LEGALINK

INTERNATIONAL BUT PERSONAL

CANNABIS REGULATION AND CANNABIS DERIVED PRODUCTS

LEGALINK

CANNABIS REGULATION AND CANNABIS DERIVED PRODUCTS

INTRODUCTION

As more jurisdictions around the world move to legalize various forms of cannabis, including hemp and CBD products, recreational marijuana, and medical marijuana, the global cannabis industry continue to blaze forward. But changing and even inconsistent laws and an evolving regulatory environment have created legal uncertainties and tensions in the development of the industry and marketplace. This booklet aims to provide practitioners a summary reference for cannabis laws and regulations in various jurisdictions across the globe. Practitioners should note that because cannabis laws are quickly evolving, through the legislative process, ballot initiatives and regulatory rule implementations and changes, each jurisdiction's most recent cannabis laws and regulations should be reviewed and assessed.

A QUICK PRIMER ON CANNABIS BASICS

Cannabis vs. Marijuana vs. Hemp

Cannabis refers to a genus of plants that has three species – indica, sativa, and redueralis. Marijuana and hemp are both cannabis. Despite popular misconception, marijuana and hemp are not different species of cannabis.

Marijuana, in the common parlance, is cannabis that, when consumed, results in a "high." The "high" in marijuana is produced as a result of high tetrahydrocannabinol or THC content. Hemp, again in common usage, does not cause intoxication because it has low levels of THC.

INTRODUCTION

Some jurisdictions around the world still do not distinguish between marijuana and hemp. For example, for decades, the federal government in the U.S. did not distinguish between hemp and marijuana or the level of THC content in either – both were illegal cannabis and a controlled "Schedule I" drug.

As cannabis laws and policy have changed over the years, now, in the U.S. and, as applicable, in other jurisdictions, the legal difference between marijuana and hemp is often based upon THC content level. In the U.S., again by way of further example, the Agriculture Improvement Act of 2018 defines legal hemp as "Plant Cannabis sativa L. and any part of that plant, including cannabinoids with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." Thus, under federal law in the U.S., cannabis that has no more than 0.3% THC is legal hemp, but cannabis that contains more than 0.3% remains illegal marijuana. Each jurisdictions' definitions for each should, of course, be consulted to determine whether hemp and marijuana are distinguished from one another and where the lines of cannabis legality or illegality are drawn.

THC vs. CBD

THC and CBD are both cannabinoids found in cannabis. A cannabinoid is a naturally occurring compound that reacts with cannabinoid receptors found in our nervous system that are part of our endocannabinoid system, involved in appetite, mood, and sensing pain.

As noted, THC is a psychoactive cannabinoid in marijuana that produces a "high." CBD, or cannabidiol, is a non-psychoactive cannabinoid that may have some health benefits. But more studies are needed. CBD can be derived or extracted from hemp and marijuana. Many CBD products are derived from hemp, containing low levels of THC and higher levels of CBD. Whether CBD or CBD products are legal in any particular jurisdiction will be driven by legal definitions and parameters established by applicable regulatory authorities.

AUSTRIA

Polak & Partners Rechtsanwälte Gmb

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Austria?

1.1. Narcotics framework

In Austria, cannabis is subject to the provisions of the Austrian Narcotic Substances Act (Bundesgesetz über Suchtgifte, psychotrope Stoffe und Drogenausgangsstoffe; Suchtmittelgesetz (SMG)). The classification of cannabis as a narcotic substance is based on the UN Single Convention on Narcotic Drugs. As required by Article 36 of the UN Single Convention on Narcotic Drugs, the cultivation, production, manufacture, extraction, preparation, possession, offering, offering for sale, distribution, purchase, sale, delivery on any terms whatsoever, brokerage, dispatch, dispatch in transit, transport, importation and exportation of drugs contrary to the provisions of this Convention shall constitute punishable offences. This Article was implemented via Section 27 et seqq in Austria as follows:

a) § 27 (1) SMG – Illegal handling of narcotics (basic criminal offence):

It is a punishable offence to acquire, possess, produce, transport, import or export, or to offer to, give to or procure for a third person, cannabis containing more than 0.3% tetrahydrocannabinol (THC). The penalty is imprisonment for up to one year or a fine.

b) § 27 (1) SMG in conjunction with § 27 (2) SMG – Personal use (mitigating factor):

Pursuant to § 27 (2) of the SMG the maximum penalty is reduced to imprisonment for up to six months, if and when a person only commits an offence pursuant to § 27 (1) SMG for personal consumption of the narcotic substance.

c) § 27 (1) SMG in conjunction with § 27 (5) SMG – Addiction (mitigating factor):

Pursuant to § 27 (5) SMG the maximum penalty is one year, if and when a person commits an offence for commercial purposes (§ 27 (3) SMG; meaning with intent to

create a continued income from, among others, the sale of cannabis pursuant to § 27 (1) SMG) as part of a criminal organisation, but such person is also addicted to a narcotic substance.

d) § 35 SMG in conjunction with § 27 (1) (2) SMG – Suspension of the case:

Pursuant to § 35 SMG the public prosecutor's office must suspend criminal proceedings for a probationary period of one to two years, if and when the accused person

- was found with a quantity of narcotic substances less than the threshold quantity defined in the Threshold Quantity Regulation (Grenzmengenverordnung (GV)). For instance, for cannabis the threshold is a pure substance mass of 20 grams THC. Depending on the THC content of the product, this corresponds to 80 to 300 grams of dried cannabis flowers. The threshold quantity constitutes the quantity of an active substance that may pose great danger to life and health.

  and

- committed an offence pursuant to § 27 (1) or (2) SMG only for his or her personal consumption or the personal consumption of a third person without gaining an advantage (monetary or otherwise) from the offence.

The legislative intention is to protect from excessive criminalisation persons who commit an offence pursuant to § 27 (1) or (2) SMG for personal consumption only. However, the proceedings will be resumed in the event another narcotic drug offence is committed within the probationary period. The preliminary discontinuation of penal proceedings requires a report from the health authority as to whether the person being reported is a long-term consumer of narcotics and therefore needs a health-related measure according to § 11 SMG (medical examinations, withdrawal measures, psychotherapy, counselling interviews, provision of urine samples). However, pursuant to § 35 (4) SMG the public prosecutor must refrain from requesting a report of the health authorities, if and when the accused committed the above-mentioned offences for exclusively personal consumption or for the personal consumption of another person without gaining an advantage and if the offence was committed with regard to certain narcotics (e.g. substances or preparations derived from the cannabis plant).

e) § 27 (3) and (4) SMG in conjunction with § 27 (1) SMG – Commercial commission and commission as part of a criminal organisation (aggravating factor):

Pursuant to § 27 (3) SMG the maximum penalty could be imprisonment up to three years, if and when a person commits an offence pursuant to § 27 (1) SMG with intent to thereby create a continued income for him/herself or as a member of a criminal organisation (§ 27 (4) SMG).

f) § 28 SMG in conjunction with § 28a (1) SMG – preparation of narcotic substance trafficking (aggravating factor):

Pursuant to § 28 and § 28a SMG the maximum penalty could be imprisonment for up to three years, if and when a person illegally acquires, possesses or transports a narcotic substance exceeding the threshold quantity (pure substance mass of 20 grams THC) and with the intent to sell it.

Further aggravating factors are if such crime is committed as a member of a criminal organisation or the amount of the drug exceeds 15 times the threshold stipulated in the GV.

f) § 28a SMG concerning the actual trafficking of narcotic substances (aggravating factor):

Pursuant to § 28a SMG the maximum penalty can be up to five years imprisonment, if and when a person illegally produces, imports, exports or offers, gives to or procures for a third person a narcotic substance exceeding the threshold quantity stipulated in the GV.
Further aggravating factors are if such crime is committed as a member of a criminal organisation or the amount of the drug exceeds 15 times the threshold stipulated in the GV.

How are Cannabis sativa as a plant and its seeds regulated? Plants and seeds thereof are subject to the SMG if they contain more than 0.3% THC. However, seeds and young plants that can grow into potent cannabis plants can be purchased in many shops in Austria. Whether the possession of the plants or seeds constitutes an offence depends on the intended use of the plants and seeds.

The unauthorised cultivation of cannabis plants for the purpose of obtaining narcotic substances is an administrative offence which is punishable by a fine of up to €36.30 according to § 6 (2) in connection with § 44 (1) no. 1 SMG (in case the person cannot pay the financial fine, imprisonment for failing such fine can be up to six weeks). In principle, only the act of obtaining addictive substances, i.e. the separation of the THC-containing plant parts from the plant for the purpose of obtaining addictive substances, is punishable by law. In practice, however, the courts often regard cultivation as attempted production within the meaning of the SMG.

How is Cannabidiol classified in Austria? Cannabidiol (CBD) as such (if not diluted with THC) does not qualify as a narcotic substance and is therefore not subject to the provisions of the SMG. Thus, the import and possession of Cannabis sativa plants (if the THC content is below 0.3%) with the intent to extract CBD from them is permissible.

1.2. Food products framework

In December 2018 the Austrian Federal Ministry of Labor, Social Affairs, Health and Consumer Protection (Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz (BMASGK)) issued guidance restricting the use of CBD in cosmetics, food and food supplements, and as liquids for electronic cigarettes.

Austrian authorities consider food products to which CBD extract as a food ingredient is added as novel foods under Regulation 2015/2283/EU regardless of whether the extract was naturally or synthetically produced.

Novel foods are defined as foods that were not used for human consumption to a significant degree in the European Union before 15th May 1997 ("history of safe consumption") and fall into at least one of the categories listed in Article 3 (2) lit. a of the above-mentioned Regulation. Only novel foods authorised by the EU Commission and included in the European Union list of authorised novel foods in the Commission Implementing Regulation 2017/2470/EU may be placed on the market as such or used in food products in accordance with the conditions and labelling requirements laid down in the European Union list.

According to the EU novel food catalogue, synthetically obtained cannabinoids are considered novel foods, and thus require authorisation in accordance with the Novel Food Regulation. Even if extracted in a natural way, CBD is classified as a novel food, as

it is when added to traditional hempseed products. Therefore, only traditional food itself such as hempseeds, hempseed oil, hempseed flour or fat-free hempseed proteins can be legally marketed within the European Union.

The novel food catalogue is not legally binding, but many authorities in the EU use it as a reference for the purposes of the Novel Food Regulation 2015/2283/EU. Based on the novel food catalogue, authorities in the member states may refuse to permit supply of foods and food supplements containing cannabinoids, as Austria did, pending formal approval by the European Food Standards Agency (EFSA) under the Novel Food Regulation. Therefore, the Austrian position is in line with the recommendations at EU level.

The first application to the EFSA for a food supplement containing CBD for adults with a daily intake of up to 130mg was submitted by the Czech company Cannabis Pharma s.r.o. If the application is successful, the European Commission will issue an implementing regulation adding CBD as a food/ingredient to the list of approved novel foods. That approval will also specify any applicable conditions of use (e.g. maximum daily intake) or labelling requirements. Any product which differs from the approval will require a further application under the Novel Food Regulation. The application for the authorisation of food products containing cannabinoids is currently pending; no authorisation by the EU Commission has been granted yet.

1.3. Medicinal products framework

Whether a product is classified as a medicinal product, food product, food supplement, food for special purposes, medical device or cosmetic product determines the financial effort required to bring the product on the market. This classification also determines the future marketing strategies, in particular the limitations (e.g. prohibition for certain claims concerning medicinal products). Although the terms “food”, “food supplement” and “medicinal product” have been defined on a European Union level, the delimitation still causes practical problems. Therefore, the Court of Justice of the European Union (CJEU) is regularly confronted with the question of whether or not a certain product is to be classified as a medicinal product or not.

a) Definition of medicinal product

According to Article 1 no. 2 of the Human Use Directive 2001/83/EC as amended, a medicinal product is defined as follows:

> "Any substance or combination of substances presented for treating or preventing disease in human beings.
>
> Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product."

Concerning the first sentence of Article 1 no 2 leg cit, CJEU further explained that a so-called presentation medicinal product is a product which, by its name or presentation (advertising), gives the impression to the average consumer that it is intended to cure or prevent human disease, whereas the second sentence of Article 1 no 2 leg cit describes a functional medicinal product. Based on CJEU case law, these are products which have a significant effect on human physiological functions by exerting a pharmacological action linked to the prevention or cure of a disease or to a medico-therapeutic benefit, the therapeutic efficacy of which must be scientifically demonstrated.

Cannabis undoubtedly has a pharmacological effect when the THC content exceeds 0.3% – including, among other things, an anti-psychotic, neuroprotective or anti-inflammatory effect. Whether such products fall under the scope of the Human Use Directive depends on, among other things, the intent of the manufacturer. Products simply for research purposes outside of a clinical trial would not be covered (if they can be sold at all), but when health claims can be found on the package or in the advertising such product would be considered a medicinal product. Cannabis sativa products are also available as homeopathic products (below the 0.3% THC threshold).

Not only can the pharmacological properties trigger the application of the Human Use Directive, but as mentioned above so can the presentation of the product per se. If the product is advertised using disease-related claims, the product would qualify as a medicinal product even if the THC content is below 0.3%. Austrian authorities are increasingly checking homepages advertising CBD products.

b) Marketing authorisation

To obtain a marketing authorisation for the whole European Economic Area (EEA) (the EU, Iceland, Liechtenstein and Norway) the medicinal product must go through the centralised procedure pursuant to Regulation 2004/726/EC. Applications have to be filed with the European Medicines Agency (EMA).

Because of the restrictions posed by the centralised procedure it is unlikely that a product containing cannabidiol will be authorised by this route (except where the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorisation in accordance with this Regulation is in the interests of patients or animal health at EU level.) Thus, at least a national authorisation is required.

The national procedure is regulated by the Austrian Medicinal Product Act (Bundesgesetz vom 2. März 1983 über die Herstellung und das Inverkehrbringen von Arzneimitteln; Arzneimittelgesetz (AMG)) implementing the Human Medicinal Products Directive 2001/83/EG, which stipulates in its Article 8 that an application for a marketing authorisation for a medicinal product must be submitted to the competent authority of the member state concerned. In Austria this is the Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen (BASG)). The application form can be downloaded from the homepage of the BASG. Therefore, in essence medicinal products can only be marketed if and when they are approved by the BASG or by the European Commission with certain limited exemptions, such as in the case of a named patient sale.

c) Medicinal products currently available in Austria

The finished medicinal products Sativex and Canemes, containing cannabis active substances, are authorised for medical purposes in Austria. They consist of a mixture of psychotropic THC/dronabinol and non-psychotropic cannabidiol. Sativex has its approval for spasticity associated with multiple sclerosis and Canemes for nausea and vomiting as a result of chemotherapy as well as cachexia and loss of appetite in HIV patients.

The medicinal product Epidyolex containing highly purified CBD was approved by the EU Commission for the treatment of paediatric epilepsy.

For therapeutic use, cannabinoids (dronabinol and cannabidiol) can also be made available as magistral preparations via a pharmacy. This means that a physician shall prescribe, for instance, highly purified dronabinol and predefine the exact method of its preparation. Dronabinol is synthesised from hemp flowers and is taken in fluid or capsule form. The prescribed preparation must be made directly at the pharmacy (this cannot be outsourced). Magistral preparations are normally not reimbursed by the sick funds, but there are certain exemptions.

At this stage a magistral preparation of cannabidiol is still not reimbursed because, based on the reimbursement conditions for inclusion of a medicinal product, such preparations still lack sufficient proof concerning efficacy from a social security perspective (this is a different standard as for obtaining a marketing authorisation). In an individual case, they can be reimbursed, namely if there is a medical need and no comparable product is listed in the Reimbursement Codex. This means that a physician being employed by the sick fund will review the case and can approve that the costs are taken over. If the assessment is in favour of the patient, magistral preparations of dronabinol or CBD are reimbursed.

Magistral preparations are most likely to be used for patients with spasticity, paralysis, multiple sclerosis and other nervous disorders, for the relief of chronic pain that does not respond to any other therapy (cancer, diseases of the nervous system), or loss of appetite, nausea and vomiting in cancer and AIDS patients.

1.4. Tobacco products framework

The distribution of

- tobacco products or
- nicotine-containing e-cigarettes or liquids

containing vitamins or other additives, which give the impression that these products have a health benefit or present lesser health risks is expressly prohibited pursuant to the Austrian Tobacco- and Non-Smoker Act (Bundesgesetz über das Herstellen und Inverkehrbringen von Tabakerzeugnissen und verwandten Erzeugnissen sowie die Werbung für Tabakerzeugnisse und verwandte Erzeugnisse und den Nichtraucherinnen- bzw. Nichtraucherschutz (Tobacco- and Non-Smoker Act or TNRSG)) based on EU Directives 2014/40/EU and 2001/37/EG (TPD II).

The background of this regulation is above all that certain additives could mislead the consumer into believing that the consumption of a tobacco or related product has a health benefit and poses fewer health risks in comparison to normal cigarettes.

Recent analysis results of the Austrian Agency for Health and Food Safety (Agentur für Gesundheit und Ernährungssicherheit (AGES)) as well as relevant studies showed that THC acid (THCa) in normal cigarettes is converted into THC when tobacco or related products are heated or consumed, thus increasing the THC content, even beyond the 0.3% THC limit. Such consumption would then be covered by the SMG, triggering the penalties as stipulated in the SMG. In the view of the former Austrian Ministry of Health, the mandatory 0.3% THC limit must be interpreted in the context of tobacco law as meaning that it is only considered to be met if the THC content does not exceed 0.3% even after conversion of THCa into THC during the incineration process.

Tobacco and related products to which CDB or hemp are added that do not meet the legal requirements of the Tobacco- and Non-Smoker Act therefore cannot be sold to consumers. If such products are found on the market, they must be reported to the locally competent administrative authority. The latter shall conduct administrative penal proceedings in this regard – if necessary, on the basis of an official inspection and examination by AGES – in accordance with § 14 TNRSG.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Austria?

In a European Union context, Austria has always been seen as a rather conservative country when it comes to the regulation of the consumption of narcotic substances. Even though the liberal Green Party is currently part of the Government, a general legalisation or decriminalisation of cannabis comparable to the Dutch model is currently not up for discussion.

Concerning the needs of patients: In its 2019 report, the Austrian Supreme Sanitary Council, an advisory body to the BMASGK, stated that, based on the current legal situation, Austrian patients have sufficient access to cannabis-based medicinal products, either in the form of magisterial preparations or as finished drugs (Sativex and Canemes). Dronabinol, which is used in pain therapy and is subject to the Narcotic Substances Act, could be prescribed in the form of drops or capsules.

The Council also confirmed that reimbursement of the costs is possible if there is a medical justification approval by a physician of the sick fund and no comparable product is listed in the Reimbursement Codex.

With regard to the use of medicinal hemp (dried flowers of the cannabis plant), the report states that there is no scientific evidence that this has advantages over the use of cannabis-based preparations already available on the market. In general, knowledge about the useful medical use of cannabinoids is still very patchy, the authors say. Further clinical research should therefore be conducted.

As for all medicinal products, the authorisation procedure for medicinal products, be it before the EMA or the BASG, is long and costly. Mandatory pre-clinical and clinical studies, the gathering of necessary documentation and the back and forth between applicant and the competent authorities take up a lot of resources. This is a general challenge.

With regard to cannabis-based medicinal products, a further hurdle arises in Austria, namely that only AGES may cultivate medical cannabis and distribute it to authorised buyers (see Question 3). Also, the reimbursement of cannabis-based medicinal products is dependent on the individual formulation (oral, nasal, etc) of the product.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Austria?

The production, processing, transformation, acquisition and possession of narcotic drugs is, according to § 2 (1) Narcotic Substance Decree (Verordnung der Bundesministerin für Arbeit, Gesundheit und Soziales über den Verkehr und die Gebarung mit Suchtgiften (SV)), generally only permitted with the approval of the Federal Minister of Health.

Since an amendment to the SMG in 2008 the AGES may cultivate medical cannabis and distribute it to authorised buyers, usually pharmaceutical companies. According to § 6 (2), in connection with § 6a SMG only AGES or a subsidiary established for this purpose is permitted to cultivate plants to produce narcotic drugs, in concreto for the manufacture of medicinal products.

The amendment also gave private pharmaceutical companies the opportunity to buy up to a quarter of the subsidiary's shares from AGES.

AGES has been producing cannabis through its subsidiary commercially since 2010 in 3,000 square metres of greenhouses in Vienna, where production and research are carried out simultaneously.

In 2016 the Austrian Constitutional Court (Verfassungsgerichtshof (VfGH)) ruled that restricting the permission to cultivate medical cannabis to a company owned by the Republic of Austria guarantees – in a constitutionally justifiable manner – the control necessary to prevent abuse and to protect public health (VfGH 24.11.2016, G 61/2016).

4. Which body is responsible for legislative controls relating to CBD?

The BMASGK is responsible for proposing new laws or amendments thereof, enacting regulations in the field of narcotic substances, issuing, amending and revoking administrative decrees and deciding on applications for import and export licences of drugs.

BASG is subordinate to the BMASGK and has been entrusted with a large number of tasks concerning marketing approvals for medicinal products, approvals and inspections for clinical trials of medicinal products and medical devices, and pharmacovigilance and vigilance in the field of medical devices. The BASG relies thereby on the expertise and personnel of AGES.

AGES advises the BMASGK on questions of public health, animal health, food safety (novel foods), food safety and consumer protection. AGES is a private entity owned by the Republic of Austria, represented by the BMASGK as well as the Ministry of Agriculture. As mentioned under Question 3, only AGES is legally entitled to produce medicinal cannabis in Austria.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in Austria?

In its decree of December 2018, the BMASGK classified CBD extracts as novel food pursuant to the Regulation 2015/2283/EU. This means that CBD cannot be used as a food ingredient as long as it is not authorised by the EU Commission as mentioned

above under question 1.2. Most sellers have therefore adapted their CBD product labels and sell oils, flowers etc only as aromatic products rather than food products. Nevertheless, there can be additional requirements for certain food products. Natural hemp oil, for instance, must be extracted from hemp seeds authorised in the EU plant variety database which is published based on Article 17 of Council Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species.

The BMASGK based its 2018 decree concerning CBD on the EU Regulation on Novel Foods, although the accompanying catalogue of novel foods clearly states that CBD extracts are a novel food only if the CBD content exceeds the CBD content naturally occurring in the plant. However, the Regulation 2015/2283/EU does not specify what percentage of CBD is considered natural. The BMASGK considers food products or cosmetics containing CBD and products suitable or intended for consumption with CBD, as well as extracts such as CBD oil, to be illegal. But if the same CBD oil is sold as an aromatic oil for fragrance lamps, it is not subject to any prohibition or restriction on sale.

Whether this legal opinion of the BMASGK is in line with EU law, in particular the Cosmetic Regulation, can be doubted. Until recently, CBD oils were still sold in pharmacies as food supplements, but the clever pharmacist no longer advertises them as such.

Until the CJEU rules on this subject, there is a risk that selling CBD food products containing CBD as an ingredient or cosmetics triggers an administrative fine (see question 1.3.).

6. What are the testing specifications in Austria for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

6.1. Narcotic Substances

If the official examination of a product shows a THC content of more than 0.3%, the possession or distribution of it is reported to the responsible public prosecutor's office in accordance with SMG.

If a person is stopped and searched by the police and possesses CBD flowers, such person will be treated as having violated the SMG. Simply based on the suspicion of a violation of the SMG, the police can then confiscate the flowers and interrogate such person. The CBD flowers will be examined by an official lab and the case may end up at the public prosecutor's office if the THC content exceeds 0.3%.

6.2. Food products

According to § 76 of the Food Safety and Consumer Protection Act (Bundesgesetz über Sicherheitsanforderungen und weitere Anforderungen an Lebensmittel, Gebrauchsgegenstände und kosmetische Mittel zum Schutz der Verbraucherinnen und Verbraucher; Lebensmittelsicherheits- und Verbraucherschutzgesetzes (LMSVG)) the Austrian Food Book (Codex Alimentarius Austriacus) serves to stipulate designations, definitions, testing methods and evaluation principles as well as guidelines for the production and marketing of goods.

From a legal point of view, the Austrian Food Book is classified as a (refutable) "objective expert opinion". The administrative courts as well as the civil courts in unfair trade practices cases normally refer to the Austrian Food Book.

For example, the entry for hemp oil says:

> "1.6.6 Hemp seed oil (hemp oil)
> Hemp seed oil is obtained from the seeds of the hemp plant (Cannabis sativa). Cold-pressed hemp seed oil has a green-yellowish, sometimes also a brown-green colour with a grassy scent and a tart nutty taste.
> Not to be confused with essential hemp oil (obtained from leaves and flowers) or hashish oil (oily resin extract with a high THC content).
> For the production of hemp seed oil, only hemp seeds from seed varieties are used which meet the applicable approval conditions (see also EU Register of Varieties of Hemp:
> http://ec.europa.eu/food/plant/plant_propagation_material/plant_variety_catalogues_databases/search/public/index.cfm?event=SearchVariety&ctl_type=A&species_id=240&variety_name=&listed_in=0&show_current=on&show_deleted=).
> With regard to the cannabinoid content, suitable preparation of the raw materials must be ensured within the framework of good manufacturing practice."

The last sentence of 1.6.6. Austrian Food Book above imposes on companies an obligation to establish, based on good manufacturing practices, a quality system ensuring that the legal THC threshold of 0.3% is complied with.

6.3. Medicinal products

The Regulation concerning the Manufacturing of Medicinal Products (Arzneimittelbetriebsordnung 2009 (AMBO 2009)) applies to all companies that manufacture, control or place on the market medicinal products or active substances, unless they are excluded from the scope of the AMBO 2009.

The AMBO 2009 stipulates that every company must operate an effective and functional pharmaceutical quality assurance system.

Within the framework of the quality assurance system, manufacturers are obliged to comply with Good Manufacturing Practice (GMP). According to § 2 Z 8 AMBO 2009, Good Manufacturing Practice is the part of pharmaceutical quality assurance which ensures that medicinal products are consistently manufactured and controlled according to quality standards that correspond to their intended use. As a source for the principles and guidelines of Good Manufacturing Practice for medicinal products, the AMBO 2009 refers to among others, Volume 4 of the Notice to Applicants. For the Good Manufacturing Practice for active substances, the Delegated Regulation (EU) 1252/2014 applies.

This system shall ensure that any medicinal product manufactured in the EU, even only for export purposes, is produced in line with GMP, thus guaranteeing a high protection for human health.

6.4. Tobacco products

In the course of their regular inspections of traders, manufacturers and importers, the inspection bodies of the BMASGK take samples of tobacco products and related products, which are then examined and assessed by AGES. If infringements of the provisions of the Tobacco- and Non-Smoker Act (TNRSG) are detected, a report is made to the competent local administrative authority on the basis of the penal provisions of § 14 TNRSG.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

There are no regional limits on the quantity of CBD.

For air travel within the EU and the Schengen countries, the legal situation in the country of entry is taken into account. In Austria the THC limit of 0.3% applies. “Cannabis herbs and cannabis resin" (exceeding 0.3% THC) are explicitly mentioned in § 24 (6) Narcotic Substance Decree as narcotic substances which may not be imported to, exported from or carried along in Austria. This could pose an infringement on the free movement of goods, so according to the Ministry of Health "the examination of a possible necessary adaptation of the Austrian provisions on the cross-border transport of medicinal products containing narcotic drugs in international travel is pending.”

Contacts in the firm

Dr. Karina Hellbert
Head Life Science
Email: k.hellbert@fplp.at

Mag. Philipp Felbermair, BA
Associate
Email: p.felbermair@fplp.at

BRAZIL

Felsberg Advogados

The use of cannabis for medical purposes and the discussion regarding its legalisation is a controversial issue in Brazil. In recent years, there have been protests for and against cannabis legalisation. Notwithstanding this, as of December 2019, the import, manufacture, commercialisation and prescription of products derived from sativa cannabis ("Cannabis Product") is permitted in Brazil through the approval of RDC n. 327/2019. The planting of cannabis for medicinal and/or scientific purposes, however, remains prohibited in the country. Thus, according to the National Health Surveillance Agency in Brazil (ANVISA), to manufacture products derived from sativa cannabis the pharmaceutical ingredient shall be imported in the form of plant derivative. Additionally, only the medicinal use of cannabis is authorised, and its administration must be oral or nasal, which means that cosmetics, smoking products, health products or cannabis-based foods are not allowed in Brazil. Cannabis derived products may only be commercialised by pharmacies and drugstores, with exclusive indication by medical professional and in oral and/or nasal form of administration.

It is also worth mentioning that, to be commercialised and registered in Brazil, cannabis-derived products shall contain predominantly cannabidiol (CDB) and no more than 0.2% tetrahydrocannabinol (THC). An exception is made for palliative care of patients who are in terminal clinical situations without other therapeutic alternatives. In these specific situations the product can contain THC above 0.2%. Furthermore, either the pharmaceutical ingredient or the products must not: (i) contain substances that are potentially toxic in the dosages used; or (ii) be added to isolated substances of synthetic or semi-synthetic origin (with the exception of those that have an excipient function). Additionally, the imported cannabis-derived products must be duly regulated by the competent authorities in their country of origin.

