THE HODGES REVIEW

FROM CONTAINMENT TO NURTURING:

How the UK can become a world leader in cannabinoid innovation

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Association for the Cannabinoid Industry

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The Centre for MEDICINAL CANNABIS

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Glossary

ACI	The Association for the Cannabinoid Industry
ACMD	Advisory Council for the Misuse of Drugs
APPG	All-Party Parliamentary Group
BEIS	Department for Business, Energy and Industrial Strategy
BMJ	British Medical Journal
CBD	Cannabidiol
CBG	Cannabigerol
CBN	Cannabinol
CBMP	Cannabis-Based Medicinal Product
CBPM	Cannabis-Based Product for Medicinal Use in Humans
CMC	The Centre for Medicinal Cannabis
CQC	Care & Quality Commission
DHSC	Department of Health and Social Care
EFSA	European Food Safety Authority
EU	European Union
FDA	Food & Drug Administration
FSA	Food Standards Agency
FSS	Food Standards Scotland
GMC	General Medical Council
cGMP	Current Good Manufacturing Practices
GLP	Good Laboratory Practices
GP	General Practitioner
HO	Home Office
ISO	The International Organisation for Standardisation
MDA	Misuse of Drugs Act
MDR	Misuse of Drugs Regulations
MHRA	Medicines and Healthcare products Regulatory Agency
NCA	National Crime Agency
NHS	National Health Service
NHSBSA	NHS Business Services Authority
NICE	National Institute for Health & Care Excellence
NIHR	National Institute for Health Research
NPCC	National Police Chiefs' Council
OBCR	Outcome-Based Cooperative Regulation
OTC	Over the counter
POCA	Proceeds of Crime Act
R&D	Research & Development
RPS	Royal Pharmaceutical Society
THC	Tetrahydrocannabinol
TIGRR	Taskforce on Innovation, Growth and Regulatory Reform
TS	Trading Standards
TGA	Therapeutic Goods Administration
UKRI	UK Research & Innovation
VMD	Veterinary Medicines Directora

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About this report

This report is the outcome of a review led by Professor Christopher Hodges on behalf of The Centre for Medicinal Cannabis (CMC) between March-June 2022. The project involved industry engagement facilitated by the CMC/Association for the Cannabinoid Industry (ACI) and also benefited from consultation responses from the public and other interested stakeholders via a dedicated website (www.hodgesreview.com). The findings of this report are based on original research and results of new opinion surveys conducted by Stack Data Strategy in June 2022 (see Annex). The report covers three linked but separate areas of the legal cannabinoid sector: cultivation (hemp); medicinal cannabis, and consumer cannabinoids (CBD).

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Objectives

To create a settled public policy and regulatory environment that provides optimal support for the UK cannabinoid industry to grow and flourish.

The hope is that this report will help maximise growth, profits, consumer and patient satisfaction and the industry's potential. In this way, the UK can create a competitive advantage in dealing with this nascent sector, putting Britain at the forefront of global cannabinoids.

I

To build a strategic engagement with government and associated agencies – move from containment to nurturing

II

To establish a footprint / landing zone for the sector within government i.e. Department for Business, Energy and Industrial Strategy (BEIS)

III

To establish a new coherent regulatory framework for CBMPs and consumer cannabinoids in the UK

IV

To optimise the potential public funding opportunities for the sector

V

To align ourselves with current government thinking with regard to future regulation

Scope

The review will consider the size and nature of the UK's legal marketplace in cannabinoids, and make policy and industry recommendations.

The scope of the report will cover two main areas – medicinal and consumer cannabinoids – and it will take account of the entire supply chain from cultivation and research and development to product development, manufacturing and sale.

It will not consider wider arguments for legalisation of cannabis for adult use, as the Government's recent ten year drugs strategy implies this is not a near-term political prospect at the current time. The UK's large illegal market in cannabis is therefore out of scope for this project.

Terminology

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.

Foreword

The UK polity has an odd relationship with cannabis. Whilst there is no great public clamour to legalise it recreationally, access for medicinal use has been cleared in quick response to concerted activism and regulation of ubiquitously available cannabis extracted products, such as CBD, has been accelerated faster than other regions, notably the EU and US.

The cannabis sector that exists today is not a product of centralised government design but more a marriage of latent public demand, focused civic campaigning and business lobbying, and the post hoc regulatory responses they have elicited.

This report sets out a compelling, urgent rebuttal to governmental responses characterised by wilful blindness, then containment.

Millions of Britons today routinely purchase cannabis products as medicine and food supplements without any effective regulation or public policy stewardship.

The essential argument at the heart of this report is for our government to recognise the existence of the UK's very particular legal cannabis market, to create a public policy and regulatory framework that is nurturing rather than constraining towards it and to embrace more collaborative approaches to engagement to this new seemingly accidentally created industry.

The prize for doing so remains a handsome one. For all the myriad reforms being taken by countries across the globe in relation to cannabis access, no jurisdiction has a marked competitive advantage in relation to cannabinoid research and development.

By adopting the proposals and recommendations laid out here, the UK can inaugurate a timely opportunity to harness its global strengths in life sciences to become a world leader in medicinal and nutraceutical cannabinoid innovation.

Steve Moore & **Paul Birch**

Co-founders of the CMC & ACI

Preface

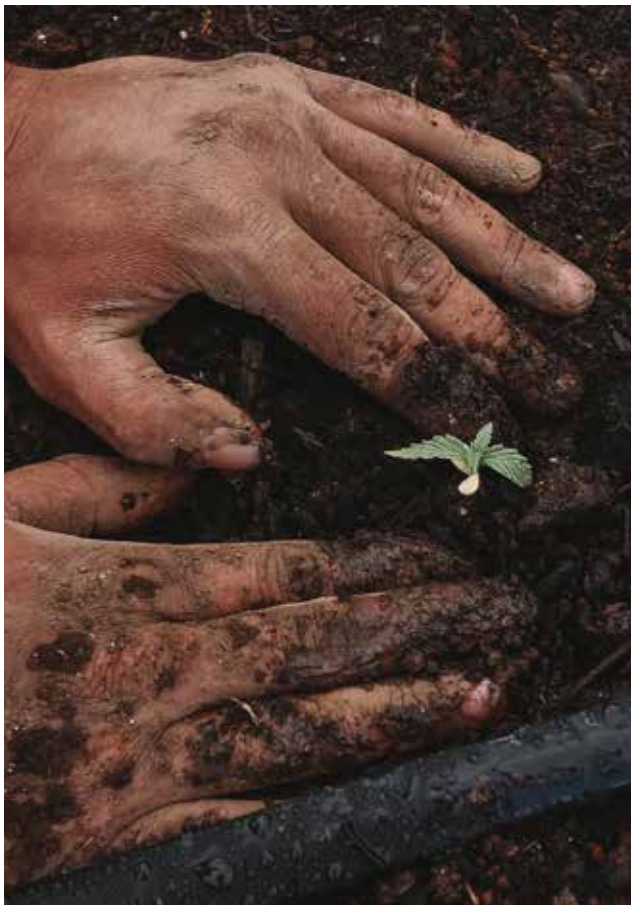
The advent of a legal pathway for medicinal cannabis in the UK in 2018 was a critical moment. After three years of permitting legal medicinal use, and the ongoing growth of the consumer / CBD cannabinoid market, along with new opportunities in cultivation and industrial applications, it is an opportune time to explore this important policy agenda.

For this project, we start from the position that there is a sizable and dynamic legal cannabis sector in the UK and it is not the same - and does not deserve to be bracketed with - the illegal market in street cannabis, which is also widely consumed and very resilient. How to approach the latter, and the question of whether Britain will follow other countries like Canada and Germany in choosing to regulate adult-use cannabis is another subject for another study by other experts.

We recognise the history, and the context of the illicit market and where we start from. We also respect the diversity of views on that important subject and the questions it raises about consent, respect for the law, and social harms to communities and individuals. However our purpose was clear: to examine how best to support the safe and responsible growth - economic and social - of a sector that is already in existence and operating legally. It may be subject to stigma and misunderstanding, but it is nonetheless real and engaged in meaningful and regulated activities that are taxed and licensed.

The political debate on cannabis legalisation, while legitimate, is therefore not relevant to this report, and as a policy question often covered in the media, should not divert attention from the serious issues that the legal cannabinoid market is already involved with, namely the production of industrial outputs with economic and environmental benefits, new consumer wellness products for the cosmetics and nutraceutical market, and medicinal treatments and clinical trial opportunities for healthcare applications. In short, how we regulate the legal cannabinoid sector in the UK is about people, and their health and wellbeing, not politics.

We accept that debate is still live on many of the policy questions we cover: the science is



advancing, new products are challenging the status quo around health and lifestyle, and with opportunities also comes risk. But because this sector is exploiting a plant that is a controlled drug, regulations will always play a critical role. The people who stand to benefit can only do so if the law and regulations are optimised - geared for both prosperity and protection, and based on our current understanding of the science and a proportionate view of risk that is also balanced by the need to encourage innovation and enable benefits to be enjoyed.

We think that regulations and their effectiveness (or not), are critical issues, not just in terms of the future trajectory of this sector, but in order to help set the UK apart as it decides the economic and political path it wants to adopt post-Brexit. Divergence from EU rules is now possible in many areas but so is the ability of the UK to choose to update old regulations so that they align better with regulatory developments in the EU and elsewhere -

the choice will not always be about the UK forging a distinctive path, but rather how it chooses to compete and what regulatory disadvantages need to be ironed out.

We argue that for regulations to be effective, in this sector as in almost every other, they need to be based on a philosophy of trust and of cooperation, and people need to be brought in, not shut out. This lends itself to greater transparency on the part of government and regulators, and more proactive cooperation with industry and with their end users - patients and consumers.

This means that our approach is guided by a framework based on some key outcomes that we argue all parts of the legal cannabinoid sector should be able to subscribe to. How those outcomes are achieved requires reforms by industry and regulators, and action by government. Our recommendations are open to discussion, because there may be many ways to address the same problem.

We nonetheless hope that the principles we recommend, and the outcomes we highlight, are informative and also occasionally provocative. The opinion research conducted for this project shows the scale of public uncertainty and misunderstanding about the law and what this sector is all about. However it also reveals an encouraging level of openness to cannabis and its potential and a growing familiarity with how it might benefit people and British society now and in the future. For that reason alone, the course of this important legal industry needs to be more widely debated and its profile, problems and possibilities elevated within the media and political circles.

In this report, we describe the context in the UK (Introduction), summarise the respective sectors as they stand today (Chapter 1) and diagnose some flaws in the current regulatory model (Chapter 2).

