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A legal roadmap for Cannabis



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Why this guide?

In recent years cannabis trade and related activity has developed into a growth business area. In the life sciences and healthcare fields there have been increases in the numbers of patients having access to medicinal cannabis and more general acceptance of the potential medicinal value of cannabis for patients. The number of countries allowing its recreational use has increased. Additionally, there is growing awareness of the potential for and actual use of cannabis plants across a range of different industry sectors, not least in cosmetics and food.

Taking account of the evolving political and ethical implications of cannabis production, trade and use it is important to be aware of differences in approach across different countries to assess which businesses and activities are viable in different (EU and non-EU) jurisdictions.

This guide provides high level information about the legal approach to regulating cannabis across a variety of jurisdictions in different regions. In each case the guide focuses on (i) medical use; (ii) recreational use; (iii) industrial use and (iv) the patentability of cannabis-based products.



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Key concepts

Cannabis plant

The cannabis plant has a wide range of industrial and medical applications. The hemp strain is used in building materials, textiles, paint and biofuel, to name a few examples, while other cannabis varieties are grown for their cannabinoid profiles. Tetrahydrocannabinol (THC) and cannabidiol (CBD) are the best-known cannabinoids, but there are more than a 100 other compounds in this class. This huge versatility has led to a burgeoning industry centred around the cannabis plant.

Medical use

The medical use of cannabis exploits the action of cannabinoids synthesised by the cannabis plant. Conditions that are treated with cannabis-derived products include chronic pain, pain associated with multiple sclerosis and spinal cord injury, nausea and vomiting caused by chemotherapy, radiotherapy and HIV therapies, appetite stimulation in cachexia, anorexia, loss of appetite in cancer patients and those with AIDS or anorexia nervosa, the hypotensive effect of glaucoma and the reduction of involuntary body and facial movements in Gilles de la Tourette syndrome.

Medical use is widespread around the world, with some notable exceptions. Obtaining authorisation is generally necessary to be able to produce, import and sell cannabis for medical use. Patients generally gain access to these products via a prescription.

Industrial use

Before discovering the healing properties of cannabis, its use was mainly connected to industry. Although some countries (especially in Europe) have adopted a distinction between the varieties of cannabis that, generally being used in the industrial sector, do not fall within the scope of laws on psychotropic substances, not all countries have made this distinction.

In the European Union, the cultivation of industrial cannabis (hemp) is permitted provided the variety is registered in the EU's '*Common Catalogue of Varieties of Agricultural Plant Species*' and the THC content does not exceed 0.2%. This measure has been taken with the aim of encouraging cultivation.

Industrial cannabis usually contains only traces of THC, while CBD is present. Not all countries have clear regulation on CBD.

Patentability

Cannabis-based products are potentially patentable in most territories. The normal principles of patentability generally apply to these products, without ad hoc legislation.

Summary of legal approaches

	Medically allowed?	Recreational use?	Industrial use?	Patentable?
Austria	There are circumstances in which cannabis-containing pharmaceuticals can be prescribed but not cannabis in its purest form			
Brazil			It is possible to import hemp-based products, such as clothing	
Bulgaria				Under certain circumstances, cannabis-based food supplements and cosmetics may be patented
Chile		Sale and import is not allowed but self-cultivation is allowed		
Colombia				
Czech Republic				
France				
Germany				
Hungary				
Italy				
Mexico	Recent changes have resulted in lack of legal clarity	Sale and import is not allowed, but self-cultivation is allowed		
The Netherlands				
Peru			Activities relating to non-psychoactive cannabis are pending approval	Current situation is not completely clear
Poland				
Romania				
Russia	Cannabis cannot be used as a medicine itself but can be used as a raw material and reprocessed into another drug			
Slovakia				
Spain				
Switzerland		Only cannabis containing less than 1% THC is allowed		
United Arab Emirates			Sale and purchase of hemp seed oil is legal	
United Kingdom				

■ Allowed

■ Not allowed, with exceptions/clarifications indicated

Austria



Medical use

According to the Addictive Drugs Act, only the Austrian Agency for Health and Food Safety (AGES; supervised by the Austrian Federal Ministry of Labour, Social Affairs, Health and Consumer Protection) is permitted to cultivate cannabis for the purpose of manufacturing pharmaceuticals as well as for related scientific purposes. The same right is granted to subsidiaries in which AGES holds at least 75% and that are founded for this purpose.

Production, manufacturing, conversion, purchase and possession of medical cannabis require a specific authorisation for trading of pharmaceuticals according to the Austrian Trade Act. Furthermore, trade of medical cannabis products requires an authorisation issued by the Federal Ministry for Health.

There is no access for patients to cannabis in its purest form for medical use as cannabis is considered as an addictive drug according to the Addictive Drugs Act and the Ordinance for Addictive Drugs. Therefore, it in principle may not be prescribed. However, there are two exemptions for pharmaceuticals containing cannabis which may be prescribed: (i) formulations of cannabis extracts that are authorised as proprietary medicinal products, and (ii) the active substance delta-9-tetrahydrocannabinol, if it has a standardised purity of more than 95% used for magistral preparations (production in the pharmacy on the basis of a medical prescription).

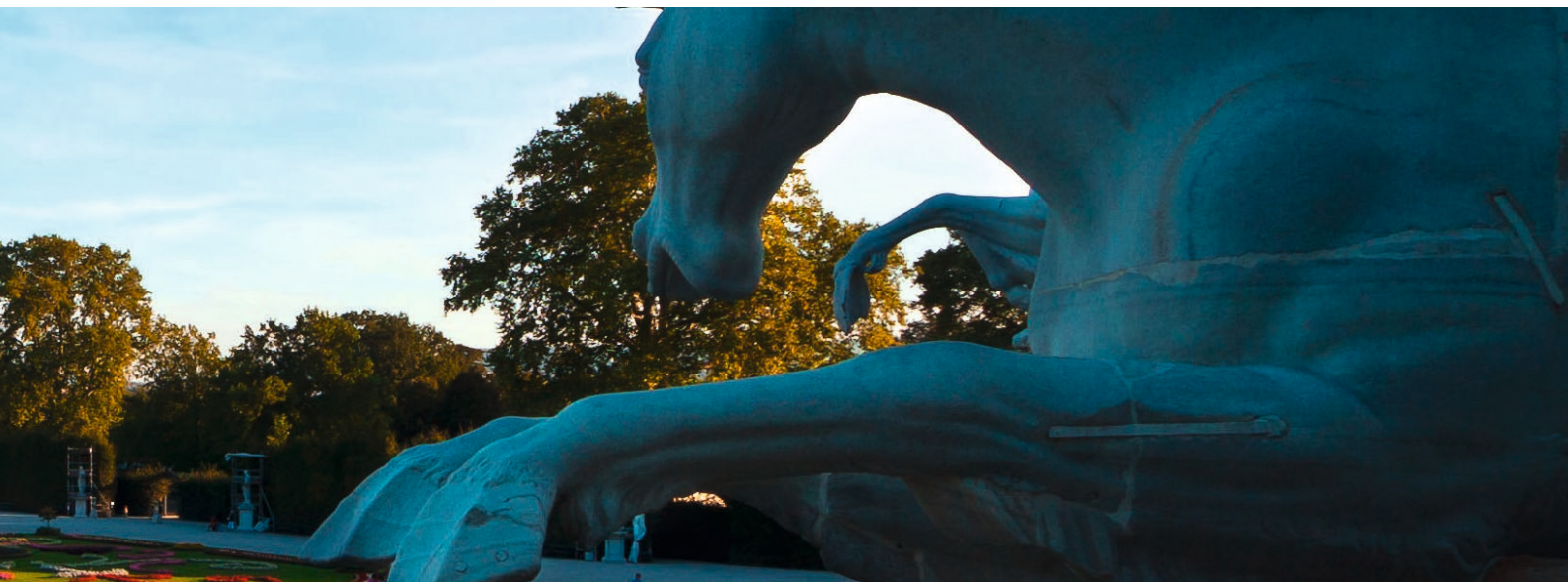
Violations of the Addictive Drugs Act are subject to administrative fines up to EUR 36,300 and - in case of non-collection – to imprisonment of up to six weeks. Besides, anyone who illegally purchases, owns, produces, transports, imports, exports or offers, transfers or procures cannabis to another, or cultivates the cannabis plant for the purpose of obtaining addictive drugs shall be punished with imprisonment of up to one year or with fines of up to 360 daily rates. When it comes to drug trafficking on a larger scale, harsher punishments may be given.

Recreational use

Production, import and sale of recreational cannabis is strictly forbidden according to the Addictive Drugs Act.

Industrial use

The use of industrial cannabis is permitted, if the THC content of the cannabis variety does not exceed 0.3% before, during and after the production process. In this case the Addictive Drugs Act is not applicable. This makes it possible to obtain cannabis-containing foods e.g. cannabis leaves (tea), cannabis seeds, cannabis (seed) oil, cannabis (seed) flour, cannabis (seed) protein and drinks (beer, lemonade). Also, production of cannabis fibre is permitted within the 0.3% THC limit.



CBD as a pure substance is not defined as an addictive drug and thus is not subject to the legal provisions applicable to addictive substances such as the Addictive Drugs Act and the Ordinance for Addictive Drugs.

May CBD be used in food? Food containing CBD extracts are considered as novel food according to regulation (EU) 2015/2283. Only authorised and registered novel food may be placed on the market. No CBD extracts have been authorised yet.

May CBD be used in cosmetics? Natural and synthetic narcotics are prohibited in cosmetic products. Cannabis and its extracts are considered as such and thus may not be placed on the market.

Patentability

It is possible to patent a cannabis-based product if the product consists of a technical invention that is new, inventive and commercially applicable.

Latest developments

The Austrian Chamber of Pharmacists lobbies for the use of cannabis for medical purposes, however revision of any cannabis related provisions or a change of policy is not expected.

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Brazil

Medical use

Under Brazilian Federal Law it is possible to import and sell cannabis for medical purposes subject to the authorisation of the Ministry of Health. To date, only one drug has been authorised for commercial importation. There is a list of other cannabis-based medical products that can be imported by patients directly once they have also been authorised to do so. It is not currently possible to grow cannabis in the country as further regulation regarding the licensing process and requirements for doing so is still pending.