A Sanitary Authorisation (AS) needs to be obtained upon presentation with respect to the companies that are willing to manufacture, import and/or commercialise cannabis-derived products in Brazil. For obtaining the AS, it is mandatory to present (i) the company's Operating Licence (AFE) issued by ANVISA for the activity of manufacturing or importing medicines; (ii) the Special Authorisation (AE); (iii) the Good Manufacturing Practices (CBPF) certificate for medicines for the company manufacturing the product; and (iv) the technical documentation of the product's quality.

Finally, a legislative bill which shall review the regulation of cannabis and cannabis-derived products is being analysed by the Brazilian Congress. It shall also permit the planting of cannabis for medical and scientific purposes in the country. It is expected that the new law will be approved three years from now. For the moment, only certain judicial decisions grant the right to plant cannabis, mainly for scientific reasons.

Contacts in the firm

João Carlos Mendonça
Partner
Email: joaomendonca@felsberg.com.br

Marianne Albers
Partner
Email: mariannealbers@felsberg.com.br

COLOMBIA

MTA – Muñoz Tamayo Asociados

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Colombia?

The regulatory framework for the use of cannabis for medicinal and scientific purposes is established across a series of legal norms, as follows.

1. Legislative Act 02 of 2009

As indicated above, Legislative Act 02 of 2009, which modified article 49 of the Colombian Political Constitution, paved the way for the regulation of cannabis and cannabis derived products in Colombia, by allowing the medicinal use of cannabis for the first time. Pursuant to this Legislative Act "possession and consumption of narcotic or psychotropic substances is prohibited, unless prescribed by a doctor."

It is important to mention that the constitutional reform introduced by Legislative Act 02 of 2009 prohibited drug use without medical prescription, abolishing the so-called personal dose (dosis personal), meaning that the use of cannabis was only permitted with medical prescription. However, the above-mentioned constitutional reform did not impose any sanctions for the consumers of cannabis without a medical prescription.

2. Law 787 of 2016

As a result of the constitutional reform introduced by Legislative Act 02 of 2009, the Colombian Congress enacted Law 1787 of 2016, which aims to create a regulatory framework that allows safe and informed access to the medicinal and scientific use of cannabis and its derivatives or by-products in the Colombian national territory. Law 1787 establishes: (i) the authorities responsible for controlling the use of cannabis in Colombia; (ii) the system and method for calculating the fees charged by the competent authorities for the issuance of the various licences; and (iii) the penalties that might be imposed on licence holders that do not comply with the provisions of Law 1787, among other general provisions.

3. Decree 613 of 2017

Decree 613 of 2017 established the regulatory framework of Law 1787 in relation to the secured and informed access for the medical and scientific use of cannabis. In this sense, Decree 613 introduced definitions such as the difference between psychoactive and non-psychoactive cannabis (as mentioned, the latter has less than 1% THC in dry weight content) and regulates the different types of licences (and their modalities) that can be requested before the competent authorities to develop activities in relation to cannabis in Colombia, namely:

(i) Licence for the cultivation of psychoactive cannabis (Licencia de cultivo de cannabis psicoactivo).

(ii) Licence for the cultivation of non–psychoactive cannabis (Licencia de cultivo de cannabis no psicoactivo).

(iii) Licence for the manufacturing of cannabis derivatives or by-products (Licencia de fabricación de derivados de cannabis), and

(iv) Licence for the use of cannabis seeds for sowing or planting (Licencia de uso de semillas para siembra).

Decree 613 further makes it compulsory to comply with certain conditions and standards. For example, the licences for use of seeds and for cultivation of non-psychoactive cannabis require a description of the equipment and the areas of land to be used under the licence, as well as relevant safety protocols. Similarly, the licences for cultivation also require prior approval involving an inspection visit from the competent authority, and licences for cultivation of non-psychoactive cannabis require a manufacturing permit or a contract with the buyer of the relevant harvest, a description of the equipment and areas of land to be used thereunder, and a cultivation plan that covers all the years for which the licence is requested.

In turn, if the purpose of the application is scientific research, regardless of the type of licence, documentation is required accrediting the research project to be conducted by a university or an established company that proposes to engage in scientific research.

Decree 613 also regulates the allocation of quotas (cupos), that is, the maximum number of psychoactive cannabis plants each licence holder is allowed to grow. This norm established the Technical Group on Quotas (Grupo Técnico de Cupos (GTC)), whose function is to analyse, evaluate and monitor all matters related to the allocation of quotas in conformity with the Single Convention on Narcotic Drugs of 1961. The Technical Group on Quotas is also responsible for designing a guide to quantify the need for psychoactive cannabis and determine the quota that Colombia will register with the International Narcotics Control Board (INCB).

Finally, Decree 613 also regulates and establishes certain protective measures for small and medium-scale growers. It establishes the criteria to define small and medium-scale growers, as well as the need to design alternative mechanisms that will ensure effective access to the licensing system with a differentiated approach, which aims to protect applicants in indigenous communities or in minority groups. Additionally, as part of its social approach, Decree 613 obliges the holders of a licence to manufacture cannabis derivatives to source at least 10% of their assigned quota of cannabis from small or medium-scale growers who hold licences for the cultivation of cannabis. Furthermore, the decree gives smaller growers priority in the allocation of quotas and the advantage of being able to apply for a licence to grow cannabis for scientific purposes without the need to have a licence to manufacture derivatives, or links with someone who holds one.

Decree 613 was followed by a series of resolutions that aimed to strengthen the legal framework of cannabis for medicinal and scientific purposes, the most relevant of which are established below.

4. Resolution 579 of 2017

In relation to the small and medium national cannabis growers, producers and sellers, Resolution 579 of 2017 issued by the Ministry of Justice and Law establishes the criteria to define whether a person can be considered as a small or medium cannabis grower, producer or seller. Under said resolution, small and medium cannabis growers include not only growers but also medicinal cannabis producers and traders who, acting as individuals, cultivate the plant on a total area not exceeding half a hectare. The resolution also allows for licences to be awarded to associations (esquemas asociativos) of small and medium-scale growers.

5. Resolution 2891 of 2017

Resolution 2891 of 2017 issued by the Ministry of Health and Social Protection establishes the tariff schedule for the evaluation, monitoring and control of the manufacturing licences for cannabis derivates for medicinal and scientific use.

6. Resolution 2892 of 2017

The Ministry of Health and Social Protection issued Resolution 2892 of 2017 establishing the technical regulations related to licensing for the production and manufacturing of cannabis derivatives or by-products.

7. Decree 2106 of 2019

Finally, Decree 2106 of 2019 modified the provisions of Law 787 and unified the platforms and requirements demanded by environmental authorities for applications for environmental concessions, authorisations or licences. Additionally, pursuant to Decree 2106 of 2019, INVIMA is the competent authority for the issuance of licences for the manufacturing of cannabis derivatives or by-products (licencia de fabricación de derivados), which were formerly being issued by the Ministry of Health and Social Protection. Thus, all regulations which refer to the Ministry of Health and Social Protection as the authority responsible for issuing the above-mentioned licences should now be interpreted as referring to INVIMA, except for the provisions of Article 9 of Law 1787, concerning the establishment of the relevant fees.

The table below summarises the current regulatory framework for the use of cannabis and cannabis derivatives for medicinal and scientific purposes. It is important to note that the recreational use of cannabis in Colombia is prohibited.

Regulation	Comment
Legislative Act 02 of 2009	Legalises the use and consumption of cannabis with a doctor's prescription.
Law 1787 of 2016	Creates a regulatory framework that permits safe and informed access to cannabis and its derivatives
Decree 613 of 2017	Regulates Law 1787 of 2016, introduces definitions and conditions for obtaining the various types of licences.

Decree 631 of 2018	Introduces modifications and instructions concerning the source of seeds (fuente semillera)
Resolution 577 of 2017	Establishes technical regulations governing the assessment and monitoring of licences for the use of seeds for planting/sowing and licences for the cultivation of psychoactive and non-psychoactive cannabis plants.
Resolution 578 of 2017	Establishes the tariff schedule for the assessment and monitoring services that must be paid for by individuals and companies applying for licences.
Resolution 579 of 2017	Establishes criteria for defining small and medium-scale growers, producers and traders of medicinal cannabis in Colombia.
Resolution 2891 of 2017	Establishes the tariff schedule for assessment, monitoring and control services applicable to licences to manufacture cannabis derivatives for medicinal and scientific purposes.
Resolution 2892 of 2017	Establishes technical regulations governing the award of licences for the production and manufacture of cannabis derivatives.
Decree 2106 of 2019	Amends Law 1787 and aims to simplify applications and proceedings.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Colombia?

There are different challenges in allowing the medical and recreational use of cannabis and cannabinoids in Colombia. On one hand, as previously mentioned in this document, there are social, political, cultural and historic conditions of the Colombian society that must be overcome.

Colombia has been one of the epicentres of the "war on drugs" and, paradoxically, one of their major producers. This has created a complicated scenario that requires a shift in the approach towards cannabis and other cannabinoids, conceiving them as a medicinal product and a raw material with a high potential for the manufacturing of various products (such as paper, bricks and fuel, among others) and as an alternative to pharmaceuticals, rather than as an illicit and harmful drug.

In addition to the above social, political, cultural and historical challenge, the so-called "green gold" boom has led to other practical issues. For instance, there has been an

avalanche of requests and applications for licences, which has led to the authorisation processes taking longer than expected.

Furthermore, companies are facing challenges in obtaining the quality certification required for the industry. Indeed, manufacturers of products for human use or consumption must comply with a series of rules and procedures to guarantee the high quality standards that will prevent harm to consumers. These procedures are called Good Manufacturing Practices (GMP) and they are an essential condition for meeting the standards recommended by the agencies that control authorisation and licensing for the manufacture and sale of products such as food, drinks, dietary supplements, medicinal products, active pharmaceutical ingredients and medical devices.

Additionally, the industry has encountered significant difficulties with the financial sector. Indeed, difficulties in opening bank accounts, access to credit and monetising funds has been another obstacle in taking the medicinal cannabis business forward. To the extent that there are significant federal restrictions on the transfer of funds associated with the cannabis business, as well as the fact that some Colombian banks hold securities in the United States, where the trade and distribution of cannabis is still prohibited, they fear that the US Government could take reprisals, and this has brought several corporate investment initiatives to a halt.

Finally, there have been challenges faced by small and medium growers, who see the arrival of large corporations as a threat to their local businesses. The main obstacle that small and medium producers have faced comes from the legislation itself, as it appears to aim to create a pharmaceutical industry, which necessarily implies complying with certain production standards and protocols, and this in turn requires investing considerable sums that are unaffordable for small businesses wishing to compete on a level playing field.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Colombia?

Decree 613 establishes the different types of cannabis licences (and modalities) that may be requested by growers, producers and sellers in Colombia, as well as the obligations that each of the licence holders must fulfil.

With regards to such type of licences, article 2.8.11.2.1.2 of Decree 613 establishes the following licences, each of which has different modalities:

LICENCE	MODALITIES	ACTIVITIES	ISSUING AUTHORITY
Licence for the cultivation of psychoactive cannabis plants (Licencia de cultivo de cannabis psicoactivo).	• To produce seeds for planting • To produce buds/grain • To produce derivatives (Under this modality, the applicant must already have a licence for the manufacturing of cannabis derivatives or have it in process) • For scientific purposes • For storage • For final disposal	Cultivation of psychoactive cannabis that includes the sowing or planting, acquisition and production of seeds, storage, marketing, distribution and final disposal, as well as export and use for medical and scientific purposes	Ministry of Justice and Law
Licence for the cultivation of non–psychoactive cannabis (Licencia de cultivo de cannabis no psicoactivo)	• To produce seeds for planting • To produce buds/grain • To produce derivatives • For scientific purposes • For storage • For final disposal	Allows holders to carry out activities of cultivation of plants whose THC percentage is less than 1% in dry weight, which may include sowing, procurement and production of seeds; storage, marketing, distribution and final disposal of plants, as well as export and use for medical and scientific purposes.	Ministry of Justice and Law

Licence	Modalities	Activities	Issuing Authority
Licence for the manufacturing of cannabis derivatives or by-products (Licencia de fabricación de derivados de cannabis)	• Production of derivatives for use within Colombia • Production of derivatives for scientific research • Production of psychoactive cannabis derivatives • Manufacture of derivatives for export	For the processing of cannabis for medical and scientific purposes, which may include the manufacture, acquisition on any terms, import, export, storage, transport, marketing and distribution of psychoactive and non-psychoactive cannabis derivatives	INVIMA (formerly by the Ministry of Health and Social Protection)
Licence for the use of cannabis seeds for sowing or planting (Licencia de uso de semillas para siembra)	• For sale or supply • For scientific purposes	This licence may include acquisition on any title, import, storage, marketing, distribution, possession and final disposal, as well as export and use for medical and scientific purposes.	Ministry of Justice and Law

As mentioned above, the recreational use of cannabis in Colombia is prohibited.

4. Which body is responsible for legislative controls relating to CBD?

INVIMA is the competent authority to issue licences for the manufacturing of cannabis derivatives or by-products. Before Decree 2106 of 2019, the competent authority was the Ministry of Health and Social Protection (Ministerio de Salud y Protección Social), through its Directorate of Drugs and Health Technologies (Dirección de Medicamentos y Tecnologías de la Salud). Once the licence has been issued, administrative and operational control of activities related to the handling of cannabis and its derivatives will be carried out through the National Narcotics Fund (Fondo Nacional de Estupefacientes), which is also the competent authority for the control of finished products derived from psychoactive cannabis (in which THC content is equal to or greater than 1% in dry weight).

On the other hand, the Ministry of Justice and Law, through its Directorate of Control and Inspection of Chemical Substances and Narcotics (Subdirección de Control y Fiscalización de Sustancias Químicas y Estupefacientes), is the competent authority for issuing licences for the use of seeds for sowing/planting and licences for the cultivation of psychoactive and non-psychoactive cannabis plants. It is also the entity in charge of the administrative and operational control over activities related to the management of seeds for sowing and the cultivation of psychoactive and non-psychoactive cannabis.

Finally, the Colombian Agricultural Institute (Instituto Colombiano Agropecuario (ICA)) is authority responsible for sanitary and phytosanitary matters applicable to products containing CBD.

AUTHORITY	ACTIVITY
National Institute of Food and Drug Surveillance – INVIMA	To issue the licence for the manufacturing of cannabis derivatives and to carry out control and evaluation visits.
Ministry of Justice and Law, through the Sub-directorate for the Control and Inspection of Chemical Substances and Narcotics	To issue the licence for the use of cannabis seeds for sowing and the licences for the cultivation of psychoactive and non-psychoactive cannabis plants and administrative and operative control of the activities related to the management of the seed for the planting and sowing of cannabis.
National Narcotics Fund	Administrative and operative control of activities related to the management of cannabis and its derivates and control and evaluation visits.
National Institute of Food and Drug Surveillance – INVIMA	Control of finished products from psychoactive cannabis, without prejudice to competence in sanitary and phytosanitary matters, once the licence is issued.
Colombian Agricultural Institute – ICA	
National Police	To support the authorities in the administrative and operational control, as well as in the visits that take place.

5. Currently is there any possibility to commercialise CBD products without a novel food approval or medicinal product marketing authorisation in Colombia?

Currently, there is no possibility of commercialising CBD products without novel food approval or medicinal product marketing authorisation in Colombia. According to national legislation, the commercialisation of CBD products requires the corresponding licences or registries before the authorised national entities.

Pursuant to article 85 of the Decree 2106 of 2019, the Licence for Manufacturing of Cannabis Derivatives or By-products (Licencia de Fabricacion de Derivados de Cannabis) is the authorisation granted by the INVIMA, through an administrative act, which allows the following modalities: import, export, production, manufacture, acquisition, storage, transport, marketing, distribution and use of cannabis derived products, as well as any products containing cannabis. This licence may be issued for one or more of the above-mentioned modalities according to the requirements and/or activities of the applicant.

6. What are the testing specifications in Colombia for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/ or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

The National Narcotics Fund is responsible for monitoring and controlling the content of cannabis in cannabis derived products. The licensees will have to carry out an analysis, by means of a valid analytical methodology, of the content of tetrahydrocannabinol (THC), cannabidiol (CBD) and cannabinol (CBN), in each property and lot, which will have to be registered before the National Narcotics Fund. Such methodology must comply with a protocol including the calibration curve, detection limit, quantification limit and all the analytical chemistry parameters. This measurement may also be made through the National Narcotics Fund. If necessary, the Ministry of Health and Social Protection may request changes or adjustments in the methodology in order to review comparable results.

Furthermore, the licensee must submit a bimonthly report regarding their production, within the first 10 days of the bimester, by means of the formats established for this purpose. The national entities have prepared the corresponding formats to submit the information and documentation for the compliance of the regulatory requirements.

In general terms, these formats specify information related to plantations, harvests, delivery of product to third parties, quantity of seeds at the end of the period, storage of seeds and losses in the crop, among others. If applicable, and in the event that the licensee has additional observations or comments, the corresponding documents must be specified and attached to the format.

7. Are there any regional limits on the quantity of CBD that can be purchased on imported?

Currently, the national regulation does not provide a limit for the purchase, sale, import or export of cannabis derived products.

However, the limitation set forth in the Colombian cannabis legislation refers only to the quotas that may be granted. Quotas are the maximum annual amount of (i) psychoactive cannabis plants that may be grown, or (ii) cannabis allowed to be acquired or received for cultivation, by those who have obtained the corresponding licences. This means that only those who aim to grow or cultivate psychoactive cannabis will have to apply for quotas.

The Sub-Directorate for the Control and Monitoring of Chemical and Narcotic Substances and the Directorate of Drugs and Health assign the quotas allocated by the Technical Group on Quotas, which in turn shall set the limits in accordance with the national quotas granted by the International Narcotics Control Board (INCB) (Junta Internacional de Fiscalización de Estupefacientes (JIFE)).

Contacts in the firm

Diego Muñoz Tamayo
Managing Partner
Email: diego.munoz@mtalegal.co

Silvia María Méndez Parodi
Senior Associate
Email: silvia.mendez@mtalegal.co

Alonso de Reyes Lanfranco
Associate
Email: alonso.dereyes@mtalegal.co

Andrea Usme Castillo
Junior Associate
Email:andrea.usme@mtalegal.co

Verónica María Díaz
Junior Associate
Email: veronica.diaz@mtalegal.co

Granados Guerra
Junior Associate
Email: granados.guerra@mtalegal.co

GERMANY

Rittershaus

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Germany?

a) Cannabis as a narcotic

In Germany, all plants and parts of plants belonging to the cannabis species are classified as narcotics and are therefore subject to the regulations of the German Narcotics Act (BtMG). The same applies in principle to synthetic cannabinoids, which are an essential substance group of the new psychoactive substances. This classification is based on the UN Single Convention on Narcotic Drugs of 1961, which means that all handling of cannabis and cannabinoids in Germany is generally subject to the BtMG.

1. Consumption of Cannabis

The German regulatory framework for the use of cannabis seems in a certain way paradoxical. The consumption as such is not a criminal offence, but this is practically irrelevant, since according to §§ 29, 29a BtMG both the acquisition and the possession – as necessary intermediate stages for the consumption – are subject to criminal punishment.

However, the BtMG provides for some exceptions for consumers of cannabis:

(1) In the case of minor violations, a court may, pursuant to § 29 para 5 BtMG or § 31a BtMG, refrain from imposing a criminal penalty if the offence is committed for personal consumption in small quantities. The limit for small quantities of hashish or marijuana is 0.045g of THC. However, such decision by the court is discretionary. Usually, no penalty is then imposed on first-time offenders and occasional consumers who have not previously committed other criminal offences.

(2) In addition, according to § 31 BtMG, the court can mitigate the penalty or refrain from punishment if the offender voluntarily assists in the investigation or the prevention of further offences (leniency programme).

(3) Finally, according to § 37 BtMG, punishment can be waived if the drug-addicted offender has voluntarily undergone therapy.

2. Economic Use of Cannabis

Since all plants and parts of plants of the cannabis species are classified as narcotics in Germany, the cultivation and production of, as well as any trade in, cannabis products is a criminal offence under §§ 29, 29a BtMG. In this context, the term "trading" is interpreted broadly by the courts and covers any activity directed at the sale of narcotics, even if it is only occasional, one-time or exclusively mediatory in nature.

With the passing of the so-called "Cannabis Law" in March 2017, the legal framework for the marketing of cannabis in Germany was somewhat liberalised and the use of the cannabis plant for certain medical purposes was legalised. In the following cases the classification as narcotic and thus the criminal liability was abolished:

(1) For the seed, provided that it is not intended for illegal cultivation (BtMG Annex 1 Cannabis lit a)).

(2) For products in which the content of tetrahydrocannabinol (THC) does not exceed 0.2%, provided that the trade of these products (with the exception of cultivation) is exclusively for commercial or scientific purposes, which excludes the purpose of intoxication (BtMG Annex 1 Cannabis lit b)).

However, the scope of this exemption is discussed controversially in Germany. The (still) predominant opinion holds that such commercial or scientific purpose must exist not only on the part of the seller, but also on the part of the end user. When selling products with low THC content, it must therefore be ensured that the buyer processes this product and ultimately manufactures a harmless product, such as rope, paper or textiles. Such commercial purpose does not exist when cannabis products made from industrial hemp are sold to end users for consumption.

According to this opinion, this exemption provision is only intended to develop the market potential of hemp as raw material and its potential uses for industrial and possibly energetic purposes and not to supply the population with low-THC-content preparations for personal consumption, and especially not to soften the general legal ban on cannabis.

Although according to the wording of the statute and the (still) prevailing opinion this constitutes a criminal offence, many low-THC-content cannabis products, especially cosmetics, are now also sold to consumers in Germany on the basis of the aforementioned exemption. In practice, a kind of legal grey area has been established where these transactions are tolerated by the authorities. However, there are also increasing voices that want to generally allow the distribution of low-THC-content cannabis and cannabinoid products on a secure legal basis.

(3) For cannabis plants, if they are planted as protective strips beet plants and destroyed before flowering (BtMG Annex 1 Cannabis lit c)).

(4) For cannabis plants the cultivation of which exclusively uses certified seed of varieties listed in the joint catalogue of agricultural plant species (useful hemp) referred to in article 9 of Delegated Regulation (EU) No 63912014 on 15th March of the year of cultivation (BtMG Annex I Cannabis lit d)).

(5) For cannabis plants from a cultivation that is used for medicinal purposes under state control according to articles 23 and 28 para 1 of the 1961 Single Convention on Narcotic Drugs, as well as in preparations that are authorised as finished medicinal products (BtMG Annex 1 Cannabis lit d)).

However, irrespective of the exceptions described above, the cultivation of cannabis plants in Germany always requires governmental authorisation. Only the cultivation of cannabis by an agricultural enterprise according to para (4) above is subject only to notification.

b) Food

3. Foods with Added Cannabis (with low THC content)

There also exists controversy on the question whether the distribution of food and beverages produced by using ingredients with a THC content of less than 0.2% is permissible or banned under the BtMG, so the legal situation in this respect is unclear as well.

According to one opinion, the distribution of food or beverages made with hemp with a THC content of less than 0.2%, such as bakery and pasta products, confectionery, sausages, dairy products, tea mixtures, lemonades, beer etc is only permitted if the end consumer purchases the product for a commercial or scientific use and not for consumption. As a consequence, the sale of such products for purposes of consumption would always be prohibited and, at least formally, even subject to criminal punishment.

According to the opposing opinion, trade in food products containing cannabis is permitted if the processing has resulted in a "harmless product", which excludes the possibility of abuse for intoxication purposes. The assessment of whether a product is “harmless” is based on the following thresholds issued by the Federal Office of Consumer Protection and Food Safety (BVL):

- 5μg/kg THC for alcoholic and non-alcoholic beverages
- 5000 μg/kg THC for edible oils
- 150 μg/kg THC for all other foods

If these thresholds are adhered to, the cannabis-containing products are harmless, since an abuse for intoxication purposes can be excluded and the consumption does not pose any health risk. In this case, food containing hemp ingredients is subject to the exemption of the BtMG and not subject to criminal law, but only governed by food law. However, this question has not yet been finally decided in Germany.

Apart therefrom, it is clearly permissible to distribute food only containing or made from cannabis seeds, as these are not subject to BtMG.

4. Food with added CBD

According to the EU Commission and the competent authorities of the EU member states, foods and food ingredients containing extracts of Cannabis sativa L. and derived products (CBD) generally fall within the scope of Regulation (EU) 2015/2253 Novel Food Regulation (NFR) as novel foods. Whether or not a product fulfils the requirements to be classified as a novel food under Article 3 para 2 lit a and therefore subject to authorisation must be determined by the respective manufacturer in each individual case. CBD is not classified as a novel food or novel food ingredient if the substance has been used for human consumption to a significant extent within the EU before 15th May 1997 or the substance has a history of use as a safe food in the EU.

In their decisions rendered so far, German authorities have always classified CBD products as a novel food. Currently, a number of applications for approval under the Novel Food Regulation are pending before the EU Commission. In this context, the European Industrial Hemp Association (EIHA) has commissioned the scientific studies necessary for such applications, which must prove the safety of CBD-containing products on behalf of all its members, since the costs of such studies are prohibitively expensive for the individual applicant.

Surprisingly, in June 2020 the EU Commission issued a preliminary assessment that products containing CBD should generally be classified as narcotics or pharmaceuticals and would therefore not be marketable as food. This would be a severe blow for the European hemp industry. However, a final decision is still pending.

c) Hemp as Tobacco Substitute

The production of cigarettes, cigars, tobaccos, inhalants or incense sticks made from cannabis for distribution to end consumers for purposes of consumption is always subject to the provisions of the BtMG, as the consumer does not pursue any economic purpose that excludes abuse for intoxication purposes.

d) Medicines

1. With Added Cannabis

In Germany, drugs are defined and regulated by the German Medicines Act (AMG) as substances that are intended to cure or prevent diseases. Cannabis can be used both in finished medicinal drugs and in drugs individually produced by pharmacies. For these individually produced medicinal drugs, as long as the main manufacturing steps of the

individual drugs are carried out by a pharmacy, no manufacturing authorisation or drug approval is required.

However, in any case the customer or patient needs either a medical prescription or a special permit to obtain such drugs.

2. Medical Prescriptions

A physician may only prescribe cannabis as a medicinal drug if he has concluded, based on his own examination, that its use is permissible and necessary according to the recognised rules of medical science. The prescription must be made in the context of medical treatment, must be medically indicated and may not be made if the intended purpose can be achieved by other means, for example by therapy with a drug that is not a narcotic. Otherwise, a medical prescription of narcotics such as cannabis is not permitted. According to § 13 para 2 sent 1 BtMG, prescription narcotics may only be dispensed in pharmacies and only on presentation of a special medical prescription for narcotics.

3. Exemption

Another possibility for the legal acquisition of cannabis as a medicinal drug is to obtain an exemption for acquisition or self-cultivation. This may only be granted for a purpose in the public interest, which may also be the therapy of an individual, if this is indicated from a medical point of view and if this indication is confirmed by a public health officer. Such an exemption is not possible, however, if the illness of the person concerned can be treated with a similarly effective prescription drug. Finally, the applicant for such exemption must prove he has necessary expertise and reliability.

bb) Medicinal Drugs with Added CBD

The Committee of Independent Experts on Prescription Medicinal Products has determined that CBD has a number of pharmacological effects and should therefore be classified as a medicinal drug. As a result, CBD was included in Annex 1 of the German Drug Prescription Ordinance (AMVV) in October 2016, which, however, only regulates the dispensing and not the general classification of the drug. The classification of products with added CBD must therefore be made by the competent state authorities on a case-by-case basis. Currently, there are only two products on the market in Germany that contain cannabinoid-based active ingredients.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Germany?

See question 1

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Germany?

See question 1

4. Which body is responsible for legislative controls relating to CBD?

The responsibilities of the various authorities depend on the nature of the products with added CBD.

In Germany, the Federal Opium Agency (BOPST) which is part of the Federal Institute for Drugs and Medical Devices (BfArM) is responsible for issues related to CBD as a medicinal drug.

The enforcement of regulations for food and food supplements in Germany is basically the task of the respective competent authorities of the federal states. However, these authorities work closely with the Federal Office of Consumer Protection and Food Safety (BVL).

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in Germany?

a) CBD as a Medical Device?

An extremely creative but dubious option to market CBD products without Government approval is currently used by the Hamburg-based manufacturer LeafPharma, which classifies its product as a medical device.

Unlike medicinal products, medical devices achieve their main effect primarily by physical means and have no significant pharmacological, immunological or metabolic effect.

The manufacturer LeafPharma explains its classification of over 50 CBD products as medical devices as follows: "Thanks to our unique manufacturing process, the substance acts remotely through electromagnetic waves and triggers a purely physical impulse without chemically binding to the receptor. Once the signal receiver has reacted to the

electromagnetic waves, a conformational change takes place so that no more substances can dock. Consequently, only a physical effect takes place".