After exploring the policy gaps and incoherence affecting the sector, we then discuss public attitudes and awareness as well as the level of understanding based on our opinion research (Chapter 3). The report then examines what makes for effective regulation and the concepts behind Outcome-Based Cooperative Regulation (Chapter 4) and then applies this approach to the issues we have reviewed, including some issues like trust, which are key to a well-functioning market as it applies to cannabinoids.

In Chapter 5 we describe how this could apply to the legal cannabinoid sector and set out some outcomes and shared goals for the whole sector. Finally (Chapters 6 & 7) we outline a suite of 20 policy recommendations that should be adopted to help realise those goals in the years ahead. Further analysis on international competitors and how cannabis is regulated in comparable jurisdictions, plus further detail on regulatory issues and potential medicinal applications, is included in Appendices.

Executive Summary

- This report's main objective was to examine the current landscape and outline how best to support the safe and responsible growth - economic and social - of **a sizable and dynamic legal cannabis sector that is already established in the UK.** Despite the growth potential and dedication within this industry, it is clear that this **market has evolved by accident, without coordinated government action** or a coherent strategy to steward it to maturity.
- Thus far, **the government has neglected to plot a course for the sector,** or even recognise its potential to be successfully scaled with the right regulatory and grant support - like the UK Space Industry has. Furthermore those working in the UK sector feel incredibly restricted by current regulatory conditions and shut out of policy engagement with key decision-makers on issues like patient access and education.
- The result of this is that the country which produced the first cannabis unicorn is struggling to find its feet in the international market. **The legal sector is not as attractive to investors because it is hamstrung by the UK's own rules.** As a result the UK is missing the opportunity to learn from other jurisdictions and craft a set of policies that will give the sector the best chance for future growth.
- This report describes **a vision that moves beyond a policy of control and containment to one of support and stewardship**, so that the UK can maximise the potential it has to advance scientific discovery and innovation, improve well-being, create jobs and investment in local economies, and enhance the health outcomes of potentially millions of people.
- Cannabinoids now make up a fast-growing global industry, and by not being a first-mover, **the UK holds an advantage in that it can learn from the successes and failures of other comparable regimes**. Moreover, **Brexit has given the UK the freedom to choose to align or differentiate itself from the markets with which it is competing**, for example on hemp cultivation and consumer/CBD regulation.
- The report summarises the respective sectors - medicinal, consumer and industrial - as they stand today, exploring the policy gaps and incoherences, and draws on original public attitudes research to understand where the public sits on these issues. It then sets out some **shared goals for the sector** and **outcomes to be adopted**, alongside actions by government and industry to bring these goals closer, comprising a **suite of 20 policy recommendations**.

Regulations matter

- **The law and rules which govern any regulated industry are fundamental to how it develops, and its ultimate growth trajectory**. Case studies on the evolution of the legal (medical) markets in Canada and Australia demonstrate this. Regulations should at least be crafted in a way that attempts to be coherent and consistent, but this is not the case for the UK cannabis industry currently.
- **Regulations around a product are designed to safeguard citizens from harm - but they must do more than this**. The regulations around cannabis and how it may be used under licence must be justified in terms of risk and protection of the public from harm, but simultaneously not depress economic growth and scientific and technological innovation.

Outcome-Based Cooperative Regulation

- The report views the cannabinoid sector through the lens of Outcome-Based Cooperative Regulation (OBCR), a regulatory philosophy pioneered by Professor Hodges which centres on an ethical and trust-based regulatory schema.
- The report argues that for regulations to be effective, the science supports them being based on **trust and collaboration**, not top-down enforcement and sanctions. This provides

a valuable framework for thinking about how the legal cannabinoid sector can develop in the UK, as it necessarily involves industry-wide coordination, and a different, more permissive approach from government and regulators to the trusted actors in the sector.

- When **applying OBCR to this sector** the report recommends that the legal cannabinoid industry should coalesce around the following shared goals:

  1. **Demonstrate that the sector is trustworthy**, legitimate and responsible
  2. **Improve the evidence base** and generate new insights in the UK
  3. **Improve health outcomes for patients** and maximise access to these benefits
  4. **Fully explore and exploit the value of the cannabis plant**
  5. **Set a world standard for regulatory and scientific best practice** and innovation with a level playing field for producers

- The report also identifies some **outcomes** that everyone in the legal sector should be united in seeking to deliver:

  - **Reducing harm and improving health and well-being**
  - **Expanding knowledge and evidence**
  - **Increasing confidence**
  - **Securing competitive advantage**
  - **Delivering collaboration between industry, end-users and regulators**

- Currently **the UK's legal cannabinoid sector lacks some key elements of an OBCR approach** - namely lack of legal clarity, clear rules, or ethical codes or vision statements, and there is poor data availability, poor feedback mechanisms and a lack of effective intervention mechanisms.

- The report argues that **the sector needs to work to develop trust,** and more freedom should be given to the **trusted actors already in the market** (prescribers, pharmacists, regulated suppliers, government-funded trial sites, licensed researchers).

Public support for the sector and its future

- A new survey of public attitudes by STACK Data Strategy should give the industry and government renewed confidence that the British people have embraced the concept of a legal cannabis sector. Clear majorities support it as a healthcare concept, being optimistic about its potential, and not fearful, cynical or dismissive.

- The UK's legal cannabinoid sector is a relatively new industry, and yet **the public do seem to show a high level of experience and/or awareness** of some of its elements, especially medicinal access and the general availability of CBD:

  - **Almost two-thirds of people were aware of CBD products before taking the poll**, with women showing generally higher levels of awareness than men
  - **1 in 10 people said they had 'tried/used/purchased' CBD in the last year.**

- There is a deep and broad level of support for the idea that cannabis can be an effective medical treatment:

  - **One in five (19%) respondents said they personally know someone whose health has benefited from medicinal cannabis**
  - **A big majority (63%) of respondents would be supportive if a family member was taking medicinal cannabis** to address a health condition, with only 8% saying they would be somewhat or very opposed to it
  - **Almost 1 in 7 people (14%) admitted that they have used cannabis 'for health**

reasons or to treat a medical condition' at some point in their lives

- Of those who had used for medicinal reasons (whether prescribed by a doctor or not) - a smaller sample of 215 - **the vast majority (90%) experienced positive benefits, including a fifth (21%) whose symptoms were 'completely resolved'.**

- When asked about consumer/CBD:
  - **More than a third (38%) of respondents said they buy their CBD products online,** and 30% in high street shops
  - 6% of all those surveyed - a higher than anticipated number - said they had given CBD products to their pet
  - The **most concerning thing for 43% of respondents was if the product was synthetic and not from natural ingredients, or if the product was not tested for purity** (42%)
  - Hesitant CBD considerers would be most likely to try a CBD product if there was more public information about CBD and how to take it (32%) and if the government made it clear that CBD was legal (32%)
- On the reforms for the sector:
  - There was strong support for allowing all doctors, not just specialists, to prescribe cannabis as a treatment. **Two-thirds of respondents (65%) believe GPs should be allowed to prescribe medicinal cannabis** and family doctors/GPs scored highly on who would be trusted to prescribe it to you - more than a third (37%) of respondents would trust their GP to prescribe them medicinal cannabis
  - **People believe the government should help lower the cost of cannabis supplied by private clinics (59%) so more people can afford it**
  - Almost half of respondents (46%) agreed that the government should allow British companies with a licence to grow cannabis here to export it overseas, and only 13% disagreed
  - **A large majority (64%) of respondents believe the government should do more to support scientific research into cannabis in the UK**
  - **At (23%), respondents thought cannabis medicines rank as an important future industry where Britain could try and become a global leader,** alongside green technology and sustainable energy
  - Respondents were also asked whether they thought in ten years the medical benefits of cannabis would be more widespread and accepted, with a majority (59%) agreeing and only 8% disagreeing

Conclusions

- **It is not sustainable or acceptable for the government to continue to take an uncoordinated, disinterested or laissez faire attitude to the sector** as a whole, as it has done since the cannabis sector's 2018 inception.
- **The seeds are there for rapid growth but it cannot happen without a clear strategy built upon coordinated government stewardship and the ambition to not just tolerate, but actively nurture the sector to expand and mature,** so it attracts more investment, jobs and innovations, and secures political support and public recognition.
- The regulations encompassing the cannabis sector are wide-ranging and complex, but right now **the present rules are poorly calibrated to the risks associated with each product and stifling of economic opportunities**. Our conclusion from this research was not that the UK's legal cannabis sector is over-regulated, or merely suffering from outdated rules, or simply needs red tape and unwarranted regulations to be stripped back.
- In some areas, such as **hemp farming**, not only are there insufficient incentives, but existing

regulations are too restrictive, disproportionate to the risks involved and antithetical to the growth of a UK-industry and the economic opportunity hemp cultivation could offer to rural economies, not to mention environmental benefits.

- In other areas, such as consumer cannabinoids and **CBD**, we have seen the result of too little regulation that caused the emergence of a large grey market that now needs tighter rules in order to safeguard the consumer and build up and sustain public trust, backed up by targeted but sustained enforcement
- And in the arena of **medicinal cannabis**, the picture is far more complex, with regulations too onerous and restrictive in some areas, and too lax or entirely absent in others.
- If adopted, the regulatory framework outlined in this report will achieve three important objectives:
    - **Competitive advantage for the UK post-Brexit,** helping the country to leverage its historic and economic strengths in a rapidly growing and unprecedented global industry;
    - **Regulatory best practice giving early mover advantage**, helping to pioneer new approaches to regulating a novel industry that other jurisdictions on a similar path can choose to emulate;
    - **Scientific advances and innovations**, with pioneering new treatments, manufacturing methods, and end-user product innovations, helping the UK to reinforce its reputation as the home of world-leading inventions and discoveries that improve our environment, our health and our quality of life.

Key Recommendations

1. **Establish a single 'steward' authority to govern and guide the entire sector, at arms length from ministers.** This new agency would require legislation to set up but it would inherit clear responsibilities and could become the home for developing a specialist agency with expert staff recruited from a range of sectors.
2. **Provide long-awaited legal clarity in respect of trace amounts of controlled cannabinoids in retail products and revise the 2001 MDR to set the permitted 'zero THC' level**. This will give industry the confidence to invest in a high quality supply chain with robust analytics to support proof of compliance, and clear up any remaining confusion among retailers and ultimately consumers.
3. **Encourage the creation of a UK 'Centre of Excellence' to advance the evidence base for cannabinoids and their applications**. Drawing on the strength of the UK's higher education sector, this institute could be established with the support of major universities.
4. **Roll-out a national trial for GP prescribing of CBPMs based on an opt-in model for doctors' consent and systematic data collection to inform future guidelines**. Another dimension could be that such prescriptions, when issued in the private or public system, would need to involve patient enrollment in a national registry to help gather real world evidence.
5. **Update hemp farming rules to permit licensed growers to extract the controlled parts of the cannabis plant on site under the right conditions**. Farmers would need to partner with an approved transport provider or third party distributor to move controlled substances to market and maintain more detailed records of their seasonal yields.
6. **Modernise the Proceeds of Crime Act provisions to create an explicit exemption for private enterprise by entities operating in legal jurisdictions**. Modelled on the changes already incorporated into law in Jersey, the UK government should update POCA to permit investment by entities involved in cannabinoid commerce
7. **Permit licensed suppliers to export CBPMs in bulk outside the UK where their customer is**

a licensed party in the overseas jurisdiction. This would help UK-based CBPM companies with supply chain efficiencies such that medicinal patients in the UK could benefit from reduced costs for their treatment.

