NAVIGATING THE CANNABIDIOL REGULATORY LANDSCAPE

A pharmaceutical packaging perspective

SGD PHARMA

NAVIGATING THE CANNABIDIOL REGULATORY LANDSCAPE: A PHARMACEUTICAL PACKAGING PERSPECTIVE

Contents

Abstract

The regulatory space around cannabidiol (CBD) – a non-psychoactive compound found in the hemp species of cannabis increasingly used to treat an array of medical problems – is ever-changing and complicated. Regulations vary across different geographies and are constantly being updated. CBD manufacturers must not only navigate the CBD regulatory landscape, but that of cannabis itself, making it one of the most complex markets to operate in. It is thought that by 2021, every state in the United States (U.S.) will legalize cannabis for medical use,[1] with Western Europe and Latin America closely following suit. The highly competitive and fast-moving market is primarily driven by growing demand for alternative therapy and natural remedies – with concentrated CBD oil representing an increasingly popular format. This trend is likely to influence partnerships between CBD manufacturers and packaging companies, as smaller producers look to scale up their operations. The U.S. CBD market is expected to reach 16 billion USD by 2025,[2] but there are currently few CBD oil packaging solutions that meet the compliance standards coming into place across the world, including Good Manufacturing Practice (GMP) and child-resistant closure (CRC) guidance. This paper discusses the current regulations in key regions across the globe and, given the fast changing developments in this area, we will continue to update this information as new developments emerge. It also highlights the need for dedicated, compliant packaging that is designed with pharmaceutical experience in mind. Do come back and download future versions of the paper for the most up-to-date insight from SGD Pharma.

Introduction

Cannabidiol (CBD) is a non-psychoactive compound belonging to a group of chemicals known as cannabinoids, found in the *Cannabis sativa* plant, of which there are many species including marijuana and hemp. These species contain different concentrations of CBD and delta-9-tetrahydrocannabinol (THC) – the psychoactive cannabinoid responsible for the "high" from cannabis use. Hemp contains trace amounts of THC (0.3 %) compared with marijuana (15-20% THC) and is the species from which CBD is extracted and produced for a range of commercial purposes, such as food ingredients, cosmetics, and medicinal products.

Although the Cannabis plant has been used for medical purposes for thousands of years, research into the therapeutic advantages of CBD has driven the demand for this compound for mainstream medicinal use over the last few years.

Cannabinoids bind with receptors all over the human body as part of the endocannabinoid system (ECS), which mediates their biological effects. The two receptor subtypes – CB1R and CB2R – are predominantly located in different areas of the body: CB1R is the prominent subtype in the central nervous system (CNS), so has been the subject of interest for developing therapies for neuropsychological disorders and neurodegenerative diseases; CB2R shows prominent expression in immune cells and peripheral tissues, such as the gastrointestinal (GI) tract, kidneys, skeletal muscle, reproductive system, cardiovascular system, and liver.

The rising global trend towards self-medication and general wellness, as well as the switch to natural and organic alternatives to traditional pharmaceuticals, is driving CBD market growth. An increasing number of pharma laboratories are developing drugs containing CBD molecules (Figure 1).

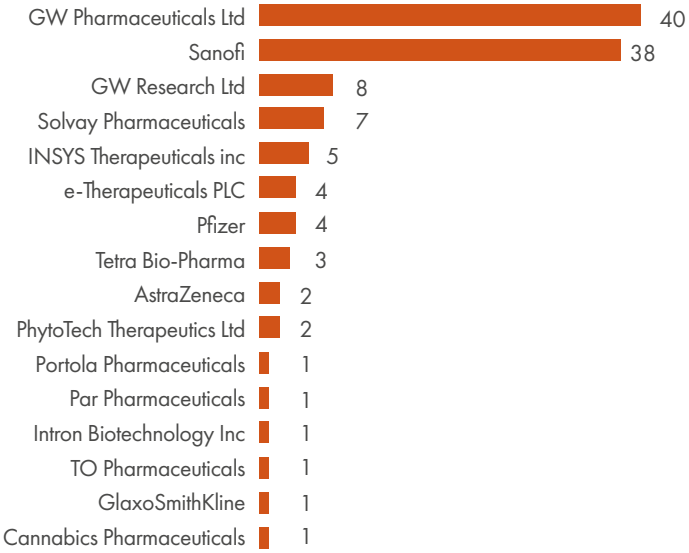


Figure 1: Number of cannabinoid (CBD) clinical trials registered by the U.S. Food and Drug Administration (FDA) in July 2019.

The U.S. Food and Drug Administration (FDA) approved the first drug using CBD as an active ingredient, EPIDIOLEX® (oral solution), in June 2018 to treat patients 2 years of age or older with one of two severe and life-threatening forms of childhood-onset epilepsy – Lennox-Gastaut or Dravet syndrome.