However, this is heavily criticised, especially by pharmacists, and described as dubious. It is also extremely doubtful whether this classification would stand up to judicial review.

b) Cosmetics

The use of CBD in cosmetics is currently experiencing a real hype, with consumers able to purchase numerous CBD oils, creams and lotions both online and in a number of physical stores mainly in major cities.

From the perspective of narcotics law, both the seeds and the other components of the cannabis plant can be used for the production of cosmetics, as long as the cannabis plants used for this purpose either originate from a cultivation with certified seeds or their THC content does not exceed 0.2 %. In addition, unlike food or beverages, cosmetics cannot be abused for intoxication purposes, so they are generally considered to fall under the exemption of the BtMG.

From a regulatory point of view, according to Article 14(1)(a) of Regulation (EC) No 1223/2009, cosmetic products may not contain narcotics as defined in Tables I and II of the Single Convention on Narcotic Drugs. These are e.g. cannabis, cannabis resin, extracts and cannabis structures, but not cannabis seeds and leaves, as long as they are not accompanied by the flowers.

Thus, cannabis seeds can be used for cosmetics regardless of their origin, but the leaves and stems can only be used if the cannabis plants either originate from cultivation with certified seeds or if their THC content does not exceed 0.2 %.

For advertising claims relating to cosmetic products, the requirements of Regulation (EU) No. 655/2013 must be taken into account. According to this regulation, such claims must be substantiated by sufficient and verifiable evidence and must not advertise properties beyond the proven effects. Since the cannabis plant and its effects are still quite unexplored in many areas, restraint is therefore required, especially in connection with the advertising of the supposed numerous positive effects in the field of personal hygiene, and in particular statements on health-related topics should be avoided.

c) Other use (e.g. as a fragrance, aroma or similar)

Products with CBD added can also be sold as unregulated products, e.g. as a fragrance or flavouring that is explicitly not intended for consumption. The distribution of these products is permitted if the THC content is below 0.2%.

d) European Court of Justice

The grey area of the legal treatment of CBD products will possibly be clarified in many areas by a judgement of the European Court of Justice (Case C-663/18) which is expected shortly. In this case, the French authorities have prohibited the import and sale of a vape for e-cigarettes containing CBD with a THC content of less than 0.2% which was legally sold in the Czech Republic and have criminally prosecuted the directors of the importing company. This case was brought before the ECJ by the Court of Appeal in Aix-en-Provence, asking the court to answer the question whether a member state can prohibit the import of cannabidiol oil from another member state if it is derived from the whole hemp plant and not only from its fibres and seeds.

In his opinion published on 14th May 2020, the Advocate General considered that the measures taken by the French judiciary were violations to the principle of the free movement of goods:

"Articles 34 and 36 TFEU [free movement of goods] preclude a Member State from prohibiting the importation of cannabidiol oil from another Member State if it is extracted from the whole hemp plant and not only from its fibres and seeds, since, according to the current state of scientific knowledge, it is not established that CBD oil has psychotropic effects. It is, however, for the national court to satisfy itself that no risk has been identified and exhaustively assessed scientifically, in particular in relation to the non-psychotropic effects of CBD. If it concludes that such a risk exists and that such an assessment has been made, it must satisfy itself that an alternative measure less restrictive of the free movement of goods could have been adopted, such as the fixing of a maximum level for CBD."

If the ECJ follows the opinion of the Advocate General, which it does in the majority of cases, this ruling is likely to have a significant impact on the regulatory treatment of CBD products in all EU member states.

e) Conclusion

The marketing of products with added CBD in Germany currently still happens in a legal grey area. Nevertheless, the trade with CBD products is booming in Germany too. In the

big cities numerous stores are opening which exclusively sell CBD products, even if this business model does not have a secure legal basis. Some large drugstore chains have therefore removed CBD products from their shelves - at least in the food and beverage sector.

6. What are the testing specifications for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

a) Food

Food must not be unsafe in accordance with Article 14 of Regulation (EC) No 178/2002. Against this background, it must be ensured that the thresholds for THC set by the Federal Institute for Risk Assessment (BfR) are not exceeded for foods made from hemp which are not medicinal products or novel foods.

In 2000 the German Federal Institute for Health Consumer Protection and Veterinary Medicine (BgVV) published thresholds for the maximum Δ9-THC content in different food groups. These are 5 µg/kg for non-alcoholic and alcoholic beverages, 5000 µg/kg for edible oils and 150 µg/kg for all other foods and refer to ready-to-eat processed foods (BgVV 2000).

It is the responsibility of the producers to comply with the corresponding thresholds, otherwise sanctions according to the food and narcotics regulations may be imposed.

b) Medicinal Drugs

For medicinal drugs, on the other hand, a very extensive approval procedure applies, in which the pharmaceutical quality, the efficacy and the safety of the medicinal drug must be proven in clinical studies with detailed documentation. When a marketing authorisation is granted, it is initially valid for only five years, and in special cases only for one year. After five years it must be reviewed whether the medical benefit of the medicinal drug is still greater than its possible risks, e.g. due to side effects. The holder of the marketing authorisation must also notify the Federal Office for Drugs and Medical Devices (BfArM) of any changes to the medicinal drug. Larger changes may only be implemented with the prior approval of the BfArM.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

There exist currently no such limits. However, this could change if necessary following the judgement of the European Court of Justice (Case C-663/18), which is expected shortly.

Contacts in the firm

Dr. Markus Bauer

Partner

Email:Markus.Bauer@rittershaus.net

GIBRALTAR
HASSANS INTERNATIONAL LAW FIRM

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Gibraltar?

The Drugs (Misuse) (Amendment) Regulations 2019 (the Regulations) provide for the supply and possession of certain cannabis-based products for medicinal use, in limited circumstances.

Cannabis and/or cannabis resin, cannabinol and cannabinol derivatives are "controlled drugs" for the purposes of the Crimes Act 2011. The supply, possession, importation and exportation of such substances is therefore prohibited, subject to the Regulations.

The prohibition does not apply to products with a THC content of less than 0.3%.

It is envisaged that Gibraltar may seek to introduce legislation to control, licence and regulate medicinal cannabis. In particular, it is expected that this new legislation could be introduced at some point during 2021 to capture, inter alia, the import, export, manufacture and processing of cannabis for medicinal purposes in and from Gibraltar.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Gibraltar?

   The use of cannabis-based products for medicinal purposes is restricted to use by an individual to whom such product has been supplied by an authorised medical practitioner, for the limited purposes set out in the Regulations (see paragraph 3 below).

   The recreational use of cannabis is not legal in Gibraltar.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Gibraltar?

   The Regulations provide for registered medical practitioners in the employ of the Gibraltar Health Authority to authorise the supply of cannabis-based products for

medicinal use to patients. Practitioners are able to supply, or direct the supply of, such products to patients who have been diagnosed as suffering from the following conditions:

(a) moderate to severe muscle spasticity in multiple sclerosis that has failed to respond to standard medications;

(b) severe, refractory epilepsy that has failed to respond to standard medications;

(c) severe and life-altering pain that has failed to respond to standard and rising levels of pain control medications; or

(d) intractable nausea and vomiting associated with chemotherapy, despite the use of standard treatments under supervision.

The authority to dispense approved cannabis-based products to the public is also limited to the Gibraltar Health Authority pharmacy.

Cultivation of any plant of the genus Cannabis is specifically prohibited by section 508 of the Crimes Act 2011.

As set out above, it is envisaged that a draft bill in connection with medicinal cannabis may be presented in the near future. It is anticipated that this could lead to legislation specifically seeking to licence and regulate, inter alia, the import, export, manufacture and processing of cannabis for medicinal purposes.

4. Which body is responsible for legislative controls relating to CBD?

The Gibraltar Health Authority is responsible for the training of medicinal cannabis practitioners and the supply to the public of products for medicinal purposes.

The Ministry of Health is responsible for Government policy on health-related matters.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in Gibraltar?

Each product to which the Regulations apply must also have first been specifically approved by the Gibraltar Health Authority, after consultation with practitioners, as a product which is safe and effective for use by affected patients.

6. What are the testing specifications in Gibraltar for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

There is currently no regulatory framework of testing of CBD products. Each individual product must first be approved by the Gibraltar Health Authority in consultation with practitioners.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Products with a THC content of more than 0.3% can only be purchased or imported by the Gibraltar Health Authority, or at the direction of the Gibraltar Health Authority, for the limited purposes referred to in paragraph 3 above.

There is no quantity limit on the importation or sale of products with a THC content of less than 0.3%.

Contacts in the firm

Ian Felice
Partner
Email: ian.felice@hassans.gi

Peter Montegriffo
Senior Partner
Email: peter.montegriffo@hassans.gi

Gian Massetti
Associate
Email: gian.massetti@hassans.gi

Andrew Montegriffo
Senior Associate
Andrew.montegriffo@hassans.gi

LEGALINK

HONK KONG
CHARLTONS LAW

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Hong Kong?

Both the medicinal and recreational use of cannabis is illegal in Hong Kong by virtue of the Dangerous Drugs Ordinance (Cap.134) (the DDO) which classifies cannabinol and its tetrahydro derivatives (commonly known as tetrahydrocannabinol or THC) as dangerous drugs. However, cannabidiol (CBD) is not classified as a dangerous drug by the DDO. CBD products are therefore legal to import/export, procure, supply, use and manufacture in Hong Kong, provided that the CBD products contain no THC. Any level of THC in a CBD product will result in the CBD product being classified as a dangerous drug, making it illegal under the DDO.

The DDO makes it a criminal offence to traffic in, import to and export from Hong Kong, procure, supply, deal in or with, or manufacture cannabis and controlled cannabinoids. The maximum penalty is life imprisonment and a fine of HK$5 million. Illicit possession, smoking, inhaling, ingesting or injecting dangerous drugs is subject to a maximum penalty of imprisonment for seven years and a fine of HK$1 million. The DDO further makes it a criminal offence for any person to have in his/her possession any pipe, equipment or apparatus fit and intended for the smoking, inhalation, ingestion or injection of a dangerous drug (s.36). Cultivation of and dealing in cannabis plants (defined by s.2 of the DDO as “any plant of the genus cannabis”) are specifically prohibited by section 9 of the DDO, however there is an exception for Government chemists so far as is necessary for the exercise of their employment (s.9(1)), an exception which was added in 1994.

While many jurisdictions are moving to legalise and regulate the medicinal use of cannabis, the Hong Kong Government takes a strict view that “the cannabis plant is not a medicine”, but does recognise that certain cannabinoids may act as pain relief and counteract negative side effects of certain medicines. Relevant research is apparently being undertaken in Hong Kong on whether cannabis can be used effectively as a medicine, however there has been no change in the regulatory position.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Hong Kong?

The regulatory challenge is that cannabis and controlled cannabinoids (such as THC) are dangerous drugs under Hong Kong law.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Hong Kong?

The Dangerous Drugs Ordinance (Cap.134) is the relevant legislation which criminalises various activities (possession, manufacture, supply, import/export, cultivation) relating to cannabis and controlled cannabinoids. CBD isolate products are legal as CBD is not designated as a dangerous drug by the DDO.

The relevant regulatory framework for CBD products (those which are legal) varies depending on the product specifications (i.e. whether it is considered a pharmaceutical product or medicine or a food or drink product) and the activity in question (i.e. in certain circumstances relevant licences and registration requirements may apply).

If the CBD product is considered a pharmaceutical product or medicine, the relevant legislation is the Pharmacy and Poisons Ordinance (Cap.138).

The import/export of pharmaceutical products (including CBD pharmaceutical products) and the import/export of other CBD products is regulated by the Import and Export Ordinance (Cap.60) if the products are being imported/exported for reasons other than personal use. Where the CBD products being imported are food or drink products, the relevant legislation is the Food Safety Ordinance (Cap.612).

Advertising and labelling of pharmaceutical products (including CBD pharmaceutical products) is regulated by the Undesirable Medical Advertisements Ordinance (Cap.231). The labelling of food and drinks (including CBD food and drink products) is regulated by the Food and Drugs (Composition and Labelling) Regulations (Cap.132W).

4. Which body is responsible for legislative controls relating to CBD?

CBD, when contained in a pharmaceutical product, is regulated as a prescription-only medicine under the Pharmacy and Poisons Ordinance. The Pharmacy and Poisons Board is the relevant body responsible for carrying out functions in accordance with the provisions of the Ordinance and subsidiary legislation. Meanwhile, the Department of Health is the body responsible for ascertaining the control status of any pharmaceutical products. The Customs and Excise Department is responsible for preventing the importation and exportation of any prohibited products and controlled substances (including dangerous drugs) and/or ensuring that the relevant licensing requirements for the importation/exportation of any prohibited products are fulfilled.

As for CBD products which are food or drink products, the Food and Environmental Hygiene Department and the Centre for Food Safety are the relevant bodies responsible for the operation of the Food Safety Ordinance (Cap.612).

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in Hong Kong?

CBD, another cannabinoid present in cannabis plants, is not classified as a dangerous drug under the Dangerous Drugs Ordinance, and CBD products which do not contain THC or any other cannabinoid may be legally sold, possessed and distributed in Hong Kong. However, Hong Kong adopts a zero-tolerance policy to THC and CBD products which contain low levels or trace levels of THC, and these will be classified as a dangerous drug within the meaning of the DDO. Whether the product containing CBD is subject to other regulation, registration or licensing depends on the product type.

Pharmaceutical Products Containing CBD

Pharmaceutical products containing CBD (but no dangerous drugs within the definition of the DDO) must be registered with the Pharmacy and Poisons Board in accordance with the requirements under the Pharmacy and Poisons Ordinance before the products can be sold, offered for sale, distributed or possessed for the purposes of sale, distribution of other use. The sale of unregistered pharmaceutical products is an offence under the Ordinance and the maximum penalty is a fine of HK$100,000 and two years' imprisonment.

In the case of a pharmaceutical product manufactured in Hong Kong, the manufacturer is required to obtain the registration. In the case of a product manufactured outside Hong Kong, the local importer is required to obtain the registration. To date, there are no registered pharmaceutical products containing CBD in Hong Kong.

Manufacturers and distributors of pharmaceutical products must also obtain the relevant licences from the Pharmacy and Poisons Board. In order to be licensed, the manufacturer or distributor (whichever may be the case) must meet certain requirements, including demonstrating compliance with Hong Kong Good Manufacturing Practices (GMP).

In the case of importing pharmaceutical products, an import licence must also be obtained under the Import and Export Ordinance (Cap.60). Licensing applications must be submitted to the Drug Evaluation and Import/Export Control Division of the Drug Office of the Department of Health. In the case of importing pharmaceutical products into Hong Kong in accompanied personal baggage, such products may be exempted from the licensing requirement if they are of a "reasonable quantity" and for personal use. However, if the pharmaceutical products containing CBD are purchased in a jurisdiction which legally permits higher concentrations of THC in CBD products (for example, Canada and the EU permit no more than 0.3% THC concentration), any such products with a THC concentration greater than 0% will be considered "dangerous drugs" within the definition of the DDO.

Additionally, advertising of pharmaceutical products is regulated by the Undesirable Medical Advertisements Ordinance (Cap.231), which restricts advertisements (including product labels) which may "induce the seeking of improper management of certain health conditions". Any advertisements published in Hong Kong for pharmaceutical products containing CBD therefore must comply with the restrictions and requirements of Cap.231. In the case of pharmaceutical products imported from overseas, the importers and distributors also have the responsibility to ensure that the products sold in Hong Kong and their advertisements published in Hong Kong comply with Cap.231.

Non-pharmaceutical Products Containing CBD (including food and drink products)

CBD products which are not considered "pharmaceutical products" or "medicine" under Cap.138 and are not "dangerous drugs" within the definition of the DDO (i.e. they contain no THC and/or other cannabinoids) may be legally sold in Hong Kong.

As for food and drink products containing CBD, these products may be legally sold in Hong Kong provided they contain no THC and/or other cannabinoids. However, the Hong Kong Government strongly advises against the import or manufacturing of such products owing to the difficulties of extracting pure CBD (CBD isolate products). The Hong Kong Government therefore states that these food and drink products are highly likely to contain other cannabinoids controlled under the DDO, namely THC.

If CBD isolate food and drink products are imported into Hong Kong, the food importer is required to register with the Director of Food and Environmental Hygiene under the Food Safety Ordinance (Cap.612). The Food and Drugs (Composition and Labelling) Regulations (Cap.132W) specify certain requirements in relation to information that must be marked in either English or Chinese (or both) on the label of pre-packaged food, unless an exemption applies. The requirements relate to:

- name or designation;
- list of ingredients;
- "best before" or "use by" date;
- any special conditions for storage or instructions for use;
- name and address of manufacturer or packer;
- count, weight or volume; and
- nutritional values.

The labelling requirements apply to CBD food and drink products which do not fall within the list of exempt items in Schedule 4 of Cap.132W, which may include, for example, certain CBD alcoholic drinks, depending on the alcoholic strength by volume, pre-packaged CBD food products sold at catering establishments for immediate consumption and pre-packaged CBD food products with a surface area of less than $10cm^2$.

Developments in the Market - Commercialisation

Hong Kong's health and wellness industry has increasingly moved to embrace CBD products, and a number of Hong Kong-based CBD start-ups, stores and cafes have emerged over the past year, demonstrative of the increasing consumer interest. There are also suggestions that Hong Kong may, in the future, emerge as the Asian hub for CBD, owing to the relatively lax regulation in comparison to neighbouring jurisdictions such as Singapore.

An example includes Heavens Please, which operates an e-commerce website which sells a range of CBD products in Hong Kong which are also available at selected retail outlets. Heavens Please imports CBD products manufactured in the US and Europe, but is seeking to retail more made-in-Hong Kong products.

In January 2020, Hong Kong-based OH5 launched a CBD beer in partnership with One Kick Brewery, with the CBD being sourced from Heavens Place. The beer is available for consumers to purchase at a range of bars and pubs in Hong Kong and various alcohol retail stores. OH5 has expressed interest in exporting the products to other Asian countries in the future, subject to regulations.

6. What are the testing specifications in Hong Kong for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Hong Kong adopts a zero-tolerance policy to THC and other cannabinoids. In order for a CBD product to be legal, its THC (or other cannabinoid) content must be zero (known as CBD isolate products), otherwise the CBD product will be deemed a dangerous drug and will be subject to the provisions of the Dangerous Drugs Ordinance. Therefore, full-spectrum CBD products (CBD extracts containing trace amounts of THC) and broad-spectrum CBD products (CBD extracts containing cannabinoids other than THC) are classified as dangerous drugs under Cap.134.

In relation to pharmaceutical products containing CBD, the process of registering under Cap.138 requires the manufacturer to provide documents in relation to the product to support its safety, efficacy and quality. These documents are usually the manufacture and quality control procedure, clinical study reports and overseas post-marketing study results of the product. It therefore must be proved through submission of the documents that the CBD product is THC-free.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Hong Kong does not prescribe any limits on the quantity of CBD that can be purchased in or imported to Hong Kong. However, an import licence may be required in certain circumstances. For example, if CBD products are imported by an individual in their accompanied personal baggage, an import licence is not required if the CBD products are of a "reasonable quantity" and for personal use.

However, as mentioned, Hong Kong Customs has advised those entering Hong Kong to not bring cannabis products from overseas into Hong Kong and urges those purchasing products overseas to carefully check the packaging to avoid breaching the law inadvertently.

Contacts in the firm

Julia Charlton
Partner
Email: juliacharlton@charltonslaw.com

Kim Larkin
Solicitor
Email: kimlarkin@charltonslaw.com

INDIA
DUA ASSOCIATES

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in India?

NDPS Act – With regard to the regulatory framework in India concerning Cannabis, we refer back to the NDPS Act, that prohibits cultivation, production, possession, sale, purchase, trade, import, export, use and consumption of narcotic drugs and psychotropic substances except for medical and scientific purposes in accordance with the law. The Governments' policy has thus been to promote the use of narcotic drugs and psychotropic substances for medical and scientific purposes while preventing their diversion from licit sources and prohibiting illicit traffic and abuse.

The NDPS Act covers three broad classes of substances: (1) narcotic drugs, that is, those covered under the 1961 Convention; (2) psychotropic substances or those covered under the 1971 Convention as well as other psychoactive substances such as ketamine which are not yet classified under international conventions; and (3) "*controlled substances*" that are used to manufacture narcotic drugs or psychotropic substances.

It may be noted that while the NDPS Act is predominantly punitive, it also contains provisions to regulate drugs. In this regard, the NDPS Act empowers both the Central and State governments to frame rules and authorize drug-related activities within the rubric of "medical and scientific purpose", a term which is neither defined nor described in the NDPS Act. While some activities are reserved exclusively for the government, others can be carried out by private entities under a license.

It may also be pointed out that the NDPS Act divides the powers and responsibility of regulation of licit activities. Section 9 of the NDPS Act has listed various activities which the Central Government can, by rules, regulate while Section 10 lists various activities which the State Governments can, by rules, regulate. Thus, we have NDPS Rules of the Central Government and the State NDPS Rules framed by each State Government under the same NDPS Act. These are enforced by the Central or concerned State Government.

The NDPS Act has been amended three times - in 1988, 2001, and most recently in 2014. The 2014 amendment recognizes the need for pain relief as an important obligation of the government. It creates a class of medicines called Essential Narcotic Drugs (ENDs). Power for legislation on ENDs has been shifted from the State Governments to the Central Government so that the whole country now can have a uniform law covering these medicines which are needed for pain relief.

Prohibition, Control and Regulation of Cannabis under the NDPS Act - '*Cannabis (hemp)*' has been defined under Section 2 (*iii*) of the NDPS Act as:

(*a*) *Charas*, that is, the separated resin, in whatever form, whether crude or purified, obtained from the Cannabis plant and also includes concentrated preparation and resin known as hashish oil or liquid hashish;

(*b*) *Ganja*, that is, the flowering or fruiting tops of the Cannabis plant (excluding the seeds and leaves when not accompanied by the tops), by whatever name they may be known or designated; and

(*c*) any mixture, with or without any neutral material, of any of the above forms of Cannabis or any drink prepared therefrom.

General Prohibition: As per Section 8 of the NDPS Act, no person can *inter alia* cultivate any Cannabis plant or produce, manufacture, possess, sell, purchase, transport, warehouse, use, consume, import inter-State, export inter-State, import into India, export from India or tranship any narcotic drug {*Under section 2(xiv) of the NDPS Act the term "narcotic drug" means coca leaf, cannabis (hemp), opium, poppy straw and includes all manufactured drugs*} except for medical or scientific purposes and in the manner and to the extent provided by the provisions of the NDPS Act or the NDPS Rules or orders made thereunder and in a case where any such provision, imposes any requirement by way of license, permit or authorization also in accordance with the terms and conditions of such license, permit or authorization.

Section 20 of the NDPS Act deals with the offences related not only to the consumption but also cultivation, possession, use, sale/purchase, import/export, transportation and warehousing of Cannabis, except for medical or scientific purposes in India. As per the said Section 20 of the NDPS Act whoever, in

contravention of any provision of the NDPS Act or any rule or order made thereunder, or condition of license granted thereunder:

(*a*) cultivates any Cannabis plant is liable to be punished with rigorous imprisonment for a term which may extend to 10 years and shall also be liable to fine which may extend to Rs.100,000.00; or

(*b*) produces, manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses Cannabis, is liable to be punished, where such contravention:

(i) involves small quantity, with rigorous imprisonment for a term which may extend to 1 year or with fine which may extend to Rs.10,000.00, or with both.

(*ii*) involves quantity lesser than commercial quantity but greater than small quantity, with rigorous imprisonment for a term which may extend to 10 years and with fine which may extend to Rs.100,000.00.

(*iii*) involves commercial quantity, with rigorous imprisonment for a term which shall not be less than 10 years but which may extend to 20 years and shall also be liable to fine which shall not be less than Rs.100,000.00 but which may extend to Rs.200,000.00.

As per the said Section 20 of the NDPS Act a court may, for reasons to be recorded in the judgment, even impose a fine exceeding Rs.200,000.00.

The only exception to the aforesaid is *Bhang* which is a preparation made from Cannabis leaves consumed in parts of India on some festivals. As it is not made from Cannabis resin or from flowering tops, it is not covered under the NDPS Act. Production and sale of *Bhang* is permitted by many State Governments. Whoever is so licensed to produce *Bhang* is allowed to produce it from the leaves of the wildly growing Cannabis plants only. The use of the flowering tops or the resin produced from the plants to make *Bhang* is not permitted. Anyone found mixing with *Bhang* any part of flowering tops or the resin produced from the Cannabis plants, is liable to be punished under the relevant provisions of the NDPS Act and if such person happens to be a licensee, his license can also be cancelled.

The above being said, although the NDPS Act allows consumption of *Bhang*, various states keeping in line with the fact that the NDPS Act allows State Governments to frame their own rules to regulate various activities in relation to *inter alia* the usage of Cannabis or Cannabis related products have their own laws

banning or restricting its use. For example, in Assam, the Assam Ganja and Bhang Prohibition Act, 1958, prohibits sale, purchase, possession and consumption of *Ganja* and *Bhang*. In Maharashtra, Section 66(1)(b) of the Bombay Prohibition Act, 1949, bans manufacture, possession and consumption of *Bhang* and *Bhang* - containing substances without a license. On February 21, 2017, Gujarat legalized *Bhang* by removing it from the list of "*intoxicating drugs*" covered under Section 23 of the Gujarat Prohibition Act, 1949.

Cultivation of Cannabis for Medical and Scientific purposes: Section 10 of the NDPS Act read with Section 8 of the NDPS Act empowers the State Governments to license cultivation of Cannabis for medical and scientific purposes. Medicinal use of cannabis has so far been extremely limited and confined to alternate medicine such as Homeopathy and Ayurveda. State Governments have actually not been licensing cultivation of Cannabis despite the growing international interest among scientists in exploring possible medical uses of Cannabis of late. As per the extant National Policy on Narcotic Drugs and Psychotropic Substances the cultivation of Cannabis will not be permitted given its limited proven uses for medical purposes. However, the cultivation of Cannabis will be permitted for research including trials of various varieties of Cannabis.

In tune with the aforesaid India has begun its medical research of Cannabis in government authorized research premises. The Indian Institute of Integrative Medicine (IIIM) has taken the legal license to cultivate Cannabis for scientific and medical research purposes to develop products for epilepsy and cancer treatment. Under a tripartite agreement, the Council of Scientific & Industrial Research (CSIR), the India Council of Medical Research (ICMR) and the Department of Biotechnology have agreed to develop the epilepsy and cancer treatment products. In terms of the aforesaid, the CSIR will cultivate various varieties of Cannabis and then carry out clinical work in connection therewith. The ICMR will then administer the clinical trials at the Tata Memorial Centre in Mumbai and All India Institute of Medical Sciences (AIIMS) in New Delhi. In February 2020, the IIIM and CSIR entered into a cross-border agreement with the Canada-based Cannabis research company IndusCann. This research and development collaboration aims to create ample opportunities for developing varied medicines from Cannabis.

Cultivation of Cannabis for Horticultural and Industrial purposes: As per the extant *National Policy on Narcotic Drugs and Psychotropic Substances* the Cannabis

plant can be a source of biomass and fibre for industrial purposes. Cannabis seeds can be used to produce Cannabis seed oil - a high value oil. Some countries license cultivation of Cannabis varieties which have very low content of THC (Tetrahydrocannabinol), the active ingredient which has the intoxicating effect. These varieties of Cannabis are used to produce fibres which are, in turn, used in production of fabrics and for production of biomass.

Section 14 of the NDPS Act empowers the Government to, by general or special order, permit cultivation of Cannabis exclusively for horticultural and industrial purposes. In fact, as per the extant *National Policy on Narcotic Drugs and Psychotropic Substances*, the Central Government is also required to encourage research and trials of cultivars of Cannabis with low THC content. The Central Government, however, is required to follow a cautious, evidence-based approach towards cultivation of Cannabis for horticultural and/or industrial purposes and is required to take decisions based on results of research.

Cannabinoid Drugs: Cannabinoid Drugs are preparations made out of extracts or tincture of Cannabis. If a drug contains cannabinoids which have been synthetically manufactured, they would be regulated as drugs, except for drugs containing THC since THC is regulated as a psychotropic substance in India. Cannabinoid Drugs may be sold in India in accordance with the requirements laid down by law. Cannabinoid Drugs which are an extract or tincture from Cannabis would require a license under the NDPS Act, the NDPS Rules, the Drugs Act and the Drugs and Cosmetics Rules, 1945 (Drugs Rules) for sale in India. In this regard it may be noted that narcotic drugs can be manufactured only after obtaining a license from the Narcotics Commissioner. The Narcotics Commissioner issues a license only if certain prescribed conditions are fulfilled including producing a manufacturing license under the Drugs Act and the rules made thereunder from the State Drugs controller and the licenses to be obtained from the State Government under the State NDPS Rules for possession, use and sale of narcotic drugs.

