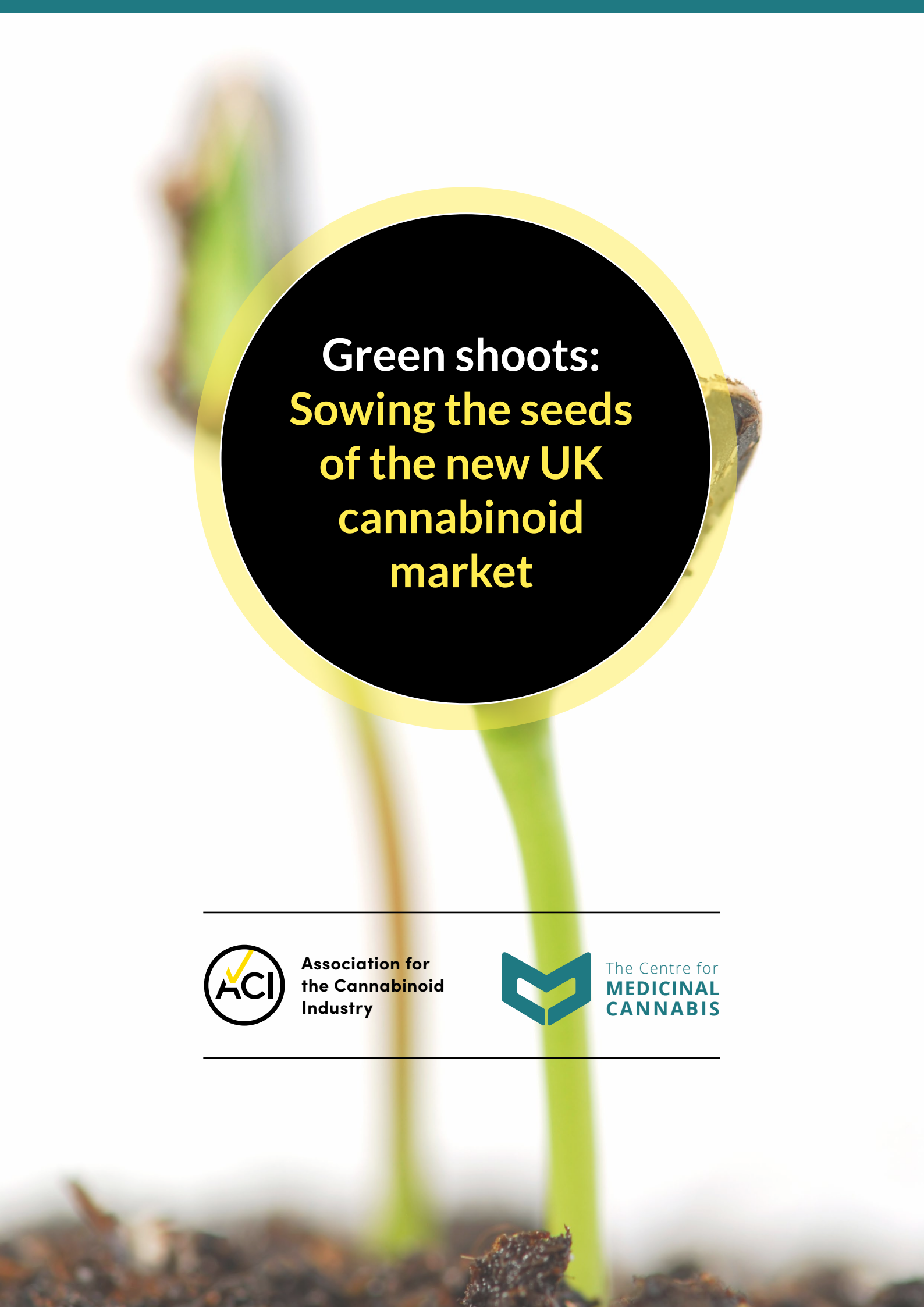

Green shoots: Sowing the seeds of the new UK cannabinoid market

Association for the Cannabinoid Industry

The Centre for MEDICINAL CANNABIS

Green Shoots: Sowing the seeds of the new UK cannabinoid market

As the Government's lockdown-lifting roadmap unfurls in line with the plan set out by the Prime Minister in late January, attention is now inevitably turning to the pace and nature of the economic recovery that will follow the pandemic. That this is happening in the months after the end of the Brexit transition period - and in light of the extraordinary success of the vaccine programme - has only increased speculation about what regulatory innovation opportunities may exist to give the UK a new competitive edge.

Deliberations and submissions made to the Prime Minister's Taskforce on Innovation, Growth and Regulatory Reform (TIGRR) in recent weeks have demonstrated the eagerness across many business sectors to engage with these new affordances, and share ideas to fuel new business opportunities and job creation across the country.

One industry now overripe for development, facilitated by new regulation and legislation, is our largely unheralded cannabinoid sector.

Despite recent developments in US states legalising cannabis for recreational use we seem as far away as ever here in the UK. In the medical field, despite the changes to the law in 2018, we are probably many years from generating the clinical evidence which will enable many cannabis-based medicines to be prescribed in the NHS.

However, it is in what is now defined by the Government as the consumer cannabinoid market, notably cannabidiol (or CBD) that a quiet commercial, legal cannabis revolution is taking place.

The size of this cannabinoid sector is getting impossible to ignore. Today, the trade body I founded for the sector in 2019 published its second annual market sizing survey. It reveals that sales of CBD products for 2021 will be valued at £690m, this has increased from £314m since 2019 and is almost a third higher than our last projection in 2019.

Almost without notice, and certainly by accident rather than design, the UK has improbably become the world's second largest consumer cannabinoids market after the US. We now spend more on cannabis extracts than Vitamin B and C combined.

In the course of the past few months the Food Standards Agency has become the first regulator in the world to start the process of approving CBD products for legal sale, the Home Office have launched a consultation process to consider what is a safe and tolerable THC presence in a consumer product - again no other jurisdiction has gone this far - and the first positive human clinical study results have been published. More safety studies will report in the coming months.

These important recent, and upcoming, developments are however still taking place in a disparate and incoherent fashion and without the sector having a proper footprint in Whitehall or Westminster. This has consequences that are disadvantageous to the UK economy.

In this paper the Association for the Cannabinoid Industry and the Centre for Medicinal Cannabis define a new vision for the UK's consumer cannabinoid and medicinal cannabis market.

In *Green Shoots - Sowing The Seeds of the New UK Cannabinoid Market* we set out 20 key recommendations that cover the need for:

- Governmental and market-led deep dives into the economic and regulatory frameworks of the cannabinoid sector.
- Reducing administrative barriers to scaling up businesses via hemp plant regulation reform; establishing a dedicated cannabinoids regulator; robust enforcement action against non-compliant products; and establishing quality standards and industry guidance for product labelling and exportation.
- Encouraging innovation and commercialisation of new technologies.
- A dedicated 'centre of excellence' for cannabinoid science in the UK.
- Reducing barriers to entry, and making the UK market more dynamic and economically competitive.

The cannabinoid market is only going to become bigger as levels of product innovation escalates, new research emerges and exploration of the potential of other minor cannabinoids such as CBG emerge.

The wilful blindness that allowed a`grey' market to flourish before retrospectively imposing market authorisation regulations has created huge consumer demand for these products, one the pandemic has predictably accelerated given what we know about why people purchase CBD. But it remains a sector that is wholly dependent on overseas import of raw materials and is now crying out for a public policy framework to reap the latent economic and social benefits of cannabinoids.

With the government's support the accidental consumer cannabis revolution that has allowed CBD to become available on every high street in the UK could become permanent, nurturing hundreds of new businesses, thousands of jobs and billions of pounds in exports.

It's hard to imagine there are many more industries that could benefit almost immediately from the proposals set out in our report.

Steve Moore
ACI Founder and Lead Counsel

Aims, Objectives and Opportunities:

- Encouraging innovation and accelerating the commercialisation and safe adoption of new technologies, cementing the UK's position as a global science and technology superpower.
- Reducing barriers to entry in specific markets and making markets more dynamic and contestable across the economy.
- Reducing administrative barriers to scaling up productive businesses; and tailoring any necessary processes to the needs of UK start-ups and SMEs, while maintaining the Government's commitment to high environmental standards and worker protections.
- Improving small and medium business' experience of necessary regulatory requirements.
- Understanding which sectors of the economy or regulatory frameworks which should be prioritised for further regulatory deep dives.

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1. State of the UK cannabinoids sector

Introduction

1. Inadvertently, the United Kingdom has become a leader in the global cannabinoids marketplace, but successive UK governments remain slow to recognise this. Politicians, policymakers and regulators have been even slower to embrace the potential for the UK's leading position to be built upon proactively. Within Whitehall, Parliament, and the broader policy-making community, there remains a lack of knowledge of the sector and widespread skepticism about its value and merit, the motives of those engaged in it, and whether its emergence is a welcome development at all.

2. We argue that the market is important; it represents a key growth sector for the UK, and it is time for the government to adopt a proactive strategy to seize opportunities in the cannabinoids sector that leverage key British strengths whilst reinforcing other core cross-governmental goals.

3. For the purposes of this report, the use of the word cannabinoid, unless otherwise stated, is defined as a molecule that is capable of modulating the cannabinoid receptors. Cannabinoid molecules can be derived by extraction from the cannabis plant or synthesised chemically or biosynthetically to be identical to those molecules found in the plant. They can also be derived from chemical synthesis using structural activity related to the molecules found in the plant but be chemically distinct i.e., 2nd, 3rd and 4th generation cannabinoids. Given that a significant percentage of today's cannabinoid sector in the UK is related to cannabinoids extracted from the plant, the majority of this report will be related to these. However, any changes adopted following this report must be able to accommodate the emerging cannabinoid sectors of synthetics and biosynthetics.

Progress

4. The genus Cannabis is a controlled drug in Class B of The Misuse of Drugs Act 1971 (MDA and Schedule 1 of The Misuse of Drugs Regulations 2001). Despite the plant's prohibited status and no premeditated policy or political agenda to support the growth of a cannabinoids sector (arguably, the very opposite), in the last twenty years the UK has managed to:

- Generate the first listed cannabinoid pharmaceutical company (GW Pharmaceuticals, sold for $7.2bn in 2021);
- Host four world-renowned universities producing pioneering cannabis research (University of Nottingham, King's College London, University of Aberdeen, and Imperial College London), including influential studies into the mental health impact of unregulated high strength cannabis use on developing brains;
- Establish a legal framework for Cannabis Based Medicinal Products (CBMPs) to be prescribed and studied in patients, in 2018, ahead of many other EU states;
- Set proportionate rules that allow for the listing of medicinal cannabis companies on the London Stock Exchange (with two debut IPOs in the first quarter of 2021);
- Become home to the largest retail cannabidiol (CBD) market in Europe with widespread use of CBD as a wellness product.

5. Recent developments – like the consumer CBD boom, the purchase of EMMAC Life Sciences by US-based Curaleaf for $285M[1] and the first listing of foreign medical cannabis companies on the London Stock Exchange[2] – prove the value of the sector. They also indicate the areas of the UK's comparative advantage in what is a rapidly evolving global industry.

This is an industry where supply chains are international, and competition is rife for attracting new investment in high-value activities. The rapid growth of international trade in cannabis commodities has also been spurred by the resurgence of the hemp sector, especially since the 2018 US Farm Bill was enacted which allowed for mass domestic cultivation of hemp in the USA.[3]

6. After years of stasis, the Conservative government, since the 2017 election, have made important changes to the law including:

- Commissioning expert advice from the Chief Medical Officer on the evidence base for cannabinoids as efficacious medical treatments in 2018;[4]
- Rescheduling cannabis for use as a treatment prescribed by specialists as unlicensed Cannabis-Based Medicinal Products (CBMPs) in 2018[5].

