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Medical Cannabis & Cannabinoid Regulation 2023

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Spain: Law & Practice

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SPAIN

Law and Practice

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Contents

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1. Legal/Regulatory Framework

1.1 Source of Regulations

The main regulations on cannabinoids or affecting medicinal cannabis are the following:

- Law 17/1967, on the updating of narcotic and psychotropic regulations to the provisions of the Single Convention on Narcotic Drugs of 1961 ("Law 17/1967"); and
- the Single Convention on Narcotic Drugs of 1961, signed and ratified by Spain on 3 February 1966 (the "Single Convention").

According to the aforementioned regulations, cannabis is included in List I of the Single Convention, and is therefore considered a narcotic. According to the Spanish Agency of Medicinal Products and Medical Devices (AEMPS), its production, manufacture, exportation, importation, distribution, trade, use and possession must be limited to medical and scientific purposes. Cannabis is also included in List IV of the Single Convention, and is therefore considered a prohibited article or genre.

Other than the above, there is no specific regulation addressing the use of medicinal cannabis in Spain. However, in October 2021, the Subcommittee of the Congress of Deputies on the regulation of cannabis was formed. This Subcommittee, dependent on the Spanish Committee on Health and Consumer affairs, was composed of experts in the field of medicinal cannabis from universities, healthcare centres, European authorities and research centres. The purpose of the Subcommittee was to study and submit to the Congress of Deputies clinical and scientific evidence in connection with the uses of medicinal cannabis. The Subcommittee issued its final report on 27 June 2022, where several conclusions and recommendations were included, the most relevant of which are that:

- the AEMPS is encouraged to define the most appropriate mechanisms, within the current regulations, for permitting the prescription and use of medical cannabis (ie, through magistral formulas or standardised preparations);
- the therapeutic areas for which medical cannabis can be prescribed and used are limited to those supported by scientific evidence (and listed in the final report);
- patients treated with medical cannabis must be inscribed in a central registry with the purpose of further evaluation of the relevant treatments;
- dispensation of medical cannabis should be limited to the pharmacists of the National Health System (NHS), with preference for hospital pharmacy services;
- the Spanish regions and the inter-territorial health council are encouraged to draw up clinical guidelines for the use of medicinal cannabis; and
- measures should be taken to ensure that this medicinal use of cannabis favours the consumption of cannabis outside the healthcare sphere.

Additionally, the republican parliamentary group *Esquerra Republicana de Catalunya* (ERC) submitted before the Spanish Congress of Deputies a proposal for a law on the comprehensive regulation of cannabis, including regulation for therapeutic and medical use, in February 2023. This proposal was rejected by 78 votes in favour, 261 against and two abstentions.

Recently, in the plenary session of the Congress of Deputies on 27 March 2023, a deputy of the Basque Nationalist Party (PNV) asked the Min-

ister of Health about the deadline for Spain having a regulation on medical cannabis. The Minister of Health replied that the Spanish Ministry of Health (MoH) is working with the AEMPS to define the best regulatory framework for medicinal cannabis.

Finally, there are no regulations on the use of cannabinoids in other products, except for the informative note issued by the Spanish Food Security Agency (AESAN) in March 2019 (confirmed in December 2022) on the use of cannabinoids such as THC, CBD, CBG and others in food products. According to this informative note, the use of these cannabinoids as added to other food products (for example, to an oil or a beverage), regardless of their having a natural or synthetic origin, leads to their being considered novel foods and thus subject to the relevant EU regulations.

1.2 Regulatory Authorities

The main regulatory authorities would depend on the purpose of use of the medical cannabis or cannabinoid.

- The AEMPS – this agency has been appointed to further regulate the use of medical cannabis according to the final report of the Subcommittee for the study of medical cannabis mentioned in **1.1 Source of Regulations**. The AEMPS oversees the use of cannabinoids in cosmetics and personal care products and is responsible for the authorisation of medicinal products (including those containing cannabis derivatives). It also grants authorisations for the cultivation of cannabis plants for research purposes, and for the production and/or manufacture of cannabis-derived products for medical and scientific purposes according to Law 17/1967.
- The AESAN – this agency oversees the production and commercialisation of food products containing cannabinoids, such as food supplements with CBD.

1.3 Self-Regulation

There are no self-regulatory authorities governing or overseeing the industry in Spain, apart from the national associations for medicinal products, medical devices and self-care products.

In addition, the Spanish Observatory on Medical Cannabis (OECM), comprised of researchers, doctors and patient associations involved in the use of medical cannabis, has been very active in demanding a proper regulatory framework for medical cannabis, but to date is not acting as a self-regulatory body. Other than this entity, Spain lacks a structured industry lobby.

1.4 Key Challenges

The most important challenge is the development of a sensible regulatory framework to ensure patients have access to cannabis-based products with high standards of quality and safety.

At present, there is a legal vacuum on the use of cannabis derivatives that do not qualify as narcotics under the Single Convention. In January 2019, the Secretary General of the World Health Organization (WHO) recommended that the United Nations (UN) amend Schedule I of the Single Convention so as to clarify that CBD is not a narcotic drug, firstly by deleting “extracts and tinctures of cannabis” therefrom, and secondly by adding a footnote reading “Preparations containing predominantly cannabidiol and not more than 0.2% of delta-9-tetrahydrocannabinol (popularly known as THC) are not under international control”.