So far, no cannabinoid drugs have received market approval.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in India?

Regulatory challenges at Policy formulation: Any move towards allowing the medical and recreational use of Cannabis and cannabinoids in India would gather traction at a regulatory level only if the Government/courts, as the case may be, are furnished with satisfactory answers to the following questions supported with cogent and empirical evidence:

1. *Does Cannabis have proven Medicinal benefits?*

While one of the common uses of Cannabis is in the control of nausea and vomiting, however, studies show that there is no statistically significant benefit of Cannabis derivatives over available drugs. Paradoxically, few case reports have described a condition known as cannabinoid hyperemesis (*excessive vomiting*) syndrome in marijuana addicts. With regards to appetite-stimulating actions of Cannabis, we have more effective drugs that are easily available. Cannabis is effective in pain management, but it is weaker and less safe than opiates that are approved. A study did show beneficial effects of Cannabis in a small percentage of extremely rare form of epilepsy and multiple sclerosis. However, most studies are not designed properly to offer any conclusive evidence. In summary, its medicinal benefits are not as strong as presented by the proponents of legalization - safer and effective alternatives are available in the market.

2. *What about health consequences of Cannabis use?*

The severity of the adverse effects of Cannabis depends upon type (*marijuana being the worst*), duration and frequency of use. Adults who smoke marijuana regularly show impaired neural connectivity. Marijuana users are at an increased risk of developing chronic psychotic disorders (*including schizophrenia*). There is an increased incidence of vehicle accidents in those who may be either short-term or long-term users of marijuana. Cannabis smoking is associated with an increased risk of bronchitis, pneumonia and respiratory distress, as also transient ischemic attacks, stroke, myocardial infarctions and Cannabis arteritis. Studies have shown a positive association between marijuana smoking and cancers of the lung, and an increased risk of developing other cancers. Moreover, the interactions between Cannabis and chemotherapy (*or any drug*) are largely unknown.

3. *Does legalization of Cannabis help?*

India has a history of misuse of even prescription drugs that are otherwise beneficial. Weak opiates (*derivatives of opium*) are one of the easily available alternatives to Cannabis for medical conditions. Codeine-based cough syrups are effective for controlling severe cough, but after reports of rampant misuse, the Narcotics Control Bureau asked the Drug Controller General of India to reduce its availability despite proven effectiveness. In Indian context, when prescription drugs are grossly misused, how can we ensure disciplined used of Cannabis is a big question?

4. *Will legalization worsen our overburdened healthcare system?*

India is struggling to control the three addictive substances *viz.*, tobacco, alcohol and areca nut. The younger generation is living in an era of personal liberty and rising affluence which makes them more prone to addiction. Introduction of yet another psychoactive drug will wreak havoc on a population still struggling with tobacco, alcohol and pan masala. It is unlikely to solve the drug menace in Punjab, Rajasthan and other states. Predatory marketing of Cannabis companies will hit the vulnerable population most, such as youth, poor, insecure, illiterate. Once introduced, it will establish a big market that would make subsequent tighter regulations impossible. Following legalization in the West, various newer products with marijuana are available in the market and on online portals, without proper prescription. These include marijuana chewing gums, candies, etc., which youngsters can easily take to.

Regulatory challenges under the NDPS Act: Besides the aforesaid challenges which effectively rule out a policy shift in the drug policy of India for the time being, the following are the regulatory challenges which exist under the currently existing regime which have the effect of rendering the implementation of even the current drug policy of India somewhat difficult:

Uneven co-ordination amongst Government Agencies

Drug policy administration in India is divided not only between the Central and State governments but also between Ministries and Departments at the same level. The distribution of subjects between the Center and State has already been

discussed hereinabove. The division between Ministries and Departments is described in the First Schedule under the Government of India (Allocation of Business) Rules, 1961, which demarcates the scope of work of each agency. As per these rules, the Department of Revenue under the Ministry of Finance (MoF) is entrusted with the administration of the NDPS Act as well as with matters relating to the international conventions on narcotic drugs, psychotropic substances and precursor chemicals, except those managed by the Ministry of Home Affairs (MHA). The Department of Internal Security within the MHA is tasked with handling all matters relating to Narcotics Control Bureau (NCB) {*which coordinates actions by various functionaries (Central and State) under the NDPS Act*} and with the coordination of drug control measures. It also deals with matters relating to the international conventions in respect of illicit traffic in narcotic drugs, psychotropic substances, and precursor chemicals except those allocated to the Department of Revenue, MoF. Matters pertaining to Drug Demand Reduction are handled by the Ministry of Social Justice and Empowerment (MSJE). The MSJE supports various Non-Governmental Organizations (NGOs) involved in Drug Demand Reduction. Ministry of Health, Government of India, which is responsible for all health issues, runs several drug de-addiction centers in the government hospitals across the country.

An inconsistent stand between the MoF and the MHA was seen on the question of the death penalty under the NDPS Act. In May 2012 while the then Finance Minister announced support for making capital punishment discretionary under the NDPS Act, the NCB filed a petition in the Supreme Court to preserve the mandatory death penalty under the NDPS Act. Another example of poor coordination and accountability was apparent in the case concerning human rights abuses against people who use drugs in treatment centers, where neither the Ministry of Health nor the MSJE took responsibility for private, unfunded centers as they ostensibly do not have rule making powers under the NDPS Act. In addition, the MoF said that while it is in charge of making NDPS Rules, it was not responsible for treatment and therefore could not make rules on the subject.

Owing to the aforesaid the implementation of the drug policy of India has sometimes seen a confusing overlap and, at times, an abdication of responsibility.

Lack of consultation in Policymaking

The lack of policy co-ordination is compounded by the non-application of consultative mechanisms provided in the NDPS Act and the NDPS Consultative Committee Rules, 1988 ("Committee Rules").

The NDPS Act allows the Central Government to establish a 20-member NDPS Consultative Committee ("Committee") as a policy-advisory body with a broad mandate. The Committee Rules allow the Committee to review the NDPS Act and the NDPS Rules, advise the government on policy matters, and consider any other issue requested by the government. The Committee may prepare a special report on any topic of importance for the government's consideration. The Committee may delegate specific policy matters to sub-committees, including sub-committees that review policy enforcement and treatment, rehabilitation, social reintegration and other connected matters. The Committee can draw upon experts and civil society representatives to review and recommend changes in nearly all areas of drug policy. Sadly, these provisions have not yet been invoked.

In 2008, the government announced the setting up of a National Consultative Committee on De-Addiction and Rehabilitation (NCCDR) under the Chairmanship of the MSJE to advise the Central and State governments on drug demand reduction, especially education/awareness building, deaddiction and rehabilitation. The composition of the NCCDR does not appear to be in accordance with the law. Not much is known about its role and functioning.

In 1961, driven by Western nations, the UN sponsored an international treaty to prohibit the production and supply of drugs including Cannabis. India resisted and negotiated exceptions, loopholes, and deferrals. It is ironic that the West is now legalizing Cannabis and other drugs. Given that some in India are clamouring for the same, India should carefully consider all the risks associated with Cannabis use and consider alternatives. One possible way of dealing with the situation could be the decriminalization of Cannabis coupled with the forbidding of the commercialization thereof. Alternately, if India were to liberalize its policy on Cannabis altogether, it should at the same time ensure that there are enough protections for children, the young, and those with severe mental illnesses, who are most vulnerable to its effects. Finally, before any of the aforesaid steps are considered treatments for those who become addicted to Cannabis should be in place.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in India?

In order to determine what regulatory framework would be relevant for the medicinal and recreational Cannabis products cultivation, manufacture and supply in India it would be relevant to take note of the following emerging trends towards regulation of Cannabis in India:

Trends in the Legal Sphere: The Indian Cannabis market has gathered significant attention recently, with various activists/NGOs filing court petitions demanding legalization of Cannabis. They argue that the medicinal benefits of Cannabis are hard to ignore, and the ideal climatic conditions for Cannabis cultivation have the potential to boost the Indian economy and create millions of jobs. One of these NGOs is the Great Legalization Movement India (GLM), which is working to legalize the use of Cannabis for medical and industrial purposes in India. In the summer of 2019, the Delhi High Court admitted a writ petition filed by GLM seeking decriminalization of Cannabis under the NDPS Act. The public interest litigation argues that the grouping of Cannabis with other chemical drugs under the NDPS Act is "arbitrary, unscientific and unreasonable" Although originally planned to be heard in February 2020, the hearing has been pushed back.

Trends in the Political Sphere: There is also traction among some government officials for the legalization of Cannabis. Officials including Maneka Gandhi and Tathagata Satpathy have spoken in favour of Cannabis decriminalization. In November 2019, Madhya Pradesh, the second largest state in India, decided to legalize the cultivation of Cannabis for medicinal and industrial purposes. Even more recently, it was announced in February 2020 that the Bhartiya Janata Party (BJP) government in Manipur is also considering the legalization of Cannabis for medical and industrial purposes.

Ayurveda, Unani, Siddhi and Homeopathy (AYSUH) system of Medicines: AYUSH experts as recently in August 2019 pitched for the legalization of medicinal use of Cannabis, saying that India can revolutionize pain management with Cannabis by using ayurvedic knowledge. The experts were speaking at the third edition of Oja Festival organized in August 2019 by NirogStreet (*India's first technology-led*

Ayurveda platform) in association with the AYUSH Ministry and co-organized by CSIR-IIIM Technology Business Incubator.

A statement said that renowned ayurvedic experts, researchers and practitioners voiced their opinion on critical issues related to Ayurveda and its relevance in the modern healthcare system. "*The government is working very hard as medicinal marijuana or cannabis will be legalized soon. Scientists are aggressively working to find out the active components of cannabis*." Dr Saurabh Saran, CSIR-IIM Technology Business Incubator, Jammu said.

Trends in the Commercial/Industrial Sphere: A number of promising Indian Cannabis start-ups have arisen in recent years, some of whom are collaborating in order to grow in the domestic market. These start-ups are generally focusing on medicines, cosmetics, textiles, accessories and foods. One of the most promising is Boheco (*the Bombay Hemp Company*), which is backed by high-profile investors including Google India's Managing Director Mr. Rajan Anandan, and Mr. Ratan Tata of Tata Sons. The company is agro-based and intends to reimagine the future of Indian agriculture and sustainable living with hemp. It is also a major supplier of raw material to fellow start-ups, Hempster and B.E. Hemp.

In February 2020, the India-based healthcare start-up HempStreet (*which concentrates on the use of cannabis in Ayurvedic medicine*) raised USD $1 million in pre-series A funding. The company will use the funding to support its technology growth, research development and to launch a new set of cannabis-based products. Abhishek Mohan, HempStreet's co-founder said they intend to set new milestones for the medicinal Cannabis sector in the country. They are also building blockchain technology to track the Cannabis from seed to sale, eliminating the risk that the Cannabis they grow will add to the substance abuse problem.

Despite being a trusted ingredient in the treatment of various ailments for thousands of years, the use of Cannabis in modern medicine is restricted by India's outdated Cannabis laws. Although legalization is still some way off, the rising number of cannabis and hemp start-up companies, and the growing popular support for the plant's legalization, is encouraging. Considering the medical and economic reasons in favor of legalizing

cannabis, it may not be long before the Indian Government unlocks the full potential that legalization of Cannabis would bring.

4. Which body is responsible for legislative controls relating to CBD?

As discussed above, the Central Government, in the year 1985, brought into force the NDPS Act, which is the central legislation that provides for a regulatory framework under which narcotic drugs and other psychotropic substances are regulated in India. It is to be noted that the legislative framework in India governs and regulates the use of Cannabis, in its entirety, and that there are no specific legislations, as such, which separately govern CBD as a substance. It may, however, be noted that THC is separately categorized as a psychotropic substance in the NDPS Act. It is therefore understood that the bodies that are responsible for legislative controls relating to a Cannabis plant, as a whole, would also be responsible for the regulation of CBD. It would also be important to note that Cannabis is defined in such a manner in the NDPS, such that it specifically excludes the seeds of the Cannabis plant and the leaves, as long as they are without the flowering and fruiting tops.

The NDPS Act, which governs Cannabis, as a narcotic drug, extends to the entire territory of India, and requires the constitution of certain bodies for enabling the implementation and for ensuring the strict enforcement of the NDPS Act. As has also been discussed above, the NDPS Act segregates the powers and responsibilities of regulation of activities between the Central and State Governments.

In terms of the NDPS Act and the NDPS Rules, the Central Government is vested with certain powers, such as to permit and regulate the manufacture, possession, transport, import, sale, etc., of 'essential narcotic drugs'[1] , while the State Governments are vested with certain powers to permit specific activities related to 'Cannabis' within the jurisdiction of each respective state. It must be noted that Cannabis, as on date, has not been classified as an 'essential narcotic drug'. The State Governments are therefore required to formulate rules for the purposes of regulation of the cultivation, manufacture and use of Cannabis.

[1] Section 9, The Narcotic Drugs and Psychotropic Substances Act, 1985.

Notwithstanding the above, the Central Government has categorically stated in the NDPS Act that Cannabis can be cultivated, manufactured and used only for: (i) industrial uses; and (ii) medicinal and scientific purposes.

Several states in India, such as the states of Kerala, Rajasthan, Uttar Pradesh, etc., have enacted their own NDPS rules, in order to regulate the cultivation, manufacture and use of Cannabis. These rules relate to permitting and regulating the cultivation of any Cannabis plant, the production, manufacture, possession, transport, inter-state import and export, sale, purchase, consumption and use of Cannabis.

The legislative controls therefore in relation to Cannabis lie with both, the Central Government and the State Governments.

The nodal organization under the Central Government that is responsible for introducing reforms/amendments to the existing legislative framework is the Department of Revenue under the MoF[2] . The Department of Revenue has the responsibility to frame rules to regulate the various activities as set out in the NDPS Act[3] , and is also responsible for activities such as the administration of the NDPS Act, and the examination of proposals for the amendment of the NDPS Act and the rules made thereunder. The Department of Revenue ensures compliance with its duties and responsibilities through bodies such as the Central Bureau of Narcotics, and other bodies under the Narcotics Department.

The enforcement of the provisions of the NDPS Act and the NDPS Rules have been allocated to multiple departments of the Government and to various bodies. The allocation is on the basis of the Government of India (Allocation of Business) Rules, 1961, which provides for separate ministries, departments, and/ or bodies to enforce the NDPS Act. Accordingly, under the Central Government, certain bodies such as the Narcotics Control Bureau, the Central Bureau of Narcotics, the Central Economic Intelligence Bureau, the Directorate General of Revenue Intelligence, the Customs Department, the Indian Coast Guard, etc., have been vested with specific and separate powers to ensure the enforcement of the NDPS Act and the NDPS Rules.

---

[2] The National Policy on Narcotic Drugs and Psychotropic Substances.

[3] The List of Subjects Allocated to the Department of Revenue (Revenue Headquarters), The Government of India (Allocation of Business) Rules, 1961.

At the state level, the State Governments broadly require its police departments and its excise officers to ensure compliance with the NDPS Act, the NDPS Rules and the relevant state NDPS Rules in the particular State.

Parallelly, the MHA has also been given certain responsibilities in terms of the administration of the NDPS Act, such as the examination of drug related agreements, and is also vested with certain administrative functions such as overseeing the budget and carrying on the financial monitoring of the Narcotics Control Bureau, which has been established by the Ministry[4]. The MHA undertakes and implements its duties and obligations through the Narcotics Control Bureau, which is the body that is engaged in discharging various functions[5], including coordinating with various central and state agencies that are engaged in the enforcement of drug laws.

While the central legislative framework empowers the States to frame rules for the issue of licenses to cultivate Cannabis, in practice, the mechanism of issuing licenses is still evolving at the state level. At present, few states in India, such as Uttarakhand and Uttar Pradesh, have been able to formulate a mechanism for issuing such licenses. Such licenses are issued, subject to certain conditions which are to be strictly followed by the license holders. While the legislative framework is silent on the specifications for the cultivation of Cannabis, the conditions attached to the licenses set out requirements such as area of the land, the specific level of CBD/THC that should be present, the purpose for use, etc.

While the use of Cannabis and Cannabis related products are primarily governed by the NDPS Act, the NDPS Rules, and the relevant State rules, the use of Cannabis in drugs and cosmetics is also governed by the Drugs Act. In terms of the Drugs Rules, the Central Drugs Standard Control Organization (CDSCO), headed by the Drug Controller General, is the Central Drug Authority for discharging functions assigned to the Central Government under the Rules[6]. While the Drugs Act and the rules thereunder were introduced by the Ministry of Health and Family Welfare, the CDSCO is responsible for making any amendments to the Drugs Act and the relevant rules.

---

[4] S.O. 96 (E), dated March 17, 1986, issued by the Department of Revenue, Ministry of Finance.

[5] Office Memorandum No.50/71/86-Ad.I, dated February 2,1987, issued by the Department of Revenue, Ministry of Finance.

[6] Rule 2(b), The Drugs and Cosmetics Rules, 1945.

In addition to the above, the manufacture and consumption of any food substance, in India, is governed by the Food Safety and Standards Act, 2006 (FSS Act). While there are certain countries which have recognized the use of certain parts of the Cannabis plant as well as CBD in food products, India has not, as on date, recognized Cannabis or CBD as a food product. possibility of the regulation of the use of Cannabis or CBD in a food product, the same will be regulated by the FSS Act whereunder the Food Safety and Standards Authority of India (FSSAI) has been established and is the regulating authority who would have the powers to legislate on this subject.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in India?

As an introduction, it is understood that while CBD is primarily extracted from the seeds and leaves of the Cannabis plant, it is also found and can be extracted from the other strains of the plant. As discussed above, the definition of the term 'Cannabis (hemp)' for the purposes of the NDPS Act and its categorization as a narcotic drug, excludes the seeds and the leaves, as long as the leaves do not have the flowering and fruiting tops with them. It is therefore understood that CBD, when extracted from the seeds and leaves, may not be classifiable, as a narcotic drug, but when extracted from the other strains of the plant, could be categorized as narcotic drug, as all such other parts are so categorized.

Novel Food Approval:

'Food' means any substance which is intended for human consumption, however, does not include any drugs, medicinal products, cosmetics or 'narcotic or psychotropic substances'[7]. In terms of the FSS Act, food has been broadly categorized as standardized foods, novel foods, nutraceuticals, health supplements, foods for special medical purposes, proprietary foods, novel foods, other non-specified foods, etc. Each of these categories are governed by separate provisions, and the products made available to consumers are required to conform with all the mandatory requirements stipulated in the regulations governing them.

[7] Section 2(j), The Food Safety and Standards Act, 2006.

In India, in order for a person to commence or carry on any food business[8] , a compulsory license or a registration is required to be obtained by the food business operator[9] from the FSSAI. As most of the categories of food products are regulated in terms of the FSS Act and the regulations thereunder, such categories are not required to obtain a separate approval from the FSSAI, other than obtaining the license/registration which is a permission to manufacture, etc. For example, for the manufacture of a standardized food product, i.e., foods for which specific standards have been set out in the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, the food business operator does not require a separate product approval, as the product would be required to comply with the standards that have been set out for the same, however, the required licenses/registrations would have to be obtained.

The use of Cannabis or CBD as a food product or food ingredient in the Indian market has not been recognized or standardized as yet, by the relevant government authorities. The reason behind this may be the consideration of certain parts of the Cannabis plant as a 'narcotic drug', in terms of the NDPS Act, and the fact that the definition of the term 'food' specifically excludes 'narcotic or psychotropic substances'. The FSSAI has, as a matter of fact, in the year 2017, issued a letter[10] to various food business operators, stating that 'hemp' is a product for which no standard has been prescribed due to the lack of certain data and information and any hemp product that is marketed using a FSSAI license is an illegal and unauthorized act.

At this juncture, while categories of 'non-specified foods' and 'novel foods' exist in terms of the FSS Act, and these categories mandatorily require an approval from the FSSAI for its manufacture, the question that remains is whether Cannabis or any part of it can be used as a food or a food ingredient, as the same being a 'narcotic drug/substance', is excluded from the definition of the term 'food'.

In relation to the above, there could be a possibility of drawing a distinction between a 'narcotic CBD' and 'non-narcotic CBD', for the reasons, as set out

---

[8] Section 2(n), The Food Safety and Standards Act, 2006.

[9] Section 2(o), The Food Safety and Standards Act, 2006.

[10] File No. 4(37) 2017/States/RCD/FSSAI (Vol. 1), dated October 17, 2017, issued by the Food Safety and Standards Authority of India.

above, and it could be possibly interpreted that CBD, which is extracted from the seeds and leaves of the Cannabis plant, may be used as an ingredient in food as the same may not be a narcotic drug, which is categorically excluded from the definition of the term 'food'. This is, however, only a possible argument and at present there is no regulation or discussion on this subject under the FSS Act.

It may, however, be noted that even if there could be a distinction created between narcotic CBD and non-narcotic CBD, under the FSS Act, a food business operator would not be permitted to simply use the non-narcotic CBD as an ingredient in any food product. The use of this, whether as a food or an ingredient, would require a specific approval from the FSSAI, either as a 'novel food/ ingredient' or as a 'non-specified food/ingredient'[11].

Medicinal Product Marketing Authorization:

The Drugs Act and the Drugs Rules are the legislations which govern the licensing of drugs and cosmetics in India. The legislation has been framed in a manner such that there are several categories of drugs, cosmetics and ayurvedic drugs and each category is separately governed by the Drugs Act and the Drugs Rules. In addition, the Drugs Act and the Drugs Rules also lay down the concepts of 'new drugs' and 'patent or proprietary medicines' which may not necessarily be categorized under any of the Schedules under the Drugs Act and the Drugs Rules, however, they may have certain other specific criteria and standards that have to be complied with.

Every person intending to manufacture a drug or a cosmetic, is required to submit an application in terms of the Drugs Act, for the proper licenses, permissions, authorizations, etc., on the basis of the Schedule under which the drug falls. Schedule H to the Drugs Rules contains a list of drugs which are 'prescription drugs' and which can be sold only by a registered pharmacist[12]. This Schedule expressly lists down all the 'narcotics drugs' as listed in the NDPS Act, as prescription drugs. This would therefore mean that a drug or a medicine, being a narcotic drug, or which contains narcotic drugs as an ingredient, can only be sold as a prescription drug by a registered pharmacist. The licenses that have to be

[11] Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017.

[12] Rule 65, The Drugs and Cosmetics Rules, 1945.

obtained for the manufacture of Schedule H drugs/medicines are the licenses to manufacture for sale or for distribution. At present, it must be noted that there is no separate marketing authorization, as such, that would be required for the marketing and advertising of these products, other than the license for the sale of the product. It is however understood that the conditions that would be set out when such licenses are issued and which the licenses would be subject to, would clearly and properly set out conditions in relation to the marketing of these drugs.

As, however, stated above, there could be a possible distinction between narcotic CBD and non-narcotic CBD, and it could possibly be interpreted that Schedule H to the Drugs Rules would be applicable to narcotic CBD and use of the same as a drug/medicine, as a whole, or as an ingredient in a drug/medicine.

In view of the above understanding, the use of the non-narcotic CBD, if not governed by Schedule H to the Drugs Rules, could possibly be governed by such other relevant Schedule under which the drug/medicine, in which non-narcotic CBD is used, would be classified. Further, while there is no express or separate authorization required for the marketing or advertising of these other drugs/ medicine, other than the license required for the sale of the drugs/medicines, it is understood that the conditions attached to the licenses that would be issued would properly and adequately set out conditions in relation to marketing and advertising products containing non-narcotic CBD.

The Drugs Act also regulates the manufacture of Ayurvedic, Siddha or Unani drugs (ASU Drugs), and the ingredients and formulae used for the manufacture of ASU Drugs should be exclusively in accordance with the formulae prescribed in the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine[13]. While there is no express reference to CBD in the Drugs Act and Drugs Rules, a reference to '*bhaang*', '*ganja*' and '*çharas*', being forms in which Cannabis can be consumed, is present in the Drugs Rules and the same have been listed as poisonous substances[14] in relation to ASU Drugs. It has been clarified that if the substances of '*bhaang*', '*ganja*' and '*çharas*' are used in ASU Drugs, for internal uses, the label of such product should clearly set out the words "Caution: to be

[13] Section 3(a), The Drugs and Cosmetics Act, 1940.

[14] Schedule E-(I), The Drugs and Cosmetics Rules, 1945.

taken under medical supervision", in both the Hindi and English languages[15]. There is, however, no provision as such, which requires a separate marketing authorization for the marketing and sale of such products, other than the license required for the sale of the products and as stated above, the conditions of license should more than adequately provide for the compliances/restrictions in relation to the advertising of the products which contain any form of Cannabis, including CBD, if so permitted.

The Drugs Act similarly also regulates the manufacture of cosmetics and there are certain standards set out for varied kinds of products such as ointments, ophthalmic preparations, and the like. The Drugs Act also specifically sets out that there are other cosmetic items, such as, attars, perfumes, etc., for which standards have not been set out in the Schedules laid down therein. The Drugs Act however, in relation to cosmetics as well, has not set out any provisions which relate to CBD (whether narcotic or non-narcotic) being used as an ingredient and if being so used, whether a separate marketing authorization is required to be obtained. In a similar manner, as set out above, it could be understood that the Licensing Authorities will set out specific conditions in relation to the marketing and advertising of products that contain CBD in them while issuing the required licenses for the manufacture and sale of cosmetics.

While the Drugs Act and the Drugs Rules do not discuss the requirement of obtaining a separate marketing authorization for the advertising and promotion of drugs, ASU drugs or cosmetics, which may contain CBD or any other form of Cannabis in them, there are rules as well guidelines which set out principles of advertising for all kinds of drugs and cosmetics. In particular, the Drugs Rules prohibit the manufacturers of ASU Drugs from advertising any ASU drug which claims to be used for the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder, syndrome or conditions[16]. In addition, the other principles have been framed to ensure that all advertisements in relation to drugs are truthful and not misleading in any manner for the safety of consumers[17].

---

[15] Rule 161(2), The Drugs and Cosmetics Rules, 1945.

[16] Rule 170, The Drugs and Cosmetics Rules, 1945.

[17] These principles are laid down in the provisions of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, the Advertising Standards Council of India Code, the Uniform Code for Pharmaceutical Marketing Practices, Organization of Pharmaceutical Producers of India Code of Pharmaceutical Practice, the International Federation of Pharmaceutical Manufacturers and Associations Code and such other codes.

6. What are the testing specifications in India for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

The United Nations Office on Drugs and Crime has released a document on the recommended methods for the identification and analysis of Cannabis and Cannabis products, which acts as a manual to be used by the drug analysis laboratories across the world. The purpose of the manual is to deal with the identification and analysis of drugs, and it has therefore made an attempt to harmonize and establish certain recommended methods of analysis to be followed by laboratories around the world, in addition to specific legal requirements. The manual particularly specifies that on an international level, the THC levels in 'industrial hemp' should be recognized to be 0.2% (zero point two percent).

Considering that the current legislative framework for the manufacture, sale and use of Cannabis in India is still in the nascent stage, it appears that there is no specific and separate legislation which regulates CBD in particular and which sets out any standards, that CBD is required to comply with. Further, there also appear to be no specifications or testing methods to analyze the level of any controlled substance in CBD or the level of purity of CBD in the legislative framework. As stated above, the State Governments have been empowered to issue the licenses for the manufacture, sale, etc., of Cannabis under the NDPS Act, and it appears that such State Governments through the conditions attached to the licenses being issued, are regulating the level of CBD and THC in Cannabis. For instance, the State of Uttarakhand has allowed the cultivation of 'industrial hemp', only if the level of THC is less than 0.3% (zero point three percent), however, there have been no testing methodologies or specifications that have been set out in the legislative framework in relation to the same.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

The cultivation and production of hemp falls under the State list of the Constitution of India, therefore, the proliferation of entrepreneurial activities in the hemp industry comes under the purview of the State governments.

Cannabis grows mainly in North India, particularly in the States of Uttarakhand, Uttar Pradesh, Himachal Pradesh and Jammu & Kashmir[18], however today only the State of Jammu and Kashmir and the State of Uttarakhand have formulated hemp – related cultivation policies.

Regarding the State of Himachal Pradesh[19] policies seem to be still in the making on the lines of the neighbouring State of Uttarakhand to legalize the cultivation of Cannabis for the production of life-saving medicines and some other limited number of industrial products. With Uttarakhand taking the lead[20], States like Uttar Pradesh and Jharkhand are also coming forward to disrupt the prevailing policies and to pave a path for skilled entrepreneurs of India to grow, prosper, and strengthen Indian economy[21].

