



CBD IN THE UK

Towards a responsible, innovative and
high-quality cannabidiol industry

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Executive Summary

The Hype

- Consumer interest in cannabidiol (“CBD”) has risen rapidly and is growing fast. The shift reflects a wider trend in society and is further demonstrated by the changing economic drivers of the agricultural hemp sector. Several indicators suggest the current ‘hype’ around CBD is likely to endure and is not a passing fad.
- CBD’s popularity in the UK has been hard to gauge, but new data for this report indicates that it has reached a level of market penetration that is unlikely to dissipate, with consumption across age groups and classes, not just trendsetting millennials.
- The complexity and vagueness of the law governing CBD in the UK (see Chapter 3) has given rise to a profitable, competitive, and largely unregulated CBD sector with a diverse array of retail products and strong revenue growth.
- The interest in the health and wellbeing potential of CBD is driving consumer curiosity in the UK, and major condition charities have started publishing educational output in response to this demand.
- The ongoing prohibition of cannabis itself, and the severely limited availability of legally-prescribed medicinal cannabis products may explain some diversion of this pent up demand into the under-regulated market for CBD wellness products.
- Agencies seeking to regulate the UK’s CBD market should regard it as a permanent feature of the wellness sector that is likely to expand in future. This requires regulators to have a better understanding of the market, the habits and motivations of consumers, and the business practices of CBD companies operating in the UK.

The Compound

- CBD is one of the major constituents of the Cannabis sativa plant of increasing interest due to its broad range of therapeutic properties coupled with a favourable safety and tolerability profile.
- Unlike THC, cannabidiol does not have any intoxicating or psychotropic effect in humans and

has shown no addiction risk, however it is mistaken to describe it as having no ‘psychoactive’ effect, because it acts on the brain and appears to impact cognitive functions.

- The best evidence now available confirms that pure CBD is not addictive, is well tolerated by the human body and presents no health risks from sustained use. In addition CBD may prove beneficial for a range of conditions beyond certain rare forms of epilepsy.
- New studies are underway around the world, including in the UK, to further explore the compound’s therapeutic potential. There has been a steep rise in the number of studies globally into CBD and 1 in 10 are underway in the UK.
- New research findings will stimulate the pharmaceutical investment in CBD as a medical treatment. Areas that look promising for a pure CBD treatment relate to sleep disorders and insomnia, as well as anxiety, inflammation and pain.

The Law

- Pure CBD is legal in the United Kingdom and is not classed as a controlled substance. However the CBD industry is engaged with a product that can (and often does) touch on what is permissible under the criminal law, as a result of other elements within the same product.
- Many CBD retailers in the UK are trading according to a folk interpretation of domestic law governing controlled substances that is incorrect; however, this is not surprising because the law is complex, and legal clarity - though sought repeatedly - has not been provided.
- Common misreadings of the law regarding CBD are a major and widespread problem in the UK CBD sector that undermines the industry and can mislead consumers.
- Beyond the legal status of the product under the UK’s existing drugs laws, certain CBD products are also subject to domestic law in respect of rules governing food, or cosmetics, where legal status is determined by a separate set of factors.

- Any product containing CBD that is used for medicinal purposes is a medicine and must have a product license, CBD products must therefore avoid making any medical claim or act as a medicinal product by virtue of its presentation, its claims or its composition or face enforcement by the MHRA.
- The legal framework that now impacts CBD products is decades old, and the applicable regulations were enacted in 2001 - long before the emergence of a mass consumer market in cannabidiol products. The laws have not been affected by the wider changes enacted for the recent legalisation of cannabis-based medicinal products.
- The most important new legal development arises from the European Union’s Novel Food regime, which led to the classification of all extracted cannabinoids as “novel” in January 2019. As currently drafted, it presents a serious challenge to the CBD market as it exists in the UK today - however it is yet to be enforced in the UK.

The Regulations

- All cannabinoids for human and animal consumption exist within a regulated regime, with varying levels of restriction. The CBD market in the UK is under-regulated, and this poses challenges for the industry and consumers.
- Regulations governing CBD products are not specific to cannabidiol, and there is no separate regulatory pathway that has been designed for these products in the UK.
- The CBD industry, like any consumer market, is subject to a range of generic regulations governing food, cosmetics and medicines, and the end product category determines the rules by which those products can be produced, distributed and marketed.
- The regulators have clear roles depending on the product category, and their remits are designed not to overlap - so what is a medicine, cannot be a food, for example.
- Regulators have not provided clarity on recent developments relating to cannabidiol and this has perpetuated the uncertainty about which products are compliant, and what is to be expected by way of enforcement action for companies breaching the law.

The Consumer

- For the first time, robust public attitudes data reveals a high level of CBD use in the UK, consistent with the size of the market estimated in the sector analysis, and demonstrating that CBD has now gone mainstream in the UK.
- Two new surveys conducted in May and June 2019 by Dynata and YouGov indicates that between 8- 11% of UK adults respectively - approximately 4-6 million people - have tried CBD. The CBD consumer base is broad - and there is familiarity and recent use among a sizeable proportion of all age groups and social classes.
- Those who had consumed cannabis to help alleviate symptoms of any kind were significantly more likely than the group as a whole to have used CBD products in the last year – almost 6 times more likely. Overall, 7% of the population have used cannabis for medicinal purposes in the past year, rising to 41% among those who have used CBD in the past year. And support for legalisation of cannabis increases from 47% among the total population to 75% among past year CBD users.
- Consumers have clear preferences that drive their buying decisions, and prioritise quality and purity over origin or legality. Clear labelling information and advice on use and consumption tips, followed by a preference for British produced CBD products, were the purchasing priorities that scored highest, more than price, brand or organic status.
- User comments supplied for this project reflected a similar theme - that CBD is effective for them, and should be made more widely available, however costs was raised as a factor.
- A sizeable proportion of regular CBD users are deriving - or claiming to experience - a medicinal or therapeutic benefit from the CBD they buy. However, consumers are unable to access good quality and impartial information about CBD products in the UK at present.

The Market

- To date, estimates of the size and nature of the CBD market in the UK have not been comprehensive or robust. Without an accurate picture of how UK consumers are buying CBD, in what product categories, where and for what reason, it is difficult to devise effective policy and proportionate regulations.

- For this project, the CMC commissioned an independent market insight and research agency to conduct a bespoke piece of market sizing analysis for the CBD sector in the UK. The headlines of that research - published in this report - demonstrate how large and important the CBD market already is and that it is rapidly growing.
- The size of the UK CBD market is between 3-6 times larger than previous well quoted estimates (£300M per year vs £100M (Brightfield report) and 1.3 M users vs 250K users (CTA) depending on which measure you take; value or users. This is larger than the total UK Vitamin D (£145M) and Vitamin C market (£119M) combined.
- The market is currently growing at double digits and expected to be just short of £1B in 2025. This would be equivalent to the entire UK herbal supplement market in 2016.
- Over 70% of UK consumers are purchasing tinctures/oils or capsules suggesting a desire to use products systemically and at higher “therapeutic doses” for CBD. In addition those users from the CBD user panel, with a presumed medically orientated usage, are spending on average 2-3 times a month more (£55 vs £25) than the general population, on these formulations.
- The majority of UK consumers of CBD products are purchasing them online, and not in High Street stores, despite their wide availability in pharmacies, health food stores, and supermarkets.
- The research also reveals that UK consumers are currently paying high prices for CBD products, with buying habits driven by a range of motivations.
- A key conclusion of this analysis is that politicians and policy-makers must now approach the question of how to regulate CBD proportionately in the knowledge that the UK already has millions of regular CBD consumers, not a few tens of thousands.

The Industry

- The CBD industry in the United Kingdom is one of the largest in Europe, but it is entirely built upon a raw ingredient produced elsewhere in Europe or further afield, not one harvested domestically.
- The complex global supply chain for CBD is scaling quickly. The industry in the UK is not building from the same agricultural foundation that other

countries take for granted, and this undermines UK competitiveness in a key growth sector.

- The hemp industry is not financially viable in the UK long-term unless it can compete on a level playing field with other hemp producers. There was overwhelming support from three quarters of respondents to the YouGov survey when asked whether UK hemp farmers should have the freedom to process the flowers and leaves of hemp crops grown in the UK to supply CBD.
- The UK’s strengths in pharmaceuticals means it is likely to play an important role in the development of pharma-grade CBD.
- The industry has an obligation to behave responsibly around how it uses and promotes CBD - otherwise there is a risk that negative associations will accrue to CBD and have a wider effect on public perceptions of cannabis and its potential as a therapeutic treatment.

The Test

- The first major third-party testing exercise to be undertaken of CBD products in the United Kingdom was commissioned for this report. In total, 30 oil products available in the UK (both on and offline) were selected for the blind testing exercise using PhytoVista - a reputable UK-based laboratory.
- The exercise was designed to verify the range of quality of those CBD products being sold today, and to determine where the areas of concern might be. Those areas were defined as: health and safety; consumer rights; and criminal law.
- The results are highly revealing and provide a good overview of the true nature of the CBD products being sold in the UK. They reveal a wide range in terms of quality, and some concerning poor practice in a minority of cases. The best products are very high quality and are good options for today’s consumers, but a larger group of products present issues in one area or another.
- The biggest issues related to accuracy of labelling; the presence of controlled substances and some contaminants; and in one example from a high street pharmacy, the complete absence of any cannabinoids. Highlights:
 - Only 11/29 (38%) of the products were within 10% of the advertised CBD content and 11/29 products (38%) actually had less than 50% of the advertised CBD content. One product had 0% CBD.

- Almost half (45%) of the selected products had measurable levels of THC (mean content 0.04%) or CBN (mean content 0.01%) and are thus technically illegal within the UK.
- 1 sample had ZERO cannabinoid content - this was a High Street pharmacy product (30ml) retailing for £90.
- 1 product had 3.8% ethanol (3.4% qualifies as an alcoholic beverage)
- Dichloromethane was detectable in 7 products (3.8-13.1ppm) and cyclohexane was found in one product (27.9ppm). However, these percentages of solvents and heavy metals are still below the permitted daily dose levels in pharmaceutical products, although above food limit safety levels
- The industry as a whole must use these results to understand the areas of weakness in producing a quality product that consumers can trust, and use the findings to justify additional steps they should take for their own production, or for reassurance across their supply chain, that some of these negative results are not reflected in their own products.
- The exercise also exposed regulatory gaps - with no rules that set basic standards for important supply chain activities like testing of cannabinoid products, so those laboratories (in the UK or elsewhere) that conduct these examinations all use different processes and testing methodologies, and they may not be to a standard that is reliable, or would satisfy UK authorities.

The Future

- The analysis for this report suggests the prospects for the UK’s CBD market are strong, with rising demand and a willingness among British consumers to try CBD products and spend significant sums on a regular wellness routine that encompasses CBD.
- There are a number of future trends for the CBD sector in the UK and globally, and some fundamental market developments that the British CBD sector can expect to encounter in the next three years.
- Among the most important will be increased product diversification and greater competition and imports into the UK, along with the issues around provenance and traceability.
- The frontier of synthetic cannabinoids remains a major known unknown, but it could be highly disruptive for today’s CBD industry that is

dependent on extracting organic cannabinoids.

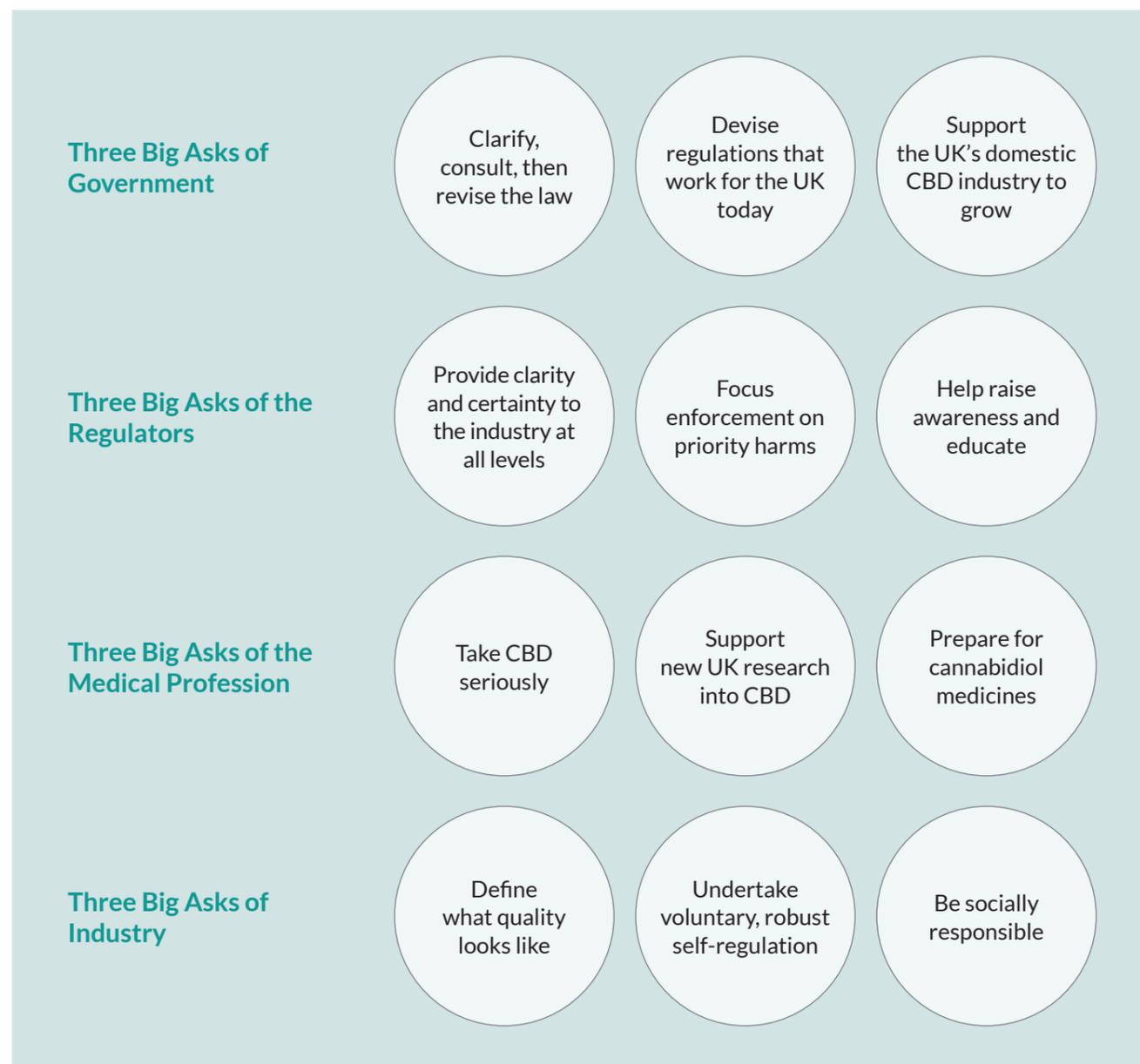
- In respect of how regulations might evolve, many jurisdictions are reviewing their laws and several have updated them. Other comparable jurisdictions around the world - including New Zealand, South Africa and the Channel Islands - have recently adopted new approaches to CBD and their examples provide inspiration for how the UK might modernise its own regulations.
- Recent developments hint at a possible evolution towards three related, but distinct, sectors for cannabidiol - all utilising CBD in different ways and serving different goals, and also potentially under revised (or entirely new) regulatory regimes.

The Challenge

- The growth and success of CBD in the United Kingdom depends upon overcoming key challenges in the years ahead. These challenges are similar in many jurisdictions and all require open dialogue between government, regulators, the industry, the healthcare profession, and consumers, in order to reach the right outcomes.
- The main market challenges are: improving the education of consumers; defining a proportionate regulatory pathway; rooting out bad practice; creating an infrastructure to support a quality standard; maintaining incentives to invest in clinical trials; and taking the necessary steps to level the playing field in support of UK producers.
- Some of these challenges can only be addressed by government, and others should only be addressed by industry taking a lead. The consumer will influence how the CBD sector evolves, but the public cannot, by their consumer habits alone, change the trajectory of this industry - that requires government action.
- The course and development of the CBD market will have an impact on wider public perceptions of cannabis, and its medicinal efficacy. The challenge is to not allow the normalisation of the cannabis conversation that CBD invites, to be undermined down the road by the bad players that do exist in the fast-growing and disruptive CBD market.
- Addressing poor practice and promoting CBD products responsibly will require proper self-regulation and a focus on compliance and public education efforts. Credibility will come from advancing the evidence-base.

The Ask

- There are a number of asks that need to be made of the government, regulators, the medical profession, and the industry itself, if we want the UK to have a thriving and well regulated CBD sector.
 - We have outlined 3 key asks of every player in this sector and alongside it, a clear proposal of how to act in order to improve the CBD marketplace and deliver real benefits for consumers and patients.
- Working in collaboration, politicians, policy-makers, regulators, producers and retailers can play their part to achieve the shared goal of a CBD sector that is innovative, responsible and high-quality, delivering both economic benefits, social value, and individual wellbeing.



1. The Hype

Summary

- Consumer interest in cannabidiol (“CBD”) has risen rapidly and is growing fast. The shift reflects a wider trend in society and is further demonstrated by the changing economic drivers of the agricultural hemp sector. Several indicators suggest the current ‘hype’ around CBD is likely to endure and is not a passing fad.
- CBD’s popularity in the UK has been hard to gauge, but new data for this report indicates that it has reached a level of market penetration that is unlikely to dissipate, with consumption across age groups and classes, not just trendsetting millennials.
- The complexity and vagueness of the law governing CBD in the UK (see Chapter 3) has given rise to a profitable, competitive, and largely unregulated CBD sector with a diverse array of retail products and strong revenue growth.
- The interest in the health and wellbeing potential of CBD is driving consumer curiosity in the UK, and major condition charities have started publishing educational output in response to this demand.
- The ongoing prohibition of cannabis itself, and the severely limited availability of legally-prescribed medicinal cannabis products may explain some diversion of this pent up demand into the under-regulated market for CBD wellness products.
- Agencies seeking to regulate the UK’s CBD market should regard it as a permanent feature of the wellness sector that is likely to expand in future. This requires regulators to have a better understanding of the market, the habits and motivations of consumers, and the business practices of CBD companies operating in the UK.

The rapid rise of cannabidiol

In the space of a few short years, cannabidiol – or CBD for short – is rapidly becoming the most popular and exciting of all the chemicals that are contained in the cannabis plant. As one of scores of naturally occurring phyto-cannabinoids in *Cannabis Sativa L*, CBD was previously dismissed as inconsequential, compared to the intoxicating properties of the plant, and interest and (where permitted), research largely ignored CBD and instead focused on THC (tetrahydrocannabinol).

So recent has the market and scientific interest in CBD been, that an extensive study of the hemp industry in Europe published in 1996, makes only a single reference to CBD.¹ For decades, the economic potential of hemp was considered solely in relation to the industrial purposes of the fibre. Today, in contrast, while the applications of hemp as a sustainable material for construction and as a plastic-replacement in packaging are widespread, it is the cannabinoid value in the flowers and leaves that is driving the renaissance in

hemp cultivation in Europe, Asia and North America.

Despite a history of consumption of cannabinoids for several thousand years in various forms across the world, before the last decade and the advent of a new trend where CBD is extracted at volume to supply a consumer wellness sector, there was little to no focus on the rules governing CBD. In some jurisdictions, it was explicitly prohibited as part of general narcotic control policies underpinned by legislation passed in the 1970s or earlier, which prevented production but also severely restricted scientific studies.

However, even in such places – like the United States – CBD was not the target of such laws nor the focus of comment or opposition because there was not the means nor the demand to isolate and extract cannabidiol from strains of the cannabis plant. Even as the first medical cannabis regimes emerged in the US from the late 1990s, CBD was not discussed as a major feature of that development, nor was it pushed by legalisation advocates as a reason for permitting doctors to issue cannabis prescriptions.

Furthermore, the intent behind narcotic control policies of the 1970s and 1980s – to suppress the circulation of addictive, psychotropic substances that impacted negatively on health – seemed not to be directly relevant to CBD. The framing of such conventions (and their associated national laws) targeted cannabis, and they preceded the research that set out the structure of cannabidiol as a key component of the plant, let alone any research into its principal effects. To this end, the illicit status of the ‘whole’ plant had consequences for the individual parts, even as scientific knowledge about the relative properties of THC and CBD expanded, and it became clear that of the two main cannabinoids in the plant, it was THC that had the intoxicating, psychotropic properties and addictive potential, and CBD was at worst benign.

Laws around the world and their associated regulators are now playing catch up with this modern realisation, and it means that market forces driving the consumer demand for CBD are running ahead of governments.

The wellness trend

Around the world in the last few years, interest in CBD has been spiking. In the United States, consumer research by Cowen & Co. in January 2019 found that almost seven per cent of US adults said they had consumed CBD, which exceeded many expectations, and led them to project that 10 per cent might be consuming cannabidiol in some form by 2025.² The number of people using - or saying they are willing to use - a CBD product is now at a level where major consumer packaged goods brands are paying attention and considering whether and how to enter the space. Product offerings look set to grow to cater to an expanding population of consumers who are curious to try CBD or use it in new ways.

In the United Kingdom, the complexity and vagueness of the law governing the cannabis plant (see Chapter 3) has given rise to a profitable, competitive, and largely unregulated CBD sector with a diverse array of retail products and strong revenue growth. And the UK’s so-called ‘CBD craze’ seems to be more than a passing fad. Research by the analytics firm Pulsar³ in 2019 captured the social media and online hype associated with CBD and compared this to other trends in the wellness space. They concluded that CBD’s popularity “is outpacing many other wellness trends, as measured by multiple virality metrics, across several markets and lifestyle areas – from sports, to wellness, to pets.”

It is no coincidence that CBD’s popularity is growing now, given how it fits with (or is seen as supporting) existing societal trends. Across the developed world, there is a demonstrable shift in attitudes in a direction of self-improvement (spiritual, emotional and physical), and a rising trend in personalised self-care, health tech

devices and preventive treatment, alongside electoral support for investment in public healthcare services and coverage. This coincides with an apparent lack of public trust in pharmaceutical companies (alongside a host of other established corporate sectors), reflected in (and encouraged by) the media, especially in how they have reported on licenced drug development and the costs of medicines to patients.

In fact, in contrast to 50 years ago, one of society’s defining features is a preoccupation with wellness, or as the EIHA argued in their submission to EU authorities, hemp products fit with “people’s growing desire to improve one’s health condition, reduce the risk of disease and try to find the best possible quality of life.” Access to cannabidiol is a part of this story, and for many first-time consumers, it is where the curiosity comes from. The motivation for using CBD is an angle we explore further in Chapter 5. The same research by Pulsar showed a strong medicinal component to the online discussion about CBD which was motivating users to try CBD products.

The medical alternative

The recent change in UK legislation has not resulted in any prescriptions being issued for Cannabis-Based Medicinal Products (CBMPs) within the National Health Service. However, the public recognition of the medical value of cannabis, coupled with many high profile media stories of patients getting significant relief with CBMPs, has created rising demand for these products.

Currently, because of the difficulty UK patients are having trying to access CBMPs through their healthcare providers, some are increasingly turning to over the counter (OTC) cannabis-based products, a fact acknowledged by the NHS in its guidance to prescribers. In response to this demand, there are numerous examples of major condition charities in the UK issuing their own guides⁴ and educational blogs⁵ to help patients and their families understand more about CBD.⁶ And since CBD is not a scheduled drug in the UK (see Chapter 2), CBD-based products have thus become widely available, primarily in an oil format (often called cannabis oils), although also in some cosmetics, food and beverage products.

The governmental agencies seeking to regulate the UK’s market should not see CBD as hype, but instead treat it as a new permanent feature of the wellness sector that is already established and likely to expand in future. This requires the regulators to engage properly with this recent market phenomenon and develop a better understanding of the habits and motivations of consumers, the nature of the supply chain, and the business practices of CBD companies operating in the UK - all aspects that are explored in this report.

2. The Compound

Summary

- CBD is one of the major constituents of the Cannabis sativa plant of increasing interest due to its broad range of therapeutic properties coupled with a favourable safety and tolerability profile.
- Unlike THC, cannabidiol does not have any intoxicating or psychotropic effect in humans and has shown no addiction risk, however it is mistaken to describe it as having no ‘psychoactive’ effect, because it acts on the brain and appears to impact cognitive functions.
- The best evidence now available confirms that pure CBD is not addictive, is well tolerated by the human body and presents no health risks from sustained use. In addition CBD may prove beneficial for a range of conditions beyond certain rare forms of epilepsy.
- New studies are underway around the world, including in the UK, to further explore the compound’s therapeutic potential. There has been a steep rise in the number of studies globally into CBD and 1 in 10 are underway in the UK.
- New research findings will stimulate the pharmaceutical investment in CBD as a medical treatment. Areas that look promising for a pure CBD treatment relate to sleep disorders and insomnia, as well as anxiety, inflammation and pain.