8. **Consult with patient groups and police forces to introduce Home Office guidance for frontline officers to check and verify patients** who have a valid, current CBPM prescription

9. **Take forward commitments for a national patient registry** and begin coordinated data collection efforts for real world evidence.

10. **Create and mandate a consistent set of manufacturing and labelling standards for CBPMs that provides more information to patients and links to a batch-specific Certificate of Analysis (CoA)**. Modelled on the Rule 93 Guidance imposed by the TGA in Australia, this would require CBPM suppliers to adopt best practice around product safety with, for example, child-proof containers.

11. **Require end-product testing for all CBPM and consumer cannabinoid products (imported or locally produced) using independent ISO accredited laboratories in the UK**. This would also stimulate expansion in ancillary services like laboratories for ensuring the industry standards are adhered to. In time the sector should adopt an industry-wide set of benchmarks for testing quality.

12. **Permit licensed CBPM suppliers to utilise mainstream, trackable, signed-for delivery options to reduce the cost to patients of private CBPM prescriptions**. With auditable records of licensed pharmacists and new rules requiring child-safe packaging, it is no longer necessary to require expensive controlled drug couriers for delivering CBPMs to patients.

13. **Create a single formulary of available CBPMs which provide doctors with an up-to-date list of medicinal cannabis products available in the UK market**. This would enable patients to request certain types of product and for prescribers to have a wider view of what types of quality assured products are currently available.

14. **Provide clarity on the legal status of CBD vaping products and issue guidance on the permitted ingredients in a vaporizer used for cannabinoids**, either as a consumer CBD or CBPM delivery device.

15. **Establish an expert committee to review the approach of the Veterinary Medicines Directorate to explore options for a more proportionate approach to CBD use by veterinarians.** A rethink on the approach announced in 2019 would reflect how pet owners and farmers are already using CBD unofficially, and would bring consistency with the pragmatic approach of the FSA.

16. **Examine and integrate policy on hemp cultivation activity into broader Net Zero efforts.** DEFRA should begin a policy development process to devise incentives within the new post-Brexit agricultural subsidy regime that rewards farmers for carbon sequestration and soil remediation using hemp cultivated domestically, with the possibility of such licensed activity generating tradable carbon credits for off-setting.

17. **Develop and roll-out more comprehensive surveillance of the UK border to detect illicit imports and non-compliant CBD products entering the UK by sea or air freight**. UK Border Force should resource a suite of methods to discourage the importation of illicit cannabinoid material and deter the grey market from seeking to exploit the UK's large consumer market.

18. **Clarify with guidance that any product derived from synthetic cannabinoid synthesis is by definition novel** and must follow the conventional risk-based route for approval as a medical treatment or as an ingredient in food.

19. **Proactive and proportionate enforcement from regulators to pursue breaches of food law**. The FSA, working with Trading Standards, needs to develop a strategy for enforcing the

Novel Food regime based on a proportionate approach.

20. **Collaborate on an education initiative to improve general understanding among distinct professional and public audiences.** Institutional partners in respective sectors could partner with industry bodies to support education and training to improve understanding about cannabinoids and help inform consumer and patient choices.

Three Quick Wins

In the next 12 months, the following would represent the first steps on the road of reform:

- **Set up a single online portal** - designed to bring together all government advice and guidance in a single place, covering the three distinct sub-sectors. This portal would help inform the market and guide applicants, as well as hosting the most recent published data relevant to the industry
- **Establish a legal industry roundtable** - taking inspiration from the Canadian Government's commitment to do the same in 2022, this new arrangement would give the legal sector a conduit to policy-makers and provide a single forum for raising issues, and offering constructive proposals to government. It could also act as the venue for deliberating on a future industry-wide Ethical Code or equivalent to help foster trust.
- **Publish more and better data** - on prescribers, licence holders, prescriptions, and enforcement, so that the political and policy debate can be informed with real data on the current state of the sector. Prescriber and prescription data should be published quarterly, on an anonymised basis, in line with current GDPR requirements.

Introduction

Regulating new and emerging industries

Traditionally, the debate about regulation focuses on two distinct angles: the regulation of a product, or the regulation of a profession. In the context of cannabinoids, the legal status of the Cannabis sativa plant is the source of the regulatory issues in question, and there is no distinct 'profession' that is in play. The UK is also not in a unique position, insofar as cannabis is a controlled drug in most countries in the world, and in respect of medicinal access, has been available in a legal format only in recent years. Nevertheless, how the product is regulated is different in every jurisdiction, and in most countries, the emergence of a legal market has been uncoordinated and even 'accidental' in terms of planning.

Furthermore the nature of the plant's controlled drug status, and the uses to which it can be put - from its agricultural and environmental uses, to its nutraceutical, cosmetic, veterinary and medicinal applications - mean that the policy considerations have a direct bearing on millions of consumers, thousands of patients and the hundreds of jobs and millions of pounds of investment tied to the wider agritech and life sciences sector. The right regulatory approach will therefore depend upon some conventional trade-offs seen in other industries between protecting users from harm, and allowing room for innovation, consumer choice, and commercial activity that drives economic growth.

Alongside this are more novel considerations which only apply in the context of regulated activity that is genuinely new, and which was previously not regulated because it was not widespread (by virtue of not being lawfully permitted). The law change in 2018 created a legal access pathway for medicinal cannabis in the UK for the first time. The emergence of a consumer cannabinoid market after 2015 built upon a non-controlled compound like cannabidiol (CBD), throws up new regulatory challenges because there is no precedent. This combines with the wider societal and economic context of a large, diverse and well established illicit market, which presents its own challenges.

Taken together, this means that the regulatory path forward is not well-lit and there are many directions a legal cannabinoid sector in the UK could take. By the summer of 2022, and despite growing public awareness and consumer demand - demonstrated by new polling undertaken for this report - the UK Government has not yet set out a coordinated approach that acknowledges these unique regulatory circumstances and attempts to bring some coherence and order to the legal cannabinoid market in the UK. Wider policy developments are also surging ahead, and these also present opportunities which the cannabinoid sector should be playing its part in - especially in terms of responding to the Net Zero agenda and environmental degradation. The plant derived cannabinoid innovation is not only giving birth to a new pharma industry and functional food sector but is also making an impact on the carbon industry and offering new ways to reduce the human impact on the planet. Carbon market has operated for decades but now there is an opportunity for hemp farmers to sell their carbon credits to companies/countries who want to offset their emissions.

The purpose of this review is to sketch out the market as it exists today, identify where policy and regulatory gaps exist, and outline a regulatory approach for the future - one that ultimately will need to be set and adopted by government and the key regulators in this space. We hope that our findings and recommendations give some impetus to that necessary and overdue exercise within Whitehall.

Backdrop to the legal market: illicit cannabis

The terms of reference for this review do not encompass consideration of the case for the UK adopting a legal, regulated market in recreational (or 'adult-use') cannabis. The Government's recently launched ten year drugs strategy - From Harm to Hope[1] - clearly signals that this is not a

1 Home Office (2021). From harm to hope: A 10-year drugs plan to cut crime and save lives. https://www.gov.uk/government/publications/from-harm-to-hope-a-10-year-drugs-plan-to-cut-crime-and-save-lives#full-publication-update-history

political possibility in the short to medium-term, and evidence to support such a change is still emerging in comparable jurisdictions, such as Canada, where this reform has been adopted in recent years[2].

Nevertheless, even though a fully liberalised market in cannabis is not imminent, or a scenario that is relevant to the findings and recommendations of this review, the current nature of the illicit market in the UK is directly relevant to the issues we cover in deciding the right regulatory framework for the UK.

The challenge of regulating a 'new' industry such as medicinal cannabis, or the consumer cannabinoid sector, is further complicated by the large and well entrenched illicit market. Regulating a brand new technology such as drones, or gene editing, or autonomous vehicles, is a qualitatively easier proposition, because although they present unique ethical or human rights challenges, there was no forerunner technology or service that emerged to dominate the market before the authorities could set the market rules and legal parameters. As the CMC/ACI submission to the Prime Minister's Taskforce on Innovation, Growth and Regulatory Reform remarked: "The wilful blindness that allowed a 'grey' market to flourish before retrospectively imposing market authorisation regulations has created huge consumer demand for these products".

The pre-existing cannabis market, comprising hundreds of underground cultivation sites, thousands of suppliers and millions of domestic consumers – either those offering street cannabis or those supplying unapproved grey market CBD products – is large and diverse. Furthermore, it is a market that is estimated to have expanded in the last decade, with annual consumption reaching 240 tonnes in 2021 according to the National Crime Agency[3], combined with a more benign enforcement environment, where less police activity against users has gone hand-in-hand with more tolerant attitudes among the general public, according to recent polling.

The result of these developments creates a unique context where a newly legal sector is trying to establish itself and navigate new regulations and some restrictive rules, against the backdrop of a legacy market in illicit products that is outside any regulatory influence or control. While this is not unprecedented, it does mean policy choices about how to control and nurture this new legal sector must take account of current human behaviour and the available alternatives. In simple terms, if approved medicinal cannabis is too difficult to access, an informal economy of illicit cannabis will continue to be sought out by patients. If the approval process to retail CBD and associated products is too costly and onerous, and enforcement continues to be absent or limited, a grey market in unapproved products will continue to exist.

One of the primary goals of regulation should be to protect the end-user or consumer from harm. In this respect, the illicit market on any measure presents more harm, both real and potential, than the legal regulated market. It is necessary to weigh up the relative costs and risks of regulation on the legal cannabinoid sector, in full acknowledgement of this fact. If the constraints on the sector are disproportionate, not only will the legal sector struggle to expand to serve legitimate patient needs and consumer demand, but it will, by extension, result in no net reduction in harm because the illicit market will continue to thrive.