7. Since the current government took office in 2019, they have gone further by:

- Relaxing rules around named patient imports in 2020 to allow licensed distributors to hold limited supply of CBMPs, to support supply chain efficiency and lower costs for patients;[6]
- Confirming the legal regulatory pathway for CBD products as 'Novel Foods' administered by the Food Standards Agency (FSA) (applying their standard authorisation process and setting market deadlines for compliance);[7]
- Commissioning the Advisory Council on the Misuse of Drugs (ACMD) in 2021 to advise on the right thresholds for trace elements of THC in consumer CBD products (following advice to Ministers) with a consultation now underway;
- Committing, in the Government's 2020 Research and Development (R&D) strategy, to review how the laws governing scientific research using controlled substances can be amended to address barriers to innovation in areas like cannabinoids and psychedelics.

8. These British developments, and the global industry's continued growth, while providing a positive trend for the future, also illustrate what needs to change in the UK. The poster child for cannabis as a viable medicine (GW Pharmaceuticals) is no longer a UK company (listed on the Nasdaq and acquired by Jazz in 2021). This British-built unicorn took two decades and hundreds of millions of Pounds to turn a Schedule 1 licence to cultivate, into a company with a public listing and two legal medicines licensed in the US (and from where almost all its revenue derives). That biotech business model route is exceptional, but is too slow and expensive to be mirrored again very often, if at all.

Barriers

9. There are significant structural barriers that are depressing the economic potential of the cannabinoids sector in the UK:

- There is primary research taking place in the UK (at fewer than a dozen universities) however it is subject to onerous licensing controls and is largely pre-clinical in nature. Thus, British studies have not generated major clinical trial evidence for medicinal efficacy (such evidence is American, Canadian, Australian or Israeli in origin) - albeit the global evidence base is expanding;[8]
- The UK's large and maturing CBD sector (which we estimate based on new analysis shown below to now be worth £690 million in 2021) has a domestic base of millions of consumers but grew rapidly in under five years and is still largely unregulated and reliant on imported finished products and raw ingredients.

Therefore, product quality and provenance are highly variable,and many users have had their consumer rights infringed with mislabeled or contaminated products;[9]

- The UK's outdated laws governing extracting and processing of the cannabis plant (for non-controlled extracts like pure CBD), prohibit extraction from the flowering tops and leaves. This means that British growers cannot supply into this large domestic consumer market, so almost all of the economic value of the UK CBD boom continues to accrue to foreign companies (mostly European and North American);
- Whilst prescribing, manufacturing and conducting clinical trials for CBMPs is allowed, no studies have been completed, whilst others have only recently begun[10]: there continues to be a lack of UK-generated trial data to support use within the NHS, and major ongoing challenges for free and equitable patient access;
- Clinical trials conducted using CBMPs and other synthetic cannabinoids are still subject to the most onerous Misuse of Drugs Act (MDA) Schedule 1* licensing provisions for the majority of the early R&D cycle of pre-clinical, safety assessment, formulation development, drug substance and drug product manufacture. It is only when CBMPs have achieved a clinical trial authorisation or ethics committee approval that the scheduling under the Misuse of Drugs Regulations (MDR) 2018 is downgraded to Schedule 2*. For modern 2nd and 3rd generation cannabinoids they currently remain under the highest level of Schedule 1 throughout the clinical trial meaning that even NHS hospitals wishing to participate require Home Office approval;
- Restrictive prescribing rules – British GPs are unable to prescribe a CBMP and only a small number of consultants on the General Medical Council (GMC) specialist register have used their authority to do so. This inevitably means that patient access will always be hampered;
- Private prescribing of unlicensed CBMPs as 'specials' is occurring, but the sector is small when compared to un-met patient demand. In fact, projections of patient numbers issued in 2019[12], have not proved accurate, and fall far behind the demand seen in comparable jurisdictions like Germany and Australia, which allow GP prescribing and legalised cannabis for medicinal use around the same time. A 2019 survey estimated that 1.4m people in the UK use black market cannabis to directly treat medically diagnosed medical conditions; this compares extremely poorly with the Department of Health and Social Care (DHSC) estimates of between 149 and 224 unique patients between November 2019 and October 2020[13];
- Specialist companies involved in supplying this small clinic market encounter complex rules and unclear guidance relating to testing requirements, manufacturing, and importation; together with an ongoing bar on exports, the CBMP sector has been prevented from flourishing.

*Substances are classified into five schedules according to their medicinal value and perceived risk: Schedule 1 contains those of no medicinal value, Schedule 2 contains those of medicinal value but with high abuse potential.

10. If the UK wants to see a legal, licensed cannabinoids sector that may produce other companies of the size and importance of GW Pharmaceuticals, then domestic reforms are needed that build on the modest progress already made.

There are four major barriers to achieving that goal for the UK cannabinoids sector currently:

1. Limited expertise across government.

Lack of specialist knowledge can inhibit engagement with the industry, contributes to regulatory uncertainty around what is permissible activity, and limits the vision and appetite among politicians and policymakers to take steps to support the sector's growth. The controlled status of the plant, decades of a restrictive licensing regime, and lack of policymakers with domain knowledge and a scientific skill set derived from researching cannabis, has led to a landscape where the authorities are under-educated in the activities they seek to govern and oversee.

2. Lack of legal clarity and coherent regulatory pathways.

Uncertainty about financial crime exposure has a chilling effect on foreign investment by cannabis companies in the UK market, and the absence of clear rules around the legitimate status of innovative product types, like beverages and CBD vape products, discourages innovation and leaves the market open to illicit suppliers. Legitimate companies, involved in the conduct of pre-clinical and clinical research, import or export CBMPs, or production of hemp derived products, currently deal with a Home Office licensing regime which, at best, is slow and has little understanding of patient and business need and, at worst, views the activities with suspicion and is un-empathetic to what the business is trying to achieve. These difficult licensing requirements have suppressed R&D in this sector and resulted in a lack of required skill sets to handle these cannabinoids.

3. Outdated rules governing research and cultivation.

Academic research into the cannabis plant is discouraged by the costs and burdens involved in a schedule 1 drug licence. The ongoing ban on harvesting the controlled parts of the cannabis sativa plant, which prevents British growers from utilising the full crop, is a legacy of outdated rules which are now redundant; they act as the biggest barrier to capturing the value of the cannabinoid industry for the UK.

4. Absence of institutional infrastructure.

There is a distinct lack of institutional infrastructure to support the domestic, scientific and clinical evidence base to grow, develop regulatory expertise, and provide a dedicated resource for licensing commercial activity in this sector. A dynamic market with high investor appetite needs the right infrastructure to help facilitate legal growth and maintain high quality standards.

11. This paper argues that the UK is not currently able to capture the full value of the cannabinoids sector because successive governments have chosen to ignore its growth; have never measured its economic value; have under- and over-regulated key elements of it; and in some areas, have chosen to stand still and watch a large consumer-driven grey market in CBD boom, when the law was unclear and breaches of controlled drug rules were widespread, rather than adapting and setting (and then communicating) new rules to shape the market, regularise commercial activities and drive out illicit activity.

12. This failure has been a decade or more in the making and has resulted from a lack of a coherent policy framework in which success metrics are defined, clear parameters for lawful activity are set, and key incentives and regulatory pathways are promoted. Without that, the UK's cannabinoid market in the next decade will struggle to operate ethically, legally and profitably. Currently the UK's cannabinoid strategy is not just incoherent – it simply does not exist.

A brief history of hemp and cannabis in Britain

The cannabis plant was cultivated widely in the British Isles for centuries as the raw commodity "hemp" which was used widely in many domestic sectors, including as a key industrial product for the Royal Navy. As alternative materials for rope and fabrics displaced hemp in the nineteenth century, the agricultural relevance declined, and it became more marginalised in the economy and in public understanding. The Victorians allowed the commercial application of cannabis (and opium) in formulations and food products sold by pharmacists and apothecaries, during the early modern era of Western medicine, and trade in the product throughout the Empire was not restricted. However, the long-observed intoxicating effects of smoking high-THC cannabis – understood by the press and politicians at the time through the colonial lens of the higher strength cannabis consumed in North Africa and the Indian subcontinent – became more of a concern in the early part of the twentieth century. After World War I, British officials and legislators along with their peers in other developed nations began to consider stricter controls, and the whole plant eventually became a scheduled narcotic as part of international drug conventions, starting with domestic legislation in the UK in the 1920s.[34] This plant remains a scheduled drug a century later, and its cultivation or use (for certain defined purposes) is governed by strict regulations, and is only permissible with a licence granted by the Home Office. Within these confines, primary research has been undertaken in the UK and some limited cultivation still takes place, but the environment has not been conducive to studying the plant. The general bracketing of 'cannabis' with much more harmful illicit drugs in the public policy domain has militated public understanding of the plant's history and properties. Nonetheless, British academics have contributed disproportionately to the scientific understanding of the Cannabis Sativa L plant and its medicinal potential. Since the 1980s, a number of distinguished academics at the University of Nottingham, University of Aberdeen, King's College London, Imperial College London, Aberystwyth University, and Manchester Metropolitan University have all conducted primary research into cannabis as holders of a schedule 1 research licence. The pioneering science of Roger Pertwee led to the creation of GW Pharmaceuticals in the 1990s and the important research by Robin Murray at King's College London in the 2000s shaped the public health debate about the impact of consumption of street cannabis on the human brain. Until 2018, there was no legal avenue for exploiting the value of cannabinoids in terms of human application, other than a traditional drug discovery pathway for a licensed medication (the route adopted by GW Pharmaceuticals beginning in 1998). The November 2018 rescheduling of products of cannabis designed for medicinal use in humans created, overnight, a new legal pathway for the beneficial application of cannabinoids. This followed the conclusion of the Chief Medical Officer's review that there was now sufficient evidence of cannabis' medical efficacy for some patients with a small number of conditions, although as an unlicensed product category, which only specialist doctors can prescribe, it is not widely dispensed even in the UK's private healthcare system, and major barriers to access for patients persist.[35]

Opportunities

13. Other countries have recognised a shift in consumer behaviour and rising patient demand for plant-based medicines.

Some have already been moving to amend their domestic laws to attract the big cannabinoid investors and regulated companies of the future, including countries such as Malta, Israel, Denmark, the Netherlands, the Isle of Man and the Channel Islands.

14. This paper argues that currently the UK's outdated and uncoordinated laws and regulations are preventing it from competing with these other jurisdictions in what is a fast-moving global industry. This means the UK is not capturing the full value of today's cannabinoids market, let alone positioning itself to profit from the future high-value innovations that will emerge in response to investment. This paper therefore promotes the goal of a single, overarching strategy for the UK cannabinoid sector, which would cover the whole range of scientific, commercial and industrial activities involving hemp and cannabinoids, and give the country a competitive advantage.

15. By setting a strategy that recognises the value in the cannabinoid sector, and by taking steps to leverage the UK's existing strengths, the sector can support many more jobs and drive major direct investment into areas of the economy that need it, especially following Brexit: namely agriculture, manufacturing, life sciences, and technology-led innovation. If a coherent strategy across a range of sectors is adopted, these would reinforce other cross-government goals.

