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Medical Cannabis & Cannabinoid Regulation 2022

Spain: Trends & Developments

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SPAIN

Trends and Developments

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The Cannabis Industry in Spain

The definitions of "cannabis" and "cannabis derivatives" used in this article follow those set out in the UN Single Convention on Narcotic Drugs 1961 and by international drug control authorities. "Cannabis and its derivatives" mean all products that derive from the cannabis plant, including flowering or fruiting tops, resin, oils, tinctures, extracts and preparations (capsules, oils, infusions, etc).

Spain ratified the 1961 UN Convention and the 1971 UN Convention on Psychotropic Substances and, thus, the general law regulating controlled substances was passed in 1967 (*Ley 17/1967, de 8 de abril por la que se actualizan las normas vigentes sobre estupefacientes y adaptándolas a lo establecido en el convenio de 1961 de las Naciones Unidas*). To date, there are no developments or amendments to this piece of legislation, nor are there clear guidelines or secondary legislation providing a clear view on some of the more pressing aspects of regulation around the cannabis industry.

Hence, in terms of regulatory activity, Spain can be described as both a conservative and "follower" jurisdiction regarding cannabis. This notwithstanding, as of this date – based on the expanded social and media coverage and spurred by the pressing need to tackle the growing illegal market – the Spanish Congress of Deputies has created a specific sub-commission to start gathering up (yet again) evidence and analysis to reflect on the possibility of legislating further on the medical aspects of cannabis. Any further regulation that would address recreational use is still far away, notwithstanding the popularity of the drug in Spain.

Spain, to date, lacks a structured industry lobby. The authors believe that the incorporation of an association or a similar body is critical for pushing a sensible regulatory framework, which would open the local market and ensure patient access to cannabis-based products with high standards of quality, safety and consistency. Increasing awareness of politicians, legislators and key opinion leaders (doctors, etc) is key and needs to be channelled.

Spain has a thriving "cannabis culture" and, hence, a huge commercial potential that remains untapped due to stagnant regulation and insufficient advocacy.

The latest news

During 2020, two events took place that might have an impact on cannabis regulations in Spain. However, their effects remain to be seen.

The first is the ruling of the Court of Justice of the European Union (CJEU) dated 19 November 2020 (C-66318, the Kanavape case).

Briefly, the CJEU found that:

- cannabidiol (CBD) is not expressly included in the list of international and EU psychotropic substances;
- the CBD upon which the main dispute was based – produced in the Czech Republic,

extracted from a cannabis plant that was used in its entirety – "does not appear to have psychotropic or harmful effects on human health on the basis of the available scientific data"; and
- the prohibition on CBD would not affect the marketing of synthetic CBD that had the same properties as CBD extracted from the *Cannabis sativa* plant in its entirety.

In light of the above, the CJEU concluded that any national legislation which prohibits the marketing of CBD lawfully produced in another member state, when extracted from the *Cannabis sativa* plant in its entirety and not just from fibre and seeds, would contravene the Treaty on the Functioning of the European Union, unless such legislation can be deemed as appropriate to secure the aim of protecting public health and does not reach beyond what is strictly necessary for such purpose, which is something to be assessed by national courts.

As per the considerations of the CJEU, the prohibition on CBD obtained from the plant as a whole is neither consistent nor systematic in accordance with the ultimate target of protecting public health. The ruling is binding and sets a relevant precedent for all EU member states and institutions.

The second event was the vote, on 2 December 2020, by the United Nations (UN) on the recognition of the medicinal and therapeutic potential of cannabis. The UN urged to remove cannabis and cannabis resin from Schedule IV of the Single Convention on Narcotic Drugs, which includes the most dangerous substances with limited or no medical value, such as heroin. Thus, from now on, cannabis and cannabis resin should only be classified under Schedule I of the aforementioned Convention, which includes substances that, despite their addictive potential, are not deemed harmful to health and have a therapeutic value.

As stated, the authors cannot anticipate any tangible influence of these two events in terms of future cannabis regulations in Spain, although they consider themselves as optimists in this regard. This article aims to forecast the potential consequences, in particular of the Kanavape sentence, and their impact on the Spanish market, as well as a general overview of the cannabis industry from a legal point of view.

Summary of main economic indicators and political trends

Spain's population is just over 47 million and, according to the Spanish Health Ministry, total healthcare expenditure was 7.9% of GDP during 2020, whereas before the COVID-19 pandemic it was stabilised around 6.5%; in 2021, it was 6.6%.

