maple tree

Mackrell. Solicitors

UK MEDICAL CANNABIS & CBD MARKET

DISCUSSION PAPER
TEN RECOMMENDATIONS FOR GOVERNMENT

By Maple Tree Consultants and Mackrell. Solicitors
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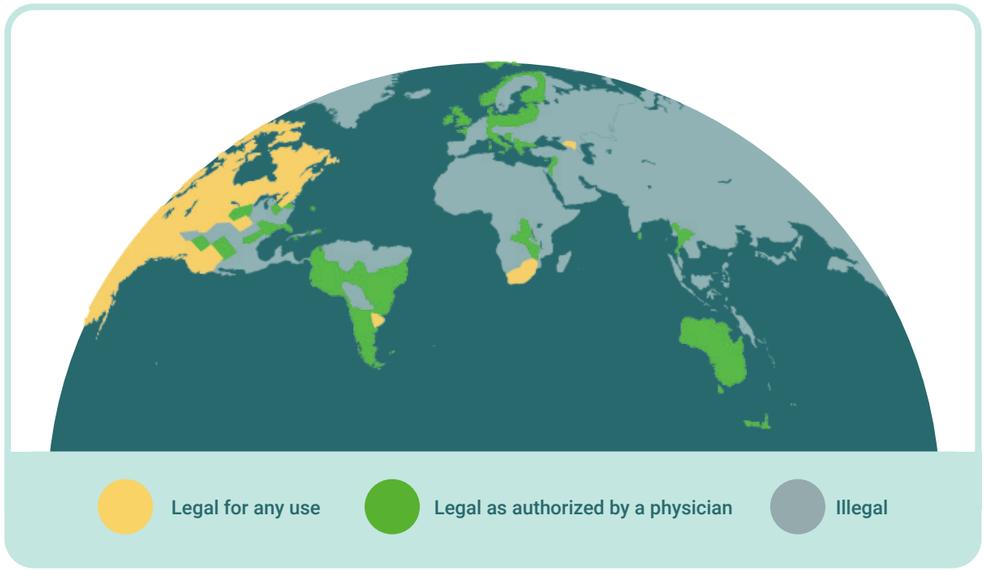
EXECUTIVE SUMMARY

The recognition that cannabis has medicinal properties, and a role in the mix of medical treatments, has spread across the globe in recent years. As a result, an increasing number of jurisdictions have legalised access to it to varying degrees. Currently, this comprises over 50 countries, including Canada, Australia, Germany and over half of the US states. This increased recognition and legalised access has resulted in a global medicinal cannabis industry currently estimated to be worth £16.5 billion now and reaching to over £55 billion by 2027.[1]



The recognition of the medical properties of cannabis has come relatively late in the day to the UK. This late recognition combined with a restrictive and cautious approach means that the UK is at risk of missing out on the commercial and industrial benefits of this rapidly developing sector. The situation is further compounded by the fact that:

a. responsibilities relating to medicinal cannabis are spread across several Government departments and agencies resulting in an incoherent Government approach; and

b. the various UK regulatory authorities are still in the early stages of changing their guidance to recognise that investment in, and the running of, medicinal cannabis enterprises and organisations has become a legitimate exercise.

[1] Prohibition Partners – Global Cannabis Report 2019

For this reason, this paper sets out ten recommendations that should be implemented if the UK is to avoid missing out on commercial, industrial and patient benefits of a medicinal cannabis industry. These include:

- Summary Recommendation: Establishing a new "Office for Medicinal Cannabis" to bring together the various regulatory responsibilities and oversee the implementation of these recommendations.

1

Reform the high-THC cultivation / controlled drugs license system for medicinal cannabis to make the process simpler and speedier.

2

Allow the cultivation of hemp flowers in order to extract CBD under an Industrial Hemp (low THC) license.

3

Increase the THC limit for approved hemp seeds from 0.2% to 1% to align with international competition and allow a far greater variety of cultivars for farmers and ultimately the public. All industrial use hemp crops should be exempt from licensing.

4

Review the Human Medicines Regulations 2012 to allow CBD product suppliers to make justifiable medical and wellness claims.

5

Ensure that the FCA's guidance on allowing cannabis-related companies to float on the LSE continues unencumbered.

6

Reform the Proceeds of Crime Act 2002 to ensure it is fit for the UK's legal medicinal cannabis market.

7

Ensure the application of the Novel Foods Regulations to cannabis-related wellbeing supplements does not impinge upon smaller market participants. Hemp extracts produced using food safe techniques and designed for food supplement use should be exempt from Novel Foods regulations and be removed from the Misuse of Drugs Act. Synthetic CBD and isolated CBD should remain Novel.

8

Reassess the NICE guidelines. Reconvene with a new panel that should include academics and medical practitioners and cannabis experts not only from the UK but abroad, from countries where cannabis research is more advanced and it is accepted as a medicine.

9

Encourage wider, appropriate patient access by allowing General Practitioners to prescribe medicinal cannabis.

10

The Government should conduct or contract for a proper and thorough health economic analysis of the cost of introduction of medicinal cannabis and hemp flowering tops in the UK.

The UK has a strong reputation across a swathe of medical fields. However, without urgent action along the lines of the recommendations set out above, it risks missing out commercially, industrially, and in terms of patient benefit, in this rapidly developing sector.

INTRODUCTION

Maple Tree Consultants and Mackrell.Solicitors have produced this authoritative report on the need for a strong UK medicinal cannabis market.

The coronavirus pandemic has disrupted the business landscape in ways that were unthinkable just a year ago. The Government lockdowns have put the brakes on everyday business life, which is affecting even the most profitable sectors and has plunged the UK into the deepest recession since records began. Economists have warned that the 'worst is yet to come' after redundancies in the three months to November 2020 reached a record high of 14.2 per thousand.[2]

With the economy in real difficulty and unemployment rates likely to climb higher, there has never been a more urgent need to grasp the opportunities that emerging lucrative markets can offer by providing support now.

One such market is the medicinal cannabis industry. Despite being one of the most tightly regulated and restricted industries in the UK, the sector has undeniable potential. Clinical trials and academic studies are expanding, and our understanding of the cannabis plant is continuously evolving. In parallel, market opportunities are developing in the industry as creativity, funding and technology expand.

Yet as it stands, there are many restrictions on full medical access due to unclear Governmental bureaucracy, a lack of medical education, and restrictive guidelines by The National Institute for Health and Care Excellence (NICE) and other bodies. Since the law change of 1st November 2018, the regulatory hindrance has had severe repercussions for the industry as well as for UK patients in need of medicinal cannabis.[3] The process for cultivation and extraction license applications regarding cannabis products is convoluted, confusing and time-consuming.

There are about 1.4 million people in the UK who currently use cannabis for medical purposes.[4] However, in the two years since legalisation, there have been only three NHS prescriptions for full-spectrum cannabis products and only about 6000 in the private sector.[5] The latter remains expensive and unaffordable for many who would benefit from less restrictive access.

The UK medicinal cannabis industry finds itself in serious risk of being subject to a pharmaceutical monopoly, as the current regulations favour the large pharmaceutical companies, who have the resources to adhere to them. The issue stems from the misconception of medicinal cannabis being a single pharmaceutical product. But it is not. Cannabis is a botanical plant made up of 100s of compounds, many producing various medical benefits, and we do not yet have the regulatory system to reflect this reality. Clearly, the opportunity here is to nurture and grow a truly domestic industry that can provide not only assistance in the recovery of an ailing economy post-Brexit and post-Covid but also serve to be a pioneer in the medicinal cannabis sector globally.

This Discussion Paper exposes gaps in the Government's policies on medicinal cannabis and details how the emergence of a legal medicinal cannabis industry would help fill these gaps and stimulate the UK economy post-pandemic and in the aftermath of Brexit. Our intention is to summarise concisely the complex issues cannabis businesses face in the UK whilst calling upon the Government to make meaningful, progressive changes to the outdated laws and regulations hindering the industry.

This Discussion Paper is designed to stimulate debate. We hope that the Government takes notice of the report and opens discussion on the necessary detail that lies behind these Recommendations.

[2] https://www.ons.gov.uk/employmentandlabourmarket/peoplenotinwork/redundancies
[3] See here for further articles on issues with supply
https://metro.co.uk/2020/12/27/families-still-pay-thousands-for-medicinal-cannabis-2-years-after-legalisation-13783161/
https://www.bbc.co.uk/news/uk-england-coventry-warwickshire-55558094
[4] Research by Centre of Medicinal Cannabis and YouGov https://www.healtheuropa.eu/brits-using-street-cannabis-to-treat-chronic-health-conditions/94751/
[5] Information from The Medical Cannabis Clinics Ltd and the UK Medical Cannabis Clinicians Society

THE REPORT STRUCTURE

This report will provide a comprehensive investigation into the state of the cannabis industry in the UK and will be structured into three chapters, addressing the following areas:

1 **The current state of play in the UK cannabis industry – an outline of the current legal landscape and state of play for the industry as a whole.**

2 **The potential value of an established medicinal cannabis industry post-pandemic and post-Brexit – this chapter investigates evidence of the value and growth of the cannabis market, exploring the potential benefits for the post-pandemic economy, not often considered in the mainstream discourse surrounding cannabis.**

3 **Recommendations and calls to action for the Government – a summary of the detailed recommendations for the Government to consider when discussing the cannabis industry.**

Appendix – A explanatory introduction to medicinal cannabis and relevant terminology.

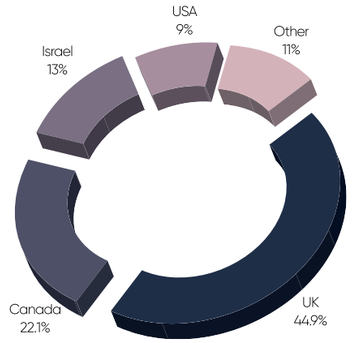
CHAPTER ONE:
THE CURRENT STATE OF PLAY IN THE INDUSTRY

1.1 Medicinal Cannabis in the UK - current status

Unbeknownst to many, the UK is one of the largest exporters of medicinal cannabis in the world. Despite this, and the fact there is a huge need amongst the British population for cannabis-based medicines, the UK currently imports 100 per cent of its medicinal cannabis. The situation surrounding CBD is equally baffling. Although the UK has a growing CBD market, already worth £300 million in 2019,[6] the great majority of CBD products on British shelves come from foreign sources.

In this chapter, we will look at the current state of the cannabis industry in the UK and the benefits that a fully domestic industry would bring.