16. The goal of the TIGRR is to focus on sectors which are important to the future growth of the UK economy and to identify opportunities to unleash innovation and investment so those high-growth sectors can flourish. The hemp and cannabinoids sector, tied to the scientific and commercial exploitation of the Cannabis Sativa plant and its compounds, is just such a sector for the UK economy.

17. This paper focuses on what the government can, and should, do to capture the value of the cannabinoids sector for the UK. The UK hemp and cannabinoids sector has never been the subject of a full economic analysis to determine its size, value and net fiscal contribution. The first step would be an internal deep-dive analysis, cross-government, that would be vital to evidence this and to support effective policymaking. To inform this necessary work, this paper provides an updated estimate of the value of one element of that sector, which proves the fundamental value proposition and should encourage the government to adopt the proposals outlined here.

18. This paper's recommendations are pragmatic and require changes that are minor in terms of government action and require no major government investment or new primary legislation. They also support the general direction of travel which has been to accommodate and regulate the market (for example, the emerging CBD sector) rather than try to enforce it out of existence. This shift is evident in the ACMD consultation issued in March 2021 and the Home Office intention (made explicit in the letter from the Minister of State[14]) to seek a new settlement that will regularise the large grey market in consumer CBD products and provide legal clarity for the wider industry. Such moves to regulate the sector by the Home Office and FSA are only underway now however, and unless they are expedited, the market will take much longer to consolidate and become compliant, to the detriment of businesses and consumers.

19. As the global evidence base expands for the potential applications of cannabinoids in health and wellness, and as new applications are pioneered for industrial and sustainable uses of the plant itself, the government is presented with a new landscape in the next decade and a big opportunity.

The UK's cannabinoid USP

20. A comprehensive strategy would be a significant catalyst for investment and job creation in the UK and would position the UK as a world-leader in the responsible, science-led dimension of cannabis policy. This is a distinctive path for the UK which would distinguish the country from the focus on consumer and recreational marketisation of the high-tetrahydrocannabinol (THC) plant in North America, which has become inseparable from a very different political debate about drug prohibition.

21. The UK can profit from cannabinoids – attracting foreign investment, creating highly skilled jobs, generating tax revenues, lowering the medicines budget for the NHS and advancing scientific knowledge and medical innovations – by setting clear parameters, removing key barriers to legal growth, and encouraging this global industry down the path of a well governed sector, operating in a jurisdiction that has inherent scientific assets, skills, and regulatory strengths.

22. The UK's cannabinoid market should be a world-leader – defined by responsible, proportionate regulation, for legitimate, sustainable end uses. This approach would leverage the UK's historic strengths in agri-tech, pharmaceuticals, clinical research, and technology, within a dynamic market society with a foundation of a robust, publicly funded healthcare system. The British cannabinoids sector should seek to pioneer the highest standards in terms of consumer protection, scientific research, clinical trials, and patient safety, combined with innovation, new commercial applications and the creation of trusted retail brands. However, none of this will happen on its own.

23. A distinctive UK approach requires policymakers and Parliamentarians to recognise that hemp and cannabinoids represent a new frontier in healthcare and environmental policy, and are nothing to do with the commercial exploitation of an intoxicating, illicitly supplied narcotic that was traditionally seen as posing a threat to Britain's social fabric. In fact, nothing recommended in this paper requires or presumes a more liberal attitude to the illicit use of street drugs (including cannabis) and is entirely consistent with maintaining current drug laws. It may even help in reinforcing them: allowing an estimated 1.4 million patients in the UK who currently self-medicate using black-market cannabis to access legitimate CBMPs. In fact, until the economic and scientific potential of cannabinoids is appreciated as a distinct agenda, unrelated to the controversial recreational legalisation debate, with its own evidence-based research agenda and legal commercial rationale, then the UK will continue to under-value and under-exploit this important sector.

24. The laws prohibiting cannabis in their modern form have remained largely unamended for fifty years (after the 1971 Misuses of Drugs Act[15]) and remain incorporated into three international treaties to which the UK is a founding signatory. Despite this, the cannabinoids sector developed here organically, without government stimulus, and has become too large to ignore. Those engaged in the market in the UK are confident that it is ready to expand further – and thereby create thousands of British jobs, but it will not do so unless the government agrees a strategy and adopts the right policy framework.

25. For this government, such a strategy is not just about jobs and investment, including in many areas of the country that need new employment opportunities, but will support a low-carbon economy and a diverse agricultural sector, raise farm incomes, provide hundreds of millions in tax revenue, offer lower cost treatment options for a cost-conscious NHS, better protect consumers and drive forward new medical innovations and scientific discoveries. That is the agenda we mean by capturing the value of cannabinoids.

Size of the UK's consumer CBD market: £690m in 2021

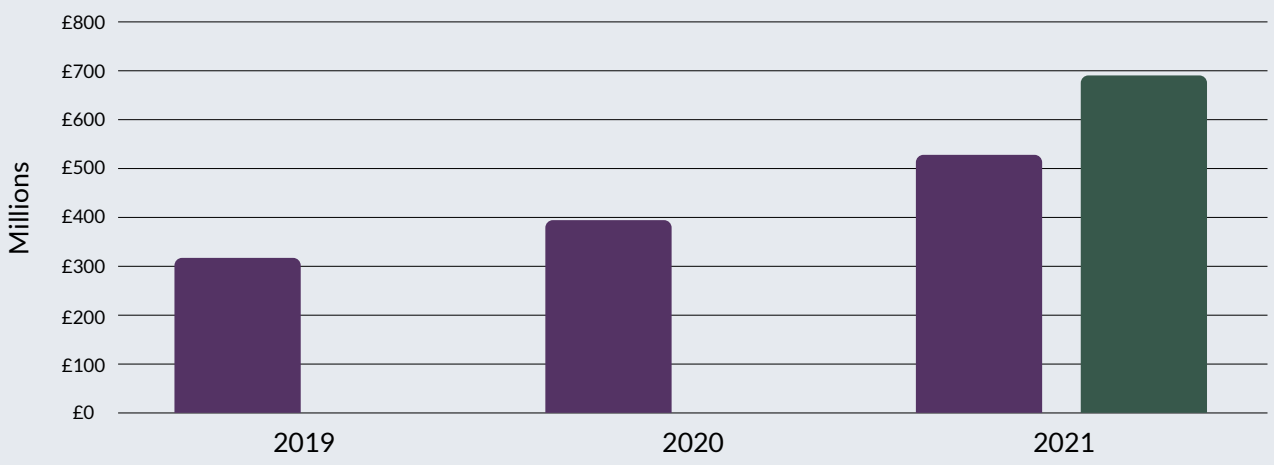
The cannabinoids sector in the UK is becoming an important source of investment and employment, but no one has a good estimate of what the sector overall is worth and the value it provides to the wider economy and the UK exchequer. The market has not been officially measured and the available estimates of its size and value are either partial, dated, or sector specific. Current difficulties include:

- Some estimates of CBD usage reported in the media for example are derived from unweighted surveys that are not representative of the UK population and therefore are not robust estimates for guiding policymaking.
- There has been no comprehensive assessment, by industry bodies or by the government itself, of the whole value chain of hemp and cannabinoids in the UK.
- Estimates of the medicinal market for CBMPs exist, but these relate only to projected patient caseloads (and prescriptions), and not the wider economic contribution of the sector. Some widely quoted estimates made in 2019-20 have not proven to be accurate, with anticipated patient numbers far below expected levels in 2021.
- No accurate data exists for the number of hectares of hemp currently planted in the British Isles, or the revenue generated from such crops. We understand that the Department for Environment, Food and Rural Affairs (DEFRA) did undertake an internal assessment as part of a review of novel crops in 2019-20 but this has not been made public.

CBD is the most popular and widely used cannabinoid and the best estimate of the size of the retail CBD market (online and in-store), was produced in 2019 by Navigant Research, using data from a Dynata survey, for the Centre for Medicinal Cannabis (CMC).

For this submission, and to reinforce the argument about the sector's economic value, Public First were commissioned to undertake new polling to allow a reassessment of the Navigant market-sizing. On the basis of new survey results from polling in April 2021 by Public First, and new ONS population data, we estimate that the UK's consumer cannabidiol sector in 2021 is worth £690m – which has increased from £314m since 2019. This is almost a third higher than Navigant's 2019's projection of the CBD market's size by this year (of £526m). This new calculation helps to demonstrate that the CBD sector remains a valuable market that is still growing and exceeding projections made just two years ago.

Value of the UK's CBD market 2019-2021



Source: Navigant / Dynata Public First / Dynata + Google Consumer Survey

2. Factors limiting growth and innovation

Limited expertise across government

1. Cannabis policy is 'owned' by the Home Office, which acts as both the parent department for policy and law relating to all controlled substances, and also is the home for the regulatory function which licenses applicants who grow, study, or process cannabinoids for scientific or medical purposes. The Home Office does not employ cannabis subject matter experts (from plant biology or other related fields) and receives only ad-hoc scientific advice on matters relating to cannabinoids when Ministers commission it from the ACMD. The Department for Health (DMSC) has developed expertise in CBMPs since the 2018 rescheduling, but their depth of experience and resources are limited. Plant science expertise in The Department for Environment, Food and Rural Affairs (DEFRA) and its agencies have not been focused on hemp because of its status as a niche crop and the very small acreage currently devoted to hemp growing in the British Isles. The regulators whose functions touch the cannabinoid sectors – the FSA (for Novel Foods authorisations) and the Medicines & Healthcare products Regulatory Agency (MHRA) (for drug licensing) are also not experienced in cannabinoid science and have had to adjust to the rapidly evolving sector in real time as the consumer and patient demand for cannabis-based products has spiraled.

2. Together this explains the general lack of deep subject knowledge within the government and may explain the absence of a drive by other departments to seize the opportunities that the sector offers. In the context of pandemic recovery, and the economic mission of TIGRR, it is important to stress the need for a more holistic understanding of the relative value of this sector and its growth potential, where the entire social and economic impact of the cannabinoid and hemp sectors can be properly analysed.