The global CBD market was valued at USD 4.6 billion in 2018 and is expected to grow at a compound annual growth rate (CAGR) of 22.2% from 2019 to 2025.[3] North America is currently the dominant region with the largest market share, owing to the increasing legalization of medicinal cannabis in many U.S. States as a result of more widespread acceptance of CBD for pharmaceutical, wellness and personal use. Canada has also legalized the production and sale of both CBD and THC-potent marijuana for medical purposes, further supporting the growth of the market in North America.

The European medicinal CBD market is also surging, pioneered by the United Kingdom (UK) and Germany, and Latin American countries are increasingly adopting medical cannabis programs. The medical segment (non-prescribed products) dominated the CBD market in 2018, but the pharmaceutical segment (prescribed products with market authorization) is expected to experience the highest growth rate over the next few years, driven by companies manufacturing pharmaceuticals with CBD as an active ingredient for treating various medical conditions such as epilepsy and managing multiple sclerosis (MS) symptoms.

Such products, unlike many medical CBD products, require pharmaceutical-level approval following successful clinical trials.

There are several challenges facing companies trying to navigate the CBD regulatory landscape:

- Many countries are restricted by a lack of clear distinction between cannabis and CBD. The overlap of CBD with cannabis, which is tightly regulated in most regions due to its psychotropic effects, limits the easing of restrictions surrounding CBD products.
- The end use of CBD significantly impacts regulations worldwide. For example, CBD for medicinal use is carefully regulated and strict rules apply to making therapeutic claims.
- In Europe, companies must obtain Novel Food authentication to market food products containing CBD as food supplements. The complexity of the application process is a barrier to many organizations, which may not have the resources to complete the application.

Today, CBD is available in several dosage forms. Liquid dosage forms dominate the market, with approximately 53% being in oil/tincture product form (Europe) as the most popular way to ingest CBD. As such, these products - mostly packaged in amber glass dropper bottles - have experienced a significant rise in online sales (Figure 2).[4] This separates the CBD oil market from traditional pharmaceuticals and makes the regulation of these products challenging. However, like the pharmaceutical industry, strict packaging requirements must be met to ensure compliance with both global and regional regulatory guidelines and safety criteria. CBD packaging should also meet consumer needs. As an example, understanding the appropriate dosing of CBD for each intended application remains one of the primary challenges for consumers, with most – particularly those using CBD for general wellness – ingesting less than 5 mg per serving.

As well as accurate dosage, consumers are looking for convenience and safety. Designing CBD packaging that is both convenient and safe, for example with child-resistant closures (CRC), in a rapidly growing market where legislation is constantly evolving, is a significant challenge facing the CBD industry. The disparity between regional, national, and even local level regulation of cannabis and CBD is impacting the value chain at every stage, with manufacturers and retailers increasingly looking to outsource packaging as the market grows, and consumers calling for more consistency from brands. Not only can contract packaging provide this consistency, but it can relieve some of the responsibility companies face in complying with often complex regulations.

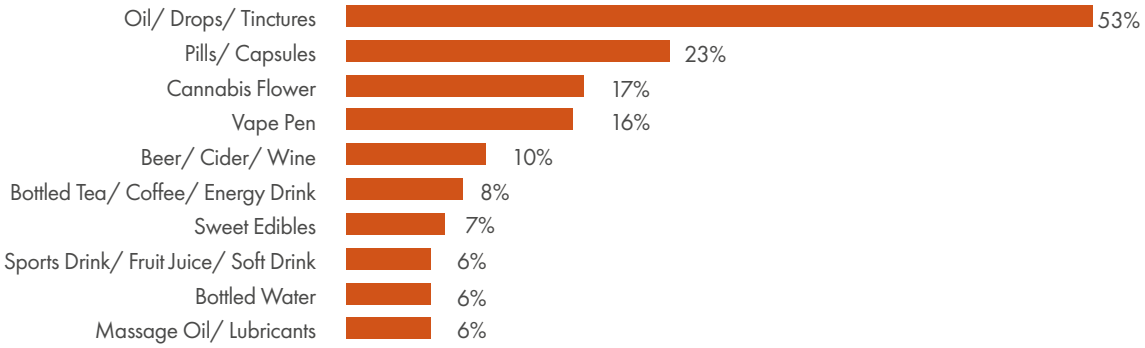


Figure 2: Proportion of different cannabidiol (CBD) formats used in the European market.