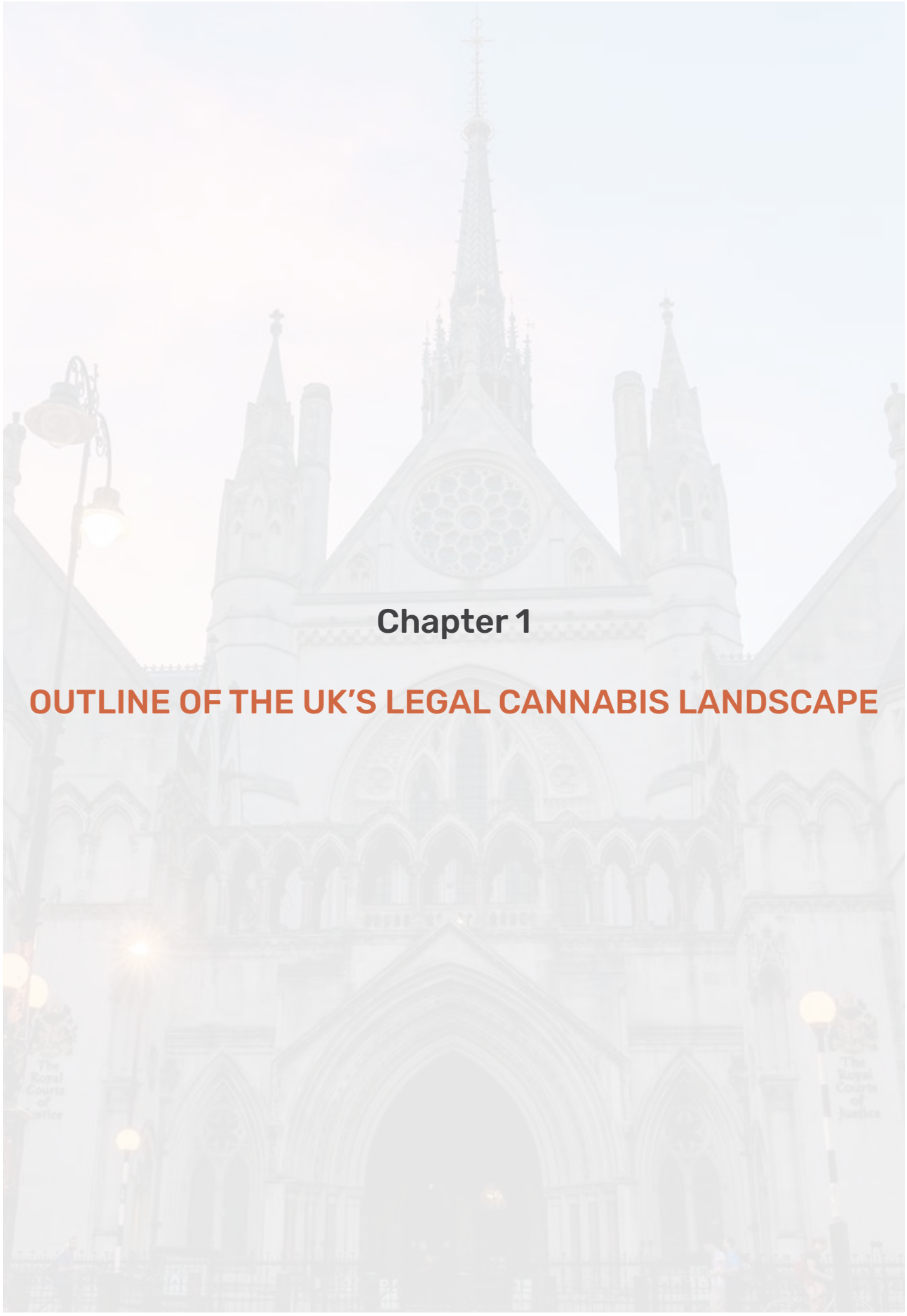
In fact, the situation is less static than this trade off implies, because the legitimate use of legal cannabis products, even if only among a small minority of eligible patients, helps to 'normalise' the public perception of cannabis itself, which may actually serve to further encourage engagement with the illicit market, despite the harms it inherently presents because of poor quality of production, lack of content or purity controls and the absence of supplier surveillance or traceability, not to mention the social harms from human

2 B Gibbs (2021). Cannabis Legalisation: Canada's Experience. Public First. https://www.publicfirst.co.uk/new-research-on-canadas-legalisation-experience.html

3 National Crime Agency (2021). Annual Strategic Assessment: 2021. https://www.nationalcrimeagency.gov.uk/news/online-is-the-new-frontline-in-fight-against-organised-crime-says-national-crime-agency-on-publication-of-annual-threat-assessment

trafficking, money laundering and child exploitation.

Our strategic goals of regulation for the legal cannabinoid market in the UK, set out in chapter 5, have been created in recognition of these factors, and were developed alongside a realistic assessment of where we start from. Despite general rates of prevalence far below those seen in North America, cannabis is very far from being a new phenomenon in the UK, and the legal cannabinoid sector – especially the medicinal cannabis market supplying products containing THC – starts out at a competitive disadvantage. The right regulatory environment would address this disadvantage by removing unreasonable constraints, streamlining access and improving quality controls, so that patients are able to access safe, consistent and affordable legal cannabis medicines. In doing so, patients would be less incentivised to use street cannabis, thereby withdrawing support for the ongoing operation of an illegal market.



Chapter 1

OUTLINE OF THE UK'S LEGAL CANNABIS LANDSCAPE

1.1. Science, status and history of the Cannabis sativa plant in Britain

In modern times, the British position on cannabis was not exceptional: successive UK governments adopted a legal and policy approach to the cannabis plant consistent with most other nations who are signatories to the UN's drug control conventions - essentially very tightly controlled access in limited circumstances entirely geared towards only two narrow purposes (licensed pharmaceutical drug development, and industrial materials derived from hemp).

Scientific profile of the plant

Cannabis plant contains over 100 phyto-cannabinoids, including cannabidiol (CBD) and tetrahydrocannabinol (THC), the best known psychoactive components. Potency of the product (and therefore the potential for impairment) is determined by percentage of THC. The most commonly used naturally occurring cannabinoids purified from plant sources are cannabidiol (CBD) and delta-9-tetrahydrocannabinol (THC), but other minor cannabinoids are beginning to be exploited commercially.

Some cannabinoids have been synthesised in the laboratory: examples include CB1 agonists (CPP-55, ACPA), CB2 agonists (JWH-133, NMP7, AM1241), CB1/CB2 nonselective agonist (CP55940), ajulemic acid (AJA), nabilone, and dronabinol. Our scientific understanding of the plant's potential is comparatively recent. The structure of the main psychoactive phytocannabinoid, THC, was determined in Israel by Mechoulam and Gaoni in 1964, and CBD and its operation were not isolated until much later. This discovery opened the gate for many of the subsequent developments in the field of endocannabinoid system (ECS) research[4]. A number of university research efforts involving cannabinoids are now underway in the UK and as a contributor to the global evidence base on cannabinoids, the UK's universities play a disproportionately influential role (notably King's College London, Aberdeen, Nottingham, Manchester, and Aberystwyth).

With the exception of small research sites, and a handful of farmers with licences to plant low-THC hemp, this status quo persisted and until the first two decades of this century, there was no legal cannabis activity occurring anywhere in the UK. The first commercial licences to cultivate cannabis for clinical trial purposes were only granted in the late 1990s and before then, all cannabis produced or used in Britain was illegal. This report is concerned with the legal cannabinoid sector which is therefore comparatively new, and in the case of consumer cannabinoids and retail CBD products, still in its infancy.

Legal status in the UK

It is an offence to cultivate any plant of the genus Cannabis except under a Home Office licence. Cultivation or possession of cannabis plants cannot lawfully be undertaken without the requisite Home Office Licence. The cannabis plants cultivated for the production of drug material (e.g. hemp fibre or oil) are controlled via controlled drug or Industrial Hemp licence. There are two separate licensing regimes relating to cannabis cultivation, according to whether the varieties are high or low THC (as differentiated in the Misuse of Drugs (Fees) Regulations 2010). British law does not apply controlled status to cannabidiol (CBD), one of the most dominant cannabinoids in the plant when harvested, although even small, detectable amounts of controlled substances like THC or CBN would make the end product non-compliant with UK laws. Possession of class B drugs can lead to 5-year custodial sentence and an unlimited fine, while distribution of class B drugs can lead to 14-year imprisonment. While supplying medicinal cannabis is now legal in the UK if appropriate government licences have been obtained, cannabis grown, possessed or supplied for recreational use is illegal in all circumstances. Any cannabinoid imports should meet UK's legal limits for THC or should be covered by an appropriate licence if a medicinal product, otherwise Border Force has powers to seize the consignment.

Even though cannabis is still illegal in the UK, with only limited availability for medical use, the

4 *Russo, E. B., Jiang, H. E., & Li, X., et al., (2008). Phytochemical and genetic analyses of ancient cannabis from Central Asia. J Exp Bot. 59(15):4171-4182. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2639026/*

United Kingdom is the world's largest exporter of legal cannabis because of the presence of GW Pharmaceuticals' British assets that supply production of their two licensed drugs: Sativex and Epidyolex. Markets like Australia and Germany are growing in importance in terms of export of cannabis medicines and in both cases, have made progress towards expanding domestic cultivation in the last few years. The UK's claim to being the largest legal exporter is unlikely to be sustained in light of these fast-growing legal sectors in both Europe and further afield.

History of consumption and classification

Most used cannabis is a plant-based, or botanical, product with origins tracing back to the ancient world. Evidence suggesting its use more than 5,000 years ago in what is now Romania has been described extensively[5]. In the early 1900s, cannabis was popular both as a recreational and a medicinal compound in the UK and elsewhere in Europe. Earlier editions of the British Pharmacopoeia from this era reference its potential application (included in the 1914 Pharmacopoeia and its subsequent editions until 1927). Cannabis was first made illegal in the UK in 1928. Following international treaties designed to harmonise national laws to uphold prohibition of narcotics, new domestic legislation was adopted in most Western countries. The 1971 Misuse of Drugs Act was introduced by the Conservative Government in the UK as a framework for classification, prohibition and control of a range of narcotics, and to provide the legislative underpinning for subsequent rules and guidance on controlled drugs. As a result, cannabis was classified as a 'class B' drug. For a brief period in the mid 2000s the drug was moved to class C by the Home Secretary David Blunkett but reclassified back to class B (with heavier penalties for unauthorised possession or sale) in 2008 by the Labour Government of Gordon Brown where it still remains to this day.

