fieldfisher

Cannabis

Unlocking the UK market

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Introduction

In recent years global interest in cannabis products has rocketed, with projections that it will be worth a staggering $75 billion by **2027**[1]. Perhaps unsurprising, given the shift in public perception on cannabis and the loosening of regulatory bottlenecks worldwide, but it is still a sector facing prejudice and challenge.

Despite economic downturns and general instability in certain regional markets, investment into cannabis production has continued to boom. This indicates that the use of cannabis in products is not just a fad, but a market with long-term potential.

However, many businesses involved in cannabis from investment, production and R&D through to sales and distribution, still face frustration at the myriad of hurdles in getting to market.

In the UK, pure cannabidiol (CBD) – an active, but non-psychoactive ingredient in cannabis derived from the hemp plant – is not classified as a controlled substance and can therefore be sold in the UK, although changes for ingested products are imminent.

In Europe, the recent Court of Justice of the European Union (CJEU) KanaVape decision[2] raised expectations that barriers to free trade of CBD products in individual countries across the EU will be dismantled.

But we enter a grey area when it comes to low levels of tetrahydrocannabinol (THC) – the main psychoactive ingredient in cannabis that gets recreational users "high" – where the industry is currently at the mercy of interpretations of vague and inconsistent UK and European laws.

Post-Brexit (as of 1 January 2021) the UK has the potential to take a different route in numerous areas of regulation.

One of these is the approach it takes to how cannabinoid products are to be regulated and how they get to market. Arguably this journey is already underway.

While it has been generally quite difficult to scope out the value of the legal cannabis market in the UK, the Centre for Medicinal Cannabis has placed it at around £300 million and expects this to increase to almost £1 billion by 2050[3].

Due to potential value of this market, post-Brexit Britain could unlock this market and position itself as another hub for the global cannabis industry and its products.

In view of this opportunity, now is a good time look at the current landscape regarding cannabis products within the UK and EU and where the pockets of opportunity are.

[1] www.grandviewresearch.com/press-release/global-legal-marijuana-market

[2] www.courthousenews.com/wp-content/uploads/2020/11/cannabis-ecj.pdf

[3] static1.squarespace.com/static/5f1ebab9df1a5a6c6f4a9fd0/t/5f2afe8d4db5d05efe95920f/1596653198725/Exec+Summary.pdf

Introduction continued

Cannabinoid products are wide-ranging but can be roughly divided these into five core groups:

- ingested CBD products (food, beverage and tinctures)
- licensable medicinal cannabis
- cosmetics and topical ointments containing CBD
- vaping products and
- recreational (non-medicalised) cannabis

Behind each of these sectors sit growers, producers, importers and distributors who supply the ingredients required for these products.

In this paper a team of Fieldfisher experts from the UK, Belgium, France, Ireland and Spain with insights from external experts in the field, consider the approach in particular to CBD as a novel food and also wider and evolving issues for cannabis producers, manufacturers and distributors across Europe.

Cannabinoids

Definitions are very important in getting a product across the line to market.

While cannabis refers to all the products found in the Cannabis Sativa plant, cannabinoids refer to the naturally occurring elements. There are thought to be over 144 cannabinoids found in cannabis but the most notable is tetrahydrocannabinol (THC), the primary psychoactive compound in cannabis.

Another major constituent chemical compound which can be extracted from the cannabis plant is cannabidiol (CBD).

Hemp refers to cannabis plants, which – containing less than 0.2-3% THC – can be grown legally. Marijuana, on the other hand, contains more THC. THC has more pronounced psychoactive effects (produces a high), and above trace levels is classified as an illegal substance in most European countries.

Cannabis products as a novel food in the UK

The novel food classification has had the biggest impact to date on non-psychoactive cannabis products sold in the UK.

The novel food classification only came in 2019 and currently there are no authorised products in this classification. Various countries within the EU are threatening to start enforcement proceedings against unauthorised products. In the UK this has been announced as from April 2021. Consequently, there is an urgency by those operating in this space to get novel food authorisations submitted in the EU and UK.

