation of medical cannabis requires a permit from the Chief Pharmaceutical Inspector (*Główny Inspektor Farmaceutyczny*).

Import is regulated, i.e., by the Regulation outlining the detailed conditions and procedures for issuing permits and documents necessary for the import, export, intra-community purchase or supply of narcotics, psychotropic substances, or precursors of these categories (OJ.2021.399), which regulates licences for the export or supply of narcotics or psychotropic substances.

4. Through which distribution channels may medical cannabis be distributed (e.g., pharmacies only etc.)?

As mentioned above, medical cannabis is available to patients in the form of dried hemp (authorized as pharmaceutical raw material), as well as in medicinal products (Sativex). Both types of medical cannabis are dispensed against prescription.

Only licenced medical professionals may prescribe medical cannabis, and the prescribed products may only be dispensed by pharmacists in pharmacies allowed to process the Rpw prescriptions.



Go to previous page

National laws: Poland

Part 2 – Cannabis for recreational use

1. Is the use of cannabis allowed:

a. for recreational purposes, i.e., as a drug?

Recreational use of cannabis is not allowed. Under Polish law, possession of marijuana is illegal and punishable by up to three years imprisonment (Article 62 of the Act on Counteracting Drug Addiction). In minor cases, the offender faces a fine, restriction of liberty or imprisonment of up to one year. The prosecutor may, however, discontinue the case before issuing a decision to initiate proceedings if the offence involves a small amount of narcotics and it would be considered inappropriate to punish the offender in view of the circumstances of the offence and the degree of social harm caused by the offence. It should be noted that it is the prosecutor's discretion to drop the case at this stage. Discontinuation of the proceedings on that basis is not possible if there is a significant amount of the narcotic substance. Nevertheless, in any case the proceedings should be discontinued if the social harm of the alleged offence is negligible.

b. in food and beverages?

Use of cannabis is allowed in food and beverages only in very small quantities which, according to national legislation, preclude the substances from being considered narcotics (i.e. it is difficult to speak of "recreational use of cannabis via/in food"). The maximum limits for the amount of delta-9-tetrahydrocannabinol equivalents in food is set by the Regulation 2023/915:

- Hemp seed – 3.0 mg/kg
- Ground hemp seed, (partially) defatted hemp seed and other processed products derived from hemp seed, except hemp seed oil – 3.0 mg/kg
- Hemp seed oil – 7,5 mg/kg

It should be noted that hemp containing no more than 0.3% of THC (Δ9-THC, Δ9-THCA) is considered to be fibre hemp, which is not subject to Act on Counteracting Drug Addiction (i.e. is not regulated as narcotic substance, contrarily to non-fibrous hemp).

c. in cosmetics?

As mentioned above, cosmetics containing ingredients coming from fibrous hemp are not subject to provisions governing narcotic drugs. For the rest, the use of THC in cosmetics is prohibited by Regulation 1223/2009.

2. What is the legal framework and what are the restrictions for the advertising of recreational cannabis containing products?

As outlined above, according to Article 20(1) of Act on Counteracting Drug Addiction, it's prohibited to advertise and promote psychotropic substances, narcotics, substitutes or new psychoactive substances. It is therefore not permitted to promote cannabis as a psychoactive substance.

3. What laws govern the sourcing of recreational cannabis as raw materials from producers?

Use of cannabis for solely recreational purposes is illegal in Poland.

4. Through which distribution channels may cannabis for recreational purposes be distributed (e.g., pharmacies only etc.)?

Use of cannabis for solely recreational purposes is illegal in Poland.

Continues on next page

National laws: Poland

Part 3 – CBD

1. Is the use of CBD allowed:

a. in food and beverages?

Contrarily to *Cannabis sativa* L. seeds or herbal infusions, CBD (and cannabinoids in general) is considered novel food by the Commission. Since this has been the subject of controversy in the past, legal situation of food products containing CBD that have been already placed on the Polish market without the novel food procedure is unclear. In practice there have been cases in which the authorities have questioned their legality. *Cannabis sativa* L. seeds or herbal infusions are considered traditional food and therefore are not subject to the novel food procedures (see also judgment of Administrative Court Warsaw of 17.02.2022, case no. V SA/Wa 5258/21).