CBD regulations – A global view

At the international level, the United Nations (UN) drug control treaties – under which the medical use of cannabis is very strictly limited – provide a backdrop to the regulatory frameworks for the medical use of cannabis and cannabinoids in all signatory countries. These frameworks, rather than being unified, differ vastly depending on the country or state, and authorization to sell depends on the interpretation of regulations by different national health agencies. The regulated use of cannabinoids, such as CBD as an ingredient, depends on the final usage product: food, pharmaceutical and cosmetic CBD products are subject to different regulatory standards in different geographical regions.

Additionally, the part of the *Cannabis sativa* plant that the CBD is derived from (seeds, flowers, or fiber/stalks) plays a significant role in whether certain products are permitted or prohibited (Figure 3). While the regulations are diverse and rapidly changing, the following summary addresses the regulatory infrastructure in the key regions of North America, Europe, and Latin America, in 2020.

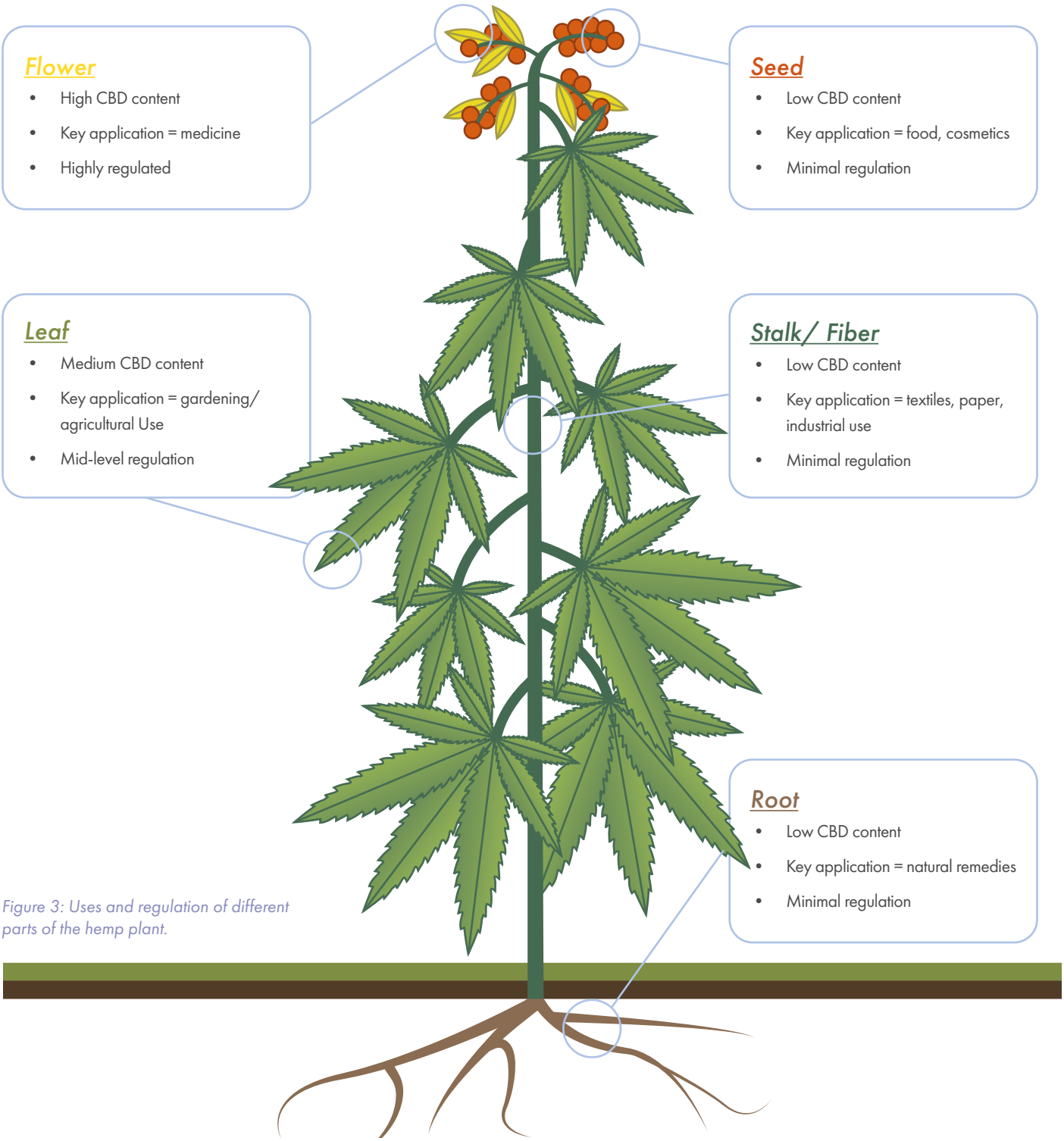


Figure 3: Uses and regulation of different parts of the hemp plant.

