Chambers AND PARTNERS

CHAMBERS GLOBAL PRACTICE GUIDES

Medical Cannabis & Cannabinoid Regulation 2024

Definitive global law guides offering comparative analysis from top-ranked lawyers

Spain: Law & Practice

Anna Gerbolés
Faus Moliner

SPAIN

Law and Practice

Contributed by:
Anna Gerbolés
Faus Moliner

Contents

Faus Moliner is a modern boutique law firm, specialised in dealing with legal matters typical of the pharmaceutical industry and companies that operate in the life sciences sector. Founded in 1997, Faus Moliner focuses on pharmaceutical law, commercial contracts, corporate transactions, corporate governance, compliance, competition law, public procurement, product liability, advertising, litigation and arbitration. The firm advises pharmaceutical and healthcare clients, acts on behalf of large companies and smaller biotech start-ups and is frequently called upon to advise public authorities on matters such as draft legislation.

Author

Anna Gerbolés is an associate at Faus Moliner and is specialised in pharmaceutical and food law, and in complex regulatory matters of borderline products. Her experience in these sectors includes the provision of legal advice on issues related to regulation and advertising of medicinal products, medical devices, food products and other borderline products. Since becoming part of the Faus Moliner team in 2021, she has provided highly specialised advice to companies operating in the life sciences sector. Anna is a member of the Barcelona Bar Association.

Faus Moliner

Rambla Catalunya 135
3rd floor, 2nd door
08008
Barcelona
Spain

Tel: +34 9329 22100
Email: bcn@faus-moliner.com
Web: www.faus-moliner.com

1. Regulatory Framework

1.1 Primary Laws & Regulations

The main regulations on cannabinoids or affecting medicinal cannabis are as follows:

- Law 17/1967, on the updating of narcotic and psychotropic regulations to the provisions of the Single Convention of Narcotic Drugs of 1961 ("Law 17/1967"); and
- the Single Convention of Narcotic Drugs of 1961 on narcotic drugs, signed and ratified by Spain on February 3, 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, export, import, 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 this 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, including several conclusions and recommendations. The most relevant are as follows:

- the AEMPS is encouraged to define the most appropriate mechanisms, within the current regulations, to permit 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 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 proposition was rejected by 78 votes in favour, 261 against and two abstentions.

As a consequence of the recommendations made by the Subcommittee of the Congress of Deputies on the regulation of cannabis, the Spanish Minister of Health (MoH) worked with the AEMPS to define the best regulatory frame-

work for medicinal cannabis. In February 2024, the MoH released the prior public consultation for the Royal Decree project on the conditions for the production and dispensing of cannabis-derived products. This is the only regulatory proposal for medicinal cannabis at this time. The project establishes that medicinal cannabis preparations can only take the form of "magistral formula" and solely for a specific set of therapeutic indications. The proposal also intends to limit the preparation of magistral formulas derived from cannabis to those that have a monograph in the National Formulary. Note that the National Formulary is a list that contains the typified magistral formulas, their categories, indications and raw materials involved in their composition or preparation, as well as the standards for correct preparation and control.

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, adding these cannabinoids 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 Bodies

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

- 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 Primary Laws & 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.
- AESAN – this agency oversees the production and commercialisation of food products containing cannabinoids, such as food supplements with CBD.

1.3 Self-Regulatory Authorities

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), composed 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 Challenges for Market Participants

The main challenge faced by market players will be the ability to truly participate in the medicinal cannabis industry by manufacturing and selling cannabis-derived products. If the proposal for the Royal Decree on the conditions for cannabis production and dispensing moves forward, cannabis products will only be authorised under the format of "magistral formulas". These can only be prepared and dispensed by pharmacy offices and will require an individualised patient medical

prescription. According to Spanish regulations, pharmacy offices can only be owned by a single natural person holding a degree in pharmacy, thus excluding the possibility of companies holding ownership of pharmacy offices. Therefore, industrial manufacturing and commercialisation of cannabis derivatives may encounter a significant barrier to entering the Spanish market.

1.5 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, a food supplement containing a non-authorised cannabinoid that does not pose a health risk);
- administrative sanctions (ie, cannabis-derived products that may qualify as a medicinal product but without the pertinent marketing authorisation); and
- criminal offences (ie, use of medical cannabis if 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 prosecuted, the promotion of medical uses 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 the 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).

1.6 Enforcement & Penalties

See **1.2 Regulatory Bodies**. In the event that a particular product qualifies as a narcotic drug, it would fall within the scope of criminal offences.

2. Cross-Jurisdictional Matters

2.1 Cross-Jurisdictional Issues

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

3. Legal and Regulatory Developments

3.1 Access to Medical Cannabis

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

See **1.1 Primary Laws & Regulations** in connection with the final report, dated 27 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 patient access to medical cannabis. This is in connection with the draft bill for a Royal Decree on the conditions for the production and dispensing of cannabis-derived products, which limits the use of these products to certain and predefined therapeutic indications, and only under the format of “magistral formulas”.

3.2 Non-controlled Cannabinoids in Food

According to the informative note issued by the AESAN in March 2019 and confirmed on December 2022 (see **1.1 Primary Laws & Regulations**), on the use of hemp and cannabinoids in food products, hemp-derived foods – including beverages – are authorised in the European Union only regarding 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 them having a natural or synthetic origin, since it has not been possible to demonstrate a history of significant or safe consumption in the European Union 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 European Union (unless covered by a novel food authorisation), and therefore the principle of mutual recognition cannot be applied to market products containing cannabinoids or extracts of the Cannabis sativa L plant in Spain.

3.3 Decriminalisation

See **1.1 Primary Laws & Regulations** and **1.5 Legal Risks** on the bills for comprehensive regulation of cannabis presented by the ERC before the Congress of Deputies, which have been rejected. Reasons for the rejection always revolve around the fact that cannabis is a dangerous drug and that it poses a risk to public health.

Additionally, the final report of the Subcommittee of the Congress of Deputies on the regulation of cannabis (dated June 2022) 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".

In Catalunya only, a law on cannabis clubs was passed in June 2017 (promoted by popular legislative initiative, which obtained 67,500 signatures) and was practically unanimous, with 118 votes in favour and only 8 votes against (from the Popular Party). This law was subsequently annulled by the Spanish Constitutional Court in 2018.

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

CHAMBERS GLOBAL PRACTICE GUIDES

Chambers Global Practice Guides bring you up-to-date, expert legal commentary on the main practice areas from around the globe. Focusing on the practical legal issues affecting businesses, the guides enable readers to compare legislation and procedure and read trend forecasts from legal experts from across key jurisdictions.

To find out more information about how we select contributors, email Katie.Burrington@chambers.com