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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 reductalis. 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 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.

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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.

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.

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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 2^a del Tribunal Supremo de 19th Noviembre 2001).



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