Although the NDPS Act allows the State governments to grant permissions/licenses for the cultivation of hemp for specific purposes, the actual process of obtaining these permissions/licenses is far from easy. This is because of the absence of a standardized

[18] Available at https://www.forbesindia.com/article/sustainability-special/on-the-hemp-trail-bohecos-attempt-to-build-a-new-narrative-around-cannabis/50349/1

[19] Available at https://himachalwatcher.com/2019/10/29/cannabis-legalization-in-himachal-pradesh/

[20] A few salient features of the Uttarakhand State Policy, notified on 5 December 2016, are stated hereunder:

(a) Any person, institution or entity may cultivate industrial hemp subject to prior license granted by the collector. The cultivation shall only be for the purposes of obtaining seeds and/or fibres. The license granted shall not be transferable from one person/entity to another;

(b) Any land owner or any entity in collaboration with the land owners may apply to the collector for the license to cultivate in the prescribed format annexed to the State Policy and provide such details as are mandated;

(c) The licensee shall be required to provide a character certificate along with the application for the license;

(d) The license may be granted or rejected by the collector upon scrutiny. In the event the application is rejected, the collector shall be required to provide cogent reasons for the same and the licensee shall have the right to appeal to the Excise Commissioner within 30 (thirty) days from the rejection of the application;

(e) The license for cultivation and storage shall be submitted before the collector along with a fee of INR 1000.00 per hectare per year and the license shall be issued in the prescribed format after scrutiny;

(f) The licensee shall be permitted to only cultivate industrial hemp with THC count under 0.3. Licensee shall have to present the seeds before the licensing authority along with a certificate stating the THC count to be under 0.3. The seeds shall be verified by the licensing authority and confirmed for use for cultivation;

(g) The licensee shall also be required to intimate the collector for carrying out measurement of THC count prior to undertaking harvesting. The harvesting shall be undertaken subject to the permission of the appropriate authority. Such confirmation shall be provided by the concerned authorities within 7 (seven) days. The crop may be destroyed in the event the THC count is over 0.3;

(h) The Excise Superintendent of the Excise Department and the Nayab-Tehsildars from the Revenue Department shall have the right to investigate into the existing licenses and the licensees shall be required to maintain registers as may be prescribed.

[21] Available at https://www.entrepreneur.com/article/331292

government route. For instance, there is no clarity on which State government departments are responsible for the granting of permissions to cultivate hemp[22]. This affects the ease of doing business and creates unnecessary barriers to entry for firms interested in the industrial/medical/scientific use of hemp.

- *Purchase*

  The NDPS Act[23] mandates that sale, purchase, consumption or use of a psychotropic substance such as Cannabis shall be only for medical and scientific purposes. The Jammu & Kashmir Excise Act, 1958 does not regulate the purchase of hemp, it limits the regulation to the import, export, transport, manufacture, sale and possession of intoxicating drugs including hemp in the State of Jammu & Kashmir.

  The Uttarakhand State Policy in respect of intoxicated Hemp Abolition and Cultivation of Industrial Hemp for Commercial and Horticulture purposes under Section 14 of the said Act, enables the purchase on the following conditions: the units of hemp not used for the cultivation, can be used for purchase, use and storage of the fibers and seeds of the plants of industrial hemp from the licensed farmer prior purchase license application before the Collector of the concerned area, in the prescribed proforma[24]. However, the licensee is not authorized to get any kind of psychotropic substances from the plant of industrial hemp and to do the purchase-sale, use and storage for himself, except the industrial and horticulture use may be made as per the Rules[25]. It is mandatory to maintain the details of the purchase in the required registers by the licensee, that might be submitted for inspection on demand by any competent authority[26]. Presently, the Indian startup HempCann Solutions has launched its first research-based Cannabis clinic in Bangalore that can prescribe Cannabis infused tablets produced by Vedi

---

22 Available at https://www.ikigailaw.com/hemp-high-time-for-legalisation/

23 See Rule 65 A of the Act "Sale, purchase, consumption or use of psychotropic substances. No person shall sell, purchase, consume or use any psychotropic substance except in accordance with the Drugs and Cosmetics Rules, 1945:

Provided that sale, purchase, consumption or use of a psychotropic substance specified in Schedule I shall be only for the purposes mentioned in Chapter VIIA".

24 See Rule 3, available at http://uttrakhandexcise.org.in/Docs/bhang.pdf

25 See Rule 7 and 11, available at http://uttrakhandexcise.org.in/Docs/bhang.pdf

26 See Rule 9, available at http://uttrakhandexcise.org.in/Docs/bhang.pdf

Herbals. HempCann has received a pan-India license to distribute these medicines on a prescription basis, which can be given by any Ayurvedic doctor or through an online consultation[27].

- *Import*

Import into India of the narcotic drugs and psychotropic substances is prohibited except with an import certificate from the Narcotic Commissioner for each consignment, issued under the provision of Chapter VI of the NDPS Act.

The NDPS Act does not lay down proper procedures for hemp cultivation, procurement, use and does not provide any limits on the quantity of CBD that can be imported, unlike that in the case of legal opium[28].

The Jammu & Kashmir Excise Act states that no intoxicating drugs shall be imported into Jammu & Kashmir except (a) after payment of any duty to which it may be liable under this Act, or execution of a bond for such payment, and (b) in compliance with such conditions as the Government may impose[29].

The Uttarakhand State policy does not regulate the import of hemp.

[27] Available at https://www.vice.com/en_in/article/qjdv9p/indias-first-medical-cannabis-marijuana-clinic-is-finally-here

[28] Opium regulation available at http://cbn.nic.in/html/GN-OP-19-20.pdf

[29] See Section 5 of the Act, substituted by Act XIV of 1966, available at http://jkexcise.nic.in/documents/eact.pdf

Contacts in the firm

N.U. Subaya

Partner

Email: subaya@duaassociates.com

Salil Gulati

Partner

Email: salil@duaassociates.com

Janini Somiah

Partner

Email: janini@duaassociates.com

Sahil Dhawan

Principal Associate

Email: sahil@duaassociates.com

Francesca Gatti

Translation Consultant

Email: francesca@duaassociates.com

ISRAEL

AYR - Amar Reiter Jeanne Shochatovitch & co

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Israel?

   a. The use of cannabis in Israel is prohibited since cannabis defined as a "dangerous drug" in accordance with the Israeli Dangerous Drugs Ordinance [New Version] 1973 (and not registered as a remedy).

   b. Notwithstanding the above, in August 2011, the first governmental resolution (number 3609) was adopted with respect to the foundation of a governmental agency under the supervision of the Israeli Ministry of Health by the name of the Israeli Medical Cannabis Agency (IMCA or YAKAR). The main objective of the IMCA is on one hand to provide patients with continuous and appropriate supply of cannabis for medical purposes and, on the other hand, licensing occupations in the cannabis field.

   c. Further to the governmental resolution mentioned above, a Government resolution (1587) resolved in 2016 sets the guidelines for the regulation of any activity regarding the cannabis plant, including growing, exporting, distributing, possessing, transporting, laboratory testing, dispensing or research of the cannabis plant or its products. Such activities are mandated to comply with the provisions of any law, including obtaining the adequate licences according to the Dangerous Drugs Ordinance from the YAKAR.

   d. In addition, it is important to note that there is a new bill submitted to the Israeli legislature, the Knesset Israel, for the purpose of regulating private consumption of cannabis for recreational purposes. It is unclear at this stage weather the bill shall be adopted. Furthermore, although cannabis is not legalised, the non-official policy of the Israeli police is to not submit charges against private consumption of cannabis.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Israel?

a. The regulatory challenges in allowing the medical use of cannabis are, among others, related to the establishment of the new agency. Agency duties such as approving licences and supervision and research of cannabis require continual governmental support.

b. In addition, the regulatory challenges are focused on ensuring the quality of the cannabis products for potential patients and the security required for all the custody chain of cannabis.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Israel?

As stated above, the consumption of cannabis in Israel for recreational purposes is currently prohibited.

1. Medicinal Use

   There are two ways in which a licence to possess and use medical cannabis can be obtained for patients meeting the criteria specified in Procedure 106 – licences for cannabis use, as follows:

   1.1. Through a doctor authorised by the IMCA to issue a licence at the time of the visit.

   1.2. Online application by a specialising doctor.

2. Occupation in the cannabis field

3. In order for individuals or corporate bodies to be occupied in the Israeli cannabis field, they must obtain the appropriate licence from the IMCA. There are seven different licences, as follows:

4. Production Licence – regulates the cultivation and replication stage of cannabis. The procedure is based on the general requirements for appropriate cultivation (GAP) for plants and World Health Organization guidelines and international standards for growing fruits and vegetables, as well as the "Best Known Practices" standards used by leading countries worldwide. Cannabis will only be grown on cannabis farms, in suitable growth homes which will hold a valid licence under the Dangerous Drugs Ordinance. Any growing licence holder will be allowed to exclude cannabis from the farm area only to a licenced manufacturing plant.

    4.1. Licence to manufacture cannabis products – Cannabis products are only manufactured in cannabis product manufacturing plants that hold a valid licence under the Dangerous Drugs Ordinance. Cannabis plants shall be processed into products in cannabis product manufacturing plants only and to be used in accordance with appropriate professional standards.

    4.2. Commercial house Licence (Storage) – Cannabis products shall be shipped to cannabis commercial houses with valid licences under the Dangerous Drugs Ordinance. The commercial houses shall operate in accordance with appropriate professional standards (the existing GDP for a drugstore, tailored to cannabis products) and from there the products shall be distributed to the pharmacies.

    4.3. Pharmacy licence to issue cannabis products – Cannabis products shall be issued at pharmacies applying to do so and meeting the required conditions. In such pharmacies, cannabis products shall be issued to patients holding a licence to use cannabis and in accordance with the licence conditions. The dispensing and administration of cannabis products shall be carried out in accordance with the instructions of the Israeli Ministry of Health.

    4.4. Cannabis service Laboratory – Cannabis products shall be examined, developed and researched at laboratories that hold a valid licence under the Dangerous Drugs Ordinance.

4.5. Cannabis extermination licence – Cannabis including cannabis products shall only be exterminated by a licensed exterminator.

4.6. Cannabis transportation licence – Cannabis products shall be transported only by transporters with valid licences under the Dangerous Drugs Ordinance.

5. Cannabis importation

In order for individuals or corporate bodies to import cannabis, they must obtain the following conditions/licences:

5.1. Receiving of commercial house licence (storage) from IMCA.

5.2. Receiving approval of the Ministry of Agriculture & Rural Development to import a dangerous drug.

5.3. Receiving the approval of the Ministry of Health Drug Import Department with respect to importation licence and dangerous drugs importation licence.

5.4. Importing the cannabis.

5.5. Releasing the cannabis from the Israeli customs in accordance with the Dangerous Drugs Ordinance.

4. Which body is responsible for legislative controls relating to CBD?

Although a bill to exclude CBD from the Dangerous Drugs Ordinance has been submitted in the year 2019, it has yet to be adopted; hence CBD is not legalised and the use and/or occupation in the field of CBD requires the same licences and approvals as hereinabove mentioned for cannabis.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in Israel?

Not relevant – please see answer above.

6. What are the testing specifications in India for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Not relevant – please see answer above.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Not relevant – please see answer above.

Contacts in the firm

Advocate Yoav Caspi
Head of corporate and commercial department
Email: YoavC@ayr.co.il

MALTA
DF ADVOCATES

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Malta?

The regulatory framework for medical cannabis and cannabinoids in Malta is composed of one principal comprehensive piece of legislation, the Production of Cannabis for Medicinal and Research Purposes Act (Chapter 578 of the Laws of Malta) (the PCMR Act), which is supplemented by other subsidiary and relevant legislation, as well as official guidelines.

The PCMR Act was enacted in April 2018, making Malta one of the first European countries to have specific legislation to permit and regulate the production of cannabis for medicinal and research purposes. This legislation followed amendments to the Drug Dependence (Treatment not Imprisonment) Act (Chapter 537 of the Laws of Malta) (the Drug Dependence Act), which provides for the possibility for medical practitioners to prescribe to patients medicinal preparations of cannabis and cannabinoids.

Other relevant laws applicable to the production and supply of cannabis for medicinal use include the Medicines Act (Chapter 458 of the Laws of Malta) (the Medicines Act), which is the main legislation related to all medicinal products and which transposes Directive 2001/83/EC as amended, and subsidiary legislation entitled the Production of Cannabis for Medicinal and Research Purposes (Fees) Regulations,(Subsidiary Legislation 578.01 of the Laws of Malta) which sets out the fees relating to the application for a licence to cultivate, manufacture and supply medicinal and recreational cannabis products in accordance with the PCMR Act.

Within the regulatory framework relating to the production of cannabis for medicinal use, the Medicines Authority in Malta has published a comprehensive set of general guidelines on the production of cannabis for medicinal and research purposes (the Guidelines) which supplement the provisions of the PCMR Act.

In Malta, the production and use of cannabis for recreational purposes remains a criminal offence, although specific provisions within the Drug Dependence Act provide for lower penalties for minor use-related offences and also aim to rehabilitate persons suffering

from drug dependence. In this regard, the Dangerous Drugs Ordinance (Chapter 101 of the Laws of Malta) provides that no person shall import, bring into or export from Malta any resin obtained from the plant cannabis. It also provides that the possession, production, supply and cultivation (except where these relate to medicinal preparations) of cannabis is a criminal offence.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Malta?

The use of medicinal cannabis in Malta is mainly regulated by Article 10 of the Drug Dependence Act. This provision has addressed the main legal challenge relating to the prohibition of the use of cannabis in Malta. By virtue of this provision, any licensed medical practitioner who is registered to practice in Malta is entitled to prescribe to patients medicinal preparations of cannabis and synthetic cannabinoid products, licensed under the Medicines Act or manufactured under Good Manufacturing Practice. Thus, patients are allowed to use medical cannabis upon prescription only. Being a thoroughly regulated medicinal preparation, the prescription and thereby the use of medical cannabis may only be considered where there is no viable alternative to such prescription and use, after due consideration is taken of any protocols which may be in force from time to time in respect of the prescription of medicines, of the interests of the patient and of the costs. Moreover, an application for such medicinal preparations may only be made on a named patient basis following approval by the Superintendent of Public Health.

Other challenges which may be encountered, though not essentially of a purely regulatory nature, include the identification of medical conditions to be treated with medicinal cannabis products, the reluctance of medical practitioners to prescribe cannabis preparations and uncertainty about clinical indications and dosing.

The use of cannabis for recreational purposes remains a regulatory challenge since, as provided in question 1 above, it is until today not permitted and, although certain mitigation provisions have been included into our legal framework for minor personal use, it is considered to be a criminal offence.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Malta?

The PCMR Act is the principal legislation that regulates production, including the cultivation of cannabis for medicinal and/or research purposes. According to this Act, the cultivation, importation or processing of cannabis or production of any products intended for medicinal and/or research purposes deriving or resulting from the use of cannabis, as well as any trade in cannabis and/or any preparations intended for medicinal and/or research purposes as deriving from cannabis, may take place in Malta upon the issuance of the necessary approvals, authorisations, licences and/or permits under the PCMR Act and all other applicable laws. The latter, though very widely drafted, essentially refers to the Medicines Act and certain subsidiary legislation which is also relevant to the manufacturing and supply of medicinal cannabis products.

In Malta, as stated in question 1 above, the Dangerous Drugs Ordinance makes the cultivation, manufacture and supply of cannabis for any other purpose that is not medicinal or research purposes a criminal offence.

4. Which body is responsible for legislative controls relating to CBD?

The Medicines Authority, established in terms of the Medicines Act, is the body responsible for legislative controls relating to CBD.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in Malta?

Presently in Malta CBD products which are required for medicinal purposes require an authorisation, as specified under the PCMR Act.

6. What are the testing specifications in Malta for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Testing specifications are provided for in the Guidelines, which require that cannabis plants are identified using microscopic examination, microscopic identification and

chromatographic procedures. Tests should comply with the guidelines provided by the European Medicines Agency, which provide, among others, guidelines on the quality of herbal medicinal products, testing procedures, accepted product criteria and product preparation.

A certificate of analysis, based on the respective European Pharmacopoeia methods and limits, must provide, but is not limited to, the following set of tests:

- Aflatoxins (Ph Eur 2.8.18)
- Pesticides (Ph Eur 2.8.13)
- Foreign matter (Ph Eur 2.8.2)
- Heavy metals (Ph Eur 2.4.27)
- Loss on drying (Ph Eur 2.2.32)
- Content Tetrahydrocannabinol (THC)
- Content Cannabidiol (CBD)

The CBD (as well as THC) levels should be tested using validated chromatographic methods following samples as per Ph Eur 2.8.20. These tests should also be accompanied by a description of the validated analytical procedure and the specifications and limits applied.

The level of CBD (and THC) in a representative sample of cannabis flowers must correspond with the product specifications and labelling of the product, as a minimum, to not less than 90% and not more than 110%. CBD (and THC) levels in cannabis oil products must be at least 95% and not more than 105%.

Mandatory tests regarding the certificate of analysis should include:

- Content THC
- Content CBD
- Loss of drying
- Microbiology
- Pesticide analysis
- Heavy metal analysis
- Aflatoxins
- Foreign matter
- Identity tests

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

While Maltese law does not specify any limits on the quantity of CBD that can be imported for processing, the Guidelines stipulate that the Medicines Authority will, at periodic intervals, require the licence holder to submit estimates of the intended amount of cannabis that it will import for further processing over a stipulated period. The licence holder must also furnish the Medicines Authority with details regarding the number of finished product packs that shall be produced over the subsequent quarter.

For end consumers, a licenced medical practitioner who is duly registered in accordance with the Health Care Professions Act is entitled to prescribe to patients medicinal preparations of the plant cannabis and synthetic cannabinoid products licensed under the Medicines Act or manufactured under Good Manufacturing Practice, in the doses he deems fit, if it is considered that there is no viable alternative to such prescription, due account being taken of any protocols which may be in force from time to time.

Contacts in the firm

Maria Deguara
Partner
Email: maria.deguara@dfadvocates.com

Celia Mifsud
Lead Senior Associate,
Email: celia.mifsud@dfadvocates.com

Name: Andrew Massa
Associate
Email: andrew.massa@dfadvocates.com

NETHERLANDS
EKELMANS & MEIJER ADVOCATEN

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in the Netherlands?

Pursuant to the Opium Act (in Dutch: Opiumwet), it is a criminal offence in the Netherlands to possess, produce or deal in drugs. The Opium Act makes a distinction between category I drugs (hard drugs) and category II drugs (soft drugs). This distinction is relevant because an offence relating to a category I substance can carry a more severe punishment than an offence relating to a category II drug. Cannabis is listed as a category II substance.

The Opium Act contains the possibility of an exemption to the prohibition of producing drugs for the purpose of public health. These exemptions are intended for businesses or agencies wishing to work with drugs referred to in the Opium Act. Under certain conditions, the prohibition does not apply to pharmacists, dispensing general practitioners and veterinarians, nor does it apply to Government-affiliated agencies or to persons or agencies that stock drugs for medicinal or dentistry purposes or for their own medicinal use. The Bureau for Medical Cannabis (BMC) is tasked with the production of cannabis for medical and scientific purposes.

Although the cultivation, production and possession of cannabis is prohibited under the Opium Act, the Netherlands has developed a policy of toleration (in Dutch: gedoogbeleid) regarding small quantities of soft drugs. This means that the cultivation, production and possession of cannabis is still illegal and punishable under Dutch law, but a person will not be prosecuted when he is not exceeding the tolerated limits. These quantities are defined as follows:

- Maximum of 5 grams of cannabis per person (marijuana or hash);
- Maximum of 5 cannabis plants for personal consumption.

Furthermore, so-called coffee shops are allowed to sell cannabis, provided that they observe the rules. These coffee shops:

- may not cause any nuisance;
- are not permitted to sell hard drugs;

- are not permitted to sell cannabis to minors;
- are not permitted to advertise drugs;
- are not permitted to sell large quantities (over 5 grams of cannabis) in a single transaction;
- are not permitted to have more than 500 grams of cannabis present in stock.

Municipalities (cities) may determine whether coffee shops are allowed to operate within their boundaries and, if so, how many. They may also impose additional rules.

Lastly, the consumption or use of drugs by persons aged 18 or above is not a criminal offence in the Netherlands. However, municipal authorities may issue a local decree (in Dutch: Algemene plaatselijke verordening) that prohibits the use of drugs in designated areas. When a person uses drugs in one of the designated areas, this person may be arrested or ordered to pay a fine.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in the Netherlands?

The toleration policy has led to a seemingly paradoxical system. The coffee shops are allowed to buy and sell soft drugs to consumers. At the same time, the large-scale production of these drugs is prohibited and the cultivation of more than 5 cannabis plants is punishable and likely to be prosecuted. And inevitably the coffee shops can only acquire their cannabis from the criminal circuit.

The Dutch Government has acknowledged this discrepancy and is currently working on an experiment where coffee shops in certain cities can legally acquire cannabis from a state-appointed producer. The aim is to examine the effects of the experiment on the problems experienced by some municipalities in terms of crime and public health.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in The Netherlands?

See answers under question 1 and 2.

4. Which body is responsible for legislative controls relating to CBD?

The Dutch Ministry of Health, Welfare and Sport.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in The Netherlands?

Currently many CBD products are being sold on the Dutch market. However, CBD products are often made from a concentrate of cannabis (hemp) oil. Cannabis oil is ranked in category I of the Opium Act. Its preparation, possession and sale are therefore prohibited. In practice, its sale is currently tolerated under the toleration policy.

6. What are the testing specifications in The Netherlands for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Tetrahydrocannabinol (THC), one of at least 113 cannabinoids identified in cannabis, is the principal psychoactive constituent of cannabis. Under Dutch law, CBD products containing less than 0.2% have been legalised.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

See above. In practice this may vary since municipalities may set their own rules

Contacts in the firm

Adriaan de Buck
Partner
Email: buck@ekelmansenmeijer.nl

PORTUGAL
SÉRVULO & ASSOCIADOS

General

The debate regarding the prohibition or permission of the use and supply of Cannabis has been fuelled by the legalization foreseen for the supply and the use of cannabis for medicinal and recreational uses. Different solutions were adopted across the world. Even in the Europe Union member States the solutions adopted were not harmonized. In fact, Portugal is the third country with approved legislation in this sense, after Uruguay and Canada.

The main concern of legalizing Cannabis drug for all the possible uses, including the recreational use, is linked with the increase of the Cannabis use and serious related side effects, which will have an enormously public health impact.

Notwithstanding, nowadays, national administrations generally oppose the legalization of cannabis for recreational use (and in a few cases even the decriminalization). The medicinal use is allowed if some very specific requirements are fulfilled, and only under certain circumstances. The same applies to Cannabis derived products.

The discussion under decriminalization or legalization of cannabis for recreational use is not over and the direction of this discussion is not still clear, as we will explain below.

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Portugal?

Related to cannabis and its use and commercialization, three fields must be distinguished: - recreational use, industrial use and medicinal use.

Our focus will be essentially on industrial and medicinal use, since the recreational use of cannabis and cannabinoids is forbidden and constitutes a crime.

Additionally, there are two major regimens:

a) For medicines, the Medicines Act apply and they are subject to a MA *(autorização de introdução no Mercado*);
b) For preparations and substances, they are subject to an authorization of market placement (*autorização de colocação no Mercado* - ACM) subject to more specific regulatory framework.

INFARMED, IP (Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.), the national medicines and health products authority – a *Instituto Público* integrated in the Portuguese administration as a part of the so-called indirect administration, subject to supervision (but that may not receive orders) by the Ministry of Health – is the competent regulatory authority in all the *cannabis* regimens.

As it happens with any other medicine for human use, it is mandatory to get a marketing authorization (MA) for the marketing of medicines based on cannabis plant, and the Cannabis legislation determines that the Medicines Act (*Decreto-Lei* no 176/2006) is applicable is all relevant areas. This means that all other legal and regulatory requirements apply, including the ones regarding the use of filing platforms (e.g. Portal SMUH – AIM), filing fees or other administrative costs legislation (e.g. Decree-Law no. 282/95; or https://www.infarmed.pt/documents/15786/2213281/GP_ACMCan%C3%A1bis/8f4e6241-8184-460e-91f1-0ffd0c897a20).

We will mainly focus our attention in the cannabis preparations and substances regimens, which cover the product chain from cultivation to post-market surveillance.

In regard to the industrial use, the regulatory framework is Regulation (*Decreto Regulamentar*) no. 61/94, of 12 of October, on the authorization for the production of hemp, as amended.

As for the medicinal use, the regulatory framework includes (*i*) Law (*Lei*) no. 33/2018 of 18 July, on the use of cannabis for medication, preparations and substances with cannabis for medicinal use, (*ii*) Decree-Law no. 8/2019, of 15 January; (*iii*) Ordinance no. 44-A/2019, of 31 January.

In what concerns to cultivation, manufacture and/or distribution of preparations and substances, the most important requirements to be met may be described as follows:

- The production and supply chain, from planting to distribution, is controlled; an administrative authorization must be obtained at the National Medicines and Health Products Authority (Infarmed, I.P.);
- the MAH (also named TACM – *Titular da Autorização de Colocação no Mercado*) shall maintain updated records of all entries and exits of the plant species;
- INFARMED may set limits on the quantities of substances and preparations to be cultivated, manufactured, subject to wholesale, import and/or export;
- The requests and procedures related to the granting of the authorizations, including for the exercise of the cultivation activity for other non-medicinal purposes, are defined by ordinance of several Government ministries, including the areas of finance, internal administration, justice, health, economics and agriculture;
- The security measures must observe the technical characteristics established in Ordinance no. 273/2013, and the company shall appoint a security officer who fulfils the requirements of the security director category provided for in article 22 of Law no. 34/2013 (Private Security Activity Regime);
- The MAH must comply with all marketing authorization provisions within the Medicines Act;
- The authorization must be renewed annually, under penalty of forfeiture.

Regarding the medicinal use, the marketing of cannabis plant-based preparations and substances is subject to a specific authorization, which is obtained as follows:

- The application is submitted to INFARMED, including all the documentation referred to in article 7 of Decree-Law no. 8/2019;
- INFARMED decides within 90 days and the decision is published in its website;
- After the ACM is granted, its holder shall inform INFARMED of the price to be charged for the preparation of the authorized substance;
- The authorization is valid for a period of 5 years, and after the first renewal may have and undefined duration, unless, for reasons of pharmacovigilance, INFARMED determines that the renewal will be only for 5 years;
- Application for renewal must be submitted with 9 months in advance in relation to the expiration of the period of validity of the initial authorization, under penalty of its expiration at the end of the term;
- The marketing and its interruption date, temporary or definitive, must be communicated to INFARMED.

The holder of the authorization has the obligations set forth in article 12 of Decree-law no. 8/2019, namely to market, ensure the supply and fulfil the pharmacovigilance obligations.

Regarding the price of these products reference is made to Ordinance (*Portaria*) no. 44-A /2019, of 31 of January, that provides the following:

- The price to be practiced is communicated to INFARMED, who will have 15 working days to decide on its adequacy; INFARMED'S silence will correspond to the tacit acceptance of the proposed price;
- INFARMED may oppose the price submitted, when it is disproportionate to the price practiced in the international market, where the said preparation and substance is being marketed;
- The MAH (TACM) is obliged to communicate electronically to INFARMED the commencement of marketing, as well as any decision of suspension or termination of supply to the market.

The application for the marketing authorization, its respective renewal and amendment are subject to the payment fees to INFARMED.

The marketing of preparations and substances is also subject to the payment of the "marketing administrative fee" provided for in Decree-Law no. 282/95 of October 26.

Since even the legalization of cannabis for medicinal uses remains largely a highly controversial issue, the recreational use of cannabis is not legalized, since the legislator is aware of the difficulty in establishing the limits to its use, and above all, aware of the consequences that the use of cannabis may eventually cause, such as traffic accidents, violence and suicide, death by overdose, HIV and Hepatitis, Liver cirrhosis, among others.

However, some legislative initiatives to legalize it, even with clear limitations, have been lodged and as yet did not progress to legislation.

As to the medicinal use of cannabis, Portugal has moved to a system where the medicinal use of cannabis is controlled, with controllable side effects. The legislator must always have in mind the consumption patterns, particularly to detect at an early stage any attempts to buy it unlawfully.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Portugal?

See question no 1.

We highlight the importance of Decree-law no. 8/2019, laying down the principles and objectives regarding prescription, dispensing in pharmacy, detention and transportation, scientific research, information to professionals, as well as regulation and supervision of activities related to the use of the cannabis plant for medicinal purposes were established, and, most important the Decree-Law expedited patient access to treatments using cannabis-based preparations and substances, which had no legal provision, and represented a huge paradigm shift in Portugal.

3. Which body is responsible for legislative controls relating to CBD?

In Portugal, the entity that monitors the application of the legal framework applicable to cannabis and its derivatives, such as CBD, is INFARMED.

Law no. 33/2018 states, in article 2, that all cannabis-based medicines, preparations and substances are subject to authorization by INFARMED.

Article 9 also tasks INFARMED with the regulation and supervision of the cultivation, manufacture, extraction and production, wholesale commerce. Distribution to pharmacies, importations and exportations, traffic, acquisition, sales and deliveries of cannabis-based medicines, preparations and substances. INFARMED is also the body responsible for approving the therapeutic indications of these products.