Due to restrictions on cultivating cannabis in Brazil, to enter the medical cannabis business in the country it is necessary to import either the final medical product or the cannabis extract for manufacturing in Brazil. In order to do this, a company must obtain Federal and Special Authorisations from the Brazilian National Agency for Sanitary Surveillance (ANVISA) to import, distribute and commercialise the product and obtain a local sanitary licence from the relevant local authority. The plant where the medical product is manufactured must have a Certificate of Good Manufacturing Practices from ANVISA. In order to commercialise the final product, it is also necessary to obtain a Marketing Authorisation from ANVISA.

Currently, patients can only purchase one cannabis-based medicine in the country. Alternatively, it is possible for patients with a medical prescription to obtain authorisation from ANVISA to import a number of other pharmaceutical products directly from a list of authorised products.

Unless approved pursuant to the ANVISA process, importation, cultivation, sale etc. of cannabis for medical purposes will be treated as a crime concerning illicit drugs. The penalties include lengthy imprisonment sentences and heavy fines.

Recreational use

Brazilian Federal Law prohibits the plantation, cultivation and harvesting of drugs, except for medical or scientific purposes and Decree No. 9,761/19 prohibits the plantation, cultivation and importation of plants related to illicit drugs unless formally and expressly allowed by the Federal Union.



Industrial use

There is no distinction made between industrial cannabis and the rest of the *Cannabis* genus under Brazilian law. It is, therefore, prohibited to plant, cultivate or import the plant even for industrial purposes. It is, however, possible for individuals and companies to import cannabis-based products manufactured outside of the country, such as clothing. In this case the concentration of both CBD and THC must be limited to 30mg/ml by Ordinance No. 344/98 of the Ministry of Health.

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Patentability

It is possible to patent a cannabis-based product in Brazil. A pharmaceutical laboratory patented the first product using a CBD extract manufactured in the country in 2018.

Latest developments

On 11 June 2019, ANVISA approved a resolution regulating the technical and administrative requirements to grow cannabis commercially for medicinal and scientific purposes. The proposal is now pending a public consultation. If approved, this legislation will facilitate the cultivation of cannabis by companies (but not individuals) for medicinal and scientific purposes.

Bulgaria



Medical use

Bulgarian legislation does not allow the use of cannabis for medical purposes.

The use, cultivation, import, export and control of cannabis is generally regulated by the Bulgarian Narcotic Substances and Precursors Control Act (NSPCA). Cannabis falls within Schedule I of "Plants and substances with high degree of risk for the public health due to the harmful effect from its abuse, which are forbidden for use in the humane and veterinary medicine". The NSPCA provides a general prohibition on the production, processing, trading, storage, import, export, re-export, transit, transfer, transport, supply, acquisition, use and possession of the plants and narcotic substances listed in Schedule I. This means that growing, importing and selling of cannabis for medical use in Bulgaria is forbidden.

Patients in Bulgaria cannot have access to cannabis for medical use.

Any doctors who prescribe in violation of the regulatory requirements for narcotic substances and their analogues or medicines containing such substances can be sanctioned by imprisonment for up to five years and by a fine up to BGN 3,000 (approximately EUR 1,500), and the court may also rule deprivation of medicinal rights.

Recreational use

The production, import and sale of recreational cannabis is explicitly forbidden in Bulgaria. Even personal recreational use of cannabis is criminalised.

Industrial use

The applicable law allows cultivation of cannabis plants only if they are intended for fibres, seeds for animal feed or sowing, with a content of less than 0.2% THC by weight, determined by the foliage, flower and fruit tips, and after obtaining a licence by the Minister of Agriculture, Food and Forestry.

Import of cannabis seeds not intended for sowing is also allowed to holders of importer licences, issued by the Minister of Agriculture, Food and Forestry. However, cannabis seeds not intended for sowing may not be released for free circulation where their germination capacity exceeds 10 percent.

No reference is made to CBD in the relevant statutes. The only regulations in this regard concern THC.



Patentability

The cannabis medical business in Bulgaria is illegal and importing of cannabis-based products is illegal. The Bulgarian Patent Act does not explicitly refer to prohibition in respect of products with narcotic substances, but it does prohibit the patenting of a product (invention or utility models) for which commercial use would contravene the public order and morality. Cannabis-based food supplements and cosmetics are allowed though, under certain conditions, and therefore patentable.

Latest developments

Bulgaria is one of the most conservative countries within the EU with respect to reforms related to cannabis. Major regulatory developments are not foreseen soon.

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Chile



Medical use

It is permitted to grow, sell and import cannabis for medical use.

The Agricultural and Livestock Service (State Agency in charge of the control of flora and fauna in Chile) must provide an authorisation for any initiative that seeks to plant cannabis.

In relation to medical use, it is the Institute of Public Health (State Agency in charge of the surveillance, authorisation and supervision of the development of activities in the area of public health) that issues the authorisation and sets the conditions of use.

Patients can purchase medical cannabis in authorised places, with a prescription withheld.

For doctors who prescribe cannabis without adequate justification, the sanction is prison sentence in its minimum to medium grades (5 years and 1 day to 15 years) and a fine of approximately USD 2,800 to USD 28,000. For the supplier, the same penalties are provided, in addition to the closure or temporary closure of the establishment.

Recreational use

The sale or import of cannabis for recreational purposes is not allowed.

Self-cultivation is allowed, so that each person can produce cannabis, but it must be exclusively for personal use.

Industrial use

There is no legal authorisation for industrial use. Only cultivation for medicinal use or personal use is regulated.

No reference is made to CBD in the relevant statutes.



Patentability

There is no specific prohibition on cannabis, but the IP legislation states that patents may not be granted for inventions whose commercial exploitation must necessarily be prevented to protect public order, state security, morality or proper practice, the health or life of persons or animals, or to preserve plants or the environment, provided that such exclusion is not solely for the purposes of a legal or administration provision that prohibits or regulates such exploitation.

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Latest developments

In 2015, the regulations for narcotic drugs and psychotropic substances were modified in order to facilitate access to treatments and medicaments derived from cannabis. The Institute of Public Health proposed adjustments to the current regulations in order to allow the use of cannabis and its derivatives for scientific or medical research purposes and in medical treatments.

Colombia



Medical use

Growing, selling and importing cannabis for medical use is allowed.

There are several authorities involved in the authorisation processes. ICA - Colombian Agency for Agricultural and Animal Husbandry Products shall confirm that any kind of industrial crop farming has obtained certain phytosanitary and food safety approvals. The Ministry of Justice shall authorise the cultivation. The Ministry of Health issues the authorisation to process the raw materials into processed ingredients such as resins and oils that are not to be sold to the public. INVIMA is the agency that conducts market approval procedures for finished products.

As per these regulations, patients are not supposed to have access to raw cannabis. The regulations aim for the patients to have access to pharmaceutical products. If a patient prefers to use raw cannabis, the regulations provide for the possibility of growth for personal consumption (up to 20 plants). No processing or commercialisation is allowed for this personal consumption option.

Being a product with a very sensitive background in Colombia, and strong enforcement against recreational use, any breach that attempts to profit from commercialisation of recreational use will be sanctioned as a criminal offence.

Specifically, for the medical use regulations, licences might be cancelled if an administrative probe has proven that the regulations were not complied with.

Recreational use

Recreational use of cannabis continues to be illegal and will be prosecuted as a criminal offence.

Consumption is not punished but any commercial activity, import, export or production is prohibited and criminally prosecuted.

Industrial use

The regulations provide for the possibility of industrial use for non-THC cannabis (CBD) but do not specifically describe which industrial uses these are.

Sanctions connected to industrial cannabis would be the same as described above for violations for medical cannabis.

The regulations provide for the use of both THC and CBD. THC can only be used as active ingredient on pharma products, but CBD can be used as an active ingredient in cosmetics, dietary supplements and in pharmaceutical products.



Patentability

Patenting of cannabis-based products is possible in Colombia to a certain extent.

Pursuant to patent law, Decision 486/2000, an Andean Community Act enforceable in Bolivia, Colombia, Ecuador and Peru, cannabis-based inventions are in general non-patentable inventions that go against moral principles or public order.

Given that in Colombia certain commercial exploitations related to cannabis are allowed, an invention where scope falls within those limits could be granted. An invention that goes beyond that authorised exploitation and enters illegal fields would be rejected.

It is also interesting to point out that Colombian patent law provides protection for traditional knowledge of local indigenous or Afro-American communities. If an invention was developed using material or knowledge from these sources, it needs to produce evidence on the proper acquisition and compensation for said materials.

Latest developments

Although the main regulations on the growing and commercial exploitation of cannabis-based products are in force, Colombia is still awaiting specific regulations for market approval of some consumer products that include these ingredients.

For instance, it has been established that these ingredients can be allowed in dietary supplements, but the dietary supplements regulations needs to be updated.

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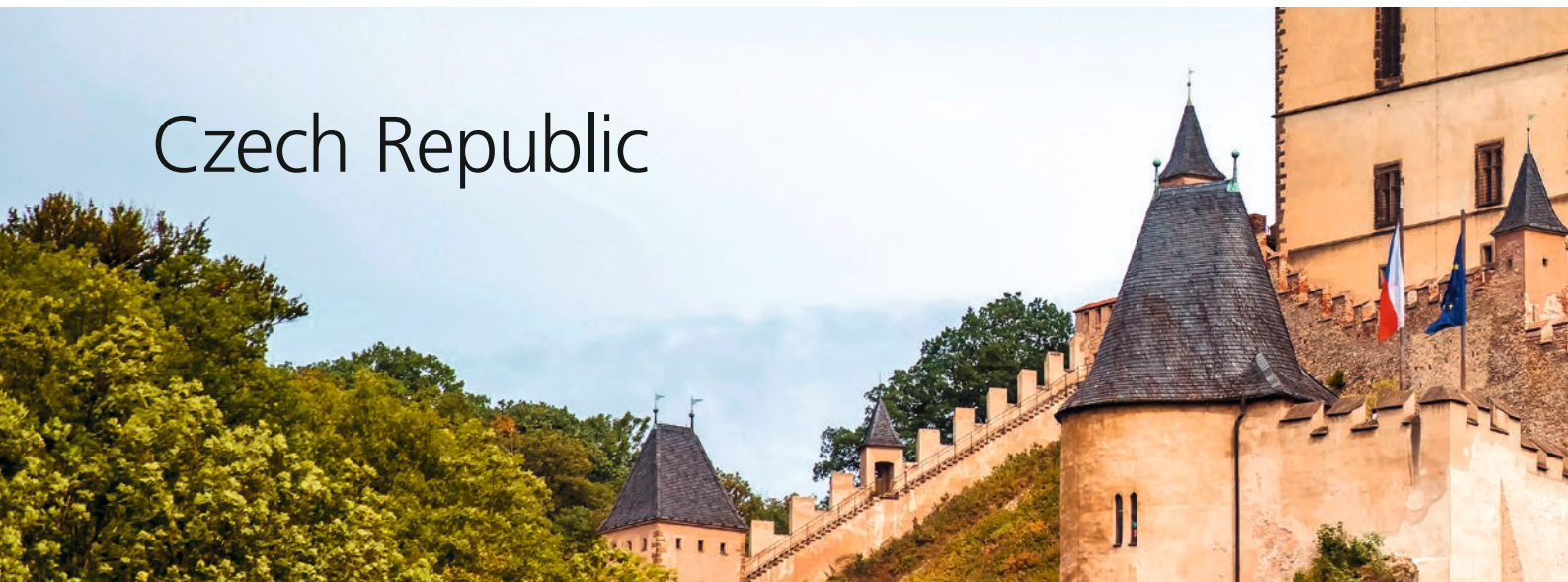
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Czech Republic



Medical use

Growing cannabis for medical use is allowed provided that a licence from the State Institute for Drug Control is obtained. The licence is issued in a public tender proceeding for a maximum of five years. Cannabis for medical use cultivated in the Czech Republic may only be sold (transferred) to the State Institute for Drug Control. Further, permission to dispose of medicaments from the Ministry of Health is required.