The complex pharmacology of the cannabis plant

5 *Bennett C. Early/ancient history. In: Holland J, editor. (2010)The Pot Book: A Complete Guide to Cannabis. Rochester, Vermont: Park Street Press*

1.2 Three related cannabinoid sectors

due to its constituents means it has potential to produce both medicinal benefit and misuse, so even within the context of advances in our scientific understanding, it is inconceivable that governments would not continue to regulate cannabis in some capacity. Proven therapeutic benefits of cannabis will widen its application in health settings and in the context of wellbeing, but this would not mean that consumption is risk-free and need not be subject to appropriate controls. Canada's legalisation decision in 2018 demonstrates this reality: where even the first major country to permit access to cannabis for adult (non-medical) use, did so within the context of a new legislative framework with strict regulations and stiff penalties for selling, trading or growing cannabis outside of approved and licensed channels.

In the United Kingdom, there are presently three broadly related but distinct subsectors of the legal cannabinoid industry:

Medicinal

"Medicinal Cannabis" and "Cannabis-based Products for Medicinal Use in Humans" (CBPMs) are terms applied to products available from clinics, or private hospital-based specialist consultants, but are distinct from 'cannabis/CBD/hemp oils' available for Over-The-Counter (OTC) purchase in shops/pharmacies or online as food grade products or 'wellness' remedies (see below). The former is the subject of well-developed regulations administered through the Medicines and Healthcare products Regulatory Agency (MHRA); the latter contains a much broader range of unregulated products that are lower quality and of much weaker potency.

Persons authorised to procure unlicensed CBPMs in the UK are:

- doctors on the GMC Specialist Register
- specialist importers with a Home Office import and domestic licence and MHRA licence
- registered pharmacies or retail pharmacy businesses (with Home Office domestic licences, where appropriate)
- licensed wholesale dealers for supply to the order of any of the above

According to industry estimates, there is a rising number of prescriptions being issued annually in the private clinic sector, with c.7,000 unique patients in the UK receiving a CBPM (at the end of 2021)[6].

Consumer

Consumer cannabinoid products encompass nutraceuticals, food supplements, cosmetics and vaping products. The largest category is 'consumer' health and wellness products containing CBD, which are regulated in the EU and the UK under food law as a 'Novel Food', not as a medicine.

1. Food Supplements. A food supplement is defined as "any food the purpose of which is to supplement the normal diet, and which is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination and is sold in dose form"[7]. Food supplements are intended to correct nutritional deficiencies, maintain an adequate intake of certain nutrients, or to support specific physiological functions. They are not medicinal products and as such cannot exert a pharmacological, immunological or metabolic action. Therefore, their use is not intended to treat or prevent diseases in humans or to modify physiological functions.
2. Nutraceuticals. A nutraceutical is "any substance that is a food or a part of a food that has medical or health benefits". This is not a common term used by UK regulator's but generally covered under dietary supplement regulations. The term "nutraceutical" was first introduced by Stephen De Felice, who defined a nutraceutical as a "food, or parts of a food, that provide medical or health benefits, including the

6 https://decalogue.info/wp-content/uploads/2022/03/Decalogue_final.pdf
7 Food Standards Agency (2021). Food supplements. https://www.food.gov.uk/business-guidance/food-supplements

prevention and treatment of disease"[8]. These products can be single nutrients like Vitamin C, Omega 3, CBD or any other cannabinoid or combinations of ingredients.

3. Cosmeceutical or Vape products containing CBMPs/ bioactive ingredients purported to have medical benefits have no established evidence base and no legal requirement to prove the claims but are governed by cosmetic[9] and tobacco[10] regulations respectively (if containing nicotine).

Hemp (Industrial)

There are well defined uses of hemp stalk and fibre for industrial applications. The flowering tops and leaves of the hemp plant have no legal route to market even for farmers with a low-THC licence to cultivate from the Home Office because these constituent parts of the plant are controlled. Hemp products, such as cold-pressed oils from seed, are not novel because there is evidence to show a history of consumption before May 1997. This is not the case for CBD extracts[11]. However, as things stand, the onus is on the company to show compliance only when requested by authorities. This is becoming an area for abuse by companies seeking to bypass the Food Standard Agency(FSA)'s requirement for a novel food application and continue to benefit from cheaper source material and domestic sales.

8 *Jha, S. K., Roy P., & Chakrabarty, S. (2021). Nutraceuticals with Pharmaceutics: Its Importance and their Applications.. Int J Drug Dev & Res Vol.13 No.S3:002 https://www.ijddr.in/drug-development/nutraceuticals-of-pharmaceutical-importance-and-their-applications.pdf*

9 *Office for Product Safety and Standards (2021) Making cosmetic products available to consumers in Great Britain. https://www.gov.uk/guidance/making-cosmetic-products-available-to-consumers-in-great-britain#making-cosmetic-products-safe-for-users*

10 *Public Health England (2021). E-cigarettes and vaping: policy, regulation and guidance - A collection. https://www.gov.uk/government/collections/e-cigarettes-and-vaping-policy-regulation-and-guidance#uk-e-cigarettes-regulation*

11 *Medicine & Healthcare products Regulatory Agency (MHRA) (2020). A guide to what is a medicinal product, MHRA Guidance Note 8. Appendix 10. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/872742/GN8_FINAL_10_03_2020__combined_.pdf*

	CULTIVATION		CONSUMER		MEDICINAL		
Activity	**Hemp Growing**	**Cannabis Growing**	**Food supplements**	**Cosmetics / vaping**	**Unlicensed CBPMs**	**Pre-clinical / clinical R&D**	**Licensed cannabis medicines**
Law and government oversight	Home Office						
Licenses required	Low-THC industrial hemp Export & Import	Sc1 Export & Import	Novel Food authorisation	None	Sc1 & Sc 2 Export & Import	Sc1 & Sc2 Export & Import	Sc2, Sc4, Sc5 Export & Import
Other government departments involved	DEFRA	DEFRA	DHSC FSA	BEIS DHSC	DHSC MHRA	BEIS DHSC MHRA DIT	BEIS DHSC MHRA DIT
Current regulatory incentives	None	None	None	None	NIHR research funding for pilots/trials	HMG grants for R&D	HMG grants for R&D NIHR grants for research Other funding for drug development Potential for patent protection from licensed medicine approval
Current regulatory controls and constraints	HO License conditions Restrictions on use Limited strains	HO License conditions, including location, scale, end user, security controls Surveillance/ HO inspection	Novel Food requirements Trading Standards activity to ensure compliance MHRA rules on making unfounded medicinal claims	Existing cosmetics regulations Existing e-cigarette regulations (only if product contains nicotine)	HO License conditions CQC inspection regimes for private clinics	HO License conditions	HO License conditions Surveillance/ HO inspection
Current issues and challenges	Restricted list of approved strains No clarity on access to post-CAP subsidies based on biodiversity benefit Not a Net Zero crop for carbon sequestration / off-setting Unable to exploit entire plant for cannabinoid extraction Availability of skilled staff	Small domestic market High cost of indoor cultivation No subsidies or economic incentives in the UK Availability of skilled staff Suitable sites and capital costs Imported product from overseas markets	Raw ingredients imported from abroad No clear THC zero levels in product UK leading in terms of legal, ethical, and quality CBD industry No requirements on testing, traceability or labelling	Raw ingredients imported from abroad No clear THC zero levels in product No regulator has any oversight of CBD vape products No requirements on testing, traceability or labelling	Import of CBMPs is complex, fragmented and expensive. UK manufacturers of CBPMs are unable to export Low volume of patients in the private sector and no NHS prescribing Lack of requirements on testing, traceability or labelling Perception challenges among clinicians	Research is hampered by Sc1 status of cannabinoids Sc2 for THC only applies for clinical studies, not before Availability of experienced researchers	GW Pharmaceuticals is the only company to have succeeded in this area, but now owned by Jazz (and listed in America) Multi-billion dollar potential in indications known to have benefit for cannabinoids Conventional clinical trial pathway is slow and expensive
Primary operators or licensed companies in the UK sector	*Margent Farms*	*Celadon, Glass Pharms, Sativa Wellness*	*Mile High Labs, Newell Sciences, Naturecan*	*Kanabo*	*Columbia Care, Grow Biotech, Curaleaf, Brains Bioceutical*	*Artelo Biosciences, TTS Pharma*	*GW Pharmaceuticals*
Opportunity areas for growth	Carbon credits Plant genetics New materials	Domestic CBPM market	New product innovation / brands Overseas markets	Domestic 'wellness' market	Domestic CBPM market Export of CBPMs	Synthetic cannabinoids Personalised medicine	New licensed medicines in domestic and international markets

1.3 Medicinal applications

Delopments in medical technology and therapeutics are likely to make healthcare an increasingly valuable global market for Britain to develop and to access, and although market size projections are imperfect, novel treatments involving cannabinoids can be expected to play more of a role in two decades' time than they do now.

In the UK, most prescribed medicines are licensed by the MHRA after they have shown the appropriate safety, quality, and efficacy and only then it goes through cost-effectiveness evaluation by the National Institute for Health and Care Excellence (NICE) for its recommended use. There are a small number of licensed cannabis medicines, though even these are not widely prescribed on the NHS. The alternative route to access medicinal cannabis is through unlicensed medicines ('Specials') defined as Cannabis Based Products for Medicinal use in humans (CBPMs) which were made available after the law change in 2018.

Licensed medicine prescribing

Prescribing of licensed medicines derived from cannabis was possible before the law change in 2018 and a very small number of patients continue to access these products on the NHS. Even though these same drugs – namely Sativex and Epidyolex – are also now licenced in Europe and North America, uptake in the UK's public health system remains low, reflecting the low levels of awareness among clinicians.