Hemp ingredients can be marketed, as long as they are compliant with Regulation 2023/915.

Moreover, CBD products in the form of dried hemp (intended for e.g. smoking) are available on the market.

b. in cosmetics?

CBD is allowed in cosmetics as it's been removed from the list of substances prohibited in cosmetic products (annex to Regulation 1223/2009). It should be noted that a call for data on the safety of CBD in cosmetic products has been opened by the Commission and will be pending until 1 October 2024, so possible future developments are to be expected.

c. in OTC pharmaceuticals?

It could be possible pursuant to general rules on marketing authorization of medicinal products. We're not aware, however, of any OTC product authorised in Poland that contains CBD as active substance.

d. in prescribed pharmaceuticals?

Yes, but only under medical prescription pursuant to the provisions of the Pharmaceutical Law. The only prescription medicine already registered in Poland is Epidyolex, which is available against Rpz prescription ("restricted use" prescription for medicines intended for outpatient treatment) as an oral solution (100mg/ml).

2. What is the legal framework and what are the restrictions for the advertising of CBD-containing products?

Due to the unclear legal status of CBD, the rules for advertising such products are no less vague. General sectoral legal provisions are applicable to CBD products. Medicinal products can be advertised pursuant to the Pharmaceutical Law provisions. Advertising of prescribed medicines is prohibited. Cosmetics, and food and beverages can be advertised in accordance with the respective legislation.

Continues on next page

National laws: Poland

Part 3 – CBD

3. What laws govern the sourcing of CBD as raw materials from producers?

Cultivation of fibrous hemp (i.e. not containing THC, but which may contain CBD) is also regulated. In particular, such cultivation may be carried out after registration in respective register held by National Agricultural Support Centre (*Krajowy Ośrodek Wsparcia Rolnictwa*).

4. Through which distribution channels may CBD be distributed (e.g., pharmacies only etc.)?

There are no specific distribution channels for products (food, beverages, cosmetics) containing CBD. Such products are available online and in stores, pharmacies, drug stores, etc. Vending machines with CBD dried hemp or other products are also present.

“She [Agnieszka] has in-depth expertise in the life sciences and healthcare sector, and manages intricate national and international patent, trade secret, and trademark disputes in the retail, telecommunications, chemistry, life sciences and healthcare industries.”

Dr. Agnieszka Sztoldman recognized in top 50 ‘Shining Light’ influential women in IP in the prestigious World IP Review’s Influential Women in IP.

Continues on next page

National laws: Spain

Part 1 – Cannabis for medical use

1. Is the use of cannabis allowed:

a. in OTC pharmaceuticals?

No. As cannabis is included in Schedule I of the 1961 Single Convention on Narcotic Drugs of the United Nations, cannabis for medical use must be prescribed, pursuant to Royal Decree 1675/2012 of 14 December, which regulates official prescriptions and special requirements for the prescription and dispensing of narcotic drugs for human and veterinary use.

b. in prescribed pharmaceuticals?

Yes, pursuant to Article 4 of the 1961 Convention. As cannabis is included in Schedule I, its production, manufacture, export, import, distribution, trade, use and possession should be limited to medical and scientific purposes only.

2. What is the legal framework and what are the restrictions for the advertising of medical cannabis-containing products?

In Spain, neither prescription-only medical products nor those that contain psychotropic or narcotic substances can be promoted to the public, as defined in the international conventions. Spain signed and ratified the aforementioned 1961 Convention in 1972.