To import cannabis for medical use, an import permit from the Ministry of Health is required.

Patients can have access to cannabis for medical use only upon healthcare professionals' electronic prescription and only for certain sicknesses, including chronic intractable pain, nausea and treatment for HIV disease. The amount is limited up to 180g of dry cannabis per person per month.

Violation of the statutory obligations can result in administrative fines of up to CZK 10,000,000 (approx. EUR 394,000).

Recreational use

The recreational use of cannabis is not allowed in the Czech Republic.

Industrial use

Cannabis that contains a maximum of 0.3% of THC is permitted for industrial, technical and garden purposes, including sales. Growing of industrial cannabis on more than 100 m² of land must be notified to the competent customs authority. Violation of the statutory obligation to notify growing of industrial cannabis on more than 100 m² can be subject to administrative fine up to CZK 1,000,000 (approx. EUR 39,400).

In the Czech Republic CBD is not regulated as an addictive substance, therefore there is no specific regulation concerning CBD.

Patentability

In the Czech Republic it is possible to patent a cannabis-based product. Nevertheless, if such a product is considered to be contrary to public order or good morals (e.g. narcotic product) it is not allowed.



Latest developments

One of the Czech political parties submitted a legislative proposal to legalise growing of recreational cannabis for personal use (up to 5 plants). The bill has not yet been discussed in the House of Representatives.

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France



Medical use

In principle, the production, manufacture, transport, import, export, holding, offer, transfer, acquisition or use of cannabis (plant and resin) and THC are prohibited.

Nonetheless, derogations exist, and medical use is allowed:

- for the purposes of research, product control or the production of authorised derived products, as authorised by the Director of the French Health Agency (ANSM);
- if the concerned product received a Market Authorisation (MA) or a Temporary Marketing Authorisation (ATU).

Any cannabis-based medicine must obtain a Market Authorisation or a Temporary Marketing Authorisation (ATU) which is granted according to scientific criteria of quality, safety and efficacy like any other medicinal product. If the Health Agency deems appropriate, a treatment protocol can be established by both the ANSM and the MA holder, in order to assess side effects, efficiency of the drug and data about the targeted population.

Authorised drugs containing THC will require a prescription by a physician. Moreover, since cannabis-based drugs are considered narcotic drugs, the prescription procedure is more strict.

In the event that infringements are detected within the framework of the treatment protocol established by the Health Agency, the following sanctions apply: (i) fine not exceeding 10% of the turnover achieved, up to a maximum of EUR 1m (ii) a daily penalty payment which may not exceed EUR 2,500 per day if the offender has not complied with its requirements by the end of the period set by a formal notice.

Moreover, the unlawful transport, possession, offer, transfer, acquisition or use of drugs is punishable (i) by 10 years' imprisonment and a fine of EUR 7.5m if committed by natural persons, and (ii) by 10 years' imprisonment and a fine of EUR 37.5m and various other sanctions that lead to the entity's dissolution if committed by legal persons.

Recreational use

In France it is forbidden to produce, import and sell recreational cannabis.



Industrial use

Certain varieties of cannabis, without narcotic properties, can be used for industrial and commercial purposes under some cumulative conditions:

- the plant is one of the authorised varieties of cannabis;
- only seeds and fibers can be used;
- the use of flowers is prohibited;
- the plant (and not the end product) must have a THC content of less than 0.2%.

France has no specific regulation on CBD. CBD-based products are legal if they comply with the general regulatory scope.

Patentability

The French Intellectual Property Code provides that inventions whose commercial exploitation would be contrary to public policy shall not be patentable. Pursuant to this principle, if the invention is not contrary to public policy then it is possible to obtain a patent.

Latest developments

The “Agence nationale de sécurité du médicament et des produits de santé” (ANSM) is currently assessing the viability of a specific program in order to allow the medical use of cannabis, particularly for epilepsy, multiple sclerosis and palliative care. The “Comité Scientifique Spécialisé Temporaire” (CSST) should report on the feasibility of using therapeutic cannabis in late 2019.

This potential development shall only apply, in the near future, to certain clinical situations and in cases of insufficient relief or poor tolerance.

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Germany



Medical use

It is permitted to grow, sell and import cannabis for medical use.

Pursuant to the German Narcotics Act an authorisation is necessary for all forms of business. Furthermore, when medicinal cannabis is imported from outside the EU, an import authorisation pursuant to the German Medicinal Product Act is necessary. The cultivation is managed by means of tender process.

Patients can have access to medical cannabis in the form of dried blossoms or extracts only on prescription and only for serious illness, if (i) a generally accepted standard therapy (a) does not exist or (b) in particular cases does not apply according to the justified assessment of the treating physician, considering expected side effects and the disease status of the insured patient, or (ii) there is a reasonable possibility that the cannabis will have a positive effect on the disease process or on serious symptoms.

Violation of the German Narcotics act due to illegal cultivation, import, possession or promotion can be a crime and there is a risk of high criminal sanctions (imprisonment for up to five years or a fine).

Recreational use

In Germany it is strictly forbidden to produce, import or sell recreational cannabis.

Industrial use

The cultivation of industrial cannabis by agricultural undertakings does not need authorisation when certified seeds of the varieties listed in the Art. 9 Regulation (EU) No. 639/2014 are used; in this case only a notification to the authorities is necessary.

Apart from cultivation, all other uses of industrial cannabis need an authorisation pursuant to the German Narcotics Act, except when the THC content of industrial cannabis is below 0.2%, it is used for scientific or commercial purposes only and an abuse is excluded. Commercial purposes are allowed in case the cannabis is processed and becomes a harmless product that cannot be used for drug abuse.

CBD as a pure substance is not defined as a narcotic pursuant to the German Narcotics Act. However, products with CBD may be considered as illegal if they also contain more than 0.2% THC.



Patentability

There is no general prohibition on patenting cannabis-based products, however no patents can be granted for inventions if their commercial exploitation would be contrary to “public order” or morality.

Latest developments

Legalisation of cannabis for medical use took place in 2017. Since 2017 health insurers must reimburse the costs for cannabis therapy.

German authorities announced that medicinal cannabis from cultivations in Germany will likely be available in the fourth quarter of 2020.

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Hungary



Medical use

Generally, it is not permitted to grow, import or sell cannabis for medical use in Hungary provided that the activity in question involves a substance prohibited under Hungarian law.

The manufacturing, export, import, transfer, purchasing, sales, storage, handling, usage of narcotics and psychotropic substances as well as related education, research and analysis may only be carried out with an activity licence issued by the National Institute for Pharmacy and Nutrition (Hungarian abbreviation: "OGYÉI"). Such a licence for medical purposes may be issued for an activity involving narcotics and psychotropic substances aimed at pharmaceutical research and development, marketing authorisation or therapeutic use of medicinal products. The application for an activity licence for medical purposes requires a licence for manufacturing or trading a specific medicinal product.

According to Hungarian law, the use of THC strains is only permitted for research or industrial purposes (unless individual authorisation is granted, as described below). Currently there is no medicinal product containing cannabis or its derivatives as an active ingredient that has been authorised for marketing in Hungary.

Medicinal products containing cannabis that have been authorised for marketing in another country may be accessed by Hungarian patients only in exceptional cases. OGYÉI may give its authorisation if it is justified by patient care interests.

Producing, selling, purchasing, trafficking or importing cannabis containing THC for medical use are strictly prohibited by the Hungarian Criminal Code and shall be punished with imprisonment for up to 20 years depending on the scale of prohibited activity and, more importantly, the level of THC in the cannabis.

Recreational use

As for medicinal cannabis, producing, selling, purchasing, trafficking or importing cannabis containing THC for recreational use are all strictly prohibited by the Hungarian Criminal Code (sanctions stated above).

Industrial use

The Hungarian law does not provide an exhaustive list of uses permitted for industrial cannabis, it is always subject to an individual authorisation process by the relevant authority. As a rule, any industrial activity with cannabis suitable for the production of narcotic drug can only be carried out with an activity licence.

CBD is not regarded as a controlled substance in Hungary. The specific requirements of its use depend on the type of the product, i.e. whether the product in question is a medicinal product or a food supplement, etc.



Patentability

The Hungarian Patent Act provides that inventions are not patentable if their commercial exploitation would be contrary to public morality/public order. However, exploitation does not qualify as being contrary to public morality/public order merely because it is prohibited by law.

Under Hungarian law, a cannabis-based product is patentable as long as its planned use is not contrary to public morality/public order. The fact that the Hungarian legal regime, as a general rule, does not allow use of cannabis in Hungary, does not necessarily mean that cannabis-based products are not patentable. If the planned use is in line with the pharmaceutical regulatory and criminal laws, the invention is potentially patentable.

Latest developments

There are several recent initiatives from the political as well as from the civil sector (e.g. from the Hungarian Medical Cannabis Association) aimed at achieving full legalisation of medical cannabis, or at least the introduction to the Hungarian healthcare system of those medicinal products containing cannabis or derivatives that are already authorised for marketing and successfully used abroad. According to a recent survey, the majority of respondents agreed with legalisation of cannabis for medical purposes.