Medicinal Cannabis in the UK – where we currently stand



In 2016, the UK's production of legal cannabis accounted for 44.9 per cent of the world total.[7] Leading market intelligence firm Prohibition Partners predicts the worth of the global medicinal cannabis market will reach $62.7bn (£48.5bn) in 2024.[8] Therefore, so long as the Government continues to support the production of medicinal cannabis products, the UK has the potential to take a similar percentage of the market.

This poses the question: as the market grows, will the UK be able to keep up?

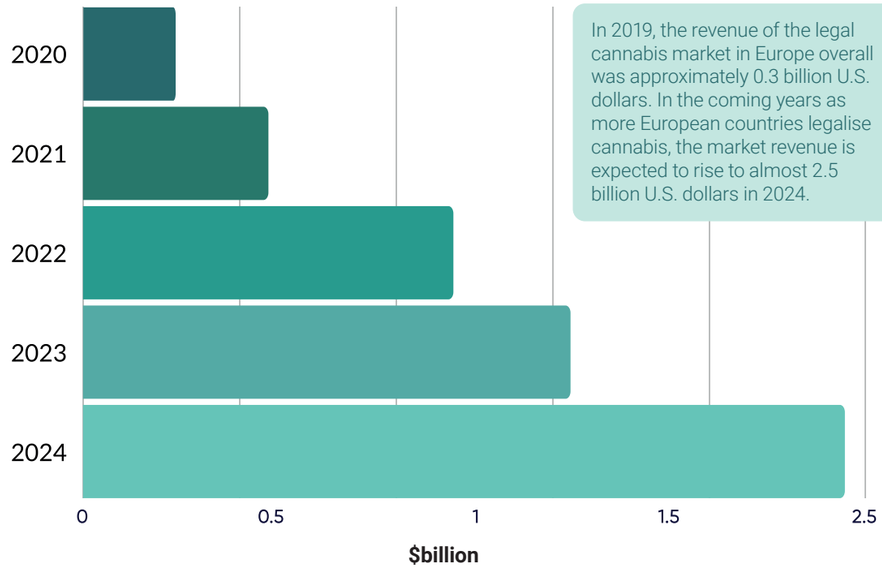
[6] https://www.savills.co.uk/research_articles/229130/296363-0#summary
[7] http://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2017/7_Part_2_comments_E.pdf
[8] https://prohibitionpartners.com/2019/11/07/key-insights-from-the-global-cannabis-report/

Currently, production within the UK is confined to one main grower – British Sugar – and one main producer – GW Pharmaceuticals. In 2016 the UK was supplying 44.9% of the reported world total of legal cannabis, yet this relates almost solely to two products, Sativex and Epidiolex.[9] These two products are licensed for use in the UK, to treat the common MS symptom of spasticity and specific forms of epilepsy. However, they are rarely used by the internal UK market – medicinal cannabis patients are usually prescribed full-spectrum products, but these are not produced in the UK.

One reason for this, is the real difficulty of obtaining a growers high-THC growing license from the UK Home Office. As of October 2019, there were just 19 extant licenses to cultivate high-THC cannabis in England, Wales and Scotland, and many of these are owned by GW Pharmaceuticals.[10] This is a pitiful number, considering applications to the Home Office to grow cannabis for medical purposes have been open for several years. To summarise, the picture is bleak. Despite the UK having a reputation as a globally dominant medicinal cannabis producer, almost all of the medicinal cannabis products prescribed in the UK have, to date, been imported. The result – dissatisfied and desperate patients, who even after being lucky enough to receive a medicinal cannabis prescription face high costs and long waiting times, this leading to frustrated businesses, and severely hampered economic prospects.

The UK is a world leader with a global reputation in pharmaceuticals, so there is a strong argument that if we were able to both develop and export more cannabis-based medicines, we could continue to be a global leader and increase our market share even further.

Annual legal cannabis market revenue in Europe from 2020 to 2024



In 2019, the revenue of the legal cannabis market in Europe overall was approximately 0.3 billion U.S. dollars. In the coming years as more European countries legalise cannabis, the market revenue is expected to rise to almost 2.5 billion U.S. dollars in 2024.

[9] https://news.sky.com/story/uk-is-worlds-largest-producer-of-legal-cannabis-11278131
[10] Official reporting from the Home Office, 29 November 2019

1.2 CBD in the UK - current status

Industrial hemp has a long and uneventful history in the UK. For many years, it had been considered an uncontroversial crop – simply a harmless strain of the cannabis plant, without a street value due to its minute traces of THC. Its stalks are used for industrial items such as rope, clothing, shoes and building materials such as insulation, and its seeds to sprinkle on your salad.

However, hemp contains another cannabinoid: cannabidiol, or CBD.

CBD mania started in the USA and Canada in 2018 and the trend was quick to make its way over to the UK. The growth rate has been incredible – according to Prohibition Partners, the UK's CBD market was worth £300 million in 2019, making it the second largest market globally. This figure is expected to reach £1 billion by 2025.[11]

As the market continues to grow, hemp farmers and others looking to get into something new, had high hopes of turning their crops into extraordinary yields of CBD, at a crop value of £10,000 per acre. This is certainly far more appealing than the average of £400 per acre of wheat and £1,000 per two acres of industrial hemp.[12]

However, UK law will not allow the production of hemp without a license. Under the term of this law, the stalks of the hemp plant can be used for textiles and the seeds for food products, but its flowers and leaves must be destroyed – and that's where the CBD resides.[13]

The result is that despite the UK having a growing CBD market, (a YouGov poll published in October 2019 estimated 11% of UK adults had tried a CBD product), the great majority of CBD products on British shelves come from foreign sources.[14] Of course, we can't deny that wholesalers and retailers are making margins on imported CBD products, but much of the sale price comes from the production of the plant itself. Currently, despite the domestic demand for CBD products being quite substantial, this income is almost entirely lost to abroad.

[11] https://prohibitionpartners.com/2019/11/07/key-insights-from-the-global-cannabis-report/
[12] https://www.ft.com/content/d37e21ae-3d14-11ea-b84f-a62c46f39bc2?accessToken=zwAAAXX7bu_okdPTfiGuPRQR6tO4T6YsRvObwg.MEQCIHqbSqYm4fKu0KQowy03EGX6Rjist2qUiGeYenFOKvcQAiAMOPikJ9ZaiU4ZoviSEoKmrbZYLThl80LnEJ6G596TpQ&sharetype=gift?token=6ed38b34-4c7d-47a6-b4f2-5b56f985ae86
[13] https://www.gov.uk/guidance/controlled-drugs-industrial-hemp
[14] https://yougov.co.uk/topics/health/articles-reports/2019/10/18/quarter-britons-tempted-cannabis-extract-products

The UK's CBD market is expected to reach

£1 BILLION BY 2025

but this figure is almost entirely lost to abroad

11%

of UK adults have tried a CBD product (2019)

1.3 The UK's legal position on medicinal cannabis

Cannabis, cannabis resin, cannabinol and cannabinol derivatives are all substances of Class B (controlled drugs) under Part II, Schedule 2, the Misuse of Drugs Act 1971 ("MDA 1971") and Schedule 1 substances under the Misuse of Drugs Regulations 2001 ("MDR 2001") (where not presented as CBPMs). Some of the controlled cannabinoids within the cannabis plant include the commonly known psychoactive cannabinoids THC, THCV and CBN, as well as their derivatives.

Section 37 of the MDA 1971 defines cannabis as[15]:

> *"Any plant of the genus Cannabis or any part of any such plant (by whatever name designated) except that it does not include cannabis resin or any of the following products after separation from the rest of the plant, namely —*
>
> **(a) mature stalk of any such plant,**
>
> **(b) fibre produced from mature stalk of any such plant, and**
>
> **(c) seed of any such plant;"**

Therefore, only the buds, flowers and leaves are controlled, the seeds and stalks of the mature plant are not. The definition covers **all** cannabis plants, meaning the hemp plant as well as the high-THC cannabis plant.

The Home Secretary and the Secretary of State for Health and Social Care published details of rescheduling of cannabis on 1st November 2018. The Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015 was amended to allow for the rescheduling of cannabis-based products for medicinal use (CBPMs) in humans to Schedule 2 of the MDR 2001. This meant that from 1st November 2018 there was a legal route for CBPMs to be prescribed by doctors on the General Medical Council (GMC) Specialist Register.

General Practitioners were not allowed to be primary prescribers but could prescribe under the guidance of a specialist for follow-up prescriptions – although very few GPs have issued a prescription for an unlicensed CBPM (probably just three in the entire UK). Specialist doctors can prescribe for any condition but are hampered, particularly in the NHS, by restrictive guidance issued by the National Institute for Health and Care Excellence (NICE) and some medical establishment bodies. About 6000 CBPM prescriptions have now been issued in the private sector (as at March 2021) and three in the NHS. This excludes GW Pharmaceutical's Epidyolex and Sativex and is believed to be made up of mostly whole plant/full spectrum products.[16]

[15]https://www.legislation.gov.uk/ukpga/1971/38/section/37
[16]Circular 018/2018: rescheduling of cannabis-based products for medicinal use in humans - GOV.UK (www.gov.uk)

1.4 Industrial Hemp in the UK

Whilst there is a focus on medicinal cannabis, it should not be forgotten that hemp (the variety of cannabis sativa L with a negligible THC content) is a very valuable plant. It has a myriad of uses including paper, rope, cloth, building material (hempcrete), animal food, eradicating toxins from the soil, CO2 removal from the atmosphere, and weed suppression.

1.4.1 Hemp and CBD

Hemp has a higher proportion of CBD and, by definition, very low THC. It is also relatively low in other minor cannabinoids and terpenes, compared to the "high-THC" strains. However, hemp-based CBD still has medicinal value and can be legally sold over-the-counter in the UK.

Any CBD containing end-product, such as an oil, extracted from hemp, can only be legally sold if it falls under the definition of an "Exempt Product" in the MDR 2001. The definition of an Exempt Product is:

> ***An "exempt product" means a preparation or other product consisting of one or more component parts, any of which contains a controlled drug, where— a) the preparation or other product is not designed for administration of the controlled drug to a human being or animal; b) the controlled drug in any component part is packaged in such a form, or in combination with other active or inert substances in such a manner, that it cannot be recovered by readily applicable means or in a yield which constitutes a risk to health; and c) no one component part of the product or preparation contains more than one milligram of the controlled drug.***[17]

The final element is an odd requirement as the 1mg rule applies regardless of the size of the container and sometimes it is hard to ascertain whether an end product does contain 1mg or less. A further dilemma arises when a producer is importing or producing CBD products in bulk. The accumulation of the amounts of cannabinoids contained in the bulk "container" (as a result of the upscaling) will inevitably increase exponentially, thus making it practically impossible for an importer or producer of CBD products to adhere to the Exempt Product criteria throughout their production process.

