CBD IN THE UK

Executive Summary

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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 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.

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 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)

Dichoromethane 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.

### 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