3. The Home Office oversees all activity (scientific, commercial) relating to cannabis and a range of other governmental actors also have a role depending on the category of activity:

Cannabinoid sector	Hemp growing	Cannabis growing	Non-controlled food supplements and cosmetics	Unlicensed cannabis based medicinal products	Pre-clinical and clinical R&D	Licensed cannabis based medicinal products
Home office oversight	Home office					
Licenses required	Low-THC industrial hemp Export & Import	Sc1 Export & Import	Sc1 or LONO or exempt product Export & Import	Sc1 & Sc2 Export & Import	Sc1 & Sc2 Export & Import	Sc2 & Sc4, Sc5 Export & Import
Other gov depts involved	DEFRA	DEFRA	FSA	MHRA	MHRA	MHRA
Current best indicator or value	???	???	£300M (UK)[1]	£6.5B (ww)[2]	£500M[3] £150M[4]	$300M (ww)[5]
Key issues to address	• Currently only allowed to use seed and stalk • Only allowed to grow EU-approved strains • Delays from HO on licence approval and companies in UK missed out on external investment due to Licence delays	• Bulk of the dried Bio-mass imported • Post Brexit border force issues leading to delays and project cancellation • Same as Hemp growing - Licence delays but further financial burden on security cost to main safety stands for growing / storage facility	• Raw ingredients imported from abroad • No clear THC zero levels in product • UK leading in terms of legal, ethical and quality CBD industry	• Import of CBMPs is complex, fragmented and expensive • UK manufacturers of CBMPs are unable to export	• Research is hampered by Sc1 status of cannabinoids • Sc2 for THC only applies for clinical studies not before	• GW a UK founded company is the only company to have succeeded in this area • Multi-billion $ potential in indications known to have benefit for cannabinoids
UK companies in the sector	MRC AGRI	MRC AGRI	Dragonfly, Naturecan, Sativa Wellness	Grow, EMMAC, Brains	Artelo biosciences, UCL Uni, Nottingham Uni	GW Pharmaceuticals

1 CBD in the UK; Report by The Centre for Medicinal Cannabis 2019; **2** Total sales from listed cannabis companies including recreational; **3** Total R&D expenditure from private companies listed with a cannabis medicine focus ($171M of this total was spent by GW Pharmaceuticals) 2019; **4** Total public spending for cannabis/cannabinoid R&D - **https://hellth.com/#/welcome** ; **5** GW Pharmaceuticals 2019 annual report; **6** Total R&D spend by 442 development phase biotech; **7 https://www.evaluate.com/vantage/articlesinews/deals/gw-succumbs-jazz-overture**; **8** https://www.savills.co.uk/landing-pages/landscope/HempSpotlight.pdf w.w. - world wide value UK - UK value

Lack of legal clarity and clear regulatory pathways

4. Regulations around cannabis created a carve out for scientific research involving small test samples (the 'exempted product' example) and the 2018 amendments created a defined category of 'Cannabis Based Medicinal Products' to legalise the dispensing of cannabis products to patients with certain conditions by an authorised prescriber. The framework underpinning the prohibition of the cannabis plant was left unamended and as such, the cultivation of the cannabis plant under licence in the UK currently has only two approved legal routes to market:

a. As a raw material for industrial uses (when the stems and stalks of approved hemp strains are harvested under a low-THC licence), or;

b. For supply into pharmaceutical channels for clinical trials or licensed drug production (utilising the extracts of cannabis containing controlled substances under a schedule 1 drug licence).

As the Home Office has stated: "Where a product is neither a CBPM nor an 'Exempted Product', licenses would not ordinarily be issued to enable the use of a 'Schedule 1' controlled drug product outside of bona-fide research or a recognised UK clinical trial."[16]

5. There is no 'third way' of utilising a licence and yet the biggest market segment for cannabinoids in the UK today is outside industrial and pharmaceutical channels. The enormous array of grey market products of the UK's CBD industry has proliferated under a cloud of uncertainty and misunderstanding that "CBD products" were legal because pure cannabidiol was (and never has been) a controlled substance in UK law. As the CMC outlined in their 2019 report, the complexity of the law and the lack of market guidance and coordinated enforcement allowed this development. The result was that the UK, without making any changes to law, was suddenly able to attract a fast-growing unregulated 'cottage industry' of CBD suppliers based on online sales of foreign-imported products, typically of unknown origin.

6. By their own inaction, and the absence of a legal regulatory pathway for the licensed production of cannabinoids in the UK for supply into the nutraceuticals market, the Home Office left a gap that was exploited rapidly by foreign companies and their UK wholesalers. It was only in 2019 that the FSA – mirroring the approach of the EU – adopted the established 'Novel Foods' authorisation process for ingestible CBD consumer products and issued accompanying guidance. This set out a route by which such products could be legally sold in the UK and is currently the means by which hundreds of companies hope to have their products approved for sale.[17]

7. The FSA's approach, however, did nothing to address the upstream supply problem – that there was no legal route to market accepted by the Home Office as grounds for granting a cultivation licence, and so unlike in the USA, British hemp farmers were still unable to direct their own raw products into the domestic CBD supply chain to profit from this valuable consumer market. Ancillary businesses like testing laboratories did emerge to service CBD suppliers and to provide assurance to their major retail partners (including major supermarket chains) but they were, and are, testing and validating CBD derived from cannabis or hemp grown in other countries, not here in the UK. Whilst the regulations governing CBD look set to be tightened further, there remain inconsistencies with how CBD is governed in the consumer space for humans, and the tighter controls applied to CBD products for pets, and other gaps around cosmetics, and CBD vape products, which fall outside of the tobacco control regulations.

8. Further issues arise from the uncertainty around the legality of North American businesses seeking to operate in the UK which is not conducive to growth. Because cannabis remains prohibited under US federal law (as it is in the UK), it is argued that any investment (or dividends) accruing to individuals in the UK that derive from this commercial activity in the USA are proceeds of crime and make the person subject to criminal charges under the wide ambit of the UK's money laundering legislation.

No prosecution under the Proceeds of Crime Act (POCA) or any legal challenge has yet been mounted but the lack of clear guidance drawing a distinction between legitimate commerce in the UK (or Israel, Canada, Germany or Australia…) principally, by licensed medicinal cannabis firms, and illegitimate foreign activity (typically, companies with revenue from adult-use cannabis sales) will be preventing some companies from investing here. This issue was first flagged in 2019 after Canada's legalisation of adult-use cannabis took effect, but no government guidance was ever issued.[18] It has a particularly serious chilling effect on the willingness of larger listed pharmaceutical companies from considering investments in the UK cannabinoids market. Ironically, these concerns have not prevented major UK public companies investing in legal licensed cannabis companies in Canada.[19]

9. Licensing is currently a Home Office responsibility, and applicants may seek either a low-THC (industrial hemp) licence, or a high-THC (medical) licence. There is no licence for companies who want to cultivate hemp strains to extract CBD and other non-controlled cannabinoids, or to cultivate cannabis to extract controlled cannabinoids for end-uses other than as a medical compound in a clinical trial context. The licence process is lengthy and can take in excess of 18 months for the first application. Licences are renewable but the team is small, and the fees are low so applicants cannot be assured that new licenses will be processed expeditiously. There is no published guidance for potential applicants as there is in Canada,[20] and those with applications under consideration can expect no guaranteed timeframe for decisions.

10. There is no official data on the number of current/active cultivation licences that have been issued by the Home Office, though it is understood the majority are for research purposes to universities and other similar organisations, and there are few, if any, issued for commercial producers. The oldest licensee is GW Pharmaceuticals, which continues to operate a large cultivation programme as part of the British Sugar facility in East Anglia. In response to a recent Freedom of Information request and after a review of the public interest, the government refused to publish this data on the grounds that "could damage the commercial interests of the companies licensed by the Home Office and would also make them potential targets of criminal activity." The public interest is not upheld by maintaining a slow and secretive licensing process where there is no certainty for businesses in how long an application might take, and no transparency for the market and the wider public on who holds a licence and under what conditions.

11. Emerging markets need clear regulatory pathways and these need to be navigable. In the UK, the Home Office licensing process is the opposite of what a functioning market needs to operate efficiently. It is:

- opaque (no published criteria)
- uncertain (no clarity on review timelines or decision points)
- closed (no obvious contact point or specialist to speak with)
- confusing (challenging and ambiguous guidance documents)

From the outside, it is viewed as secretive and even capricious, with no transparency about who holds licenses and no appeals process for disputing a decision not to grant a licence. As one applicant remarked:

> *"[It] feels like being thrown into jail on suspicion of a crime you haven't committed. No one will explain what the charge is, no one informing you of your rights or when you can expect to be released and no one that seems very interested in plight. You ask your solicitor what happens next, and they tell you that they don't really know, it depends on the person who is in charge of your case. You have faith in the legal system, but you start to lose it pretty quickly".*

12. Another major disincentive for applicants is the need to invest in the infrastructure that can be inspected before any license will be granted. For an applicant seeking a high-THC licence for the indoor cultivation of medical cannabis, this represents significant upfront capital expenditure on a facility that may not be able to lawfully operate.

Together, these factors discredit the whole system and create incalculable risk throughout the entire process. Many overseas companies seeking to invest in the UK have been discouraged by a negative experience with a Home Office licence application.

Outdated rules governing research and cultivation

13. UK academics engaged in scientific and clinical research using controlled substances of any kind need to hold a schedule 1 licence and this involves upfront costs and complex audit and record keeping. The UK should be encouraging more primary research at our universities, but burdensome licence requirements discourage academics from pursuing research projects in the field of cannabinoid science. In the Government's Research & Development Roadmap, the barrier to research was identified:

> *"[S]pecific regulations still have the potential to slow down and stop innovation. For example, in healthcare, while the regulatory system is integral in preventing the misuse and diversion of harmful drugs, we need to have proportionate controls around access to controlled drugs in the area of legitimate R&D. Working with key industry and regulatory stakeholders, we will review the current regulatory system around controlled substances for scientific research to ensure it does not inhibit the development of new therapies and the full potential of the innovative life sciences industry."*[21]

14. Most laws relating to the cannabis plant are decades-old and have not been updated to reflect new scientific findings, and even most regulations - including in the UK - that directly bear on CBD are from the early 2000s: long before over-the-counter CBD became an important consumer trend. When the 2001 regulations were devised, the 'exempt product' category was intended to exempt scientists working with test samples from being criminalised for handling-controlled substances without a licence. There was no conception that a major wellness market, in online and over-the-counter CBD products, would arise and the 2001 regulations do not provide any lawful route to market for such products. This is because almost all will contain trace amounts of controlled cannabinoids and the exempt product criteria would not be met. The black-market production of cannabis to service the illicit drugs trade was joined by a large grey market in products derived from cannabis (or hemp) that was purporting to be legitimate, but was, in fact, outside any legal framework. It was only the good safety profile of CBD itself that worked in its favour, discouraging heavy-handed enforcement and leading authorities to tolerate the industry's expansion.

15. The outdated rules governing cultivation have allowed the UK's CBD market to profit foreign suppliers at the expense of British farmers who could be enjoying a strong trading demand for their hemp crops. As VolteFace has argued:

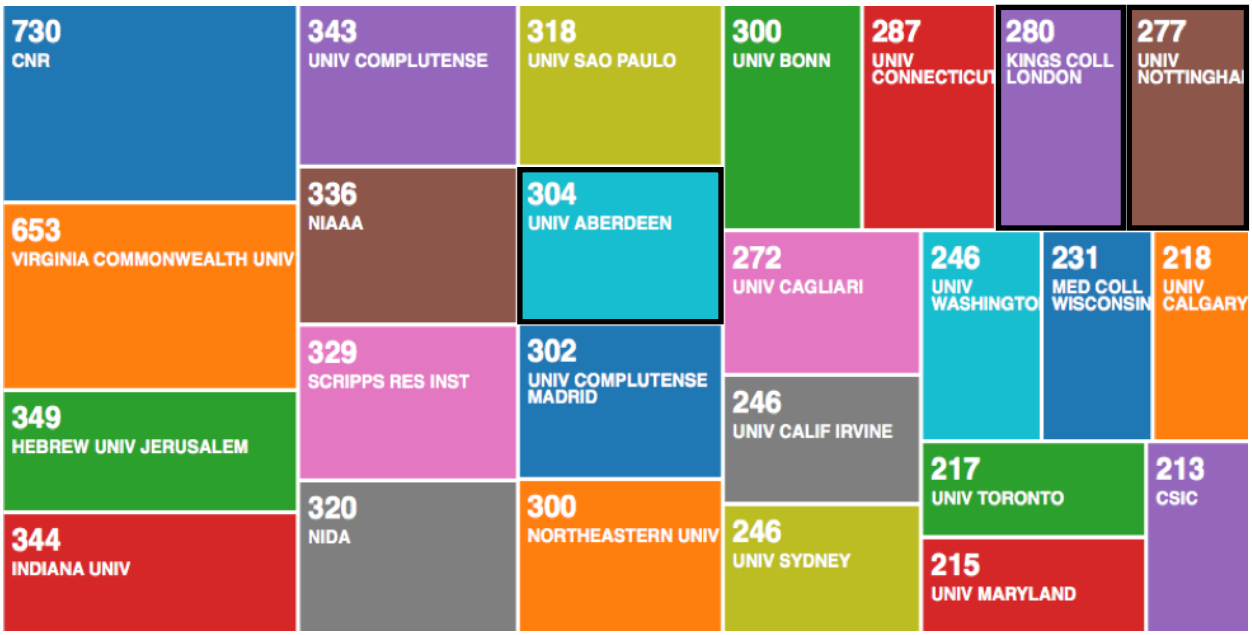
> *"The current set up gifts a significant competitive advantage to international companies that operate within more rational regulatory frameworks."*

As these rules are not mirrored in other European states, they create a structural disadvantage at the root of the British cannabinoids sector which cannot be compensated for by the vibrant end product market of consumer CBD.