Since 1 January 2018, novel foods in the EU have been regulated under Regulation (EU) 2015/2283, which updated earlier and more complicated Directives in the sector. Under the Regulation, once a product is authorised, the authorisation is generic.

This means that any food business operator can place an authorised Novel Food on the EU market, provided the authorised conditions of use, labelling requirements, and specifications for the authorised product are respected.

This is a change from the previous applicant-specific, restricted novel food authorisations under the old Novel Food regime.

Novel food will only be authorised for use in the EU, if it does not present a risk to public health, is not nutritionally disadvantageous when replacing a similar food, and is not misleading to the consumer. It must undergo a scientific assessment prior to authorisation to ensure its safety.

The authorisation sets out the conditions for its use, its designation as a food, specific labelling requirements and post-market monitoring requirements.

There has been much debate about the status of ingested CBD and other cannabinoid products in Europe. The novel food status of extracts of Cannabis Sativa L and derived products containing cannabinoids in Europe was confirmed in January 2019, and the Novel Food Catalogue has been updated to reflect this change. Synthetically obtained cannabinoids are also considered as novel.

Cannabis products as a novel food in the UK continued

In the 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% (w/w).

Some products derived from the Cannabis Sativa plant or plant parts such as seeds, seed oil, hemp seed flour, defatted hemp seed, and products including cold-pressed oils, have a history of consumption in the EU and therefore, are not novel. However, other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States.

The Novel Food Catalogue is used by the European Commission to show the decisions made on novel food status and it is these decisions that have legal status. This makes it clear that cannabinoid extract and isolate products are legally novel foods. The European Food Safety Authority (EFSA) website advises that there are currently no authorised cannabinoid extracts or isolates on the market.

The UK has had to develop its own approach to novel foods to apply post-Brexit. At the end of the transition period and having exited the EU, the UK will have its own "List of authorised novel foods", and will be free to establish and update a list of novel foods authorised to be placed on the market within its jurisdiction. Only novel foods authorised and included in the list will be allowed to be placed on the market within the UK as such, or used in or on foods, in accordance with the conditions of use and the labelling requirements specified in the list.

The Food Safety Agency (FSA) is responsible for regulating cannabinoids as a novel food in England, Wales and Northern Ireland (there is a separate body Food Safety Scotland which covers Scotland). In February 2020, these agencies announced that pregnant women, breastfeeding mothers and people taking medication should not consume CBD products. It also advises otherwise healthy adults to think carefully about taking the supplement, and take no more than 70mg a day. This is due to a recent study by the Government's Committee on Toxicity (COT), which found there are 'potential adverse health effects'

In the UK, technically the legal limit of THC in finished CBD products is 0%, although debate continues about the detectability of THC and how "no THC" can be evidenced when laboratory testing cannot be this precise. Because it is legal to grow industrial hemp containing up to 0.2% THC with a licence, this is commonly misunderstood as applying to CBD products.

The UK version of the list will, like the EFSA have no CBD novel food authorised products in early 2021. Therefore, there is no possibility, until products begin to receive authorisation, of operators simply placing their own brand of a generic product on the market (one which matches conditions of use, labelling requirements, and specifications).

In due course this will be possible but it requires authorised products to be listed (and for the data to be publicly available and not subject to data protection provisions which allow for confidentiality around newly developed scientific evidence and proprietary data).

The race to submit

In February 2020, the UK's Food Standards Agency (FSA) announced a deadline of 31 March 2021 to submit valid novel food authorisation applications. After 31 March 2021, only products which have submitted a valid application will be allowed to remain on the market.

Products that have not submitted a valid application cannot be lawfully supplied or placed on the market and it is expected that Local Authorities (via their Trading Standards teams) and retailers will take steps to enforce this.

Enforcement would be under the Novel Foods (England) Regulations 2018/154 (and relevant equivalent legislation) which it is anticipated will be amended pursuant to the Novel Food (Amendment) (EU Exit) Regulations 2019/702 which have been passed and are expected to come into force on 31 December 2020.