Furthermore, it is advantageous for industrial hemp to only be grown from the limited number of seeds that appear on the EU Plant Variety Database, as seed types appearing on this database are eligible for subsidies. There is, however, no legal requirement to restrict use to such EU approved seeds - and yet the UK Home Office requires, in the application for an industrial hemp cultivation licence, that only seeds from this EU approved database can be used.[18] We suggest that non-EU seeds should be allowed under UK hemp regulations and not just those that appear on the EU Plant Variety Database, as subsidies are not relevant to all cultivators, and many would benefit from a wider choice of seed types from which to cultivate.

Another issue is that of THC thresholds that apply to the seeds. The seeds listed on the EU Plant Variety Database, by definition, should not produce a plant that contains more than 0.3% THC; however if the limit was increased to just 1% then this would hugely expand the variety of cultivars available and make our hemp industry highly competitive internationally.

[17]https://www.gov.uk/government/publications/cannabis-cbd-and-other-cannabinoids-drug-licensing-factsheet/drug-licensing-factsheet-cannabis-cbd-and-other-cannabinoids
[18]EU Plant variety database (v.3.2.1) (europa.eu)

1.4.2 Industrial Hemp Cultivation Licence

One of the pre-requisites for the cultivation of industrial hemp in the UK is an Industrial Hemp (low THC) Licence from the Home Office. In the UK, hemp is allowed to be grown for industrial application using only the non-controlled parts of the plant, the fibre and seeds. The "controlled" parts of the plant (leaves and flower) must be destroyed on site, as an industrial hemp licence does not allow for their possession or supply. The Home Office produced a fact sheet on the licensing process.[19] Again, this application process can be long and convoluted with applications taking in excess of 12 months. In order to streamline this process we suggest that hemp cultivation, except for flower production, be removed from the need for a Industrial Hemp licence.

As of early 2020, only 31 low THC licenses had been issued by the Home Office.[20]

1.4.3 Medicinal Claims for CBD Products

A (hemp) CBD product producer is legally prohibited from making any medicinal claims about its product which makes it difficult for the consumer to know what type of product to buy and what size of dose to take.

Medicinal products are regulated by the Human Medicines Regulations 2012 ("HMR 2012"). The UK regulator, the Medicines & Health products Regulatory Agency ("MHRA") has determined that CBD is itself a medicine, but as long as medicinal claims are not made about it on any product packaging or linked marketing, then they will not intervene.[21] Some of the references that may amount to medicinal claims are:

- references to medicinal conditions
- comparison with licensed medicines
- references to interference with the normal operation of a physiological function
- product names which refer to adverse medicinal conditions
- references to medicinal and / or clinical research and testing
- references to the health risks of not taking a particular product
- editorial medicinal claims
- recommendations by Doctors/health professionals
- testimonials that include/imply medicinal claims
- graphics that imply medicinal uses
- references to or reproduction of "generic" information
- juxtaposing with any examples of the above
- inclusion of details in an Ailments Section.

General claims that a product can "cure", "restore", "prevent", "avoid", "fight" or "heal" are likely to be considered as medicinal as well. Making such claims without authorisation is prohibited under Regulation 279 of the HMR 2012.

[19]https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/919292/Hemp-_FAQs-Grower_notes-2020.pdf
[20]official government statistic issued by the Home office Drugs and licensing unit November 2019
[21]Page 8 of the MHRA Guidance Note 8 on Medicinal Products https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/872742/GN8_FINAL_10_03_2020__combined_.pdf

1.4.4 CBD Novel Food applications

Under the Novel Food Regulations ((EU) 2015/2283) (the "NFR"), specifically Art.3 of the NFR, the definition of novel food means food that was not consumed by humans to a significant degree within the EU before 15th May 1997. The NFR requires that novel foods be authorised at European Community level and provides an authorisation procedure by way of keeping a 'Union List' (better known as 'Novel Foods Catalogue').

Until January 2019, Cannabis Sativa L was not considered to be a novel food (subject to the levels of cannabidiol not being higher than the CBD levels in the source i.e. Cannabis Sativa L).

In January 2019, it was decided that the NFR reference to Cannabis Sativa L should be extended to include the entry of cannabinoids. The EU implemented this by amending the Novel Foods Catalogue to include extracts of Cannabis Sativa L and derived products containing cannabinoids (as well as CBD itself). With this amendment, and currently, any cannabis extract would be considered novel. Only cold compressed Hemp seed oil is considered not novel and consequently authorisation is not required.[22]

In the UK, the Food Standards Agency ("FSA") regulates the UK food market generally to prevent harm to public health and ensure consistent quality and standards are maintained. On 13th February 2020, the FSA released a statement in relation to the novel food authorisation process and provisional guidelines for the safe consumption of CBD.[23] It advised that vulnerable groups (without further definition on what constitutes 'vulnerable') should not take CBD, and healthy adults should not take more than 70mg a day. There is no valid basis for this assertion and indeed the generally accepted medicinal dose for an adult is around 60-100mgs daily and hence often above this arbitrary 70mg limit.[24] The FSA further stated at that time that businesses must have a validated application by 31st March 2021, or those products already being sold (as or before 13th February 2020) would be removed from the shelves.

At the time of the above statement the UK was still in the Brexit transition period and all Novel Food Applications were required to be made to the EU Commission (European Food Safety Authority). Since 1st January 2021 the FSA has been accepting such applications on its portal and is the appropriate body for Novel Food applications in England and Wales.

The FSA and the Home Office have stated they do not consider CBD to be a narcotic and that they will be formally processing novel foods applications in relation to CBD related food products.[25] However, the FSA limited themselves to a very tight window of 3 months (January to 31st March 2021) in which to process such applications and have them validated.

In addition the FSA seems to have created a monopoly for those companies that were selling their CBD food products as or before 13th February 2020.[26] Our reasoning for this is because the current application process has created two situations:

1. An applicant (Business A) has had their product on the shelf on or before 13th February 2020, they submit an application before 31st March 2021 with the FSA, which the FSA accepts was of sufficient standard to progress to the next stage of the application process (validated), Business A in this situation will be permitted by the FSA to continue selling its products to the public.

2. You have a situation where another applicant (Business B) which has an identical product, to that of Business A, which was never sold in the UK within the period identified by the FSA (on or before 13th February 2020), makes an identical application to that of Business A, which is validated and moved onto the second stage of the process but yet - Business B would have to wait until they had been granted full authorisation by the FSA before selling their product to the public, which could take a minimum of 18 months.

The two possible scenarios identified above, cause further concern by the fact that Business A would not at first instance, need to supply any toxicology data in respect of its products linked to its application, as it is still unclear what safety and toxicity data is required to accompany the application. On this particular issue, it is understood that the FSA is awaiting policy guidance from the Committee of Toxicity (CoT) in association with the Advisory Committee on Novel Foods and Processes (ACNFP). Whilst the FSA has outlined the need for toxicology tests, it still awaits clarification from the CoT on what tests must be done.[27]

Yet, Business B's application could be supported with full toxicology data and other safety data, they would still not be able to sell their products to the public until full authorisation is obtained. It is clear to us that this is not a fair playing field for applicants, and it is unclear who the FSA is attempting to safeguard. Surely the position should have been that all applicants who submitted a validated application should have been permitted to sell their products. We would not be surprised if businesses in a similar position to that of 'Business B' attempt to challenge this via Judicial Review.

Although it was clear to many that the FSA had given themselves a tight deadline (3 months) to review and accept novel food applications for those businesses wishing to continue to sell their products beyond 31st March 2021, they stood by their decision and repeatedly kept saying to the CBD industry that applications would need to be in by mid-February 2021 so to afford them time to review and validate applications by 31st March 2021. However, on the morning of 11th March 2021 the FSA announced that applications no longer needed to be 'validated' but 'submitted' by 31st March 2021. Their press release stated:

"The criteria for products which can remain on sale from 1st April 2021 has been updated. Previously, only products which were on sale at the time of the FSA's announcement (13th February 2020) and were linked to an application which had been validated by 31st March 2021 were to be included. To maximise the opportunity to pass validation, this now includes all products on sale on 13th February 2020 and linked to an application submitted before 31st March 2021 that is subsequently validated."[28]

it is estimated by many in the industry that the full Novel Food application process is likely to cost in excess of £300,000. This is an expensive process which the majority of businesses in this industry just do not have.

The current state of play with regard to a Novel Food application is fraught with confusion. It is clearly a very expensive and time-consuming process which will drive medium and small CBD companies out of business – at a time when we need to encourage a new and profitable sector.

[22] https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32015R2283
[23] https://www.food.gov.uk/news-alerts/news/food-standards-agency-sets-deadline-for-the-cbd-industry-and-provides-safety-advice-to-consumers
[24] UK Medical Cannabis Clinicians Society correspondence
[25] just-food.com
[26] https://www.food.gov.uk/business-guidance/cannabidiol-cbd
[27] https://businesscann.com/uk-regulators-confirm-testing-guidelines-for-cbd-safety-studies/
[28] https://www.food.gov.uk/news-alerts/news/update-to-criteria-of-cbd-products-which-can-remain-on-sale-from-1-april-2021

1.4.5 CBD Cosmetic Products Regulation

The legislation concerning cosmetics is Regulation (EC) No. 1223/2009 ("the EU Cosmetics Regulation") and Schedule 34 of "The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019. In these regulations, a cosmetic product is defined as:

> ***"any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;"***

Only products that meet the above definition will be regulated by the EU Cosmetics Regulation. The cosmetic ingredients database is the EU's official database for cosmetic ingredients, as of 2nd February 2021 the cannabinoid has been added to the database.[29] Cannabidiol in and of itself (CBD), irrespective of its source, is not listed in the Schedules of the 1961 Single Convention on Narcotic Drugs ("the UN Convention"). However, an ingredient is still prohibited from use in cosmetic products (Annex II of the EU Cosmetics Regulation) if it is a "narcotic".