North America

North America was the first region to introduce the medical use of cannabis, following the passage of a citizen-initiated referenda in the U.S. to legalize medical use of cannabis in the mid-1990s.[5] As the different States of North America continue to liberalize laws related to the recreational and medical use of cannabis, more companies are expected to enter into this market in order to address the surging demand. High public and private investments in this sector are further propelling research related to cannabis products, actively driving the growth of the market, which is expected to reach $36.7 billion in 2025.[6] However, despite the legalization of cannabis in Canada and many States in the U.S. for both medical and recreational use, its cultivation, production, distribution, and possession are highly controlled under strict regulations, potentially impeding future market growth.

Canada

Canada was one of the first nations to fully legalize recreational cannabis in 2018 at the federal level, and is the only country to permit the growth, consumption, and sale of cannabis. While the cultivation, processing, and production of cannabis is controlled federally, regulations regarding the distribution and sale of non-medical cannabis are the responsibility of each province or territory.[7] Despite legalization, in 2019, legal cannabis sales only accounted for 29% of sales in the Canadian market, meaning the black market retained a dominant share.[8] This has been attributed to the restricted forms of legal cannabis – currently only flower and oils – so the black market is still fulfilling the majority of consumer demand post-legalization. There is also no legal pathway for producers to sell hemp-derived CBD products intended for ingestion outside of dispensaries, and Health Canada is yet to approve CBD as an ingredient for food or beverage, although this is currently under review.

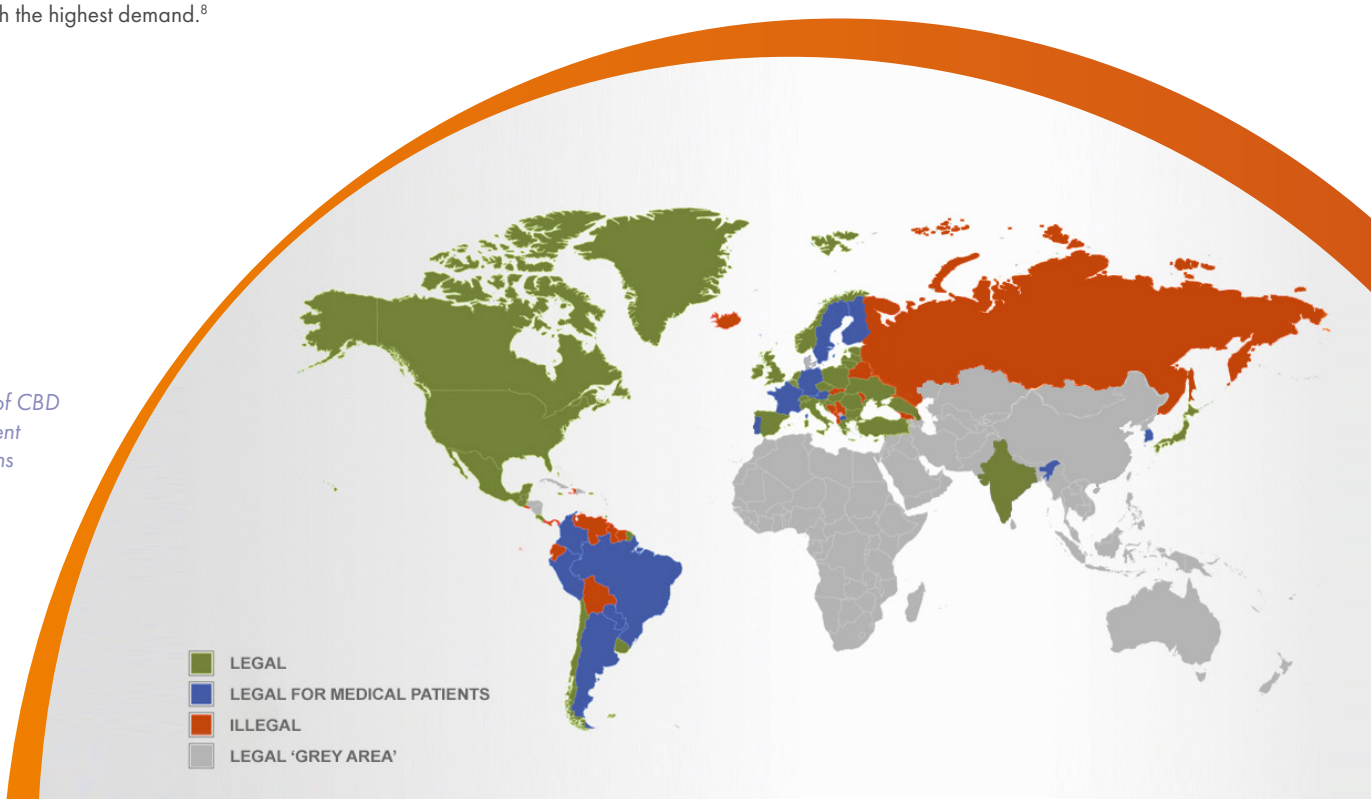
These restrictions have led to slowed market growth in Canada, particularly for medical cannabis. Difficulties with licensing for dispensaries has contributed to this, where each province is responsible for dispensary licensing within their territory, resulting in a patchwork of regulations that has created a shortage of physical dispensaries in provinces with the highest demand.[8]