The UK's FSA is clear that food businesses should apply for authorisation of their cannabinoid extracts and isolates. It states:

"This is the only route to compliance for these CBD products, and no separate arrangement has been made with any specific business or industry sector. In most cases this may be the manufacturer, but others such as trade bodies and other suppliers may also apply. What is important is that the specific novel CBD products you sell must be included within an application and they must be made the same way as detailed in the application but the application can be made by someone else, such as your supplier."

The FSA website is also clear that:

"Where a business buys CBD products from others, they must ensure these products are correctly authorised, and that they only use them in ways described in the authorisation."

Novel food product authorisations are unique to individual products (but not to the applicant). Once a cannabinoid product is authorised, that authorisation applies to that exact product only. This means anyone relying on an existing authorisation must use the same detailed production methods, for the exact same uses as described within the authorisation, and using the same safety evidence base.

CBD products will start to be authorised at some point in 2021 but it is not known what products and how long after the March 2021 deadline this will start to happen.

While the authorisation itself is not specific to the applicant, where the applicant requests it and is granted confidentiality, key aspects of production and the research evidenced base may not be available to others for five years making it impossible to know how to comply with the authorisation. It is possible that rival, similar/identical products will need to be authorised as the detail may be protected by confidentiality provisions.

Cannabis products as a novel food in the UK continued

Article 4 of the Novel Food Regulations provides a consultation process for a business to check if their product is novel or not, but an Article 4 submission is not a route to compliance for any novel food, including cannabinoids.

For businesses seeking to place products on the market in both the UK and the EU, in addition to submitting a Novel Food application to the European Commission (to the EFSA), the UK's FSA strongly recommends businesses also send applications to it via the links on its Novel Foods page, which there is currently no fee to do.

The FSA has indicated it will give businesses guidance and answer any queries they may have, in order to ensure they progress at pace through the UK authorisation process from 1 January 2021.

However, despite reassurance from the FSA, the European Food Safety Authority (EFSA) is the primary body and there is a growing concern about what is happening with the applications made to the EFSA.

Treading the fine line

In July it was reported that EFSA had paused over 50 novel food applications for non-synthetic CBD products while the European Commission decides whether to classify extracts from hemp flowers as narcotic or psychotropic.

The concern at the European Commission level derives from the current classifications of cannabis under the United Nations drug treaties. However, change is afoot. In January 2019, after a critical review of cannabis and cannabis-related substances, the World Health Organisation's (WHO) Expert Committee on Drug Dependence (ECDD) recommended that cannabis should be reclassified under these treaties, and CBD should be exempted from international control.

The United Nations' Commission on Narcotic Drugs (CND) is due to vote on these proposals in December 2020 and rescheduling at the UN level would be likely to lead to a change of approach for the European Commission. When combined with the recent European Court decision in KanaVape, there is every reason for optimism in the EU, at least for CBD products.

If the Commission retain the position that CBD is a narcotic these applications cannot legally be considered a food and cannot proceed through the EU Novel Food approval process, which could be a huge blow to the many businesses waiting on the greenlight. Speaking to a Head of Purchasing at an online retailer, they mentioned the:

"lack of certainty over the Novel Food classification is a great risk for them when choosing not only which CBD products to stock but whether to stock them at all".

A glimmer of hope, perhaps, for the UK novel food CBD is that it is understood that the UK agencies are not concerned about the narcotic or psychotropic classification and therefore CBD will continue to be treated as a novel food requiring an application. The early adoption of this position, while the rest of the EU considers its approach, paves the way for positioning the UK as a key market for CBD novel food products.

Medicinal cannabis

The current landscape regarding medicinal cannabis is again very complex and often emotive due to pleas for legalisation from those suffering with chronic illnesses.

With significant strides being made in medicinal cannabis treatments being seen in other parts of the world, particularly North America, over the years stories of UK families obtaining prescription for medicinal cannabis abroad and having them confiscated upon entering the UK have made headlines and led to calls for a change in regulation in this area.