According to the latest CIS barometer survey, published in April 2021, 90.1% of the population surveyed argue that medical "marijuana" (the word used in the questionnaire) should be legalised, and 49.7% would support legalising its recreational use. The CIS is an independent entity assigned to the Ministry of the Presidency whose main remit is to contribute scientific knowledge on Spanish society.

Spain is home to well-known seed companies and is said to have nurtured a skilled workforce. Users and activists have managed to establish a relevant network of stakeholders (associations, patient groups, seed banks, shops, researchers, etc) and several companies seem to be making significant revenues out of the sale of hemp-related products.

As evidenced by increased media presence, industry events and publication of research, Spain's know-how is growing. Associations and

organisations are flourishing and becoming more vocal, but, unfortunately, in a very unstructured way, lacking a real "industry lobby" that would advocate for regulation of the medical market.

Political trends

A few years ago, in 2017, cannabis came back on to the political agenda in the wake of a changing international and European attitude towards regulation of the industry. Since then, several political initiatives around cannabis have been put forward in the Spanish Congress.

To summarise, the position of Spanish political parties on cannabis is as follows. At the end of 2021, *Mas País* and *Esquerra Republicana de Cataluña* (ERC), on the one hand, and Podemos, on the other hand, all left-wing political parties, submitted two proposals of bills to regulate cannabis. They understood that cannabis must be regulated in Spain to ensure its safe use and avoid illegal traffic. However, neither of these bills passed.

Partido Socialista Obrero Español (PSOE), currently the governing party, has been pleading for the opening of a comprehensive and in-depth debate on the matter. *Ciudadanos* (Cs) suggests the opening of a study paper, in the Health Commission, about the regulation of the medicinal cannabis market. On the other hand, the *Partido Popular* (PP) seem to oppose what they call the "legalisation" of cannabis, but have been less vocal lately.

These political initiatives have consolidated on the creation of a sub-commission within the Spanish Congress of Deputies that is currently studying the future regulation of medical cannabis, having started its work analysing the regulatory experience of other countries.

Lack of a Concrete Regulatory Framework

General overview

Unlike Germany, Italy or other EU countries, Spain lacks a specific approach to the regulation of cannabis, other than under international drug control treaties, Law 17/1967 and criminal and administrative legislations, covering controlled substances and licensing for medicinal or scientific purposes, which is currently causing both social/political alarm and legal insecurity.

The *Agencia Española de Medicamentos y Productos Sanitarios* (AEMPS) is the state agency within the Spanish Ministry of Health that guarantees quality, safety, efficacy and accurate information on medicines and medical devices marketed in Spain. AEMPS protects public health by means of authorisations, registration and controls of manufacturing and marketing carried out on medicines for human use, veterinary medicines, medical devices, cosmetics and personal care products, and support of clinical research. Regarding cannabis, the AEMPS is in charge of issuing the relevant licences – and their supervision and control – to cultivate cannabis for medical or research purposes, as well as the authorisation of medicines containing cannabis derivatives and supervision of cosmetics.

In compliance with its mission, the AEMPS strictly follows the EU framework for cannabis. The AEMPS, as a regulatory body, is characterised by being very low-profile and conservative. In the authors' experience, any approach to this agency should be made prudently and in a co-ordinated manner, as the regulator is under constant pressure from both the industry and politicians.

Market access – licensing

Cultivation licences under Law 17/1967

In Spain, the cultivation of cannabis that is not aimed at producing fibres, grains or seeds and with a high content of tetrahydrocannabinol

(THC) (above 0.2%, pending an update to 0.3%) may only have two different purposes, which are relevant for the grant of licences and authorisations:

- the licence for cultivation of cannabis plants for research purposes, such as the creation of cannabis varieties or seeds for therapeutic use or research of the physical and pharmacological properties of cannabis and its products, will be granted for a year, renewable (for subsequent one-year periods) upon request until the end of the research project;
- the licence for cultivation of cannabis plants for medicinal and scientific purposes is designed in applicable regulations as a "two-step process" – ie, a general licence is needed, which authorises concrete activities, which is subsequently complemented by specific authorisations regarding each concrete plot of land or cultivation site.

The grant of licences and authorisations is subject to the fulfilment by the applicant of certain requirements. Licences and authorisations of the AEMPS are specific to the persons or entities, plots of land, timing and products for which they have been issued and, consequently, do not confer any rights to otherwise dispose of the products or plants out of the scope of the licence granted.