United States

Unlike Canada, cannabis is not legal at the national (federal) level in the U.S. Legalization is determined on a State-by-State basis. As of January 2020, 11 States approved full cannabis legalization, 33 have approved medical legalization – permitting the sale of cannabis to adults with a doctor's prescription – and 15 states have decriminalized the possession of small quantities of marijuana. The passage of the 2018 Farm Bill set the ball rolling for the growth of the US CBD market. The signed bill removed hemp, defined as cannabis (*Cannabis sativa L.*) and derivatives of cannabis with no more than 0.3% THC concentration, from the definition of marijuana in the Controlled Substances Act (CSA).[9] However, the bill has been widely misinterpreted to mean that all products made from hemp, including those made with CBD, are legal to sell in interstate commerce, resulting in a flood of online retailers selling CBD products, often with unsubstantiated therapeutic claims.

In fact, under the Farm Bill, cannabinoids are only legal if the hemp is produced in a manner that is consistent with the Bill, with associated state and federal regulations, and by a licensed grower. All other cannabinoids are illegal, with the exception of pharmaceutical-grade CBD products that have been approved by the U.S. FDA for medical use, such as GW Pharmaceutical's EPIDYOLEX®.

Along with legalizing industrial hemp, the 2018 Farm Bill also assigned federal regulatory authority for its production to the U.S. Department of Agriculture (USDA), but designated provisions where the U.S. FDA retained its ability to regulate products subject to the federal Food, Drug and Cosmetic Act (FDCA).[10] So, while the Bill provided the USDA with jurisdiction of hemp production, it also left intact the FDA's authority of certain hemp and hemp-derived products (cosmetics, dietary supplements, food, and drugs), meaning that hemp and hemp products must also be compliant with the FDCA and its related regulations, which vary depending on the product type.



Legal status of CBD across different global regions

Europe

CBD in the pharma sector

At the European Union (EU) level, the European Medicines Agency (EMA) is responsible for the scientific evaluation, supervision, and safety monitoring of medicines, and it coordinates a network of national regulatory authorities.[5] National regulatory authorities license the use of a medicinal product based on the European requirements for marketing authorizations, which stipulate the evidence of sufficient manufacturing quality and safety/efficiency indications from clinical trials.[11,12]

In September 2019, the EMA followed in the FDA's footsteps and approved EPIDIOLEX®. Based on the results of four Phase III clinical trials, the approval is valid in all 28 countries of the EU, as well as in Norway, Iceland, and Liechtenstein.

CBD in the food sector

In January 2019, the European Commission added *Cannabis sativa* extracts, including CBD, to the Novel Foods Catalogue, requiring pre-market authorization from the European Food Standards Agency (EFSA) to sell food, drink and food supplements containing CBD. (As of February 2020, the EFSA had received around 20 novel food applications, two of which have been validated and entered the risk assessment phase, but so far none has been granted the status of approved novel foods).[13]

Despite the seemingly united approach to CBD regulation in Europe, the situation is still fragmented on a localized level country-by-country. Every country has a different method of regulating CBD production, sale, and consumption. Part of the challenge is the disparity of what is available on the market. While consumers tend to look for high-quality products, the market is flooded with a confusing array of products that make unsubstantiated claims about health benefits. The increasing interest in medical CBD products from within the EU is likely to lead to some much-needed harmonization of rules.

United Kingdom

The UK is one of the key European countries leading the way in the CBD industry. Although CBD is legal in the UK, the regulatory picture is complicated. Importing and selling CBD depends on the THC concentration of the product and its format. Regulations are relatively lenient on CBD import, and sellers do not require a 'hemp license' providing THC is not detected above 0.01%, as verified by an ISO accredited laboratory. However, it is illegal to sell CBD flowers or buds, even if the THC concentration is below 0.2% (required level for EU approval, unless medicinal).[14] Despite the restrictions on buds and flowers, the UK's approach to enforcement is comparatively relaxed, which has led to some confusion in the retail space and prohibited products are still commonly sold in shops and online.