As the CMC argued in their 2019 report: *"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…. A thriving CBD industry in the UK should not be reliant on imports. Even if the UK will never become a global leader in hemp cultivation because of climate, land values and crop acreage, that does not mean it should be made uncompetitive."*

Absence of institutional support

16. Even despite the licensing burden placed on university researchers, the United Kingdom contributes a disproportionate amount to the published scientific literature on cannabinoids. The USA, Italy, Canada and Israel are important centres for academic research into cannabinoids with the USA dominating the field of published studies. However, three UK universities have an influential volume of output and together produce more cannabinoids research than other European institutions:



Source: Institution of Origin of published literature 1970-2020 search term cannabinoids - Web of Science accessed 22nd Sept 2020

17. Despite this record, the funding directed at research has been declining steadily since 2011, and the majority is focused on exploring the harms of cannabis as an illicit drug, and not on the medicinal potential of cannabinoid therapies. UK universities are home to world-leading specialists, but the limited funding opportunities prevent them from pursuing large-scale translational research that would have major pharmaceutical applications and feed into domestic clinical trials. It is notable that despite pioneering our understanding of the plant, many British university research has not managed to generate commercially successful spin-offs in the field.

18. The National Institute for Health Research (NIHR) committed to funding cannabis medicine trials in 2018-19 but funding was allocated to only one study and the research priorities of the agency may no longer align with public commitments made to medicinal cannabis companies exploring the potential for new clinical trials in the UK in 2018. [22] The funded trials that are underway will not, by themselves, generate a large volume of data and there are no major Randomised Controlled Trials involving private sponsorship on the scale needed to reach thousands of participants.

19. Without a dedicated centre of excellence – as the CMC argued in their 2018 paper on how to deliver an effective system for medicinal cannabis access – the UK-generated research is likely to continue to rely on the uncoordinated efforts of individual university departments. The most efficient way to fund, direct and synthesise the evidence base in the emerging life sciences sector is to brigade resources under a single sponsor who can leverage external funding, and oversee and steer research efforts across the entire landscape. The UK lacks such a body, and the niche nature of cannabinoids science suggests that new innovations will be faster to emerge and will attract more sponsors if they are catalysed by a dedicated centre of excellence.

3. Case for a coherent cannabinoids strategy

1. The world has changed since 1998 when GW Pharmaceuticals set out on their mission to produce an effective, licensed medicine from the cannabis plant. According to the 2021 assessment by Prohibition Partners, the European medical cannabis market is now estimated to be worth €406 million by the end of 2021: a year-on-year growth of 75% compared to 2020, with a total of 185,000 patients across the continent, and Germany the most important market. The same report projected the European cannabis market is forecast to grow with a compound annual growth rate (CAGR) of 67.4% to reach €3.2 billion by 2025.[23]

2. Taking a wider view, according to Grandview Research (2020), the CBD market globally *"is expected to reach a value of USD 23.6 billion by 2025 growing at the CAGR of 22.2%."* Against this backdrop the UK's regulatory and licensing framework has not changed substantially, or has been updated in an uncoordinated ad-hoc way, and it is now a barrier to the future prospects of seeing another GW emerge, quite apart from the value created by new healthcare breakthroughs in an ageing society that requires better treatments.

3. Instead of standing still in the face of this rising tide of investment and innovation that other countries are moving to capitalise on, the British government should be proactive and devise a coherent industrial strategy for cannabinoids so the UK can capitalise on this industry and attract new investment, jobs and scientific endeavours to the UK. We argue that a do-nothing-approach will see jobs and investment move to North America, Australia and parts of Europe (including the UK's Crown Dependencies of Jersey, Guernsey and Isle of Man, where new laws have already been adopted).

4. The cannabinoids industry is unusual in being an area where the UK already has underlying strengths and relevant experience (despite being unsupported by government), and which requires only modest investment and regulatory modernisation to create the conditions for more growth. The cannabinoids sector is also at the intersection of at least three high-growth sectors for the global economy out to 2030 which promise major institutional investment, namely, **Health and Wellness**, **Technology**, and the **Green Economy**. Any strategy should be comprehensive and recognise the distinct contribution that cannabinoids can make in these high-growth sectors.

5. There are four themes which a comprehensive cannabinoid strategy must cover:

- **Medicines** – including creating the manufacturing, research and clinical trial pathway for the 'pharmafication' of the existing cannabis sector (and development of more companies of the scale of GW. This should also foster new biotech companies wanting to exploit cannabinoid medicine so we can deliver and licence new, efficacious treatments for a range of conditions, at a lower cost to the NHS and export products and innovation, more quickly. With a well-established life sciences sector and top-tier university research base, the UK already has one of the most profitable and innovative pharmaceutical sectors in Europe, alongside Germany and France. The UK has been a European leader in the Active Pharmaceutical Ingredient (API) field, with research indicating strong growth for this sector up to 2020. Dominated by established pharmaceutical players, the market will expand to accommodate demand for API quality cannabinoids, including CBD;
- **Nutraceuticals** – including the advantages of a modern framework for the robust regulation of wellness products to enable UK consumers to access CBD products produced from hemp grown, extracted and developed in the UK (ensuring quality and traceability) and to export this "gold standard" to foreign markets;

- **Environment** – including the use of hemp to supply raw materials to a range of sectors including, but not limited to, automotive, aerospace, and construction, where low-carbon products attract a premium and by using increased cultivation of hemp in the British Isles to make a meaningful contribution to achieving Net Zero by 2050;
- **R&D and Technology** – including new agri-tech and med-tech innovations to exploit new opportunities in the areas of plant genomics, extraction and formulation, and medicinal devices. Also using advanced data analytics to provide security, privacy and traceability for growers, clinicians, patients and consumers.

6. In a globally competitive, emerging industry, the UK has three comparative strengths in the cannabinoids sector around medicines and life sciences, financial services, and technology-led innovation (specifically in plant sciences, environment and sustainability). The UK's strength in **financial services** is already attracting interest from the global cannabinoid sector. A recent catalyst for the investor interest in the medicinal cannabis sector in the UK was the recent decision, set out publicly by the Financial Conduct Authority (FCA)[24], to permit certain companies in the sector to list on the London Stock Exchange for the first time, with MGC Pharmaceuticals and Israeli-based Kanabo both joining the exchange in Q1 2021. Permitting foreign (and domestic) companies to list in London, but not those engaged in recreational cannabis markets abroad, was an important decision that clearly distinguishes the UK as a market to trade and invest in, for legitimate, regulated goals in the medicinal market.

7. The companies listed in London do not need to hold a UK licence, but they do need to demonstrate compliance with their local regulatory regimes. As more companies pursue this route, the ability of foreign companies to raise money in London will make the UK more attractive as a place to pursue the commercial goals of building new cannabinoid businesses. The challenge is to translate the high finance activity in an increasingly globalised industry, into real jobs and investment in the UK itself, and tax revenue for HM Treasury. There are some signs that the tax regimes of offshore jurisdictions like the Isle of Man and the Channel Islands are proving attractive as places to incorporate global cannabis businesses with European ambitions.[25]

8. With respect to the UK's commitment to Net Zero, and the adoption of ambitious carbon reduction goals for 2050, the environmental advantages of embracing domestic hemp cultivation make **sustainability** a key pillar of any strategy. There is growing recognition of the value of hemp as a crop, and the benefits that the UK could realise from encouraging a return to mass cultivation of hemp within the British Isles:

Key advantages of hemp crops	
Break-crop Hemp can serve as an efficient 'break crop' to help farmers who need rotation options and can no longer rely on oilseed rape.	**Carbon sequester** Hemp is a highly efficient crop to offset CO2. Plants can grow up to 5 metres in only 12-16 weeks. It is estimated to absorb more CO2 per hectare than virtually any other plant. The products derived from hemp lock up carbon.
Low input crop Hemp can grow successfully without pesticides or herbicides and the crop needs minimal water, which makes it highly resilient and cost-effective to plant.	**Sustainable products** There are now 10,000+ sustainable products derived from hemp, including fuel (from biomass), plastics, and construction material (Hempcrete). Major clothing companies (Levis, Adidas) and automakers (BMW) are shifting to sustainable hemp products.
Soil remediator Hemp can serve to bio-remediate contaminated soil, and it improves structure and nutrient levels, which then leads to greater yields in follow-on crops.	**Whole plant value** Hemp can provide economic value from the seeds, stems and stalks, as well as the leaves and flowering heads, making it a crucial crop for diversification and raising farm incomes.

Source: BHA, EIHA, NFU

9. The agricultural value extends far beyond the return to large-scale domestic hemp crops. If the UK owned its own sovereign list of approved strains for cultivation, it could become the home of a mini revolution in cannabinoid plant science. In departing from the limited EU list, the UK would accrue some competitive advantage that researchers and new agri-science start-ups could exploit. If admission to the list was permitted for strains with trace THC up to 0.3% (or even 1%), then the variety of legal strains for domestic cultivation and trial breeding would significantly increase. There are already newly created strains of hemp that are cultivated in North America (and licensed for growing under the federal Farm Bill in the USA) that produce very high amounts of non-controlled cannabinoids like CBD, low amounts of THC, and are not currently on the EU list.

10. Setting a strategic goal of growing the legal cannabinoids sector would not just make sense economically, but it is also smart politically: it aligns with at least three **core cross-government objectives** (all of which will remain important for the next three decades):

- *Net Zero* (e.g., industrial low-THC hemp being an effective means to support carbon sequestration, soil remediation, and diversify away from plastics and other petroleum-based consumables);
- *Science* (e.g., with cannabinoid R&D supporting new drug discovery for healthcare and wider commercial applications from industrial hemp);
- *Levelling up* (e.g., with prospects for expanded manufacturing, domestic supply chains, and cultivation opportunities supporting local employment in all parts of the Union, as well as raising farm incomes).

11. Lastly, there is a window of opportunity now to create a growth strategy for cannabinoids because of the additional freedoms obtained by Brexit. For example, the chance to support farmers to transition to hemp growing, or to create a sovereign list of approved hemp strains. The prize for UK farmers is to breed and cultivate novel varieties from an expanded list that farmers in Europe cannot legally grow, rather than just being permitted to extract cannabinoids from the same variety of hemp that a Bulgarian farmer can already grow on cheaper land using cheaper labour. This list could then become the basis for an industry geared to 'genetics innovation' where the UK becomes a sandbox environment to cross breed strains to create low-THC, high CBD/CBG/CBC etc. strains with a wide range of potential human and industry applications. As Hanway Associates have argued: *"UK continuation of EU policy is in effect mandating that UK farmers use foreign seed suppliers who supply sub-optimal genetics"*.

