



**LEGALINK**

INTERNATIONAL BUT PERSONAL

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 continues 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 ruderalis. 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.

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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 jurisdiction’s 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.

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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.

## 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 or 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<sup>2</sup>.

#### 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.

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