Number of licences issued and rejected so far

As stated above, the grant of research and medical and scientific licences in Spain has been increasing in the last years, although the AEMPS still maintains a conservative approach. It must be considered that, even though laws and regulations do indeed lay down a set of principles and requirements for the grant of licences and authorisations, the AEMPS has been following its own procedures to assess applications, particularly in regard to the concrete order and requests of information, the depth and detail thereof and other relevant aspects. A transparent approach in compliance with applicable laws is key to obtain and maintain licences and authorisations.

In this respect, the AEMPS regularly publishes a list of granted licences on its website. Hundreds of applications have been rejected by the AEMPS, which is very selective and makes a thorough assessment of the commercial plans, solvency and reliability of applicants in order to preserve the legal cannabis market in Spain.

Cultivation of hemp

Cannabis for strict industrial uses (hemp) is excluded from the licensing regime, provided it "lacks the narcotic active principle", as stated in Law 17/1967.

In the European Union (EU), the cultivation of *Cannabis sativa L.* varieties is permitted provided they are registered in the EU's Common Catalogue of Varieties of Agricultural Plant Species and the THC content does not exceed 0.2%. Although hemp cultivation is not subject to authorisation, it must comply with some requirements, including: use of certified seeds; cultivation aimed exclusively to obtain fibres, seed or grains; and farmers must be registered as a producer of seed and nursery plants.

Use of cannabis in medicines

Medicines are regulated throughout their entire life cycle. All medicines used in Spain must obtain a previous marketing authorisation, which AEMPS will grant, after assessing their quality, safety and efficacy. Likewise, any variation of the medicine must be authorised or reported to the AEMPS. These assessments are intended to ensure a positive balance between the benefit and risk of the medicine throughout its progress on the market.

To date, the AEMPS has authorised Sativex and Epidyolexas pharmaceutical medicines containing Delta-9-THC and CBD.

Cosmetics

Regulation 1223/2009 defines "any substance or mixture intended to be placed in contact with the external parts of the human body [...] or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours".

EU regulation is binding and enforceable for each of the member states (including Spain) through their local authorities, which have powers to oversee and regulate in compliance with the EU standards regulatory framework – in Spain, it is the AEMPS. Products meeting the provisions of said Regulation have access to the EU market and may circulate freely within the EU, subject to compliance with certain local law requirements. No pre-market approval is needed (although certain exceptions apply) as the system is based on an internal market control and alert scheme.

The pivotal principles of the EU cosmetics regulation are:

- safe assessment prior to product placement on the market (carried out by manufacturers under high standards);
- appointment of a "responsible person", without which cosmetics cannot be placed on the market;
- cosmetics need to be included in the Cosmetic Products Notification Portal (CPNP) centralised database; and
- reporting of serious undesirable effects (SUE) by responsible persons to local authorities, who will share them with the EU.

Use of CBD in cosmetics

Annex II of Regulation 1223/2009 lists the substances that are prohibited from use in cosmetics. This list includes: "306 – Narcotics, natural and synthetic: All substances listed in Tables I and II of the Single Convention on narcotic drugs signed in New York on 30 March 1961".

CosIng (ie, Cosmetic Ingredients) is the EU Commission's database for information on cosmetics substances and ingredients. However, the CosIng glossary does not constitute a list of ingredients that are to be deemed as authorised for use, is not exhaustive and does not provide proof of a regulatory status. The use of substances in any cosmetic product must always be supported by an assessment of its safety.

Spanish authorities still follow the former entry related to CBD in the CosIng, according to which: "Cannabidiol (CBD) as such, irrespective of its source, is not listed in the Schedules of the 1961 Single Convention on Drugs. However, it shall be prohibited from use in cosmetic products if it is prepared as an extract or tincture or resin of cannabis in accordance with the Single Convention." In other words, natural CBD obtained from non-audited parts of the plant or of synthetic origin is allowed, while CBD obtained from audited parts of the plant is forbidden as a cosmetic ingredient. In this regard, the AEMPS has taken what seems an even more conservative approach, supporting a very strict interpretation around the sources and uses of CBD.

Food

Some products derived from hemp (under 0.2% THC) – such as seeds, seed oil, hemp seed flour and defatted hemp seed – have a history of consumption in the EU and, therefore, are not novel and can be consumed in Spain, according to the Spanish food agency. Regarding CBD, the EU authorities understand that, according to the

information available, this product was not used as a food ingredient before 15 May 1997.