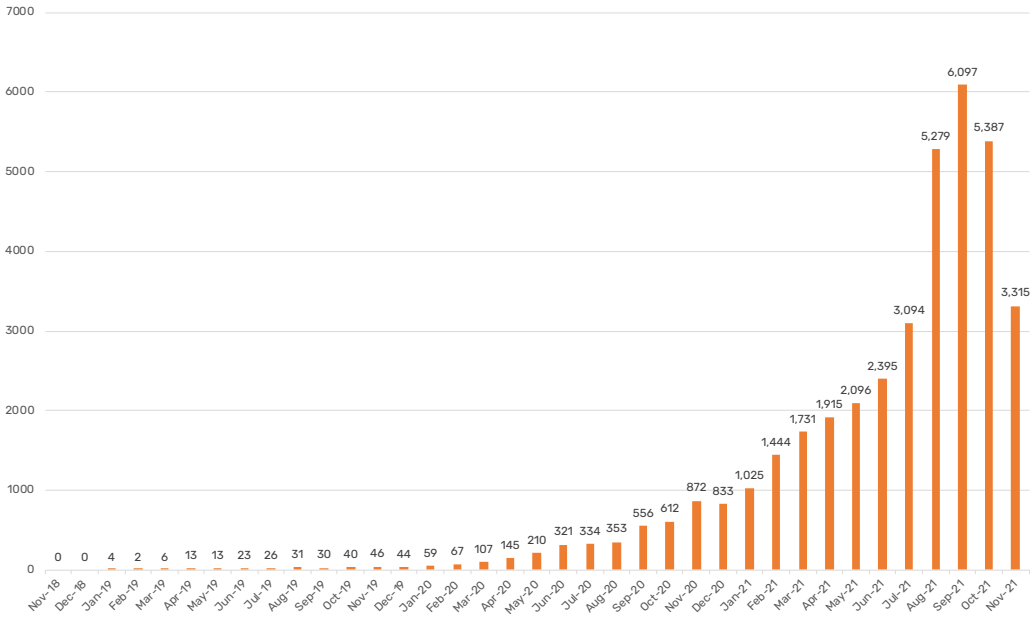
The Advisory Council on the Misuse of Drugs (ACMD) has noted[12] that prescribing of these licensed medicines did appear to increase after medicinal cannabis was made available for prescribing as CBPMs in 2019, but the data excludes private prescriptions and is collected differently across the four nations. Compared with much larger sales in North America, recent NHS England data suggests a small volume of NHS prescriptions, but a steady increase in prescribing of the two main licensed medicines in recent years:

	March 2018 - February 2019	March 2021 - February 2022	Percentage Increase
Dronabinol	1,466	2,115	44%
Sativex	Unavailable	1,797	N/a

Source: OpenPrescribing.net – Bennett Institute for Applied Data Science, University of Oxford, 2022

As unlicensed medicines, there is no standardised data collection on CBPMs and because prescribing authority is limited to specialists on the GMC register, almost all the prescription episodes occur in the private clinic sector. That sector is regulated and inspected by the Care Quality Commission (CQC) but private clinics are not required to share or publish data on prescriptions by product brand or class.

12 *Advisory Council on the Misuse of Drugs (ACMD) (2020). Cannabis-based products for medicinal (CBPMs) for use in humans. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/939090/OFFICIAL__Published_version_-_ACMD_CBPMs_report_27_November_2020_FINAL.pdf*



CBPM prescribing

Source: NHS Open Data Portal - FOI 22354 (2022)[13]

The unlicensed CBPMs (specials) in the UK market have not been through the normal MHRA approval process. Because of policy decisions that were designed to keep tight controls on the prescribing of these unlicensed products, the rescheduling of CBPMs in November 2018 has not led to a large number of patients being able to benefit in the UK. Unlicensed CBPMs are only prescribed by specialist physicians who take the responsibility (and liability) for safety, quality and efficacy. Other barriers for access include poor levels of physician understanding, a lack of evidence on cost effectiveness, and the relatively high costs of these unlicensed CBPMs.

Note that CBPMs cover a range of products like:

- Single, highly purified individual cannabinoids e.g., CBD (extracted from Hemp or Marijuana or synthetic)
- Or mixture of cannabinoids
- Or full spectrum extracts (mixture of cannabinoids, terpenes, flavonoids & other plant matrix)

Companies applying for prioritised clinical trials (PCTs) should demonstrate batch to batch chemical consistency and acceptable shelf life. There are also companies who specialise in pure cannabinoid Active Pharmaceutical Ingredients (API) for clinical trials and drug development, and which do not currently supply the UK's patient population.

Clinical efficacy

There is evidence-based data[14] [15] for certain disorders already being treated by CBPMs - ADHD, Anxiety, Appetite, Arthritis, Atherosclerosis, Autism, Cachexia, Cancer, Colitis, Crohn's disease, Diabetes, Epilepsy, Heart attacks, Inflammation, Mood disorders, Motor function disorders, Neuroprotection, Obesity, Pain, Prader-Willi Syndrome, Psychosis, PTSD, Schizophrenia, Sepsis, Sickle cell anaemia, Sleep disorders, Smoking and Stroke. There are about 139 registered and

13 https://opendata.nhsbsa.net/dataset/foi-23354

14 Kogan, N. M., & Mechoulam, R. (2007). Cannabinoids in health and disease. Dialogues in clinical neuroscience, 9(4), 413–430. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3202504

15 Pauli, C. S., Conroy, M., Vanden Heuvel, B. D., & Park, S. H. (2020). Cannabidiol Drugs Clinical Trial Outcomes and Adverse Effects. Frontiers in pharmacology, 11, 63. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7053164/

active clinical trials examining CBD across the globe[16], about 83 trials in phase 2/3 (some of them detailed in Appendix 1) and about 70 active trials for cannabis[17]. It should be noted that in many cases for rare conditions, the data is for a limited number of patients. Clearly, further clinical studies on well characterised medicinal cannabis products need to be performed to establish their true efficacy potential. However, the examples shown in Appendix II, are sufficient to suggest that this is a fruitful area for further study and one where the UK could be a leader.

The medicinal use of cannabis and the future potential for health benefits from cannabinoid drugs is the focus for most of the policy, advocacy and scientific activity in this arena. As venture capital and institutional investment in this category increases, it is funding new commercial activity in the UK life sciences and healthcare sectors. Even with patient numbers far below the level predicted at the outset, in just the three years since medicinal access was introduced, dozens of new clinic settings and medicinal suppliers have emerged to utilise the legal pathway to supply cannabis medicines to patients.

16 https://www.clinicaltrialsregister.eu/ctr-search/search?query=cannabidiol
17 https://www.clinicaltrialsregister.eu/ctr-search/search?query=Cannabis

1.4 Consumer CBD

The UK's large and maturing CBD sector did not exist a decade ago. The CBD retail market made up of Over-The-Counter (OTC) products containing cannabidiol is growing rapidly in the UK. It has confounded some critics who predicted it was a 'fad' in 2017-8 and now has a domestic base of millions of consumers. The most recent market sizing estimate in 2021 suggests the sector (at 690M) is larger than the value of the vitamin C and D sectors combined, according to ACI estimates – more than double the level of sales recorded in 2019, when the market was valued at £314 million. The UK is now the world's second largest market for consumer CBD, behind only the USA.

As both a cause and consequence of being largely unregulated, the CBD sector grew rapidly in under five years and is still poorly supervised, with complex supply chains that are reliant on imported finished products and raw ingredients. As the CMC[18] [19] and others[20] have shown, one consequence of this diverse and rapidly expanding market is that the product quality and provenance are highly variable, and many users have had their consumer rights infringed with mislabeled or contaminated products. Unlike medical products or even wellness or cosmetic products from major FMCG companies, CBD products do not provide their users with good information on their content, manufacturing process, or origins.

Beyond CBD there is now growing interest in the market for minor cannabinoids (such as CBG) and terpenes that could be isolated and marketed to the consumer as another alternative to cannabidiol that is also non-controlled. There is a high potential for product diversification and innovation in the field of minor cannabinoids, especially the likely interplay with rapid developments like personalised nutrition, which regulators need to prepare for. It is not, however, currently acknowledged by the FSA in their latest (June 2022) horizon-scan of emerging risks and opportunities[21].

Beginning in 2019 the FSA has taken steps to move the CBD industry to compliance under the established Novel Foods regimen[22]. In March this year, FSA produced the first iteration of a public list to show which companies have submitted a valid application and are permitted to remain on sale pending the outcome of the authorisation process. If a product is not on the public list, it should be removed from sale because it is not attached to a credible application for market authorisation. This list is now in place as a tool to help local authorities and retailers prioritise the non-compliant products to be removed from sale. A next and final iteration of this list is due to emerge by July 2022.

Despite a slow start, the approach adopted by the FSA is coherent and has no viable alternative. Novel Food processes mean that the UK now has a clear pathway for CBD products to be fully regulated. In fact, with the Food & Drug Administration's ongoing delays in deciding its own approach in America, and the slower pace taken by the EFSA in evaluating Novel Food applications of CBD products in Europe, this now means the UK is edging ahead in the global CBD sector. This is giving certainty to the private sector and confidence to investors that the UK has a clear process established to ensure products on sale are compliant and safe for consumers.

18 *The Centre for Medicinal Cannabis (2018). Medicinal Cannabis in the UK: A Blueprint for Reform. https://irp-cdn.multiscreensite.com/51b75a3b/files/uploaded/Report%20-%20Medicinal%20Cannabis%20in%20the%20UK%20_%20A%20Blueprint%20for%20Reform%20%281%29.pdf*

19 *Association for the Cannabinoid Industry (2021). Green Shoots: Sowing the seeds of the new UK cannabinoid market. https://theaci.co.uk/wp-content/uploads/2021/05/Green-shoots-Sowing-the-seeds-of-the-new-UK-cannabis-market-ACI-_-CMC-report.pdf*

20 *Morrison, O. (2020). UK cannabinoid industry spots opportunity as EC considers reclassifying CBD a narcotic https://www.foodnavigator.com/Article/2020/07/15/UK-cannabinoid-industry-spots-opportunity-as-EC-considers-reclassifying-CBD-a-narcotic.*

21 *Food Standards Agency (2022). FSA 22-06-06 - Foresight Function and Horizon Scanning – Annual Update to the Board. https://www.food.gov.uk/about-us/fsa-22-06-06-foresight-function-and-horizon-scanning-annual-update-to-the-board*

22 *World first for consumer cannabinoids as UK's FSA releases list of permitted CBD products - The Association for the Cannabinoid Industry (theaci.co.uk)*

1.5 Hemp and the environmental prize

Hemp is now recognised as a crop with huge potential that can be utilised in a number of ways to advance economic and environmental goals. Combined with the burgeoning agritech industry, hemp could play a key role in the future of both the cannabinoid sector as well as further afield.

After Brexit, the FSA adopted the European approach to consumer cannabinoids, and so all Novel Food Applications submitted in the UK before March 2021 used the EFSA based regulatory framework. This is an example of how post-Brexit Britain has chosen to align itself with European regulations, but the smaller market size has allowed for quicker and more effective implementation of such regulations. Conversely, the simultaneous decision to retain European regulation and continue to only permit EU-approved hemp strains has restricted the potential for hemp in the UK.

Innovation in genetic engineering and the agriculture sector is growing at such a pace that there are already seed strains available that are enriched in desired cannabinoids or particular mixtures of key cannabinoids. The UK would benefit enormously from authoring and expanding its own sovereign list of approved strains for cultivation - as Canada does [23]- this would cement a competitive advantage over the EU and allow the UK to become the home of a mini revolution in cannabinoid plant science, with possible applications in manufacturing, consumer and medicinal sectors[24] [25].

Existing British infrastructure presents an exciting opportunity to use genetic tools to shore up strain reliability and target specific desired cannabinoids. This would have major implications for our nascent industries, as these seed strains are already becoming the reliable source of product quality and reproducibility required for any commercial product[26].