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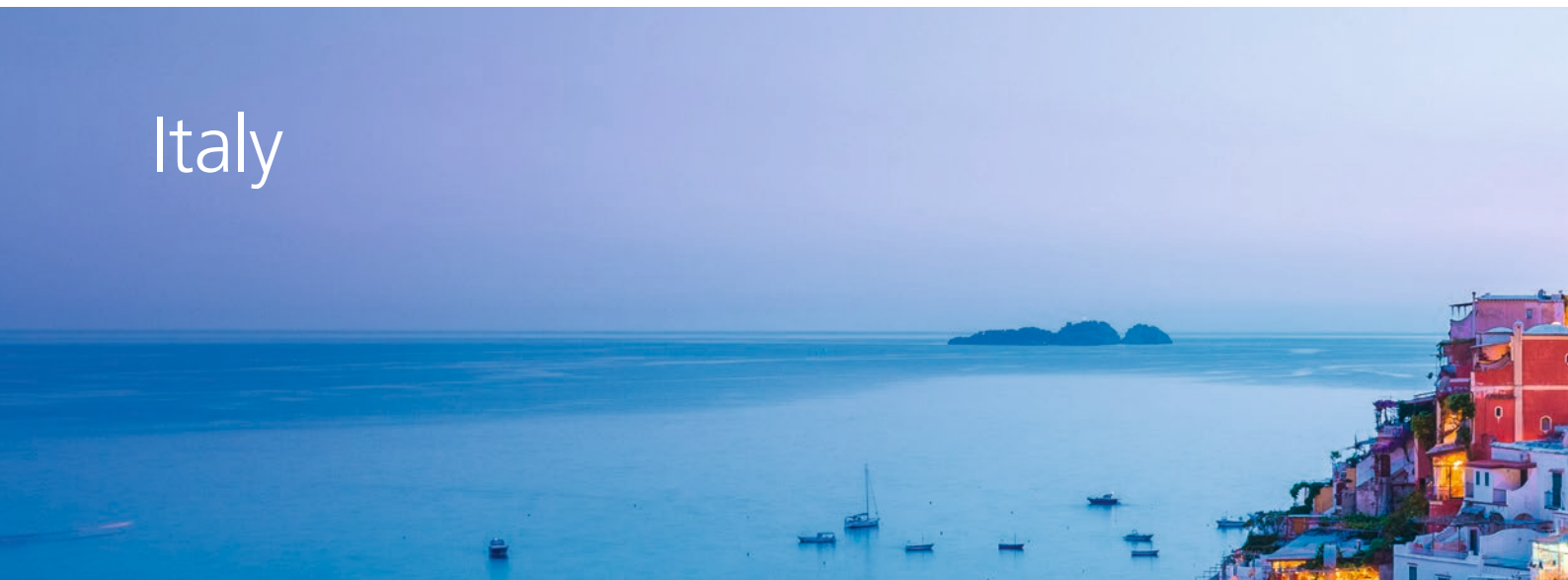
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Italy



Medical use

Growing, selling and importing medical cannabis is allowed on condition that the authorisation of the Ministry of Health is obtained. Cultivation, sale and import are currently mainly managed by the State through internal production or public tenders for the supply.

Authorisation by the Ministry of Health is mandatory. Such authorisation is personal and cannot be sold or transferred. Moreover, it can be granted only to institutions or companies whose owner or legal representative, if they are companies, is of good behaviour and offers moral and professional guarantees.

Medicines based on cannabis, already authorised in Italy, can be prescribed to patients by doctors by using a special form approved by Ministry of Health. If the medicinal product is not authorised in Italy but duly authorised in a foreign country, the Italian doctor is required to send a request to the Ministry of Health and to the competent customs office for the importation of the medicine in Italy. The request must include the special needs that justify the use of the unauthorised medicine, in the absence of a valid therapeutic alternative.

Anyone who, without the authorisation, imports, exports, purchases, receives or holds medicines containing narcotic or psychotropic substances, which exceed the prescribed quantity, is sanctioned with imprisonment from six to 20 years and with a fine of EUR 26,000 to EUR 260,000. The aforementioned penalties can be reduced by a third to a half.

Recreational use

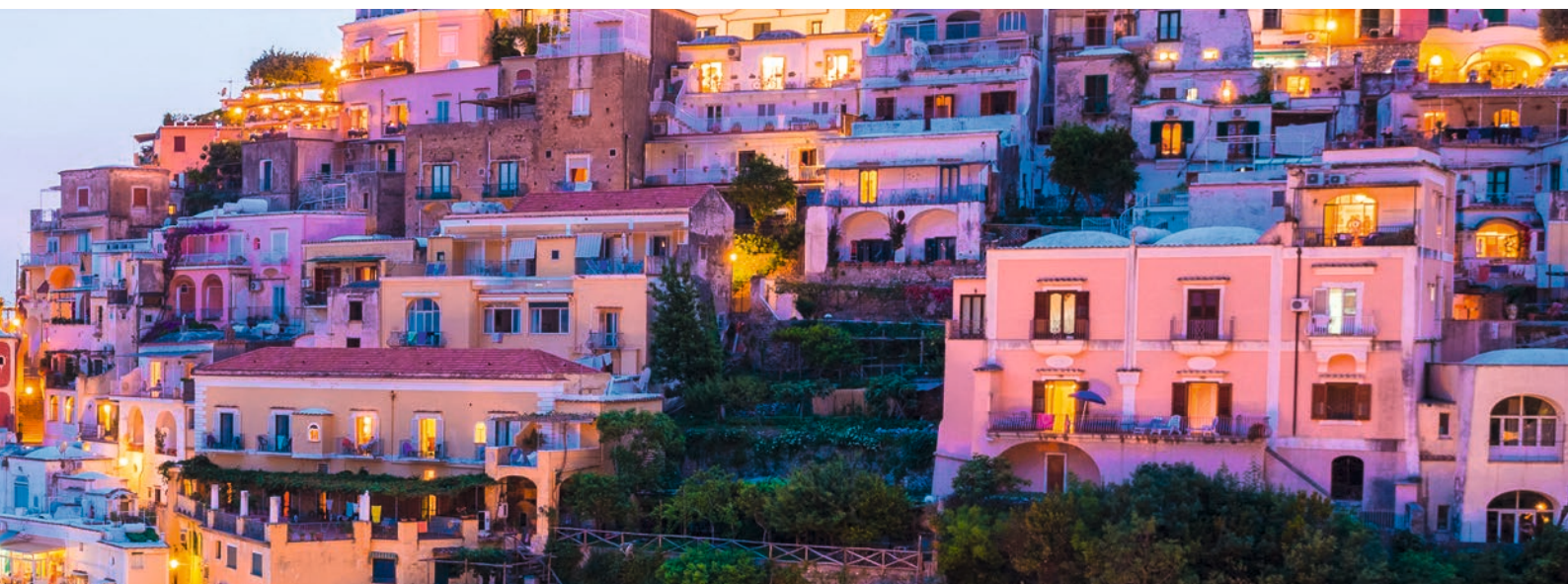
In Italy it is not permitted to sell cannabis for recreational use.

However, some companies have chosen to market a product with low THC content whose sale is permitted based on industrial cannabis legislation only. In short, on the Italian market "recreational cannabis" is essentially "cannabis for industrial use", which however, not being a smoke product, is sold with the explicit warning "product not for human use" - "do not smoke".

Industrial use

Industrial cannabis can be used for (a) foods and cosmetics, (b) semi-finished products, such as fibre, powders, oils or fuels, (c) material intended for use as green manure, (d) organic material for bioengineering works or products useful for green building, (e) material aimed at phytodepuration for the remediation of polluted sites, (f) crops dedicated to teaching and demonstration activities as well as research by public or private institutions and (g) crops intended for floriculture.

The only sanctions currently provided by the law on industrial cannabis are the seizure or destruction of the cannabis if the THC content in cultivation is higher than 0.6%.



The law does not provide for sanctions related to the marketing of industrial cannabis, which must be derived from the general legislation on product safety and consumer protection.

If, on the other hand, a farmer grows, without authorisation, cannabis that does not fall within the definition of “industrial cannabis”, he is punished with imprisonment from six to twenty years and with a fine ranging from EUR 26,000 to EUR 260,000.

There is no proper regulation on CBD in Italy. CBD is a substance with recognised pharmacological activity that is not included in the table of drugs. The Ministry of Health has explained that if the CBD is used for the production of medicines, not being present in the tables of narcotic or psychotropic substances, the current legislation on medicinal products should be applied. As a consequence, the rules on medicinal products containing psychotropic substances, which applies to THC, cannot be applied to CBD.

Patentability

There is no specific prohibition on patenting a cannabis-based product, provided that the commercial exploitation of the invention does not infringe any law and is not contrary to public order.

Latest developments

The latest relevant event is an opinion from the Health Council stating that the free sale of industrial cannabis to consumers is dangerous. Currently the Ministry of Health is considering whether to modify the law on industrial cannabis to prevent free sale to citizens, or on the contrary, whether to allow it, possibly subject to authorisation. On May 2019 the Supreme Court issued a ruling stating that free sale to the public of inflorescences is considered to be criminal conduct, unless such products do not produce psychotropic/ narcotic effects.

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Mexico



Medical use

Mexico is transitioning from a prohibitionist policy to a regulation policy. Nevertheless, although the laws were modified in order to legalise cannabis for medical use in Mexico, the scope and limits of legalisation are still not clear.

During the pre-reform period, a Federal Judge (Third District in Mexico City) granted constitutional protection (amparo) to an eight-year old girl so that her parents could import cannabinal oil to treat her epilepsy. This precedent urged the legislative power to change the law.

Several authorisations are required for manufacture and commercialisation since cannabis is still classified as a controlled substance. A premarket clearance for drugs for human use, which is granted by COFEPRIS, is mandatory. A manufacturing licence, the appointment of a sanitary officer and certificates of good manufacturing practices are required. Also, additional import/export, wholesale commercialisation and transportation permits are required for individual allotments of narcotics and psychotropics.

Patients need to file an import permit for personal use with COFEPRIS, attaching a medical prescription and label of the intended product to be imported. Because the rules about issuing authorisations for growing, manufacturing, distribution and sale of cannabis and its derivatives are on hold, the only way to get access is by an import permit.