Due to the intensity of these campaigns, in the UK and across the EU some cannabis medicines are now being licensed, i.e., gaining authorisation from the European Medicines Agency (EMA), often in parallel with Food and Drug Administration (FDA) approval in the US.

Nabilone, a synthetic cannabinoid, is licensed for use with some patients with chemotherapy-induced nausea; Nabiximols (Sativex) is licensed for multiple sclerosis (MS) related muscle spasticity; and Epidyolex is licensed for certain types of epileptic seizures.

In the UK, ideally medicine manufacturers want to be reimbursed by the NHS, however, currently, prescriptions through the NHS are still very difficult to obtain, so are more readily available to private health clients, severely limiting the reach of their products in the UK.

The difficulty comes as the National Institute for Health and Care Excellence (NICE), which is the reimbursement gatekeeper, is concerned about the lack of a good clinical evidence base for the use of cannabis to treat epilepsy and pain in particular, and has called for more research before it is comfortable with the drugs being reimbursed by the NHS.

Medicinal cannabis continued

A short-lived victory in the industry of UK medicinal cannabis came in November 2018, when the Government changed the law so that specialist doctors could prescribe medicinal cannabis, including unlicensed medicines, where they feel the particular needs of the patient could only be met by these medicines. However, despite this, reports show that NHS doctors are not willing to prescribe such medicines and outside the NHS many doctors are still hesitant due to the lack of research, knowledge and education. Since the law was changed on 1 November 2018 campaigners believe that only three NHS prescriptions for cannabis-based medicines containing both CBD and THC have been written for children with epilepsy[5]. In July 2020, Health Europa reported that since the easing of medicinal cannabis prescriptions, only two prescriptions have been given by the NHS and only 400 privately[6].

Speaking to Ardra Partners (specialist consultants advising clients in a range of high growth subsectors), they believe that there are 'positive signs already to be seen'. They noted that the Medicines and Healthcare products Regulatory Agency (MHRA) decision to join up with the Australia-Canada-Singapore-Switzerland (ACSS) Consortium "is proof of this". The objective of this consortium is to provide high quality, safe and effective therapeutic products across the five countries, three of which (Australia, Canada and Switzerland) have the most progressive Cannabis laws globally.

Likewise, more light in the area of medicinal cannabis in the UK could come from the Project Twenty21 initiative spearheaded by Drug Science, launched in November 2019. The Royal College of Psychiatrists is taking part in this project and plans to enrol 20,000 patients by the end of 2021, creating the largest body of evidence for the effectiveness and tolerability of medical cannabis.

In something of a 'catch 22' situation, as more medicines become licensed, NICE will have more research on which to draw, which should mean more drugs will eventually be reimbursed.

There is ongoing tension between the Government's preferred approach of Randomised Controlled Trials (RCTs) and families who also want observational studies of children who are already benefitting from private prescriptions and who would not wish to risk being placed on placebos.

In the meantime, the MHRA will continue to crack down on any manufacturers making medical claims for any cannabis-based products without a licence.

[5] www.healtheuropa.eu/calls-for-uk-government-to-deliver-on-medical-cannabis-commitment/103606/

[6] www.healtheuropa.eu/a-national-disgrace-call-to-improve-medical-cannabis-access-in-the-uk/101357/

Cosmetic CBD

When it comes to cosmetics products that contain CBD, the regulation is a lot more specific due to the EU's Cosmetics Regulation being directly applicable in the UK.

This legislation is broken down according to whether the cannabidiol comes from the seed, leaf extract, is synthetic or plant derived. Therefore, all cosmetic products need to comply with the requirements before they are placed on the UK or EU market. The Regulation requires that any cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use and not make medicinal claims.

CBD is only permitted for use in cosmetics products when specific ingredient standards are met. For instance, the seeds of the cannabis plant and any extracts or oil from the seeds can be used in finished cosmetic products in the UK provided their use and the finished product are safe.