A "narcotic" is defined as "All substances listed in Tables I and II of the single Convention on narcotic drugs signed in New York on 30th March 1961".[30] Under Table 1 of the UN Convention is included "cannabis" and "cannabis resin", but also "extracts and tinctures of cannabis". However, under the UN Convention, "cannabis" is defined in Article 1 as:

> ***"the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.[31]"***

However, in a vote that took place in November 2020 the United Nations voted to remove cannabis from Schedule IV of the Single Convention on Narcotic Drugs, lessening the plant's notoriety. Most recently, too, with the result of the Kanvape case, what previously meant that a cosmetic product is legal to market in the UK and EU if it contains CBD that has not been extracted from the flowers or buds of the plant (hemp or marijuana) OR from the flowers or buds if the resin has already been extracted now means all parts of the plant can be used to extract CBD. Nevertheless, this is completely disjointed from the requirements for other CBD products which simply requires that the controlled substance is limited to the 1 mg rule. It would be far better for the industry if there was some conformity in relation to what could be extracted and the levels of controlled substances, at least that way there would be less confusion and this, in turn, would be far more cost effective for manufacturers / producers as they would not be limited by these unfair and irregular differences.

[29]https://ec.europa.eu/growth/sectors/cosmetics/cosing_en
[30]https://www.incb.org/documents/Narcotic-Drugs/1961-Convention/convention_1961_en.pdf
[31]http://www.ecad.net/uncd-english/84-un-convention-on-drugs-1961

1.4.6 Vaping Products Regulation

The vaping sector is regulated by the Tobacco and Related Products Regulations 2016 ("TRPR"). Part 5 of the TRPR covers herbal products for smoking. A herbal product for smoking is defined in the regulations as follows:

> ***"a product based on plants, herbs or fruits which contains no tobacco and that can be consumed via a combustion process".[32]***

Given this product will not be consumed through the process of combustion (i.e. a process of burning like traditional cigarettes); it cannot be a "herbal product for smoking" and will not be subject to TRPR Part 5. Part 6 on e-cigarettes will only apply where the e-cigarette can be used for the consumption of a nicotine containing vapour.[33]

1.5 Growing high-THC cannabis in the UK

Specific licenses are required for companies that wish to grow a cannabis plant containing a controlled cannabinoid for medical use, and further licences will be required to produce and market the active ingredients, and the final cannabis based medicines. The main controlled cannabinoid is THC but cannabinol (CBN) is also controlled, as are several other THC and CBN type cannabinoids.[34] The application process is long and complex. It requires an application for a **Controlled Drugs License** and although the Home Office has granted these licenses, they are few and far between.[35] The applicant will need to register with the MHRA to manufacture, import or distribute (as appropriate) an **Active Pharmaceutical Substance (API)**, and if the applicant wishes to produce the cannabis based medicines themselves, they will also need a **Manufacturer's Specials License** as the MHRA will want to ensure that the product complies with **EU GMP** standards.[36] To sell or supply medicines to anyone other than the patient using the medicine, a wholesaler licence – also known as a **Wholesale Dealers Authorisation** or **WDA** will be needed to ensure that applicant complies with good distribution practice.

There are many requirements in these applications. For example, all movements and transactions concerning the cultivated crop must be accounted for, as well as how and when the destruction of excess produce will occur. Security is often a chief concern and must also be considered within the proposal. Guidance on the content of this plan is sparse and frankly unclear for businesses who wish to acquire one.

[32]https://www.legislation.gov.uk/uksi/2016/507/regulation/2/made?view=plain
[33]https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products
[34]https://www.gov.uk/government/publications/cannabis-cbd-and-other-cannabinoids-drug-licensing- factsheet/drug-licensing-factsheet-cannabis-cbd-and-other-cannabinoids
[35]https://www.gov.uk/guidance/controlled-drugs-domestic-licences
[36]https://www.gov.uk/guidance/apply-for-manufacturer-or-wholesaler-of-medicines-licences
[37]https://www.gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice

1.6 Summary of the state of play

This chapter has highlighted that the legal landscape for CBD products and medicinal cannabis remains laden with regulatory issues, as well as an almost complete absence of clarity and guidance from the Government. Consequently, the cannabis industry is being held back and there is a real and damaging lack of access for patients in need of these products across the UK.

The Home Office reiterates that they do not wish to be too prescriptive in the requirements to apply for the various cultivation and control drugs licences available. However, the fact is that the lack of detailed guidance gives the Home Office more scope to reject applications as the officers appointed to review the applications may not have been given the adequate education for them to fully assess these applications.

CHAPTER TWO:
THE NEED FOR AN ESTABLISHED MEDICINAL CANNABIS MARKET

Despite being one of the largest exporters of medicinal cannabis across the world, the UK currently imports 100% of its cannabis-based medicines.[38]

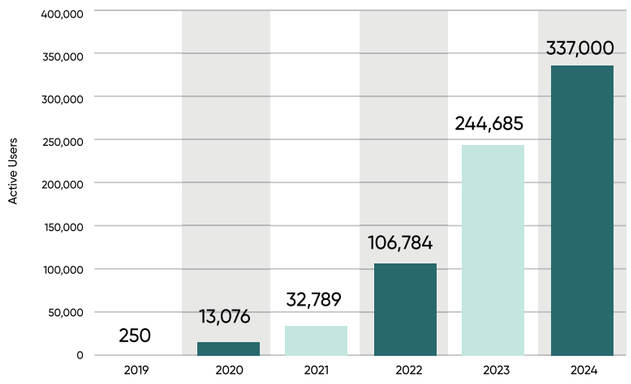
In this chapter, we will look at the plethora of benefits in the creation of a fully domestic industry would bring for medicinal cannabis patients, employment, investors and the economy alike.

2.1 Medicinal cannabis - potential market worth

To determine the need for an established domestic market, there first needs to be an assessment of the potential domestic customer base. According to The UK Cannabis Report by Prohibition Partners, by 2024, there will be around 337,000 potential medicinal cannabis patients in the UK, representing a potential economic value of $1.3 billion (£1 billion).[39] This alone is an impressive figure, but it is only half the story.

In fact, there are approximately 1.4 million people in the UK (just over 2% of the population) using cannabis illegally for medical reasons[40], due to the inaccessibility of the drug. This figure may seem high, but there are a huge number of groups in need of medicinal cannabis products; people with epilepsy, MS, people with mental health disorders such as anxiety and depression and those suffering with any kind of chronic pain. Also remember there are potentially many more people who would benefit but do not wish to criminalise themselves by buying products on the black market.

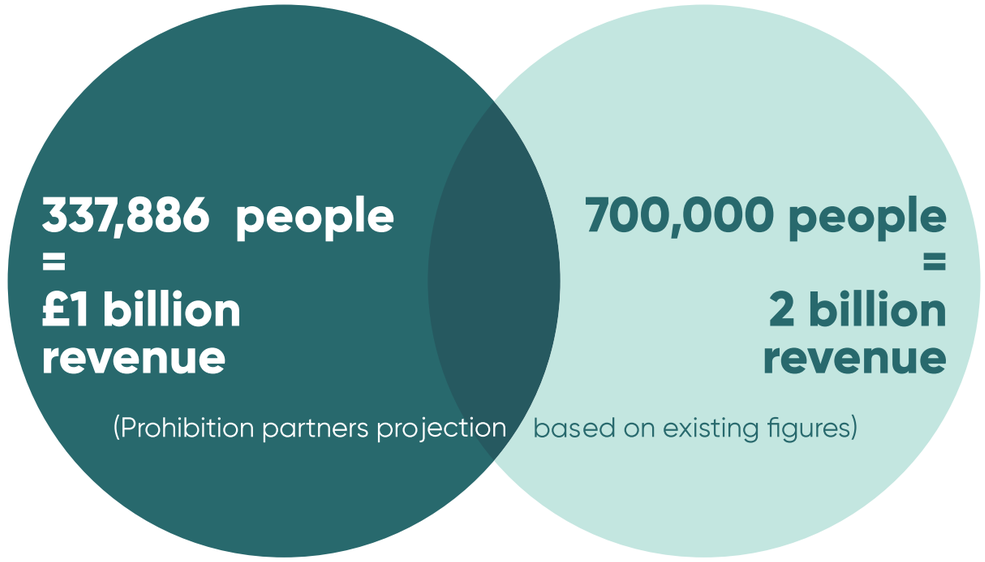
If Prohibition Partners is correct that around 337,000 patients could represent a total revenue of £1billion, then if even half of the suggested 1.4 million people were to be granted a justifiable medical prescription, the potential value would actually be somewhere in excess £2 billion.



Number of active medicinal cannabis patients in UK from 2019 to 2024 on existing trajectory

- From 250 in 2019 to approx. 337,000 in 2024

[38]https://www.consultancy.uk/news/23334/legal-cannabis-market-of-uk-could-pass-2-billion-mark-by-2024
[39]Prohibition Partners, UK Cannabis Report, December 2019
[40]https://www.independent.co.uk/life-style/health-and-families/cannabis-medicinal-uk-health-chronic-conditions-street-yougov-a9198081.html



This significant amount of money is well within the UK's grasp – but, as discussed in chapter one, this is currently being hindered by the licensing process required to grow cannabis plants. If the UK is to capitalise on the opportunities within the medicinal cannabis industry, the Home Office policies and procedures for budding growers and producers must be reconsidered.

The USA is a good example of how relaxing laws to allow for the creation of a domestic market can lead to substantial tax revenues for governments. Looking at Oklahoma as a specific example - the state has a population of approximately 4 million people and since legalising medicinal cannabis in 2018, is already generating $30m per annum in tax from medicinal cannabis.[41] If extrapolated to the UK population, with a population of 66 million people, this would mean an income of $495m per annum, an amount which should be looked upon favourably by a Government on track to hit a peacetime deficit record. These figures are dwarfed by the tax revenue in the US States where cannabis is also legal for recreational use. For example, in Colorado, which has a population of 5.7 million, over $1billion of sales were generated in 2019[42], with over $250m in tax income.[43] For another interesting comparison, look to Australia. The country's medicinal cannabis industry is generating a huge amount of money. Recreational cannabis is still illegal (except for the Canberra region), but medicinal cannabis was made legal in 2016. Since then, the industry has completely taken off and is expected to be worth $1 billion within Australia by 2025.[44] In 2019 alone, Australia's medicinal cannabis programme witnessed an annual product sales run rate of approximately USD 50 million in 2019. As of 1st January 2020, 92 licences had been granted to cultivate cannabis in Australia, including 31 for commercial cultivation, 20 for research and 41 for production of medicinal cannabis products.[45] All this has been achieved in the four short years since legalisation in Australia – if the UK Government was to simplify the currently cumbersome process of license application, there is potential for similar levels of industry development and growth on home soil.