The science of CBD

Cannabidiol (CBD) is one of the major constituents of the Cannabis plant of increasing interest due to its broad range of therapeutic properties coupled with a favourable safety and tolerability profile.⁷

CBD is not addictive, and does not produce the ‘euphoric high’ that is caused by the other principal chemical in cannabis, delta-9 tetrahydrocannabinol (THC). The latter is responsible for the psychotropic effect of cannabis use, and all the positive and negative associations and proven psychological impacts of the drug as an intoxicant. However, it is not true to say that CBD, unlike THC, is not ‘psychoactive’. According to the cannabinoid researcher Dr Ethan Russo: “Very simply stated, what is clear about CBD is that it must be considered psychoactive because of its ability to act as an anti-anxiety agent and an antipsychotic agent”.

Referencing clinical trials that have shown CBD as effective at treating schizophrenia, Dr Russo has said: “So clearly, that’s got to be considered a psychoactive drug.”

But again, simply stated, it is not intoxicating in the way THC is, it does not produce a high, nor does it produce any craving or withdrawal effects. So it has no drug abuse liability that’s been observed.⁸

Scientific studies show how the analgesic, anti-inflammatory, antioxidant, anxiolytic, anticonvulsant and anti-tumoral effects of CBD are mediated through multiple molecular targets including cannabinoid receptor 1 (CB1), cannabinoid receptor 2 (CB2), serotonin receptors, opioid receptors, adenosine receptors, orphan receptors such as G protein-coupled receptor 55 (GPR55), GPR18, GPR3, GPR6 and GPR12, peroxisome proliferating activated receptors (PPARs), transient receptor potential (TRP) channels, as well as transporters and enzymes.⁹

Clinically, CBD is being investigated in phase II and III trials in diverse areas including schizophrenia, drug dependency, tumour reduction, pain conditions and post-traumatic stress disorder (PTSD). A pure CBD product, Epidiolex, recently became the first Food and Drug Administration (FDA) approved cannabidiol medicine; indicated for use in Lennox-Gastaut or Dravet syndrome (childhood epilepsy) and is currently under regulatory review in Europe.

Expert Verdict on CBD

The most authoritative statement on the science of CBD was by the World Health Organisation (WHO)'s Expert Committee report in 2017-18¹⁰ which stated:

CBD is generally well tolerated with a good safety profile. Reported adverse effects may be as a result of drug-drug interactions between CBD and patients' existing medications ...

On the addiction risk, the WHO were clear:

To date, there is no evidence of recreational use of CBD or any public health related problems associated with the use of pure CBD.

While the number of studies is limited, the evidence from well controlled human experimental research indicates that CBD is not associated with abuse potential.

Beyond the documented benefit as an epilepsy treatment in some cases, the WHO report also summarised the current evidence base for therapeutic impact:

There is also evidence that CBD may be a useful treatment for a number of other medical conditions. However, this research is considerably less advanced than for treatment of epilepsy. For most indications, there is only pre-clinical evidence, while for some there is a combination of pre-clinical and limited clinical evidence.

In 2019, the WHO subsequently recommended that international narcotic convention should be amended so that cannabidiol was no longer scheduled. This recommendation is due to be voted on by UN member states at some point in 2020, and if adopted, would further liberate CBD from regulatory controls and unwarranted restrictions stemming from the ongoing prohibition of the plant itself.¹¹

The Evidence Base

The evidence base for cannabidiol's benefits is expanding, but not yet adequate. This is also true of the wider subject of cannabis-based medicines, as explained in the CMC's policy Blueprint published in December 2018. Other jurisdictions have published their own independent assessment of the state of the science in respect of CBD's proven therapeutic effects. The consensus in Europe – also reflected in the UK – is best summarised by the Swiss Federal Authorities in a 2018 report, who stated: "The therapeutic potential of CBD in most of the numerous applications circulating on the Internet has as yet either not been scientifically demonstrated or at best inadequately demonstrated."¹²

By itself, the quality of the evidence base on CBD does not explain (or justify) the huge popularity of the chemical as a product with some therapeutic benefits. However, many new studies are in train and there is likely to be further advances in our scientific understanding of CBD's potential in the next few years. One fact is undeniable - cannabidiol is generating significant excitement in the research community who are exploring many aspects of CBD's therapeutic potential as an alternative to conventional pharmaceutical treatments.

Cannabidiol production

The Processing

According to the European Industrial Hemp Association (EIHA), the processing of cannabidiol uses well understood and long-practiced extraction methods.¹³ There are three main extraction methods used to obtain the oil from the plant and isolate cannabidiol. Supercritical systems use heated carbon dioxide (CO₂) under pressure as a solvent to extract the oil. CO₂ is considered a cleaner, purer form of extraction because there is no residue after extraction. Hydrocarbon and ethanolic solvent systems use alternative solvents (i.e. a hydrocarbon such as hexane or pentane or ethanol) to extract the cannabinoids from the biomass.

To isolate the individual compounds from the plant isolate (CBD being one of them), the extracted oil needs to be distilled after extraction. The first step is a process called Winterization (or filtration of undesirable plant based contamination such as fats, waxes and lipids), followed by distillation to remove the solvent and distil the cannabinoids into their component parts.

Even if supercritical CO₂ is used as an extraction process the resulting extract must be diluted in ethanol to perform Winterization thus all CBD isolates will come into contact with an organic solvent during processing.

Methods of CBD extraction

Cold pressing	The most simple extract from hemp fruiting tops is hemp seed oil
Ethanol extraction	Using alcohol to whole fruiting tops (infructescences) and leaves
CO ₂ extraction	Using Carbon Dioxide to whole fruiting tops (infructescences) and leaves
Fat extraction	Can easily be used for home-made preparations

1. Extract can be left raw or decarboxylated and added to consumer products without further processing
2. Extracts are usually winterized in order to remove plant waxes
3. An extract can be further distilled/rectified in order to remove unwanted elements such as chlorophyll

Source: EIHA

There is very little information in the peer reviewed literature comparing the quality of the isolates obtained from the different processes. However, one study showed that the products from super-critical CO₂ extraction have a significantly different cannabinoid and terpenoid profile to that of the flower which was extracted demonstrating the process does lead to modifications in the final product.¹⁴ There are pros and cons¹⁵ for each extraction method employed to obtain CBD (see Annex).

CBD in medicines in the UK

Cannabidiol is an existing treatment in the UK, but only in the form of several licensed medicines and for a very limited range of conditions. Some areas of the country show very low volumes of NHS prescribing for cannabis based medicines. One is Sativex, the licensed cannabis medicine produced by GW Pharmaceuticals, which contains CBD (in a ratio of 1:1 THC/CBD).

These generally low volumes suggest that the NHS is some way from accepting the potential medical benefit of CBD even in a licensed medicine format, and the rescheduling of cannabis-based medicinal products (CBMPs) on 1 November 2018 appears to have had no effect on rates of prescribing of dronabinol (or Sativex). Data for Scotland, Wales and Northern Ireland is not yet accessible in the same open format, so it is not possible to say if prescribing of these drugs varies in those places, although Sativex is known to be more widely prescribed in Wales.

A second licensed medicine from the same UK company, Epidiolex, has attained licensed status in the United States receiving FDA approval in June 2018. This drug, a cannabidiol formulation, is the first plant-based cannabinoid to gain regulatory approval, and costs \$32,500 annually per patient.¹⁶ However as of June 2019, it has not yet been approved in the European Union, and as such, has no licence to be marketed or prescribed in the UK. Consensus forecasts project that Epidiolex will reach annual sales valued at \$1.7 billion in the US by 2024, indicating substantial clinical demand for an approved CBD-based medicine and the conditions it is designed to treat.¹⁷

As research advances, and the medicinal and therapeutic benefits to humans and animals of CBD are explored, it is feasible that its classification (and therefore how it is regulated) will change – including potentially moving it from being a food supplement or novel food to being classed as a medicine. However, unless and until there is more established evidence of CBD's curative effects, it seems unnecessary and unreasonable for UK regulators to regulate it as a medicine, with the cost and regulatory burdens that such a move would invite.

Medicinal Cannabis in Europe

The UK now has a legal regime for prescribing cannabis-based medicinal products (CBMPs), and like other European countries, has also licensed other cannabis medicines for certain conditions (see Glossary).

There is a lack of consistent regulations for medicinal cannabis in Europe, and there are still major economies where no legal access regime exists. As lobby groups like Cannabis Europe have advocated, it would help the emergence of a European industry that supported patients, if a consistent set of standards could be agreed upon for medicinal access, including for CBD products (not containing controlled substances), so eligibility was not so dependent on country of residence.¹⁸

Moves are underway in the European Parliament to urge the European Commission to adopt this agenda, though no progress is now likely until the new Parliament and E.U. Commission is in post after September 2019. Nevertheless, healthcare systems are regulated and funded at a national level, and so for the medium-term, the access to medicinal cannabis products, including how CBD is retail and/or prescribed, is a matter for individual countries and their respective regulators.

The key exception to this is the use of CBD (and other cannabinoids) in food supplements, where the EFSA's 'novel food' regimen applies in all member states, including the UK (see Chapter 3 and 4).

The Opportunity

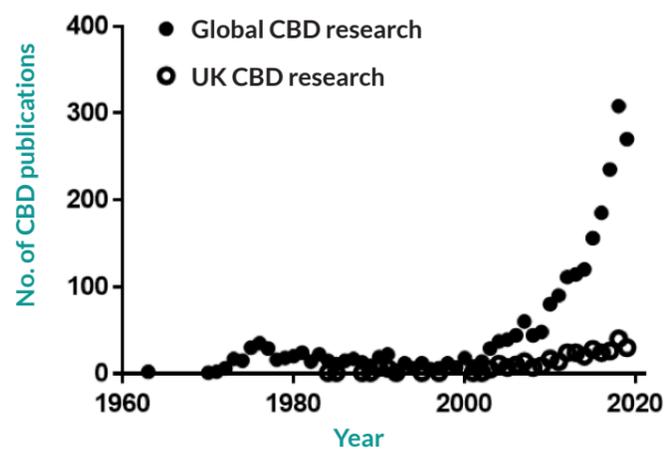
To view CBD as simply a consumer nutraceutical or wellness product that has little or no medicinal potential is short-sighted. Not only has it been approved in two licensed medicines, it is also being studied as part of robust clinical phase II and III trials in several jurisdictions, but it is also already showing promise beyond the pre-existing focus on rarer conditions in paediatric neurology. As Mr David Horn, former surgeon and NHS commissioner and now Medical Lead of the CMC states: "Early completion of successful research into the efficacy and safety of CBD will have profound effects [on medical establishment opinion]."

New research avenues

The advances in our understanding of cannabinoid science has generated fresh research interest into CBD, with several studies underway at UK universities exploring the impact of cannabidiol on human health.

Analysis of the published literature shows that CBD research in the UK has been steadily growing since 2000, which is roughly the same year that CBD research began growing internationally. The UK currently contributes about 10% of the global research into CBD. This research is mostly based in three sites; most of the London universities, the University of Nottingham and the University of Reading. This research is mainly at the preclinical stage (before being used in humans i.e. through cellular or animal testing) or with CBD being used in healthy volunteers.¹⁹

There is only one UK-based clinical trial currently registered/active looking at CBD being conducted at Kings College London.²⁰ Other excellent and active Russell Group universities with strong plant science research departments like Cambridge, Edinburgh, Manchester, Leeds and Southampton are notably absent however. See Annex.



There is an active and growing CBD research community in the UK covering a broad range of research areas. One of the areas of research in which there is a notable absence of UK based research is in CBD and pain. Major efforts should be made to increase the breadth (involving more universities and increased areas of expertise) and volume of CBD research in the UK to ensure we become world leaders in this field. We particularly need to encourage

clinical research trials that translate this ongoing research into a firm evidence base for the medicinal benefits of CBD in order to promote its clinical use.

Role of CBD - A Medical View

Cannabidiol in the UK is the key to a sea-change reduction of reasoned medical inertia and accelerated future wider medical deployment of Cannabis Based Medicinal Products (CBMPs).

CBD is the unexpected late pregnancy and in contradistinction to THC, appears potentially a star-child. It doesn't exhibit a significant side-effects profile, indeed such problems as it may exhibit are in high dose and entirely manageable, or ultimately reversible upon abstinence.

CBD and THC are "chalk and cheese", and yet their destinies have in the past been inappropriately too tightly bound as a necessary sacrifice upon the altar of legal clarity. Now the medically unthinkable has happened: a "black swan event". CBD proved not to be a clinically inert irrelevance, but of undoubted clinical benefit in small numbers of, but highly emotive cases of childhood epilepsy syndromes.

This will likely prove to be the Achilles Heel for prevailing medical indifference. Little now stands between CBD and large markets: simple proof of efficacy is all that prevents wider medical deployment and lucrative commercial success. It is the low-hanging fruit both for further significant market development and medical benefit.

Mr David Horn

The Health Risks

The official view of the NHS regarding the safety or otherwise of cannabidiol is as follows: "Information regarding CBD safety is limited to few human studies and information should be interpreted cautiously. Further studies are needed to evaluate the full safety profile." However, the most comprehensive review of the evidence on CBD led the World Health Organisation (WHO) to conclude in 2017 that "in its pure state, cannabidiol does not appear to have abuse potential or cause harm".²¹

Drug interactions

The Special Pharmacy Service, a division of the UK's National Health Service (NHS), issued a guidance note²² in 2018 on adverse effects and possible interactions with cannabidiol, "due to an increasing popularity of self-administration of over-the-counter bought CBD". It summarises these as:

- The most common adverse effects found in studies were somnolence, decreased appetite, vomiting, diarrhoea and elevated liver enzymes.
- Moderate to severe impairment of kidney or liver function may theoretically reduce the clearance and/or excretion of CBD.

- The data available suggests that CBD interacts with cytochrome p450 enzymes consequently, caution is recommended when CBD is co-administered with medications that are metabolised by this pathway.

However, the guidance also concludes: "The extent to which CBD may interact with other medicines is relatively unknown." The guidance advises that "If a patient is self-administering CBD they should inform their doctor or pharmacist."

CBD product risks

There are known health risks associated with cannabidiol products, as opposed to cannabidiol itself. Many of these risks have only been identified through batch-testing by universities, or other researchers, and not proactively by regulators involved in licensing activity.

Risks to human health from the consumption of products sold as CBD is not theoretical. There have been cases where cannabidiol products have been proven to contain dangerous contents that have harmed users (see Annex). Were similar events to occur in the UK, the impact on public health, and the wider negative effect on the product class, could be substantial and enduring. Even without the detection of potentially hazardous synthetic compounds in a CBD product, given the prevalence of nut allergies in the general population, even a mislabelled carrier oil in a CBD product could pose a serious risk to certain consumers.

3. The Law

Summary

- Pure CBD is legal in the United Kingdom and is not classed as a controlled substance. However the CBD industry is engaged with a product that can (and often does) touch on what is permissible under the criminal law, as a result of other elements within the same product.
- Many CBD retailers in the UK are trading according to a folk interpretation of domestic law governing controlled substances that is incorrect; however, this is not surprising because the law is complex, and legal clarity - though sought repeatedly - has not been provided.
- Common misreadings of the law regarding CBD are a major and widespread problem in the UK CBD sector that undermines the industry and can mislead consumers.
- Beyond the legal status of the product under the UK's existing drugs laws, certain CBD products are also subject to domestic law in respect of rules governing food, or cosmetics, where legal status is determined by a separate set of factors.
- Any product containing CBD that is used for medicinal purposes is a medicine and must have a product license, CBD products must therefore avoid making any medical claim or act as a medicinal product by virtue of its presentation, its claims or its composition or face enforcement by the MHRA.
- The legal framework that now impacts CBD products is decades old, and the applicable regulations were enacted in 2001 - long before the emergence of a mass consumer market in cannabidiol products. The laws have not been affected by the wider changes enacted for the recent legalisation of cannabis-based medicinal products.
- The most important new legal development arises from the European Union's Novel Food process, which led to the classification of all extracted cannabinoids as "novel" in January 2019. As currently drafted, it presents a serious challenge to the CBD market as it exists in the UK today - however it is yet to be enforced in the UK.

Cannabidiol's legal status

Countries with similar approaches to the regulation of consumer goods and of medicines, nonetheless have chosen (for a host of local reasons) to classify and therefore regulate cannabidiol differently. The current status of CBD in any particular jurisdiction reflects the status of that country's laws, and regulations flowing from them, and they are not consistent.

Most laws relating to the cannabis plant are decades old and have not been updated to reflect new scientific findings, and even most regulations - including in the UK - that directly bear on CBD are from the early 2000s, and long before OTC cannabidiol became such an important consumer trend.

UK law makes no distinction between CBD products derived from hemp (certified strains or otherwise), and CBD products derived from high THC cannabis plants. The North American terminology - 'marijuana' to mean high-THC cannabis (which remains a schedule 1 drug under US Federal law), is clearer, insofar as it is distinct from hemp (low-THC cannabis sativa L) that was de-scheduled following the passage of the US Farm Bill in 2018 - though it is the same plant. The distinction broadly follows the United Nations Office for Drug Control (UNODC) equation to distinguish the two types (fibre cannabis vs. drug cannabis), based on the ratio of THC and CBN to CBD.²³ However, this is unhelpful in the UK context of CBD because the cultivation of any cannabis variety is unlawful without a Home Office licence.

Products for sale in the UK that contain only pure CBD, and no other cannabinoids (e.g. a pharmaceutical-grade

CBD isolate) are deemed legal because of the status of the finished product, not because of their original source material. Customers in the UK therefore deserve to know the purity of the end product they are buying, which is only possible through secondary testing of a finished product by a third party laboratory (not in-house analysts) and by having result certificates available to read (see Chapter 8). The same customers also need a clear statement of UK law regarding CBD products, which presently does not exist (see our recommendation in Chapter 11).

The three legal dimensions of CBD

In the United Kingdom, cannabidiol falls under the provisions of one of three legislative domains - controlled drug statutes (a matter for the Home Office); medicines law (a matter for the Department for Health and Social Care, and the MHRA regulator), and food safety law (a matter for the FSA).²⁴ A single CBD oil product manufactured abroad and sold in the UK may interact with, and need to comply with, each of these three legal frameworks.

Controlled substances

Prohibition of cannabis in the UK stems from the original Dangerous Drugs Act (1920) but the current legal status flows from the 1971 Misuse of Drugs Act²⁵ and the associated 2001 Regulations. However, one of the principal chemicals - cannabidiol - is not referenced in any UK drug control legislation, and is not considered a controlled substance (and never has been).²⁶

The recent legalisation of medicinal cannabis products confirmed this status. Following advice²⁷ commissioned by the Home Office and presented by the government's Chief Medical Officer, Dame Sally Davies, was explicit - rescheduling (from schedule 1 to schedule 2) was required for Cannabis-Based Medicinal Products (CBMPs).²⁸ However, no change was needed with respect of cannabidiol, because - "*Cannabidiol is not a controlled substance and is therefore not included in Schedule 1*" (a fact repeated five times in the report). The Home Office states: "*CBD as an isolated substance, in its pure form, would not be controlled under the MDA 1971 / MDR 2001.*"²⁹

In respect of the cannabidiol compound, because "pure" CBD is not a controlled substance in the UK, this places this phytocannabinoid on the sidelines of national efforts to police controlled drugs arising from the 1971 Act and from various UN conventions. This is a key reason why traditional law enforcement efforts - which have focused on the cannabis plant (and other controlled substances) - have not borne down heavily on CBD products, and they are widely tolerated in the UK.

But this lack of enforcement should not be interpreted as making all CBD products legal. The status of individual CBD products, is dependent on their overall composition. The 'greyness' of the law arises because the CBD industry is engaged with a product that can (and often does) have a bearing on what is permitted under the criminal law, as a direct result of other elements within the same product that are themselves controlled - principally THC and cannabinol (CBN).

The government's position - reflecting the Home Office's view of the law - is the five page 'factsheet' that is undated, but is now in its fourth iteration (and available for download on the gov.uk website).³⁰ It is presented as an opinion, and not as a statement, but it provides the only clear statement of the law relevant to CBD products. The factsheet is clear that a product that contained a controlled substance (e.g. a hemp oil containing THC) "*could not practically be prescribed, administered, or supplied to the 'public' unless it is an exempt product or a CBPM.*"

This important distinction between the non-controlled status of the chemical in pure form, with the legality of the finished CBD product, is often missed. It is also widely (and perhaps wilfully) conflated so that FAQs on multiple CBD retail websites mix up the two positions. The 0.2% limit for certified hemp varieties for licenced cultivation is then typically invoked to claim that traces of THC under this set level are lawful. As one example, a UK CBD retailer³¹ that describes itself as "The Safe and Legal CBD Cannabis Shop" mis-states the law by claiming their products are legal because - "*A Full Spectrum CBD extract contains all the terpenes - yes, traces of the THC as well, but only at a non-psychoactive legal max 0.2% level.*"

Many CBD companies and even some major brands have mass marketed themselves as compliant with the law, when their products would not be if they accurately accorded with the description they apply to them - in one example where they confirm that their CBD oils contain cannabinol (CBN) and up to 0.05% THC.³² The Home Office states:

If a CBD 'product' contained any controlled cannabinoids, unintentionally or otherwise (e.g. THC or THC-V), then it is highly likely that the product would be controlled. It is our understanding that it is very difficult to isolate pure CBD, and in our experience many products in fact do not fully disclose their contents or provide a full spectrum analysis at an appropriate level of sensitivity to accurately and consistently determine their true content or control status.

In one respect, this misunderstands the market – it is possible to remove THC, and that is becoming cheaper to do every year, and is likely to become a more common feature as the customer base moves to demand that assurance and to source better quality products that have the THC removed (even if they retain other cannabinoids).

The presence of cannabidiol – the other major controlled drug – is a further complication, which many CBD companies overlook in their efforts to address traces of THC.

Some larger companies with the means to conduct more expensive extraction and filtering during their CBD production have eliminated THC (below detectable limits), and been explicit that this is a distinguishing feature of their products that gives consumers confidence and helps reassure regulators (especially when such companies are shipping product across federal borders, like many US-based producers that sell into the UK and E.U.).³³

The only exception to these rules, would be for exempt products under the same 2001 Regulations. However even here, the restrictions are very tightly drawn, and where the “one milligram limit” in the finished product is applicable is also widely misinterpreted (see Annex).

This all means that the UK’s current law, though complicated and often misunderstood, provides no room for a CBD product of any origin that cannot prove that it is free of other naturally-occurring controlled substances (a consequence of traditionally produced botanical hemp extracts, alongside accompanying terpenes and flavonoids). Some producers can and do invest in additional processing to ensure controlled cannabinoids are filtered out, and testing of products for this report shows that some UK products do achieve this (see Chapter 8). Furthermore, a pure CBD isolate product at high concentration would be in a different position too, though depending on its intended purpose and product category, would be caught by either medicines law or food law (see below).

UK authorities themselves appear to know that the CBD oil market may contain controlled substances and not be fully compliant with the law. The NHS guidance on the safety of cannabidiol states - “*CBD-containing products, although commonly advertised to be free from THC, have the potential to contain traces of THC.*”³⁴ For the purposes of the law, it is irrelevant that traces of THC at or below 0.2% in a CBD product would not intoxicate the user or pose a risk to human health.

Medicines

The UK’s health sector regulator - the MHRA - issued an important opinion on cannabidiol in 2016 stating that CBD when used to treat medical conditions (and

marketed or advertised as such) was a medicine, and such companies could therefore only legally do so if they have received a marketing authorisation from the MHRA.³⁵

There are no such products yet available in the UK. Every CBD oil product sold in-store or online in the UK in 2019 does not meet the Human Medicines Regulations 2012 definition of a medicinal product. At the time of issuing that opinion, the MHRA also wrote ‘cease and desist’ letters to 18 CBD companies it identified as being in breach of medicines law, which is standard practice. However, these firms were not identified or the letters published (as they are in the United States), and as such, this intervention was less instructive for the wider industry than it should have been.