CBD in the pharma sector

In October 2016, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) announced that CBD-containing products advertised for medical purposes must be licensed.[15] Under this license, medicinal products must have marketing authorization before they can be legally sold, supplied or advertised in the UK, unless exempt. Licensed medicinal products must meet safety, quality, and efficacy standards to protect public health. The CBD industry was already rife with products claiming medicinal benefits, and these companies faced withdrawing their products from sale or changing their marketing in the three-month period provided.

Many manufacturers who could no longer sell CBD products marketed for medicinal use due to the 2016 MHRA regulation have instead focused their attention towards gaining novel food status. However, the application process is both resource- and time-intensive, which has led to CBD products remaining on the market under medicinal applications, as the MHRA's position is not strictly enforced. Steps are being made to improve this situation. The Centre for Medicinal Cannabis (CMC) initiated the Cannabinoid Industry Quality Charter in August 2019 to facilitate a more legally compliant, socially responsible, and innovative CBD industry in the UK.[16]

CBD in the food sector

In February 2020, the UK Food Standards Agency (FSA) announced that it was giving the CBD industry a deadline of 31 March 2021 to submit valid novel food authorization applications, as per the European Commission announcement. After this deadline, only products that have submitted a valid application will be allowed to remain on the market.

France

France ranks among one of the most important EU producers of industrial hemp. However, French law restricts the number of authorized varieties of hemp, confining its legal use to seeds and fibers and therefore limiting the hemp industry to the production of textile, paper, or seeds for human and/or animal consumption.[17] In June 2018, the Interministerial Mission for Combating Drugs and Addictive Behaviours (MILDECA), a unit within the cabinet of the French Prime Minister, issued a non-binding interpretation of the legislation with respect to CBD, stating that CBD-based products are prohibited if they contain any THC in the end product (regardless of amount) and are not derived from the seeds or fibers of an authorized cannabis variety.

Similar to the UK, it is well known that the French authorities are inconsistent with enforcement. A cross-party parliamentary task force was therefore officially launched in January 2020 to address the challenges with cannabis and CBD regulations, for medical, well-being and recreational use, recognizing the economic potential of the plant and its various derivatives.

In May 2020, an opinion statement from Advocate General Tanchev at the Court of Justice of the European Union (ECJ) was issued following a request from the Court of Appeal, Aix-en-Provence, France, over the marketing of an electronic cigarette containing CBD.[18] The directors of the company, which markets the e-cigarette under the name 'Kanavape', were convicted of a criminal offence by the Criminal Court of Marseille, on the grounds that the CBD oil was extracted from the whole hemp plant, including the leaves and flowers. French legislation restricts the cultivation, importation, exportation, and industrial and commercial use of hemp solely to its fiber and seeds. However, as the CBD oil contained in Kanavape was imported from the Czech Republic, where the hemp plant was cultivated and the CBD was extracted, the Court of Appeal of Aix-en-Provence argues that, under articles 34 and 36 of the FEU Treaty, an EU member country cannot ban imports of CBD oil from another member state when the integrality of the CBD oil is extracted from the whole hemp plant (rather than only the fiber or seeds). The Advocate General's conclusion, which considers the non-psychotropic and non-harmful effects of CBD oil, was that there is no legal basis to ban the import of CBD oil on French territory. If confirmed by the ECJ, this opinion will be an important catalyst for discussion of the sale of CBD in Europe.

CBD in the pharma sector

The French National Agency for Medicines and Health Products Safety (ANSM) issued a positive statement on the experimentation of medical cannabis usage in July 2019, also publishing the conditions required for experiments, valid for two years thereafter. The purpose of the experimentation of cannabis for medical use is to assess the feasibility of the routes for making cannabis available to patients, i.e. prescription by doctors, dispensing by pharmacists, product supply, and patient monitoring.[19] Its second objective is to collect the first French dataset on the efficacy and safety of the use of cannabis in a medical setting. The decree has been published on the 9th October 2020 by the health ministry, to validate the launch of therapeutic cannabis experimentation for 2 years, where 3000 patients will be treated and monitored. Five diseases/conditions have been selected: neuropathic pain, some forms of epilepsy, some oncology symptoms, spasticity caused by multiple sclerosis, palliative situations, and other pathologies of the central nervous system.

Germany

According to the German Narcotic and Psychotropic Drugs Act (BtMG), cannabis and cannabis resin are classified as scheduled substances. Exemptions from the definition of cannabis include: seeds, hemp grown from certified seeds when grown for commercial or scientific purpose, industrial hemp (grown by agricultural entities from certified seeds of varieties listed in the EU Common Catalogue), and medical marijuana (cultivated for medical purpose under state control and when used in approved finished medicinal products).[20]

CBD in the food sector

According to the Federal Office of Consumer Protection and Food Safety (BVL), CBD products are not marketable in Germany. The BVL states that only food products derived from hemp seeds (hemp seed oil, hemp seed flour, defatted hemp protein) can be marketed in Germany. According to the BVL, all foods containing cannabinoids (from hemp or other sources) require authorization either as a Novel Food or as a drug.[17] There are no legal implications in this, however.