In Germany, where medicinal cannabis was legalised in 2017, the market has grown at an impressive pace. Part of the German market's success can be attributed to the Government's commitment to creating a solid framework for domestic cultivation. BfArM's (German Federal Institute for Drugs and Medical Devices) dedicated cannabis agency has gone on to create a one-step application process for tenders to obtain locally grown cannabis. In addition to this, applicants need only have experience in growing and processing medicinal plants, which has opened up opportunities to many agriculturists and the limit has been raised on how much cannabis each licensed cultivator can produce. Germany hopes to cultivate 6.6 tonnes of cannabis domestically by 2022.[46] Aurora, Aphria and Demecan delivered their first German harvest in 2020 with production of some 10,400 kilograms expected by 2023. This is hoped to reduce Germany's reliance on imported products and improve access to domestically produced cannabis for Germany's 60,000 strong patients.[47]

It could be argued that as an increasing number of nations are starting to produce cannabis products to GMP standard, then there is potential for these to be imported, meaning the UK would not retain all income related to the value of the domestic market. However, there are further arguments for a domestic industry aside from the potential economic value.

2.2 Securing the supply chain

Aside from the economic benefits, there is another important argument for the creation of a domestic industry – patients taking medicinal cannabis products are in dire need of a secure supply chain. If they do not receive their medicines, epileptic children, for example, can become extremely ill very quickly, whilst those using medicinal cannabis for chronic pain will swiftly revert to experiencing disabling symptoms.

During the Christmas week of 2020, this exact situation played out, when the Department of Health announced that medicinal cannabis prescriptions issued in the UK would no longer be lawfully dispensed in EU Member States, due to the end of the Brexit transition period. Delivered to the prescribing doctors of over 40 medicinal cannabis patients, the news came as a bombshell to the families affected, who were effectively given just two weeks' notice before losing access to the life-saving medicine Bedrocan from Holland. Supply chain issues really are a matter of life and death for children depending on medicinal cannabis, which is why a fully domestic industry is so vital.

Furthermore, if patients are affected by poor product availability through a disrupted supply chain, there is risk they will be pushed to the black market, which continues to provide an accessible alternative. Patients are therefore left with a choice – wait in pain for the legal market to fix its supply issues or turn to unlicensed and potentially dangerous products.

2.3 Investment opportunities

In September 2020, medicinal cannabis companies have been cleared by the UK's financial regulator (Financial Conduct Authority) to float on the London Stock Exchange.[48] This gives many investors a significant opportunity to invest in the UK Market, which is welcome news for investors looking for new viable forms of investment revenue which have been impacted due to the pandemic. Three cannabis companies have now listed.

However, there is a serious obstacle for overseas producers looking to make profit from their own legal, recreational market – they must demonstrate that their operations comply with the UK's Proceeds of Crime Act 2002 (PoCA) even though making a profit from the recreational market is legal in that jurisdiction. This is currently hindering progress for cannabis investment opportunities on the UK stock market.

Compare the UK situation to Australia, which has over 30 medicinal cannabis companies currently listed on the Australian stock exchange (ASX), despite medicinal cannabis only being legalised in 2016.[49] This is considerably more than the number of publicly listed cannabis companies in all of the countries of Europe combined.

[41]https://cannabislaw.report/oklahoma-medical-marijuana-generates-34-5-million-in-tax-revenue-for-state/
[42]https://www.cnbc.com/2019/06/12/colorado-passes-1-billion-in-marijuana-state-revenue.html
[43]https://www.mpp.org/issues/legalization/financial-information-on-states-with-adult-use-legalization/
[44]Prohibition Partners, Oceania Report Second Edition
[45]Prohibition Partners, Oceania Report Second Edition
[46]Prohibition Partners, European Cannabis Report, 5th Edition
[47]Prohibition Partners,OceaniaReport Second Edition
[48]https://www.fca.org.uk/news/statements/listings-cannabis-related-businesses
[49]Prohibition Partners, Oceania Report Second Edition

2.4 Job opportunities

There is a potentially huge job market for cannabis related industries, which require farmers, researchers, production workers, accountants, lawyers, IT specialists, financial experts, researchers, and lab technicians to name a few. With unemployment expected to peak at 7.5% in the second quarter of 2021, with around 2.6 million people likely to be out of work, the need for new employment streams is significant.[50]

In the USA, ZipRecruiter highlighted that over the course of 2017 the number of cannabis industry jobs grew by 445%, outpacing both the technology (254%) and healthcare (70%) industries.[51] As more states move towards legalisation and nascent markets become more established, this trend has continued. The US state of Florida, for instance, reported registering 170,000 new patients in 2020 alone and their purchases drove Florida's cannabis industry to a new high of 31,444 total jobs.[52] The state now sells more cannabis products than any other state except California and Colorado, even though it's only legal for medical cannabis patients. If extrapolated to the UK, that is the equivalent of creating over 97,000 jobs. That's more than four times the number employed through the UK's fishing industry (24,000) and is exactly what is needed in the face of an unemployment crisis - plentiful opportunities in an exciting, nascent industry.[53]

97,000
new UK jobs to be expected in the cannabis industry

445%
growth in cannabis jobs in US outpacing technology and healthcare industries

[50]https://www.bbc.co.uk/news/business-52660591
[51]https://www.ziprecruiter.com/blog/cannabis-job-growth-tech-job-growth/
[52]https://www.forbes.com/sites/julieweed/2020/10/02/250000-americans-work-in-legal-cannabis-and-jobs-are-growing/?sh=176305e3a7c0
[53]https://www.bbc.co.uk/news/uk-scotland-scotland-politics-46372153

2.5 CBD / hemp

It is difficult to estimate how much the CBD industry could bring to the economy if licenses were easier to obtain and the whole flower permitted to be used to produce a wider variety of CBD products

However, what we do know is that CBD has huge potential within the UK. The market is already worth £300 million, due to 11% of the British public already using CBD products. If we were able to produce a greater variety of high-quality products here, both for domestic use and for exportation, much more money would be retained within the UK economy, rather than being lost abroad.[54] [55]

The foundations are already there. In 2019, the UK was home to a mere 900 hectares of hemp farmland,[56] used to produce farm products such as rope, textiles and seeds. The Financial Times reported one acre of hemp could be worth £10,000 per annum, so if the whole plant could be used and therefore used to harvest cannabinoids, these 900 hectares (2224 acres) alone could actually be worth over £22 million per annum in revenue.[57] If farmers were able to grow hemp for CBD purposes more easily, it is likely many would choose to do so, and the worth of their land would therefore increase.

Looking to the US as a comparison, hemp was removed from the controlled drug category in the Farm Bill in 2018.[58] In the first year after the law changed, US farmers more than quadrupled the land planted with hemp from 27,424 acres in August 2018 to 128,320 acres in August 2019.[59] If the UK also allowed hemp to be grown for CBD production more simply, it is highly likely more farmers would choose to grow hemp as a valuable and lucrative product. Total sales for hemp-based products in the US were about $1.1 billion in 2018.[60]

In Australia hemp cultivation is also increasing. In June 2019, there were over 90 licensed hemp growers in WA, for instance.[61] In the 2019-20 growing season, approximately 1600 hectares was planted in Tasmania, with a farm gate value of $4.5 million.[62]

Looking closer to home, Switzerland is the place to be if you want to enter the hemp market in Europe. In most European countries, the THC limit is 0.2%, but in Switzerland, this is 1%.[63] This limit, unique to Switzerland, allows the plant to grow to its fullest potential and hence provide the best of its medicinal properties. Additionally, a CBD cultivation license in Switzerland is not needed, meaning in theory, anyone can grow their own CBD hemp plant at home. What is more, no specific license is needed to sell hemp products. This relaxed and open market has allowed for impressive, rapid growth and the economic benefits are strong. The Swiss government imposes a flat tax of CHF (Swiss Franc) 38/kg (USD $40) as well as 25% of the retail revenue. The legal, low-THC market (i.e., under 1% THC) has been booming and shows no sign of abating, bringing in a windfall for the Swiss tax office. In 2018, tax revenue reached CHF 15.1 million (USD $16 million), up 37.8 times from CHF 400,000 a couple years earlier.[64]

[54]https://www.savills.co.uk/research_articles/229130/296363-0
[55]https://newfrontierdata.com/cannabis-insights/value-of-uk-cbd-market-greater-than-that-of-vitamin-c-d-combined/
[56]https://sensiseeds.com/en/blog/how-to-start-a-hemp-business-in-the-uk/
[57]https://www.ft.com/content/d37e21ae-3d14-11ea-b84f-a62c46f39bc2
[58]https://www.fda.gov/news-events/congressional-testimony/hemp-production-and-2018-farm-bill-07252019
[59]https://theleafdesk.com/hemp-becomes-the-fastest-growing-crop-for-us-farmers/
[60]https://www.cnbc.com/2019/05/24/newly-legalized-hemp-industry-set-to-create-a-jobs-boom-in-the-us.html
[61]Prohibition Partners, Oceana Report Second Edition
[62]https://hemptoday.net/tasmania-hemp-fields-grow/
[63]https://newfrontierdata.com/cannabis-insights/swiss-cannabis-market-enjoys-advantages-unavailable-to-eu-competitors/
[64]https://newfrontierdata.com/cannabis-insights/swiss-cannabis-market-enjoys-advantages-unavailable-to-eu-competitors/

Extrapolating the Swiss figures to the UK shows the vast potential there is for any nation whose Government permits the production of a variety of CBD products.

In 2018, the population of Switzerland was 8.48 million people, whilst the UK's was 66.7 million in the same year, so 7.8x larger than that of Switzerland.

In 2018 the Swiss Government collected $16 million in tax revenue from hemp strains.

If the UK was to relax its licencing laws, impose a tax on hemp products and allow for the production of a variety of CBD products (from strains over the 0.2% THC limit currently in place), it could in theory have collected approximately $124.8 million (£113.31 million) in 2018.

Aside from the impressive monetary value hemp can offer, there are also a myriad of environmental benefits to growing this crop. Hemp is arguably the most sustainable and versatile crop farmers can grow - it is robust, fast-growing, requires little water and is even carbon-negative, having been shown to absorb more CO2 per hectare than any forest or commercial crop. What's more, hemp can be used to replace environmentally harmful materials such as plastic and can even replace petroleum as a fuel when converted into biodiesel. All in all, the hemp market has huge potential globally. To catch up with the likes of Switzerland and the US, the UK must relax the laws on the use of the whole plant. The subsequent increase in returns will encourage more farmers to cultivate hemp, which in turn will have huge environmental benefits.