All CBD cosmetics require a Cosmetic Product Safety Report (CPSR), ensuring the safety and high quality of the products. In addition, a 'Responsible Person' must register cosmetic products in the EU cosmetic products notification portal (CPNP) prior to the products being placed on the market.

While this detail is very stringent, it does provide clear guidelines that businesses can follow to get their products to market.

Regarding how CBD cosmetic products will be impacted by Brexit, if there is a no-deal at the end of the transition period, then from 1 January 2021, the UK will be governed by a regulation that is very similar to the present EU legislative regulatory requirements for cosmetics with a few requirements.

As Brexit negotiations are still ongoing the regulatory future of CBD containing cosmetic products is still being carved as the UK is yet to clarify its position on CBD as a cosmetic ingredient. However, Brexit does present an opportunity for the UK to adopt a UK-specific regulatory framework for CBD cosmetics.

Vaping products

Most vaping products are governed under the relevant tobacco product legislations, but e-liquid products that do not contain nicotine but contain CBD when sold (e.g., disposable electronic cigarettes and 0% nicotine e-liquids) are not deemed to fall within the scope of the Tobacco Product Directive, but are regulated under the EU legislation, which is implemented in the UK by the General Product Safety Regulations 2005 (GPSR).

Under the GPSR, in the absence of specific provisions governing the safety of a product, the general safety requirement must be assessed against other available standards (compulsory or voluntary) drawn up in the UK. Therefore, CBD vaping products must comply with the same safety standards as nicotine vape products and assessment criteria as per the UK Tobacco and Related Products Regulations 2016 (TRPR) which implements the EU Tobacco Products Directive 2014/14/EU (TPD) in the UK.

The CBD vaping industry is a precarious one that always seems to be treading a fine line. Back in 2019, uproar broke out over the connection between vaping (particular CBD products) and respiratory problems as dozens of young people were hospitalised (and some even died) in the US.

This news led to Public Health England (PHE) releasing a response to concerns about lung disease associated with vaping in the US in October 2019, stating that the issue is confined to products containing THC, the psychoactive cannabinoid in cannabis that gets recreational users 'high'. In order to sell CBD based products in the UK, the Home Office considers that products should generally contain 0% THC.

PHE is therefore generally confident that legal CBD-containing vape products are safe to consume and there is a vibrant market for this in the UK.

But what's the outlook post-Brexit? Although the product safety landscape will not change dramatically following the UK's exit from the EU, amendments are required to create a framework to replace the EU's.

Despite the TPD being a European Directive, it has been implemented into UK law. So, regardless of the outcome of Brexit it will still be a legally binding piece of legislation in the UK and therefore current safety standards are likely to continue to apply.

Legalising recreational cannabis

The case for legalising recreational cannabis is an extremely controversial one, not only in the UK but on a global scale.

There continues to be pressure from various lobby groups for the legalisation of cannabis, which is making some waves and attitudes appear to be relaxing.

Estimates suggest as many as 100,000 people are growing cannabis for medical or recreational purposes and are risking prison sentences for doing so. The criminal justice system has seen a steady decline in prosecutions and cautions for cannabis possession, which is thought to reflect a change in policing attitudes to the drug.

The reclassification of cannabis-based products for medicinal use in humans to Schedule 2 of the Misuse of Drugs Regulations 2001 from 1 November 2018 created a legal route for cannabis-based products for medicinal use. It can now be prescribed by doctors on the General Medical Council (GMC) specialist register in the strictly controlled circumstances without the requirement for a Home Office licence (which was previously the only way such medicines could be in someone's possession).

However, despite the growing intensity of calls to legalise cannabis, this is unlikely to happen imminently, as it is not a priority for the current government despite calls from some MPs, senior police officers and also police and crime commissioners. Businesses hoping to operate in this space will have to be in it for the long run and are probably best shifting their focus elsewhere. Whilst some cannabis products remain outlawed this can raise concerns for investors and financial institutions interested in supporting the legitimate aspects of the sector but anxious to avoid any association with the proceeds of crime.