12. By recognising the value in the cannabinoid sector and taking steps to leverage the UK's underlying strengths, the sector can potentially support many more jobs and drive major direct investment into areas of the economy that need it, especially following Brexit: namely agriculture and manufacturing.

Key enablers of a coherent strategy

13. There are 3 key, separate but complementary, enablers of a strategy to drive growth and support economic investment in the UK:

- **Supercharging our existing academic expertise** to seed a new centre of excellence which can fund, evaluate and explore all aspects of cannabinoid science and innovation;
- **Modernising the outdated and unfit legal framework** that contributes to uncertainty, and prohibits certain investments; introducing a clearer legal framework with supporting infrastructure to properly monitor, regulate and guide the growth of the cannabinoid industry;
- **Creating a modern, fit-for-purpose licensing and approvals regime** that is clear, proportionate and instills confidence among businesses. Such a regime would have three tiers for licensing businesses, should be transparent and customer-centric, and could be made self-funding.

The best future approvals process for non-controlled cannabinoids in ingestibles, vapes, and other wellness products may warrant a wholesale redesign of the Novel Foods process to make authorisation faster and cheaper.

Supercharging the UK's existing cannabinoids expertise

14. The UK should support the academic expertise in cannabinoid science by using life science funding in the R&D budget to establish a dedicated centre of excellence. This would bring together, coordinate, and multiply the research efforts of many different universities and create a vehicle for coordinating privately funded research. A new National Institute for Cannabinoid Science (NICS) should be university-affiliated to ensure impeccable research credentials and academic independence. It should also be unrelated to the licensing of scientific or commercial activity. It should, however, control a dedicated pot of money from public-private partnership to fund research across the spectrum of science including:

- **Basic science to understand cannabinoid biology and develop new intellectual property that can be spun out or licensed to existing players**
- *Crop science* – to further support the agricultural sector in producing increased yields of crop, assess and generate optimised sovereign strains more suited to the UK climate and customised to growing cannabinoids of interest, and work to understand the relationship of cannabis growing and its role in reducing carbon footprint.
- *Analytical sciences* – The cannabinoid industry has been hampered by the lack of recognised and standardised analytical methodology. Without reliable and accessible analytical methods, it is impossible to police future laws and policy, and makes operating in the cannabinoid sector challenging for legitimate businesses. This lack of analytical excellence is not just limited to the UK and this research would be entirely exportable to support the expanding global cannabinoid sectors world-wide.
- *Food/Nutrition science* - The nutraceutical and wellness cannabinoid market is a significant and growing value sector. It is open for the non-controlled cannabinoids to be used in subject to novel food provisions. It is currently dominated with CBD, but this is likely to evolve to other cannabinoids such as Cannabigerol (CBG), Cannabidiolic acid (CBDA) and Cannabigerovarin (CBGV). Understanding the benefits and harms of novel cannabinoids is going to be an important area to understand.

- **Translational science to prepare for clinical research and bolster the IP portfolio that can be spun out or licensed to existing players**
- Both pre-clinical models and novel clinical proof-of-mechanisms for key indications related to the emergence of potential uses of cannabinoids, are largely lacking in the scientific literature. This hinders the furtherance of proof-of-concept and regulatory studies as they become too risky to finance without the underlying science.
- There is surprisingly little known on the basic pre-clinical and clinical pharmacokinetic and pharmacodynamic interactions between cannabinoids used in combination. Research has tended to be biased towards single cannabinoid research or 1:1 mixtures of CBD and THC. Research into how different cannabinoids interact, and therefore provide novel pharmacology to address different indications, would be a welcome addition to the field.
- Cannabinoids derived from plants are often implicated with an "entourage effect" when used in a raw extract. The belief by some is that the diverse range of cannabinoids, plus other plant derived compounds such as terpenoids and flavonoids, contribute to additional effects above and beyond the major cannabinoids present in the extract. By implication, it may be that whole plant extracts are more useful as medicines than the isolated cannabinoids, but this has not been evidenced in any robust scientific or clinical experiment. Understanding this fundamental question would help cannabinoid researchers design the right clinical trials in the future.

- **Clinical science to generate the evidence that will be needed for physicians, payers, health technology assessments (HTAs) and regulators (e.g., NHS, NICE, MHRA)**
- Using the Innovative-Licensing and access clinical pathway (ILAP)[26] which is the new UK initiative supporting innovative approaches to the safe, timely and efficient development of medicines to improve patient access, it will be possible to work with private industry and NICS/NIHR funding to run clinical trials which will raise the bar from the current unlicensed special medicines to provide solid and compelling evidence and safety to support the wider use of these medicines, in both private settings and the NHS. Allowing a permissive environment of trialling in the UK will draw inward investment as the data generated will be applicable in world-wide markets. Generating clinical evidence to support current challenges within the NHS (e.g., long-COVID, opiate addiction, chronic pain, fibromyalgia, intractable neurological conditions) will generate new therapy options to help alleviate patient suffering and the increasing burden of drug and treatment budgets.

Update and clarify the legal framework

15. Without resorting to primary legislation, the UK government can make new rules that will create conditions conducive to investment and growth. A market that is already reliant on imported hemp will not generate value across the whole supply chain in the UK unless British farmers are also able to compete. The growth of imported products from North America and the downward pressure on prices will also further risk a deterioration of the quality that British consumers deserve. The answer is to permit UK farmers to handle the controlled parts of the plant, and therefore become domestic suppliers to licensed processors who – with a new licenced, regulatory pathway – could supply CBD companies in the UK (or abroad). Under this approach, farmers would still need a hemp licence, and could only grow strains below a set limit of THC, but the change would make the growing of hemp in the British Isles much more profitable and likely lead to a major agricultural shift as more growers enter the market.

16. In addition, the processing industry – operating under a new licence – would emerge to service the demand with established CBD companies investing in new UK-based facilities to extract, process and refine their products. Mandating traceability in the supply chain for hemp would also catalyse domestic production, rather than relying on complicated international sourcing.

17. We estimate around one third of the entire domestic market of consumer CBD products could be serviced by homegrown hemp supply if the current estimated acreage of hemp grown in the UK (c.2,000 acres) increased 10-fold within two years. This would still be 1/12th of the total 285,000 acres cultivated in the USA in 2020, two years after the passage of the 2018 Farm Bill, so may be an underestimate of how much cultivated acreage would increase in the UK, even accounting for the UK's greater density and smaller scale farming and field sizes.

18. The UK Government has stated its intention to update the regulations in the 2001 Misuse of Drugs Act to amend the exempted product definition to clarify its purely scientific purpose, and to provide clarity over the trace elements of controlled cannabinoids permitted in a legal CBD product.[27] The ACMD have been commissioned to advise on what this safe de minimis limit should be, and after considering their advice, secondary legislation will be updated later in parliament. The ambition here is the right one, and it will provide much needed regulatory certainty and legal clarity to the UK's large and dynamic CBD sector. The CMC have separately proposed a limit that would provide clarity and allow for a viable market with the necessary testing infrastructure to ensure quality and compliance. Whatever level is set in law, the industry needs this change as soon as possible; there will need to be an expansion of the UK's laboratory market to accommodate the demand from suppliers seeking to prove their CBD can comply with the new requirements.

19. With the passage of the 2018 Farm Bill in the US, removing hemp products containing CBD (but not THC or the cannabis plant itself) from threat of enforcement by the Drug Enforcement Administration, this move has already provided a significant boost to US agriculture, given the value of the biomass for this burgeoning consumer CBD market. Major hemp producers in the United States are now gearing up for international expansion, with hemp grown in areas like Arizona specifically to be supplied for export.

20. New guidance on the **importation** of raw biomass or distillate/isolate from extraction overseas should be issued alongside a clear statement of the legality of medicinal cannabis companies operating in the UK under money laundering regulations. Providing this clarity on the law to the whole cannabinoids market will encourage investment. It will lift the cloud of uncertainty from ancillary businesses looking to work with the sector, and the major listed companies, that could prove valuable partners for driving investment and forging new collaborations, to take the cannabinoid industry to the next level. In addition, associations with a prohibited plant should not prevent UK-based CBD businesses from being able to access the same start-up incentives and innovation grants as any food, healthcare or technology company, or the banking services required to support retail to consumers.

21. Despite administrating the Novel Food authorisation process, it is not yet clear what a proportionate enforcement approach by the UK's FSA will look like as it relates to CBD products after 31 March this year. New action is needed to warn and deter, and it would support the legitimate growth of the industry if **smart enforcement** by Trading Standards was intensified in 2021 to remove certain illicit products and protect consumers. Now a pathway for regulatory approval is open, the responsible cannabinoid industry should be united in its desire to see this kind of enforcement action, which will discourage grey market activity and improve the competitiveness of legal companies.

22. Following on from the UN vote on rescheduling CBD in 2020, international efforts are underway to bring some coherence to how cannabis cultivation, production and import/export for medicinal purposes are regulated. Countries engaged in the initiative want to agree common approaches on how production and distribution are monitored and reported under the narcotics control treaties, and recent meetings at the International Narcotics Control Board may yet create new rules for signatory countries like the UK to follow.[28]

23. If the UK permits domestic extraction of cannabinoids from plants grown under licence in the UK (as other signatory states do), then the volume of imports and exports will be impacted and reporting the activity under UK treaty obligations will continue to be a requirement. It is possible to pursue a strategy for a mature, well-regulated and competitive cannabinoids industry without the UK falling foul of **international treaty obligations**, or undermining the spirit of the original conventions which placed a strong emphasis on coordinated international approaches to control and limit the access to controlled drugs. Countries that have legalised cannabis for adult-use, even within a strict framework like Canada, are going much further and adopting a stance that is incompatible with the spirit and letter of the drug control treaties, and it is not the argument of this submission that the UK should head in this same direction.

Create a modern, fit-for-purpose licensing and approvals regime

24. The UK needs a new regulatory front door to a global industry that is geared towards encouraging legal actors to invest in the UK, rather than the opaque system of Home Office approvals that ignores all economic considerations and merely tolerates the applications it receives, while offering little or no incentive or support to companies to follow the rules.

25. In response to the size and value of the cannabinoid market, and in order to foster genuine expertise and regulatory innovation, the UK should seek to create a dedicated regulator, and remove this function from the Home Office, by establishing the '**National Cannabinoid Control Authority**' or NCCA. This new agency should be empowered to grant licenses; review, amend or revoke licenses; inspect the supply chain to ensure compliance; and promulgate new guidance and rules relating to cannabinoids to provide market certainty and encourage investment. It should provide licensing based on a published criteria and transparent scoring (with feedback given to applicants). The NCCA would be the single cannabinoid regulator discharging government functions outside of a department of state, but would not be a scientific advisory body – this function should be separate and constituted as part of a national institute that can leverage top-tier academic partnerships.

26. The UK also needs a tiered licensing system with costs and controls that are proportionate to the end use and the risks that need to be mitigated. A three (or four) tier model would allow fewer controls on academics so we can **lift barriers to primary and clinical research** on cannabinoids (in line with commitments already made in the R&D strategy), potentially with the creation of a light-touch, low-cost, 'research licence' available to registered academics associated with bona fide higher education institutions. Above this would be a more expensive (but affordable) hemp licence, and then a separate category of extractor licence for companies seeking to extract from raw biomass and process into a non-controlled consumer product. Finally, the most costly and restrictive licence, for the cultivation (indoor or outdoor) of high-THC cannabis for supply into the medical market.