3. What laws govern the sourcing of medical cannabis as raw materials from producers?

Both import and domestic sourcing of raw materials for medical cannabis are subject to the following respective provisions:

a. Order ICT/920/2018 of 30 August 2018 on the authorisation and control system for the import of hemp seeds not intended for sowing (*Orden ICT/920/2018, de 30 de agosto, sobre régimen de autorización y control de importación de semillas de cáñamo no destinadas a la siembra*) stipulates that seeds may only be imported into Spain by importers who have been authorised by the Subdirectorate General for International Trade in Goods of the Directorate General for Trade Policy and Competitiveness (*Subdirección General de Comercio Internacional de Mercancías de la Dirección General de Política Comercial y Competitividad*).

b. Law 17/1967 of 8 April 1967 (*Ley 17/1967, de 8 de abril, por la que se actualizan las normas vigentes sobre estupefacientes y adaptándolas a lo establecido en el convenio de 1961 de las Naciones Unidas*) updates the existing rules on narcotic drugs, and bringing them into line with the 1961 Convention. It's essential to have an authorisation from the Spanish Agency for Medicines and Medical Devices (*Agencia Española de Medicamentos y Productos Sanitarios* – "**AEMPS**"), which grants licences for the cultivation of cannabis plants for research and/or medical purposes.

4. Through which distribution channels may medical cannabis be distributed (e.g., pharmacies only etc.)?

Medical cannabis can only be prescribed by medical practitioners and distributed at legally authorised pharmacies or the pharmacy services of hospitals, health centres and the Primary Care premises of the Spanish National Health System.

Continues on next page

National laws: Spain

Part 2 – Cannabis for recreational use

1. Is the use of cannabis allowed:

a. for recreational purposes, i.e., as a drug?
No, as cannabis is included in Schedule I of the 1961 Convention, its use and possession should be limited to medical and scientific purposes only.

b. in food and beverages?
No, as per above in 1a.

c. in cosmetics?
No, as per above in 1a.

2. What is the legal framework and what are the restrictions for the advertising of recreational cannabis-containing products?
Promotion of recreational cannabis is not allowed since its use its prohibited by the 1961 Convention.

3. What laws govern the sourcing of recreational cannabis as raw materials from producers?
Sourcing of raw materials for recreational cannabis is not allowed since its use its prohibited by the 1961 Convention.

4. Through which distribution channels may cannabis be distributed for recreational purposes (e.g., pharmacies only etc.)?
Distribution of recreational cannabis is not allowed since its use its prohibited by the 1961 Convention.

Continues on next page

National laws: Spain

Part 3 – CBD

1. Is the use of CBD allowed:

a. in food and beverages?

The Spanish Agency for Food Safety and Nutrition (*Agencia Española de Seguridad Alimentaria y Nutrición* – "**AESAN**") has reiterated that CBD must be categorised as a "novel food", as it doesn't have a history of safe and significant consumption. For this reason, its use would require prior authorisation by the EU Commission (pursuant to the Novel Food Regulation), and to date, no such authorisations have been issued. It should also be noted that CBD may not be obtained from extracts and tinctures of cannabis.

b. in cosmetics?

Yes, the use of CBD in cosmetics is allowed unless CBD is obtained from extracts and tinctures of cannabis.

c. for non-medical purposes?

The use of CBD for non-medical purposes is allowed unless CBD is obtained from extracts and tinctures of cannabis. It should be noted, that when used in food or beverages and pharmaceuticals additional obligations and restrictions might apply – as indicated in the answers for part III, question 1a. and 1d.

Other uses might also be subject to additional regulatory provisions.

d. in OTC pharmaceuticals?

The use of CBD in OTC pharmaceuticals is allowed with a prior authorisation from the Spanish Agency for Medicines and Medical Devices (*Agencia Española de Medicamentos y Productos Sanitarios* – "**AEMPS**") unless CBD is obtained from extracts and tinctures of cannabis.

e. in prescribed pharmaceuticals?

If CBD is obtained from extracts and tinctures of cannabis, then the conditions set in Part I (Cannabis for Medical use) would apply. If not, it would be allowed under medical prescription, providing it has been authorised by the AEMPS.

2. What is the legal framework and what are the restrictions for the advertising of CBD-containing products?

If the CBD-containing product is a prescribed pharmaceutical, then the conditions set in part I, question 2 would apply. OTC CBD-containing pharmaceuticals would be subject to:

a. Royal Decree 1416/1994 of 25 June 1994 (*Real Decreto 1416/1994, de 25 de junio, por el que se regula la publicidad de los medicamentos de uso humano*), which regulates the advertising of medicinal products for human use;

b. The Code of Good Practices of the Pharmaceutical Industry; and

c. Other general pharmaceutical legislation.