CHAPTER THREE:
RECOMMENDATIONS FOR GOVERNMENT

Overview

The regulatory landscape for medicinal cannabis is currently fraught with problems. Although we have just passed the two-year anniversary of it becoming legal in the United Kingdom, many issues remain prominent in the sector. Namely, the lack of accessible pathways to patient access, a complete lack of confidence offered to physicians in prescribing medicinal cannabis and an incredible amount of latent economic value that has yet to be tapped. With estimates that the UK medicinal cannabis market could be worth over £2.4bn by 2024, almost double the value of the UK's fishing industry, medicinal cannabis has the potential to revolutionise patient care and turbocharge the UK economy post-COVID.[65] [66]

The environment faced by medicinal cannabis producers, suppliers and importers is clearly convoluted at present. Guidance, regulation and legislation span agencies including the Home Office, MHRA, FSA, NICE, the NHS and others. When considering the vast range of hurdles faced by medicinal cannabis companies in providing good quality medicine it is clear that a new approach is required.

[65]https://prohibitionpartners.com/reports/#the-uk-cannabis-report
[66]https://www.dw.com/en/uk-fishing-industry-or-brexits-red-herrings/a-51418061#.~:text=Under%20the%20surface&text=The%20UK's%20fishing%20and%20fish,of%20Commons%20research%20library%20briefing.

1 **Recommendation for Government:**
Reform the high-THC cultivation license system to make the process simpler and speedier. We ask that the Home Office and MHRA work together to produce a simple guide to those applying for high THC cultivation licenses. Those two bodies should streamline and coordinate the application process.

THC Regulation

In order to produce high-THC products a Home Office Controlled Drug License for cannabis cultivation, production possession and supply is required, as well as an MHRA Manufacturer's Specials license. This is a time-consuming and confusing process. Whilst applying for a Home Office license to possess, supply and / or produce controlled drugs is rightly a strict and regulated process, the bureaucratic barriers and confusing process are only likely to lead to smaller market participants deciding to not enter the space. This will have ramifications for competition, investment and patient access to high-THC products.
In order to successfully secure a license, companies must have enough land, infrastructure, established supply chains and distribution routes. Considering this, it is not just the overhead cost of purchasing a significant area of land, greenhouses and irrigation systems but the logistical challenges currently faced in the United Kingdom.

It is well documented that industries dominated by a single company are unlikely to have competitive pricing structures. As such, medicinal cannabis products are unlikely to be seen as commercially/ financially viable by the NHS. It is imperative that the Home Office makes the application process simpler and it must also allow for smaller market participants by making the licensing process and clearer.

2 **Recommendation for Government:**
Allow the cultivation of hemp flowers in order to extract CBD under an Industrial hemp (low THC) license. This will allow farmers and investors to make more advantageous returns on hemp growing and assist with more readily available high CBD medicines and supply for the wellness market.

3 **Recommendation for Government:**
Increase the THC limit for approved seeds from 0.2% to 1% to align with international competition and allow a far greater variety of cultivars for farmers and ultimately the public. All other industrial use hemp crops should be exempt from licensing.

4 **Recommendation for Government:**
Review the Human Medicines Regulations 2012 to allow CBD suppliers to make justifiable wellness claims – and recognise the reality that many hundreds of thousands of people use hemp-derived CBD for wellness and health purposes.

Hemp Regulation

Industrial hemp is a strain of the cannabis plant which contains only traces of THC. As such, hemp is not associated with the black market and instead its stalks are used in a variety of industries, such as clothing and upholstery. However, hemp contains CBD, one substance contained within medicinal benefits of cannabis, yet under the Home Office industrial hemp license required to grow hemp, it is mandated that the flowers and leaves are destroyed. These are the parts of the plant that contain the most amount of CBD.

Hemp's propensity to grow in the British climate makes it extremely viable as the basis for domestically grown CBD medicinal cannabis in the UK. However, in order to do so, it is crucial that the Government reforms Home Office licenses in order for UK hemp growers to extract CBD from the plant. This would radically transform the balance of trade for UK medicinal cannabis, ensuring that the UK is self-reliant and has a thriving industry supporting thousands of jobs. It will also increase patient access as prescriptions become cheaper with a supply of UK products.

The government also needs to reconsider the requirement that only seeds that will grow into a plant with less than 0.2% THC are legal.[67] If that limit was even modestly increased to 1% then the range of cultivars and the choice to the grower and consumer would be increased significantly and allow the UK to compete more readily in the international market.

The CBD market is also hampered by the advertising / marketing restrictions placed upon the industry by the Human Medicines Regulations 2012.[68] This needs urgent revision to enable CBD producers and retailers to make sensible and justifiable wellness claims.

5 **Recommendation for Government:**
Ensure that the FCA's guidance on allowing cannabis-related companies to float on the LSE continues unencumbered.

Legislative barriers to investment

Medicinal cannabis is both cheap and effective for patients in need. However, its development could also be a powerhouse for the UK economy, at a time of incredible need. Recently, the Financial Conduct Authority (FCA) set out its approach in assessing applications by cannabis-related companies for listing in the UK. The news that the FCA is to allow cannabis-related businesses to float on the London Stock Exchange poses one of the most exciting developments in regulation in the last couple of years.[69] Attracting, enticing, and encouraging investment in the UK medicinal cannabis market is one way in which the UK economy can be invigorated post-Brexit and post-Covid. The FCA's ruling will allow larger corporations to enter the space, with the knowledge and means to serve industry needs. At the time of writing three companies with cannabis interests have been admitted to the Exchange.

[67] https://www.euractiv.com/section/health-consumers/news/cbd-is-not-a-narcotic-under-eu-law-highest-court-rules/
[68] https://www.legislation.gov.uk/uksi/2012/1916/contents/made
[69] https://www.cityam.com/medical-cannabis-firm-mgc-pharmaceuticals-to-float-on-lse/

6 **Recommendation for Government:**
Reform the Proceeds of Crime Act 2002 to ensure it is fit for the UK's legal medicinal cannabis market.

At present though, investors remain cautious as whether to enter the space, owing to the risks associated with the Proceeds of Crime Act 2002 (POCA) . As a consequence of POCA,[70] proceeds from overseas medicinal cannabis business may constitute "criminal property" even if fully legal and authorized in the foreign state. POCA was not devised with the modern medicinal cannabis sector in mind.

The bureaucratic nature of POCA means that outside investors with the wherewithal, means and understanding to drive the medicinal cannabis market forwards in the UK are being put off by the prospect of criminal prosecution. With this in mind, it is essential that the Government conducts an urgent review of the Proceeds of Crime Act 2002 and ensures it is fit for the modern landscape in which medicinal cannabis has been legalised.

7 **Recommendation for Government:**
Ensure the application of the Novel Food Regulations to cannabis-related medicines does not impinge upon smaller market participants. The Government is asked to reconsider the need for Novel Foods applications for CBD products or at least to publish a complete process for obtaining an approved application. The current time frame should be extended so as to make it clear which element of the application can be "shared" with other producers and which need to be "producer specific". Hemp extracts produced using food safe techniques and designed for food supplement use should be exempt from Novel Foods regulations and be removed from the Misuse of Drugs Act. Synthetic CBD and isolated CBD should remain Novel.

Novel foods

Although cannabis has been used for thousands of years as a medicinal tool, its regulation is in the early stages of development. As such, CBD products have recently come under the guidance of "novel foods" by the UK Food Standards Agency. This means that CBD products not on sale prior to 13th February 2020 cannot be on sale without a validated Novel Food application. However, companies selling CBD products prior to this date have a grace period until 31st March 2021 to submit an application.[71] Consideration should be made as to how the application of Novel Foods legislation will impact smaller market participants who are often defined by focusing on niche aspects of the industry from an agile and flexible perspective. The process of gaining authorization is expected to take a minimum of 18 months, with producers required to jump through significant hurdles in order to comply. The estimated cost is around £300,000+ to comply with all the necessary product testing. Consortia may be formed to spread some of these costs but it is still a really expensive process. As previously mentioned, the FSA, although having stated that Toxicology tests will be required are yet to receive guidance from the Committee on Toxicity concerning what exactly these tests will be. With an extremely high associated cost surrounding a novel food application, companies will be unwilling to begin toxicology tests until they can be certain that the tests are indeed required. Many smaller firms will not have the capacity or the capability to participate in the process and this will subsequently block the emergence of niche CBD businesses. These small and agile firms will be the lifeblood of the UK economy in a post-COVID landscape and it is essential that the FSA deploy a more holistic approach which does not prevent market entrance and only favours the largest producers.

[70]https://www.legislation.gov.uk/ukpga/2002/29/contents
[71]https://www.food.gov.uk/business-guidance/cannabidiol-cbd

8 **Recommendation for Government:**
Reassess the NICE guidelines. Reconvene with a new panel that should include academics and medical practitioners and cannabis experts not only from the UK but abroad, from countries where cannabis is accepted as a medicine.

9 **Recommendation for Government:**
Allow General Practitioners to be primary prescribers of medicinal cannabis.

Patient Access

Patient access to medicinal cannabis is still appalling, considering that the Government wished to allow access in November 2018. There are still just three NHS prescriptions for whole plant CBPMs and only about 6000 private prescriptions and the latter are far too expensive for most people.

The most restrictive aspect of medicinal cannabis regulation comes from the guidelines provided by The National Institute for Health and Care Excellence (NICE). At present, NICE guidelines approve the prescription of three cannabis-based drugs, those being Epidyolex, Nabilone and Sativex.[72] No full spectrum products are recommended, and thus unlicensed medicines are effectively not allowed. Whilst the NICE guidelines are not mandatory they are treated as such by doctors and hospital Trusts who are reluctant to allow prescription against those guidelines. The very recent clarification by NICE that there is no recommendation against the use of cannabis-based medicinal products for severe treatment-resistant epilepsy is to be welcomed".[73]

Sadly, the guidelines are written as though cannabis is a pharmaceutical product. They are heavily reliant on the pharmaceutical concept of the double-blind placebo-controlled study. However, cannabis is a botanical product and needs assessment using the full panoply of evidence including some controlled trials but also case studies and observational data - so called "real world" evidence. There are thousands of such studies that are all currently ignored by NICE.