It is still not clear whether the companies identified in 2016 were making general health maintenance claims (legal), or more explicit and unproven claims that CBD can cure illnesses or other conditions. What is clear is that some companies continue to make claims that breach MHRA rules, including a UK CBD company that describes its mission as bringing customers the “*benefits of CBD after successfully relieving fibromyalgia & chronic pain along with other friends with arthritis, eczema, psoriasis*” and who sell CBD balms alongside the claim that “*When the body products are massaged into the skin, they can provide soothing relief to joints and muscles*”.³⁶

One online retailer³⁷ avoids making health claims, and demonstrates awareness of their need to comply with the law, whilst recognising that customers will be seeking such information elsewhere on the web: “*Clinical trials are currently looking into the effect of CBD on the body. So far the findings that we can legally share with you are the discovery of two main receptors in our bodies. Unfortunately, due to the nature of this commodity, we are limited to what we can say on this matter. However, there is lots of information available [sic] online that we believe might be of huge interest to our customers.*”

The large and unregulated market in CBD products has a significant online marketing dimension where companies promote products and blog about CBD in order to generate customer visits and ultimately webstore traffic. The official statement that sets out what medical marketing is banned (the MHRA’s BlueGuide) covers claims made by companies on social media.

Not being medicines, but rather food supplements, the CBD oils that continue to be sold are under fewer production controls when compared to medicines - for example, they are not required to meet good manufacturing practice (GMP), including safety, quality and efficacy standards. Some CBD companies do claim to be GMP compliant, but under food supplement rules, they do not need to be.

The official NHS view is that over the counter CBD oil products are not medicines in law, and “*as a result, the safety and quality of such products may not be guaranteed.*” In other advice available online, the NHS goes further and states that these CBD products “may be illegal and potentially dangerous”.³⁸ It also cautions consumers, and those looking for relief from symptoms, that - “*Some products that might claim to be medical cannabis, such as “CBD oil” or hemp oil, are available to buy legally as food supplements from health stores. But there’s no guarantee these are of good quality or provide any health benefits And they tend to only contain very small amounts of CBD, so it’s not clear what effect they would have.*”

Food

With the exception of e-liquids for vaping, and cosmetics³⁹ (which have their own rules), most retail CBD products today are classified as food and fall under the EU frameworks governing food (see Chapter 4 and Glossary). Recent changes now mean that one aspect of those frameworks - the Novel Food process - now applies to CBD and all cannabinoids, regardless of origin (although the interpretation and applicability to natural hemp extracts is being disputed).⁴⁰ The Novel Food catalogue entry explains that cannabinoids are covered because “*this product was not used as a food or food ingredient before 15 May 1997. Therefore, before it may be placed on the market in the EU as a food or food ingredient a safety assessment under the Novel Food Regulation is required.*”⁴¹

The established law governing novel foods in the Single Market is the product of the EU directive, which Member States are required to uphold. This directive sets out the definition of a novel food, the rules determining what is a novel food, and the process for assessing the safety and granting the approval to market a novel food product legally in any EU state.⁴²

The Novel Food classification has been interpreted as having direct legal effect, or of being a single, EU wide directive applying to the whole market. However, the Novel Food Catalogue⁴³ is only an advisory reference guide for national authorities, each of which have their own domestic legal framework (and agencies), for applying food safety standards. In the UK it is the Food Standards Agency (FSA), working to the Food Safety Act 1990 and related legislation, that has the role of monitoring and policing the market for food safety.⁴⁴

The decision by the committee has been contested and will be legally challenged, but no alternative pan-EU approach exists at present. However, as no CBD product has yet secured a Novel Food marketing authorisation, no supplier of any product currently sold in the EU market complies with this new definition in order to be legally sold as a food supplement.

As Catherine Wilson, board member of EIHA has argued, the decision was unexpected, has caused major confusion, and will have a profound (and potentially devastating) effect on existing European producers:

“*On 20 January 2019, the same committee that previously acknowledged in writing to the hemp industry 20 years earlier, that hemp flowers and leaves is a food now changed their minds and changed the Novel Food catalogue only permitting seeds for food use. Overnight the legitimate hemp foods industry was declared novel. The recent rewording of the Novel Food catalogue therefore threatens the entire European hemp industry as the process is expensive and a novel food application takes several years to assess.*”

All 28 Member States are obliged to uphold the novel food regime in their own jurisdiction as part of a general surveillance and enforcement infrastructure that can identify products that give rise to food safety concerns, remove them from sale and penalise the suppliers. In the UK, the Food Standards Agency (FSA) – a non-Ministerial department that is politically independent – has this role. In line with clause 38 of the EU directive, *The Member States should lay down rules on penalties applicable to infringements of this Regulation and should take all measures necessary to ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.*

UK law specifies what enforcement tools the FSA can deploy, however, it is not yet clear what a proportionate enforcement approach by the UK’s FSA would look like as it relates to the novel food classification affecting CBD products. Unlike regulators in North America, a lack of transparency makes it difficult to gauge the scale and nature of enforcement (if any) already underway in the UK. It is not known how many warning letters or stop notices have been issued in respect of CBD companies in recent years, although the Novel Food update has caused Food Standards Scotland to issue guidance and a call for local intelligence.⁴⁵

The impact of the Novel Food regime to the UK’s CBD market is further complicated by Brexit (see Chapter 10) and what the authorisation process might involve once the UK is no longer part of the E.U. The ICCI, in their report on Novel Foods, argued that the so-called ‘grey zone’ was likely to continue for some time, even within the E.U., and that there continues to be uncertainty about what is caught by the ‘cannabinoids’ entry. They concluded - “*The question remains as to whether or not extracts of cannabis are a novel food.*”⁴⁶

How the law is interpreted

Many established CBD suppliers make explicit reference

to the need to ensure consumers access safe and quality products. Doubts about the health risks and anxieties about the legal status of CBD crop up frequently in the online marketing material of cannabidiol suppliers. One UK retailer – Provacan – states on their website landing page: “Our customers are safe in the knowledge their health and legal standing is not at risk when consuming our products produced under compliant and ethical business practices.”⁴⁷ Dozens of CBD companies cite their membership of a membership group⁴⁸ as evidence of their compliance, even though no regulatory standard, from this or any other group, has been accepted or endorsed by the UK government or any of its agencies or regulators.

Law firms operating in the UK cannabis space are regularly asked for counsel opinion on the meaning of the law, and the valid interpretation. It may reflect a lack of clarity on behalf of the government and regulators that they themselves have not produced a single, clear statement of the legal position regarding CBD. As a result, certain assumptions have gone unchallenged, even established media outlets like the BBC have misreported what the law says⁴⁹, and the legality of certain behaviour has not been tested.

Examples of common misreadings of the UK law applying to CBD products include:

(1) “It is legal to sell any cannabis products so long as they come from hemp”

Reality: The status of the end product dictates its legal status. The source material must be grown under a licence. Licenced growers can not lawfully process the cannabinoid content in the hemp plants flowers. It is therefore not relevant that a hemp flower has a low-THC content. If it is sourced from a UK farm it is a part of a prohibited plant containing a controlled substance that no farmer can lawfully sell. If it is imported from a foreign hemp farm, it is still classified as cannabis and would be prohibited because of (2).

(2) “It is legal to sell products with THC so long as they are 0.2% or below”

Reality: The 0.2% limit is the EU standard (replicated in UK law) for the permissible level in certified-hemp strains. Hemp varieties that are tested and shown to exceed this, lose their certified status. The 0.2% standard is what licensed UK hemp farmers must abide by when choosing what varieties to plant. It was not designed to reflect any per se limit for a finished cannabinoid product. In practice, because of the confusion, it is commonly seen as the legal threshold, but the UK law makes no such stipulation. Extracted hemp products that contained high percentages of CBD might contain more than trace elements of THC, and in any ratio, and any packaged amount, could only be lawfully distributed in the UK by holders of a controlled drugs licence.

(3) “It is legal to buy and sell CBD without any restrictions because it does not get you high”

Reality: Some CBD retailers attempt to show their compliance with the law by referencing the ‘absence’ of THC in their products. Common phrases include “THC-Free, will not cause you to fail a drugs test”.⁵⁰ However, it is the presence of THC and other controlled substances that prohibits a product from being manufactured, imported, distributed or sold in the UK, other than with the required Home Office licence. Products that contain a full spectrum extract of cannabinoids in a concentration unlikely to intoxicate the consumer, may nonetheless breach UK law by containing more than trace concentrations of THC. Manufacturers of highly purified CBD isolate and pharma-grade CBD with an API certification are in a different position.

The change to the law on the scheduling of medicinal cannabis products requires CBD products containing even trace THC to meet a separate definition in order to be prescribed clinically (and only then, by specialist clinicians, working to guidelines). In the context of some high concentration broad spectrum CBD products lawfully produced in places like Israel and Canada, the UK law would limit them to being sold (or imported) as a CBMP and only to be produced or distributed with the requisite special licence. Even a pure CBD product could only be marketed as a medicine if it attained a marketing authorisation, and without that, could only be sold in health food stores and supermarkets as a food supplement, without making any medical claims whatsoever.

Legal exposure, liability and other consequences

Enforcement

Recent enforcement at a local level by police forces and Trading Standards have targeted hemp flower products. This may also reflect an emerging consensus among police forces - independent of the Home Office and not a radical departure - that flower products that are being sold (whether they are smoked or used as herbal tea preparations) are not legal and will not be tolerated. These raids appear uncoordinated at present and seem to be reactive, based on local complaints received from the public. So far in 2019, several media reports have covered numerous police raids on retailers who have reportedly been selling flower products.

There have been no reported cases of convictions at court for the sale of CBD products that have been deemed illegal, but it will depend on the nature of the

business and the available evidence, including testing of the products being sold. These events have not stopped other CBD retailers mistakenly claiming that hemp flowers comply with applicable UK law: “Our CBD flowers are derived from the highest quality hemp strains. They are bred specifically to yield high CBD and low THC contents and are legal in the EU.”⁵¹

At present, one interpretation of recent enforcement activity is that police have decided as an operational policy to draw a distinction between CBD oils and flower products - the latter being easier to identify for frontline staff, and more likely to raise concerns among members of the public (for their resemblance to illicit street cannabis, and the smell when smoked). This would explain recent efforts in certain police areas to pursue the open selling of hemp flower products, targeting retail stores and some distributors.

In relation to Novel Food enforcement, this activity is handled by individual member state’s authorities across the EU and is at present sporadic. A central database tracks food safety incidents and alerts across the EU and now provides a regular update on product seizures and enforcement against suppliers and retailers for breach of the novel foods classification. Enforcement is now occurring but it is not uniform and some countries are not yet registering any activity (import stops, retail seizures).

Legal risks for companies and CBD users

In UK law there are side offences related to cannabis that leave consumers exposed, especially if they ingest controlled substances unknowingly – for example, impaired driving laws⁵², or for professional athletes, the World Anti-Doping Agency (WADA) rules.⁵³ In the United Kingdom, because cannabis remains proscribed, any THC detected is sufficient to deem the driver impaired and to fail a roadside test.⁵⁴

There is anecdotal evidence in the UK that roadside drug tests deployed by the police (a binary test of THC presence in a sample, based on current equipment) have on occasion resulted in positive returns for consumers who claim only to have consumed CBD products. These consumers are likely to have inadvertently consumed THC in a CBD product that was mislabelled and therefore mis-sold, increasing their chances of prosecution for driving under the influence of a banned substance, as well as risking unintentional impairment.

The legal liability for purchasing and then consuming a cannabidiol product bought from a store or online (e.g. a registered trading business), that contains a controlled substance does not fall on the consumer, insofar as the United Kingdom – in common with many countries, and at least 15 members of the E.U. – does

not make consumption of cannabis a criminal offence. Membership of international counter-narcotics conventions that underpin domestic prohibition laws are directed at controlling supply, restricting trade, and eliminating cultivation. Some countries in Europe, notably France, Greece, Sweden and Norway make consumption itself an offence that can be imprisonable on conviction.⁵⁵

Single government position

Research for this report suggests that legal clarity is not only needed on the part of consumers and the industry itself, but also government, to avoid capricious enforcement activity by the police and others. In respect of importation and retail, authorities appear to be acting in ways that do not reflect fair treatment and consistent application of the law.

If the current 2001 regulations render almost all CBD products unlawful on a strict interpretation (as yet untested in an appeal case), then UK Border Force should be preventing every shipment they stop until tested at an independent laboratory to show an absence of controlled substance, and HMRC should not be collecting any applicable import duties. This is not the reality. Furthermore, CBD companies have been actively advised by HM Revenue & Customs which import/tariff category code to register under to pay the applicable charges. And CBD companies are paying tax on these traded products, and on their own profits.

There is anecdotal evidence that CBD shipments that are stopped at the border but can prove THC content below 0.2% (with a laboratory test certificate) are being granted safe passage into the UK. This would be a curious misreading of the applicable law, and takes no account of whether those test results are from a trusted, licensed lab. One explanation is that this common view of where the legal limit for compliance sits, though ill-informed, has nonetheless been informally adopted as the de facto threshold to make enforcement a practical possibility.

If this is the case, it might be justified as a rational approach for operational staff with finite resources, as opposed to a costly effort of blanket enforcement against all CBD products (that would then require huge amounts of testing to build a case strong enough to secure a conviction), however it would not be a sustainable practice so long as the law remained unamended. Research for this report has seen no documentary evidence of any guidance to this effect (or conversely, against this practice) being issued to UK Border Force or the police.

4. The Regulations

Summary

- All cannabinoids for human and animal consumption exist within a regulated regime, with varying levels of restriction. The CBD market in the UK is under-regulated, and this poses challenges for the industry and consumers.
- Regulations governing CBD products are not specific to cannabidiol, and there is no separate regulatory pathway that has been designed for these products in the UK.
- The CBD industry, like any consumer market, is subject to a range of generic regulations governing food, cosmetics and medicines, and the end product category determines the rules by which those products can be produced, distributed and marketed.
- The regulators have clear roles depending on the product category, and their remits are designed not to overlap - so what is a medicine, cannot be a food, for example.
- Regulators have not provided clarity on recent developments relating to cannabidiol and this has perpetuated the uncertainty about which products are compliant, and what is to be expected by way of enforcement action for companies breaching the law.

Regulatory confusion on cannabidiol

There is general confusion around who is responsible for regulating CBD. This confusion partly arises from the variety of laws that exist that govern cannabis, but also how regulators classify the products derived from the plant, and how CBD is used in end products for consumers.

The UK's regulatory landscape for CBD

All cannabinoids for human and animal consumption exist within a regulated regime, with varying levels of restriction. The over-the-counter CBD market in the UK is under-regulated, and this poses challenges for the industry and consumers.

Countries across the world take different approaches and vest the regulatory function for cannabidiol products in different agencies, often as a result of historical context and how CBD is defined in domestic law. In the UK – and not unlike the United States – the regulation of CBD does not fall to a single department or agency. The source of much of the confusion and misinformation about the legality or otherwise of CBD retail products and customer-facing businesses arises from this, as the industry interfaces with several authorities on the same issue or in unexpected ways.

Nevertheless the use, production and marketability of CBD products derives from their classification, which in turn, places them in different regulatory regimes.

In summary, there are three departments of state with a role in the CBD market in the UK, and two national regulators who have a remit, depending on the product concerned, in addition to the enforcement agencies who must police the market itself (see Annex). In common with many countries and regardless of the legal status of medicinal cannabis, the UK has no dedicated agency or regulator with expertise in cannabinoids, and the main food safety regulator has only begun developing expertise in CBD and other ingestible cannabinoids in the last few years.

Regulations applying to CBD products

The way CBD products are produced dictates which regulatory regime applies. The main regulations affecting human CBD products are those relating to general food law, food supplements, and food labelling. However, the variety of CBD products on the market in the UK also means regulations governing cosmetics, e-liquids, and pet products are also relevant.⁵⁶ Rules around vaping and the legality of consumption for these also varies at a national level across the EU.

Regulatory confusion is made worse by the conflicting determinations made by authorities as to CBD's correct

classification. Not only is CBD classified differently in different countries; it is also sometimes classified differently within the same country. For example, in the United Kingdom, though not a controlled substance, cannabidiol is regarded as a food supplement when used in products designed for humans (unless medical claims are made, in which case it becomes subject to medical marketing approvals), but is classified as a medicine in all circumstances when used in products designed for pets.

In this respect, the two UK regulators in the same jurisdiction (the MHRA and the VMD) do not concur. The differing classification relates to use as a medicine, because the metabolism of humans and other mammalian animals can be substantially different. However, given CBD products have been used by pet owners on themselves and their pets, the verdict is confusing. It also means that the regulatory barrier for supplying cannabidiol to animals (mostly pets) in the UK is higher than it is for supplying the same compound to humans.

CBD for pets

The VMD determined that cannabidiol products were a medicine, and prohibited vets and pet stores from prescribing or selling them unless the CBD product had received medical approval for use in animals (currently no product has this). That announcement led to major pet stores withdrawing CBD products from shelves, though hemp seed oil based products are still sold. This means no veterinary practice can use CBD, but the same CBD products are being routinely consumed by humans. And the VMD decision has not stopped UK pet owners from buying CBD products online, and administering them to their own pets at home. This is a practice that the VMD could not prevent even if it had the legal powers to do so. Animal welfare charities have raised no concerns to date about this practice, and other jurisdictions in the US have demonstrated strong consumer interest in CBD for pets. Advice groups on social media exist where pet owners share their opinions on what works for their dog or cat and the best CBD products to use. Companies in the UK, including Sativa Group, are exploring clinical trials of CBD pet products with the goal of being licensed to market them as medicines.

Blogging vet David Harris, from Vet Help Direct, said: *“Increasing numbers of animal owners are sourcing cannabidiol as a ‘nutritional supplement’ but are using it to treat disease, in some cases apparently without veterinary input. This is seen as a concern for animal welfare, because products manufactured as food supplements are not as well regulated as medicines which have a potent active ingredient.”*⁵⁷

CBD Products within General Food Law

The most common end product is an oil extract that consumers apply as a tincture, and as such, is classified across the EU as a food supplement. Rules governing supplements arise from the same rules governing food in general.

In addition to regulations that have a specific bearing on cannabidiol products (because of their origins in a restricted plant), there are a number of overarching regulations applicable in the European Union under general food law, governing the safe production and sale of food and food supplements (e.g. CBD oil products), and their marketing and product labelling.⁵⁸ All these rules are mirrored at the national level⁵⁹, and in addition, anyone operating a food business in the United Kingdom - including distributing food products - needs to be registered with their local council.⁶⁰ None of these regulations should provide any obstacle to operating a retail business selling cannabidiol, but

some CBD businesses appear to operate as if they are unaware of these provisions, or mistakenly assume these generic consumer laws do not apply to them.

Position of the Food Standards Agency

The FSA has issued two public statements on the issue of cannabidiol in the last six months - neither of which have any legal force. The first was a press statement made in response to a media article in a national newspaper about the possible impact on UK businesses of the Novel Food classification. The second was a proactively issued 'FSA Explains' info box on the FSA's general Novel Food section of their website.⁶¹ In the latter they state -

There has been a recent change to the EU Novel Food Catalogue which affects some cannabidiol (CBD) products [emphasis added]. ... The FSA accepts the clarification from the EU that CBD extracts are considered novel foods. We are committed to finding a proportionate way forward by

working with local authorities, businesses and consumers to clarify how to achieve compliance in the marketplace in a proportionate manner.

By themselves, these statements contained no technical detail useful for the sector, and neither amount to official guidance or a determination by the regulator. In particular, the updated FSA webpage on cannabidiol invites other questions (“some CBD products” - but which ones?), and implies a degree of discretion or flexibility around how EU law is applied in the UK that is not spelled out, and has no clear precedent.

In 2017, prior to the decision to include CBD products as novel foods, the FSA conducted a public consultation on how they should prioritise the enforcement of novel food rules against food businesses.⁶³ No response to this exercise has been published but it clearly has implications for how the FSA would approach the policing of the CBD market going forward. The current novel food regulation for England from 2018 provides for a range of measures that might be taken. Enforcement powers range from issuing compliance

notices, to stop notices, to levying fines and working with local trading standards officers to visit premises, and seize stock. It is not known how many warning letters or stop notices have been issued in respect of CBD companies in recent years, although the Novel Food update has caused Food Standards Scotland to issue guidance and a call for local intelligence.⁶⁴

In response to changes to the EU Novel Foods catalogue, Ireland’s authorities have decided to demarcate hemp products that are cold-pressed, from the non-traditional extraction methods, and classifying all products involving modern extraction methods as novel.⁶⁵ This interpretation may yet be replicated in other Member States, but it is not yet known if this has or will influence the UK, or how robust it would be under legal challenge.

5. The Consumer

Summary

- For the first time, robust public attitudes data reveals a high level of CBD use in the UK, consistent with the size of the market estimated in the sector analysis, and demonstrating that CBD has now gone mainstream in the UK.
- Two new surveys conducted in May and June 2019 by Dynata and YouGov indicates that between 8-11% of UK adults respectively - approximately 4-6 million people - have tried CBD. The CBD consumer base is broad - and there is familiarity and recent use among a sizeable proportion of all age groups and social classes.
- Those who had consumed cannabis to help alleviate symptoms of any kind were significantly more likely than the group as a whole both to have used CBD products in the last year – almost 6 times more likely. Overall, 7% of the population have used cannabis for medicinal purposes in the past year, rising to 41% among those who have used CBD in the past year. And support for legalisation of cannabis increases from 47% among the total population to 75% among past year CBD users.
- Consumers have clear preferences that drive their buying decisions, and prioritise quality and purity over origin or legality. Clear labelling information and advice on use and consumption tips, followed by a preference for British produced CBD products, were the purchasing priorities that scored highest, more than price, brand or organic status.
- User comments supplied for this project reflected a similar theme - that CBD is effective for them, and should be made more widely available, however costs was raised as a factor. These comments help to explain how CBD has become so popular in the UK so quickly.
- A sizeable proportion of regular CBD users are deriving - or claiming to experience - a medicinal or therapeutic benefit from the CBD they buy. However, consumers are unable to access good quality and impartial information about CBD products in the UK at present.

Public attitudes

Many surveys of CBD users reveal a large cohort who admit to using CBD to self-medicate, with surveys of users/patients in the United States revealing that cannabidiol is being consumed for a wide range of diseases and conditions, some of them chronic and even terminal. A 2015 survey of over 600 users who had been taking CBD consistently for the last 30 days showed a range of beneficial results based on the self-reported scores of the consumers.⁶⁶ Questions exploring motivations for CBD user among UK consumers were included in work conducted by Dynata (see below).

Almost all of these types of surveys provide some insight into motivation and the perceived benefits that CBD users are claiming (and which are therefore

motivating how they use CBD and what they look for when shopping for CBD products), but in themselves they do not provide robust metrics. To provide reliable data, much larger (1000+) surveys, based on a weighted and representative sample of the population is needed. Fortunately, given the prevalence of CBD, and the increase in CBD coverage in print and online media, the general awareness of CBD is high, and now makes it possible to explore via standardised opinion polling of the UK adult population.

Experience using CBD

For this project, the Centre for Medicinal Cannabis commissioned YouGov⁶⁷ to survey public attitudes to CBD and medicinal cannabis in the United Kingdom. In a representative sample of 2,056 UK adults (aged 16+), conducted in June, the poll found that 11% had consumed a CBD product in the last year, against 81%

who had not. That is in line with the Cowen & Co. consumer survey reported in April 2019, of just under 7% of US adults. Recent use rates were higher in the under 55 age groups, ranging from 15% of 25-34 year olds, to 7% of 55-64 year olds and 8% of those aged 65+. Usage was also higher on average among females (13%) than males (9%), which supports similar findings in surveys underpinning this report's market sizing exercise.

In practice, this means that approximately 6 million adults have used CBD in the UK, and it can be assumed that a proportion of those are routine users, or at least, that the use was recent - a finding that the Dynata survey work also implies. Use was also higher among the lowest (DE) socio-economic group, and indicated elevated use in certain parts of the country, namely Wales and Northern Ireland.

Public support for regulation

The survey also sought to explore public attitudes to how CBD products are regulated and how they should be made available. After an explanation of what Novel Food rules require, and how CBD might be regulated, these questions revealed support for regulation of CBD products, but no clear consensus on how CBD should be made legally available for sale. Almost half (47%) of respondents agreed that CBD products should be removed from store shelves unless they have passed a Novel Food safety assessment. However, a fifth of respondents were unsure, and more than half (53%) of those who have used CBD products in the last year opposed such a move.