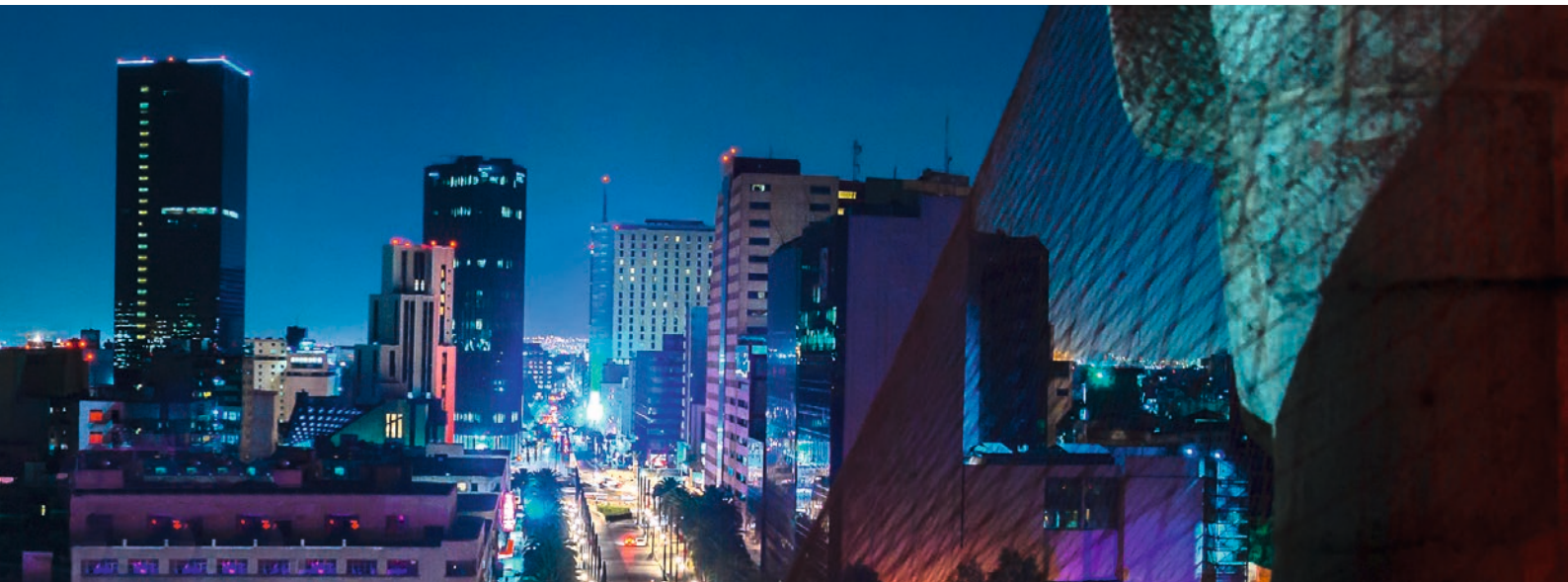
As for the sanctions, the federal criminal code provides that individual possession and consumption of cannabis in quantities up to five grams are not penalised. Violations to the provisions of the Health Law constitute a crime punishable with three to 25 years in prison.

Non-compliance with the provisions in the Health Law governing medical use of cannabis may additionally result in administrative fines from USD 880.00 to USD 2,200.00 which are imposed by the Ministry of Health.

Recreational use

In Mexico the law does not permit production, import or sale of recreational cannabis.

This problem, however, has been overcome by constitutional trials. The Supreme Court of Justice has recognised the right to consume cannabis recreationally. The Court considered that recreational use of cannabis is a human right allowing citizens to acquire the seeds, grow, prepare, possess and transport for their own consumption. This precedent has risen to the level of binding jurisprudence, so all Federal Judges are obligated to apply it in all cases. Lastly, the commercialisation of recreational cannabis is forbidden and punished, and courts have not granted any authorisation for said purposes (excluding the acquisition of the seeds).



Industrial use

The Mexican General Health Law provides that products containing derivatives of cannabis with concentrations of 1% or less of THC and that have wide industrial uses, may be commercialised, exported and imported, if fulfilling the sanitary requirements. The sanitary regulation regarding cannabis has not been issued yet. As the regulation has not been issued yet, the seeding, growth, possession and commercialisation of cannabis are still considered a crime and are severely punished by Mexican law.

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Patentability

There is no prohibition on patenting a cannabis-based product in Mexico, although the petitioner shall present evidence that the composition has the claimed therapeutic activity.

Latest developments

Currently, a legislative proposal on the rules for medical, scientific and industrial use of cannabis is under Federal Congress review, which includes recreational use; however, there are several different opinions on its development and approach to the subject. In the future, a law governing the licences/permits or authorisations for the production, import/export and commerce of cannabis for recreational use including cannabis-derived products for industrial use is expected.



The Netherlands

Medical use

The Dutch Opium Act distinguishes drugs with a low risk of harm ('soft drugs') from drugs with a high risk of harm ('hard drugs'). Cannabis is listed under the soft drugs category (Category II), which means that use, possession and trade are forbidden by the Dutch Opium Act, but openly tolerated under certain circumstances by official policy (see below; recreational use).

The use of medicinal cannabis has been allowed in the Netherlands since 2003. The Dutch framework is an example of a long-established system that allows access to medicinal cannabis. However, it is a closed system. All activities related to medicinal cannabis are strictly regulated and the Dutch Office of Medicinal Cannabis (BMC) has full control. This means that authorisations have to be obtained for the cultivation, import, and sale of medicinal cannabis. Authorizations will only be granted in a limited number of circumstances. In the Netherlands, so far only one company – Bedrocan – is authorised to cultivate cannabis for medical use.

Since medicinal cannabis is subject to the Dutch Medicines Act, a marketing authorisation is required in order to bring the product onto the market. This requirement does however not apply to the medicinal cannabis cultivated by Bedrocan; a special access scheme allows the medical use of this particular cannabis product without marketing authorisation.

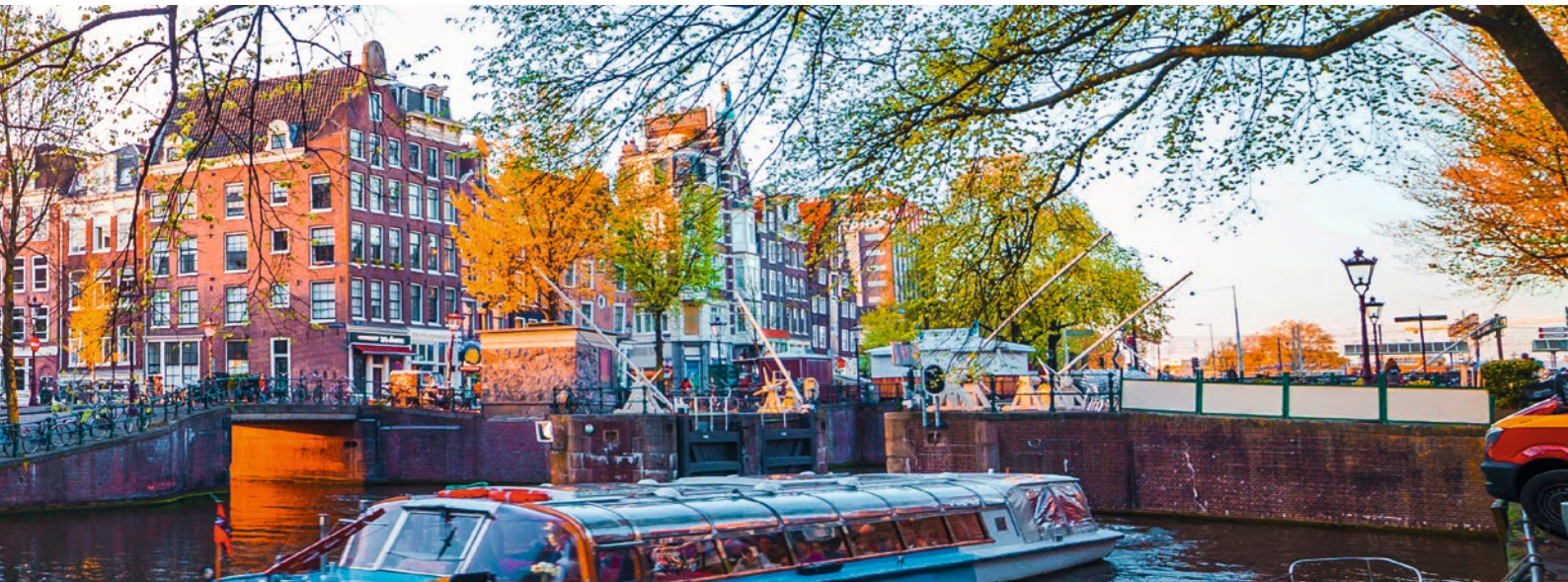
Patients have access to medicinal cannabis through their pharmacies, provided they have a prescription. Cannabis can also be obtained from 'coffee shops' since sale and possession of small amounts of cannabis (under 5 grams) for personal use is tolerated. However, the quality of medicinal cannabis obtained through pharmacies is better protected since it is subject to strict regulations.

Violation of the Dutch Opium Act due to illegal cultivation/ import /possession/promotion can be a crime and there is a risk of high criminal sanctions (imprisonment for up to twelve years or a fine). A recidivism scheme applies.

Recreational use

Recreational use of cannabis is openly tolerated in the Netherlands. Cultivation of five or less hemp plants at home is not prosecutable either, according to the guidelines of the Dutch government.

Following the national guidelines, the retail sale of recreational cannabis to consumers is tolerated if the coffee shops meet the so-called AHOJ-G criteria: no overt advertising, no hard drugs, no nuisance, no underage clientele and no large quantities. The small-scale dealing of cannabis is thus an offence from a legal viewpoint, but is not prosecuted under certain conditions. However, cultivating and supplying recreational cannabis to coffee shops is still strictly illegal.



Industrial use

It is legally permitted in the Netherlands to cultivate, import and sell industrial hemp as long as the hemp is intended for fibre production or seed production for fibre varieties. According to European guidelines, the cannabis variety must be listed in the Plant variety database and the THC level cannot exceed 0.2%. There are no requirements regarding the CBD level.

Patentability

Cannabis-based-products are patentable in the Netherlands, as long as the commercial exploitation is not contrary to public policy or morality. However, commercial exploitation cannot be held contrary to public policy or morality on the mere fact that exploitation is prohibited by law. The chances of a successful appeal to public policy or morality are very limited in the Netherlands. Therefore, even a patent on an invention of a cannabis-based-product that is illegal in the Netherlands, is in principle allowed.