27. To further boost the UK's competitive advantage in agriculture outside of the EU, it should choose to expand the **catalogue of approved strains**, and create research and breeding licenses for unapproved strains as New Zealand has done, leading to a distinctive sovereign list of varieties (as also exists in Canada). Hemp grown in the EU before 1984 could reach 0.5% THC, this was lowered to 0.3% and then again in 1999 to 0.2%, and applied across all Member States. The United States and Canada both adopted 0.3% and continue to apply this level. The UK cannot compete in the global hemp market through scale, so it has to distinguish itself as a destination to trial hemp innovations, and to explore novel new genetics; that necessitates a longer list of permitted strains with levels higher than 0.2%.[29] DEFRA should commission an expert study to examine the genetic potential of raising the limit to 0.5% or even 1%, as adopted in Switzerland in 2011.[30] As Volteface argue in their report *Pleasant Lands*:

> *"As a wet and windy island, the UK is unlikely to emerge as a hub for mass cultivation, but if a liberal regime for permitted crop varieties were to be introduced, the UK would be an ideal hub for investment in plant science, agri-tech and plant genetics. A permissive THC limit framework in line with the Swiss model would allow UK farmers a competitive advantage; Switzerland increased their THC limit to 1% in 2011 and cultivation is not limited to EU-authorised varieties, enabling the development of specialised CBD-dominant genetics and Europe's largest hemp tobacco substitute market. The full benefits of this innovation would however only be felt if CBD extraction was permitted under an updated licensing regime."*

28. When it comes to the approvals process for cannabinoids in nutraceuticals, further reforms should be considered. **The Novel Food process** is an important standard to help ensure food safety for all consumers and is not by itself defective. For this reason, the UK took steps to mirror this regulation after exiting the European Union in 2020 (as it is no longer party to the European Food Safety Authority or its committee structures). For example, highly purified isolates are clearly novel in food and given the large market and routine consumption, the assurances provided by safety studies is the responsible approach. Outside of the EU, the UK is free to pursue a bespoke regulatory process for non-controlled cannabinoids. The best approach is to maintain high standards for approval, as these will best serve the UK in the long-term, but do more to expand the FSA's capacity to process applications efficiently, speed up the authorisation process and reduce certain upfront requirements that act as a barrier to smaller companies.

29. Policymakers in the FSA should explore ways to offer a more light-touch authorisation process that requires less upfront investment, and be more proportionate given the nature of the consumer CBD products under consideration. Such a process would need to be designed following extensive engagement with stakeholders and scientific bodies. Other important peers are moving in this direction: for example, in the USA, federal regulators have yet to determine how they intend to authorise the licensing of CBD products, and the Food & Drug Administration announced a public consultation on this, which began on 31 May 2019 and has yet to report.

4. Recommendations

1. The changes to law and regulations can happen in parallel to building out the architecture needed to institutionalise a well-regulated, high-quality, science-led cannabinoids strategy for the UK. The UK's large and dynamic CBD sector is an asset to be supported and nurtured, but it must mature into a well-regulated, innovative and responsible industry as quickly as possible. For that to happen, the legal framework needs to be amended and a modernised licensing regime is required, but there is an institutional gap that needs filling too.

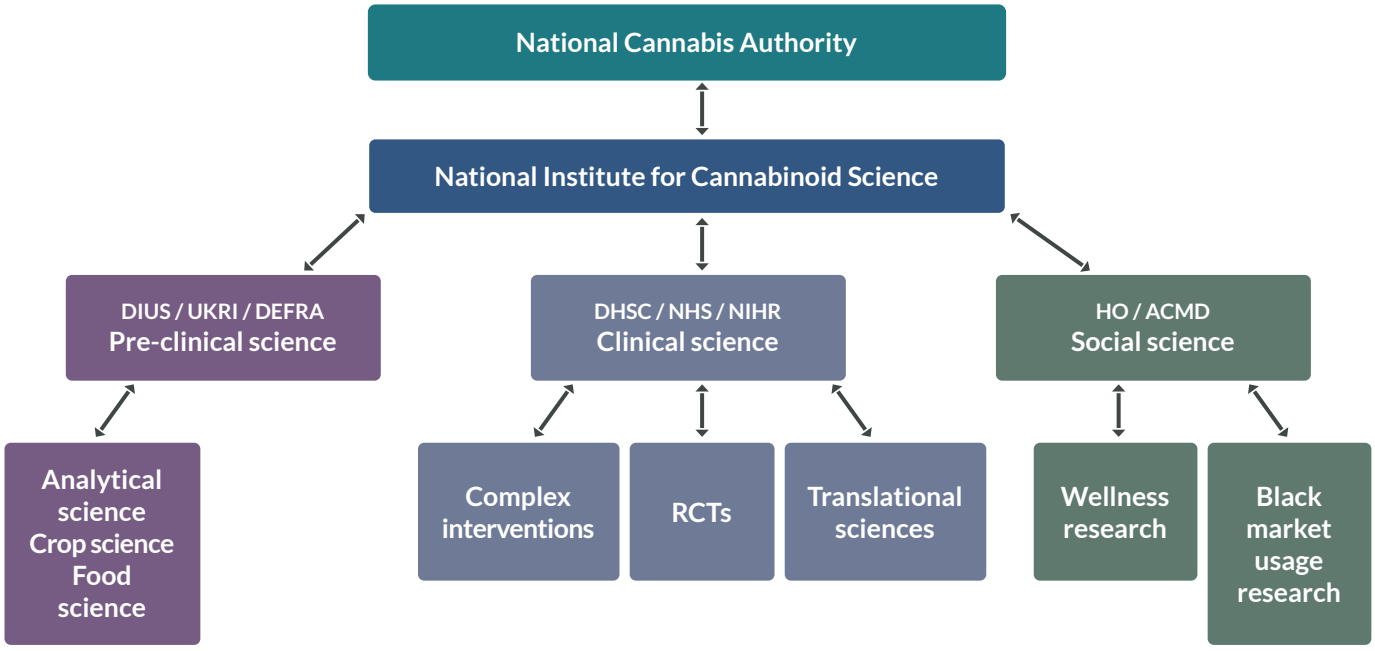
Outline of a new architecture

2. The key pillars of this architecture include:

- a dedicated agency to licence and oversee the industry;
- a centre of excellence to fund, synthesise and promulgate the best new evidence;
- an ongoing role for the Home Office in overseeing research into drug markets and drug harms (including cannabis);
- and an ongoing role for the DHSC and its funding agencies (NIHR) to sponsor clinical research involving cannabinoids.

3. Such a landscape would ensure licensing and commercial activity was conducted by a dedicated regulator with specialist expertise that was arm's-length from the Home Office (helping to normalise and de-politicise the activity), operating alongside a world-leading institute that was independent of government, and able to support, steer and harness the emerging scientific evidence across the whole spectrum: from agri-science and plant genetics, to novel synthetics, new therapies and clinical trials.

4. This structure would provide an architecture for the industry to grow and expand, and for the evolving evidence base to find efficient ways to be translated into commercial or pharmaceutical applications. It would avoid the complexity of dividing the licensing function between departments of state, or leaving the UK's cannabinoid R&D agenda at the whim of a handful of universities.



5. TIGRR seeks input on a range of changes that would support the goals of the taskforce, and the recommendations below relate to these goals:

Sectors of the economy or regulatory frameworks which should be prioritised for further regulatory deep dives

Recommendation 1: The UK Government should commission an internal deep dive of the cannabinoids sector. The UK hemp and cannabinoids sector has never been the subject of an economic analysis to determine its size, value and net fiscal contribution. The goal of this would be to accurately capture the range of legal activity currently underway, estimate the value of the current cannabinoid sector, and the barriers to future growth. This analysis should be through an economic lens to identify the level of consumer demand, retail activity, supply chain value, foreign direct investment, and projections for future growth. This deep dive should be led by the Department for Business, Energy and Industrial Strategy (BEIS) so that the economic dimension is properly captured, with key input from the Department for International Trade (DIT) (on investment potential and import/export issues), the Home Office (on licensing and convention compliance), DHSC (on medical use and clinical research) and DEFRA (on hemp farming and sustainable uses for industrial hemp products). In parallel, DIT, DEFRA and BEIS should collaborate on an industry consultation looking at the commercial potential for industrial hemp products in the UK and global supply chains, to estimate where agricultural production of hemp could contribute to innovate sustainable products in the wider economy.

Recommendation 2: DEFRA should conduct a cost-benefit analysis of amending rules on hemp cultivation. A full impact assessment of the benefits of liberalising cultivation rules on hemp needs to include the costs associated with an expanded licensing agency or team, and the extra resources needed to monitor licence-holders' compliance. The policy change is likely to significantly increase hemp licence applications and the amount of hemp being grown, so additional surveillance capacity and adequate resources devoted to processing applications will be required.

Recommendation 3: The Cabinet Office should review recent international experience of regulating this sector and this overview should inform the deep dive led by BEIS. The example of other Common Law jurisdictions (in particular, Canada, Australia, New Zealand, South Africa, and the Channel Islands) plus peer group countries (Israel, Malta, Switzerland), will provide options for how to create a robust, dynamic and inviting regulatory framework for the UK which would maintain high standards (and convention compliance), but do more to support UK investment and job creation.

Recommendation 4: Commission a deep dive into the market for Consumer Cannabidiol Products (CCPs) to determine market behaviour, value, and commercial activities that undermine consumer rights. A detailed and up-to-date picture of this diverse and rapidly evolving sector will be critical in informing the activity of regulators, and for empowering the respective authorities to prioritise compliance checks so they can decide where enforcement should focus. Lack of enforcement cannot continue once new THC levels have been set and there are lawful regulated pathways. Trading Standards and the FSA will need accurate market intelligence to coordinate their activity to deter illicit products and uphold the rules.

The reduction of administrative barriers to scaling up productive businesses; and tailoring any necessary processes to the needs of UK start-ups and SMEs - while maintaining the Government's commitment to high environmental standards and worker protections.

Recommendation 5: Level the playing field for UK farmers by permitting them to utilise the whole plant, under licence. 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 in 2019 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. As VolteFace argue: "Legal and policy experts agree that these changes would enable UK businesses big and small to benefit our future national economy in a way that is just, rational and fair." Utilising the legal authority under the MDA that grant broad powers to the Secretary of State, or preferably by amending the 2001 Misuse of Drugs Regulation via a statutory instrument (secondary legislation), could create new rules to permit farmers to sell the flowering tops and leaves of the cannabis plant to a licensed processor to utilise the non-controlled cannabinoid content.

Recommendation 6: The UK should establish a dedicated cannabinoids regulator – a 'National Cannabinoid Control Authority' – built upon expertise from several departments of state (Home Office, DEFRA, DHSC and DIT), combined with regulatory skills from MHRA, FSA and the Environment Agency (EA). Such an agency is deemed a requirement of signatory states to the 1961 Convention as part of their creation of a licensed regime, which, until now, has been conducted by civil servants within the Home Office.[31] Together the NCCA would develop the experience to provide a single 'front door' to the cannabinoid sector for applicants of all kinds. Consideration should be given for this agency to be a non-ministerial department so it could operate independently and without political interference, as the FSA or Forestry Commission do.[32] The NCA could provide a dedicated licensing branch and a surveillance and inspection function, with annual reports to Parliament and the sponsoring department. A dedicated licensing body could also be required to publish all applications and the full details of the licenses granted on a regular basis, as they are in Canada.