The European landscape

Europe is a key market for cannabis production and distribution, second only to North America. Europe represents around 31% of the global market as recorded in 2019[7].

While the perception may be that Europe is a golden ground for cannabis, most likely due to the liberal approach to the recreational cannabis in the Netherlands, outside of recreational use, the rules around the different forms and uses of cannabis is still quite complex and restrictive.

There is a lack of harmonisation regarding getting cannabis products to market, with each country presenting its own hurdles.

Below we draw on the expertise of our international team to highlight the current landscape in key access markets Belgium, France, Ireland and Spain.

[7] www.talk-business.co.uk/2019/08/23/cbd-in-europe-where-is-it-legal-and-where-is-it-not/

The European landscape
continued

Belgium

Belgium used to be known as one of Europe's key cannabis hubs, even though it has been technically illegal since 1912. The popularity of CBD in Belgium led to a crackdown by Brussels, making CBD products a lot harder to obtain.

Medicinal cannabis is not authorised for sale in Belgian pharmacies, since June 2015 when specific legislation was brought in to regulate THC products. While this is under review by the competent authorities, there is no predicted date for a decision.

It is theoretically possible to buy medicinal cannabis from a pharmacy abroad, with a prescription from a Belgian doctor and import it into Belgium, but only with a nominative Schengen declaration. The catch is that the Agence Fédérale des Médicaments (AFMPS) is the only body in Belgium authorised to validate such declarations, and will not do so as it is forbidden to supply cannabis in Belgium.

Currently, the only medicines containing cannabis that are authorised for sale are Sativex (for multiple sclerosis symptoms) and Epidyolex, which is authorised for sale in the EU but is not yet marketed in Belgium.

Sativex is currently being studied and tested for an authorisation for pain relief.

Apart from a few exceptions, no food products containing cannabis are authorised for sale, even if the THC content is < 0.2%. This has been embedded in law since 1997. This includes food supplements containing CBD, which are considered by the law as novel foods. These need a prior authorisation, and so far no supplement containing CBD has been given this authorisation. Exceptions are however made on a case-by-case basis, but will be subject to a THC threshold much lower than 0.2%.

Regarding cosmetic products, they are authorised in Belgium but under strict conditions. Extracts and tinctures can only be made from seeds and leaves, and not from the flowers or fruit of the plant. These products also must be explicit in that there is no intention for human or animal consumption and there must not be any health-related claims against that product.

This is similar to Belgian's approach regarding CBD smoking/vaping products. Products intended to be smoked or vaped are authorised but must not have a THC level above 0.2%, they cannot be sold as herbal teas or potpourris, again there must not be any health-related claims against that product. Also, these products are considered the same as tobacco when it comes to tax purposes so they must be labelled accordingly.

The European landscape
continued

France

Currently, the French regulatory framework prohibits the marketing of products derived from the whole hemp plant, with the use of hemp flowers and leaves forbidden in France. Only the use of the plant's fibre and seeds is authorised in France, so importation is allowed for products made from fibre and seeds but authorised products should not contain more than 0.2% of THC. However, synthetically produced CBD is generally permitted.

Regarding medicinal cannabis, therapeutic use of cannabis is authorised for certain therapeutic indications or clinical situations such as patients suffering from serious illnesses. Further developments are expected in this area as in October 2020, the Ministry of Health announced that it had authorised the first experimentation of cannabis for therapeutic use in France, in a very controlled and limited framework. According to the announcement, the experiment will last two years, beginning before March 2021 and is proposed to involve 3,000 patients.

When it comes to vaping products containing CBD, the recent final decision by the Court of Justice of the European Union (CJEU), Case C663/18 – KanaVape has broken new ground.

The case concerned an electronic cigarette with CBD oil but also looked at the general ban on natural CBD in France. The 19 November 2020 decision was clear that a general ban, based on CBD being a narcotic/psychotropic was not sustainable and was contrary to EU law on free trade and the European Single Market.