The current NICE Guidelines are far too restrictive and fail to prioritise the one thing which the medicinal cannabis sector should focus on - the patient. It is essential that the Government conducts an urgent review of the NICE guidelines and convenes a new panel consisting of academics, cannabis experts and patients from the UK and abroad in order to produce new guidance that takes into account the full, real-world, evidence base for cannabis as a medicine and make clear recommendations on prescribing a botanical product.

The NICE Guidelines are not just a barrier to patient access though. They have far reaching implications for the commercial viability of the medicinal cannabis market. Namely, that if there are significant barriers to patients accessing medicinal cannabis, then a thriving market and businesses supplying cannabis will not be created.

It is also worth noting that when patients or parents of patients are not able to access legal medicinal cannabis on prescription that they can make the decision to use black market products. In fact, a recent YouGov survey showed there are 1.4 million people using black market cannabis to treat their chronic illness and/or pain.[74] This is putting families and children at risk of prosecution. This is a totally unacceptable strain to place on chronically ill patients and their families. Black market products are not tested for safety, they are not consistent, and they can contain contaminants and pesticides.

As an example, there are around 26,000 child patients which refractory epilepsy, currently in the UK.[75] These children will need 24-hour care, and this is usually provided by the parents. Carers are usually unable to work or to have any sort of

[72]https://www.nice.org.uk/guidance/ng144
[73]https://www.nice.org.uk/guidance/ng144/resources/cannabisbased-medicinal-products-clarification-of-guidance-march-2021-9070302205
[74]https://www.thetimes.co.uk/article/more-than-a-million-britons-buying-cannabis-illegally-to-treat-illness-v87jsnl7p
[75]https://www.drugscience.org.uk/too-much-pain/

social life. We have seen through stories from parents that medicinal cannabis, mostly when used alongside mainstream medications, can have a profound effect on epilepsy. This enables families of refractory epilepsy children to have a more normal life and this also means, parents are more likely to be able to work and have a life where they are able to do things that they want to do, as well as taking care of their child. The social impact of not making medicinal cannabis available to patients with refractory epilepsy and other conditions is very real and must be considered when making decisions about the nature of a UK medicinal cannabis industry. Investor opportunities are likely to increase if medicinal cannabis can more easily be prescribed in the United Kingdom. At the moment it is only medical practitioners on the GMC specialist register that can initiate a medicinal cannabis prescription. This excludes half of the UK doctors – the General Practitioners. They are likely to make knowledgeable prescribers, being attuned to the needs of people in their practice with chronic health conditions, such as pain and anxiety (which account for around 85% of all prescriptions), sleep and appetite problems. GPs should be given the opportunity to prescribe CBMPs.

It is encouraging to note that the MHRA and with the support of partners have created a new innovative pathway known as ILAP (Innovative Licensing and Access Pathway for medicines) for the assessment of new medicines and we hope that this new, enlightened approach will apply to botanical medicines such as cannabis.

10 **Recommendation for Government:**
The Government should conduct or contract for a proper and thorough health economic analysis of the cost of introduction of medicinal cannabis and hemp flowering tops in the UK.

Health economic analysis

Cannabis is basically a cheap product and in some parts of the globe can be produced for around 10 US cents per gram of dried flower. The average UK prescription for dried flower is about 1 gram per day and thus, at the cheapest, the constituent product costs only about $3 per month. Obviously, producer, importer and retailer profit margin, and license costs need to be factored in. However, through the Twenty 21 programme run by Drug Science 1 gram of dried flower can be prescribed for around £7 per gram – capped at £150 per month.[76]

A proper and comprehensive health economic analysis of the financial impact of providing medicinal cannabis widely in the UK through the NHS is urgently required. The medicine cost can be offset by savings in other drug costs, such as less opioid prescription (and less opioid deaths). Evidence from the USA indicates reduced opioid prescriptions of about 29% and a similar reduction in opioid dosage amounting to a Medicaid saving of also 29%. This equates to an overall saving of many millions of dollars.[77] Additionally, there would be less anticonvulsant prescribing for those with resistant epilepsy and less anti-anxiety drug prescribing for those with resistant anxiety and PTSD. Other savings could be generated due to less associated therapies, such as physiotherapy for pain and, for example, less epilepsy emergency admissions. It is entirely possible that carer costs can be reduced for those severely disabled by relevant conditions. And some patients, currently on benefits, may even return to work. The improved quality of life for those on a successful prescription should be factored into a full health economic report.

[76]https://www.healtheuropa.eu/a-deep-dive-into-drug-sciences-project-twenty21/101470/
[77]https://pubmed.ncbi.nlm.nih.gov/29989239/

Summary Recommendations

Many of our recommendations will be facilitated by the introduction of an "Office for Medicinal Cannabis". This is the case in other jurisdictions, such as the Netherlands. At the moment the legislation, licensing, health decisions, evidence assessment, product approval, etc. is spread across many Government departments including the Home Office, the Department for Health and Social Care, Ministry of Justice, the Medicines & Healthcare products Regulatory Agency (MHRA) and Food Standards Agency.

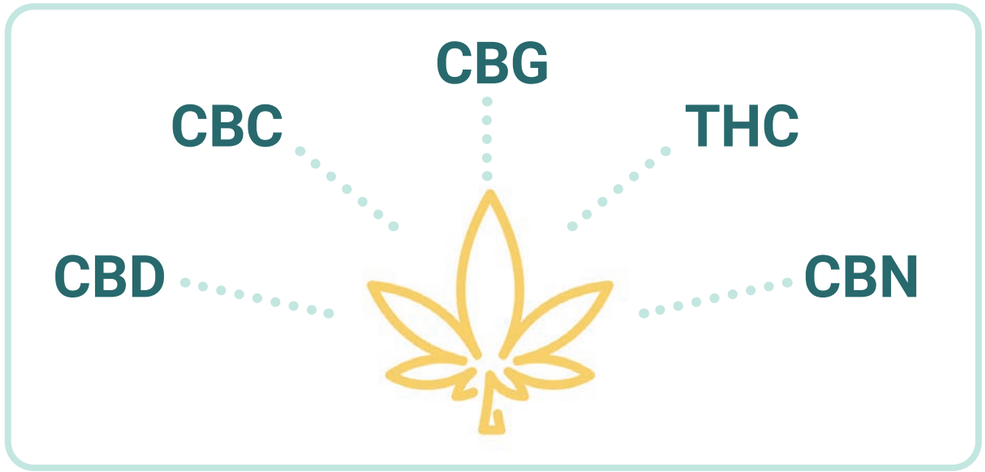
It is no wonder that the medicinal cannabis sector in the UK is a mess. Presumably, the government, in changing the law, meant to allow access to cannabis as a medicine. If that was the case they have singularly failed to grasp the opportunity not only of helping people with chronic health conditions but of helping to establish a viable and dynamic new industry. Coordinating the medicinal cannabis agenda through a unified Office for Medicinal Cannabis will help to progress this agenda.

The recommendations outlined above should be underpinned by a comprehensive review into the use of legislation facilitating the use of medicinal cannabis internationally. This review should be led jointly by the Home Office and Department for Health and Social Care and explore recommended initiatives, technologies or investments which could be beneficial for the United Kingdom.

We encourage the Government to give these Recommendations serious consideration, review the whole medicinal cannabis scene and assist this new industry, with huge potential economic benefit, to grow and develop in the UK.

APPENDIX

WHAT IS CANNABIS?

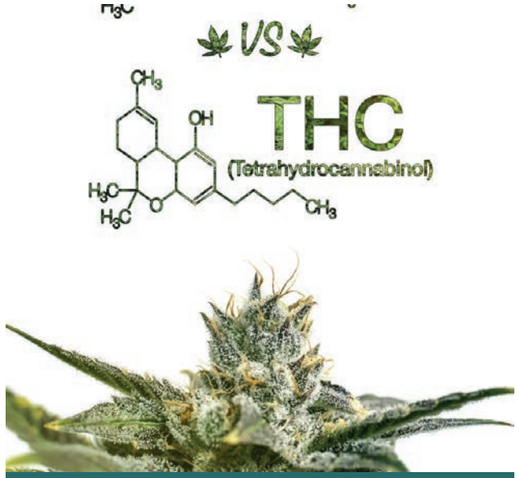


Cannabis is a botanical plant made up of over 1000 compounds, including cannabinoids, terpenes, flavonoids and others, many of which are known to have medicinal properties. The main ones studied, for their therapeutic effects, are cannabidiol (CBD) and tetrahydrocannabinol (THC). However, as a botanical product, there are many thousands of different strains (chemovars), each of which have subtly different medicinal applications.

Medicinal cannabis is the same plant as that consumed by recreational users. In general, the prescribed, medicinal product will be relatively higher in CBD and lower in THC. Getting "high" is not the aim of a medicinal prescription. It will also be produced to a good quality and more consistent standard and be free of contaminants, compared to the illegal "street" product. All UK imports (and, so far, all prescribed products are imported) are to the EU GMP (Good Manufacturing Practice) standard which ensures quality, consistency and safety.

A1 Cannabis Overview

CBD: This is a psychoactive cannabinoid, but it is non-intoxicating and non-euphoric, meaning it will not get you 'high'. The production, sale and use of CBD is not controlled in the UK, subject to certain restrictions regarding the THC content of the final product. It is widely available as an over-the-counter health supplement, although producers can make no medicinal claims about their product. Nevertheless, it has clear and scientifically accepted medicinal properties. It can be used, for example, to help reduce inflammation and pain. It may also, amongst other properties, ease nausea, migraines, seizures, and anxiety. CBD counteracts the "high" effect of THC to a large extent partly by binding to the brain receptors to which THC is bound.