In December 2020, the UN Commission on Narcotic Drugs voted to remove cannabis from Schedule IV of the Single Convention (in which the most specific deadly and addictive opioids, including heroin, are listed) and recognised the medicinal and therapeutic potential of cannabis.

In addition to this, the Court of Justice of the European Union (CJEU) ruled in a landmark decision that CBD is not a narcotic, as it did not appear to have any psychotropic effect or any harmful effect on human health.

Against this backdrop, and despite the legal vacuum, a multitude of cannabis-derived products have proliferated on the Spanish market, including CBD flowers, CBD oils and food supplements containing cannabinoids, the legality and future of which remain very unclear.

1.5 Level of Regulation

The few references to briefing notes on the use of cannabinoids issued by the Spanish authorities, and the absence of a regulatory framework on the use of medical cannabis (under permanent political debate), make for a very poor and unsophisticated regulatory regime, characterised mainly by the uncertainty faced by the industry.

1.6 Legal Risks

The legal risks that companies should consider in this industry would depend on the qualification that may be given to a particular product. These risks may include:

- product recalls (ie, for a food supplement containing a non-authorised cannabinoid that does not pose a health risk);
- administrative sanctions (ie, for cannabis-derived products that may qualify as a medicinal product but are without the pertinent marketing authorisation); and
- criminal offences (ie, use of medical cannabis where the final product qualifies as a narcotic, or offences against public health).

At present, while cannabis-derived products containing cannabinoids (except THC) are not actively subject to prosecution, the promotion of medical use of cannabis (including THC-containing products) by means that do not fit into the current regulatory framework for medicinal products would be a risky activity. Notably, Spain can be described as a conservative jurisdiction with regard to cannabis, as several bills for a comprehensive regulation of cannabis (including medicinal cannabis) submitted before the Spanish Congress of Deputies have all been rejected (October 2021, May 2022 and February 2023).

1.7 Enforcement

See **1.2 Regulatory Authorities**.

Where a particular product qualifies as a narcotic drug, it would fall within the scope of criminal offences.

2. Cross-Jurisdictional Issues

2.1 Cross-Jurisdictional Standards

The different patient access programmes regarding medical cannabis between European countries may give rise to cross-border problems. However, Spain has not addressed this issue.

3. Future Developments

3.1 Legal Elements Affecting Access to Medical Cannabis

The absence of a regulatory framework and the conservative approach to cannabis and its derivates by the Spanish political class are the main legal elements affecting access to medical cannabis by Spanish patients.

See **1.1 Source of Regulations** in connection with the final report dated June 2022 of the Subcommittee of the Congress of Deputies on the regulation of cannabis, encouraging the AEMPS to define mechanisms within the medicinal products regulatory framework, and to guarantee access to medical cannabis for patients. This is in connection with the public statement of the MoH confirming that it is working with the AEMPS to define the best regulatory framework for medicinal cannabis.

3.2 Use of Non-controlled Cannabinoids in Food

According to the informative note issued by the AESAN in March 2019 and confirmed in December 2022 (see **1.1 Source of Regulations**) on the use of hemp and cannabinoids in food products, hemp-derived foods – including beverages – are authorised in the EU only for those products originating exclusively from hemp seeds (for example, oil, hemp protein or hemp flour) as long as they are Cannabis sativa L varieties with THC content below 0.2%.

However, cannabinoids (THC, CBD, CBG and others) used as such or to be added to other food products (for example, to an oil or a beverage) are considered novel foods under the informative note of the AESAN, regardless of their having a natural or synthetic origin, since it has not been possible to demonstrate a history of significant or safe consumption in the EU before 15 May 1997. The above is also applicable to other extracts and other parts of the Cannabis sativa L plant (such as flowers, leaves and stems).

Therefore, any company wishing to commercialise these parts of the Cannabis sativa L plant (flowers, leaves and stems) extracts and cannabinoids in the food field must submit an application to the European Commission in accordance with the provisions of the Novel Food Regulation (EU) 2015/2283; once the risk has been assessed by the European Food Safety Authority (EFSA), the pertinent authorisation will be granted.

The AESAN informative note also states that the marketing of a product with these ingredients (cannabinoids) is not authorised in the EU (unless covered by a novel food authorisation), and therefore the principle of mutual recognition cannot be applied to marketing products containing cannabinoids or extracts of the Cannabis sativa L plant in Spain.

3.3 Decriminalisation or Recreational Regulation

See **1.1 Source of Regulations** and **1.6 Legal Risks** on the bills for a comprehensive regulation of cannabis presented by the ERC before the Congress of Deputies, which have been rejected. Reasons for such rejection invariably revolve around the fact that cannabis is a dangerous drug and that it poses a risk to public health.

Additionally, the final report dated June 2022 of the Subcommittee of the Congress of Deputies on the regulation of cannabis concluded that "the availability of cannabis for therapeutic use must be prevented from leading to increased

availability and use of cannabis outside the healthcare context".

A law on cannabis clubs was passed only in Catalunya (in June 2017), promoted by the popular legislative initiative, and which obtained 67,500 signatures and was practically unanimous, with 118 votes in favour and only eight votes against from the Popular Party. This law was subsequently annulled by the Spanish Constitutional Court in 2018.

In light of the above, it can be understood that Spain is far from implementing legislation decriminalising recreational cannabis.

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