When asked how CBD should be made available, 17% supported having CBD only on prescription as a licenced medicine, and a third of respondents (34%) thought it should only be available over the counter in pharmacies, albeit without a doctor's prescription. A further 31% thought it should stay available as a food supplement sold in high street stores and supermarkets as now, and just 5% thought CBD should be banned from sale until we know more about it. This demonstrates a desire for some controls, but also a sizeable minority who want the status quo to continue, where access is convenient from a range of retailers. Compared to actual consumer behaviour and the strong bias towards online purchases identified in the market research (see Chapter 6), this contrasts with the preference of a third of survey respondents who wanted to limit CBD products to only being sold in licensed pharmacies.

Priorities when choosing a CBD product

The YouGov survey also explored the factors that were important to people when choosing a CBD product,

and found a strong preference for high quality products that were uncontaminated. Knowing that the CBD product was made by a supplier that met recognised high standards (32%) and knowing that the contents were not contaminated with pesticides or heavy metals (25%) were the most important priorities when choosing a CBD product - far ahead of knowing that a CBD product was 100% legal (14%), or from where in the world it originated (5%).

Respondents said that information on the product itself was a key influence, with people wanting clear labelling about contents, and how the CBD product was produced (26%). Consumption advice on how to consume or apply the CBD product was the second highest priority (15%), indicating a desire to be educated and guided in the use of cannabidiol. And a more important influence on a purchasing decision for CBD customers was local origin in the UK "from hemp grown in the British Isles" - rated as the third most important factor (11%), on a par with price (10%), and ahead of brand (7%) and whether or not a product had organic status (6%).

Attitudes to medical cannabis and reform

The survey also examined attitudes around medicinal cannabis, with a question asking whether respondents had asked their doctor about accessing cannabis medicines. In the last 6 months since it was legalised for medicinal use via prescription, 3% of all respondents - equating to approximately 1.5 million people - claim to have asked their doctor or healthcare provider about accessing cannabis medicines. Among those who had also consumed CBD products in the last year, the number was four times as great. This may indicate that these are the same people - seeking access while using CBD products in the meantime, or being familiar with CBD and thus more inclined to ask questions of their doctor about cannabis medicines.

In an attempt to tease out the relationships between users of CBD, and respondents who use cannabis, the poll also asked questions about use of cannabis in the past, and whether those questioned had used cannabis in the past year to alleviate symptoms of any kind. Overall, a third of the sample admitted to having consumed cannabis in the past. It was revealing that as many as a fifth of those who had used cannabis in the last year had done so for medicinal purposes, equating to nearly 4 million people in the general population who are self-medicating with cannabis outside of the law.

Those who had consumed cannabis to help alleviate symptoms of any kind were significantly more likely than the group as a whole to have used CBD products in the last year - almost six times more likely - and to have asked their doctor about accessing cannabis medicines.

Overall, 7% of the population have used cannabis for medicinal purposes in the past year, rising to 41% among those who have used CBD in the past year. And support for legalisation of cannabis increases from 47% among the total population to 75% among past year CBD users.

These results indicate that the anecdotal use of CBD by consumers to self-medicate is a strong likelihood and that a portion of CBD consumers are also people who use cannabis to alleviate symptoms. CBD users are more inclined to support cannabis legalisation, and when asked whether they thought the new medical cannabis system in the UK was working, twice as many people who had used CBD thought it was (30%), compared to all respondents (15%). This means those who believe that the system for legal access to medicinal cannabis is working are disproportionately people who use over-the-counter CBD products today too - possibly with respondents conflating the two scenarios (an over-the-counter purchase of CBD is outside of any medicinal cannabis prescription path).

This might suggest a consumer population that is exploring CBD as a health and wellbeing treatment and is not concerned by, or at least not convinced of the fact that the wider system for cannabis medicine prescribing is failing. We already know that rescheduling may not have resulted in many prescriptions since 1 November, but it has so far not prevented consumers from being able to freely access CBD as they have done for years, and may have served to further normalise cannabis as a legitimate medical option or at least raised awareness about its therapeutic potential.

Conclusions from the public survey polling

The survey shows us that public attitudes to cannabis and to CBD are complex, and contain two aspirations that might appear to be in tension. First, the widespread awareness of the product, and high prevalence of declared use, is combined with an understandable desire to see CBD go on being available - or even to be liberalised completely (in the case of cannabis) - but also a view that it should be regulated properly. However the survey showed that there is no consensus currently on how CBD should be regulated in the interests of patients and consumers.

The survey does appear to be in line with other reputable estimates of CBD use among comparable adult populations, which indicate a substantial number of CBD consumers in the last year as popularity has risen. It is therefore wrong to dismiss the CBD sector as a fixation of a small consumer base following a

fashionable trend that may be broad but shallow.

If taken at face value, these prevalence figures imply that the young and fast-growing CBD sector in the UK is already much larger than people assume, and larger than regulators have been prepared to acknowledge - a finding confirmed by the market sizing research. Given the high penetration levels for CBD products, any steps to restrict their availability would be politically challenging and potentially very unpopular with a large cohort of the population.

It is time that politicians and policy-makers approached the question of how to regulate CBD proportionately in the knowledge that the UK already has millions of regular CBD consumers, not a few tens of thousands.

Surveying CBD consumers

A similar poll conducted by Dynata for the market analysis work in the next chapter surveyed 1,010 consumers and showed remarkable alignment with the YouGov poll. An average 8% of respondents indicated using a CBD product in the last 12 months with a younger population indicating up to 12% usage falling to low single digits in the >50 year old category.

Consumers using CBD indicated that they were using it primarily for overall health and wellbeing (54%), sleep (54%), pain management (42%) and as an aid to relaxation and anxiety (38%). This trend for why a consumer may use a CBD product was mirrored in users who had not previously used a CBD product in that previous 12 months but would consider using one in the future.

For the 42% of consumers who had not used a CBD product in the last 12 months and indicated they would not consider using a CBD product in the future legal concerns (35%), lack of current regulation (33%) and stigma (19%) dominated their rationale.

What British users of CBD say about it

Polling of confirmed CBD users also contained a questionnaire, and respondents were able to volunteer their opinion about CBD. A small group (n.58) wrote comments, with many reflecting a similar theme - that CBD is effective for them, and should be made more widely available. However, cost was mentioned as a factor, and a general desire to see cannabis law reform, and to be confident that CBD use was lawful.

A selection of these comments reveal some powerful anecdotes that help to explain how CBD has become so popular in the UK so quickly:

I consume CBD in some form almost every day. I take a paste daily, and then vape additionally either cartridges or flowers.... As well as taking CBD for muscle tension associated with fibromyalgia, I also take CBD for depression and anxiety related to Autistic Spectrum Disorder. I find that it reduces my background levels of anxiety when I take it every day, and when I'm having a panic attack or becoming distressed, administering a dose by vapouriser will bring me out of that state very rapidly and allow me to get on with my life.

CBD has made a tremendous change in my health, I feel better now than I have done for the last 15 years when I first became ill. I take nearly 30 prescribed tablets each day and CBD has worked better than them all. It really is a miracle product & one which I could not now do without.

My health has changed dramatically for the better since using CBD but it's very expensive and I'm struggling to buy it.

I would like medical professionals to have more knowledge of CBD and it's uses.

CBD has given me my life back from an opioid hell.

A safe product from a reliable source is key [and] reduce the confusion in social media [and] have certified suppliers.

My life and mobility has been transformed with CBD oil.

Companies selling CBD should be able to talk about illnesses and be able to advise.

There are way too many products out there that users who don't do sufficient research are being duped into buying and then give up on CBD because they don't feel/see any benefits.... [T]he oils have such low CBD content, people might as well just be consuming plain olive oil.

I have found CBD to be as effective or more effective than pharmaceutical drugs. I don't get any side effects unlike the horrendous ones I get from prescribed meds. I think that reputable manufacturers should be allowed to give advice on dosage and conditions that CBD will aid.

I am currently recovering from spine surgery and have been in constant chronic nerve pain every day for the past year and a half. I have tried various pharmaceutical medications ..all of which had undesirable side effects. CBD is the only product I have taken that eases the pain dramatically and calms the nerve pain...which no medication has ever done. I do not wish to commit any crime nor be classed as a criminal for wanting to be pain free.

UK CBD user (June 2019)

6. The Market

Summary

- To date, estimates of the size and nature of the CBD market in the UK have not been comprehensive or robust. Without an accurate picture of how UK consumers are buying CBD, in what product categories, where and for what reason, it is difficult to devise effective policy and proportionate regulations.
- For this project, the CMC commissioned an independent market insight and research agency to conduct a bespoke piece of market sizing analysis for the CBD sector in the UK. The headlines of that research - published in this report - demonstrate how large and important the CBD market already is and that it is rapidly growing.
- The size of the UK CBD market is between 3-6 times larger than previous well quoted estimates (£300M per year vs £100M (Brightfield report⁶⁸) and 1.3 M users vs 250K users (CTA⁶⁹)) depending on which measure you take; value or users. This is larger than the total UK Vitamin D (£145M) and Vitamin C market (£119M) combined.
- The market is currently growing at double digits and expected to be just short of £1B in 2025. This would be equivalent to the entire UK herbal supplement market in 2016.
- Over 70% of UK consumers are purchasing tinctures/oils or capsules suggesting a desire to use products systemically and at higher "therapeutic doses" for CBD. In addition those users from the CBD user panel, with a presumed medically orientated usage, are spending on average 2-3 times a month more (£55 vs £25) than the general population, with a presumed wellbeing usage, on these formulations.
- The majority of UK consumers of CBD products are purchasing them online, and not in High Street stores, despite their wide availability in pharmacies, health food stores, and supermarkets.
- The research also reveals that UK consumers are currently paying high prices for CBD products, with buying habits driven by a range of motivations.
- A key conclusion of this analysis is that politicians and policy-makers must now approach the question of how to regulate CBD proportionately in the knowledge that the UK already has millions of regular CBD consumers, not a few tens of thousands.

Sizing the CBD market

A pivotal market sizing exercise to understand the current and future UK CBD market was conducted during May-June 2019. We believe this to be the largest and most credible report into the UK CBD market to-date. The CMC selected an independent, globally renowned market insight and forecasting consultancy; which used their experience and proprietary methodology in forecasting complex markets to provide robust data.

Due to the CMC's unique relationship with our UK

CBD supplier partners and patient advocacy groups we were able to use proprietary insight from leading UK CBD suppliers, as well as surveying over 250 confirmed CBD users and over 1000 members of the general population, to build out a deep understanding of the current and future UK CBD market trends.

From a methodology perspective we believe that the market sizing has been treated cautiously and conservatively. Unadjusted responses from the survey indicate ~8% of UK adults have used CBD products in the last 12 months. This ranges from ~12% in the 18-29 age group to 1% in respondents >70. The model

input for CBD penetration amongst adults removed respondents who did not use CBD products at least once a month (i.e. were not considered regular users) and additionally, a correction factor using vape use estimates from the survey (13.9%) & ONS (5.5%) were also applied. This led to a reduction in CBD penetration across age groups using a discount factor, with penetration totalling ~2.5% of UK adult population.

The estimate of 6 million UK users of CBD from the YouGov polling should be set alongside the separate survey conducted by Dynata (indicating 4 million who have used CBD) and the discounting applied to reach an estimate of regular CBD users. With the latter calculation, the analysis translates to approximately 1.32 million regular CBD users in the UK in 2019 - and this figure combined with average user spend per category and category segmentation is what underpins the estimates about the value of the market.

Headline results of the market analysis

The key headlines to take from the study are:

The size of the UK CBD market is between 3-6 times larger than previous well quoted estimates (£300M per year vs £100M (Brightfield report) and 1.3 M users vs 250K users (CTA)) depending on which measure you take; value or users. This is larger than the total UK Vitamin D (£145M) and Vitamin C market (£119M) combined.

The market is currently growing at double digits and expected to be just short of £1B in 2025. This would be equivalent to the entire UK herbal supplement market in 2016.

Unadjusted responses from a 1000 plus strong UK consumer panel (Dynata) indicated approximately 8% of respondents used a CBD product within the last 12 months. This is very similar to a similar study in 2500 people conducted by Cowen in the US which reported 7% of the population have used CBD and is in-line with the 11% of the population who indicated using CBD from a UK YouGov poll (see Chapter 5).

Over 70% of UK consumers are purchasing tinctures/oils or capsules suggesting a desire to use products systemically and at higher “therapeutic doses” for CBD. In addition those users from the CBD user panel, with a presumed medically orientated usage, are spending on average 2-3 times a month more (£55 vs £25) than the general population, on these formulations. Spend on other types of formulations-topicals, vape, consumables (bars, candy etc)-was fairly constant between both groups.

Of the CBD users questioned, significant numbers indicated that they purchased their CBD online and not in High Street stores, despite their wide availability in pharmacies, health food stores, and supermarkets. This maybe troubling as the online environment (compared to a reputable high street retailer) is more susceptible to less adherence to regulations and product sourcing and quality controls; however the products that were examined for this project that came from online retailers did not indicate this - at least in the testing the CMC conducted. Nonetheless, given the wide availability of CBD on the High Street, the preference to purchase online may reflect other factors, including the desire for discreet delivery, and possibly for certain consumers, some stigma associated with cannabis that might deter them from buying CBD products in person.

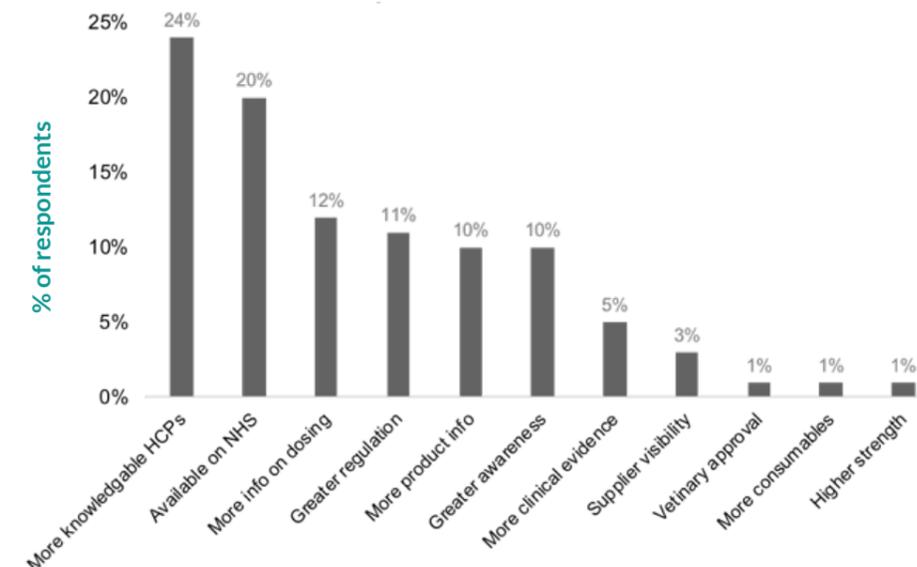
Established CBD users were asked what additional support or resources they would like to see as a consumer of CBD. Their responses are detailed on the following page. It is noteworthy that the top 4 responses provided to this question are indicating that consumers treat their CBD product and consumption seriously and look to have its health and wellbeing properties recognised in a manner to that in which a medicine is treated rather than a food supplement.

Conclusions of the market analysis

Overall this survey provides robust insight that the UK CBD market is flourishing and growing at pace. Unchecked it is predicted to be a near billion pound industry within six years.

With approximately 8% of the UK population claiming to have used CBD in the last 12 months and confirmed CBD users spending in excess of £50 per month on products the case for a pragmatic fit-for-purpose self-regulated environment is paramount to allow CBD users to access safe and quality assured products however they choose to buy them in the UK. In support of this 11% of regular CBD users indicated directly as a first preference that they would wish to see greater regulation as a value add to this sector. Other first preference responses indicate a greater wish for CBD to be treated more like a medicine than a food supplement.

Q: What additional support or services would you like to see, as a CBD consumer?



7. The Industry

Summary

- The CBD industry in the United Kingdom is one of the largest in Europe, but it is entirely built upon a raw ingredient produced elsewhere in Europe or further afield, not one harvested domestically.
- The complex global supply chain for CBD is scaling quickly. The industry in the UK is not building from the same agricultural foundation that other countries take for granted, and this undermines UK competitiveness in a key growth sector.
- The hemp industry is not financially viable in the UK long-term unless it can compete on a level playing field with other hemp producers. There was overwhelming support from three quarters of respondents to the YouGov survey when asked whether UK hemp farmers should have the freedom to process the flowers and leaves of hemp crops grown in the UK to supply CBD.
- The UK's strengths in pharmaceuticals means it is likely to play an important role in the development of pharma-grade CBD.
- The industry has an obligation to behave responsibly around how it uses and promotes CBD - otherwise there is a risk that negative associations will accrue to CBD and have a wider effect on public perceptions of cannabis and its potential as a therapeutic treatment.

Agricultural foundation of the CBD market

As an organic chemical contained in a plant, cannabidiol is produced at scale from an extraction process that relies on raw agricultural product. Farming and land use rules vary between markets, even in the European Union where common subsidy schemes exist and Single Market rules allow the free trade of agricultural products between countries. Globally, the largest areas for hemp cultivation are currently in China, and continental Europe, and also the United States.⁷⁰

The UK and Ireland permit the cultivation of Cannabis Sativa L (hemp) if done in accordance with local licensing rules, and so long as the hemp is an EU approved strain. EU certified means those hemp varieties authorized under the EU's Common Catalogue of Varieties of Agricultural Plant species (Reg. 1308/2013).⁷¹

Hemp cultivation in the UK

The hemp sector across continental Europe has recovered from its nadir in the early 1990s and recent strong growth has been partly driven by rising demand for extracted CBD. Meanwhile, UK hemp farmers are at a disadvantage, however, because the Home Office

still prohibits them from harvesting, extracting and trading the flowers and leaves – even from approved EU strains and even with a hemp cultivation licence – thus making the crop much less profitable, and denying Britain's domestic producers the ability to supply local demand for hemp-derived CBD products. When asked, the Home Office advises farmers with a hemp licence to destroy the material.

According to the British Hemp Association (BHA), this presents a complete barrier to farmers monetizing the most profitable part of the crop and all but eliminates the UK supply of CBD in the market. They estimate that currently 600-800 hectares of hemp are being grown in the UK by 11 holders of a Home Office low-THC hemp cultivation licence granted in the last year, compared to a total across Europe in 2017 of approximately 42,500 ha⁷² (which was a big increase over 33,300 ha in 2016⁷³).

This means in practice, the small number of UK hemp farmers must pay for a licence that does not permit them to plant hemp profitably, while watching UK consumers enjoying the CBD products on sale here that are derived from imported hemp from competitor EU farms. This disparity persists despite the Single Market, EU directives on agricultural production and shared subsidy schemes, standardised EU approved

hemp varieties, and EU countries all being party to the same UN conventions on controlled substances. The UK's exceptional restrictions have not been publicly justified by the Home Office, but they are not supported by the public.

In the same YouGov survey commissioned for this report, following an explanation of hemp, there was overwhelming support from three quarters of

respondents when asked whether UK hemp farmers should have the same freedom as European farmers to process the flowers and leaves of hemp crops grown in the UK to supply CBD. Fewer than 1 in 10 respondents disagreed with this. This finding gives support to the proposal that rules should be harmonised so British farmers can fully participate in an industry that is already supplying ingredients for products used by millions of UK consumers.

Hemp cultivation in Europe

In the latter half of the twentieth century, narcotic control laws in Europe and North America had serious consequences for the industrial hemp sector, which had been booming in Europe in the post-war period, and led to governments discouraging hemp cultivation or setting up onerous licencing regimes to supervise it. The consequences were a collapse in the cultivation of hemp from the late 1970s until the early 2010s. Latest data from the EIHA suggests a continent-wide revival is now underway with the hectareage expanding significantly between 2016-2017.

Under EU regulations (1307/2013), only specified varieties with a THC content not exceeding 0.2% may be planted. There are still licensing regimes at national level to determine which farmers can cultivate it, but the crop itself is eligible for subsidy payments under the current iteration of the Common Agricultural Policy. Hemp varieties with the low psychotropic content are also protected from foreign competition by EU regulations (1308/2013) that require imported hemp to be subject to the same conditions on THC limits.

In the UK, despite the prohibition of the cannabis plant, regulations allowed a carve out for the cultivation of low-THC industrial hemp, drawing a distinction between those parts of the plant that have industrial potential (for fibre, cloth, and building material), and the flowers and leaves, containing the vast majority of the plant's cannabinoids.

The stalk and seeds were legitimate commodities but only in the context of licenced production, where farmers complied with Home Office licence conditions and reported annually. However even this approach was narrow, permitting those farmers to be able to use only some of the plant, while expecting them to discard (what has now become) the most valuable parts. This applies even when the hemp in question abides by cultivation rules and belongs to an EU approved low-THC variety, and where the flowers and leaves contain only trace amounts of the controlled substance. The fortunes of the European hemp industry and its recent revival, due in part to the booming CBD market, are not being reflected in the UK.

Hemp around the world

The UK position is an outlier in Europe, and it is a legacy of regulations that have not been modernised in line with today's consumer market. However, the position regarding hemp is mirrored in other countries outside Europe too.⁷⁴ In Canada, agricultural and health food lobbies are urging the government to reclassify CBD as a food supplement rather than a prescription drug, so that Canadian hemp farmers can expand production to meet this consumer demand. Health Canada in response recently committed to a public consultation on the regulation of CBD, and in 2018 already updated the agricultural regulations to permit hemp farmers to sell the flowers and leaves (though only as

a supplier to licensed cannabis companies that can extract CBD).⁷⁵ Similar arguments are also underway in Australia, where CBD is a scheduled drug and hemp farmers cannot supply extracts to the therapeutic industry.

Similar rules applied until recently in the United States, but recent legislation has liberalised the law there to enable hemp farmers to fully utilise all parts of the plant – including the biomass that contains cannabinoids. The US market now permits CBD products that are derived from hemp (containing only trace levels of THC), because the 2018 Agriculture Improvement Act, signed into law in December 2018 by President Trump, de-scheduled hemp at the federal level, making it no longer

a controlled substance. However, this has not 'legalised' CBD products, because they fall under the Food & Drug Administration (FDA) and rules governing licensed drugs.⁷⁶ Federal regulators have yet to determine how they intend to authorise the licensing of CBD products, and the FDA has announced a public consultation on this, which commenced on 31 May 2019.⁷⁷

Removing hemp products containing CBD (but not THC or the cannabis plant itself) from threat of enforcement by the DEA and others has already provided a significant boost to US agriculture, given the value of the biomass for this burgeoning consumer CBD market. Major hemp producers in the United States are now planning for international expansion and for having hemp grown in the US specifically to be supplied for export.

Global supply issues

Currently many UK retailers source CBD products from brokers, who have several suppliers, and those suppliers may have several producers. CBD isolate is available in the UK that is derived from non-EU certified strains of hemp grown outside Europe – usually in China or North America. These products for sale in the UK that contain only pure CBD are deemed legal because of the status of the finished product, not because of their original source material.

Information on the flows of hemp exports around the world is limited. It is apparent that Chinese CBD extract is already a major source of global CBD supply, and likely to become more important in future.⁷⁸ Though not licensed to be grown in every province, the hemp industry in China is expanding rapidly, with farmers there able to grow at huge scale, with low production costs. And as hemp production in the US expands, the country will become a major global producer and exporter⁷⁹ and together with China, contribute to a long term reduction in the price of raw hemp extract.

American-based exporters of CBD extract to the UK (and Europe) must comply with US federal law to ensure that only hemp-derived (low-THC) cannabidiol is being shipped internationally. Conversely wholesalers in the UK must comply with domestic UK law that they are only importing CBD extracts that contain no controlled substances – and the plant strain itself is not a factor.

In reality, it is impractical to determine which CBD products in the UK are comprised of a European hemp extract, and which contain a non-European full spectrum extract derived from Chinese hemp, or a raw (high-THC) cannabis extract from Colorado that has

had the THC removed. This co-mingling of high and low THC cannabis source material in the general CBD supply chain in the UK is another issue arising from lack of regulation and good labelling standards, and is not easily addressed.

In the long term, full product traceability and supply chain inspection and audit requirements will be necessary to prove to governmental authorities that CBD products on sale in the UK wellness products are compliant – and this might entail not being derived from what Americans refer to as marijuana, which is probable (though not certain) to exceed current UK legal limits on THC content, for example. Whilst the UK must ensure that its own hemp farmers can participate in this market, the UK should also permit any legal CBD business to source from hemp suppliers beyond Europe too – especially in China or North America – but at the same time be held more accountable for the quality and purity or the final product by mandating traceability standards and accurate testing and product labelling.