If the CBD-containing product is a cosmetic, promotion would be subject to:

a. Royal decree 85/2018 of 23 February 2018 (*Real Decreto 85/2018, de 23 de febrero, por el que se regulan los productos cosméticos*), which regulates cosmetic products, and the general regulations on advertising; and

b. The Spanish National Association of Perfumes and Cosmetics' self-regulation code for responsible communication in the perfume and cosmetics industry.

Continues on next page

National laws: Spain

Part 3 – CBD

If the CBD-containing product is categorised as food or beverage:

a. Applicable food or beverage legislation may vary depending on the nature of the product (e.g., if the product incorporating CBD is categorised as a food supplement).

In all cases above, as well other applicable areas, general advertising legislation applies, as well as the existing co-regulation or self-regulation codes adopted by the relevant parties (which would usually involve the competent authorities and the key stakeholders) and EU regulations.

3. What laws govern the sourcing of CBD as raw materials from producers?

Domestic sourcing of CBD as an extract and/or tincture of cannabis is illegal in Spain, pursuant to Law 17/1967 of 8 April 1967 (*Ley 17/1967, de 8 de abril, por la que se actualizan las normas vigentes sobre estupefacientes y adaptándolas a lo establecido en el convenio de 1961 de las Naciones Unidas*), which updates existing rules on narcotic drugs, bringing them into line with the 1961 Convention.

Domestic sourcing of CBD outside of the above category is not prohibited, although to date no ad-hoc provisions have been made.

Notwithstanding the above, the cultivation of cannabis for industrial purposes is permitted (intended exclusively for the production of fibre, grain, and seeds), provided they are cannabis sativa L. varieties with a tetrahydrocannabinol content of less than 0.2%.

4. Through which distribution channels may CBD be distributed (e.g., pharmacies only etc.)?

a. Prescribed and OTC pharmaceuticals: see answer part I, question 4. OTC pharmaceuticals can be sold online, but only by legally authorised pharmacies.

b. Cosmetics: the distribution channels are not restricted, although the distributors are obliged to ensure that cosmetic products conform to the requisites set forth in the Royal Decree 85/2018 of 23 February 2018, which regulates cosmetic products, and the corresponding EU regulations.

c. Food or beverages: these are subject to the general food and beverages regulations.

d. Non-medical purposes: notwithstanding the answers to part III, question 4b. and 4c., additional regulatory provisions may apply depending on the type of product incorporating CBD.

Go to previous page

National laws: Sweden

Part 1 – Cannabis for medical use

1. Is the use of cannabis allowed:

a. in OTC pharmaceuticals?

In Sweden, the medical use of cannabis is illegal, except for products that have been approved as pharmaceuticals by the Swedish Medical Products Agency (*Läkemedelsverket* – "**LV**") and prescribed by a qualified doctor. This means that the use of cannabis in OTC pharmaceuticals is therefore illegal.

b. in prescribed pharmaceuticals?

Cannabis-based pharmaceuticals that have been approved and prescribed by a qualified doctor are allowed. There are currently two cannabis-based pharmaceuticals approved for sale in Sweden (*Sativex* and *Epidyolex*).

2. What is the legal framework and what are the restrictions for the advertising of medical cannabis-containing products?

EU member states have to prohibit all marketing of medical products for human use for which a MA has not been granted according to Article 87 paragraph 1 of the Community Code. This means that the marketing of pharmaceuticals that have not yet been approved for sale and the marketing of pharmaceuticals that are not approved but are sold with the support of a licence shall be prohibited. Accordingly, the Swedish Medicinal Products Act (*Läkemedelslagen* – "**LmL**") prohibits the marketing of medical products for human use that have not been approved for sale.