This case was the first time that the highest European Court has been requested to take a position on the legality of the commercialisation of CBD and CBD-based products in Europe, and has potentially extensive implications. The French (and other) national authorities have been given the possibility of still imposing a national ban, but only if the real risk alleged for public health appears sufficiently established on the basis of the latest scientific data available at the date of the adoption of such a decision.

The Court expressed a view that this would be unlikely. If the Court follows the Advocate General's opinion, it will require the disapplication of the French Regulations and is likely to cause a review of the varying EU national restrictions on hemp-derived products forcing a greater degree of harmonisation.

Regarding, the medicinal cannabis, at the end of October 2020 a new order was issued laying down the technical terms and conditions for the national electronic register on the experimentation with the medical use of cannabis. This order has stated that a national register will be set up by the French National Agency for Medicines and Health Products Safety (ANSM). This register will monitor patients enrolled in the pilot program, as well as oversee the pharmacists and physicians prescribing and dispensing cannabis based medicines and ensure traceability of medicines used in the programme. While this is still in the very initial stages, it does show that the use of medicinal cannabis is firmly on the French agenda and strides are being taken to explore the possibilities in this area.

The European landscape
continued

Ireland

In Ireland, the legality of CBD products remains very uncertain, making bringing a product to market problematic.

Generally, the Irish regulatory environment for CBD products can currently be described as inhospitable. Under the Misuse of Drugs Acts, cannabis, cannabis resin, cannabinol and cannabinol derivatives are classed as controlled drugs for the purposes of the Misuse of Drugs Acts 1977-2015, therefore making possession, sale and/or supply an offence, with some limited exceptions.

This includes an extract of cannabis that has "a concentration of not more than 30 milligrams of cannabidiol per millilitre, and not more than 30 milligrams of delta-9-tetrahydrocannabinol per millilitre, where the ratio of cannabidiol to delta-9-tetrahydrocannabinol is between 0.7 to 1.3" that is used for a medical, veterinary or dental purpose.

It is also permitted to grow certain species of hemp plants (containing less than 0.2% THC), subject to authorisation from the Health Products Regulatory Authority. Recently, there have been reports of Garda and Customs 'raids' and associated seizures in relation to CBD products being openly sold by small businesses, although the outcomes of these interventions in terms of any prosecutions or convictions is unclear and they appear to remain pending or unresolved.

Guidance published by the Food Safety Authority of Ireland (FSAI) states that some forms of hemp-derived products cannot be sold as food or food supplements in the EU, and that the use of certain extraction methods involving solvents, like supercritical CO2 or ethanol, in the production of hemp-derived foods or ingredients may bring them within the scope of the Novel Food Regulation.

Meanwhile, various recall notices have been issued by FSAI in 2020 in relation to various CBD food and food supplement products found to contain unsafe levels of THC based on the EFSA acute reference dose (0.001mg/kg body weight (1µg/kg body weight). Notwithstanding the above, and although there is very little official data available, CBD products do seem to be growing in popularity and continue to be openly marketed and sold alongside other food supplement products online and in retail outlets throughout the country.

The European landscape
continued

Spain

In Spain, no specific legislation has been enacted in relation to CBD and the other cannabinoids, and while the current left-wing government seemed inclined to pass such legislation at first, the Minister of Health has recently stated that when evidence is reviewed, it can be concluded that, contrary to what people may think, there is no sufficient scientific evidence to support such legislation.

Therefore, the commercialisation of any product containing CBD in Spain, for the moment, must comply with the applicable laws of the product to be commercialised, i.e. medicinal products, cosmetics, foodstuffs, etc.

Medicinal products with CBD may be commercialised in Spain, prior to a standard marketing authorisation, without any particular restrictions. Other pathways may also be of interest, such as magistral formulae and compassionate use or non-authorised medicinal products import programmes, but they are subject to multiple legal requirements.