Pharma-grade CBD

At present, the UK's CBD industry is comprised of mostly small to medium sized companies and recent start-ups that are sourcing, distributing and/or retailing branded CBD products from foreign suppliers and their hemp sources. These companies are almost entirely focused on the wellness sector, and most of them have neither the capability, financing nor desire to scale to become pharmaceutical companies.

However, there have been others entering the UK market who are aspiring to achieve a scale and quality of output consistent with recognised pharmaceutical players. The onset of a legal medicinal cannabis regime in 2018 has attracted major licensed producers from Canada, Australia, the Netherlands and the US, to the UK in the last 12 months. Many of these companies already meet GMP standards and produce standardised pharma-grade output. Even more recently, some of these players have struck supply deals for CBD-only products with major UK high street chains, suggesting this industry is working to meet the high UK demand with big volume supply agreements.⁸⁰

As the market expands, and product ranges diversify to meet consumer needs, the demand at the top end for quality, standardised cannabidiol that can meet pharmaceutical production standards will increase. In this arena, the UK itself might be well placed to compete. After all, the emergence of CBD in the United States in the early 2010s owes a lot to the pioneering work of the British pharmaceutical company - GW

Pharmaceuticals - and the early trials they funded that ultimately resulted in the FDA approval for Epidiolex.

With a well established life sciences sector and top-tier university research base, the UK already has one of the most profitable and innovative pharmaceutical sectors in Europe, alongside Germany and France. And the UK has been a European leader in the Active Pharmaceutical Ingredient (API) field, with research indicating strong growth for this sector out to 2020.⁸¹ Dominated by established pharmaceutical players, the market will expand to accommodate demand for API quality cannabinoids, including CBD.

The current medicinal route-to-market for CBD products in the UK will encompass clinical trials and drug development that could utilise CBD (synthetic or organic) APIs as a source material. In addition to domestic production by GW Pharmaceuticals⁸² in East Anglia for their two licensed drugs, BSPG Laboratories in Kent is licensed by the MHRA to sell an API cannabidiol product, sold in the UK via a specials product line called *PureCBD*.⁸³ They also distribute to other countries and supply both academic and commercial clinical trials. Under the new regulations for CBMPs, companies with the requisite specials manufacturing license will also be able to utilize cannabidiol in unlicensed medicines, for prescription by a specialist clinician.

The industry and the reputation of CBD

The emergence of cannabidiol presents opportunities for new applications, greater understanding, and a general normalisation of the cannabis plant as the organic source that contains some potentially beneficial components. The growth of consumer interest in CBD, reflected and amplified by growing media interest in CBD, has increased public discussion about cannabis and general familiarity with the topic. When accurately reported and properly marketed, new consumers can learn what CBD is, why it is different from THC, and where it comes from. All of this is a positive development and makes CBD a gateway to a wider discussion about how society accommodates and utilises an important species of plant, irrespective of differing views on the case for adult use legalisation. As Project CBD, an online research platform has stated – *“The fact that CBD is therapeutically potent as well as non-intoxicating, and easy to take as a CBD oil, makes it an appealing treatment option for those who are cautious about trying cannabis for the first time.”* This mature public debate about cannabis and its scientific properties and health benefits is put at risk if the CBD industry produces poor quality or unsafe products, misleads consumers, or makes outlandish

claims. Rhys Cohen, from the Lambert Initiative at the University of Sydney, has argued that the current practice to experiment with putting CBD in a wide range of consumable products is scientifically flawed, and commercially misguided:

“CBD is pretty much harmless, especially in low doses. But it also doesn't do anything in low doses, so consumers are paying more for an inert, flavorless ingredient, which is a rip off. [But] more importantly, it associates medical cannabis with nonsense marketing gimmicks and gives people the wrong impression - that CBD is a fad, that it's ineffective, and a bit of a joke.”

The same approach also might cause harm indirectly by creating a substitution effect for uninformed consumers who are seeking to self-medicate with low doses of CBD in wellness products that cannot be justified as an alternative to a licensed medicine:

“[P]eople might argue the placebo effect from 'wellness' products is better than nothing. But some people will substitute these for their real medicine, causing them harm. And when the placebo effect wears off (which it will) that person will say 'cannabis didn't work' ... [So] adding CBD to everything doesn't help anyone, and has the potential to hurt plenty of people, not to mention contributing to the disrepute of medical cannabis in general and the cannabis industry in particular.”⁸⁴

The course and development of the CBD market will have an impact on wider public perceptions of cannabis, and its medicinal efficacy. The challenge is to not allow the normalisation of the cannabis conversation that CBD invites, to be undermined down the road by the bad practices that do exist in the fast-growing and disruptive CBD market.

We therefore urgently need better self-regulation, and a focus on compliance, and good consumer practices, and it requires investment in advancing public understanding, and most importantly, the building of a robust CBD evidence-base. The resources (and ultimately the research investment) for which can only come from having a commercially successful and responsible CBD industry. In order to deliver that type of industry in the future, the key recommendations of this report boil down to three big asks of every player in this space.

8. The Test

Summary

- The first major third-party testing exercise to be undertaken of CBD products in the United Kingdom was commissioned for this report. In total, 30 oil products available in the UK (both on and offline) were selected for the blind testing exercise using PhytoVista - a reputable UK-based laboratory.
- The exercise was designed to verify the range of quality of those CBD products being sold today, and to determine where the areas of concern might be. Those areas were defined as: health and safety; consumer rights; and criminal law.
- The results - summarised in this report with further detail available in a forthcoming academic manuscript authored by Professor Saoirse O'Sullivan from Nottingham University - are highly revealing and provide a good overview of the true nature of the CBD products being sold in the UK.
- The results reveal a wide range in terms of quality, and some concerning poor practice in a minority of cases. The best products are very high quality and are good options for today's consumers, but a larger group of products present issues in one area or another.
- The biggest issues related to accuracy of labelling; the presence of controlled substances and some contaminants; and in one example from a high street pharmacy, the complete absence of any cannabinoids. Highlights:
 - Only 11/29 (38%) of the products were within 10% of the advertised CBD content and 11/29 products (38%) actually had less than 50% of the advertised CBD content. One product had 0% CBD.
 - Almost half (45%) of the selected products had measurable levels of THC (mean content 0.04%) or CBN (mean content 0.01%) and are thus technically illegal within the UK.
 - 1 sample had ZERO cannabinoid content - this was a High Street pharmacy product (30ml) retailing for £90.
 - 1 product had 3.8% ethanol (3.4% qualifies as an alcoholic beverage).
 - Dichloromethane was detectable in 7 products (3.8-13.1ppm) and cyclohexane was found in one product (27.9ppm). However, these percentages of solvents and heavy metals are still below the permitted daily dose levels in pharmaceutical products, although above food limit safety levels.
- The industry as a whole must use these results to understand the areas of weakness in producing a quality product that consumers can trust, and use the findings to justify additional steps they should take for their own production, or for reassurance across their supply chain, that some of these negative results are not reflected in their own products.
- The exercise also exposed regulatory gaps - with no rules that set basic standards for important supply chain activities like testing of cannabinoid products, so those laboratories (in the UK or elsewhere) that conduct these examinations all use different processes and testing methodologies, and they may not be to a standard that is reliable, or would satisfy UK authorities.

Cannabinoid Testing

Laboratory testing has become vital to the integrity and reputation of the CBD sector, most importantly, because many studies from other countries cast doubt over the quality of over the counter CBD products (see Annex).

Third-party testing of CBD products is now a common occurrence, and many companies conduct these tests as a valuable addition to their quality control processes and as an audit measure for use when shipping products across borders. Governments - including the UK - have also conducted their own tests in the past, and used the results to focus enforcement efforts in areas giving rise to the greatest concerns. The Home Office regards testing as a necessary element to ensure that cannabidiol products are fully compliant with the law, and these should take place by independent laboratories in the UK. They state:

It is the Home Office view that, to establish that the definition [of a product exempted from controlled drug bans] is met, testing e.g. a full spectrum analysis to the appropriate threshold by an independent and licensed UK company, and provision of comprehensive and independently verifiable

*information and research of an appropriately rigorous nature will be required.*⁸⁵

To further reassure consumers, some retailers post third-party (or implied third-party) test results for batches of their product to detail the composition. Many of the UK's CBD retailers use laboratory services associated with the US or European suppliers of the CBD extract they are sourcing. These published test results vary in quality, and the authors have reviewed many examples that are incomplete, out of date, or relate to a test batch sample of one product line - not the actual stock of the specific product being marketed. This makes it difficult for consumers to rely on test certificates or to know the accuracy of the results. This problem is compounded because the Home Office do not explain what would qualify as an "appropriate threshold" for accuracy of testing purposes.

The Market for Testing Services

There is a market in laboratory services aimed at the cannabis industry and little or no regulation of how those testing services operate. Because many of the CBD products for sale in the UK are either imported from overseas suppliers, or derive from raw CBD extract manufactured in foreign jurisdictions, they are usually (but not always) accompanied by test results for cannabinoid profile from non-UK laboratories.

The absence of a common agreed methodology for the consistent batch testing of cannabinoid products, combined with the lack of oversight and due diligence that foreign laboratories are subject to, creates risks in the supply chain. The onus on retailers to prove CBD content to their customers is driving demand for testing services, but in a market where quality is not assured, the incentive exists for unregulated laboratories to generate results that will minimise compliance concerns for their customers - especially those businesses trading across international borders.

CBD suppliers rely on test results to defend their trade if and when customs or border authorities stop their consignment, and they need to show the absence of controlled substances. As such, there are many examples of laboratory results that diverge on what level of accuracy is required to show an absence of, or only 'trace' concentrations of controlled substances.

The use of the acronym 'ND' for 'not-detected' is frequently used by US-based laboratories to demonstrate that a CBD oil does not contain THC, but this is, in itself, not a scientifically accepted test result that UK regulators would necessarily accept if a product raised suspicions. Below 'detectable' limits in practice can mean different things, and a product testing at 0.0% THC is not the same as 0.00% - such that depending on the potency and packaged volume, very different milligram totals for THC in a single 30, 50, or 100ml CBD oil extract. Mile High Labs has commented: "*Non-detectable can mean a wide range of THC levels depending on the testing method used... While other companies may tout 0% THC, their samples frequently do not test at 0% with a validated test method*".⁸⁶ What is important is the individual laboratory's limit of detection (LOD) and limit of quantification (LOQ) within their methods when determining the controlled drug content in CBD. It is only when a consumer or authority can examine these parameters can they determine how reliable a result is in determining "zero THC" content.

The CMC's testing exercise

Based on the increasing CBD consumption in the UK, and the knowledge that these products may be at best misleading and at worse, dangerous, the aim of the present study was to perform detailed analysis of commonly available over the counter CBD oil products on the UK market. For the first time in a study of this type, we profiled the full phytocannabinoid content of products, as well as other potential contaminants including heavy metals, and residual solvents for a fuller safety profile of these widely used products.

For this report the CMC commissioned the first major third-party testing exercise to be undertaken of CBD products in the United Kingdom. In total, 30 oil products available in the UK (both on and offline) were selected for the blind testing exercise using a reputable UK-based laboratory. In total 29 products were analysed. The exercise was designed to verify the range of quality of those CBD products being sold today, and to determine where the areas of concern might be. Those areas were defined as:

- health and safety;
- consumer rights;
- criminal law.

The results - summarised below (and with further detail available in a forthcoming academic manuscript authored by Professor Saoirse O'Sullivan from Nottingham University) - are highly revealing. See Appendix for details on the testing process.

Taken alongside the research on the size and shape of the market, the test results provide a good insight into the CBD sector, revealing for the first time the true nature of many CBD oil products being purchased in the UK.

Summary of test results

The results reveal a wide range in terms of quality, and some concerning poor practice in a minority of cases. The best products are very high quality and are good options for today's consumers, but a larger group of products present issues in one area or another.

Labelling/Product Information

- 4 samples had neither a Batch Identifier or Use/Sell by date
- 7 samples advertised extraction method (CO₂) inconsistent with solvent analysis
- Inconsistent and confusing product information
- Various terminology to imply absence of illegal content on some but not all

Cannabinoid Content

Potency

- 8 samples had significantly less cannabinoid content than advertised
 - 7 samples under 50%, 5 under 20%
- 1 sample had ZERO cannabinoid content - this was a High Street pharmacy product (30ml) retailing for £90.
- 8 samples had significantly more cannabinoid content than advertised
 - Between 25% and 60%

Controlled Cannabinoids

- 13 samples contained no detectable THC/THCa or CBN
- 15 samples contain traces of THC/THCa, ranging from <0.1% to 0.24%
- 7 samples contain traces of CBN, ranging from 0.1% to 0.8%
- No sample contained more than 0.3% controlled cannabinoids
- 7 products marketed as "THC free" - small detectable amounts detected in 2 products

Residual Solvents

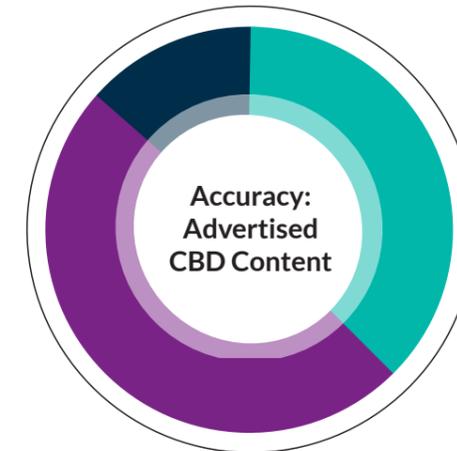
- 1 product had 3.8% ethanol (3.4% qualifies as an alcoholic beverage)
- 11 samples contain levels of solvents exceeding food regulations
 - All within acceptable levels in Pharmaceuticals
 - Based on Max Daily dosage does NOT constitute a risk to public health
- 7 samples contain disallowed solvent at higher levels than acceptable
 - Allowed for extraction of Coffee 2ppm and Tea 5ppm only
 - Based on the permitted daily exposure and the likely amount of CBD product being consumed the amounts detected does NOT constitute a risk to public health

Heavy Metals

- Only minor traces - below safe limits so nothing of concern revealed.

Only 11/29 (38%) of the products were within 10% of the advertised CBD content and 11/29 products (38%) actually had less than 50% of the advertised

CBD content. One product had 0% CBD. The mean advertised CBD content was 4.5% and the actual mean measured CBD content of product was 3.2% (P=0.0534, Student's t-test). However, the % deviation from advertised CBD content was improved if all CBD compounds (i.e. CBDA, CBDV and CBDVA) were included, and the mean % CBD content (of all CBD compounds) increased to 3.8%. These findings in UK CBD products are in keeping with published studies from other countries.



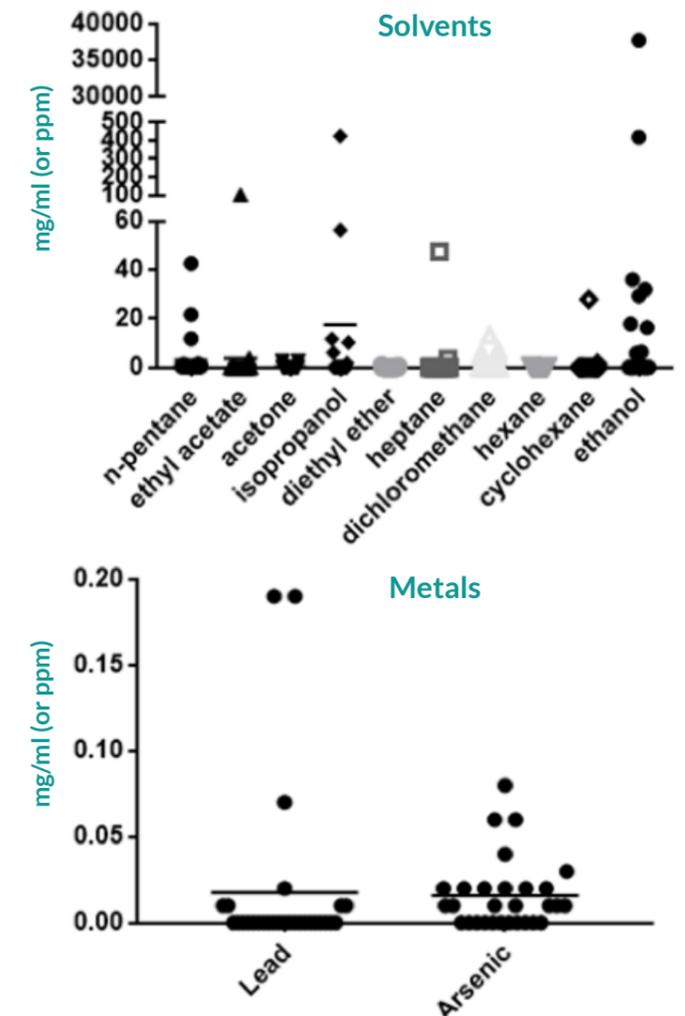
- Within 10%
- Less than advertised
- More than advertised



- No THC / CBN
- Contains THC / CBN

Almost half (45%) of the selected products had measurable levels of THC (mean content 0.04%) or CBN (mean content 0.01%) and are thus technically illegal within the UK. The range of THC content was 0-0.22% and the range of CBN content was 0-0.08%. In fact, 10% of the total cannabinoid content of products was other phytocannabinoids and CBD was 90%. The average ratio of CBD:other phytocannabinoids was 15:1 (range 0-114:1). Of these phytocannabinoids, the highest contents were of CBG (0.05%) and CBC (0.04%).

Our analysis included for the first time the range of solvents and heavy metals measured in UK CBD products. 3/29 products had levels of n-pentane above 1.5ppm (11.7, 21.7 and 42.7 ppm). 1 product had 37704ppm of ethanol, and 1 product had an ethyl acetate level of 103.8 ppm. Isopropanol levels of 56.4 and 424.3ppm were found in 2 products and heptane (47.5ppm) was found in another. Dichloromethane was detectable in 7 products (3.8-13.1ppm) and cyclohexane was found in one product (27.9ppm). However, these percentages of solvents and heavy metals are still below the permitted daily dose levels in pharmaceutical products, although above food limit safety levels.



Dichloromethane (DCM) is the worst of the solvents detected in the CBD samples, but if we consider one product with worst solvent profile, if you consumed the full 10ml with a dose of 300mg of CBD, you would be consuming 0.13mg of dichloromethane. The permitted daily exposure is 6mg per the EMEA's guidance so they would be 45 fold lower than this dose. You would need to consume approx 500 ml daily (at a total daily dose of 15 grams of CBD) to be consuming above the 6mg daily DCM threshold.

Conclusions from testing

The results reveal a wide range in terms of quality, and some concerning poor practice in a minority of cases. The best products are very high quality and are good options for today's consumers, but a larger group of products present issues in one area or another. The biggest issues related to accuracy of labelling; the presence of controlled substances and some contaminants; and in one example from a high street pharmacy, the complete absence of any cannabinoids. The industry as a whole must use these results to understand the areas of weakness in producing a quality product that consumers can trust, and use the findings to justify additional steps they should take for their own production, or for reassurance across their supply chain, that some of these negative results are not reflected in their own products.

Issues arising from the sampled products

Under food law it is a requirement for sellers to have either a batch identifier or a best before date on the label or container, ideally both. We found that there were 4 of the 29 products that had neither. This would be an issue, both in terms of regulatory compliance, but also to the producer should there ever be a need to issue a product recall, as all products, rather than just the ones with a particular date/batch number would have to be recalled, which would be very costly and likely to damage reputation.

We noted that there are a wide range of different ways that sellers advertise their contents. CBD, for instance might mean, just CBD, or it may mean a combination of CBD, CBDa, CBDv, CBDVa. Sometimes, only a "total cannabinoids" total is given. Content can be presented in "per drop", "per dose", "per ml" or even "per bottle". Lack of clarity and consistency here will be confusing to the customer.

We had half of the 29 samples tested at 2 validation labs, which confirmed that the findings for the worst product results in terms of cannabinoid testing are correct, however some of the figures, especially relating

to the levels of minor cannabinoids show significant differences from each lab which highlights the fact that there are no current UK/EU or global testing standards for cannabinoids that all labs can follow.

Policy implications of testing cannabinoid products

Three main policy implications arise from the testing exercise itself.

- The small number of UK-based laboratories capable of testing CBD products needs to expand if a competitive and high-quality service offering is going to be available as the industry grows. Ideally the testing infrastructure should be separate from the industry itself and fully independent, and there is scope for academic institutions - including universities with strong plant science departments - to develop this area of expertise to commercially benefit from the rising demand for domestic testing options.
- The lack of harmonisation for testing methodologies and best practice in the analysis of cannabinoids specifically is a barrier to regulators having the required confidence in product quality, even when tests results are produced. Foreign laboratories without full documentation of their methods and outputs may not inspire the level of confidence that suppliers in the UK will rely upon when demonstrating their compliance to UK authorities.
- There is no industry accepted standard for the presentation of test results on company websites or product labels and no consensus on how the results themselves should be depicted, e.g. using what metrics and language. The consumer could be confused and misled if CBD companies - even when not using the same testing facilities - produce results which are not standardized, and hard to interpret. It would be in the long-term interests of the industry and the consumer to agree how results should be presented, and this might form part of future regulations specific to OTC cannabinoid food supplements.

9. The Future

Summary

- The analysis for this report suggests the prospects for the UK's CBD market are strong, with rising demand and a willingness among British consumers to try CBD products and spend significant sums on a regular wellness routine that encompasses CBD.
- There are a number of future trends for the CBD sector in the UK and globally, and some fundamental market developments that the British CBD sector can expect to encounter in the next three years.
- Among the most important will be increased product diversification and greater competition and imports into the UK, along with the issues around provenance and traceability.
- The frontier of synthetic cannabinoids remains a major known unknown, but it could be highly disruptive for today's CBD industry that is dependent on extracting organic cannabinoids.
- In respect of how regulations might evolve, many jurisdictions are reviewing their laws and several have updated them. Other comparable jurisdictions around the world - including New Zealand, South Africa and the Channel Islands - have recently adopted new approaches to CBD and their examples provide inspiration for how the UK might modernise its own regulations.
- Recent developments hint at a possible evolution towards three related, but distinct, sectors for cannabidiol - all utilising CBD in different ways and serving different goals, and also potentially under revised (or entirely new) regulatory regimes.

Future trends

In a sector as innovative and fast-moving as legal cannabis, it is difficult to accurately predict what the future holds. This is especially true of the consumer sector because it is impacted significantly by the global nature of supply as more jurisdictions liberalise (and harmonise) their laws and regulations, and also because how CBD will evolve is also dependent on how governments choose to regulate in future, and those frameworks remain in flux, particularly in the United States and in parts of Europe and Asia.

With all those caveats, it is possible to identify three major trends that will likely define the future of CBD in the United Kingdom, and each of them lends weight to the challenges for the British CBD sector that we identify in Chapter 10. Those key future trends are:

- Product diversification and rising competition through imports;
- Growing emphasis on traceability and provenance;
- The new arena of synthetics.

Product diversification and rising competition through imports

Competition will increase in the UK CBD market as companies position themselves to tap into the rising consumer demand. The arrival of North American brands and the product innovations that may come to the UK in 2020 and beyond will provide a range of unfamiliar options for UK consumers. New categories and product offerings - from edibles, topicals and beverages - will help introduce even more people to CBD.

Indications from the US market suggest that certain categories of consumer may be open to introducing CBD into their daily routine via non-alcoholic beverages⁸⁷, and some CBD businesses like Kanaco in the UK are already actively pursuing this strategy.⁸⁸ The popularity of CBD consumables will be tested in a fully legalised market once Canada permits the sale of edible cannabis products in October 2019. Canada, and likely many other countries that follow them, will prohibit the sale of mixed food or drink products that contain both alcohol and cannabinoids (CBD or in legal jurisdictions, THC), and will strictly regulate product ingredients to cap THC potency and limit marketing.⁸⁹

The consumer trends will be set in North America, where legal access to the full range of cannabinoid products is possible, however the UK market will be a strategic target for large multinational CBD operators who will seek to exploit the under-regulated sector and the breadth and depth of British consumer demand for CBD - as demonstrated in this report. This will fuel a price war between producers and will lead to cheaper products coming to market. In such a race, existing British CBD companies will need to become more competitive and to distinguish themselves on more than just price.

If nothing changes to permit domestic cultivation of hemp for CBD, then British CBD companies will struggle to define a distinctive, locally authentic proposition that will be able to compete with the volume of imported products and the capacity of large overseas producers to supply CBD extracts at lower prices. The mass industrialised production of CBD is now underway in the United States.⁹⁰

A market that is already reliant on imported hemp will not generate value across the whole supply chain in the UK unless British farmers are also able to compete, and the growth of imported products from North America and the downward pressure on prices will also further risk a deterioration of the quality that British consumers deserve, unless there is concerted efforts by the best in the industry to impose standards of self-regulation (see Chapter 11).