Latest developments

A legislative proposal regarding an experiment for a closed coffee shop chain is currently under review with the Dutch Senate. This experiment involves the appointment by the Minister of Health of certain cultivators that will supply all coffee shops in participating municipalities with strictly monitored cannabis so that recreational cannabis can be legally purchased by and sold from these shops. The aim of this experiment is to legalize recreational cannabis while regulating its quality and safety.

Another recent development concerns the BMC initiating a tender process to award a second contract to cultivate cannabis. This is necessary in order to meet the growing foreign demand of medicinal cannabis and the need for new cannabis varieties on the Dutch market. The newly licensed cultivator will be announced in the first quarter of 2021.

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Medical use

In general, Peruvian laws and regulations prohibit the growing, import and commercialisation of cannabis. Those activities are exclusively reserved for the Peruvian State when there are medical or scientific reasons that support such activities.

With Law N° 30681, enacted on November 2017, (“Cannabis Law”) the Peruvian State has recently allowed individuals and legal entities to use, investigate, produce, import and commercialise cannabis and its derivatives, which are destined exclusively for medical and therapeutic purposes.

The Regulations of Law N° 30681 (“Cannabis Regulations”) were published on February 2019. These regulations make a distinction among psychoactive cannabis and non-psychoactive cannabis based on the quantity of THC, where:

(i) Psychoactive cannabis: is defined as the flowering or fruiting tops of the cannabis plant (excluding seeds and leaves not attached to the top) of which the resin has not been extracted, whatever their denomination, whose content of THC is equal to or greater than 1% (dry weight), and that are destined for medical or therapeutic purposes, as palliative therapy for some diseases. Combusted use or smoking of psychoactive cannabis is excluded. This type of cannabis is designated as “cannabis for medical use”.

(ii) Non-psychoactive cannabis: is defined as the cannabis plant, and any part of such plant, whose content of THC is less than 1% (dry weight). This term is designated as “cañamo” or “hemp”.

The consequences of the distinction are that:

- Activities related to “cannabis for medical use” are subject to the granting of licences for scientific research, import and/or commercialisation, and the production of such licences is regulated in the Cannabis Law and Cannabis Regulations.
- Activities related to “cañamo” or “hemp” are not within the scope of the Cannabis Law and the Cannabis Regulations and are therefore not subject to the granting of the licences referred therein. However, further regulation from the Ministry of Agriculture relating to the criteria and conditions to be met for the growth and industrialisation of “cañamo” or “hemp” are pending approval.

As to authorisation, Peruvian law provides for different types of licences. *Licence for scientific investigation*, to be granted in favour of universities and/or agriculture or health research institutions. *Licence for import and trade*, to be granted in favour of individuals or legal entities. *Licence for production*, to be granted exclusively in favour of public entities and certified laboratories.



Patients shall be registered in the *"Registry of Patients that consume cannabis for medical and therapeutic purposes"*. The commercialisation of products derived from *cannabis* should be in the charge of authorised pharmaceutical establishments, and the patient (registered in the Registry described above) should submit a special prescription issued by certified medical doctor.

Any violation to such law can be sanctioned with: (i) the cancellation of the licence granted; (ii) any civil, administrative or criminal sanction that may correspond. In the case of (i) public servants granting licences irregularly, or (ii) medical doctors, pharmaceuticals, or any health professional, prescribing or facilitating cannabis to patients not duly registered (in the *"Registry of Patients that consume cannabis for medical and therapeutic purposes"*), criminal consequences will apply.

The Criminal Code of Peru, sanctions (i) the acts of promotion, facilitation financing, or growing cannabis without the corresponding licence, with a prison sentence not less than eight years and no more than 15 years; and with a 180 to 365 day fine, and professional disqualification, and (ii) the act of trading and transferring seeds of cannabis without the corresponding licence, with a prison sentence of not less than five nor more than 10 years, and with a 120 to 180 day fine, and professional disqualification.

Recreational use

In Peru it is not possible to produce, sell and import cannabis for recreational use. The production, import and commercialisation of cannabis are only permitted for medical and therapeutic purposes.

However, activities related to *"cañamo"* or *"hemp"* are pending to be regulated and approved by the Ministry of Agriculture.

Industrial use

The permitted uses for industrial cannabis are limited to the production of cannabis (and its derivatives) for medical and therapeutic purposes only.

As established by the Cannabis Regulations, the Ministry of Agriculture will define the criteria and conditions to be met in order to grow and industrialise *"cañamo"* or *"hemp"*.

None of the relevant law or regulations contain specific regulations concerning CBD concentrations. Although the Cannabis Law and the Cannabis Regulations make a distinction based on THC content, it is important to mention that existing regulations enacted before the Cannabis Law and the Cannabis Regulations that prohibit the growing, import and commercialisation of drugs and psychotropic substances (for uses other than medical and therapeutic) define cannabis in a very general way with no specific mention of CBD concentration or content. In addition, the Criminal Code, when typifying specific cannabis related crimes, does not consider there to be a distinction based on the quantity of THC or CBD.

Patentability

Applicable IP laws and regulations provide that patents on inventions whose commercial exploitation should be prevented in order to protect public order or morality will not be granted (there is no specific mention of patents on inventions involving cannabis).

Considering that (i) the growth, use, import, commercialisation and production of cannabis (other than for medical and therapeutic purposes) is prohibited and has criminal consequences; (ii) the only exceptions (for the application of criminal consequences to such activities) is that the growth, use, import, commercialisation and production of cannabis is duly licenced, (being the case that currently licensing requirements are still not approved); it is probable that the competent authority will not grant a patent based on the grounds that commercial exploitation of cannabis is currently not permitted and is criminally sanctioned.

However, there are some pending patent applications related to cannabis, requested from the National Institute for the Defense of the Competition and Protection of Intellectual Property (INDECOPI). All of them are in progress and no official resolution from the INDECOPI has been given.

Latest developments

Law N° 30681, approved in 2017 now allows the investigation, growing, import, commercialisation and production of cannabis for medical and therapeutic purposes.

The Cannabis Regulations have introduced a distinction between psychoactive cannabis and non-psychoactive cannabis based on the quantity of THC; and such distinction may entail a different licensing regime.

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Poland



Medical use

Polish legislation generally does not allow the growing of cannabis that contains more than 0.2% THC in flowering or fruiting tops of plants from which the resin has not been removed ("Non-Fibrous Cannabis"). Only by way of exception, scientific entities may grow Non-Fibrous Cannabis after obtaining a permit from the Chief Pharmaceutical Inspectorate. It is, however, possible to import and sell such cannabis for medical use as a pharmaceutical raw material intended for preparing prescription drugs.

Non-Fibrous Cannabis herb, tinctures, resin and other extracts may constitute a pharmaceutical raw material after obtaining a marketing authorisation issued by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (granted for a period of five years). The provisions of pharmaceutical law regarding manufacturing and import of medical raw materials and permits required in connection with such materials apply accordingly.

Non-Fibrous Cannabis for medical use is distributed to patients by pharmacies as a prescription medicine, i.e. a medicinal product prepared in a pharmacy on the basis of a medical prescription issued by a doctor.

Violations of the laws concerning Non-Fibrous Cannabis are treated as criminal offenses and are punishable by fines or imprisonment.

Recreational use

The production, import and sale of recreational Non-Fibrous Cannabis is forbidden in Poland.

Industrial use

The applicable law does not provide a list of permitted uses for industrial cannabis ("Fibrous Hemp").

The textile, chemical, pulp and paper, food, cosmetics, pharmaceutical, building materials and seeds industries, however, are indicated as sectors for the needs of which it may be admissible to grow Fibrous Hemp (provided that an appropriate permit has been obtained).

Poland has no regulation on CBD. The applicable legislation recognises only the difference between (non-fibrous) cannabis and Fibrous Hemp (depending on the content of THC).

Patentability

It is generally possible to patent a cannabis-based product in Poland. The legislation concerning industrial property does not contain any specific restrictions in this respect. It is worth mentioning that patents are generally not granted for inventions the exploitation of which would be contrary to public order or decency. However, the exploitation of an invention is not regarded as contrary to public order only because it is prohibited by law.



Latest developments

The use of cannabis for medical purposes became permissible when the dedicated amendment to the Act on Counteracting Drug Addiction entered into force on 1 November 2017.

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Romania

Medical use

Based on art. 12, art. 15 and art. 20 of Law no. 339/2005 the growth, import and sale of cannabis for medical use is allowed in Romania, under Ministry of Health supervision.

In order to grow, process, sell, act as an intermediary, own, distribute, etc cannabis for medical purposes in the territory of Romania, it is mandatory to have legal personality and to obtain the required prior authorisations from the Ministry of Agriculture and Ministry of Health.

According to art. 38 of Law 339/2005, a patient can be prescribed cannabis for medical use only in the form of a pharmaceutical product.

Failing the requirements provided by Law 339/2005, punishments include fines between RON 200 – 20,000 or a prison sentence of between three months to seven years. Moreover, if such violation resulted in the death of a person, one risks a prison sentence of between 10 to 20 years.

Recreational use

The recreational use of cannabis is forbidden. However, in late 2018, the Romanian Supreme Court issued a ruling decriminalising the procuring of products with psychoactive effects, by a final consumer, for personal use.

Industrial use

The industrial use of cannabis is permitted only if it is processed for technical purposes, for the production of strains, fibres, seeds and oil, or for medical or scientific purposes. In Romania there is no regulation concerning CBD.

Patentability

Cannabis-based products are patentable.

Latest developments

A draft law aimed at allowing terminally ill patients from Romania to have access to painkillers made using cannabis, based on a prescription from a specialist doctor, has been lodged in June 2019 with Romanian Parliament for debate, being supported by almost 100 (out of the total of 465) Parliament members. Based on the draft law, such painkillers should be administered by oil, tincture, infusion or inhaling only, smoking being prohibited. If the Parliament debate is successful in adopting such a draft law, that bill is expected to be enacted by Parliament, and signed into law by the Romanian President.

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DUPA SECOLE DE SUFERINTA CRESTINESTE IN DURATI
PENTRU PASTRAREA FIUTEI NATIONALE DURA
DE SACRIFICIU A CIVILIZATIEI UMANE SE INDEPL
PENTRU POPORUL ROMAN DIN SABIA REC
CU AJUTORUL INTRECEI NATIONI SI CANDIL



Russia

Medical use

The use of raw cannabis in Russia for medical purposes is not permitted.