Foods or food supplements that have not been consumed to a significant degree in the EU before 15 May 1997 are classified as "novel foods" and subject to the Novel Food Regulation.

"Novel foods" are (i) recently developed or innovative types of food or food supplements that have been created using technology, and (ii) any food that may have been traditionally eaten outside of the EU. Manufacturers and distributors of such foods can only place them on the market once the EU has granted authorisation following an application.

The routes to be able to market food or food supplements in the EU (or Spain, specifically) are:

- proving a significant history of use in the EU prior to 1997 (there is an official consultation procedure laid down in Article 4);
- as traditional food from a third country with a history of over 25 years of safe usage (Article 15); and
- obtaining a novel food authorisation.

The last-named route requires a safety assessment and a pre-market authorisation before placing the product on the EU market. Such authorisation requires the filing and processing of an application and the implementing act of placing the product on the market, by means of which the novel food will be included in the EU list.

Cannabis as an ingredient of food

Extracts derived from *Cannabis Sativa L.* and derived products containing cannabinoids, such as CBD, according to the Novel Food Catalogue, fall into the novel foods category, both as extracts and as products to which they are added as an ingredient. The status of novel food further applies to extracts of other plants containing cannabinoids and to synthetically obtained cannabinoids.

At the beginning of 2022, EU regulators resumed their review of novel food authorisation applications for CBD products, after abandoning their preliminary stance that CBD should be treated as a narcotic, a change that seems to have come after the Kanavape sentence. Lately, the European Food Safety Authority (EFSA) has stated that it had validated novel food applications from a "number of companies", which means that these applications are now in the final stage of the novel food authorisation process.

Animal feed

EU regulations set out provisions regarding animal feed on:

- safety and marketing requirements;
- responsibilities and obligations of feed businesses;
- restriction and prohibition;
- types of feed;
- labelling and packaging; and
- claims (ie, messages that state, suggest or imply that a feed has particular characteristics).

Feed regulation follows the same principles already analysed regarding food. Feed cannot contain or consist of materials whose placing on the market or use for animal nutritional purposes is prohibited.

While for foods intended for human consumption there is a so-called "positive list" in which ingredients that are approved for human consumption are listed, there is no such list for feed products (only a list of prohibited or restricted materials). The regulations on animal feed are

more open and the use of any natural plant extract is allowed as long as the extracts are made from plants that can be legally cultivated in the EU and do not include any prohibited materials listed in the regulation.

As of today, registrations before the Feed Materials Register of feed containing CBD have been rejected under the consideration that CBD is a non-authorised feed addictive.

Conclusion

With 11 licensed cultivators and two licensed manufacturers currently active, commercial medical cannabis exports began in the second half of 2020 with sales to three countries. This distinguishes Spain as a production powerhouse in European cannabis cultivation, but may be only the beginning. While the opportunities proliferate for producers and Spain is leading the way in developing commercial supply, the country faces the challenge of having to adapt and increase its flexibility to fully accommodate the pressing market reality.

To reiterate: the lack of structured lobbying makes it difficult for the industry to advance and take an evidence-based approach. While the authors believe that the Kanavape case will trigger regulatory reflection, the industry will still have to push very hard in order for Spanish authorities to open their eyes and address the situation.

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Loyra Abogados was founded 39 years ago. It specialises in business advisory and public law, creating a full-service boutique for operators, suppliers, governments and investors acting in highly regulated industries. As a result, Loyra is broadly known for its extensive experience in regulated sectors such as cannabis, media, gaming and betting regulations and compliance across jurisdictions. The firm has advised on regulatory efforts and transactions in the cannabis industry (both domestic and cross-border). In addition, the corporate department (M&A, tax, IP/IT, labour and public law) has continued to provide day-to-day advice to both investors and industry companies who are looking to grow their business and rely on a close and top-of-the-range team of experts as an extension of their internal teams. Loyra has worked both on the preparation and structuring, as well as on the execution, of transactions and investments.

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Cristina Romero de Alba leads Loyra's international corporate department, where she is a partner. She has wide experience in corporate finance transactions, with a particular focus on cross-border. Cristina regularly advises investors and corporates in the cannabis space, both on regulations and business opportunities. She has a double degree in law and business administration from the Carlos III University of Madrid, took a specialisation course in common law at the London School of Economics and Political Science (LSE), and achieved a Master's degree in advisory of listed companies at the Instituto de Empresa (IE). Cristina has been a member of the Madrid Bar since 2006.

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