As explained, INFARMED is also the body responsible for authorizing the practice of the activities of cultivation, manufacture, use, commerce, distribution, importation, exportation, traffic, transport, detention and use of plants, substances or preparations, of the plants, preparations and substances specified in tables I to IV of Decree-Law no. 15/93, pursuant to its articles 2(4) and 4.

Cannabis and cannabis oil are part of Table I-C, and, as such, all activities above are subject to authorization by it.

Even if the activities are pursued under a MA or an ACM approved under Decree-Law no. 8/2019, article 3 of that diploma is clear in demanding the authorization referred in Decree-Law no. 15/93. Non-compliance with this framework constitutes a criminal offence, punishable with up to 12 years of prison, under article 21(1) of Decree-Law no. 15/93.

4. Is there any possibility to commercialize CBD products without a Novel Food approval or medicinal product marketing authorization in Portugal?

No, currently it is impossible to commercialize CBD products without Novel Food approval or a marketing authorization.

Regarding commercialization of food containing CBD, it is important to clarify that it constitutes a novel food for the purposes of Regulation (EU) no. 2015/2338. Given the European Commission's view that CBD is a novel food product, expressed in the Novel Foods Catalogue, an authorization is needed for its commercialization. The authorization is granted by the European Commission, after an Opinion of the European Food Safety Authority, pursuant to article 9 of Regulation no. 2015/2338.

Regarding the commercialization of medicines containing CBD, we recall that, as explained, there is a need for the medicine to have a MA and to comply with the Medicines Act.

Should the product amount to a cannabis-based preparation or substance, article 6 of Decree-Law no. 8/2019, requires a ACM. The procedure to obtain this authorization was introduced in our answer to question 1.

It is important to note that, in addition to these specific authorizations, it is also necessary to obtain the authorization to exercise the activities in question, under Decree-Law no. 15/93 (as explained in question 3).

5. What are the testing specifications in Portugal for determining the compliance of CBD with regulatory requirements (i.e. What are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Under Portuguese legislation, commercialization of CBD products is exceptional and always subject to authorization. The product quality control is centralized on INFARMED.

With regards to cannabis-based medicines, article 15(1)(j) of Decree-Law no. 176/2006 demands the presentation of results from clinical and pre-clinical trials in order to obtain a MA. Under this framework, there are situations where clinical and pre-clinical trial evidence may not be given to INFARMED, namely when there is a well-established clinical use, in the sense of article 20 of the same diploma, which means that the medicine active substances have been in use for a period longer than 10 years with recognized efficiency and an acceptable safety level.

Moving to cannabis-based preparations and substances, article 7 and Annex I of Decree-Law no. 8/2019 state that, in order to obtain a ACM, the applicant must provide INFARMED with the identification of the cannabis-based preparation/ substance which must include, amongst other information, a declaration of its composition and a certificate. It must also present the following documents, aiming at ensuring the quality and safety of the product to be commercialized:

a) Copies of the manufacturing authorization and a certificate of medicines good manufacturing practices (EU and national legislation apply);
b) Declaration by the supplier of the cannabis regarding compliance with the good practices on agriculture and harvest;
c) Certificate regarding the supplier compliance with existing legislation on cultivation of cannabis on its country of origin;
d) For the importation of cannabis-based preparations and substances, a certificate that the manufacture of the preparation or substance complies with the national legislation of the country of origin;
e) Documentation that proves the quality of the cannabis-based preparation or substance, in line with the guidelines applicable to plant-based medicines and preparations published by EMA (European Medicines Agency).

6. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Purchase and importation of CBD is covered by the strict rules of Decree-Law no. 15/93.

Even when the product is intended for medicinal use, article 3 of Decree Law no. 8/2019 still makes the diploma applicable. This means that, similarly to the commercialization of CBD products, the activity is subject to previous authorization by INFARMED, and that purchase and importation with no authorization is a criminal offence, pursuant to article 21.

However, seemingly there is no limit to the quantity of CBD that the authorization may cover. Under article 23 of Regulation no. 61/94, the quantity of the product to import is indicated by the applicant.

Contacts in the firm

Ana Rita Paínho / Miguel Gorjão-Henriques
Partners in *Life Sciences*
Email:arp@servulo.com
Email: mgh@servulo.com

SOUTH KOREA
BARUN LAW

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Korea?

In principle, the NCA strictly prohibits the import/export, manufacture, sale, arrangement of sale, smoking or consumption of cannabis ("prohibited acts"). Furthermore, any person who has not been approved to handle narcotics by the Minister of Food and Drug Safety is prohibited from growing, carrying, possessing, transporting, storing or using cannabis ("handling of cannabis").

However, a person is permitted to engage in the prohibited acts where such act is approved by the Minister of Food and Drug Safety, and the persons designated to handle narcotics can engage in the handling of cannabis if they have obtained a necessary permission under the NCA.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Korea?

As the prohibited acts and the handling of cannabis are strictly prohibited in Korea, the use of cannabis and cannabinoids is unlikely to be allowed for recreational purposes. However, the use of cannabis and cannabinoids may be permitted for medical purposes if certain requirements are met.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Korea?

The NCA considers all products manufactured from cannabis or its resin as "cannabis." Thus, the aforementioned regulations under our responses to Question 1 and 2 also apply to cannabis products.

4. Which body is responsible for legislative controls relating to CBD?

Since the NCA categorises CBD (i.e. cannabidiol) as "cannabis," regulations under our responses to Question 1 and 2 apply to CBD as well. The Ministry of Food and Drug Safety is responsible for legislative controls relating to CBD.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in Korea?

In principle, the act of arranging the import/export, manufacture, trade and sale of cannabis is prohibited in Korea. Commercialisation of CBD products without obtaining an approval may be difficult as such prohibited acts are permitted only upon obtaining an approval from the Minister of Food and Drug Safety for public affairs, academic research or medical purposes.

6. What are the testing specifications in the Korea for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Since handling of CBD is prohibited in principle, there are no testing specifications for determining the compliance of CBD with regulatory requirements.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

In principle, since the act of exporting, importing, selling or purchasing of CBD is prohibited pursuant to the NCA, there is no particular regional limit on the quantity of CBD.

Contacts in the firm

Jang, Joohyoung
Partner
Email: joohyoung.jang@barunlaw.com

Kim, Rieu
Senior Foreign Attorney (Partner)
Email: rieu.kim@barunlaw.com

Jang, Eunjin
Associate
Email: Eunjin.jang@barunlaw.com

Youn, Jihyun
Foreign Attorney (Associate)
Email: jihyun.youn@barunlaw.com

Kwon, Eunyoung
Associate
Email:eunyoung.kwon@barunlaw.com

SPAIN
LÓPEZ-IBOR ABOGADOS

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Spain?

Article 2 of Spanish law 17/1967 of 8th April prohibits the cultivation, production, storage, transportation or distribution in Spain of cannabis and cannabis resin as it is included in Annex 4 of the UN Convention of 1961 on narcotic drugs, which was ratified by Spain on 3rd February 1966. However, the Ministry of Health can authorise cultivation and production for scientific and medical research, including medical testing under official supervision. We consider that in Spanish law the term "cannabis" also includes cannabinoids, without any doubt.

Other relevant legislation is the Royal Legislative Decree 1/2015, which provides that cannabis will be subject to the restrictions derived from the obligations of Spain under the UN Convention with respect to the fight against illegal drug trafficking. Finally, it is worth noting that in Spain cultivation, production, trafficking or facilitating consumption of illegal drugs is both a serious crime and an administrative offence (article 368 of the Criminal Code and article 36 of the Organic Law on the Safety of Citizens).

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Spain?

As explained, the use of cannabis is permitted for medical purposes but always subject to the Ministry of Health´s approval. Regarding recreational use, there is currently in Spain a body of opinion in favour of authorising it under strict conditions. It is worth noting that both the regions of Navarre (Regional law 24/1014) and Catalonia (law 13/2017) have approved legislation applicable in the respective territories permitting the creation of private associations or clubs of cannabis users for consumption in certain premises under strict conditions, as a sort of licensed private bar. However, the Spanish Constitutional Court, in a ruling 144/2017 of 14th December 2017, has declared the legislation unconstitutional as exceeding the competence of the legislative authority of the region of Navarre. A similar decision is to be expected in relation to the Catalan law (Law 13/2017). The basis of the ruling of the Spanish Constitutional Court is that only the central Government has jurisdiction over narcotic drugs.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Spain?

The regulatory framework is dealt under Royal Decree 1194/2011 of 19th August, which regulates the conditions under which a substance can be considered as "drugs" in Spain. It provides for criteria and the administrative process of evaluation.

4. Which body is responsible for legislative controls relating to CBD?

The Ministry of Health of Spain, Paseo del Prado 18, 28014 Madrid.
Telephone: +34915961000

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in Spain?

No, Spanish legislation is very strict.

6. What are the testing specifications in Spain for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

N/A

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

No, except that under Spanish criminal jurisprudence holdings of more than 10 kg of marijuana or 2.5 kg of hashish are material amounts for the purposes of an indictment as a very serious crime under the Spanish Criminal Code (acuerdo del pleno de la Sala 2ª del Tribunal Supremo de 19th Noviembre 2001).

Contacts in the firm

Alfonso López-Ibor Aliño
Partner
Alfonso.lopezibor@l-ia.com

TURKEY
GÜN & PARTNERS

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Turkey?

Turkish law includes provisions in relation to the cannabis plant itself and to delta 9-tetrahydrocannabinol (THC); however, it does not include any provision specific to other cannabinoids. Turkish law considers THC to be a narcotic drug. As there is no regulation on acceptable levels of THC in a substance, any substance containing THC, regardless of its level of concentration, will be considered a narcotic drug as well. Therefore, cannabis is illegal in almost all of its forms (i.e. recreational use of cannabis, smoking cannabis or cannabis products for medicinal purposes) in Turkey.

The Turkish Criminal Code numbered 5237 (TCC) enumerates a series of provisions which regulate the criminal offenses related to the use, trade and possession of narcotic drugs, which also include cannabis. Article 3 of Law No. 2313 on the Supervision of the Narcotic Substances clearly provides that "growing cannabis for the sole purpose of producing marijuana and preparation, importation, exportation and sale of the same are prohibited". Turkey is also a party to the Single Convention on Narcotic Drugs 1961 as amended in 1972, which in turn lists cannabis as a drug as well. The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances dated 1988 is another convention to which Turkey is a party. The Narcotic Drugs Convention, which became an integral part of Turkish Law in 1996, provides under its Article 3 that the signatory states shall enact laws to criminalise cannabis cultivation.

Law No. 2313 also sets forth that narcotic drugs that are listed under Annex I and II of the Narcotic Drugs Convention can only be produced, imported, exported, possessed, sold and bought as per the authorisation of the Ministry of Health. In this regard, the Communiqué on the Importation Monitoring of the Substances Requiring Authorisation from the Ministry of Health numbered 2020/4 regulates this subject.

Finally, it is worth noting that there is a relatively new regulation regarding the production of cannabis plants called the Regulation on the Production and Control of the Cannabis which was published in the Official Gazette on 29th September 2016. The

Regulation lists 19 cities in Turkey where cannabis can be produced under the supervision of the Ministry of Agriculture and Forestry.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Turkey?

As explained above, the production, usage, importation and exportation of cannabis and THC is regulated, with a particular focus on the prohibition and restriction of such plant and that specific cannabinoid. All considered, it is crystal clear that all forms of cannabis are illegal for recreational use in Turkey. One caveat here would be that, as per the Single Convention, cannabis is defined as the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted. Within the context of these provisions, seeds of cannabis and leaves which are not accompanied by cannabis tops are not defined as cannabis and therefore are not subject to the restrictions on narcotic drugs. As an example, cannabis seed oil is sold in Turkey freely.

Secondly, as a general rule, cannabis, as a plant, cannot be used for medicinal purposes; only in cases where THC is used in a pharmaceutical drug and a special licence is provided for that pharmaceutical product by the Ministry of Health under the provisions of the Communiqué can cannabis be used in Turkey.

Needless to say, unauthorised and illegal narcotic drug production and trade are subject to serious criminal sanctions such as being sentenced to imprisonment and judicial fine under the TCC, unless there is a provision of law which allows for such activities.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Turkey?

Please refer to our response under Question 1 above.

4. Which body is responsible for legislative controls relating to CBD?

As indicated, there is no legislation regulating cannabinoids apart from THC (such as CBD) in Turkey at present, and therefore no Turkish authority is directly involved in legislative controls relating to CBD. However, the Ministry of Health is responsible for importation, exportation and local sales of narcotic drugs in general, which also covers

THC and/or CBD which is extracted from the flowering or fruiting tops of the cannabis plant, whereas the Ministry of Agriculture and Forestry is responsible for production of cannabis in Turkey.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in Turkey?

N/A since there is currently no legislation in Turkey regulating CBD. However, considering that Turkish legislation is very strict regarding cannabis plants and THC, we do not think that commercialising CBD products would be possible without some sort of approval from official authorities in Turkey.

6. What are the testing specifications in Turkey for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

As mentioned above, Turkish law does not allow any level of THC to be included in any substance, nor does it contain any provision specific to CBD. As a result, there is no testing specification for determining the purity and/or level of any controlled substances in CBD. Where there is any suspicion that a product (e.g. CBD) contains any level of THC, it should be evaluated as a narcotic drug as per the Law No. 2313 in light of our above explanations.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

As there is currently no legislation relating to CBD, regional limits on the quantity of CBD that can be purchased or imported are not regulated in Turkey. Nevertheless, THC and cannabis are considered narcotic drugs and their importation or local sales are subject to the authorisation of the Ministry of Health.

Contacts in the firm

Pelin Baysal
Partner
Email: Pelin.Baysal@gun.av.tr

Cansu Akbıyıklı
Senior Associate
Email: cansu.akbiyikli@gun.av.tr

UNITED KINGDOM
MISHCON DE REYA

This summary represents the cannabis and cannabis derived products regulatory framework in the UK as of 3rd July 2020.

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in the UK?

Medicinal:

Where CBD is used for medicinal purposes, such product will constitute a "medicine" and will therefore need to be subject to an MHRA licence, unless subject to a possible exemption. MHRA Guidance Note 8 includes a useful appendix on CBD-containing products. Marketers without a licence must not make medicinal claims in advertisements for products containing CBD.

The Misuse of Drugs (Amendments) (Cannabis and Licence Fee) (England, Wales and Scotland) Regulations 2018 became law on 1st November 2018. Under the regime which was implemented as an amendment to the Misuse of Drugs Act, where a CBD medicinal product is not subject to a marketing authorisation granted by the MHRA, it can only be prescribed by a specialist doctor on the General Medical Council's specialist register, and general practitioners are unable to prescribe it. Additionally, medical cannabis can only be prescribed when there is an "exceptional clinical need". How each specialist will interpret this remains to be seen, but the intention is that medical cannabis should not be prescribed unless established alternative treatments have proved to be ineffective in a particular case. If the doctors do not meet these criteria and prescribe medical cannabis which contains any THC, they risk committing a criminal offence under the Misuse of Drugs Act.

While specialists have a wide discretion on what products they prescribe, clinicians will not be permitted to prescribe the smoking of the cannabis product. The new law has met resistance from doctors, particularly those specialising in pain relief, and the debate over the overall efficacy and long-term safety profile of medical cannabis continues.

Non-medicinal:

In January 2019, the European Commission categorised CBD extracts as a "novel food" in the Novel Foods Catalogue, under Regulation (EU) 2015/2283. The UK's Food Standards Agency subsequently accepted the Commission's position. This means that businesses looking to sell CBD ingestibles in the UK must submit an application to the European Commission and the European Food Safety Authority (EFSA) by 31 March 2021 for approval to sell their CBD products in the UK.

The Advertising Standards Authority (ASA), regulating UK adverts, has stated that it understands that CBD products tend to be either medicines or food, and will regulate the CBD products accordingly.

Local trading standards authorities and local authorities also monitor the sale of CBD products both prior to and after the 31st March 2021 deadline and can remove any offending CBD products.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in the UK?

While the development in the law for medical cannabis is in some ways positive, the implementation leaves much to be desired. There is concern over the restrictiveness of the regime, as medical cannabis can only be prescribed by specialist doctors and for exceptional clinical need. While the caution of the Government is understandable, there is an argument that this does not reflect the new reality. Following the announcement by the Chief Medical Officer that there was evidence of the therapeutic benefit of medical cannabis, it is believed that sales of (at least) CBD oil have risen significantly. If people are unable to gain access to medical cannabis, the speculation is that they will look to self-medicate by obtaining products from unregulated sources, of which there are many, with unproven manufacturing standards and formulation.

If a novel food is liable to have an effect on human health, the Commission will request the EFSA to carry out a risk assessment as part of assessing the novel food application. We anticipate that this will be the case for CBD, given the reported issues surrounded the health effects of CBD. This means that a large body of information, including safety assessments, will be required in order to make a novel food application.

Each novel food application and approval subsequently granted is for a particular CBD product only, and, as such, applications cannot be reused for similar products. A novel food applicant may also request confidentiality over its application which, if granted, would mean that key aspects of its research evidence base are confidential and unavailable to others for five years. Therefore, other manufacturers cannot rely on the application even if their CBD products are bioequivalent.

There is very limited guidance available from the European Commission and the EFSA on what is required for novel food applications, which may make gaining approval very challenging.

In addition, whilst the UK has left the European Union, the UK remains in the transition phase and so the obligation to submit the novel foods application to the Commission continues until 31st December 2020. The FSA will take over novel food applications from 1st January 2021.

We anticipate that unless there is a very significant level of collaboration between producers of CBD products to meet the safety assessment requirements, many of the current CBD products on the market will cease to be available.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in the UK?

Please refer to Question 1.

4. Which body is responsible for legislative controls relating to CBD?

A Home Office licence is currently required to import, export, produce, supply or possess CBD products which contain even a trace of THC. See above.

As mentioned above, where CBD is used for medicinal purposes, it will be subject to an MHRA licence unless subject to a possible exemption. Where a CBD medicinal product is not subject to an MHRA licence, it can only be prescribed by a consultant and for exceptional clinical need.

As noted above, the UK's FSA have aligned with the Commission's position: CBD is a novel food and must be regulated as such and be the subject of a novel food application.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in the UK?

CBD-infused cosmetic products are readily available for sale in the UK, particularly within the wellness and natural beauty sectors. Provided the CBD ingredient is not sourced from the flowering or fruiting tops of the cannabis plant and does not contain any THC, CBD can be used in cosmetics in the UK market.

Until 31st March 2021, businesses will be permitted to sell their existing CBD ingestibles without novel food approval, provided that they are not incorrectly labelled, are not unsafe to eat and do not contain any substances which fall under drug legislation. Local trading standards authorities and local authorities can monitor these CBD products and remove them from sale if they fail to meet these requirements. After 31st March 2021, only those CBD products which are the subject of a novel food application will be permitted to remain on sale.

There is little regulation of CBD vapes save that CBD vapes must comply with the General Product Safety Regulations 2005, which is a broad umbrella regulation that requires all products to be safe in their normal and foreseeable usage. We do not expect this lacuna in regulation to continue.

6. What are the testing specifications in the UK for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Under the Misuse of Drugs Regulations 2001, if certain criteria are fulfilled, “exempt product” status allows up to 1 mg of a controlled substance within a product container without it being rendered illegal. The Home Office has clarified that it considers "container" to mean bottle or packet and not per dose. However, the Home Office position remains that, if CBD contains any THC, a Home Office licence is nonetheless required.

Given that cannabis is a controlled substance in the UK, the 1 mg threshold also applies to all cannabis products.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Not that we are aware of.

Contacts in the firm

Martyn Hann
Partner and Head of the Life Sciences Group
Email: Martyn.hann@mishcon.com

Oliver Felton
Legal Director – Dispute Resolution
Email: Oliver.Felton@mishcon.com

Stefania Littleboy
Managing Associate - Life Sciences
Email: Stefania.littleboy@mishcon.com

Emily Dorotheou
Associate – Commercial
Email: Emily.dorotheou@mishcon.com

Raina Singh
Indian Qualified Lawyer – Intellectual Property
Email:Raina.singh@mishcon.com

UKRAINE
ASTERS

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Ukraine?

According to the Resolution of the Cabinet of Ministers of Ukraine on Approval of the List of Drugs, Psychotropic Substances and Precursors No. 700, dated 6th May 2000, as amended, cannabis is defined as a dangerous drug, circulation of which, including cultivation, manufacturing and/or distribution, is prohibited except for cultivation of cannabis for specific industrial purposes, provided that seeds are collected from dried straw of cannabis containing 0.08% or less tetrahydrocannabinol (so-called "industrial cannabis").

Illegal manufacture, purchase or transfer of dangerous drugs (including cannabis) (a) intended for distribution leads to criminal liability in the form of imprisonment for up to 12 years with confiscation of assets (provided that a person who voluntarily surrendered drugs and disclosed the source of their acquisition or helped in investigation of relevant offences is released from criminal liability) and (b) without intent of distribution may lead to the following types of criminal liability (provided that an addicted person who voluntarily surrendered to a medical clinic for treatment is released from criminal liability):

(i) fine in the amount of up to UAH 85,000 (approximately €2,768);
(ii) corrective labour for up to 2 years;
(iii) arrest for up to 6 months; or
(iv) restraint of freedom for up to 5 years (imprisonment for up to 8 years in case of repeated offence or substances in large amounts).

Planting cannabis in the amount from 10 to 50 pieces may lead to a fine in the amount of up to UAH 8,500 (approximately €280), arrest for up to 6 months or restraint of freedom for up to 3 years (imprisonment for up to 7 years in case of repeated or group offence or quantities exceeding 50 plants).

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Ukraine?

Despite the benefits of the medical and recreational use of cannabis, the biggest challenge regarding the use of cannabis and cannabinoids for medical and recreational purposes is the current inclusion of cannabis on the list of dangerous drugs the use of which is illegal in Ukraine. Only exclusion from the list of dangerous drugs may open a path for its legal use in Ukraine.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Ukraine?

The use of cannabis is currently illegal in Ukraine except for certain industrial purposes. In 2019 a bill legalising the use of cannabis for medical purposes was submitted to the Parliament of Ukraine. However, the bill has been subsequently revoked.

4. Which body is responsible for legislative controls relating to CBD?

The Parliament of Ukraine is responsible for the adoption of new, and the amendment of existing, laws and regulations applicable to the use of cannabis.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in Ukraine?

It is not possible to commercialise CBD products, except for the industrial cannabis, unless a new regulation is adopted by the Parliament of Ukraine.

6. What are the testing specifications in Ukraine for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

A special licence is required for cultivation of industrial cannabis. The licence requirements are established in the Regulation of the Cabinet of Ministers of Ukraine No. 282, dated 6th April 2016.

Cultivation of industrial cannabis is subject to state control. There are special expert organisations authorised to inspect plants to determine the level of any controlled substances in industrial cannabis. Samples of plants for testing are collected by a representative of the expert organisation during blooming season. As a rule, such organisations issue an expert opinion on the results of testing. The regulatory authority should be informed on such testing results within 10 business days.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

It is illegal to purchase or import any quantity of CBD.

Contacts in the firm

Armen Khachaturyan
Senior Partner
Email: armen.khachaturyan@asterslaw.com

URUGUAY
HUGHES & HUGHES

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Uruguay?

The cannabis legal framework in Uruguay is mainly formed by the Cannabis Act and its regulatory decrees, among others of significance. Below I point out the main regulations:

- Law 19,172 of 2013 (Cannabis Act)
- Law 19,845 of 2019 (cannabis for scientific purposes)
- Law 19,847 of 2019 (right to access medical cannabis)
- Decree 324/1999 (non-registered products imports)
- Decree 120/2014 (recreational cannabis regulation)
- Decree 372/2014 (hemp regulation)
- Decree 46/2015 (medical cannabis regulation)
- Decree 128/2016 (cannabis and employment)
- Decree 298/2017 (commercialisation of pharmaceuticals with CBD)
- Decree 214/2020 (psychoactive cannabis exports)
- Decree 215/2020 (non-psychoactive cannabis exports)

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Uruguay?

Challenges are and were several, some of which are still to be overcome. To name a few: cannabis industry access to banking, local regulation correlation with international agreements on the subject, cannabis product access, control and compliance, stakeholder education on the subject (from doctors to policemen), etc.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Uruguay?

See answer to Question 1 for main regulation. However, other regulations, resolutions and instructions issued by the corresponding bodies may also apply (for example, Decree 403/2016 related to herbal medicines).

4. Which body is responsible for legislative controls relating to CBD?

IRCCA (Institute for Cannabis Regulation and Control)

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in Uruguay?

No, commercialisation of CBD products needs to be registered with the Ministry of Health in order to be commercialised in Uruguay.

6. What are the testing specifications in Uruguay for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Testing specifications depend on the product. For example, in the case of CBD seeds a phytosanitary certificate with a specific "free of pests" declaration is required.

To determine the percentage of CBD (as well as THC) in Uruguay, tests must be carried out by laboratories authorised by the IRCCA, using analytical techniques approved by this body. Such lab results would serve as evidence of the percentage of CBD in the product.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Uruguay's regulation does not specify a limit on quantity. The amount to be purchased or imported to Uruguay depends on that approved or indicated by the competent authority case by case.

For example, patients who want to purchase a registered CBD medical product in Uruguay need a prescription from a locally registered physician. Companies wanting to import CBD products need an import permit that requires the authorisation of our Ministry of Health or Ministry of Livestock and Agriculture, depending on the product.

Contacts in the firm

Lucia Patron
Senior Associate Lawyer
Email: lpatron@hughes.com.uy

U.S.A. - CALIFORNIA
BELL NUNNALLY

General

The California Department of Food and Agriculture (CDFA) regulates the production and distribution of industrial hemp in the state. The CDFA regulates the cultivation of cannabis in the state and issues licences for same. The Bureau of Cannabis Control (BCC) regulates the commercial distribution and sale of cannabis in the state, as well as certain licensure requirements. Additionally, the California Department of Public Health (CDPH) regulates the labelling and certain licensure requirements for cannabis in the state. CDPH also issues licences for purchase and use of medicinal marijuana.

Use and possession of medicinal cannabis and medicinal cannabis products is legal for patients with valid physician's recommendations and medicinal cannabis card. Possession of medicinal cannabis and transportation of same is also legal for a primary caregiver of a cardholder. For adults aged 21 and over, use and possession of cannabis and adult-use cannabis products is legal. Retail sale and distribution of cannabis and adult-use cannabis products is legal with the proper licence, but certain specific requirements (e.g., the products cannot be mixed with alcohol and must leave the store in an opaque container) apply. Distribution of medicinal cannabis is limited to medicinal cannabis cooperatives, collectives, dispensaries, operators, establishments and providers.

California is also subject to federal law (covered in the "US – Federal" summary).

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in the state?

California law and federal law each impose regulations on the cultivation, manufacture, distribution and use of cannabis and cannabinoids in California. Practitioners should refer to the state and federal criminal laws regulating sale, distribution and use of scheduled substances, particularly as they relate to non-adult use or distribution.

Practitioners should also be aware that California regulates different substances containing cannabinoids differently; in particular, California law defines and regulates

"industrial hemp," "cannabis," and "medical cannabis" separately. "Industrial hemp" or "hemp" means an agricultural product, whether growing or not, that is limited to types of the plant Cannabis sativa L. and any part of that plant, including the seeds of the plant and all derivatives, extracts, the resin extracted from any part of the plant, cannabinoids, isomers, acids, salts and salts of isomers, with a delta-9 tetrahydrocannabinol concentration of no more than 0.3% on a dry weight basis. 24 Cal. Food & Agricultural Code § 81000(a)(6).

"Cannabis" means all parts of the plant Cannabis sativa Linnaeus, Cannabis indica or Cannabis ruderalis, whether growing or not; the seeds thereof; the resin, whether crude or purified, extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or resin. "Cannabis" also means the separated resin, whether crude or purified, obtained from cannabis. "Cannabis" does not include the mature stalks of the plant, fibre produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture or preparation of the mature stalks (except the resin extracted therefrom), fibre, oil or cake, or the sterilised seed of the plant which is incapable of germination, and it excludes items meeting the definition of industrial hemp. Cal. Bus. Code § 26001(f). Cannabis can be sold for recreational use under California law, though federal law still prohibits this, and the federal Food and Drug Administration still does not recognise any cannabis-containing products as safe for human consumption.

"Medicinal cannabis" or "medicinal cannabis product" means cannabis or a cannabis product, respectively, intended to be sold or donated for use pursuant to the Compassionate Use Act of 1996 (Proposition 215), found in Section 11362.5 of the Health and Safety Code, by a medicinal cannabis patient in California who possesses a physician's recommendation, or in compliance with any compassionate use, equity or other similar programme administered by a local jurisdiction. Cal. Bus. Code § 26001(ai)(1).

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in the state?

Other than the conflict with federal law, there are few regulatory challenges in California in allowing the medical and recreational use of cannabis and cannabinoids. Practitioners should ensure clients are complying with the intricate state laws authorising use, production and distribution, however.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in the state?