Growing emphasis on traceability and provenance

As the CBD supply chain scales and becomes complex and diversified across multiple jurisdictions, the traceability of the product will be increasingly important - the seed to sale proposition. In the legalised consumer and medical markets in North America, blockchain technology is now being adopted by major chains to give themselves supply chain traceability and product quality assurances for their consumers.⁹¹

In addition, it is not known how much value CBD producers place on provenance, and knowing where the CBD they are consuming came from and where that hemp was grown. Based on similar sectors - notably alcohol - the consumer buying CBD products is likely to be favourable to brands that demonstrate a local presence and can describe their sourcing.

CBD companies already market according to features they believe their customers place a premium on - be that an extract from hemp that is grown organically, or as a gluten-free product - and these features of the retail CBD product are likely to become more important.

If future data on consumer habits suggest CBD users do place a premium on locally-sourced, organically grown extracts, there is an obvious benefit for UK farmers moving into this sector, and it will further justify moves to harmonise the rules across Europe so UK farmers can participate fully in the industry. It would also create a natural marketing advantage for CBD that is produced in the British Isles, and benefits from that provenance premium, even if the mass consumer market for CBD remains reliant on foreign sources.

The new arena of synthetics

Chemically synthesised cannabidiol is also a possible source of CBD within the UK consumer market, although presently we are not aware of it being used in any products currently available to consumers in the UK. This is primarily because synthetic CBD has always required approval as a novel food (it was specifically listed in the EU Novel Foods list prior to January 2019 due to it being chemically synthesised) and no manufacturer has achieved this. The relatively few companies that are producing synthetic CBD have been focused on pharmaceutical quality GMP grade CBD, which in turn has made it more expensive to acquire than plant extracted product.

Because synthetic CBD is produced chemically it is completely free from THC; making it a suitable choice for manufacturers wishing to avoid any conflict with the HO MDR scheduling issues and also consumers wishing to avoid THC due to conflict with religion, WADA, drug-driving and work-place drug testing. Synthetic CBD typically has a purity of >99.5%. It is bio and structurally identical to plant derived CBD. Unlike hemp CBD it is odourless, tasteless and its crystal form can be more easily controlled making it easier to formulate. If a manufacturer does achieve approval for use as a novel food then the UK market can expect to see more usage of synthetic CBD in its consumer products.

Future of regulations

Pressure to define a special regulatory path for CBD serving distinct markets

Consultation with regulators for this project reinforced the clear distinction in law (and in their view of their respective roles), that if (or as) CBD is a medicine, it cannot be a food, and if (or as) it is a food, it cannot also be a medicine. But this traditional distinction - providing two separate regulatory channels that do not overlap - and which governs how dietary supplements and medicines are defined and regulated in the UK, may not be sustainable for cannabinoids like CBD.

The categorisation ignores the extent to which consumption of over-the-counter CBD products is at least in part being driven by a trend towards self-medication and the pursuit of general wellbeing. Quality is therefore a critical parameter, as is dosing, and daily intake. As research advances into the proven medical benefits of CBD, the market demand for pharmaceutical grade isolated cannabidiol will increase. Even the spread of clinical trials underway across Europe will generate demand for sources of CBD from producers with a reliable supply of API quality product.

This premium product will be produced to pharmaceutical standards, in registered and licenced facilities, operating and certified as GMP compliant. Whatever the origins, this CBD will be pure and standardised, and thus be suitable for observational or full clinical trials in the UK, and as an ingredient in new formulations being devised by companies pursuing a marketing authorisation from the MHRA. The best API-quality CBD (distinct from a broad spectrum extract) may even become a chosen ingredient in premium CBD wellness products, cosmetics and other consumables, depending on what consumers are willing to pay for.

It is unclear how the market below this top tier will develop in the future, but there is a wide diversity of product quality and likely applications between raw hemp extract as it is produced today, and the more industrialised output from larger facilities that are able to produce purified distillates. Some major producers in this space in North America have already sought to target the whole vista of CBD opportunity - from pharmaceutical grade CBD isolate, to water-soluble distillate, to broad spectrum extracts.

In 2019, the governments of both the United States and Canada have undertaken to consult on a separate regulatory pathway for CBD (or cannabinoid nutraceuticals), in recognition of this market development.⁹² No commitments have been made about the intended outcome, but such a process might mean regulators there devising a proportionate channel that CBD suppliers can go down that is distinct from medicine, but more closely controlled than generic rules governing dietary supplements.

Such a process - initiated in the USA by the Food & Drug Administration (FDA) on 31 May - would also set concentration and dosage/packaging limits that could form the basis of a regulatory boundary between CBD as food (as now in the UK), and CBD as medicine. The UK faces the same essential predicament, and like the US (but unlike Canada), has already been overtaken by a large grey market in CBD products, so the argument for exploring the same pathway may become stronger.

Even if a distinct regulatory pathway between food and medicines is not conceived or adopted in the US or elsewhere, the consultation might yield greater clarity for consumers to guide their CBD use and indicate - using the latest scientific evidence - what types of product and what frequency of consumption is safe and efficacious.

Two parameters are relevant in this regard - permitted strength of CBD extract in food supplements, and a recommended maximum daily intake. The former might be established as a mandatory cap for producers in new regulations, and the latter might form the basis of new labelling requirements and stricter limits on OTC sales.

Consultation with the EIHA suggests that the following might prove a useful proposed threshold for determining CBD consumption, based on a capped strength of 5% and daily intake of 160mg per day/adult. The rationale being that clinical trials use CBD isolate at far higher amounts - at least 200mg per day/adult and often much more (because there have not been properly documented evidence of medical effects below this level):

Daily dose	Proposed use
Over 200mg	As an active ingredient in medicinal products - with or without prescription
Between 20-160mg	Available OTC as a food supplement; but capped strength and standardised CBD content
Less than 20mg	Allowed in food products of all types without restriction

Other promising regulatory approaches

Many developed countries have a legal and regulatory framework for cannabis - and by extension CBD - that has not been modernised for many years or even decades. In some countries like Denmark and Australia, CBD is a scheduled drug that is only available as a prescription drug.

As the global cannabis reform movement advances, the consumer demand and industry pressure has now driven some countries towards updating their laws to adapt to current circumstances. Even in jurisdictions

where cannabis for non-medical purposes remains a prohibited drug, new rules have been devised to liberalise the CBD market in the non-medicines domain.

Canada: Passage of the Cannabis Act (Bill C-45) in 2018 and the introduction of a legal, regulated adult use market for non-medical cannabis put the production, distribution and sale of cannabinoids under a single legal framework, overseen by Health Canada.⁹³ Cannabidiol remains a scheduled drug that cannot be sold as a food supplement, however it can be prescribed by clinicians, and many recreational cannabis products contain it in raw or extracted form. Canadian hemp farmers can now utilise the whole plant to supply CBD biomass or extract to other licensed producers (they were previously barred from doing so), and a Health Canada consultation is forthcoming on how the government might regulate CBD as a non-medical health food product or supplement. By Q4 2019, regulations permitting the sale of edibles will open up the market for those 100+ Canadian Licensed Producers who have a sales license to sell CBD-only products as an ingredient in beverages and other foods, subject to strict labelling, marketing and sourcing controls.

Switzerland: This European state has its own laws governing cannabis production, distribution and retail, with a separate regulatory regime that departs from the EU-wide rules on cultivation and THC limits.⁹⁴ Because Switzerland is outside the European Union (and also not part of the European Economic Area), it sets its own standards and need not follow E.U. rules on certified hemp strains, or all consumer directives governing the Single Market and customs union. Swiss Law also permits the sale and consumption of herbal cannabis up to a limit of 1% THC. This has allowed a market in low-THC, high CBD products to develop, including smokeable flower as a tobacco substitute⁹⁵, but there are regulations governing retail and limiting export. A process mirroring the EFSA's Novel Food regime applies in Switzerland.

South Africa: In May 2019, the government announced an updated regime governing the scheduling of cannabis, and created carve outs for the CBD sector, subject to certain conditions.⁹⁶ The country's Health Products Authority recommendations were accepted, allowing certain preparations of CBD to be placed outside the prescription-only medical system. Setting a maximum daily dose of 20 milligrams of CBD to qualify, the new regulations for a CBD product also mean cannabidiol is moved from the Schedule 7 designation to the less restricted Schedule 4, and qualifying products can be sold without prescription. Other permitted CBD products now include those that "consist of processed products made from cannabis raw plant material and processed products, where only the naturally occurring quality of cannabinoids found in the source material are contained in the product, and which contain not more than 0.001% of THC..." Such products

are allowed to have an "accepted low risk" claim or health claim, which only refers to health maintenance or general health enhancement or relief of minor symptoms that are unrelated to a disease or disorder, and without specific disease references. Because the rules permit a limited degree of health claims, it is a departure from other jurisdictions and a recognition of the therapeutic benefits that users are claiming to receive (and which motivates their product choices). There remain no standardised regulations in South Africa around the retail, labelling or advertising of cannabidiol products.⁹⁷

New Zealand: In addition to updating their laws regarding controlled substances, the New Zealand Government has committed to a referendum in 2020 on whether to create a regulated adult-use recreational market for cannabis.⁹⁸ The Labour Government has also taken steps to promote the development of a hemp industry in New Zealand with a streamlined licensing scheme⁹⁹, which generally allows cultivation of varieties containing up to 0.35% THC and also research and breeding licensing for non-approved varieties. New Zealand also has a proactive and dedicated industry association for hemp¹⁰⁰, promoting its utility as a valuable product for environmentally friendly construction, and as a plastic alternative in consumables and packaging, as well as for food.

Jersey & Guernsey: The Channel Islands, part of the British Isles but a separate jurisdiction that is governed independently and not part of the United Kingdom, have both updated their legal framework for cannabis. Being outside the E.U., the Channel Islands are not required to plant only certified hemp strains, and may choose to diverge in future. Both Jersey and Guernsey are also not required to abide by the Novel Food classification for CBD sales. In Jersey, the new regulations for THC announced in April 2019 are tied to ratios, and require that derivatives of cannabino (CBN) must not exceed 3% of the total cannabidiol (CBD) concentration. Derivatives of CBN include THC (delta 6, 8 and 9), THCa and CBN and the total sum must not exceed 3% of the final CBD concentration. This ministerial decision followed advice from experts that "concluded that it would be reasonable and proportionate to permit small amounts of THC and other cannabinoids to be present in CBD products sold as food supplements".¹⁰¹ As local producer Jersey Hemp advised the authors: "For example, if you have an extract with a 50% CBD content you would be allowed 1.5% CBN derivatives in the mix. This is solely from an end-product point of view and is not reciprocated for the cultivation or the possession of flowers which remain controlled parts of the plant.... This structure is beneficial from our perspective.... This product would only be available for distribution within the Islands but will allow for the much freer handling of cannabis extracts as well as the ability to further process products for the UK food industry which currently has no domestic supply."

10. The Challenge

Summary

- The growth and success of CBD in the United Kingdom depends upon overcoming key challenges in the years ahead. These challenges are similar in many jurisdictions and all require open dialogue between government, regulators, the industry, the healthcare profession, and consumers, in order to reach the right outcomes.
- The main market challenges are: improving the education of consumers; defining a proportionate regulatory pathway; rooting out bad practice; creating an infrastructure to support a quality standard; maintaining incentives to invest in clinical trials; and taking the necessary steps to level the playing field in support of UK producers.
- Some of these challenges can only be addressed by government, and others should only be addressed by industry taking a lead. The consumer will influence how the CBD sector evolves, but the public cannot, by their consumer habits alone, change the trajectory of this industry - that requires government action.
- The course and development of the CBD market will have an impact on wider public perceptions of cannabis, and its medicinal efficacy. The challenge is to not allow the normalisation of the cannabis conversation that CBD invites, to be undermined down the road by the bad players that do exist in the fast-growing and disruptive CBD market.
- Addressing poor practice and promoting CBD products responsibly will require proper self-regulation and a focus on compliance and public education efforts. Credibility will come from advancing the evidence-base.

Key Market Challenges

Education of consumers

Myths and misinformation combined with misleading marketing pose immediate challenges to consumers, and disadvantage the industry in the long-term by giving an unfair advantage to poor quality producers, and leaving consumers unclear on what products are legal, safe and good quality.

In the United States, where there is a longer history of cannabis liberalisation, and where the medical and wellness advice sector is less constrained by the type of marketing restrictions common in the UK, there are a range of online sources of education. One of the most popular websites is dedicated to CBD and provides a reference guide, factsheets and FAQs for a host of common questions that CBD users ask, and is geared at educating novice consumers.¹⁰²

In the UK, there is still a need for more good quality online resources from trusted sources for consumers

to research cannabidiol, to understand the science, and to explore the range of CBD applications and possible therapeutic benefits. The best current resource is provided by the United Patients Alliance (UPA).¹⁰³ Whether online, or in-store, retail staff and webchat services cannot legally provide medical advice about CBD products (which are not classed as medicines), and the content that is available is produced by private CBD companies, with content written to appeal to users and to attract new customers, without making medical claims. This leaves curious CBD consumers in the UK who are seeking to be educated about cannabidiol uninformed, and adrift.

One UK retailer¹⁰⁴ that serves customers domestically and internationally says: "For a complete and up to date account of the legal status of CBD in your locality, we recommend you consult the local or central government websites of your country."

Unfortunately, consumers seeking to follow this (reasonable) advice, would struggle to do that in the UK. Basic education of the consumer has to start with a clear,

single statement of the UK Government's position on the lawfulness of CBD products, and that does not exist.

In other consumer sectors, markets function best when there is a range of reliable, impartial information about the products available and their quality and value for money. The UK has a competitive price comparison marketplace for a wide range of consumer goods and services. As CBD becomes a mainstay of the wellness sector, it is likely that consumers will expect a similar offering that allows them to compare CBD products. These websites exist in North America, and one is even a UK company,¹⁰⁵ but they often serve as retail gateways that monetise traffic and click-throughs to CBD retailers, rather than non-profit information sources designed only to educate and guide consumers.

Both trade associations and regulators between them have a duty to keep the consumers in their respective markets informed and to challenge myths and misinformation, to enable better buying decisions. This by itself will exert grassroots pressure on the CBD industry to stay competitive, and level-up across a range of price, quality and provenance factors. It should be possible for UK consumers to compare a range of classes of CBD products in one place, according to content, country of origin, price, milligrams of active CBD, organic-certification status, etc., and currently no such initiative exists.

An impartial and independent source of information for consumers is a role that a regulator like the FSA can and should take up. However, this should be augmented by private sector initiatives which could provide greater reach (especially when linked to the evidence base and not about promoting certain brands or products or monetising web traffic). This is another key role for the kind of responsible industry group or trade association that we discuss in Chapter 11 & 12.

Defining a proportionate regulatory pathway for the UK

The biggest challenge for the market in terms of regulations is Novel Foods, and only the UK's government and regulators can lead here - with Brexit a window of opportunity to diverge.

The UK's Food Safety Agency has committed to applying EU Novel Food in a 'proportionate' way, but has not yet set out what this means. It is not clear from precedent what 'margin of appreciation' applies for a country like the UK to adapt how novel foods are regulated domestically, beyond defining a set of priorities for food safety enforcement.

If the regulatory pathway itself is unsatisfactory - and many stakeholders believe the new Novel Food

definition presents serious problems - it may be subject to legal challenge and could be amended or overturned by future committee decisions. In any event, even if it goes unchanged, it may be impractical to implement without a level of enforcement that UK authorities seem unwilling to adopt. This context is not the same across the E.U. where some countries do not have a large and growing CBD consumer market to anything like the scale of the UK.

If the approach of regulating all cannabinoids (including CBD) as a Novel Food through the EFSA process is unrealistic, and enforcement against suppliers and retailers who ignore this stipulation is impractical, then the UK Government has two options, whether or not the country remains a member of the European Union. Either it must provide a credible and proportionate regulatory pathway, backed by changes to domestic law and regulations (see Chapter 11), or it would need to secure consensus among other Member States to amend the Novel Food list. Given that the latter approach is highly uncertain politically, it may be preferable for UK Government departments - if and when Brexit takes effect - to plan to diverge from the EU process after 2019.

Policy-makers in the Department for Health and Social Care (DHSC) and the FSA should consider a distinctive approach that works for the UK, separate from the general Novel Food regulations, and consider the relative merits. In devising such a framework for cannabinoid nutraceuticals, the UK would be following Canada, and the USA, in acknowledging the complexity of this issue, and defining their own standards and approval pathways.

Even if there is no political appetite to broach wider questions around adult-use of cannabis products for non-medical purposes, and no desire to replicate the more liberal Swiss framework that permits consumer products with up to 1% THC content, the UK should nonetheless devise regulations on food safety, medicines, and nutraceuticals that provide space for a responsible CBD market to develop, and in addition, to create competitive advantage in this new and fast-growing industry.

A special approach is justified for this new consumer trend because of the major overlaps with drugs prohibition and medicines law, and is necessary if the government wants to devise a regulatory framework that is future-proofed. If such a challenge was taken on, it would require full engagement from industry and the public and could lead to a UK system that better served consumers, whilst not stifling an important new industry and maintaining the high bar set for licensed drug approval. A distinctive regulatory regime for CBD

could take inspiration from the sovereign regime that Switzerland has had in place for many decades relating to cannabis (being not an EU member, or a party to the EEA Treaty).¹⁰⁶

Rooting out bad practice

Enforcement is necessary to help raise standards and discourage poor practice but regulators with limited resources need to decide what practices they will prioritise for sanction, and where enforcement needs to focus.

Any national regulator has only finite resources and relies on partnerships at a local level with councils and the police to pursue infractions, consistent with the threat they pose to public health. Trading Standards officers are also reliant on public feedback to gather intelligence from whistleblowers and the consumer about products or retailers that warrant concern. Because public understanding is low, and confusion around CBD regulations is not uncommon, regulators can struggle to determine where bad practice exists, and what issues present the biggest concerns.

To decide what warrants their attention, regulators like the FSA have consulted on enforcement priorities in the past. In setting out what a proportionate regulatory posture looks like, the FSA and MHRA could do the same exercise for the CBD sector. This would set out a clear hierarchy where health claims marketing was considered a serious offence, and selling products containing heavy metals and pesticides, was a much higher priority given the risk that poses to human health. Equally, Home Office enforcement might prioritise importers of unregistered strains of North American hemp flower that lack a testing certificate from a registered facility.

The overriding goal is to distinguish between a risk to the public that needs immediate sanction, and a less serious breach of consumer protection law, which warrants notification and guidance to rectify. The latter category includes inaccurate labelling, which may be a widespread problem, but is not one confined to CBD products, and can be addressed through guidance.

Ultimately, the challenge of bad practice can only be overcome if the UK authorities are also supported by consumers raising their concerns and reporting questionable practice, and by industry itself choosing voluntarily to set high standards and asking companies to meet them.

An infrastructure to support quality products

Without a domestic infrastructure to support an accreditation and assurance scheme for quality CBD producers, the efforts by the industry at self-regulation will not be sufficient to satisfy the government.

Two key elements are required. First is a UK-based network of experienced, high-quality testing facilities meeting the required laboratory standards and able to do routine batch testing for high volumes of consumer products. Capacity must be expanded while also ensuring that quality is guaranteed and standardised results are produced. This will enable UK CBD companies to have assurance from a local laboratory, providing confidence to regulators and retailers, and ultimately to the end consumer.

The complex supply chain that brings CBD products to the UK consumer has a critical gap in respect of testing. For quality control and consumer confidence, CBD companies have coalesced around the need for regular testing of their source material and/or the finished product. Those companies that still sell CBD in the UK with no reference to any testing of the product itself would now be questionable. Some companies have made the purity and integrity of their ingredients central to their marketing, and promote their own test results for their products as a key indicator of quality and reliability.

The testing initiative is fraught with complexity and is not a simple statement of product quality. Firstly, many laboratories have only recent experience of testing for cannabinoids. Secondly, almost all the UK products use test results from laboratories near or at the source of the extracted CBD itself, typically in North America or Europe. Thirdly, the commercial relationships between suppliers, retailers and laboratories is not always clear, and in some cases may not offer the independence expected of third-party auditing and validation processes in other sectors.

The biggest handicap to a robust and trusted process for producing test results for CBD products is the lack of a regulatory standard that encompasses an agreed methodology. There is no government standard, or industry approved benchmark, for how cannabinoids should be tested, and no single methodology that laboratories apply. This results in variation between laboratories across the European Union, and even between testing facilities in the same jurisdiction, like the UK. This problem is replicated in the United States. As a major US-based CBD producer has argued, "Right now, many testing labs lack sufficient controls to ensure the accuracy of the data. Forcing manufacturers to implement validated testing procedures is critical to improving the quality, safety and consistency of CBD products broadly available on the market"

Second, the CBD sector needs a branded kitemark scheme to signal to consumers which products have met the quality standard. There is currently no dominant brand for a quality badge or kitemark for CBD products

in the UK, though there are several aspiring global initiatives for legal cannabis in general.¹⁰⁷ Labelling needs to improve to ensure accuracy and to make the contents clearer for consumers, but this could be enhanced if the industry could agree on a kitemark that only the best CBD producers could use, following a robust accreditation scheme.

As laws governing hemp are liberalised, similar initiatives to ensure responsible self-regulation have led to certification efforts in markets like the US, where the US Hemp Authority launched the first standards and is currently consulting on new ones to take effect in 2020. Companies that meet their standards can badge their products with a seal.¹⁰⁸ Similar efforts are being pursued at the E.U. level, to ensure consistency at a pan-European level for the first, both for agriculture – on the part of the European Industrial Hemp Association (EIHA) – and for CBD consumers, by ACTIVE, which has chapters in several countries, including France and Spain.¹⁰⁹

Maintaining incentives to invest in research

A pathway for licensed CBD medicines must be maintained in order to preserve the market incentive to conduct trials and pursue approved drug status.

Chapter 2 demonstrated that scientific research into cannabidiol is expanding globally, and the UK is no exception. Without better regulations for CBD in food supplements, the OTC sector is projected to grow significantly, and potentially uncontrollably, which will undermine the incentive for companies to invest, especially given the high costs associated with exploratory early-stage trials of CBD pharmaceuticals. The FDA Commissioner, in testimony to US legislators, recently argued that in consulting on an appropriate regulatory framework for hemp-derived CBD products, “We want to preserve the incentive to study CBD as a pharmaceutical product.”¹¹⁰

There needs to continue to be a path for CBD drugs to become licensed medicines - as Epidiolex has already achieved in the United States. And as clinical trials are established in the UK, there needs to be adequate supply of purified API-grade pure cannabidiol from reliable, licensed sources. These providers may also be involved in the creation of unlicensed ‘specials’ for private clinics and the wider health sector involved in prescribing CBMPs.

Supporting UK-based CBD businesses by levelling the playing field

A truly successful CBD industry in the UK will stay beyond reach unless the full seed-to-sale pipeline can be undertaken domestically, without relying on imported hemp.

The industrialised output of non-certified strains from North America (which are being farmed intensively indoors and cross-bred to yield larger CBD concentrations), presents a challenge. They contain different terpene and cannabinoid profiles than traditional hemp strains (whether grown in Europe or elsewhere) and it is not clear why they should have equal status to certified hemp varieties as sources of raw extract. Reliable sourcing and traceability methods are available and could be made a requirement, in order to help support the UK hemp industry to grow.

Furthermore, associations with a prohibited plant should not prevent UK-based CBD businesses from being able to access the same start-up incentives and innovation grants as any food, healthcare or technology company, or the banking services required to support retail to consumers. Presently, given US federal law, major credit card companies do not contract with CBD companies in the UK, leaving these retailers reliant on other service providers and online payment gateways.

All of these challenges require concerted efforts from many actors. Without progress on all of them, there is a bigger strategic risk that will confront CBD, and the general perception of cannabis as a valuable and medically useful plant that can benefit human health and wellbeing. We therefore urgently need better self-regulation, and a focus on compliance, and good consumer practices. It would also be good to see companies supporting public education efforts to advance patient, consumer and clinician knowledge, and most importantly, the investment need to build a robust CBD evidence-base. The resources (and ultimately the research investment) for which can only come from having a commercially successful CBD industry in the UK. In order to deliver that, the key recommendations of this report boil down to three big asks of every player in this space (See Chapter 11).