In a broader sense, hemp cultivation aligns with the British government's commitment to protecting soil and biodiversity in the agricultural subsidy regime that replaces the EU's Common Agricultural Policy, and with the legally binding targets for carbon reduction and Britain's net zero future. As well as cannabinoid innovation birthing new pharmaceutical and functional food sectors, hemp is acknowledged as being a multi-faceted but underused weapon in the fight for environmental preservation. It is valuable in a myriad of ways by: acting as a carbon sink; effectively cleaning soil; replacing more carbon intensive building materials and textiles; and having positive effects on the containment of biodiversity loss, another key parameter of the Planetary Boundaries framework[27].

By embracing domestic hemp cultivation and mastering these functions, the UK could build a comprehensive circular economic project around a cheap and durable plant. Hemp has been valued as a vital commodity in the UK in the past. It is noteworthy that during the early modern era, farmers were incentivised to plant hemp and it was widespread cultivation of hemp within the British Isles that played an important role in supplying rope and textiles to the Royal Navy and merchant shipping, which helped drive an economic transformation of the country into a global trading nation. It would be a powerful narrative for UK agriculture after Brexit if the Government recruited British farmers in the twenty-first century to contribute to a new economic opportunity for the nation arising from the same plant.

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23 https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/producing-selling-hemp/technical-policy-documents.html

24 Association for the Cannabinoid Industry (2021). Green shoots: Sowing the seeds of the new UK cannabis market. https://theaci.co.uk/wp-content/uploads/2021/05/Green-shoots-Sowing-the-seeds-of-the-new-UK-cannabis-market-ACI-_-CMC-report.pdf

25 McPartland, J. M., & Small, E. (2020). A classification of endangered high-THC cannabis (Cannabis sativa subsp. indica) domesticates and their wild relatives. PhytoKeys, 144, 81–112. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7148385/

26 Schwabe, A. L., & McGlaughlin, M. E. (2019). Genetic tools weed out misconceptions of strain reliability in Cannabis sativa: implications for a budding industry. J Cannabis Res 1, 3. https://jcannabisresearch.biomedcentral.com/articles/10.1186/s42238-019-0001-1

27 Sorrentino, G. (2021). Introduction to emerging industrial applications of cannabis (Cannabis sativa L.). Rendiconti Lincei. Scienze Fisiche e Naturali, 32: 233–243. https://link.springer.com/content/pdf/10.1007/s12210-021-00979-1.pdf

Chapter 2

CURRENT REGULATORY CHALLENGES

2.1 Accidental evolution of the UK industry

In the CMC/ACI report Greenshoots (March 2021)[28], the origins of the UK's legal cannabinoid market were described as accidental and the potential benefits as unrecognised:

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 scepticism about its value and merit, the motives of those engaged in it, and whether its emergence is a welcome development at all.

The emergence of the UK's legal cannabinoid sector was certainly not planned. Instead of a proactive agenda to leverage new commercial opportunities from what was happening internationally or in response to the improving evidence base, every development to date as been almost entirely reactive - with the Home Office and associated regulators forced into adopting a reform to the law (as with medicinal access following patient pressure in 2018), or arriving at a decision on how to regulate only after the sector was firmly entrenched in the consumer economy (as with the 2019 decision of the FSA to treat CBD food supplements under the Novel Food regime).

This series of reactive policy interventions and law changes mean that the industry itself has not been supported in any coordinated way, and the 'accidental' evolution of this sector now presents many challenges to politicians and regulators. In some areas the sector is exposing the shortcomings of existing laws (for instance, around the Proceeds of Crime Act and money laundering), and in others, it is innovating and launching new products and services at such a fast pace that policy-makers and regulators often appear to be far behind the curve. The financial and democratic forces that are shaping this market are by definition very dynamic and hard to predict, but the legal foundation has been set and it is the duty of government to ensure that it meets the needs of patients, consumers, employers and the wider public.

Although 2018 saw the first legalisation of medicinal cannabis in the UK, through the rescheduling of a new category of product - CBPMs - from Schedule 1 (controlled drugs with little or no medicinal or therapeutic use) to Schedule 2 of the Misuse of Drugs Regulations 2001, it is still difficult for patients to gain access. There are a series of barriers to prescribing that need to be overcome in order to improve patient access to medical cannabis in the UK and just changing the law and handing the decisions on a case-by-case basis over to a minority of senior doctors is not sufficient.

The Government briefly appeared to acknowledge this fact when the former Health Secretary, Matt Hancock, met with patient groups in 2019 and commissioned the NHS Improvement Agency's review into the barriers to accessing CBPMs. It concluded that the key challenge for prescribers was the lack of scientific evidence for unlicensed CBPMs/Specials. This means prescribers/ specialists need to take the responsibility for the safety, quality and efficacy of the products and combined with lack of training and education, it depresses the number of physicians willing to prescribe, even within the cohort of specialist doctors who practise in the areas where CBPMs may be appropriate.

"Despite many high hopes and big forecasts the actual number of patients is growing steadily but still only around 10,000. This has to do with lack of awareness about this option with patients, knowledge gaps with doctors about medical cannabis, confusion about cost (lower than almost everybody thinks) and a few policies like restricting export from the UK that make it difficult for the industry to scale and let patients profit from that scale."

Pierre van Weperen, CEO GROW-IPS Pharma

28 *Association for the Cannabinoid Industry (2021). Green shoots: Sowing the seeds of the new UK cannabis market. https://theaci.co.uk/wp-content/uploads/2021/05/Green-shoots-Sowing-the-seeds-of-the-new-UK-cannabis-market-ACI-_-CMC-report.pdf*

2.2 Regulations dictate how the sector evolves

One of the remarkable features of the legal sector is how it has developed unevenly, so that some aspects – such as industrial hemp products and hemp cultivation are still niche categories despite having a long pedigree – whereas the CBD industry has grown rapidly in under a decade to become much more valuable than the combined size of the markets for Vitamin C and D[29], and significantly larger in terms of employment and revenue than the fledgling medicinal cannabis industry. Although closely related and intertwined by their use and exploitation of the same raw material, underlying these economic profiles are very different regulatory constraints and incentives.

Hemp farming in the UK never enjoyed the same economic support or agricultural incentives as the same crop in parts of Asia or eastern Europe, and even now, is not incentivised to the same extent as it is in Canada or the United States and is under even tighter constraints than hemp cultivation in the rest of the EU (see table below).

Similarly, the way the new regime for medicinal cannabis was designed in 2018, introduced significant – and arguably disproportionate – constraints on its development, such that three full years after the rescheduling and the first prescribing of a CBPM, the market is comparatively small, and the patient growth seen in comparable jurisdictions like Australia has not been matched (see case study on Australia).

In contrast, without a clear legal status and before European regulators decided how to approach cannabidiol (CBD), the UK allowed a vibrant wellness and consumer products industry to emerge that could only be regulated post hoc, despite the risks that some products from certain 'grey' market suppliers presented. The principal reason that CBD was allowed to proliferate in the UK and regulators did not move more quickly to try and limit its adoption seems to be because of its good safety profile, a status recently confirmed by the World Health Organisation (WHO)'s Expert Committee on Drug Dependence (ECDD) as having "no potential for abuse and no potential to produce dependence". If this had not been the case, it is highly unlikely that the surging CBD market would have been tolerated. Nevertheless, the Novel Food process, as a pathway for branded CBD goods to become approved, and as a framework for guaranteeing that consumers are able to access safe and dependable products, is an important development that will support the market's future growth. Albeit it is one that arguably could have started sooner.

These contrasting examples of the three legal sectors within the UK cannabinoid industry tell the same story – it is the form and nature of regulation, and the constraints and the incentives imposed on producers and consumers, that is the critical dimension which determines the trajectory and economic impact of each sector, even though it is utilising the same raw material. Unless and until the legal status of the cannabis plant itself is changed – as it was by the Cannabis Act in Canada in 2018 – the future expansion of these three sectors will be decided more by the macro policy and regulation, and so by the action of regulators and Whitehall departments, than it will by elected parliamentarians.

Hemp cultivation - comparable regimes					
Country	***Extraction of cannabinoids***	***Varieties permitted***	***THC limit in crop***	***Export permitted***	***Carbon incentives***
European Union	Permitted under licence	EU approved strains only	< 0.3% (from 2023)	Yes	In some EU states
Canada	Permitted	Canada approved strains	< 0.3%	Yes	No
United States	Permitted	Any variety	< 0.3%	Yes	In some states
Australia	Permitted	Any variety	Up to 1%	Yes	No
United Kingdom	Not permitted	EU approved strains only	< 0.2%	With a Home Office licence	No

29 Ledger, E. (2019). UK CBD Market is Larger than Vitamin C and Vitamin D Markets Combined. https://canex.co.uk/uk-cbd-market-is-larger-than-vitamin-c-and-vitamin-d-markets-combined/

2.3 The jungle of regulators in the UK's cannabinoid landscape

The global interest in the cannabinoid sector means its entering into all aspects of our daily life via medicinal/specials, wellness/dietary supplements, food, cosmetic, vape and the veterinary sector. Therefore, regulatory innovation is required to develop the cannabinoid sector in each of these areas, and yet the current landscape is a jungle of outdated regulations that are either decades old, or newly emerging and so lack any strategic coherence.

The legal cannabinoid sector straddles several industries and is therefore subject to a range of regulations that separate authorities oversee. However, the lack of a comprehensive government-authored strategy for the whole industry means that these individual regulators do not operate according to a single approach and cooperation is limited. Each of these regulators are also disjointed by virtue of their remit, with some covering England, and others applying to the UK. There is also the duplication of functions and inconsistency of approach with two separate regulators for food - one covering England and Wales, and a separate regulator in Scotland.

