



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 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 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.

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.

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