11. The Ask

Summary

- There are a number of asks that need to be made of the government, regulators, the medical profession, and the industry itself, if we want the UK to have a thriving and well regulated CBD sector.
- We have outlined 3 key asks of every player in this sector and alongside it, a clear proposal of how to act in order to improve the CBD marketplace and deliver real benefits for consumers and patients.
- Working in collaboration, politicians, policy-makers, regulators, producers and retailers can play their part to achieve the shared goal of a CBD sector that is innovative, responsible and high-quality, delivering both economic benefits, social value, and individual wellbeing.

Three Big Asks of Government

- Clarify, consult, then revise the law
- Devise regulations that work for the UK today
- Support the UK’s domestic CBD industry to grow

Three Big Asks of the Regulators

- Provide clarity and certainty to the industry at all levels
- Focus enforcement on priority harms
- Help raise awareness and educate

Three Big Asks of the Medical Profession

- Take CBD seriously
- Support new UK research into CBD
- Prepare for cannabidiol medicines

Three Big Asks of Industry

- Define what quality looks like
- Undertake voluntary, robust self-regulation
- Be socially responsible

Recommendations

The three elements of this report - the policy analysis, scientific testing, and market sizing - create a detailed picture of CBD in the UK today. Together they give rise to a number of recommendations. In this chapter these are boiled down to the most important three asks that

need to be made of the government, regulators, the medical profession, and the industry itself, if we want the UK to have a thriving and well regulated CBD sector.

Below are 3 key asks of every player in this sector and underneath them, a clear proposal of how to act in order to improve the CBD marketplace and deliver real benefits for consumers and patients.

Three Big Asks of Government

- Clarify, consult, then revise the law
- Devise regulations that work for the UK today
- Support the UK’s domestic CBD industry to grow

Clarify, consult, then revise the law

The 2001 regulations were designed before cannabidiol emerged as a popular food supplement, but they are incompatible with the CBD sector as it exists today. Firstly, they are designed to govern controlled substances, and take no account of the methods used in the sourcing and processing of cannabidiol from Cannabis Sativa L. Secondly, if strictly applied, they technically render almost all the non-intoxicating CBD products currently on the UK market - even when derived from E.U. certified hemp strains and produced to GMP quality standards - non-compliant.

As there is no realistic prospect of blanket enforcement of this law, and no apparent desire to test the legal position in court, the law must be revised. That revision should follow consultation to properly account for current production methods, supply chain and market conditions, and scientific advice on intoxication and impairment. This change would not require primary legislation to amend the 1971 Act. Instead, the Home

Office should prepare a revision to the special category exemption (schedule 5) from the general rules on controlled substances to provide a legal 'safe zone' for quality CBD products that is evidence-based and proportionate.

Clarifying the law by amending the 2001 regulations presents the simplest approach. It avoids a parliamentary debate about the prohibited nature of cannabis - which the current Government has been clear it does not intend to reconsider - and using secondary legislation can be quick and uncontroversial (see Glossary). In this respect, minor amendments will create a clear legal foundation for the CBD market to develop in a responsible and well-regulated way. This is fair for producers and UK retailers because it automatically provides a clear path to legitimacy for the responsible CBD market. Simply ignoring the flaws in the law does not. As an adjunct to this, it would be advantageous if the forthcoming interim report from the Advisory Council on the Misuse of Drugs (ACMD) was to advise on this potential change as a part of their study of cannabis. A technical submission by the CMC would outline what such a revision to the 2001 Regulations might entail, that keeps all other elements intact.

Devise regulations that work for the UK today

UK medicines regulations are some of the best and most reputable anywhere in the world, and they do not need to change. It is not in the consumers' interest to relax rules around health claims for products that are not medicines. The Novel Food process is an important standard to help ensure food safety for all consumers and is not by itself defective. For this reason, the UK has taken steps to mirror this regulation when the UK leaves the European Union and is no longer party to the EFSA or its committee structures. However, the recent reclassification of all cannabinoids to be Novel Foods is not a definition that will work for the United Kingdom in the long-term. This is not the same as saying some cannabidiol formulations - for example highly purified isolates, are not novel. The best approach is to plan for an alternative system of regulation that works for the UK and accommodates the special place that the large and growing CBD market has within the wider wellness/nutraceutical space.

Outside of the E.U., the UK would be free to pursue a distinctive regulatory approach to cannabinoids, and this opportunity should be taken up - as it has already with respect to Cannabis-Based Medicinal Products (CBMPs) that have a bespoke UK definition, achieved through amendments using secondary legislation. To this end, the Home Office and the Department for Health and Social Care should consult with the Channel Islands, New Zealand, Canada, and Ireland, to gather

examples of how CBD products are regulated there - including the rationale for some of the alternative approaches announced or implemented in just the last 12-24 months (see Chapter 9).

In parallel, UK-based regulators - the MHRA, FSA, and VMD - should jointly engage with their counterparts in Canada and the United States to learn from their new consultation processes. This should form the basis of a UK public consultation on a distinct regulatory channel for cannabinoid nutraceuticals that could encompass many (but not all) CBD products, and might form the basis of a new licensing pathway for certain classes of CBMPs. In theory this might create a viable third-way between generic medicines law, and rules governing food supplements, but it would need extensive engagement with policy-makers and professional bodies.

Support the UK's domestic CBD industry to grow

A thriving CBD industry in the UK should not be reliant on imports. Even if the UK will never become a global leader in hemp cultivation because of climate, land values and crop acreage, that does not mean it should be made uncompetitive. Unlike their British counterparts, hemp farmers operating in Europe, and across the United States (and Canada), are now legally able to cultivate hemp for the commercial purpose of harvesting the flowers and leaves to extract CBD. These products are being imported at scale into the UK to meet domestic consumer demand here, but that is not a product that UK farmers can legally handle, process or transport. That is a regulatory disadvantage for the UK agricultural industry that is difficult to justify at any time, and would be especially hard to maintain in the circumstances of economic disruption caused by the UK's exit from the European Union in 2019. It is irrational and unjust to deny UK farmers access to a cultivation process for the whole hemp plant that is used by competitor producers to supply CBD products to the same customer base of UK consumers.

The Home Office should immediately agree a new hemp licencing process - with input from the Department for Environment, Food and Rural Affairs - that harmonises regulations with EU competitors and permits UK farmers with a Home Office hemp licence to handle, process and trade cannabinoid-rich hemp flowers and leaves for the cannabinoid extract. Modelled on the Canadian regulations, the UK's hemp industry should be permitted to extract CBD, and export hemp-derived cannabinoid products, under licence, so long as they are from designated low-THC strains.¹¹¹

To further boost the UK's agriculture production of CBD, when the UK is outside of the E.U., it could choose to expand the catalogue of approved strains, and create

research and breeding licences for unapproved strains as New Zealand has done, leading to a distinctive UK list of varieties (as exists in Canada). The UK could also restore the baseline of 0.3% - consistent with what applies in North America and which used to apply in Europe (and is once again being actively considered in the E.U.), to increase significantly the variety of permissible strains that farmers can grow. To prevent UK hemp producers being undercut, new UK regulations should consider restrictions on imports based on full traceability, to deter non-approved strains without clear origins. Resources for Home Office licensing of UK-based companies seeking to cultivate should also be increased to make applications quick and cost-effective.

If regulations governing CBD products are revised (as proposed above), domestic demand for CBD from existing (and future) distributors will immediately generate a big incentive for UK farmers to move into this sector, driving up the number of licence applications, which will need accommodating. A CBD industry that has a vibrant domestic agricultural base will be resilient and profitable for the UK. It will also help arable farmers diversify and raise farm incomes in the years following Brexit. Were it legally possible to sell hemp flower in the UK, the UK Exchequer would benefit from the excise and sales tax revenue of a smokeable consumer product.

Three Big Asks of the Regulators

- Provide clarity and certainty to the industry at all levels
- Focus enforcement on priority harms
- Help raise awareness and educate

Provide clarity and certainty to the industry at all levels

For the industry to move forward, the FSA needs to issue a detailed guidance note, or legal explainer, clearly describing the current opinion of the regulator, the legal position vis-a-vis firms currently trading CBD products in the UK, and advice on next steps to be fully compliant. Until the FSA's proposed 'proportionate' enforcement approach (and interpretation) of the Novel Food classification is set out clearly in the UK, the CBD market will continue to operate in a legal grey area, lacking the clarity it needs to be a normal food business sector. There is no single statement on gov.uk or another official website of what CBD is, what is permitted to be sold, what restrictions are applicable, and what products (under all circumstances) are unregulated (and illegal). It has been six months since news emerged of the Novel Food change potentially affecting CBD and so far there has been

no detailed FAQ or guidance note published about the Government's position and what this requires of the industry, and no formal FSA opinion. Even the requirement to register as a food business with local authorities has not been communicated to CBD companies. Importers need specific advice on international sourcing so the right tariff codes and customs duties are being applied. Existing food labelling law as it should apply to food supplements is a separate guidance effort.

It is a key role for a regulator to ensure that the companies operating in the regulated sector that they are responsible for knowhow to become and how to stay compliant. This clarity is needed from the top-down, and it can be complemented by a local effort to visit companies and provide guidance on-site. Given the scale of this industry and the volume of CBD sales, whatever efforts have been conducted to date by Trading Standards or Environmental Health officers to do on-site inspections has not been sufficient to arrest the growth of a grey market, and needs to be expanded. Regulators like the MHRA and FSA already have all the tools they need - but they have to be prepared to use them. Given the confusion around CBD products, the HO, MHRA, FSA and VMD should coordinate on a single statement that provides clarity to the market, and then reinforce that with some investment in compliance activity to proactively target the worst offenders.

In the United States, CBD is widely available in spite of Federal Law prohibiting interstate commerce. However, the national regulator has recently issued a number of (published) warning letters to shut down those committing egregious breaches of federal trade and medicines law, and has committed to do more as necessary. The UK should follow this example. As has been said of the booming CBD industry in the United States, the "*market is growing too fast and the public demand is too high for [regulators] to wait to act*".¹¹² But before there is new enforcement efforts, or consultation on a new regulatory approach, the industry needs clarity and certainty from regulators about what is permissible and how they can become compliant.

Focus enforcement on priority harms

Enforcement is necessary and can take many forms, with regulators, local councils and the police all able to play a role. However enforcement should prioritise according to the threats and harms posed to CBD consumers, and be intelligence-led, not simply reactive. These threats are: risk to human health, unlawful misinformation regarding health benefits or medicinal claims, non-compliance with food labelling rules, and substandard retail practices (including advertising standards) - in that order of priority. As a result of the testing exercise conducted for this report, a sample of

29 products available in the UK suggest that the first scenario is a reality, and a priority for enforcement should be those poor quality products which contain contaminants, or elevated levels of THC. Examples in this report demonstrate that other breaches of medicines law may be taking place with CBD companies making health claims, on websites and in social media, about their product, contrary to the law and against the clear guidance in the MHRA BlueGuide.¹¹³

If the law is revised to accommodate CBD extracts that can legally contain trace elements of THC, it will be simpler to draw a distinction between legal and illegal suppliers based on a measurement of the THC % or total amount in their finished products. At which point, random spot-checks and batch testing can be undertaken, supporting the work of the police and Trading Standards. While this process is undertaken, the FSA should take a proportionate approach to Novel Food regulations, avoiding all enforcement in the interim, save for unsafe and contaminated products that pose a threat to health and are already a hazard under general food law. They should nonetheless support those CBD producers who wish to file an application to do so expeditiously, and permit them to go on trading while the application is being processed.

Help raise awareness and educate

Regulators can also work to educate consumers to help them get more informed about cannabidiol. When this is supplemented by accurate media reporting and industry-led initiatives, it can generate bottom-up crowd pressure for better quality products and services. But new businesses and entrepreneurs need good information and clear guidance too, and many companies in the CBD sector are small and entering this industry for the first time - some with a handful of staff and no recent experience of regulated sectors. That information deficit is addressable if the regulators engage proactively with the industry and produce educational material and factsheets that answer common questions and dispel myths.

In the United States, after some years of limited activity on this issue, the FDA has begun to engage with industry to consult on the most proportionate regulatory path forward, and has also issued a detailed and clear FAQ to help the public and the industry understand the legal picture and what is permissible.¹¹⁴ The MHRA produces flowcharts and decision trees to guide pharmaceutical companies on how they need to act to comply with rules around APIs for example¹¹⁵. Similar information is needed for the wider CBD space, covering not just balms and tinctures, but also capsules, cosmetics and e-liquids. The NHS, as part of a webpage on cannabis medicines, also touches on CBD, but this information is oversimplified and aimed at patients.

The CBD industry would welcome a proactive effort to educate every player in the supply chain about their responsibilities. Misinformation currently circulating can only be addressed when companies and consumers have reliable sources of information from trusted, official sources. That gap needs to be filled in 2019.

Three Big Asks of the Medical Profession

- Take CBD seriously
- Support new UK research into CBD
- Prepare for cannabidiol medicines

Take CBD seriously

This is the number one ask from current established CBD users. The medical profession has previously had primary concern relating to the medical consequences associated with addiction and abuse relating to all Class A and recreational drugs. For them, Schedule 1 categorisation historically meant that they need not consider cannabis further. This of course embodied a matter of institutional prejudice, that set the scene for the “black swan event” that followed: CBD is subsequently shown to be effective in childhood epilepsy syndromes where extant licensed drugs and even draconian treatments were embarrassingly failing within a highly emotive situation. There can be no doubt that the UK medical profession is now both palpably humbled and alerted to CBMPs, if for no other reason that it risks suffering so much credibility damage that it also loses the recreational cannabis use argument in the process. Whilst there is a developing strong NHS abreaction to recreational cannabis consequent of deregulation developing internationally, care is also being made to distinguish potential medical bona fides: medical cannabis is now considered a real entity within the UK, and CBD is its most promising dimension.

Support new UK research into CBD

As a consequence of the recognition of CBMPs as of medical benefit in childhood epilepsy syndromes and the discovery over the last thirty years of cannabinoid related receptors in vitro, it is entirely within extant medical culture to pursue potential medical benefits. Most effective drugs have origins in plants. Support will now undoubtedly unfold for new research. However as a therapeutic agent, the current status of CBMPs is rather similar to the use of boiled Foxglove leaves in the middle ages for dropsy (heart failure), in that there is beneficial yet unreliable effect, because the active pharmaceutical ingredient and its method of action is not adequately and fully identified. This is likely to be increasingly the focus of research activity for the future, and the medical profession should be fully engaged in that drive. Major efforts should be made to increase the breadth (involving more Universities and increased

areas of expertise) and volume of CBD research in the UK to ensure we become world leaders in this field. We particularly need to encourage clinical research trials that translate this ongoing research into a firm evidence base for the medicinal benefits of CBD to promote its clinical use.

Prepare for cannabidiol medicines

The medical profession fully accepts that cannabidiol is not intoxicating. As such it has only ever been previously inappropriately prejudiced by association. The recent media focus on cannabis and epilepsy has already served to set CBD free to fulfil its future potential. However there is a regulatory public downside intrinsic to this eventuality: the Medicines Act defines a medicine as any chemical agent taken with the intent of symptomatic relief, correction of physiological deficit, or treatment of disease. Inevitably therefore, if the use of CBD extends meaningfully beyond the currently identified niche of efficacy, it will likely lose its classification as a novel food. Ultimately, after an extended period of careful assessment, it may become re-available over-the-counter in permitted formulation, but we are likely to see it initially become a prescription-only medicine (POM) if it falls into widespread medical use for such ills as anxiety, sleeplessness, and chronic pain. This is not only because of the relative medical knowledge vacuum around CBMPs that has to date prevailed, but also because of all cannabinoid’s known competition for bodily excretion with other commonly prescribed and dangerous drugs that will be significantly affected by their use that must consequentially be more reliably identified. Preparation therefore means careful management to ensure continuing patient access does not fall between two stools.

Three Big Asks of Industry

- Define what quality looks like
- Undertake voluntary, robust self-regulation
- Be socially responsible

Define what quality looks like. Consumer protection is the hallmark of a responsible retail industry. Many established CBD suppliers make explicit reference to the need to ensure consumers access safe and quality products, and research for this report confirms that quality is what CBD users prioritise. It is imperative that quality is achieved, and clearly understood by all who operate in the sector. Quality is the basis of trust. It is not the same as a premium brand, or a high potency formulation. As one specialist CBD consultancy has written:

“[T]he industry needs to ensure we purchase and deal with

CBD ethically and the only way to do this is by buying from reputable suppliers who can provide transparency in their product processing procedures. Products made in poor conditions are not good products regardless of the CBD content. People will be consuming these products in many forms and deserve to have it made under strict standards just like any other food or medicine.”¹¹⁶

Currently, the signs are that the responsible players in the CBD industry recognise that they need to coalesce around an agreed definition of ‘quality’ CBD, in order to be seen as reputable. In fact, the NHS advice note to prescribers acknowledges the possible short-comings in terms of CBD products on the market, and recommends: *“Anyone wishing to use a CBD containing supplement should ensure they obtain their supply from a reputable source.”¹¹⁷*

How are consumers meant to determine what is a reputable source? Either the government needs to inform them - which it has not done to date - or, alternatively, and preferably, the industry itself needs to agree what that looks like. Whoever authors the standard needs to commit to maintain it, police it, and build a marketing initiative that communicates that standard to consumers to help guide their purchasing decisions. There is nothing to indicate that government sees itself as having this role, and it has not done so in other sectors, beyond investing in public education efforts - e.g. DrinkAware.

This must be championed from outside of government, but it is not the proper role for the CMC to describe what this quality standard looks like. However, we can broker that discussion and convene the right players, starting with those CBD businesses that subscribe to the CMC and contributed to this project (see Annex). To be sustainable, it is important that the industry itself collaborates to define what it comprises, because only the industry can keep it alive. Only the industry itself can decide what activities define a reputable CBD business and what best practice looks like, and the steps needed to comply. There will not be complete agreement at the margins, but a core of good quality standards should be possible to spell out, and these will set a minimum to which any responsible CBD business should seek to attain. Some of the major issues that need agreement as part of devising such an industry standard include:

- What agricultural sources of CBD and harvesting practices are considered high quality and sustainable?
- What extraction and production methods are deemed best practice?

- What testing requirements are robust and credible for regulators?
- What labelling and product marketing approaches provide the clarity consumers need?
- What seed-to-sale traceability mechanisms are robust and proven to work?
- What steps should companies subscribe to to address product defects and supply chain problems?
- What are responsible marketing practices in the CBD sector?
- What role in environmental stewardship should CBD companies adopt?
- What activities in the CBD supply chain demonstrate a commitment to human rights, equal treatment, and sustainability?

In pursuit of consensus around these and other questions, it is unavoidable that the industry will also need to decide what bad practice looks like and when necessary, be prepared to support those poor performing CBD companies to improve, in the interests of the whole sector and the UK consumer at large.

Undertake voluntary self-regulation

There are a myriad of models of trade associations within regulated industries that already exemplify how voluntary self-regulation can work. They all share the same goal of seeking to raise (and maintain) standards throughout the sector, and to keep the confidence of end users and/or regulators. Depending on how public-facing the sector is, some of these have established branded kitemark schemes to help consumers with purchasing decisions, and others have not. The model that will work best for the CBD sector is for the companies in that sector to decide.

A balance must be struck between too much regulation and bureaucracy and too little - consistent with the goal of maintaining the confidence of government and other authorities and obviating the need for top-down government regulations. A quality standard that is merely aspirational, and reliant entirely on self-certification is not a standard that can be credible - it is a membership initiative. Conversely, a standard that is onerous to attain and comply with, and costly to supervise, accredit and enforce, is unlikely to win support and therefore the critical mass to be representative of the industry at large.

To be sustainable, any quality standard must have an independent means of verifying that those CBD companies that are members have earned their right to be promoted as reputable companies that consumers

can trust. Given that this report has identified the consumer's priority around quality and purity, it seems inevitable that a UK quality standard will need:

- A recognisable kitemark for retail stores and products;
- A partnership with a UK-based laboratory or laboratories, to undertake routine dip sample tests to verify product contents;
- An arms-length process to review, test, and accredit those CBD companies who seek to attain the quality kitemark, administered on a rolling basis.

Be socially responsible

The CBD sector is associated with cannabis whether it wants to be or not. Attitudes to cannabis legalisation differ, and even the UK's CBD users are divided on whether cannabis itself should be legally available for recreational adult use. The issue is a polarising one, and it should not be allowed to colour the debate about the right way to market CBD or to realise the benefits of CBD products.

Cannabis and CBD are different propositions - commercially and legally - however, the shared association puts CBD companies under the spotlight. This results in closer scrutiny than general wellness brands might expect to receive. With that public and media scrutiny there are upsides - news and discussion that promotes CBD and introduces it to a wider audience. But it also holds CBD companies to a high standard, and those that do not appear to meet it, can and will be vilified, undermining the reputation of the whole sector.

This means CBD companies need to be more than just compliant. They have to be proactively responsible, and work extra hard to prove they are legitimate enterprises that are focused on general wellbeing, and not businesses driven entirely by profit, and certainly not ones linked to illicit cannabis markets or the unlawful promotion of medicines.

To guard against this, responsible CBD companies need to participate in voluntary self-regulation, so the market can be properly policed. But they also need to engage with regulators on an individual basis and demonstrate compliance when asked. This is the minimum required to allow these CBD companies to have a rightful place in the market as respectable businesses that comply with regulations, pay taxes, and treat their staff, suppliers and customers properly.

However, beyond compliance and meeting minimum standards, the best companies also need to guard

their position and support the reputation of the whole industry by pursuing other activity that demonstrates that they are socially responsible as well. The Global Cannabis Partnership, originating in Canada's legal regulated market, is expanding globally as a banner for best practice and corporate social responsibility in the legal cannabis field, and in June they launched the first Responsible Cannabis Framework.¹¹⁸ CannabisWise is another initiative designed at certifying cannabis products so that consumers can be informed and guided to seek out quality.¹¹⁹ Both of these initiatives serve the interests of the full legal industry, rather than simply CBD businesses, but their elements describe a responsibility agenda, linked to specific actions or commitments, that CBD companies might want to subscribe to.

The results of the testing exercise conducted for this report suggests that many companies have some way to go before they can be deemed to be high quality, and perhaps even further before they might be regarded as socially responsible. But that journey has to start now because the expansion of this industry - and the growing customer base projected out to 2025 - will depend on it. Cannabidiol in the UK has become both too large a market, and too important a product, for the industry to not be seen as responsible. Fortunately, there are many good companies in the UK CBD market who are already working hard to demonstrate the quality of their proposition and finding new ways to serve consumers and supply innovative products. Over the long term, if CBD companies in the UK act responsibly and lead by example, they will better serve their customers and avoid damaging the reputation of cannabidiol as an important compound that has huge potential.

12. Next Steps

Advancing the CBD sector

Effective regulations that win public support rely on sound policy, and at present, the under-regulated market for CBD products has emerged in a context devoid of any comprehensive policy from government on how it wants the market in the UK to develop, to what end, and how consumers and patients will benefit.

The Centre for Medicinal Cannabis (CMC) is examining the best way to take forward recommendations in this report and consulting with our stakeholders, with the goal of advancing and promoting - rather than curtailing - the CBD sector in the UK.

Our goal is clear: the UK's CBD sector is an asset to be supported and nurtured but it must mature into a well regulated, innovative and responsible industry as quickly as possible.

This will not happen by heavy-handed enforcement or top-down government regulation alone. Instead it relies upon a critical mass of responsible, UK-based CBD companies to coalesce around this goal, and to agree on a way forward. That solution must be co-produced, and owned by industry, and directed and governed by the industry - it cannot be dictated to them or administered from the fringes.

Role of the CMC

The CMC, collaborating with our members and partners, will play its part by continuing to monitor the CBD market in the UK and provide periodic updates to inform consumers, the industry, and public authorities. Our ground-breaking CBD market sizing exercise will be repeated in future years so we can track the course of the market as it develops and measure changing consumer trends. The CMC will consider further third-party testing initiatives to validate the quality of CBD products for sale in the UK, and how such a process could be scaled.

In 2019/20, the CMC will:

- Promote the findings and recommendations of this project to all stakeholders;
- Commission and publish an updated CBD Market Survey;
- Forge a partnership with a UK-based laboratory to conduct a new round of CBD product tests;
- Convene responsible UK-based CBD companies to

align around quality standards, leaving the industry itself to decide the technical parameters;

- Engage directly with government and regulators to promote better policy and regulation;
- Support existing and future CMC members to participate in a new industry initiative, provided there is the appetite and sufficient engagement;
- Agree a partnership with a pan-European association pursuing the same goals at an EU level;
- Monitor international regulatory developments and their implications for the UK and share these widely.