See Questions 1 and 2.

4. Which body is responsible for legislative controls relating to CBD?

See Question 1.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in the state?

See Question 1. At the federal level, the Food and Drug Administration governs approval of ingestible products like food, as well as medicinal products. The Food and Drug Administration has not yet permitted commercialisation of CBD-containing products in the United States other than prescription drug Epidiolex, which is used to treat seizures.

6. What are the testing specifications in the state for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

In light of the many injuries and deaths attributed to vaping in the United States in 2018 and 2019, California began imposing strict testing requirements on all cannabis harvested or made into products within the state, whether or not it will take or has taken the form of an inhalable product. California now requires testing of at least the following contents of cannabis in the state: cannabinoids, terpene content, mycotoxins and heavy metals, in addition to moisture content, residual solvents, pesticides and microbial impurities.

In order to qualify as "industrial hemp" in California, a product must have delta-9 tetrahydrocannabinol concentration of no more than 0.3% on a dry weight basis. Anyone growing, transporting, purchasing or otherwise obtaining the industrial hemp must have and retain the laboratory test results demonstrating compliance with the concentration requirements.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Yes. Adults may possess approximately 28.5 grams of dry-weight cannabis or up to 8 ounces of cannabis concentrate (hashish). Non-adults may not possess cannabis or any products derived therefrom.

Contacts in the firm

Karen L. Hart
Partner, Bell Nunnally & Martin, LLP
Email: khart@bellnunnally.com

Ira Perez
Associate, Bell Nunnally & Martin, LLP
Email: iperez@bellnunnally.com

Troy Hales
Associate, Bell Nunnally & Martin, LLP
Email:thales@bellnunnally.com

U.S.A. - COLORADO
BELL NUNNALLY

General

The Colorado Department of Agriculture (CDA) regulates the cultivation of industrial hemp in the state. The Colorado Department of Public Health and Environment (CDPHE) has regulatory authority over processing and processed hemp materials and hemp products.

Use and possession of medicinal cannabis and medicinal cannabis products is legal for patients with the written approval of a physician. Medical cannabis is legal for use by minors with parental consent. For adults aged 21 and over, use and possession of cannabis and adult-use cannabis products is legal. Retail sale and distribution of cannabis and adult-use cannabis products is legal and is regulated much like alcohol in the state.

Colorado is also subject to federal law (covered in the "US – Federal" summary).

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in the state?

In Colorado, "industrial hemp" or "hemp" means "the plant Cannabis sativa L. and any part of the plant, including the seeds of the plant and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of no more than three-tenths of one percent on a dry-weight basis."

The CDA administers the state's industrial hemp programme, which regulates only the cultivation of industrial hemp. CDPHE regulates processing of hemp and processed hemp materials and hemp products.

The manufacturing of an industrial hemp or hemp product must comply with Colorado's Food and Drug Act. HB 18-1295 (passed in 2018) which defines an "industrial hemp product" as "a finished product containing industrial hemp" that "Is a cosmetic, food,

food additive, or herb"; "Is for human use or consumption"; "Contains any part of the hemp plant, including naturally occurring cannabinoids, compounds, concentrates, extracts, isolates, resins, derivatives"; and "Contains a delta-9 tetrahydrocannabinol concentration of no more than three-tenths of one percent." CRS § 35-61-101.

"Marijuana"/"marihuana", on the other hand, is regulated depending on whether it is meant for medicinal or recreational use. "Marijuana" means all parts of the plant of the genus cannabis whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or its resin, including marihuana concentrate. "Marijuana" does not include industrial hemp, nor does it include fibre produced from the stalks, oil or cake made from the seeds of the plant, sterilised seed of the plant which is incapable of germination, or the weight of any other ingredient combined with marijuana to prepare topical or oral administrations, food, drink or other product. COLO. CONST. Article XVIII, § 16.

Medical marijuana has been legal in Colorado since 2001. With the written approval of a physician, patients can possess up to two ounces of a "usable form of marijuana" (i.e. the plant/bud but excluding stalks, stems and roots) and six cannabis plants. Colorado's medical marijuana law expands legal access to minors, provided they have parental consent. As of June 2016, schools in Colorado are required to allow students access to medical cannabis while on school grounds after Governor John Hickenlooper signed "Jack's Law."

Recreational marijuana: Colorado voters adopted an amendment to the state constitution in 2012 permitting the sale and use of marijuana by persons 21 years of age or older. The amendment provides for regulation of marijuana in a manner similar to the sale and use of alcohol.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in the state?

Other than the conflict with federal law, there are few regulatory challenges in Colorado in allowing the medical and recreational use of cannabis and cannabinoids. Practitioners should ensure clients are complying with the state laws authorising use, production and distribution, however.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in the state?

See Questions 1 and 2.

4. Which body is responsible for legislative controls relating to CBD?

See Question 1.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in the state?

See Question 1. At the federal level, the Food and Drug Administration governs approval of ingestible products like food, as well as medicinal products. The Food and Drug Administration has not yet permitted commercialisation of CBD-containing products in the United States other than prescription drug Epidiolex, which is used to treat seizures.

6. What are the testing specifications in the state for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Colorado requires that both medical and recreational marijuana be tested for various microbials. If the marijuana incorporates a solvent-based concentrate, it must also be tested for levels of butane and other solvents. Certain other marijuana products must be tested for heavy metals. All cannabis must be tested for potency.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Yes. Adults may possess approximately 28 grams of dry-weight cannabis for recreational use. Non-adults generally may not possess cannabis or any products derived therefrom, unless it is medical marijuana, in which case children may possess it with their guardian's permission.

Contacts in the firm

Karen L. Hart
Partner, Bell Nunnally & Martin, LLP
Email: khart@bellnunnally.com

Ira Perez
Associate, Bell Nunnally & Martin, LLP
Email: iperez@bellnunnally.com

Troy Hales
Associate, Bell Nunnally & Martin, LLP
Email:thales@bellnunnally.com

U.S.A. - FLORIDA
BELL NUNNALLY

General

The Florida Department of Agriculture and Consumer Services, in consultation with the Florida Department of Law Enforcement, regulates cultivation of hemp in the state. Persons may sell or distribute hemp extract in the state so long as certain labelling, certification, and quality control requirements are met. No licence for hemp cultivation is required currently. Persons may also produce and/or sell pet food containing hemp extract if they meet certain registration requirements. Hemp-based CBD may be sold and used for topical use so long as the product complies with federal Food and Drug Administration regulations.

Florida is also subject to federal law (covered in the "US – Federal" summary).

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in the state?

Florida law and federal law each impose regulations on the cultivation, manufacture, distribution and use of cannabis and cannabinoids in Florida. Practitioners should refer to the state and federal criminal laws regulating sale, distribution and use of scheduled substances, particularly as it relates to non-adult use or distribution.

Practitioners should also be aware that, while Florida permits cultivation, distribution, sale and use of hemp and hemp extract, it disallows cultivation, distribution, sale and use of marijuana. "Hemp" means Cannabis sativa L. or any part of the plant with a total delta-9-tetrahydrocannabinol concentration of 0.3 or less (dry-weight). FLA. STAT. ANN. § 581.217(3)(d). "Hemp extract" is "a substance or compound intended for ingestion that is derived from or contains hemp and that does not contain other controlled substances." FLA. STAT. ANN. § 581.217(3)(e). Either of these substances with any greater tetrahydrocannabinol concentration is considered a controlled substance in Florida.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in the state?

In addition to the restrictions imposed by federal law, there are extensive regulatory challenges in Florida preventing the medical and recreational use of cannabis and cannabinoids. Practitioners should ensure clients are aware that recreational use of cannabis is prohibited in Florida. Practitioners should ensure clients are aware that medical use of cannabis is restricted. In particular, only licensed dispensaries may distribute medical cannabis in Florida, and only persons who have been authorised to use medical cannabis may do so. Further, they may only do so in certain places. Use of medical cannabis in public, for example, may subject the user to criminal penalties.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in the state?

See Questions 1 and 2.

4. Which body is responsible for legislative controls relating to CBD?

See Question 1. Additionally, the Department of Business and Professional Regulation has authority to regulate a retail establishment's distribution and/or sale of CBD.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in the state?

See Question 1. At the federal level, the Food and Drug Administration governs approval of ingestible products like food, as well as medicinal products. The Food and Drug Administration has not yet permitted commercialisation of CBD-containing products in the United States other than prescription drug Epidiolex, which is used to treat seizures.

6. What are the testing specifications in the state for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Hemp transported in Florida must be accompanied by a bill of lading or other documentation with the following details: (1) name and address of shipper or consignor; (2) name and physical address of receiver or consignee; (3) description of plants or plant products in shipment;(4) place and state of origin; (5) ultimate destination of shipment if different than receiver or consignee; and (6) a copy of origin hemp cultivation licence number. The hemp must be shipped in a fully enclosed container.

Further, if the hemp is unprocessed, it must be accompanied by a certificate of analysis showing the total THC delta 9. The formula used in Florida is THCA x .8777 + THC delta 9 = total THC delta 9. Unprocessed hemp plant material must be transported frozen or dried. If the hemp is processed, it must be accompanied by a certificate of analysis showing the total THC delta 9. The formula used in Florida is THCA x .8777 + THC delta 9 = total THC Delta 9, and it must be rendered nonviable.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Yes. Non-adults may not possess cannabis or any products derived therefrom.

Contacts in the firm

Karen L. Hart
Partner, Bell Nunnally & Martin, LLP
Email: khart@bellnunnally.com

Ira Perez
Associate, Bell Nunnally & Martin, LLP
Email: iperez@bellnunnally.com

Troy Hales
Associate, Bell Nunnally & Martin, LLP
Email:thales@bellnunnally.com

U.S.A. - GEORGIA
BELL NUNNALLY

General

The Georgia Department of Agriculture, in consultation with Georgia law enforcement, regulates cultivation of hemp in the state. Persons may sell or distribute hemp in the state so long as they are licensed to do so. Persons may also produce and/or sell hemp or hemp products in a retail establishment, but they may not produce or sell any food, pet food or dietary supplement products containing hemp. Low-THC cannabis oil is permitted in certain very limited circumstances.

Georgia is also subject to federal law (covered in the "US – Federal" summary).

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in the state?

Georgia law and federal law each impose regulations on the cultivation, manufacture, distribution and use of cannabis and cannabinoids in Georgia. Practitioners should refer to the state and federal criminal laws regulating sale, distribution and use of scheduled substances, particularly as it relates to non-adult use or distribution.

Practitioners should also be aware that, while Georgia permits cultivation, distribution, sale and use of hemp and low-THC oil, it disallows cultivation, distribution, sale and use of marijuana. "Hemp" is Cannabis sativa L. or any part of the plant with a total delta-9-tetrahydrocannabinol concentration of 0.3 or less (dry-weight). GA. CODE § 2-23-3(3), (5). "Low THC cannabis oil" is "an oil that contains not more than 5 percent by weight of tetrahydrocannabinol and an amount of cannabidiol equal to or greater than the amount of tetrahydrocannabinol." GA. CODE § 16-12-190. Either of these substances with any greater tetrahydrocannabinol concentration is considered a controlled substance in Georgia.

Persons may cultivate, handle or process hemp in the jurisdiction only after receiving a licence from the Georgia Department of Agriculture in consultation with Georgia law enforcement. GA. CODE §§ 2-23-4(a); 2-23-5 through -7. A person may sell hemp or hemp products at a retail establishment in Georgia, but the Georgia Department of Agriculture

still prohibits the use of CBD oil in food, pet food and dietary supplements. See Ga. Admin. Code 40-32-3-.09. Georgia provides no clear guidance on whether topical hemp-based CBD products may be sold, possessed or used.

The Georgia Department of Public Health issues permits to certain persons who register to possess low-THC cannabis oil. Only licensed dispensaries (pharmacies) may sell or distribute such oil to patients who hold a low-THC registry card, and patients may only possess up to 20 ounces of the oil at any given time. See GA. CODE § 16-12-191.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in the state?

In addition to the restrictions imposed by federal law, there are extensive regulatory challenges in Georgia preventing the medical and recreational use of cannabis and cannabinoids. Practitioners should ensure clients are aware that recreational use of cannabis is prohibited in Georgia. Practitioners should ensure clients are aware that medical use of cannabis is restricted as indicated above (regarding low-THC cannabis oil).

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in the state?

See Questions 1 and 2.

4. Which body is responsible for legislative controls relating to CBD?

See Question 1.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in the state?

See Question 1. At the federal level, the Food and Drug Administration governs approval of ingestible products like food, as well as medicinal products. The Food and Drug Administration has not yet permitted commercialisation of CBD-containing products in the United States other than prescription drug Epidiolex, which is used to treat seizures.

6. What are the testing specifications in the state for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Hemp produced or transported in Georgia is subject to inspection and sampling. Georgia's regulations require that the Georgia Department of Agriculture "conduct laboratory testing on official samples to determine the THC concentration on a dry weight basis utilizing modern scientific methods of liquid or gas chromatography for analysis" and that the Department provide each licensee information about the results. GA. DEPT OF AGRICULTURE R. 40-32-2-.05.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Yes. Non-adults may not possess cannabis or any products derived therefrom.

Contacts in the firm

Karen L. Hart
Partner, Bell Nunnally & Martin, LLP
Email: khart@bellnunnally.com

Ira Perez
Associate, Bell Nunnally & Martin, LLP
Email: iperez@bellnunnally.com

Troy Hales
Associate, Bell Nunnally & Martin, LLP
Email:thales@bellnunnally.com

U.S.A. - LOUISIANA
BELL NUNNALLY

General

The Louisiana Department of Health, in conjunction with Louisiana Alcohol and Tobacco Control (ATC) and the Louisiana Department of Agriculture & Forestry, regulates cultivation of industrial hemp in the state. Persons may sell or distribute industrial hemp and hemp-derived products in the state so long as they are licensed to do so. Persons may also produce and/or sell hemp or hemp products in a retail establishment, but they may not produce or sell any food, pet food or dietary supplement products containing hemp.

Louisiana is also subject to federal law (covered in the "US – Federal" summary).

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in the state?

Louisiana permits industrial hemp growing, processing and transportation. Carriers, growers and processors must obtain a licence from the Louisiana Department of Agriculture and Forestry before engaging in any of these activities.

It also permits retailers to apply for a permit to sell "hemp-derived product[s] that contain[s] CBD intended for consumption or topical use." The permit covers individual retail spaces, so the retailer must apply for a permit for each physical place of business or physical address from which online orders are shipped. The commissioner of the ATC issues permits.

Each product line must be registered with the Louisiana Department of Health. The Department of Health examines the labels on the products to ensure compliance with its rules and regulations. The retailer may circumvent these requirements if the product's manufacturer already has completed this process.

As part of seeking a permit, a retailer must agree to allow the Louisiana ATC to inspect upon request the place or places where the CBD products are stored, shipped or sold. Further, the retailer may not give any CBD product away for free, unless the retailer does

so at the physical place or places of business registered with the Louisiana ATC. A retailer may not sell or distribute CBD products through a vending machine.

Louisiana State University and Southern University are the only authorised growers of medical marijuana in Louisiana and are established as such by statute. The Louisiana Board of Pharmacy has authority to license entities to dispense medical marijuana. The acceptable forms of medical marijuana are oils, extracts, tinctures, sprays, capsules, pills, solutions, suspension, gelatin-based chewables, lotions, transdermal patches and suppositories. It cannot be smoked or possessed in its raw form. See LA. REV. STAT. § 40:1046.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in the state?

In addition to the restrictions imposed by federal law, there are extensive regulatory challenges in Louisiana preventing the medical and recreational use of cannabis and cannabinoids. Practitioners should ensure clients are aware that recreational use of cannabis is prohibited in Louisiana. Practitioners should ensure clients are aware that medical use of cannabis is restricted. In particular, only patients with a licence to obtain medical cannabis in the state may obtain the substance from state-licensed dispensaries. The patient may possess a maximum of a 30-day supply of medical cannabis at any given time.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in the state?

See Questions 1 and 2.

4. Which body is responsible for legislative controls relating to CBD?

See Question 1.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in the state?

See Question 1. At the federal level, the Food and Drug Administration governs approval of ingestible products like food, as well as medicinal products. The Food and Drug Administration has not yet permitted commercialisation of CBD-containing products in the United States other than prescription drug Epidiolex, which is used to treat seizures.

6. What are the testing specifications in the state for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Hemp produced in or transported into Louisiana must have a label containing a hyperlink, QR code or other similar access portal linking to a certificate of analysis for the product. The certificate of analysis must contain the following information: "(1) The batch identification number, date received, date of completion, and the method of analysis for each test conducted. (2) Test results identifying the cannabinoid profile by percentage of dry weight, solvents, pesticides, microbials, and heavy metals."

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Yes. Non-adults may not possess cannabis or any products derived therefrom. See also Question 2.

Contacts in the firm

Karen L. Hart
Partner, Bell Nunnally & Martin, LLP
Email: khart@bellnunnally.com

Ira Perez
Associate, Bell Nunnally & Martin, LLP
Email: iperez@bellnunnally.com

Troy Hales
Associate, Bell Nunnally & Martin, LLP
Email:thales@bellnunnally.com

U.S.A. - NEBRASKA
BELL NUNNALLY

General

The Nebraska Department of Agriculture, in conjunction with Nebraska law enforcement, regulates cultivation of hemp in the state. Persons may sell or distribute hemp in the state so long as they are licensed to do so. There is no express regulation on "finished hemp products" in the state, so it is unclear whether the sale of such products is legal.

Nebraska is also subject to federal law (covered in the "US – Federal" summary).

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in the state?

Nebraska defines "hemp" as "the plant Cannabis sativa L. and any part of such plant, including the viable seeds of such plant and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." NE HEMP FARMING ACT § 2-503(11). Nebraska requires that growers of hemp in the state obtain a licence from the Department of Agriculture. The Act does not define what constitutes a "finished hemp product," but the Department has indicated it does not regulate such products. The Act also requires that "brokers" (those "who engage or participate in the marketing of hemp by acting as an intermediary or negotiator between prospective buyers and sellers") and "processors" (those who "convert hemp into a marketable form") obtain licences. NE HEMP FARMING ACT § 2-506.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in the state?

In addition to the restrictions imposed by federal law, there are extensive regulatory challenges in Nebraska preventing the medical and recreational use of cannabis and cannabinoids. Practitioners should ensure clients are aware that recreational use of cannabis is prohibited in Nebraska. Practitioners should ensure clients are aware that

medical use of cannabis is prohibited in Nebraska. Currently, however, grassroots organisers have attempted through a ballot initiative to legalise medical cannabis.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in the state?

See Questions 1 and 2.

4. Which body is responsible for legislative controls relating to CBD?

See Question 1.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in the state?

See Question 1. At the federal level, the Food and Drug Administration governs approval of ingestible products like food, as well as medicinal products. The Food and Drug Administration has not yet permitted commercialisation of CBD-containing products in the United States other than prescription drug Epidiolex, which is used to treat seizures.

6. What are the testing specifications in the state for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Hemp produced or located in Nebraska must be tested "using post-decarboxylation or other similarly reliable methods for the testing of delta-9 tetrahydrocannabinol concentration." NE HEMP FARMING ACT § 2-514.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Yes. Non-adults may not possess cannabis or any products derived therefrom.

Contacts in the firm

Karen L. Hart
Partner, Bell Nunnally & Martin, LLP
Email: khart@bellnunnally.com

Ira Perez
Associate, Bell Nunnally & Martin, LLP
Email: iperez@bellnunnally.com

Troy Hales
Associate, Bell Nunnally & Martin, LLP
Email:thales@bellnunnally.com

U.S.A. - NEW JERSEY
CARTER LEDYARD & MILBURN LLP

General

Currently (as of December 2020) New Jersey's medical marijuana law is governed by the Jake Honig Compassionate Use Medical Cannabis Act (P.L.2009) (CCA). It was last amended in July 2019.

This will change soon, as the legislature is working to pass a bill to overhaul the programme and implement an amendment to the New Jersey constitution that legalised adult-use cannabis as part of a ballot initiative in November 2020. Effective January 2021, Article IV, Section VII is amended by inserting:

> "13. The growth, cultivation, processing, manufacturing, preparing, packaging, transferring, and retail purchasing and consumption of cannabis, or products created from or which include cannabis, by persons 21 years of age or older, and not by persons under 21 years of age, shall be lawful and subject to regulation by the Cannabis Regulatory Commission created by P.L.2019, c.153 (C.24:6I-5.1 et al.), or any successor to that commission.
>
> (1) The commission's or successor's regulatory authority concerning legalised cannabis shall be authorised by law enacted by the Legislature.
>
> (2) The receipts from retail purchases of cannabis or products created from or which include cannabis shall only be subject to the tax imposed under the 'Sales and Use Tax Act,' P.L.1966, c.30 (C.54:32B-1 et. seq.), as amended and supplemented, or any other subsequent law of similar effect; provided, however, that a municipality, subject to authorisation by law enacted by the Legislature, may adopt an ordinance to impose an additional municipal tax on the sale, or any other form of transfer, of cannabis or products created from or which include cannabis by an authorised party located in a municipality. The municipal tax rate shall not exceed two percent of the receipts from each sale of cannabis or products created from or which include cannabis by an authorised party or the equivalent value from any other form of transfer by an authorised party.

As used in this paragraph:

'Cannabis' means all parts of the plant Genus Cannabis L., whether growing or not, the seeds thereof, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds. 'Cannabis' does not include: cannabis dispensed and consumed for medical purposes pursuant to any law enacted by the Legislature; hemp or hemp products subject to regulation under the 'New Jersey Hemp Farming Act,' P.L.2019, c.238 (C.4:28-6 et al.), or any successor enactment thereto; or unregulated cannabis, referred to as marijuana, and products created from or which include marijuana."

This amendment will legalise cannabis for persons at least 21 years of age. The Cannabis Regulatory Commission, created in 2019 to oversee the state's medical cannabis programme, will oversee the new adult cannabis market. The scope of the commission's new authority will be detailed in laws enacted by the legislature. All retail sales of cannabis products in the new adult cannabis market will be subject to the state's sales tax. If authorised by the legislature, a municipality may pass a local ordinance to charge a local tax on cannabis products.

In accordance with the 2018 US Farm Bill descheduling hemp, the legislature adopted the New Jersey Hemp Farming Act (Hemp Act) (N.J.A.C. 2:25-1 et seq.). The New Jersey Department of Agriculture also adopted rules in accordance with the Hemp Act. Hemp-derived CBD is regulated in accordance with the Hemp Act.

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in New Jersey?

New Jersey's medical marijuana regime is governed by the CCA, which was last amended in July 2019. As noted above, New Jersey does not currently have a recreational cannabis regime, but that will change in 2021. Its contours will be determined by how the constitutional amendment is adopted and implemented through legislation and regulation. This will overhaul how medical marijuana is regulated as well.

The Cannabis Regulatory Commission oversees New Jersey's medical marijuana programme. Its regulations cover registration requirements for patients and primary

caregivers, reporting requirements, covered medical conditions, marketing, and the cultivation and distribution of medical marijuana by "alternative treatment centres."

In accordance with the Hemp Act, the Plants Division of the Department of Agriculture regulates hemp and its derivatives, including hemp-derived CBD. Among other things, the programme administered by the division established a fee schedule for hemp producers based on whether they are growing, processing or handling hemp. This includes annual fees for processing and handling CBD. The Cannabis Regulatory Commission also has authority over CBD that is used by alternative treatment centres in the manufacture and dispensation of medicinal marijuana.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in New Jersey?

Federal illegality remains a concern. On the other hand, the CCA and subsequent case law provide employees with protections in the workplace. Namely, employers may not take adverse employment action based solely on an employee's status as a medical cannabis registrant (though there is no right to be intoxicated at work). There is a general carveout for employers if allowing use would result in violation of federal law by the employer, but this is not well defined or tested as an actual ground.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in New Jersey?

See Question 1.

4. Which body is responsible for legislative controls relating to CBD?

See Question 1.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in New Jersey?

So long as the CBD rulemaking is ongoing at the US Food and Drug Administration (covered in more detail in the "US – Federal" summary), the marketing and sale of CBD remains a grey area at best. It is not well regulated at the state level in New Jersey, outside of general consumer safety laws and the requirement that it contain no more

than 0.3% THC. This may change once the cannabis laws are overhauled after the November 2020 election.

6. What are the testing specifications in New Jersey for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

The Department of Agriculture publishes guidelines for identifying THC concentration in hemp, which must comply with the federal requirement of being less than 0.3% on a dry weight basis. 15 days prior to the anticipated harvest date, an inspector from the Department or a DEA-registered third-party lab will collect samples to test for compliance with the federally defined THC level for hemp. All results are subject to review by the Department of Agriculture, which is authorised to retest and collect samples as necessary to ensure compliance. Hemp producers must agree to grant entry to the Department onto premises where hemp is grown, processed or handled for inspection purposes. In addition to individual sampling and testing requirements, the Department will also conduct an annual inspection of, at a minimum, a random sample of hemp producers.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

New Jersey allows the importation of out-of-state hemp seeds. All plants or seeds imported from other states (but within the United States) must be pre-approved by the Department of Agriculture. Licence holders must submit a request form to the Department at least three weeks in advance of any proposed transfer of materials.

As of the date of this article, the sale and transfer of CBD itself is not well regulated, and many stores sell products containing CBD that originate out of state. For hemp-derived CBD there is no separate possession limit if it contains less than 0.3% THC.

Contacts in the firm

Alexander G. Malyshev
Partner & Co-Chair of Carter Ledyard & Milburn LLP's
Cannabis, Hemp & CBD Industry Group
Email: Malyshev@clm.com.

U.S.A. - NEW YORK
CARTER LEDYARD & MILBURN LLP

General

Currently (as of December 2020), New York State's primary body of marijuana law is the New York Compassionate Care Act (NYCCA). The NYCCA regulates New York's medical marijuana programme and provides certified patients with serious medical conditions with employment protections under New York's expansive Human Rights Law.

New York has operated an industrial hemp agricultural research pilot programme since 2015 under the federal 2014 Farm Bill. It will remain in place until the USDA approves a New York hemp cultivation plan under the 2018 Farm Bill (as of 6th July 2020, New York has not submitted a plan). In December 2019, Governor Cuomo signed an amendment to the agriculture and markets law imposing additional regulations on the production and sale of hemp extracts, including CBD. In October 2020, New York published a comprehensive set of draft regulations for the manufacture and sale of hemp-derived CBD.

Under current law, limited protections exist for users of adult-use marijuana in New York. As of August 28, 2019, New York decriminalised possession of small amounts of marijuana statewide, though still punishable as a violation subject to a fine. In New York City, employers are not able to test job applicants for marijuana and THC, outside of certain safety-sensitive jobs. No protections exist for cultivation or sales.

For the past two years New York has tried, and failed, to overhaul its cannabis laws as part of the executive budget process. Governor Cuomo included the Cannabis Regulation and Taxation Act in his draft executive budget. It was stripped out of the budget passed on 31st March 2020, due to the economic impact of COVID-19. If reintroduced next year in similar form, the act will change New York's medical, adult use and hemp laws by centralising their regulation at the newly established Office of Cannabis Management which will "control the manufacture, wholesale, and retail production, distribution, transportation, and sale of cannabis, medical cannabis, and hemp cannabis in the State of New York". It will include multiple new taxes on adult-use marijuana. A similar measure failed in 2019.

New York is also subject to federal law (as covered in the "US – Federal" summary).

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in New York State?

The NYCCA (N.Y. Pub. Health Law §§ 3360 to 3369-E) became law on 5th July 2014 and will expire on 5th July 2021 unless amended or replaced. The law allows medical practitioners to certify patients with serious medical conditions like cancer, HIV, epilepsy or PTSD. Certified patients can obtain a registry card which provides them or their designated caregiver with certain protections. This includes possessing and transporting a 30-day supply of medical marijuana, which cannot be consumed in a public place. Registered patients are recognised as having a disability under New York's Human Rights Law (N.Y. Exec. Law §§ 290 to 301). This entitles patients to certain protection against discrimination, though the law on this has been sparse in New York. However, there is no right to be impaired while at work. The patient's use of medical marijuana may require the employer and employee to work on a reasonable accommodation.

The current law also regulates the sale of medical marijuana, limiting the manufacturing and dispensing of medical marijuana in the state to licensed companies, referred to as registered organisations. These registered organisations are subject to regulations prohibiting them from employing convicted felons, requiring them to manufacture marijuana in an indoor, enclosed, secure facility in New York State, regulating laboratory testing and mandating security measures. Prices are regulated by the Department of Health, though they vary from dispensary to dispensary, and advertising is also regulated (and all but prohibited).

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in New York State?

New York has one of the oldest medical marijuana laws, and no adult-use or recreational marijuana regime. Because of the significant barriers that exist, there are only about 113,000 registered patients in New York, or about 0.5% of the population.