Italy

Compared with other European countries, Italy has one of the most complex regulatory landscapes for cannabis and CBD. Inter-party politics has hindered any meaningful progress in regulating the CBD market thus far. An amendment to the current hemp law, aiming to legalize the sale of CBD flowers (with less than 0.5% THC), was proposed in June 2020 but was unanimously rejected. The proposal aimed to not only regulate the supply chain, but invigorate Italy's economy, particularly in light of the COVID-19 pandemic.

The sale of CBD-based products in Italy continues to spread despite the currently unclear regulation and confusing judgements. Inconsistent law enforcement affects company investments, and lack of regulation of CBD flowers leaves judges to make decisions on a case-by-case basis with no guidance.

Latin America

South America is an important region of growth for the CBD market,

becoming a major supply hub for the growth and processing of cannabis and hemp biomass, as well as supporting domestic end-product markets. Laws remain strict but governments are generally showing support for liberalizing the rules affecting the industry.

Brazil

CBD in the pharma sector

CBD regulation is changing at a rapid rate in Brazil. Although the country does not permit hemp or marijuana cultivation – in fact, a proposal to allow this was rejected by the Brazilian National Health Agency (ANVISA) in December 2019 – raw CBD may be imported for final manufacturing. Brazil already allowed the use of Sativex – a prescription marijuana-derived treatment for multiple sclerosis produced by GW Pharmaceuticals – but ANVISA has also recently provided "sanitary authorization" of a TCH-free oral CBD product from Brazilian pharmaceutical company Prati-Donaduzzi that has not yet completed clinical trials.

Although this may seem like an opportunity for CBD and pharmaceutical companies to capitalize on, products will still have to navigate the ban on cannabis flowers, comply with extensive Good Manufacturing Practice (GMP) requirements, and refrain from marketing with the word "medical" or similar. Consumers will need a special prescription, including for products with minimal or no THC.

Mexico

The Mexican approach to cannabis and CBD regulation is a focus on human rights, public health, and sustainable development, by combating the consequences of problematic cannabis use and reducing drug-related crime, while promoting security and well-being. In June 2017, President Enrique Peña Nieto signed a bill into law that officially legalized the cultivation, production, and use of medical cannabis products with less than 1% THC in Mexico[21] and two years later, In October 2019, the United Commissions of Justice, Health and Legislative Studies initiated specific actions aimed at proper regulation of cannabis use.[16]

Mexico took a historic first step in March 2020 towards nationwide legalization of cannabis when the Senate voted to approve the "General Law for the Regulation and Control of Cannabis" – the first in a series of legislative agreements required to decriminalize cannabis cultivation, use and distribution in the country.[22] The second step, to prepare and approve the new legislation, has been delayed by the COVID-19 pandemic, and legislators have been given until December 2020 to pass the new law.

Uruguay

CBD in the pharma sector

Uruguay became the first country to legalize non-medical cannabis at a federal level in 2015, followed three years later by Canada. Similarly to Brazil, Uruguay is taking steps to produce clear guidance to the production and use of medical cannabis. In December 2019, the Uruguayan Senate approved a bill regulating access to and promotion of medical cannabis, with the Institute for Regulation and Control of Cannabis (IRCCA) establishing a certification and quality control system and the Ministry of Public Health implementing a medicinal cannabis and therapeutic use programme.[16]

Colombia

The CBD industry in Colombia is largely centered around the details of psychoactive and non-psychoactive cannabis definitions. Colombia does not use the term "hemp", instead referring to the "top of the plant with flower or fruit which contains resin" as cannabis – parts and seeds not in contact with the top of the plant are not included within the definition – and drawing a distinction between products with a THC content under 1% (non-psychoactive cannabis) and those above that threshold (psychoactive cannabis).[23]

Colombia's Technical Resolution 315 from 2020 lists cannabis among psychotropic substances that are subject to Ministry of Health and Social Protection control, including cannabis derivatives that contain 0.2% or more THC. According to Law 1787 of 2016 and Decree 613 of 2017, cultivation of cannabis is only permitted for medicinal and scientific use, subject to a license issued by the Ministry of Justice and Law, with a distinction between cultivation of psychoactive and non-psychoactive cannabis.[24]

CBD packaging compliance

The supply chain for both pharmaceutical and food CBD products involves numerous entities, including hemp growers, manufacturers, food or pharmaceutical companies, consumer and healthcare brands, packaging suppliers, distributors, dispensaries and pharmacies, and online retailers. Knowledge and understanding of the regulatory requirements for CBD packaging varies widely across the supply chain, and those with a more comprehensive view of the strict compliance hurdles and penalties for non-compliance, will be at an advantage. By interpreting regulation of cannabis and CBD in the food and pharmaceutical segments of the industry, companies can better navigate compliance at the national and international level, rather than local.