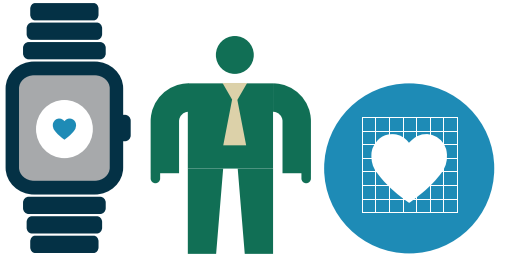
Regulation on the marketing of prescription drugs can be found in Article 88 paragraph 1 of the Community Code and Article 85 paragraph 3 of EU Directive 2001/82/EC[11]. These directives provide that EU member states shall prohibit advertising aimed at the general public of medical products that are prescribed or that contain psychotropic or narcotic substances, within the meaning of, among others, the 1961 Convention and the VC. The Swedish Medicinal Products Act accordingly provides that the marketing of prescription drugs directed at the general public is prohibited.

3. What laws govern the sourcing of medical cannabis as raw materials from producers?

There's no Swedish legislation that governs the sourcing of medical cannabis as raw materials. All sourcing of medical cannabis as raw materials is considered a criminal offence unless it's approved as per explained above.

4. Through which distribution channels may medical cannabis be distributed (e.g., pharmacies only etc.)?

It's illegal for anyone other than licensed pharmacies to sell prescription drugs to private individuals.



Continues on next page

11 *Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products.*

National laws: Sweden

Part 2 – Cannabis for recreational use

1. Is the use of cannabis allowed:

a. for recreational purposes, i.e., as a drug?

Cannabis is classified as a narcotic drug and therefore falls under the Swedish Penal Law on Narcotics (*Narkotikastrafflagen* – "**NSL**"). The buying, trading, and using cannabis constitutes a criminal offence. This offence also includes using oil that has been extracted from legally produced industrial hemp for recreational purposes.

b. in food and beverages?

Cannabis is classified as a narcotic drug and therefore falls under the NSL. The buying, trading or use of cannabis constitutes a criminal offence, including cannabis in food and beverages.

c. in cosmetics?

Narcotic substances, such as cannabis may not be used in cosmetic products. However, the LV has no objections to the ingredient "hemp seed oil", which is extracted from industrially grown hemp cannabis sativa. Hemp seed oil is not classified as a drug.

2. What is the legal framework and what are the restrictions for the advertising of recreational cannabis-containing products?

As the buying, trading and use of cannabis constitutes a criminal offence under the NSL, all promotion of recreational cannabis-containing products is prohibited.

3. What laws govern the sourcing of recreational cannabis as raw materials from producers?

As the buying, trading and use of cannabis constitutes a criminal offence under the NSL, all promotion of recreational cannabis-containing products is prohibited.

4. Through which distribution channels may cannabis be distributed for recreational purposes (e.g., pharmacies only etc.)?

As the buying, trading and use of cannabis constitutes a criminal offence under the NSL, cannabis cannot be distributed for recreational purposes.

Continues on next page

National laws: Sweden

Part 3 – CBD

1. Is the use of CBD allowed:

a. in food and beverages?

CBD oil is currently listed in the so-called "novel food catalogue", together with other cannabinoids. This means that CBD oil should be considered a "novel" food that has not yet been approved. Non-approved new foods and food ingredients may not be placed on the market within the EU as food. The use of CBD is therefore not allowed in food and beverages. (Plant parts that naturally contain CBD are not included in the novel food catalogue.)

b. in cosmetics?

Unlike THC, it's legal to use CBD in cosmetic products. According to the LV, it's permitted to use ingredients derived from hemp seeds and synthetically produced cannabidiol (CBD) in beauty products. It's therefore allowed to use seeds from the hemp plant, but nothing else from the plant as it also contains THC, which is the ingredient that produces hallucinogenic effects.

c. in OTC pharmaceuticals?

The Swedish Supreme Court (*Högsta domstolen*) ruled in 2019 that CBD is considered legal as long as it doesn't contain traces of the narcotic substance THC. In Sweden, CBD is classified as a medical product and it's therefore allowed to be possessed and may be sold as long as it's approved by the LV. CBD oil without THC is covered by the LmL, and must be evaluated and approved as a pharmaceutical to be sold. It's therefore not possible to sell CBD oil, with or without THC, in Sweden without special permission. The only approved types of cannabis-based pharmaceuticals are prescribed drugs and can therefore not be found OTC.

d. in prescribed pharmaceuticals?

Yes, CBD is allowed in prescribed pharmaceuticals.