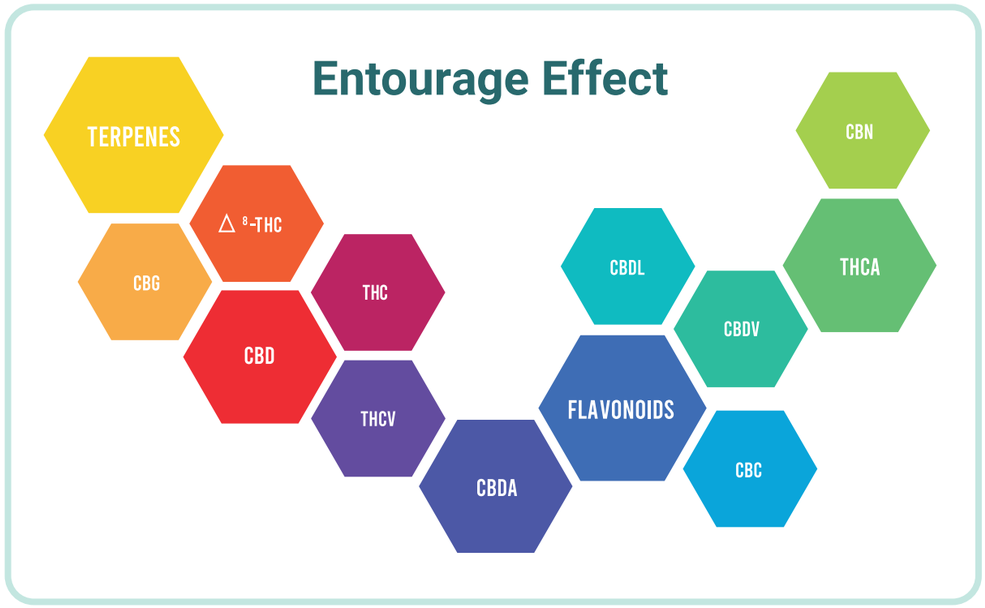
THC: This is the principal psychoactive compound in cannabis. THC is responsible for the 'high' that most people associate with cannabis. Any compound or product containing THC, or a derivative thereof, is controlled in the UK except when it is a Cannabis Based Products for Medicinal use in humans (Reg.2(1) MDR 2001) (CBPM) prescribed by a doctor on the specialist register or is an "Exempt" product (see 1.4.1). The exceptions are two licensed products – Sativex and Epidyolex made by GW Pharma - and a synthetic THC – nabilone - which can be prescribed by any registered doctor. THC can also be used in a recognised and approved research study under license. It has well recognised medicinal properties including being analgesic, anti-inflammatory, anti-emetic, a muscle relaxant and anti-oxidant.

Terpenes and Flavonoids: The cannabis plant also contains over 100 terpenes (that give cannabis its characteristic smell) and flavonoids, which give colour. These also have potential medicinal application.The terpene myrcene, for example, is sedating and helps sleep. Linalool is anti-convulsant and the flavonoid, quercetin, appears to have anti-viral and anti-cancer properties.

Hemp: The hemp plant is a variety of cannabis sativa but differs from most cannabis strains in that it has very low levels of THC and less of the other "minor" cannabinoids . It has been bred over centuries for its strong stem to produce many goods, including paper, rope, canvas, clothing, building materials and agricultural products. The hemp seeds are healthy to consume and nutrient rich, and are used to produce many consumer products like salad oils and soap, industrial products like paints and vanishes, and animal feeds. Strict conditions and fees apply to the cultivation of industrial hemp, which requires an industrial hemp license from the Home Office – and even then, only certain parts of the plant can be used.

Chemovars: This refers to the breakdown of the plant according to its chemical composition. There are thousands of cannabis chemovars with varying proportions of THC, CBD and the other cannabinoids, terpenes and flavonoids. Each chemovar may have subtly different medicinal properties. We have barely scratched the surface of our knowledge of this remarkable plant.

Entourage effect: This refers to the known (and now scientifically generally accepted) phenomenon that the whole plant has a better medicinal effect than the individual components. In other words, it is likely that an isolate (such as a pure CBD isolate) will have less benefit than the full spectrum plant for, for example, epilepsy.



Cannabis Types: Most cannabis products for prescription are either Full Spectrum, Broad spectrum, or Isolate. These definitions are used to describe which cannabinoids are in the product.

Full Spectrum: This is an extract that contains all compounds found naturally occurring in the plant, including essential oils and other cannabinoids. These are the prescribed products used in the UK for most patients and have to be prescribed due to their THC content being above the legal limit for an over-the-counter product.

Broad spectrum: This is similar to full spectrum, whereby all compounds within the plant are preserved, however, THC is removed. These products could be sold over-the-counter in the form of CBD oils, edibles etc. in the UK as long as they fully comply with the definition of an "Exempt Product" as defined in the Misuse of Drugs Regulations (MDR) 2001 (see 1.4.1) as it pertains to the level of controlled substances in the product.

Isolate: This is the purest form of cannabinoid, which is produced by removing all other compounds found in the plant. CBD isolate is typically extracted from Hemp, due to its low to non-existent THC-content.

Flowers (sometimes called flos): These are also prescribed in the UK. The dried flower will require grinding before being vaped. In the UK, the smoking of any cannabis flower (be it hemp or higher THC cannabis) is not allowed by law.

A2 Licensed products

Currently, only Sativex and Epidyolex (very pure products which are "nearly" isolates and made by GW Pharmaceuticals) and the synthetic nabilone (marketed by Valeant) have marketing authorisations in the UK and can be prescribed in the normal way.

Sativex: A mouth spray containing two cannabinoids (THC and CBD) in broadly equal proportion. It is licensed in the UK for people with MS-related muscle spasticity that is resistant to other treatments

Epidyolex: A highly purified liquid containing mainly pure CBD (1000mgs CBD per ml and 3mgs THC per ml), and thus has no intoxicating effects. Currently, it can be prescribed for patients with Lennox-Gastaut syndrome and Dravet syndrome (both rare forms of epilepsy) in combination with a licensed anti-convulsant – clobazam.

Nabilone: A synthetic capsule medicine, which has been developed to act in a similar way to THC. It is used to help relieve the symptoms of nausea caused by chemotherapy – but it is only prescribed when other treatments have not worked. Although licensed in the UK for adults, due to 'limited evidence' considered by NICE, it is not currently available to most patients.

ABOUT THE AUTHORS

MAPLE TREE CONSULTANTS AND MACKRELL. SOLICITORS

Maple Tree Consultants
Maple Tree's overall objective is to assist with the establishment of an ethical and prosperous UK cannabis industry and to support the National Health Service in providing its patients with the best possible access to cannabis medicine. Providing unrivalled expertise, Maple Tree has established itself as a leading consultancy in the field; offering strategy, development and leadership for a range of businesses entering and maturing in this exciting sector.

Professor Mike Barnes MD FRCP

Mike is a neurologist and rehabilitation physician and Honorary Professor of Neurological Rehabilitation at the University of Newcastle. He is a world leading, respected figure in his field having previously been the Founding President of the World Federation of NeuroRehabilitation and President of the British Society of Rehabilitation Medicine.

Mike has a long-term interest in cannabis as a medicine and was involved in the development of the first cannabis medicine – Sativex. He has been actively involved in lobbying for the greater acceptance of cannabis as a medicine and is Founding Chair of the UK Medical Cannabis Clinicians Society.

Hannah Deacon

Hannah Deacon is the UK's best known and award-winning medicinal cannabis campaigner. She is mother to Alfie Dingley whose doctors were the first in the UK to receive a permanent cannabis license before the law changed in November 2018. Hannah was an integral part of the End our Pain campaign which was instrumental in changing the law.

She is now the Director of the Medical Cannabis Clinicians Society and also of Maple Tree Consultants. She is passionate about establishing a patient-led cannabis sector where patients and their needs matter and all who may benefit from medicinal cannabis can receive it on the NHS.

Peter Carroll

Peter is a multi-award winning public affairs campaigner who worked at the heart of Government as Special Adviser in HM Treasury. With a proven history of success in public affairs, government relations, media and public relations, Peter began working in medicinal cannabis in 2017 and ran the successful End our Pain campaign. He would like to see appropriate access to it for patients across the globe, in both private and state-funded medical systems.

Will de Peyer

Economic Adviser and Public Affairs expert Will de Peyer spent five years working at the heart of Government as Special Adviser in HM Treasury. Will is expert in understanding complex policy issues and then devising and implementing strategies for our clients to achieve real change.

Will has been involved with medicinal cannabis since 2015 and is committed to developing the UK's medicinal cannabis market into one of the most professional and trusted in the world.

Mackrell.Solicitors
Mackrell.Solicitors is an award-winning, full service Law firm, with a truly global reach.

Headquartered in Central London, with offices in the heart of Birmingham, we have been providing high-quality legal advice and services since 1845.

Mackrell.Solicitors were also one of the founders of Mackrell International, the 33-year-old world-leading global network made up of 104 firms across 60 countries, enabling them to offer the added value of immediate international legal advice and assistance in any jurisdiction worldwide.

Mackrell.Solicitors set up the first designated cannabis legal team circa. 3 years ago, so in terms of sector specific knowledge they are at the cutting edge of the current regulatory regime in the UK and Europe. They provide regulatory advice and services for the medicinal cannabis and CBD industry, from cultivation licence applications, product and labelling reviews, advice on import/export best practice. Via the Mackrell International they provide multi-jurisdictional advice for all EU countries and beyond.

Ricardo Geada

Ricardo is a Partner in the firm and heads up the Cannabis and Regulatory team. A solicitor with more than 13 years legal experience both in private practice and in-house, Ricardo has genuine interest in drug policy reform and regulation particularly the legal developments and regulatory regimes governing CBD wellness products and medicinal based cannabis products. Ricardo is regularly instructed by global cannabis companies, handling their legal and strategic requirements both in the UK and abroad. Ricardo's in-house and international coverage makes him commercially incisive and an invaluable solicitor to his clients, being described as a pragmatic, strategic and solution focussed business partner.

Elliott Rolfe

Elliott is a Solicitor in the firm who specialised as one of the UK's first cannabis lawyers, before establishing the Psychoactive Medicines Law team at Mackrell. Having studied medical cannabis and other psychoactive medicines across a variety of fields, he has been able to assist some of the world's leading cannabis companies, and work with all corners of the industry, including policy institutes, patients, regulators, trade bodies and academics. He is keenly interested in drug policy reform, and is a longstanding supporter of national initiatives promoting these related fields.

Nick Earles

Nick is a Solicitor in the firm who practices in both the Cannabis and Psychoactive Medicines teams at Mackrell Solicitors. He provides regulatory and commercial advice to domestic and foreign cannabis companies operating in the United Kingdom or looking to do business in the jurisdiction. His deep industry knowledge helps advise enterprises successfully in an ever-changing legal landscape. Coming to law from a previous career in marketing, his commercial experience is helpful in guiding cannabis companies through the complex rules in the UK. Nick's dedication to cannabis echoes through his keen and sincere approach to reform.

THIS DISCUSSION PAPER IS SUPPORTED BY

All Party Parliamentary Group on Drug Policy Reform
British Hemp Alliance
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Cannabis Trades Association
Cannapro
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