Regarding cosmetics and foodstuffs specifically, these are regulated quite differently. In the case of cosmetics containing CBD, these can be generally commercialised, so the Spanish market may be quite attractive for cosmetic companies, even though there are important marketing restrictions depending on how CBD has been obtained that have to be taken into account.

In the past, several companies commercialised foods supplements containing CBD in Spain, but now, following the inclusion of cannabinoids in the Novel Food Catalogue, the situation has radically changed, with most foodstuffs containing CBD being withdrawn from the market.

Lastly, on the cultivation of cannabis plants, while Spain may be attractive for its weather and climate, the legal framework in that regard is not as appealing. This is because the cultivation of cannabis for research, scientific and medical purposes is subject to a licence, which is granted through a procedure characterised by its very restrictive application and lack of transparency. In any case, there are companies that have obtained said licenses, and are currently cultivating cannabis plants in Spain.

Will the UK unlock its cannabinoid market post-Brexit?

As found, there is a real lack of unity among EU countries, making it extremely frustrating for businesses in this space to work seamlessly across Europe.

In the UK, the vagueness of the law regarding CBD and THC has left some businesses operating in an unregulated space in fear of a potential crackdown.

With some products made from industrial hemp completely legal to be sold in the UK, the grey area comes when ascertaining the legal amount of THC they may contain and the classification of ingested CBD.

When the UK officially exits the EU it has an opportunity to move away from the Novel Foods classification and other regulations regarding cannabis. While the UK's FSA has stood by this legislation and stated that all products need to be approved, the Novel Foods catalogue perhaps lacks gravitas as it has only been loosely enforced in the UK.

Many economists have predicted that the UK's economy is likely to take a hit post-Brexit as its economic power within the EU has diminished over the decades. Loosening restrictions around cannabinols could be a way of drawing attention and investment to the UK, unlocking the tax and employment benefits and working towards offsetting predicted post-Brexit economic damage.

How to unlock the UK market

So, the burning question is, what can and should businesses do now?

"Ardra Partners advise businesses hoping to enter into this market or those looking to ramp up their existing operations to start 'building the right local knowledge and connections'."

Practically, for those looking to sell ingested CBD products, this would be getting the necessary scientific dossiers in place for novel food applications.

For businesses involved in medicinal cannabis, they should start looking for opportunities globally to be part of clinical trials which all regulators are keen to see. Not only will this position you as a leader but will help to forge vital relationships with key regulatory bodies and other important organisations and businesses. It's also key to get legal advice from those who are deeply embedded in the industry, working with all the different types of businesses and organisations from growers to distributors and can confidently advise on the best routes to market.

While neither the UK government nor any authorities have made any official announcements regarding the future of the UK cannabinoids market, with projections that the UK market could reach into the billions, it is likely the country will position itself to seize this opportunity and businesses should start positioning themselves to be at the forefront of this opportune change.

About Fieldfisher

Fieldfisher is a European law firm with market leading practices in many of the world's most dynamic sectors.

We are an exciting, forward-thinking organisation with a particular focus on energy & natural resources, technology, finance & financial services, life sciences and media.

Fieldfisher's Life Sciences team is an integrated team of lawyers with a presence in most of Europe's key cities. We have a deep understanding of the sector bringing together transactional expertise with regulatory and compliance advice, to provide organisations with practical solutions, whether in one country or across a range of jurisdictions.

Our flagship Life Sciences team is supporting a rapidly growing number of businesses involved in the development and sale of medicinal cannabis and cannabidiol (CBD) products in the UK, Europe and internationally.

We specialise in advising on regulatory matters affecting products in the Life Sciences sector. Our team has extensive experience in providing strategic advice to first and often best-in-class market entrants.

We guide them on what laws might apply to their products, how to shape their business and make sure they are compliant on commercial and clinical relationships, and how to mitigate legal risks.

Our understanding of the regulatory landscape enables us to advise on applicable food regulation for cannabis-based products, the regulatory position for CBD oils, prescribing cannabis therapies and reimbursement by health authorities.

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