However, the law specifically allows reprocessing of drugs included in List I (e.g. including cannabis) into principally different substances, namely (i) narcotic and psychoactive substances *used for medical or veterinary purposes*; or (ii) non-narcotic substances.

Respectively, it is permissible to use cannabis as a “raw material” and reprocess it into another narcotic or psychoactive substance being under a less restrictive regime (e.g. not included into the List I), but it is not possible to use cannabis as a medicine itself.

Notably, in July 2019 the new Law on amendments to the current Law on Narcotic and Psychotropic Substances has been enacted in Russia. It partially legalises cultivating of drug-containing plants for the manufacturing of narcotic and psychoactive substances for medical or veterinary use. The list of such plants should be adopted by the Russian Government in the near future. Possibly (but not necessarily), it will include cannabis.

Taking the above into account, at present, patients cannot get access to cannabis for medical use.

Depending on particular circumstances, a violation of the rules on cannabis circulation may be punished under different articles of the Russian Criminal Code.

Non-authorised manufacturing, sale or delivery of narcotic or psychotropic substances, their analogs or plants containing narcotic or psychotropic substances (including cannabis) will be punished under Article 228.1 of the Russian Criminal Code. Depending on different factors (such as volume/weight of the cannabis produced or sold unlawfully; whether the crime was committed by an individual or an organised crime group, etc.), the convicted can be sentenced to eight to 20 years of imprisonment or even to a life sentence if the crime is committed on an especially large scale (for cannabis this means more than 10 kg).

If a person violates special rules of circulation of narcotic and psychotropic substances, they can be punished under Article 228.1 of the Russian Criminal Code. In the worst-case scenario (if such violation led to injury), a person may be sentenced to three years imprisonment and disqualification for the same term.

Recreational use

Circulation of cannabis for recreational purposes is prohibited.



Industrial use

According to the Regulation of the Russian Government dated 20 July 2007 No. 460 which is currently in force, the use of cannabis for industrial purposes is permitted, provided that: (i) the particular kind of cannabis is included in State Register of Plant Variety; and (ii) the content of THC in the cannabis doesn't exceed 0.1%.

However, these rules may be amended soon following the amendments to the Law on Narcotic and Psychotropic Substances adopted in July 2019.

Russian laws do not provide for special rules regarding CBD content.

Patentability

It is possible to patent a cannabis-based product, provided that the product itself is allowed in Russia (for example, cannabis oil produced from *Cannabis sativa*, fiber fetlock from *Cannabis sativa* seeds, etc.).

Latest developments

In December 2018 the Russian Ministry of Sports issued Order No. 53177 stating that cannabinoids are prohibited from being used by sportsmen.

In July 2019 the new Law on amendments to the current Law on Narcotic and Psychotropic Substances was enforced. In particular, it aims to support localisation of manufacturing of opioid-containing medicines. It should facilitate access of Russian patients to such medicines.

However, said regulatory developments do not significantly change the regulatory regime for cannabis in Russia. The use of cannabis for medical or recreational purposes remains prohibited.

Legalisation of cannabis for medical use and liberalisation of criminal law regarding circulation and consumption of cannabis are regularly discussed in Russia. However, at this stage, it seems unlikely that any steps in this direction will be taken soon.

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Slovakia



Medical use

It is not permitted to grow, import or sell cannabis for medical use in Slovakia.

Recreational use

It is not possible to produce, import or sell recreational cannabis in Slovakia. Breach of this prohibition may be punished in accordance with the Slovak Criminal Code by three to 10 years imprisonment.

Industrial use

Slovak legislation does not explicitly specify the permitted uses. It generally allows growing cannabis for industrial purposes upon authorisation granted by the Slovak Ministry of Health. Every holder of the authorisation is required to take measures to prevent the abuse of the cannabis to produce narcotic drugs and psychotropic substances.

The Ministry of Health is entitled to impose a fine for breach of laws applicable to industrial cannabis in the amount up to EUR 33-193.

Slovak law currently classifies CBD as a highly addictive psychotropic substance. The use of the CBD is generally prohibited; it may only be present in a medicinal drug as an active substance. However, at this time, there is no medicinal drug registered in Slovakia which contains CBD as an active substance. The legal prohibition will probably cease soon, as an amended law has been drafted (see below).

Patentability

It is not possible to patent cannabis-based products in Slovakia.

Latest developments

In August 2019, the Slovak government passed a draft bill under which CBD will no longer be classified as a highly addictive psychotropic substance, however, this change needs to be approved by the Slovak National Parliament in order to come into effect.

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Spain

Medical use

Cannabis cultivation for research, medical and scientific purposes is prohibited unless authorised by the Spanish Agency of Medicines and Medical Devices (AEMPS).

To date, the AEMPS has granted eight authorisations to cultivate "*Cannabis sativa*" to seven entities. Five for crops for research purposes, one of which is for content lower than 0.2% THC, one licence for cultivation for educational purposes only and two for cultivation for medicinal purposes.

As medicinal cannabis is not regulated in Spain, the cultivation of cannabis or the production of derivatives for commercialisation is only allowed in case of export to a company duly authorised in its country of origin.

The authorisations that can be obtained from AEMPS in order to enter the cannabis business are:

(i) Authorisation for the cultivation of cannabis plants for research purposes for the production of varieties or seeds of cannabis with therapeutic use or for the investigation of the physical and/or pharmacological properties, among others, of cannabis and its products and;

(ii) Authorisation for the cultivation of cannabis plants for medical and scientific purposes.

Patients can have access to a cannabis-based drug only on medical prescription if they suffer from sclerosis, cancer or other chronic pain diseases.

Notwithstanding the foregoing, a patient who decides to use it for these purposes should do so through a Social Club of Cannabis (CSC) in order to prevent their conduct from being considered illicit due to the fact that the CSC is apparently covered under the doctrine of "shared use".

Article 368 of the Spanish Criminal Code criminalises the cultivation of cannabis when it promotes, favours or facilitates the illegal consumption of drugs and establishes a prison sentence of three to six years.

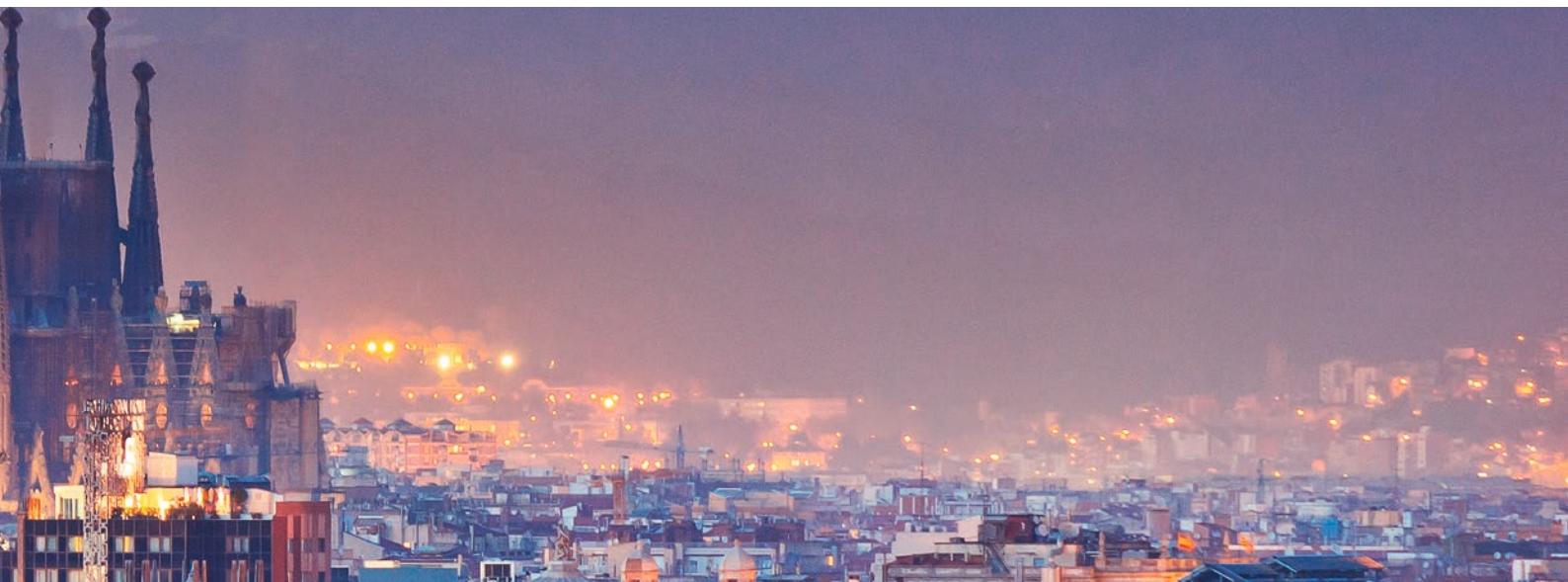
Nevertheless, the case law provides that cultivation and possession of narcotic substances that are not intended for trafficking but for one's own consumption and certain hypotheses of shared consumption in which there is no purpose or risk of diffusion is unpunished. Consequently, if the cultivation is not intended for the purposes discussed but only for self-consumption or shared use within an organisation, is an act of impunity.

Furthermore, Spanish legislation on security protection establishes that the "*consumption or possession*" of "*toxic drugs, narcotics or psychotropic substances, even if they are not intended for trafficking, in places, roads, establishments public or public transport*" is considered as a serious offence, and imposes sanctions ranging from EUR 600 to EUR 30,000.

Recreational use

It is prohibited to produce, import or sell recreational cannabis.

Notwithstanding, case law determines that the cultivation of cannabis for self-consumption is not a crime in Spain. Cultivation for lucrative purposes and cultivation in visible places is illegal.



Industrial use

Industrial cultivation of cannabis is legally permitted in Spain as long as it does not exceed the limits for THC content of 0.2% set by the European Union in Regulation (EU) No 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.

Royal Decree 1729/1999 of 12 November 1999 laying down the rules for applying for and granting aid for fibre flax and cannabis authorises 25 varieties of industrial cannabis for cultivation in Spain and lays down the rules for granting subsidies for crops intended for fibre production. In order for the crop to be legal, the seeds must be certified by the EU.

Spanish laws do not provide for special rules regarding CBD content.

In this regard, it has to be pointed out that CBD does not appear on the EU food list as an audited product and is therefore “not fit for human consumption”, which is why a large part of European production is being withdrawn from the market.