Later in 2019, the CMC will announce further developments, in collaboration with existing trade associations, towards creating the first credible, industry-owned self-regulation initiative backed by many of the reputable CBD companies operating in the UK, and with a permanent laboratory testing and accreditation partner.

Credible, industry self-regulation

A voluntary initiative of that kind will give the CBD sector in the UK the quality accreditation it needs, and the infrastructure and protocols to self-regulate so that standards are levelled up, and consumers are better protected as they deserve to be. To avert and render unnecessary any top-down regulation from government, this initiative will help distinguish those suppliers, retailers and other businesses who can meet a good standard and those that cannot.

Ultimately the consumer will dictate how this market evolves and they should be given the information and the tools to make informed decisions and to shop for the quality CBD products that are right for them, and to have the confidence to know what quality looks like. Informed CBD consumers will drive up standards and create virtuous competition between producers and retailers, to the benefit of all.

Protecting the CBD customer

The most important policy goal in respect of cannabidiol is to protect consumers. A balance must be struck that allows for experimentation and novel product formulation, and quality controls must be proportionate so as not to restrict innovation. The CBD industry is and will become, an important economic asset, creating jobs for British workers and generating tax revenue to fund public services. However, without adequate safeguards that protect the rights of consumers, these wider economic benefits will not be sustainable.

We also know from experience in other sectors, that without effective consumer protection measures, competition is undermined, risks are not identified in supply chain practices, and end-product quality can suffer. The long term impact of this is more than economic - the very reputation of products derived from compounds in cannabis will be tainted, potentially reinforcing public perceptions that such products are at best, snake oil, and at worst, dangerous.

Conclusion

The research for this report fills an important gap in the understanding of the UK's thriving CBD market. The analysis demonstrates that CBD is already so popular that it is being explored by millions of people and emerging as an important generator of jobs and tax revenue in the UK, as well as providing regular benefits in terms of health and wellbeing to over 1 million regular users.

However despite its importance and therapeutic potential, and the scale of the British consumer's appetite for cannabidiol, this report shows that we are some distance from the type of CBD sector that we need. The UK's legislation is ambiguous, out-dated and fragmented, quality is not defined, product composition is not guaranteed, and poor marketing practices are all too common. UK consumers are being let down as a consequence.

Protecting consumers means mitigating risks. It also means providing accurate information to inform choices of what to purchase and how to consume, and it also means suppliers meeting well defined quality standards. In respect of risks to human health, an under-regulated market could mean cannabidiol is in danger of being guilty by association. While no evidence exists of harm to human biology by CBD consumption, the manner in which CBD products are supplied complicates this picture. All consumers in the UK need and deserve to be safe, informed and lawful when they choose a CBD product.

Working in collaboration, politicians, policy-makers, regulators, producers and retailers now need to play their part in achieving the shared goal of a CBD sector that is innovative, responsible and high-quality, delivering economic benefits, social value, and individual wellbeing. The wave of popularity around CBD, which offers huge opportunity for the UK itself, now needs to be grounded on a strong foundation of research, proportionate regulation, and quality standards. We intend the CMC to play a role in building that strong foundation.

UK Regulatory Landscape

Government Actor	Status	Role
Home Office	Department of State	The UK's security ministry that leads on criminal law, and issues all licences relating to controlled drugs. Sponsor department for UK Border Force and accountable to Parliament for drug policy, policing and law enforcement.
Department for Health & Social Care (DHSC)	Department of State	The UK's health ministry that sets policy, regulates and funds the National Health Service, and sponsors agencies that inspect, regulate and police the healthcare industry throughout England, including the MHRA (see below).
Department for Environment, Food and Rural Affairs (DEFRA)	Department of State	The ministry responsible for environmental policy, and issues affecting food, farming, fishing and rural affairs.
Regulator	Status	Role
Medicines & Healthcare Regulation Authority (MHRA)	Agency of the DHSC	Responsible for the regulation of medicines and medical devices for humans, and responsible for assessment of post marketing surveillance.
Food Standards Agency (FSA)	Non-ministerial department	The agency responsible for food standards in the UK that is focused on safety for consumers. Powers to inspect and issue alerts, stop notices, and fines to non-compliant retailers, food businesses and restaurants. Implements EU directives via powers granted by the 1990 Act and secondary legislation. Communicates opinions and determinations to the food industry on regulatory issues and issue public health advice to consumers. Handles all applications from UK companies for Novel Food authorisations.
Veterinary Medicines Directorate (VMD)	Agency	The regulator responsible for licensing medicines and treatments for pets and animals.

Enforcement Agency	Status	Role
Police	Independent constabularies	Prevent crime, uphold the laws governing drugs, and enforce against illicit activity.
UK Border Force	Agency sponsored by Home Office	Polices the UK border at all ports and airports.
HM Revenue & Customs	Crown Agency of HM Treasury	Collection of import duties and taxes for all imported products originating outside the EEA.
Trading Standards	Local government	Local officers inspect premises and can seize non-compliant products and close down retail stores with the support of local police.

Controlled Substances

Rules governing controlled drugs of all kinds are a matter for the Home Office. The principal regulations were enacted in 2001 and are updated as required, but not regularly. The provision for up to 1 milligram of a controlled substance referred to in the 2001 Regulations is only relevant for an "exempted product" and in order to comply with an exempted product definition, the product must satisfy all three of the following conditions: 1) that the product is not designed to administer a controlled substance to humans; 2) the controlled substance must not be easily extractable; and 3) the total quantity of controlled substance does not exceed 1mg in the finished product. Clearly a CBD oil product designed for human consumption implies that any controlled substance it also contains will be consumed, thus failing the test for an exempted product.

Prescribing of Medicinal Cannabis

Since 1 November, there have been no prescriptions issued for CBMPs to patients on the NHS. What data is available covers only England, but does show where prescriptions of licensed cannabis medicines (see Glossary) have occurred. In synthetic form, one cannabis THC product – referred to by the non-proprietary name of dronabinol – is available as an anti-emetic medication that has been prescribed by NHS doctors in England for more than five years, though in very low quantities.

The latest data is now available through Ben Goldacre's pioneering open data platform.¹²⁰ This shows that over the last year (March 2018-February 2019) there

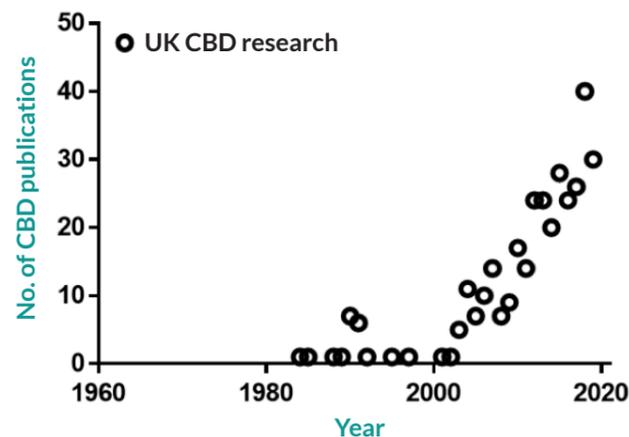
were 1,466 items of dronabinol prescribed in England, costing 551,899GBP, or about 400GBP per item, and that the NHS area with the most use was North Cumbria Clinical Commissioning Group with nine items prescribed that year.

CBD research in the UK

UK researchers are examining some of the key areas of CBD's potential therapeutic uses. Most of the preclinical research that supported the clinical trials with Epidiolex in epilepsy arose through work done at the University of Reading, and in fact one of the main investigators in this research, Professor Ben Whalley, went on to be Head of Discovery Research at GW Pharmaceuticals. The University of Reading along with University College London continue to research the therapeutic effects of CBD in epilepsy and Tuberous Sclerosis Complex (a disorder characterised by tumour growth, epilepsy, cognitive defect and autism). A number of institutions are examining the potential role for CBD in the treatment across a range of mental health disorders and learning disabilities, which are some of the major reasons that people use over the counter CBD products. This includes research on the effects of CBD in anxiety (University of Nottingham, King's College London, University of Oxford, University College London and university of Birmingham), psychosis (King's College London and University of Roehampton), schizophrenia (King's College London) and autism (King's College London, also being investigated through a registered clinical trial).

Several universities are looking at the potential role of CBD in addiction (University College London, King's

College London, University of Exeter and University of Bath) and tobacco withdrawal (University College London, King's College London and University of Exeter). This work is supported by researchers at London institutions with a programme of imaging studies on the effects of CBD on the human brain (University College London, Imperial College London, University of Bath and King's College London) and the effects of CBD on memory function and other behavioural responses (University of Exeter, University College London, King's College London, University of Bristol, University of Exeter, University of Birmingham and University of Nottingham).



Many cancer patients report benefits from the use of CBD for the relief of cancer-related symptoms, and some hope as an anti-tumoural agent. To support this, there is research ongoing across the UK aiming to establish whether CBD can reduce tumour size, growth and spread. Researchers at the London

Metro University, University of Westminster, the Open University and University of London are all investigating the effects of CBD on brain tumours.

The potential of CBD in the treatment of pancreatic cancer (Queen Mary University of London, Cancer Research UK Beatson Institute Glasgow), lung cancer (Stoke University Hospital), leukaemia (University of London and Lancaster University), as well as non-specific cancer research (London Metropolitan University, University of Westminster, University of Hertfordshire and University College London) is also being investigated across the UK. A case-review of 119 cancer patients treated at a UK centre using CBD showed that 92% of patients had a clinical response to their tumour with no significant side effects reported¹²¹.

Beyond the central nervous system, there is active research in the UK on the potential of CBD to be a treatment in gastrointestinal disorders (such as leaky guts, Crohn's disease and colitis) at the University of Nottingham, Guys and St Thomas NHS Foundation and Lancaster University, and for the treatment of diabetes at the University of Nottingham, King's College London, Barts and the London School of Medicine, and Ulster University. The effects of CBD on the cardiovascular system and its potential use in cardiovascular disorders including stroke is also being carried out at the University of Nottingham. General studies on the molecular pharmacology of CBD (how CBD acts on proteins and enzymes within our body) is being carried out at the University of Nottingham, University of Reading and Oxford University. CBD pharmacokinetics and mechanisms of improved CBD drug delivery is being investigated at the Open University and University of Nottingham.

CBD extraction

Extraction method	Positives	Negatives
CO ₂	<ul style="list-style-type: none"> Selective and tuneable for different molecular weights No residual solvents except for ethanol Cold extractions and separations are good for temperature sensitive extractions (i.e. terpene preservation) 	<ul style="list-style-type: none"> Equipment is expensive Extraction rates are slow on less expensive equipment (competitive rates for more expensive equipment)

Extraction method	Positives	Negatives
Hydrocarbon	<ul style="list-style-type: none"> Less expensive equipment than CO₂ Fast extraction rates High potency levels 	<ul style="list-style-type: none"> Not selective or tuneable Scaling challenges from limits on amount of hydrocarbon that can be on site (flammability risk) Residual solvent testing required (adds additional time and expense)
Ethanol	<ul style="list-style-type: none"> Very inexpensive equipment Very fast extractions – great for distillate products Easily scalable 	<ul style="list-style-type: none"> Not selective or tuneable Will freely extract chlorophyll Requires significant levels of secondary processing

Whatever system is used (including CO₂ extraction if ethanol is used in the wintering process) residual solvents need to be controlled, and tested for, to prevent risk to consumers. Residual solvent levels are commonly controlled in both pharmaceutical product and food content guidelines to prevent short and

long term harm to consumers (3, 4). Generally, the limits set for food products are lower than allowed in pharmaceutical products, presumably due to the increased total ingestion of the solvent when consuming food products in greater quantities (see table 1).

	Ethanol	Hexane	Dichloromethane	Methanol
Pharmaceutical guidelines ¹²²	5000 ppm	290 ppm	1870 ppm	3000 ppm
Food guidelines ¹²³	no limit set	1-30 ppm*	2 or 5 ppm*	10 ppm

* only specific food extractions are allowed for these solvents

For our analysis of CBD products obtained from the UK consumer market (Chapter 5) we indicate where residual solvent levels exceed those prescribed in the food guidelines and then if they exceed the pharmaceutical guidelines recognising that CBD food supplements are unlikely to be consumed in the same quantity as food products.

Pharma-grade API

The current medicinal route-to-market for CBD products in the UK will encompass clinical trials and drug development that could utilise CBD (synthetic or organic) APIs as a source material. According to public databases, at present, there are 9 companies in the European Economic Area that have an API certificate for cannabidiol – and five of these are in the UK, including GW Pharmaceuticals (the makers of Sativex and Epidiolex), and BSPG Laboratories¹²⁴, now owned by Brains Bioceutical Corporation.¹²⁵

Registration Holder	Site Name	City	Country
Chiracon GmbH	Chiracon GmbH	Luckenwalde	Germany (DE)
BSPG Laboratories Ltd	BSPG Laboratories Ltd	Sandwich	United Kingdom (UK)
Alpha-cannabis Pharma GmbH	Alpha-cannabis Pharma GmbH	Bad Nenndorf	Germany (DE)
Arevipharma GmbH	Arevipharma GmbH	Radebeul	Germany (DE)
Sterling Pharma Solutions Ltd	Sterling Pharma Solutions Ltd	Dudley	United Kingdom (UK)
Active Pharma Supplies Ltd	Active Pharma Supplies Ltd	Leyland	United Kingdom (UK)
GW Pharmaceuticals Ltd	GW Pharmaceuticals Ltd	Sittingbourne	United Kingdom (UK)
Galeno S.R.L	Galeno S.R.L	Carmignano	Italy (IT)
Aesica Pharmaceuticals Ltd	Aesica Pharmaceuticals Ltd	Cramlington	United Kingdom (UK)

CBD Product Testing

Other national regulators have previously undertaken testing exercises to reinforce their sanctioning of CBD business. In the US, the FDA conducted a suite of tests against CBD products in 2016, which showed a large proportion did not contain the level of CBD content marketed.¹²⁶ A study of 84 CBD products found that only 31% of products tested were accurately labelled for CBD content (within 10%) and THC was detected in 18 of the samples with a mean of 0.45% (i.e. above regulated levels) (Bonn-Miller et al., 2017)¹²⁷.

A study in the Netherlands showed that only 5 of 46 products were within 10% of the labelled CBD content, and the % deviation ranged from 0-92% (Hazekamp, 2018). A similar study in Italy showed that of 14 CBD oils tested, only 5 were within 10% of the CBD labelled content (Pavlovic et al. 2018). 12 of the 14 CBD products in this study contained THC, but mostly below the prescribed 0.2% level. Cannabinol (CBN) was also detected in most samples, which is very relevant in the UK where CBN is still a schedule 1 substance. As CBN is an artefact formed by THC oxidation, this also suggests there may have been higher levels of THC present in these products at some point.

Bonn-Miller and colleagues (2017) found that CBD vape products were the worst for mislabelling. Another US study looked at 9 different CBD e-liquid products from a single manufacturer and found that 2 of the products had THC and 4 contained a potent CB1 receptor agonist called 5-fluoro MDMB-PINACA

(5F-ADB) and one contained dextromethorphan (DXM) from the morphinan class of medications (Poklis et al. 2018). The most extensive testing in Europe has been undertaken by the International Cannabis & Cannabinoids Institute (ICCI) in Prague, Czech Republic, who have now conducted a suite of anonymise tests over three years, each with products available in the European market. It is not known how many of these, if any, were from UK suppliers.¹²⁸

Safety of CBD products

In Utah between 2017-2018, there were 52 cases of people who reported adverse reactions in products labelled as CBD (73% of these were vape products) that were inconsistent with CBD consumption including seizures, vomiting, confusion and hallucinations. One CBD product marketed as 'Yolo' was found to contain no cannabidiol but instead a synthetic cannabinoid 4-cyano CUMYL-BUTINACA (4-CCB). Of the reported cases, a quarter were aged under 18 and 60% of all cases were seen at a hospital emergency department.

In total, 15 of the people who experienced these adverse reactions were using CBD for medical reasons, which is especially worrying for vulnerable populations. Authors of the research study¹²⁹ that reviewed the contamination event and the public health response concluded: "States could consider regulating products labeled as CBD and establishing surveillance systems for illness associated with products labeled as CBD to minimize the risk for recurrences of this emerging public health threat."

In 2018, a separate US study¹³⁰ into CBD e-liquids from one manufacturer also found a sample of products contained 5-fluoro MDMB-PINACA (5F-ADB), a Schedule 1 drug with psychotropic effects similar to THC, and others contained dextromethorphan (DXM), which has abuse potential. The authors of the journal article reporting the results concluded "The analysis of these products illustrates the potential quality control

issues that can occur in an unregulated industry." The risks of contamination is not restricted to e-liquids and oil extracts. In Germany in 2016-18, researchers found hemp flower sold online from several CBD retailers was laced with synthetic cannabinoids – again with no declaration on the label and, in some examples, at dangerous concentrations.¹³¹

Explanation of some terms

CBMPs - 'Cannabis-Based Medicinal Products' (CBMPs) were instituted as a new class of unlicensed (so called 'specials') medicines in 2018 after they were rescheduled by the UK Government on 1 November, via an amendment to the 2001 regulations (see below). These products can only be issued by prescription, and authorised by a specialist clinician (in either the private sector or the public NHS). The three part definition of a CBMP is spelled out in law and is broad - e.g. the potency or ratios of CBD to THC are not stipulated. As CBMPs contain controlled substances, those involved in their importation, distribution or manufacturing must hold the requisite Home Office or MHRA licence. Alongside unlicensed CBMPs are a range of licensed medications derived from cannabis (or utilising a synthetic equivalent) that pre-existed the change in scheduling announced by the Home Office in July 2018.

Flower - Natural part of the female cannabis plant containing most of the active phytocannabinoids. Flower, buds and leaves of the cannabis sativa plant are controlled in the UK even if they are derived from an E.U. certified variety of hemp. Under no circumstances can flower or leaves from the cannabis plant be cultivated without a licence in the UK. It is assumed that there is no diversion from licenced UK hemp farms and that the hemp flower that is being sold in the UK is imported from Europe or North America - in the latter case, it is likely (but difficult to prove) that imported flowers are on sale as 'hemp', but in fact contain THC. There are some sellers of hemp flower in the UK who attempt to circumvent tobacco regulations and by extension, avoid the taxes not applicable to food, by marketing it as a 'herbal tea' that can be steeped. Retailers carrying hemp flower have been enforced against, and had products seized by the police and trading standards officers in 2019.

Legislation - Proposals considered by Parliament that when passed, receive Royal Assent and become Acts. All laws pertaining to medicines, controlled substances, and food, stem from at least one principal piece of legislation, and often several. As a Member State of the European Union, certain initiatives regarding food and medicines have been pursued by the E.U. Commission to provide a foundation of commonality for the Single Market, and E.U. Directives - approved by votes of the Council of Europe - are binding on Member States. UK legislation then translates those into domestic law (with regulations flowing from them, defining oversight, competent agencies, applicable sanctions for breach, etc).

Novel Food - This is an official process in the European Union to authorise certain food products for sale in the market based on a safety assessment. The key agency is the European Food Safety Authority (EFSA), which is "a European agency funded by the European Union that operates independently of the European legislative and executive institutions (Commission, Council, Parliament) and EU Member States." Any food product for sale in the E.U. that has no history of mass consumption must be approved as a Novel Food through a safety assessment and audit process, and the EFSA's definition of novel food is a food "that had not been consumed to a significant degree by humans in the EU before 15 May 1997, when the first Regulation on novel food came into force." The most recent entry in the guidance - the Novel Food catalogue - was adopted in January 2019. On 17 of January a new entry was added to the catalogue for generic "cannabinoids". The previous entry for CBD now refers you to the entry for "cannabinoids" which says "products containing cannabinoids are considered novel foods as a history of consumption has not been demonstrated." The Novel Food process is adjudicated in Brussels and can take 18 months or more, following submission. Companies make submissions via their national regulators (e.g. the FSA, for the UK). If granted, EFSA approvals have generic effect for all products in the marketplace matching the approved product, so cannabidiol itself needs to be authorised by EFSA as a Novel Food ingredient based on a successful application, not on a product by product basis. Among all the current applications¹³², one submission from the Czech Republic is currently being reviewed, and is based on adult daily use of up to 130mg CBD consumption.¹³³

Regulations - In the United Kingdom, these take several forms, but are all underpinned by statute. The criminal law (and associated penalties) are defined in legislation and detailed in Acts of Parliament. Regulations are often produced to implement laws by detailing their application and associated definitions. The 2001 Misuse of Drugs Regulations are periodically updated and have the force of law, but they flow from primary legislation and are enacted by secondary legislation (termed statutory instruments) which, except in rare cases, can be examined by MPs in committees, but are not subject to parliamentary votes. Agencies can be granted powers to issue regulations in their respective domains by Act of Parliament. Many regulations issued in the arena of consumer goods, environmental policy, agriculture and medicines, arise from E.U. Directives which have direct effect in Member States, and have legal effect once enacted by UK legislation.

Project background

Testing Initiative

As the facility responsible for the testing exercise for this project, PhytoVista Laboratories can answer questions regarding the testing methodology and laboratory protocols.

CMC - CBD Product Selection and Testing Process

The test initiated for this report is the first of its kind to focus solely on the products on sale in the UK, using a UK-based laboratory and blinded to guard against any potential for bias. The results have also been independently analysed by Professor Saoirse O'Sullivan and written up as part of a forthcoming journal article.

Choosing Suppliers

In the absence of any detailed existing data on the size and shape of the existing UK market, we have drawn from 3 sources of information based on published turnover, website hits and what customers and consumer support groups name as the most popular UK brands and products.

Within the available budget, we determined there was more to be gained from testing similar products from a wide range of sources than from testing a wide range of product but from fewer sources.

All product purchasing, both online and from the High Street has been fully documented so that we have shelf to lab traceability and all batch identification numbers and best before dates, where they existed were recorded, along with labelling data and other published and pertinent marketing information such as CBD and THC content, other cannabinoid content, extraction method, and carrier oil.

Choosing Products

The 30 products were chosen for their popularity and similarity across the range of suppliers. Due to cost, time and other technical complexities in testing different product types, only oils were chosen. In total 29 products were tested in a single exercise.

One product with a known quality and consistency for which we have a full set of manufacturer batch tests results has been tested at 3 separate labs to use as a baseline and to validate the testing. Some samples have been tested at a second laboratory, again, for validation. Products have been tested for:

- Cannabinoid content
- Heavy metals and other contaminants
- Residual Solvents

Purchasing Procedure

Only products sold in the UK were included, but encompassed both online and high street channels.

High Street:

- A photo was taken for each product whilst on the store shelf
- Products were purchased and a photo was taken with products and receipt including date/time/product details
- Purchased products were stored in a cool dark place in preparation for transport to the testing laboratory.

Online Stores:

- Browser history was cleared and all websites visited were recorded
- Products were “Mystery Shopped” for delivery to a secure location in London
- All products were accepted, delivered and signed for within 48 hours
- Delivered product was photographed with receipt to include date/time/product details
- Product seal checked and product labelling and marketing details entered into a tracking spreadsheet
- Purchased products were stored in a cool dark place in preparation for transport to testing laboratory.

All products were manually transferred to the testing lab. Members of CMC staff were blinded during the trial and the results and were not directing which products were included in the short-list to be tested.

The Lab

PhytoVista Laboratories¹³⁴ in Wiltshire, England was selected as the testing site. Upon receipt, all products were decanted into containers, within the lab setting and given a unique identification number before being handed over to the Lab Technicians without any product information. The link between the unique identification number and the product details was kept secure and encrypted by a single individual not involved in the testing process.

As a spur to address shortcomings and to encourage full engagement and an honest appraisal of the results, the individual laboratory certificates were shared with each of the respective companies who accepted that offer, but for this report, the overall findings are anonymised.

Market Sizing Analysis

The Centre for Medicinal Cannabis (CMC) commissioned a bespoke market sizing assessment for the consumer OTC cannabidiol products sector in May 2019.

The full details contained within the market sizing report including the breakdown from the different surveys and insights obtained will be made available to full CMC members.

Stakeholder consultation

During the course of this project, the authors and other CMC staff have met with key stakeholders including the FSA, MHRA, DHSC, and Home Office.

CMC member companies who contributed their time and data to inform the research for this report include:

- DragonFly Biosciences
- Sativa Group
- Charlotte’s Web
- Mile High Labs
- The Cannabis Oil Company

This project was not sponsored by any private company and costs were met from CMC research funds.

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