Most packaging solutions on the market dedicated to CBD oil products are yet to comply with regulatory guidance. Some concentrates, particularly those intended to be used as additives to food and beverage, are packaged in small glass bottles with a dropper top. These formats must support product integrity – for example preventing oxidative breakdown using amber glass – as well as safety, but different countries have different requirements for CBD packaging. For example, Canadian regulations require that the package: contains only one class of cannabis, is child resistant (CRC), has a security feature, does not exceed the maximum quantity of THC, and has dose control measures. There are also a series of strict labelling requirements.

Unlike in Canada, because cannabis is not legal on the national (federal) level in the US, it is necessary for individual States again to stipulate the packaging requirements for both cannabis and CBD products and therefore these vary considerably from state to state. One unanimous requirement across all States selling cannabis is that the packaging must be child-resistant, according to the standards set by the Consumer Product Safety Commission (CPSC) (16 CRF 1700.20).[25] It is thought that as the industry matures, there will be additional requirements for both shelf-life testing and expiration dating standards – both integral in the food and pharmaceutical packaging industries.

Given the regional variation in CBD regulation, recommended best practice is to adopt robust compliance with regards to packaging. By adhering to pharmaceutical and food packaging standards, CBD manufacturers that can ensure their products meet the changing requirements set by standards authorities, regulatory bodies, and government agencies. By leveraging decades of expertise in pharmaceutical primary packaging, SGD Pharma is the only partner able to navigate the complex CBD regulatory landscape and provide manufacturers with peace of mind that their product complies with appropriate global regulations.

The complete CBD oil packaging solution

More than 50% of all CBD products are formulated in liquid oil or tincture formats, which require accurate dosing, optimal effectiveness, and consumer convenience. CBD is a naturally derived product with a complex molecular structure that is sensitive to both light and air. Selecting the right packaging format that protects the product's integrity is therefore vital.

Ensiemo, the new glass dropper bottle solution from SGD Pharma, is available in amber and clear glass to provide unrivalled barrier properties to prevent CBD molecule degradation. The natural and neutral properties of glass that make it a popular material for pharmaceutical primary packaging are ideally suited to CBD oils.

Made from pharmaceutical-grade glass, Ensiemo provides CBD oil producers and distributors with the assurance that their packaging complies with global regulations, including:

- Good Manufacturing Practice (GMP) specification (ISO 15378)
- Child-resistant closure (CRC) certification (ISO 8317 for EU & Canada; US 16 CFR)
- Compliance with EU directive 75/324/CEE.

Future outlook

The CBD industry is changing at a rapid rate and will likely continue to evolve over the early 2020s. Regulation of cannabis and cannabis extracts, such as CBD, underpins the growth of this market and determines the capacity in which CBD products can be sold, distributed, and purchased. As we have seen, cannabis and CBD regulation varies widely between countries and states. The lack of consistency in both regulations and enforcement often leads to confusion in the market, making it difficult for CBD product manufacturers to establish a secure supply chain.

While North America continues to dominate the CBD market, Europe is closely following suit, with Latin American countries making considerable steps in decriminalizing cannabis, which in turn will enable the CBD industry to grow. Further U.S. States are likely to legalize cannabis to varying degrees, but unless the FDA provides clarification on its oversight of CBD products, uncertainty will remain, and the industry's growth could slow.

Companies can alleviate concerns surrounding CBD oil regulation by following best practice from the food and pharmaceutical industries, particularly with regards to packaging. In this fragmented market, leveraging the expertise from pharmaceutical packaging leaders can help companies navigate the complex landscape and ensure their CBD oil products comply with global regulations.

For more information about Ensiemo, please visit https://www.sgd-pharma.com/ensiemo or download our brochure here.

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Founded in 1896 in France and with a global footprint and a strong sales force, SGD Pharma is recognized worldwide as a key player that customers can rely on to support new product development, day-to-day delivery, quality or regulatory support. SGD Pharma benefits from a long know-how and a best-in-class manufacturing footprint. The company has a long-term investment plan to regularly leverage its manufacturing facilities and develop people competencies to be at the cutting edge of the technology. SGD Pharma commits to have the same standard in all its facilities. In 2020, all plants are certified according to ISO 15378 standard, pharma GMP's compliant and equipped with ISO 8 clean rooms. SGD Pharma is a producer of molded glass for pharmaceutical primary packaging, operating worldwide with five factories and a network of more than 90 partners and distributors. For more information, please visit www.sgd-pharma.com

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