2. What is the legal framework and what are the restrictions for the advertising of CBD-containing products?

a. Pharmaceuticals

In Sweden, the LV classifies pure CBD products (without THC) that are taken orally or inhaled as pharmaceuticals, and therefore fall under the LmL. The products may only be sold and marketed if they are first approved as pharmaceuticals by the LV. Only approved or registered pharmaceuticals may be marketed. It's illegal, however, according to the LmL, to direct the marketing of prescription drugs to the general public.

Continues on next page

National laws: Sweden

Part 3 – CBD

b. Food and beverages

Food that has not been consumed to any great extent within the EU before 15 May 1997 is called a "novel food". CBD oil is currently mentioned in the so-called "novel food catalogue", together with other cannabinoids. This means that CBD oil should be considered a novel food that has not yet been approved. Non-approved new foods and food ingredients may not be placed on the market within the EU as food. Plant parts that naturally contain CBD are not included in the novel food catalogue. As it's not allowed to sell these types of products, the promotion of them is prohibited.

c. Cosmetics

Unlike THC, CBD is not psychoactive, which means that it doesn't cause intoxication. For this reason, it's legal to use CBD in cosmetic products, and CBD-containing products can be advertised as they're sold as ordinary cosmetics.

3. What laws govern the sourcing of CBD as raw materials from producers?

If CBD contains THC, it's considered a narcotic and the sourcing of narcotics is considered a criminal offence. There's therefore no Swedish legislation that governs the sourcing of CBD with THC as raw materials from producers. CBD that doesn't contain THC is not, however, considered a narcotic. The sourcing of CBD without THC as raw materials from producers is therefore allowed. (Note that exceptions exist for food and beverages.)

4. Through which distribution channels may CBD be distributed (e.g., pharmacies only etc.)?

It's illegal for anyone other than licensed pharmacies to sell prescription drugs to private individuals. CBD-containing cosmetics are legal according to the LV and can be distributed as ordinary cosmetics. CBD in food and beverages is not allowed according to the Swedish Food Agency, and it's therefore not allowed for it to be distributed.

Go to previous page

National laws: UK

Part 1 – Cannabis for medical use

1. Is the use of cannabis allowed:

a. in OTC pharmaceuticals?

No.

b. in prescribed pharmaceuticals?

Only in very limited situations to treat the following conditions:

- children and adults with rare, severe forms of epilepsy;
- adults with vomiting or nausea caused by chemotherapy; and
- people with muscle stiffness and spasms caused by multiple sclerosis (MS).

Moreover, this is usually only when all other treatments have not been suitable or have not helped.

2. What is the legal framework and what are the restrictions for the advertising of medical cannabis-containing products?

Under the Human Medicines Regulation 2012, the advertising of prescription medicines to the general public is unlawful.

3. What laws govern the sourcing of medical cannabis as raw materials from producers?

Cannabis is a class B controlled drug under the Misuse of Drugs Act 1971 and is listed in schedule 1 of the Misuse of Drugs Regulations 2001 and in the Misuse of Drugs Designation Order 2015. The Home Office acts as the National Cannabis Agency, as required by the UN Convention on the control of narcotics.

It's unlawful to possess, supply, cultivate, produce, import or export cannabis, except under a Home Office licence. Any sourcing of medical cannabis must there be done under a Home Office licence.

4. Through which distribution channels may medical cannabis be distributed (e.g., pharmacies only etc.)?

The distribution of cannabis is highly controlled and it can therefore only be distributed by those that hold Home Office Controlled Drug licences, unless a limited licensing 'exemption' applies e.g., a pharmacist or person conducting a retail pharmacy business acting in their respective capacities.

The prescribing of cannabis-based products for medicinal use is restricted to only those clinicians listed on the Specialist Register of the General Medical Council.

"A brilliant team of lawyers, very knowledgeable, responsive, persistent, approachable and great to work with."

Health, Legal 500, 2023

Continues on next page

National laws: UK

Part 2 – Cannabis for recreational use

1. Is the use of cannabis allowed:

a. for recreational purposes, i.e., as a drug?

No, cannabis is classified as a Class B drug in the UK under the Misuse of Drugs Act 1971 and is therefore not permitted for recreational use.

b. in food and beverages?