There is also a limited number of registered organisations (it was initially limited to five by regulation, but ultimately expanded to ten). Applications are not currently being accepted, but come with a non-refundable $10,000 fee and a $200,000 registration fee for successful candidates. A registration is valid for two years, is non-transferable and

must be renewed no more than six, and no less than four, months before expiration. Similar fees apply for renewal.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in New York State?

See Question 1.

4. Which body is responsible for legislative controls relating to CBD?

In addition to federal-level regulation of CBD (covered in the "US – Federal" section), CBD is regulated under the hemp regulatory framework in New York.

Currently, the only lawful pathway to grow industrial hemp in New York State is through participation in New York's industrial hemp agricultural research pilot programme, which was authorised under the provisions of the 2014 Farm Bill. It is administered by the Department of Agriculture and Markets. New York treats industrial hemp as an agricultural commodity under it Agricultural and Markets Law.

In 2019 New York amended its Agriculture and Markets Law in relation to the cultivation of hemp and regulation of hemp extracts (including CBD). The new law includes a licensing scheme for growers, manufacturers and extractors of cannabinoids, packaging and labelling requirements, and laboratory testing and advertising regulations. The Department is accepting applications from researchers who want to grow industrial hemp for fibre, grain and CBD.

In late 2020 New York published comprehensive proposed regulation for the manufacture, distribution and sale of hemp-derived CBD. Once adopted, these rules will be Part 1005 to Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, to effectuate the provisions of Article 33-B of the New York Public Health Law (PHL). The regulations establish a scheme for licensing manufacturers and retailers of CBD products, with the overall goal of instituting consumer protections and ensuring products are manufactured, tested and labelled to standards comparable to similar products in the dietary supplement, food and cannabis industries.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in New York State?

While the Agriculture and Markets Law includes regulations related to the use of CBD, it should be noted that this is in addition to (but not in place of) the FDA's own rulemaking, outlined in the "US – Federal" summary, which is still pending. New York's Department of Agriculture has stated that no food or beverage product may be made or sold in New York State if it contains CBD as a food, a food additive or an ingredient. This is consistent with the FDA's approach.

New York has testing requirement for products intended for human consumption as dietary supplements (discussed in Question 6 below). However, the Department of Agriculture notes in its guidance that this is at odds with the FDA's position, which holds that CBD is not a dietary supplement but an active drug ingredient, and therefore subject to more stringent regulation at the federal level. This is covered in more detail in the "US – Federal" summary.

6. What are the testing specifications in New York for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Because New York is not participating in the 2018 Farm Bill programme, due to its reservations about the way the USDA's Interim Final Rule was drafted, hemp and CBD may only be grown and processed for research in New York (the only allowed purpose under the 2014 Farm Bill). New York indicated that it will convert research licences into commercial licences once a plan is adopted under the 2018 Farm Bill. This must occur by the end of 2020, because the 2014 Farm Bill pilot programme sunsets in November 2020.

In addition to federal requirements, in New York State cultivators and producers (known as research partners) making any CBD product intended for human or animal consumption or absorption into the body must ensure that their CBD products are free from chemical, physical and biological contamination. The analytical tests typically used to detect chemical, physical and biological contamination include, for example,

cannabinoid profile (THC and CBD), solvents, pesticides, heavy metals, bacteria and moulds.

The proposed CBD regulations, in addition to various licensing requirements, also impose third-party accredited laboratory testing requirements on all lots of CBD hemp products, testing for cannabinoid profile, heavy metals, microbials, mycotoxins, pesticides and residual solvents. The regulations will hold processors to federally established standards of good manufacturing practices (GMP) at the dietary supplement or food standard depending on the finished product. See §§ 1005.7-1005.8, 1005.10.

In accordance with the Department of Agriculture and Market's CBD processor research partner agreement, any facility manufacturing CBD products intended for human or animal consumption or absorption into the body shall be audited prior to sale or distribution of product to verify compliance with the relevant federal standard. Such audits must be conducted by a qualified, independent third party. The results of such a third-party audit shall be submitted to the Department prior to sale or distribution of the product. The third-party audit must provide evidence that the CBD processor is complying with the following requirements:

- A CBD product developed and/or produced under a research partner agreement, to the extent it is or will be a component of a dietary supplement, must be manufactured, tested and labelled in accordance with this agreement and FDA law and regulations concerning dietary supplements, including, without limitation, 21 CFR 111.403(L) and 21 CFR 101.

- A CBD or other cannabinoid product developed and/or produced under a research partner agreement, to the extent it introduces cannabinoids into or onto the body through topical application or other method for purposes other than as a dietary supplement, must be manufactured and labelled in accordance with 21 CFR 111 and 21 CFR 201 and comply with the provisions set forth in the research partner agreement.

The Department of Agriculture and Markets does not approve or maintain a listing of acceptable laboratories that can detect chemical, physical and biological contamination in CBD products. However, the Department will accept any tests performed by private laboratories accredited by the ISO/IEC 17025:2005,2017 standard.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

In accordance with the amended Agriculture and Markets Law, industrial hemp used for research in New York (including the production of CBD) may only be sourced from an authorised New York State industrial hemp producer. This is likely to change to some extent once a programme is developed in accordance with the 2018 Farm Bill, which will no longer be for research purposes only.

Contacts in the firm

Alexander G. Malyshev
Partner & Co-Chair of Carter Ledyard & Milburn LLP's
Cannabis, Hemp & CBD Industry Group
Email: Malyshev@clm.com.

U.S.A. - OREGON
BELL NUNNALLY

General

The Oregon Department of Agriculture (ODA) regulates the production of hemp in the state. Use and possession of medical cannabis and medical cannabis products is legal for patients with approval of a healthcare provider. For adults age 21 and over, use and possession of cannabis and adult-use cannabis products is legal. Retail sale and distribution of cannabis and adult-use cannabis products is legal.

Oregon is also subject to federal law (covered in the "US – Federal" summary).

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in the state?

In Oregon, "industrial hemp" means "all non-seed parts and varieties of the Cannabis plant, whether growing or not, that contain an average tetrahydrocannabinol concentration that does not exceed 0.3 percent on a dry weight basis." It also includes "any Cannabis seed: (A) That is part of a crop; (B) That is retained by a grower for future planting; (C) That is agricultural hemp seed; (D) That is for processing into or for use as agricultural hemp seed; or (E) That has been processed in a manner or to an extent that the Cannabis seed is incapable of germination." It expressly does not include "Industrial hemp commodities or products; or (B) Marijuana, as that is defined in ORS 475B.015."

Oregon permits the sale and marketing of hemp CBD foods, non-alcoholic beverages, dietary supplements, cosmetics and smokables so long as they contain no more than 0.3% total THC and are free of certain chemicals.

"Marijuana" means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and marijuana seeds. The term does not include industrial hemp or prescription drugs approved by the FDA. Marijuana is legal for medical and recreational uses in Oregon.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in the state?

Other than the conflict with federal law, there are few regulatory challenges in Oregon in allowing the medical and recreational use of cannabis and cannabinoids. Practitioners should ensure clients are complying with the state laws authorising use, production and distribution, however.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in the state?

See Questions 1 and 2.

4. Which body is responsible for legislative controls relating to CBD?

See Question 1.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in the state?

See Question 1. At the federal level, the Food and Drug Administration governs approval of ingestible products like food, as well as medicinal products. The Food and Drug Administration has not yet permitted commercialisation of CBD-containing products in the United States other than prescription drug Epidiolex, which is used to treat seizures.

6. What are the testing specifications in the state for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Oregon imposes extensive pre- and post-harvest testing for hemp products.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Yes.

Recreational – Adults age 21 and older can possess and use marijuana within specified limits.

- Possession – up to one ounce in public (but use/consumption in public, or in public view, is prohibited); at home, adults age 21 and older may possess all of the following:
    - Four homegrown plants per household (regardless of the number of adults of legal age in the household);
    - 8 ounces of dried flowers from the plants;
    - 72 ounces of infused liquids;
    - 16 ounces of infused solids; and
    - one ounce of extracted oil.

- Medical - A patient or caregiver may only possess:
    - Six mature plants (must be grown at registered grow site address);
    - 24 ounces of usable marijuana;
    - 16 ounces of a medical cannabinoid product in solid form;
    - 72 ounces of a medical cannabinoid product in liquid form;
    - 16 ounces of a cannabinoid concentrate whether sold alone or contained in an inhalant delivery system;
    - Five grams of a cannabinoid extract whether sold alone or contained in an inhalant delivery system;
    - Four immature marijuana plants; and
    - 50 seeds.

Contacts in the firm

Karen L. Hart
Partner, Bell Nunnally & Martin, LLP
Email: khart@bellnunnally.com

Ira Perez
Associate, Bell Nunnally & Martin, LLP
Email: iperez@bellnunnally.com

Troy Hales
Associate, Bell Nunnally & Martin, LLP
Email:thales@bellnunnally.com

U.S.A. - PENNSYLVANIA
BELL NUNNALLY

General

The Pennsylvania Department of Agriculture (PDA) regulates hemp cultivation in Pennsylvania. PDA's hemp programme is robust and imposes myriad requirements on cultivators in the state. Use and possession of medical cannabis and medical cannabis products is legal for patients with approval of a physician.

Pennsylvania is also subject to federal law (covered in the "US – Federal" summary).

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in the state?

The PDA regulates hemp cultivation in Pennsylvania. PDA has an industrial hemp programme that requires participants to submit applications and obtain permits to cultivate hemp in the state. There are fairly robust requirements to get a permit, unlike in some other states: owners must undergo federal background checks and submit detailed information about their business in order to get permitted. PDA also imposes detailed reporting requirements and requires that cultivators follow strict guidelines when growing hemp.

Regarding hemp-derived CBD products, the PDA generally follows the FDA's position and does not permit hemp-derived CBD products in foods. PDA has not directly addressed most other hemp-derived CBD products, except to state that hemp products must comply with all laws, regulations, and requirements of all authorities (including the FDA and the PA Dept of Health) that regulate products produced under the industrial hemp programme.

"Marijuana" consists of all forms, species and/or varieties of the genus Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin; but shall not include tetrahydrocannabinols, the mature stalks of such plant, fibre produced from such stalks, oil or cake made from the seeds of such

plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fibre, oil, cake, or the sterilised seed of such plant which is incapable of germination. Marijuana constituting hemp is legal in Pennsylvania. Marijuana not constituting hemp but used for medical purposes by registered patients with certain qualifying conditions and prescriptions from registered physicians is also legal.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in the state?

In addition to the prohibition in federal law, Pennsylvania outlaws the recreational use of cannabis and cannabinoids in the state.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in the state?

See Questions 1 and 2.

4. Which body is responsible for legislative controls relating to CBD?

See Question 1.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in the state?

See Question 1. At the federal level, the Food and Drug Administration governs approval of ingestible products like food, as well as medicinal products. The Food and Drug Administration has not yet permitted commercialisation of CBD-containing products in the United States other than prescription drug Epidiolex, which is used to treat seizures.

6. What are the testing specifications in the state for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Pennsylvania requires that "every variety field or lot (contiguous planting of one variety) planted … be tested for THC within 15 days of harvest by a certified sampler and [be] paid for by the permittee." Pennsylvania also requires that cultivators test floral material of all hemp varieties and supply it with a certificate of analysis for each hemp variety's total delta-9 THC percentage. Additionally, hemp processors or retailers may be required to test for heavy metals and pesticides.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Yes. Adults may possess a 30-day supply of medical marijuana if they qualify, are registered and meet all other requirements.

Contacts in the firm

Karen L. Hart
Partner, Bell Nunnally & Martin, LLP
Email: khart@bellnunnally.com

Ira Perez
Associate, Bell Nunnally & Martin, LLP
Email: iperez@bellnunnally.com

Troy Hales
Associate, Bell Nunnally & Martin, LLP
Email:thales@bellnunnally.com

U.S.A. - TEXAS
BELL NUNNALLY

General

Although marijuana remains illegal in Texas, Texas cannabis laws continue to slowly evolve. Texas has an extremely limited "medical marijuana" law under the Texas Compassionate Use Act, originally enacted in 2015 and expanded in 2019 to cover additional (but still very restricted) medical conditions, amongst other things. The Texas Compassionate Use Act permits the regulated prescription of low-THC cannabis containing not more than 0.5% THC for the treatment of only epilepsy, seizure disorders, multiple sclerosis, spasticity, amyotrophic lateral sclerosis, autism, terminal cancer or an incurable neurodegenerative disease.

Recreational marijuana remains outlawed in the Lone Star State, but Texas legalised industrial hemp in 2019, following the passage of the Agriculture Improvement Act of 2018, commonly known as the 2018 Farm Bill, at the federal level, which paved the way for state-implemented hemp programmes in the United States. Legal hemp in Texas is essentially defined as cannabis with no more than 0.3% THC. Likewise, a robust and still developing regulatory system surrounds Texas's hemp programme, which covers the cultivation, manufacturing and sale of hemp and hemp derivatives like CBD and related products.

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Texas?

Marijuana, recreational or otherwise, in Texas remains illegal, with a very limited exception for low-THC cannabis under the Texas Compassionate Use Act.

The Texas Compassionate Use Act permits limited prescriptions of low-THC cannabis containing no more than 0.5% THC by qualified, licensed, registered physicians to registered patients for the treatment of only epilepsy, seizure disorders, multiple sclerosis, spasticity, amyotrophic lateral sclerosis, autism, terminal cancer or an incurable neurodegenerative disease. The Texas Compassionate Use Act is codified in Chapter 487 of the Texas Health and Safety Code and in Chapter 169 of the Texas Occupations Code.

The Texas Department of Public Safety (DPS) administers the Act and the Compassionate Use Programme (CUP) in Texas. See Texas Administrative Code, Title 37, Part 1, Chapter 12. The DPS maintains a detailed FAQs page regarding the CUP on its website. Notably, dispensary licensing has been limited, with only three licensed dispensary companies in Texas.

On 10th June 2019, Texas Governor Abbott signed House Bill (HB) 1325 into law in Texas. HB 1325 authorises the production, manufacture, inspection and retail sale of hemp crops and products, including CBD, in Texas, subject to statutory and regulatory requirements. HB 1325 adopted the federal 2018 Farm Bill's definition of hemp:

> "Plant Cannabis sativa L. and any part of that plant, including … cannabinoids … with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

See Tex. Agricultural Code. § 121.001.

Although hemp and marijuana are both strains of cannabis, legal hemp in Texas, and federally, may not exceed a concentration of 0.3% of tetrahydrocannabinol (THC). Under federal and Texas law, legal hemp is now effectively carved out of the definitions of marijuana, which remains an illegal controlled substance in Texas and under federal law.

A consumable hemp product in Texas is a food, drug, device or cosmetic that contains industrial hemp or hemp-derived cannabinoids, such as CBD, and must not contain more than 0.3% THC concentration to be legal. See Tex. Health & Safety Code § 443.001(1). Significantly, low-THC cannabis is not a consumable hemp product. Retailers of consumable hemp products, including CBD, must be registered in accordance with Texas law and comply with all Texas Department of State Health Services (DSHS) adopted hemp programme rules and regulations, which were enacted earlier in 2020 and became effective as of 2nd August 2020. Manufacturers, processors and distributors must be licensed in accordance with DSHS rules. See Tex. Health & Safety Code §§ 443.101-443.105. DSHS has implemented rules for random testing to ensure compliance with required THC limits. See Tex. Health & Safety Code §§ 443.101.151-443.152. Retailers may possess, transport or sell a consumable hemp product that becomes part of their inventory, but must be registered as required. See Tex. Health & Safety Code §§ 443.201-443.207. Applicable DSHS rules are found in the Texas Administrative Code, Title 25, Part 1, Chapter 300.

The FDA (at the federal level) has a different stance on CBD in food products, determining that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food to which THC or CBD has been added.

HB 1325 establishes a framework for a hemp growing programme in Texas, pursuant to the 2018 Farm Bill, which authorised states to develop plans for the commercial production of hemp. The Texas Department of Agriculture (TDA) developed such a hemp plan for Texas, and the USDA approved it in January 2020. The TDA launched the permit application and licensing process for hemp cultivation in March 2020 and began issuing licences soon thereafter.

The TDA's adopted rules, found in the Texas Administrative Code, Title 4, Part 1, Chapter 24, for the Texas hemp programme may be accessed on the TDA's website, along with detailed FAQs covering various aspects of the programme and rules. The TDA is charged with administering the Texas hemp programme pursuant to Chapter 122 of the Texas Agriculture Code, which codifies certain portions of HB 1325 related to the cultivation of hemp in Texas. The Texas Agricultural Code and the TDA rules provide for inspections and testing to ensure compliance with acceptable levels of THC. See Chapter 122, Subchapter D, of the Texas Agricultural Code; Texas Administrative Code, Title 4, Part 1, Chapter 24, Subchapter D and Subchapter E.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Texas?

Recreational marijuana remains illegal in Texas.

The Texas Compassionate Use Act only permits the prescription of low-THC cannabis for specific medical conditions that the Texas legislature wrote into the Act, restraining patients and their doctors from utilising cannabis to treat conditions not enumerated by the Texas legislature. Dispensary licensing is also limited under the CUP in Texas, with currently only three licensed dispensary companies state-wide.

Smokable hemp products have recently become an industry flashpoint in Texas.

Section 122.301(b) of the Texas Agriculture Code and Section 443.204(4) of the Texas Health & Safety Code ban the processing and manufacture of hemp products for smoking in Texas.

Section 122.301(b) of the Texas Agricultural Code provides that "A state agency may not authorise a person to manufacture a product containing hemp for smoking, as defined by Section 443.001, Health and Safety Code." Section 443.001(11) of the Health and Safety Code defines "smoking" as "burning or igniting a substance and inhaling the smoke or heating a substance and inhaling the resulting vapor or aerosol."

Section 443.204(4) of the Health and Safety Code further provides that "Rules adopted . . . regulating the sale of consumable hemp products must to the extent allowable by federal law reflect the following principles:. . . (4) the processing or manufacturing of a consumable hemp product for smoking is prohibited."

DSHS rule 300.104 provides that "The manufacture, processing, distribution, or retail sale of consumable hemp products for smoking is prohibited." 25 Tex. Administrative Code 300.104. Rule 300.104 became effective in early August 2020, after a public comment period. Many in the industry were opposed to this rule because of the stifling impact it would have on the smokable hemp product market in Texas. Additionally, critics also note that the rule goes beyond the statutory prohibition of "processing or manufacturing" of consumable hemp products for smoking found in Section 443.204(4). Section 443.204(4) does not itemise a prohibition on retail sales or distribution of smokable hemp products.

Thus, in August 2020, a group of hemp companies that sell smokable hemp products in Texas filed a lawsuit against DSHS and its Commissioner seeking a declaration that Rule 300.104 is invalid and exceeds statutory authority, a declaration that Section 443.204(4), and Section 122.301(b) unconstitutional under the Texas Constitution and injunctive relief against the enforcement of these provisions. See Cause No. D-1-GN-20-004053, Crown Distributing LLC, America Juice Co. LLC, Custom Botanical Dispensary, LLC, and 1937 Apothecary, LLC v. Texas Department of State Health Services and John Hellerstedt, in his official capacity as Commissioner of the Texas DSHS, before the 345th Judicial District Court, Travis County, Texas. The plaintiffs secured entry of a temporary restraining order against DSHS in August 2020; a temporary injunction will be considered next in the case.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Texas?

See Question 1.

4. Which body is responsible for legislative controls relating to CBD?

See Question 1. DSHS has regulatory authority over consumable hemp products, including CBD. TDA administers the Texas hemp cultivation programme and related rules. DPS administers rules and regulations related to the Texas Compassionate Use Act.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in Texas?

See Question 1. At the federal level, the Food and Drug Administration governs approval of ingestible products like food, as well as medicinal products. The Food and Drug Administration has not yet permitted commercialisation of CBD-containing products in the United States other than prescription drug Epidiolex, which is used to treat seizures.

6. What are the testing specifications in Texas for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Section 443.151 of the Health and Safety Code governs testing of consumable hemp products, including CBD products. Section 443.151(b) provides:

> "Before a hemp plant is processed or otherwise used in the manufacture of a consumable hemp product, a sample representing the plant must be tested, as required by the executive commissioner, to determine:
>
> (1) the concentration of various cannabinoids; and
> (2) the presence or quantity of heavy metals, pesticides, and any other substance prescribed by the department."

Section 443.151(c) provides:

> "Before material extracted from hemp by processing is sold as, offered for sale as, or incorporated into a consumable hemp product, the material must be tested, as required by the executive commissioner, to determine:
>
> (1) the presence of harmful microorganisms; and
> (2) the presence or quantity of:
> (A) any residual solvents used in processing, if applicable; and
> (B) any other substance prescribed by the department."

As per Section 443.151(d), required testing must be conducted by a laboratory that is accredited by an accreditation body in accordance with International Organization for Standardization ISO/IEC 17025 or a comparable or successor standard to determine the delta-9 tetrahydrocannabinol concentration of the product. A consumable hemp product is not required to be tested as provided above if each hemp-derived ingredient has been tested as specified and does not have a delta-9 tetrahydrocannabinol concentration of more than 0.3%. Health & Safety Code § 443.151(e).

DSHS rules 300.301 – 300.303 further address testing requirements of the department. Rule 300.301 requires:

> "(a) All hemp or hemp derivatives used in the manufacture of a consumable hemp product must be tested as appropriate for the product and process by an accredited laboratory to determine:
> (1) the presence and concentration of cannabinoids;
> (2) the presence and concentration of THC; and
> (3) the presence or quantity of residual solvents, heavy metals, pesticides, and harmful pathogens.
>
> (b) A Certificate of Analysis documenting tests conducted under this subchapter shall:
> (1) be made available to the department upon request in an electronic format before manufacture, processing, or distribution into commerce; and
> (2) include measurement of uncertainty analysis parameters."

Relevant to CBD oils and other CBD products that may be imported into Texas for retail sale, DSHS rule 300.302(b) mandates:

> "(b) Notwithstanding any other law, a person shall not sell, offer for sale, possess, distribute, or transport a consumable hemp product in this state, including CBD oil, if the consumable hemp product contains any material extracted or derived from the plant Cannabis sativa L., other than from hemp produced in compliance with 7 United States Code (U.S.C.) Chapter 38, Subchapter VII, unless:
>
> (1) a representative sample of the oil has been tested by an accredited laboratory and found to have a delta-9 tetrahydrocannabinol content concentration level on a dry weight basis, that, when reported with the accredited laboratory's measurement of uncertainty, produces a distribution or range that includes a result of 0.3 percent or less; and
>
> (2) testing results are provided to the department upon request."

Of special note and concern to all retailers (but equally applicable to Texas manufacturers, processors and distributors) of consumable hemp products, including CBD products, in Texas, whether processed or manufactured in the state of Texas or out of state, DSHS rule 300.302(c) provides for random product testing by DSHS to ensure the products do not contain harmful ingredients, are produced in compliance with the 2018 Farm Bill, and have a delta-9 tetrahydrocannabinol content concentration level on a dry weight basis, that, when reported with the accredited laboratory's measurement of uncertainty, produces a distribution or range that includes a result of 0.3% or less.

Upon request by the department, the manufacturer, processor, distributor or retailer of consumable hemp products shall provide representative raw or finished consumable hemp product samples to the department, which must be provided at the owner, licence holder, and/or registrant expense. Rules 300.301(d), (e). Upon request by the department, test results are to be provided to the department by manufacturers, processors and distributors. Rule 300.303(b). Registrants (e.g., retailers) are to provide test results upon request of the department or consumers. Rule 300.303(c). Test results are to be maintained for at least three years from the date the results are made available to a licence holder. Rule 300.303(i).

The foregoing answer focuses on CBD as a consumable hemp product only. The TDA has a robust regulatory regime for testing non-consumable hemp in Texas. See Chapter 122, Subchapter D, of the Texas Agricultural Code; Texas Administrative Code, Title 4, Part 1, Chapter 24, Subchapter D and Subchapter E.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Retail sales of consumable hemp products processed or manufactured out of state are governed by Section 443.204 of the Health and Safety Code as well as DSHS rule 300.403. There are no limits on quantity of such out-of-state products, but as per Section 443.204 and rule 300.403, such products must be in compliance with:

> (1) that state or jurisdiction's plan approved by the United States Department of Agriculture under 7 U.S.C. Section 1639p;
> (2) a plan established under 7 U.S.C. Section 1639q if that plan applies to the state or jurisdiction; or
> (3) the laws of that state or jurisdiction if the products are tested in accordance with, or in a manner similar to, Section 443.151.

The foregoing answer focuses on CBD as a consumable hemp product only. The TDA has its own rules and regulations governing the sale of out-of-state non-consumable hemp in Texas. See Chapter 122 of the Texas Agriculture Code; Texas Administrative Code, Title 4, Part 1, Chapter 24.

Contacts in the firm

Karen L. Hart
Partner
Bell Nunnally & Martin LLP
Email: khart@bellnunnally.com

U.S.A. - WASHINGTON
BELL NUNNALLY

General

The Washington State Department of Agriculture (WSDA) regulates the production of hemp in the state. It also regulates hemp plants used as food. Use and possession of medicinal cannabis and medicinal cannabis products is legal for patients with approval of a healthcare provider. For adults age 21 and over, use and possession of cannabis and adult-use cannabis products is legal. Retail sale and distribution of cannabis and adult-use cannabis products is legal.

Washington is also subject to federal law (covered in the "US – Federal" summary).

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in the state?

In Washington, "hemp" means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3% on a dry weight basis. RCW 15.140.020. WSDA administers the state's industrial hemp programme, which regulates the cultivation of hemp.

Washington law explicitly permits the sale of "cannabis health and beauty aids" which are "product[s] containing parts of the cannabis plant" that are intended for topical use, cannot pass the blood-brain barrier, contain less than 0.3% THC and are not intended for ingestion. RCW 69.50.575. This covers hemp CBD cosmetics. Hemp CBD vapour products, on the other hand, are explicitly prohibited. RCW 70.234.030.

Washington law also says "[t]he whole hemp plant may be used as food. The [WSDA] shall regulate the processing of hemp for food products, that are allowable under federal law, in the same manner as other food processing under chapters 15.130 [(Washington's Food Safety and Security Act)] and 69.07 RCW [(Washington Food Processing Act)] and may adopt rules as necessary to properly regulate the processing of hemp for food products including, but not limited to, establishing standards for creating hemp extracts used for food." RCW 15.140.040(5). This means that under Washington law, any part of

the hemp plant may be used as food and the WSDA may regulate the processing of hemp into extracts like hemp CBD. But these hemp products have to be "allowable under federal law" which makes things complicated given that the FDA has consistently stated that it is illegal to sell hemp CBD as a food or dietary supplement.

Marijuana, on the other hand, is regulated depending on whether it is meant for medicinal or recreational use. Marijuana, under Washington law, means all parts of the plant Cannabis, whether growing or not, with a THC concentration greater than 0.3% on a dry weight basis; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. The term does not include: (i) the mature stalks of the plant, fibre produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fibre, oil, or cake, or the sterilised seed of the plant which is incapable of germination; or (ii) hemp or industrial hemp.

Recreational marijuana - Anyone over the age of 21 with a valid ID from any US state (or international passport) can legally purchase up to one ounce of usable marijuana (i.e. the harvested flower or bud), 16 ounces of marijuana-infused edibles in solid form, 72 ounces in liquid form, and 7 grams of marijuana concentrates. Marijuana can only be sold and purchased (with a valid photo ID) at state-licensed stores.

Medical marijuana – Patients with certain terminal or debilitating medical conditions may obtain authorisation from their healthcare practitioner (not just their doctor) for medical marijuana.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in the state?

Other than the conflict with federal law, there are few regulatory challenges in Washington in allowing the medical and recreational use of cannabis and cannabinoids. Practitioners should ensure clients are complying with the state laws authorising use, production and distribution, however.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in the state?

See Questions 1 and 2.

4. Which body is responsible for legislative controls relating to CBD?

See Question 1.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in the state?

See Question 1. At the federal level, the Food and Drug Administration governs approval of ingestible products like food, as well as medicinal products. The Food and Drug Administration has not yet permitted commercialisation of CBD-containing products in the United States other than prescription drug Epidiolex, which is used to treat seizures.

6. What are the testing specifications in the state for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Washington requires that hemp be tested for total THC using high-performance liquid chromatography (HPLC) for the determination of delta-9-THC and delta 9-THC acid (THC-A). Additionally, if necessary, WSDA will conduct moisture testing to determine total moisture.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Yes. Adults may possess approximately one ounce of usable marijuana, 16 ounces of marijuana-infused edibles in solid form, 72 ounces in liquid form, and 7 grams of marijuana concentrates.

Contacts in the firm

Karen L. Hart
Partner, Bell Nunnally & Martin, LLP
Email: khart@bellnunnally.com

Ira Perez
Associate, Bell Nunnally & Martin, LLP
Email: iperez@bellnunnally.com

Troy Hales
Associate, Bell Nunnally & Martin, LLP
Email:thales@bellnunnally.com

LEGALINK

INTERNATIONAL BUT PERSONAL