Recommendation 7: Regulators should pursue proportionate, robust enforcement action to remove non-compliant CBD products now that a clear approval pathway is available. A properly functioning market needs clear regulations that the respective industry can comply with, and then proportionate but robust enforcement to deter non-compliance and drive the suppliers and retailers who breach those regulations out of the market. Regulators like the MHRA and FSA already have all the tools they need, but they have to be prepared to use them. The need for this will increase once the Home Office concludes its own process of defining what 0% THC means in the context of Consumer Cannabidiol Products (CCPs) and when legal ambiguity is removed.

Recommendation 8: Support consumers with a quality standard and labelling scheme for consumer cannabinoid products based on testing by licensed UK laboratories. As recommended in the CMC's 2019 report, the CBD sector needs a branded kitemark scheme to signal to consumers which products have met quality standards. There is currently no dominant brand for a quality badge or kitemark for CBD products. Labelling needs to improve to ensure accuracy and to make the contents clearer for consumers, but this could be enhanced if the industry could agree on a common labelling and a 0% THC validation mark that only the best CBD producers could use, following a robust accreditation scheme.

Recommendation 9: The Department for International Trade (DIT) should issue new industry guidance on exporting cannabinoid products to the EU and worldwide to encourage British companies to seek new markets, while remaining compliant. Relaxing rules on domestic cultivation for hemp will open up export opportunities, and growers and extractors will need clear legal cover to encourage them to export their CBD produced in Britain. Trade in CBD as a commodity is an area of interest among Commonwealth countries and could benefit from liberalisation as the UK strikes new bilateral free trade deals with countries like Canada, Australia and India in the years ahead.

Encouraging innovation and accelerating the commercialisation and safe adoption of new technologies, cementing the UK's position as a global science and technology superpower.

Recommendation 10: Use R&D funding to establish a dedicated 'centre of excellence' for cannabinoid science in the UK. The current government has pledged to increase R&D spending over this parliament. In partnership with philanthropists and the private sector, a newly-endowed institute should be created to serve as the national hub for cannabinoid science, with a remit to cover basic science (to understand cannabinoid biology and develop new IP that can be spun out or licensed to existing players), translational science (to prepare for clinical research and bolster the IP portfolio that can be spun out or licensed to existing players) and clinical science (to generate the evidence that will be needed for physicians, payers, HTAs and regulators e.g., NHS, NICE, MHRA). This body – a 'National Institute for Cannabinoid Science' - should have a university affiliation and become the UK's centre of excellence with the credibility and authority to advise on the emerging evidence base.

Recommendation 11: Set UK-specific thresholds for THC in cultivation and trace limits in consumer end products to allow the UK to distinguish itself from the rules applying among European competitors. The Government should consider the regulations governing products in Switzerland, including the higher 1% THC cultivation ceiling and the 0.007 mg/kg of THC in finished CBD products, and provisionally adopt the proposal for a safety limit of 0.03% THC made in the CMC/ACI report 'Health Guidance Levels for THC in CBD Products'. The Home Office should also commission the additional research needed to justify the chosen limits through rigorous studies.

Recommendation 12: Exempt compliant CBD oil products from UK drug legislation. Following the ACMD consultation this year, this approach should be adopted if such products contain below 0.021 mg/kg of THC and classify products containing 0.03-0.2% controlled cannabinoids under Schedule 5 of the 2001 regulations so they can be made lawfully available for online or over-the-counter supply in the UK. These two steps together would instantly regularise the CBD market and create a distinction between compliant products and illicit ones. Market demand for robust analytical services to validate products and prove compliance with these rules would drive growth in laboratory services in the UK and the creation of hundreds of new laboratory technician roles in the UK.

Recommendation 13: Reinforce the quality standard and consumer rights around CBD by encouraging the market to utilise post-production testing at independent laboratories in the UK. New guidance should be issued for CBD companies operating in (or supplying into) the domestic market, which encourages suppliers and retailers – including major high street stores and supermarkets – to source only CBD products that are tested for purity and compliance at laboratories based in the British Isles. Guidance should clearly favour laboratories that meet independent industry approved standards (ISO17025 etc) and who are testing CBD products after importation (not in the country of origin) or after domestic extraction and finishing (when that is permitted). This will further catalyse the domestic analytical testing sector and allow credible, independent testing companies with experience of agri-food and plant science analytics to expand to serve this new consumer demand.

Recommendation 14: Issue clear statements of the legal parameters within which companies can operate in the cannabinoids sector without risk of prosecution. The government should publicly confirm the legitimacy of medicinal cannabis companies operating in the UK and their activities being lawful under POCA. Investment anxiety in the cannabinoid sector is an ongoing issue; more foreign investment and the scaling up of UK companies will be encouraged if the legal position is clearly stated by a competent authority. By amending the 2006 order or issuing guidance, the Home Office and National Crime Agency, should provide clarity that confirms – in line with the rationale adopted by the FCA for listed companies – which activities are legal. Certainty on what would put a company at risk would remove confusion and cement the UK as a destination for the high value, high-quality medicinal and nutraceutical cannabinoid market, and deter those foreign companies whose revenues come from recreational sales in some states in North America (in breach of federal law there). A similar statement from DEFRA would provide clarity to hemp producers.

Reducing barriers to entry in specific markets and make markets more dynamic and contestable across the economy.

Recommendation 15: The UK should create a sovereign list of approved Cannabis Sativa strains. Exit from the EU enables the UK to decide which aspects of the regulatory baselines linked to membership of the Single Market are suitable for the UK. In the hemp sector, the EU list of approved strains guides what farmers across the bloc are able to plant. The UK Government adopts this list unamended but is free to vary it in future if policy decisions are taken to make the UK a destination for the research and commercial exploitation of novel strains. In 2021, outside of the EU, the UK can start with the current list but should now choose to develop this and add new varieties, following consultation. The new UK list would (presumably) be longer and could be revised and added to on an annual basis. The scientific and agricultural expertise to advise on the UK list could become a function of the National Institute for Cannabinoid Science.

Recommendation 16: Mandate traceability in the supply chain for hemp. UK farmers given the authority to utilise the whole plant would sell their biomass to licensed extractors. Growers and extractors should be responsible for ensuring full traceability so the origins of the plant material are tied to the farm(s) supplying them, thus risks around diversion, provenance and accurate labelling can be mitigated. Modern authentication tools like blockchain can verify the integrity of a product through the supply chain at every stage – including those involving multiple overseas partners.

Recommendation 17: Explore a more streamlined approvals process for Cannabidiol Consumer Products. The best future approvals process for non-controlled cannabinoids in foods, beverages, vapes and other wellness products may warrant a wholesale re-design of the Novel Foods process to make authorisation faster and cheaper. This opportunity the UK has, outside the EU, to design a bespoke system should be taken up, learning from the FSA's experience of engaging with the sector and undertaking the first round of the Novel Food authorisation process. Commercial experience from applicants in this first round suggests that this gold-plated process has been confusing, costly and bureaucratic and is unlikely to be effective over the long-term.

Recommendation 18: Re-examine the recommendations in the 2017 ACMD advice on the Legitimate use of controlled drugs: research and healthcare. The ACMD has already produced guidance for the Home Office to pursue a much more R&D friendly attitude to legitimate companies and universities who want to conduct R&D on cannabinoid molecules. This advice has never been adopted by the Home Office[33]. The ACMD discusses different options for controlled substances at different stages of the R&D cycle, but appears to reject a blanket "research exemptions", given the complexity of fitting a one size fits all policy to different laws and regulations. Given that the subject of the MDA/MDR would need to be addressed to fulfil the overall goals of this cannabinoid report it would be an ideal time to ensure that cannabinoid R&D was not hampered by onerous and over-protective licencing requirements.

Improving small business' experience of necessary regulatory requirements.

Recommendation 19: Create a streamlined, transparent licensing process with controls and fees that are proportionate to the end use. The range of applications for cannabinoid production, processing, research and commercial development require a bespoke licensing framework which is proportionate to the activity and the risks associated with it, and with the product's end-use. The UK should adopt a modernised licensing regime to give certainty to applicants and make the process more customer-centric and transparent. The cost of licenses should be increased to provide more resources for the licensing review team and the higher costs should be used to deliver better service level guarantees – including a commitment to regular communication, clear decision gateways, and a timeframe for final decisions. Costs for licences should be kept low for researchers based at authorised academic institutions, and for growers of industrial hemp, but increased for the more complex and commercially valuable licences associated with nutraceuticals and medicinal use.

The licensing of basic research by universities should be the cheapest, quickest and least onerous of the licence channels, followed by a light-touch process for farmers for the cultivation of industrial hemp, followed by processing licences for approved businesses, and with commercial cultivation, processing and distribution of high-THC cannabis for medical purposes remaining the most highly regulated channel. A third licensed channel should be created for companies producing non-controlled cannabinoid end-products in the wellness space. This new middle-tier licence category for the production and processing of cannabinoids for supply into the cosmetics, nutraceuticals or vaping sectors should be developed with agreement of sister agencies like the FSA. This licence should cost less than a medicinal cannabis production licence but be more expensive than a hemp cultivation licence; the revenue should support enhanced supply chain surveillance for these products which should be subject to downstream market checks to ensure UK-production is compliant and there is qualified end-use, to guard against risks of diversion into the grey market for CBD.

Recommendation 20: Modify the duty regime to the lower costs on those businesses using ethanol extraction. HM Treasury sets the rate of excise duty, and the duty on ethanol applies broadly and so adds unnecessary cost to the cannabinoid sector. The duty is designed to raise revenue and moderate consumption when the alcohol is designed for human consumption as a beverage. However, it is also a key solvent used for Hemp/herbal extraction for development of pharmaceuticals. If companies use ethanol for medicinal development, then they are exempt from paying the duty, but this does not apply to the wider wellness/ nutraceuticals market. This means the industry has to pay the full duty on alcohol and this accounts for significant development costs. Reducing the duty rate (by creating a special category), or exempting from the duty charge, the ethanol used for nutraceutical production would reduce the operating costs for these businesses and make production onshore in the UK more attractive.

Annex - Market Sizing Methodology

New Public First polling enables an updated market-sizing estimate for the UK's CBD market. The headline estimate (£690 million) is the geometric average of two methods:

1) Public First ran a new nationally representative poll of 1,002 British adults through Dynata, replicating the previous Navigant survey question:

Have you ever tried / used / purchased any of the following products in the last 12 months?

- Healthy Cereal Bars
- Viagra
- CBD (Cannabidiol)
- Protein powder
- Diabetic Injector Pen
- E-Liquids
- Prescription Contact Lenses
- Heat Patches (For back pain)
- Methadone
- Deodorex

Public First took the weighted percentage of adults who said they had used CBD in the last 12 months and adjusted this for:

- the difference between self-reporting vaping from the same question, and the ONS' latest estimate
- an adjustment factor, based on previous Navigant study ratios, to control for CBD users who do not use it at least monthly

They then applied this adjusted percentage to the Navigant estimate of average spend per user, and use updated ONS population estimates. This produces a headline estimate for market size of £427 million in 2021.

2) Public First ran a second representative survey of 1,000 British adults through Google Consumer Surveys, in which they used a simpler question form which is more likely to pick up usage:

Have you purchased a CBD product in the last 12 months? (e.g., CBD Oil, CBD capsules, CBD creams, CBD cartridges, CBD gummies etc)

- Yes
- No
- Not sure

They took the weighted percentage of adults who choose 'Yes' on this (8.2%), and applied an adjustment factor, as before based on the previous Navigant study, to control for CBD users who do not use it at least monthly.

Public First then again applied this adjusted percentage to the Navigant estimate of average spend per user and use updated ONS population estimates. This produces a headline estimate for market size of £1.2 billion in 2021.

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Public First

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