No, as above, cannabis is a controlled drug in the UK and therefore cannot be used in food and beverages.

c. in cosmetics?

No, as above, cannabis is a controlled drug in the UK and cannot be used in cosmetics.

It should be noted that hemp (the name commonly used for specific varieties of cannabis that typically have lower levels of THC) can be lawfully cultivated and processed for industrial use with an industrial hemp licence. Hemp can be lawfully cultivated and processed for industrial use with an "industrial hemp" licence.

Hemp oil is used in cosmetics and food supplements.

2. What is the legal framework and what are the restrictions for the advertising of recreational cannabis-containing products?

The promotion of recreational cannabis-containing products is illegal as cannabis is considered a controlled drug. For this reason, there are no additional frameworks governing this area.

3. What laws govern the sourcing of recreational cannabis as raw materials from producers?

The supply and production of recreational cannabis-containing products is illegal as cannabis is considered a controlled drug. For this reason, as above, no additional frameworks exist for governing this area.

4. Through which distribution channels may cannabis be distributed for recreational purposes (e.g., pharmacies only etc.)?

The distribution of recreational cannabis containing products is illegal as cannabis is considered a controlled drug. For this reason, as above, no additional frameworks exist for governing this area.

“Extremely knowledgeable about the health sector, the OC team are very personable and approachable to discuss operational items as well as legal.”

Health, Legal 500, 2023

Continues on next page

National laws: UK

Part 3 – CBD

1. Is the use of CBD allowed:

a. in food and beverages?

Yes, if there's a Novel Foods Approval. It should be noted that at present, no novel food authorisations have been granted for CBD yet. However, the Food Standards Agency ("**FSA**") is progressing applications for authorisations.

b. in cosmetics?

Yes, as long as it doesn't contain any controlled cannabinoids such as THC and meets certain criteria depending on whether it's synthetic or plant-based CBD.

c. in OTC pharmaceuticals?

No.

d. in prescribed pharmaceuticals?

Yes. The UK's Medicines and Healthcare products Regulatory Agency ("**MHRA**") has taken the position that CBD containing products that are taken for a medicinal purpose should be treated as medicines and would need to be licensed as such.

2. What is the legal framework and what are the restrictions for the advertising of CBD-containing products?

Advertising for CBD products is only permitted for products that are not classified as a medicinal product or drug. However, this advertising is highly regulated. The main points to consider are:

- medicinal or medical claims must not be made on products which are not licensed medicinal products or medical devices that have been authorised by the MHRA;
- no claims that state or imply that CBD food supplements can prevent, treat, or cure human disease may be made;
- only health and nutrition claims authorised in Great Britain may be made in advertisements promoting foods or food supplements. At the time of writing, there are no authorised claims for CBD;
- all marketing materials should be labelled as forming part of an advertisement, e.g., by heading them "advertisement feature" that makes the commercial intent clear.

3. What laws govern the sourcing of CBD as raw materials from producers?

CBD is not a legally controlled cannabinoid in the UK, so the possession and supply of pure CBD oil doesn't require a UK Home Office licence (although it may need to comply with other product regulation when supplied for particular purposes, e.g., novel food, food supplement or cosmetic products legislation).

4. Through which distribution channels may CBD be distributed (e.g., pharmacies only etc.)?

In the UK, there are no restrictions on which distribution channels can be used for CBD.

Continues on next page

Contacts

Belgium

Vladimir Murovec
Head of Life Sciences Regulatory
T +32 472 607 628
vladimir.murovec
@osborneclarke.com

Louis Hoffreumon
Counsel
T +32 2 515 9328
louis.hoffreumon
@osborneclarke.com

France

Thomas Devred
Partner
T +33 1 84 82 41 06
thomas.devred
@osborneclarke.com

Justine Pellerin
Associate
T +33 1 84 82 46 94
justine.pellerin
@osborneclarke.com

Germany

Larissa Mößmer
Senior Associate
T +49 89 5434 8100
larissa.moessmer
@osborneclarke.com

Fabian Christoph
Partner
T +49 40 55436 4076
fabian.christoph
@osborneclarke.com

Italy

Maria Grazia Medici
Partner
T +39 06 3269 5015
mariagrazia.medici
@osborneclarke.com