A company wishing to market in Spain parts of the plant *Cannabis sativa* L. (flowers, leaves and stems), extracts and cannabinoids, in the food area, must present an application to the European Commission in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 regarding novel foods and, once the risk has been assessed by the European Food Safety Authority (EFSA), the relevant authorisation or non-authorisation decision will be taken.

However, the CBD can be used for the manufacture of products not suitable for human consumption (cosmetics or for industrial or technical purposes) under certain conditions.

Patentability

In principle it is not forbidden to patent inventions containing cannabis as long as they comply with the patentability requirements. Nevertheless, as this substance is considered illegal in many countries including Spain, the possibility of using it is limited.

Latest developments

Last year, the Political Party “Ciudadanos” and the Political Party “Podemos” tried, without much success, to establish a subcommittee in Congress to evaluate the regulation and sale of cannabis.

The idea of legalisation of cannabis for medical use is regularly discussed in Spain. However, at this stage, it seems unlikely that any steps in this direction will be taken in the near future.

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Switzerland

Medical use

Grow, selling and importing cannabis for medical use is allowed.

However, there is a distinction between cannabis containing at least 1% THC and other cannabis.

Cannabis containing at least 1% THC (irrespective of its CBD content) is qualified – in addition to its possible qualification as medicinal product and the application of the medicinal products regulation – as a narcotic and can only be grown, imported and sold for medical use if an authorisation by the Federal Office for Public Health is granted. The application procedure is administratively complex.

Cannabis containing less than 1% THC (irrespective of its CBD content) intended to be used as a medicinal product is subject to the (general) regulation on medicinal products which provides for manufacturing authorisation, wholesale authorisation and marketing authorisation.

Patients can have access to currently authorised cannabis-based drugs only on medical prescription.

For cannabis containing at least 1% THC (irrespective of its CBD content), a patient can – via their physician – apply for an authorisation for restricted medical use issued by the Federal Office of Public Health. The application procedure is administratively complex and a lot of information and documentation needs to be included in the submission.

Cannabis containing less than 1% THC (irrespective of its CBD content) intended for medical use is regulated by the (general) regulation on medicinal products. Under certain circumstances, such products can be accessed by a patient if they are manufactured in a pharmacy based on a physician's prescription.

Violation of the regulation on narcotics (e.g. unauthorised cultivation of cannabis containing more than 1% THC) can be punished with up to 20 years of custodial sentence (plus a monetary fine). Violation of the regulation on medicinal products (e.g. marketing of a medicinal product without a marketing authorisation) can be punished with up to 10 years of custodial sentence (plus a monetary fine). Legal entities can be punished with a fine of up to CHF 5m.

Recreational use

Cannabis containing at least 1% THC (irrespective of its CBD content) is qualified as a narcotic. Production of, importation of, and selling of such cannabis for recreational use is not allowed.

Cannabis containing less than 1% THC (irrespective of its CBD content) is not qualified as a narcotic and can generally be produced, imported and sold for recreational use. Note that product specific regulation (such as regulation on tobacco substitutes) might demand certain authorisations and/or notifications.



Industrial use

Industrial cannabis, understood as cannabis containing less than 1% THC (irrespective of its CBD content) is legally not qualified as a narcotic but is subject to the regulation under which the product is brought on the market (medicinal products, foodstuffs, cosmetics, chemicals, tobacco substitute, etc.).

The uses permitted are determined by these regulations. For instance, some foodstuffs containing CBD are qualified as novel foods and require marketing authorisation.

In Switzerland there is no general regulation on CBD content. Rather the content is subject to the regulation under which the product is brought on the market (medicinal products, foodstuffs, cosmetics, chemicals, tobacco substitute, etc.). For instance, CBD-containing liquids (for e-cigarettes) may only release substances in quantities that do not pose a health risk.

Patentability

Cannabis based products are patentable. It is, though, not possible to patent plant varieties or essentially biological processes for the production of plants.

Latest developments

Switzerland is planning to amend the legislation on cannabis for medical use in order to facilitate access to cannabis based medicinal products for patients. Public consultation to the draft amendment is currently (September 2019) under way.

Furthermore, it is planned to allow the conduct of temporary and strictly regulated scientific studies on cannabis use for human consumption. The amendment is currently being discussed in Parliament.

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United Arab Emirates

Medical use

Cannabis possession is illegal in the United Arab Emirates. Article 7 of Law No 14 of 1995 and its amendments (the “Anti-Narcotic Psychotropic Substances Law”) provides that “except in the cases authorised and under the conditions provided for, the procurement, import, export, manufacture, extraction, separation, production, acquisition and abuse of narcotic drugs and psychotropic substances” listed in schedules 3, 5, 6, 7 and 8 of the Law shall be prohibited. The Anti-Narcotic Psychotropic Substances Law goes further to provide that any actions connected with narcotic drugs shall be prohibited unless authorised otherwise.

Article 11 of the Anti-Narcotic Psychotropic Substances Law lists the entities which may authorise such drugs, including but not limited to, government bodies, state or licenced hospitals, clinics and sanatoriums, licenced chemical analysis laboratories or medical, scientific and industrial research laboratories. If position or acquisition is authorised, proportions of differences in weight may not exceed those “stated in established pharmacopoeias” and Schedule 4 of Law No. 4 of 1983.

The Anti-Narcotic Psychotropic Substances Law lists various penalties including Article 39 which provides for a penalty of imprisonment for not less than four years shall be imposed on anyone who has “abused, in any way whatsoever or personally used, in circumstances other than those authorised, any of the narcotic drugs or psychotropic substances specified in Schedules 1, 2, 4 and 5 of the law. The court, in addition to the preceding penalty, may impose a fine of not less than Dh 10,000.”

Furthermore, Article 46 of the Anti-Narcotic Psychotropic Substances Law provides “the penalty of imprisonment for a period of not less than 10 years and not more than 15 years and a fine of not less than Dh 20,000 shall be imposed on any person who has managed, prepared or set up a place for the abuse of narcotic drugs or psychotropic substances”.

Industrial use

The Dubai Municipality has declared that the sale and purchase of hemp seed oil, which tends to be found in cosmetics, health care products, serums, lip balms and facial oils, is legal.

On the other hand, CBD oil, which contains CBD, is illegal in the UAE and treated the same as cannabis, marijuana and other drugs.



Patentability

As a general point, inventions that violate UAE public order or morals are excluded from patent protection.

At present, it is not possible to patent cannabis related products in the UAE, however it is ultimately unclear whether the Dubai Municipality's recent announcement on the legality of hemp seed oil is likely to pave the way for an opening in this market.

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United Kingdom



Medical use

It is in principle lawful to produce, supply, offer to supply, import, export, have in possession or cultivate (in the case of the plant) cannabis products, including medicinal products, when done under a relevant licence issued by the UK Home Office.

Subject to conditions prescribed in statute, products falling within the statutory definition of 'cannabis-based products for medicinal use in humans' may be ordered for and/or supplied to patients, and possessed by the patient, without the patient or the supplying healthcare practitioner requiring a licence from the UK Home Office (though a licence is required for all possession and supply in the supply chain up to the healthcare practitioner). Certain other cannabis products are specifically excluded from the definition of cannabis-based products for medicinal use in humans but may also be lawfully supplied in the UK.

Despite allowing supply to patients without a Home Office licence for medicinal use, the legislation maintains safeguards for patients by specifying that cannabis-based products for medicinal use in humans may only be lawfully supplied in specified circumstances. The cannabis-based medicinal product must either be: (i) a medicinal product with a marketing authorisation under applicable medicines legislation; (ii) an investigational medicinal product supplied for use in the course of a clinical trial; or (iii) if an unlicensed medicine not supplied in the course of a clinical trial, a so-called 'special' meeting the requirements for 'specials' set out in the Human Medicines Regulations 2012 and supplied in accordance with a prescription by a specialist doctor.

Note that it is unlawful to self-administer a cannabis-based product for medicinal use by way of smoking (other than for certain research purposes).

As to potential criminal **sanctions for breach of the statutory requirements**, (i) possession can be punished with imprisonment up to 5 years, an unlimited fine or both; (ii) supply and production can be punished with imprisonment up to 14 years, an unlimited fine or both; and (iii) manufacturing/selling by way of wholesale a medicinal product without a valid manufacturing/wholesale distribution licence, and selling/possessing for sale an unauthorised medicinal product can be punished with imprisonment up to 2 years, an unlimited fine or both.

Recreational use

Subject to the limited medicinal supply referred to above, in general, use of cannabis is only lawful under the Misuse of Drugs Act 1971 when specifically authorised under a Home Office licence. To date Home Office policy has remained to not issue licences permitting recreational use.

Industrial use

Hemp may be lawfully cultivated and processed for industrial use under a so-called 'Industrial Hemp' licence issued by the Home Office. The Home Office only issues licences for cultivation of hemp plants from approved seed types with a tetrahydrocannabinol content not exceeding 0.2%. The legally controlled parts of the plant (i.e. the leaves and flowers) cannot be used under an Industrial Hemp licence and must be destroyed.



Industrial hemp can be lawfully used for the commercial production of hemp fibre for industrial purposes and/or the obtaining of seeds which are then pressed for their oil, for use in cosmetics and food supplements.

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

Patentability

In the United Kingdom, cannabis related products are potentially patentable including cannabinoid extracts, dried flowers, medical formulations and inhalation devices/systems. It may also be possible to obtain protection for cannabis plants in the United Kingdom, although the position on patentability of plants produced by essentially biological processes (in general, not specifically cannabis plants) is unclear in Europe at present. Plant variety rights are available to protect the plants.

Latest developments

Subsequent to the 1 November 2018 legislative changes which made it easier to prescribe and supply medicinal cannabis products in the UK, interim prescribing guidance was issued by healthcare practitioner professional bodies, including the General Medical Council guidance on prescribing unlicensed medicinal cannabis products, pending a consultation on clinical effectiveness of cannabis-based medicinal

products by the National Institute for Health and Care Excellence (NICE). The NICE guideline was subsequently issued on 11 November 2019 providing guidance on prescribing of cannabis-based medicinal products for people with intractable nausea and vomiting, chronic pain, spasticity and severe treatment-resistant epilepsy. NICE is also developing technology appraisal guidance on cannabidiol with clobazam for treating seizures associated with Lennox-Gastaut syndrome and Dravet syndrome.

The NICE guidance follows the grant of a marketing authorisation for a second, non-synthetic medicinal cannabis product, GW Pharma's Epidyolex, which has been licensed in the EU for Lennox-Gastaut syndrome and Dravet syndrome.

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