Giulia Verusio
Associate
T +39 06 3269 5008
giulia.verusio
@osborneclarke.com

Poland

Agnieszka Sztoldman
Counsel
T +48 503 973 626
agnieszka.sztoldman
@osborneclarke.com

Spain

Rafael Garcia Del Poyo
Partner
T +34 91 576 44 76
rafael.garciadelpoyo
@osborneclarke.com

Mario Gras
Lawyer
T +34 91 576 44 76
mario.gras
@osborneclarke.com

Sweden

Mikael Nelson
Partner
T +46 709 555 059
mikael.nelson
@osborneclarke.com

UK

Peter Rudd-Clarke
Partner
T +44 207 105 7315
peter.ruddclarke
@osborneclarke.com

Anna Lundy
Associate Director
T +44 207 105 7075
anna.lundy
@osborneclarke.com

Glossary

1961 Convention – UN Single Convention on Narcotic Drugs

Δ9-THC – Delta-9-tetrahydrocannabinol

AEMPS – Spanish Agency for Medicines and Medical Devices

AESAN – Spanish Agency for Food Safety and Nutrition

AIFA – Italian Medicines Agency

AMG – German Medicinal Products Act

AM-HandelsV – Ordinance on the Trade with Medicinal Products

ANSM – French National Agency for Medicines and Health Products Safety

BfArM – Federal Institute for Drugs and Medical Devices

BtMBinHV - Narcotics Internal Trade Ordinance

BtMG – German Narcotics Act

CanG – German Cannabis Act

CBD – Cannabidiol

CJEU – Court of Justice of the European Union

CSP – French Public Health Code

EFSA – European Food Safety Agency

EMA – European Medicines Agency

EMCDDA – European Monitoring Centre for Drugs and Drug Addiction

EudraLex – The collection of rules and regulations governing medicinal products in the European Union

FAMHP – Federal Agency for Medicines and Health Products

FASFC – Federal Agency for the Safety on the Food Chain

FDF – Finished Dosage Form

GDP – Good distribution practices

GMP – Good manufacturing practices

HCVO – Health Claims Regulation

HWG – German Act on the Advertising of Medical Products

JEP – Belgian Ethical Board of Advertising

KCanG – German Consume Cannabis Act

LmL – Swedish Medicinal Products Act

LV – Swedish Medical Products Agency

MA – Marketing authorisation

MedCanG – German Medical Cannabis Act

MHRA – Medicines and Healthcare products Regulatory Agency

MOH – Ministry of Health

NemV – Food Supplements Ordinance

NSL – Swedish Penal Law on Narcotics

OTC – Over the counter

StGB – German Criminal Code

THC – Tetrahydrocannabinol

URPL – the Polish Medical Products Agency/Polish Agency for Medicines and Medical Devices (referred to differently in the Poland section)

VC – Vienna Convention on Psychotropic Substances

UWG – The German Advertising Act

WHO – World Health Organisation

About Osborne Clarke

Our global connections and 'best friends'

In addition to our 26 international locations, we extend our reach across the globe through a network of like-minded, best friend firms. With trusted contacts in over 100 countries, particularly in North America, EMEA & Asia Pacific, we'll find the right local partner for you, and make sure that you receive the Osborne Clarke level of service.

1,300+
talented lawyers

working with

340+
expert Partners

in

26
international locations*

advising across

8
core sectors

with insight into

3
Transformational trends

driven by

1
client-centric approach

Our locations around the world

Europe

Belgium: Brussels
France: Paris
Germany: Berlin, Cologne, Hamburg, Munich
Italy: Busto Arsizio, Milan, Rome
The Netherlands: Amsterdam
Poland: Warsaw
Spain: Barcelona, Madrid, Zaragoza
Sweden: Stockholm
UK: Bristol, London, Reading

USA

Miami, New York, San Francisco

Asia

China: Shanghai
India*: Bengaluru, Mumbai, New Delhi
Singapore

*Services in India are provided by a relationship firm

June 2024

Publication number OSB.CLA.426 E_2303291422LSH 06/24