Regulatory actors in the UK's legal cannabinoid space

Regulator	**MHRA**	**FSA**	**CQC**	**FCA**	**NICE**
Geographic remit	United Kingdom	England and Wales	England	United Kingdom	England
Primary role	The licensing of medicines and medical devices Ensuring health claims are justifiable and evidenced	'The FSA's job, set out in law, is to safeguard public health and protect the interests of consumers in relation to food'	'We make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.	'We are the conduct regulator for around 51,000 financial services firms and financial markets in the UK'	'[To] improve outcomes for people using the NHS and other public health and social care services'
Relevant focus for the cannabinoid sector	Policing of health claims on food 'wellness' / nutraceutical product packaging or marketing material	Ensure Novel Food products such as CBD sold in the UK are safe Harmonisation & Standardisation Presence of Controlled cannabinoids Safety & Bioavailability	Monitoring the quality of private clinics Controlled drugs in care home settings	Listing of companies on UK public exchanges Compliance with POCA for trading entities	The evidence base Developing guidelines Evaluating new treatments
Current issues	Unlicenced CBMPs not undergone rigorous tests for quality, safety & efficacy & local medicines governance to safeguard patients Patient registry of CBMPs & info Import of unlicenced CBMPs Unclear pathways for CBMPs Adultration	Lack of Reference standard No Pharmacopeia guidance Bioavailability data & impact of impurities Different compliance regulations in England Wales to Scotland & NI ACMD recommendations	Growing number of private clinics Increase in uptake of CBPMs as part of palliative care	Applying POCA in a clear, consistent & proportionate way Scrutiny of applicants for listed status based on complex history and global supply and ownership structures	Evaluating cannabinoid medicines that advance to late stage clinical trials Providing evidence-based guidance on prescribing Producing quality standards for the NHS and public health providers
Future challenges	Growing home market & export of CBMPs required Growing demand in innovation & RCT's require opportunity to prioritise CT Observational & evidence base data Lack of experts in this field & growing innovation in cannabinoid sector	Growing demand & product innovation requiring continuous regulatory catch up International competition & regulations EFSA alignment or divergence	Inspection of a larger network of private clinics offering CBPMs prescribing Tele health and new access channels	Approving listings of new firms with exposure to markets where legalisation is passed (Germany, Switzerland) Future of POCA and application of future legislation	Judging efficacy and cost effectiveness of plant-based medicines

The cannabinoids sector in the UK is relatively new, but its activities are subject to a very diverse range of regulations and law, and there is a jungle of regulatory authorities that govern companies and other organisations in this space. The most important are the MHRA and FSA, however others have a key role depending on the activity in question. Sitting above all of these sector or professional regulators is the primary authority for cannabis in the UK – the Home Office.

As a department of state responsible for drug policy, it is clear why the Home Office would have an important role in this sector. It is necessary to have a lead department for the revision and drafting of new laws in this space, as is often required in response to new drug developments and technological and scientific change. Any bills proposed to Parliament impacting on the principal drug laws (the 1971 Act, or the 2001 regulations) are devised and stewarded by the Home Office (the criminal law and penalties associated with contravention of drug laws is a matter for the Ministry of Justice).

However, it does not mean that – "The Home Office [should] act[s] as the National Cannabis Agency, as required by the UN Convention on the control of narcotics"[30] – and this setup is not reflected in other jurisdictions. For example, in Canada, this role is performed by Health Canada. It would be permissible and reasonable to have another Whitehall department closer to the industry and consumer/patient interface with legal cannabis products, such as the Department for Health and Social Care (DHSC), or the Business Department (BEIS), to act as the 'national cannabis agency'. Or for greater regulatory clarity and other benefits, to have this agency stand apart as a separate entity, which would make its activities less politicised, as we propose later in this report (see Chapter 7).

The variety of existing regulatory approaches highlights the need to clarify medicinal and consumer cannabinoid regulatory frameworks and their applications in practice. Although most countries are still in the process of developing such regulations, important lessons can be learned for the successful implementation of a better medical cannabis and consumer cannabinoid regulatory framework in the UK.

Strain on existing regulatory approaches

Regulations that govern cannabinoids are complicated and multi-faceted. Cannabis is a controlled drug according to UK laws that followed the adoption of the 1961 UN Convention text which was deliberately broad, applying prohibition controls to 'extracts and tinctures of cannabis'. However, the 1971 Misuse of Drugs Act, and the subsequent regulations, embodied in the 2001 MDR, do not mean that all activity involving cannabinoids is prohibited unless undertaken with a licence. There was an explicit exemption for test samples used in scientific research, and now for the new category of CBPMs that are classified as an unlicensed medicinal product (but which are still controlled, and require manufacturers, importers and suppliers to hold a Home Office licence).

However, in addition to these developments, the most widely adopted cannabinoid, which has only been isolated and exploited at an industrial scale in the last decade in most countries is 'cannabidiol' or CBD – which unlike CBN or THC is not a controlled substance – a position acknowledged by a recent test case in the European Court of Justice. This case confirmed that trade in such products across national borders in the EU could not be restricted by reference to the legal status of cannabis in the UN conventions. This however means that laws place controls on the plant and its uses, but some of the compounds found in cannabis are permissible to handle, trade and use without any kind of regulatory controls, with the deciding factor being the end product use or purpose of the CBD itself.

In this respect, overlapping regulations for food and medicines bear on CBD products depending on whether they are designed to be administered as a medicine or ingested as a food without medical claims. In addition, it is possible to utilise CBD

30 Home Office (2021). Controlled drugs: domestic licences. https://www.gov.uk/guidance/controlled-drugs-domestic-licences#cannabis-cannabidiol-cbd-other-cannabinoids-and-cannabis-based-products-for-medicinal-use-in-humans-cbpm

in cosmetics, without contravening national laws, and to sell CBD vape liquids – without any nicotine – outside of any regulatory controls governing e-cigarettes. In a recent article in Addiction[31], one researcher summarised the existing problem: "Recent developments are putting considerable strain on existing regulatory approaches and there is increasing uncertainty as to whether certain products should be treated under EU regulations relating to drug control, medicinal products, food safety, tobacco and smoking products, or cosmetics."

31 Hughes, B., & Vandam, L. (2021). Regulatory approaches to cannabidiol in the European Union: are market developments sowing the seeds of confusion? Addiction,117, 3–4. https://onlinelibrary.wiley.com/doi/epdf/10.1111/add.15587

2.4 Ongoing uncertainty about law and regulations

Cannabinoids as part of hemp, medicinal and consumer products are still subject to widespread regulatory confusion, which not only impacts on the industry but also affects regulators. This is clear from the recently published article on 7th of June 2022 in The Journal of Trading Standards[32] which highlighted:

"At present there is confusion and disagreement across the industry, regulators and the police (who are responsible for investigating and prosecuting drugs offences) about what levels of THC are permissible, not least because there is some debate about which CBD products are exempt from control under Regulation 2 (1) of the Misuse of Drugs Regulation 2001 (the MDR). In particular, there is currently no authority on the meaning of Regulation 2 (1) (c) which requires that 'no one component part of the [exempt] product or preparation contains more than one milligram of the controlled drug'."

The limit of 0.2% Δ9-THC is for the industrial hemp licence to grow but for CBD products the legal threshold of controlled cannabinoids products is wrongly believed to be 0.2%(Δ9-THC) instead of 1mg/container. This confusion is further challenged by the common industry method of expressing content levels due to lack of industry standards like a British Pharmacopoeia. As per Home Office Industrial Hemp guidance "The 0.2% THC is to identify the varieties which can be potentially cultivated". However, finished products containing CBD should have no more than 1mg/container, in accordance with the exempt product criteria satisfying the three limbs of the regulations described in the MDR2001. This THC limit therefore does not apply to dried flowers as they are Class B drugs, and this continues to be contested and even flouted by some smaller companies.

More recently, debate about the FSA regulations on Novel Foods have given rise to some examples of CBD companies seeking to evade the requirements on extracted cannabinoids by producing 'cold-pressed' extracted products for consumption as a food supplement on the basis that this method is not novel and this is confirmed by the FSA. However, there are no clear labelling, testing or certification standards in place which can distinguish cold press vs extracted CBD products, as onus is on the suppliers to prove this until demanded by the enforcement agencies.

Furthermore, the traditional application of cold-pressing is for seed oils (which are exempt), and which contain low levels of cannabinoids for use in health food products. But cold-pressing of the controlled parts of the plant, even when using hemp plants grown under licence, is not permitted by the Home Office and hemp farmers are required to destroy that material. So the method of extraction for the legal status of the end product is not relevant when the source material itself cannot legally be utilised in this way. Under a revised hemp licensing regime, where British farmers could sell the flowering tips and leaves to a licensed UK-based company to extract and refine into a distillate or isolate product for the domestic CBD market (and the brands that are approved by the FSA under Novel Foods), then such activity would be lawful but it is not currently an option.

POCA: Lack of clarity is holding back investment

The Proceeds of Crime Act 2002 (POCA) prohibits dealing with any benefit (directly or indirectly) arising from criminal conduct, even when that activity occurs abroad if that same activity would be illegal if it occured in the UK (the 'extra-territoriality' provisions). POCA prohibits receiving, dealing with, or being concerned in a transaction which facilitates (by whatever means) the retention or movement of the "proceeds of crime". Under POCA, "proceeds of crime" means any known or suspected benefit arising from criminal conduct. Still subject to interpretation as to what is 'caught' by this conduct but it is a serious indictable offence that can lead to a 14-year prison sentence, although no prosecutions have ever been pursued. There is currently very little guidance for UK businesses about cannabis-related activity in this context. The

32 Philipps, L. (2022). Understanding the ABCs of CBD. https://www.journaloftradingstandards.co.uk/legal-policy/understanding-the-abcs-of-cbd/

position of the UK National Crime Agency (NCA) and other regulators is not clear and nowhere set out, even though legal and regulated cannabis businesses in the UK are clearly not what the UK Proceeds of Crime Act 2002 (POCA) was designed to criminalise[33]. Until such time as the POCA regime is clarified to exempt the owners and operators and those who gain (including shareholders) from the activities of legal companies in the UK, major institutional investors will be deterred from committing to the sector. Jersey recognised that the current laws were having a 'chilling' effect on potential investment in their own medicinal cannabis industry and have revised and updated their local laws accordingly to give the clarity that the UK's 2002 law lacks.

The self-regulated testing methods, which are crucial to determining the legality of products, vary widely, causing even more uncertainty. In the CMC's 2019 paper - CBD in the UK: Towards a responsible, innovative and high-quality cannabidiol industry[34] - the confusion around what the law permits was laid out. In a new retail sector, education continues to be necessary to ensure suppliers and buyers understand what products comply with the law.

The subtleties of the law and regulations surrounding industrial hemp, and cultivation and extraction of cannabis, and then the applicability of Novel Food rules and the POCA requirements for investment and commercial listing, do mean that confusion can arise. This is another reason why the Home Office and others should see it as essential for market confidence to produce a single clear statement of the law and what it does and does not permit.

"It [POCA] permeates every transaction that we come across in the cannabis sector and I would suggest creates a chilling effect for anybody looking to enter the industry. The chilling effect isn't just limited to capital becoming available for investing opportunities, but also throttles the growth of participants in the industry, limiting their availability to services we take for granted such as insurance, banking, lawyers, accountants, etc. There's no real ability to move this industry forward without the government addressing POCA. To my mind, I can categorically state it is the biggest blocker that we see to a successful industry growing within the UK as it adds significant uncertainty to business, as well as unnecessary costs to all parties - making it unsustainable over the long run.

In the future, I am quite interested in seeing the interplay between the UK and Germany, once Germany introduces adult-use as is anticipated during this Parliament. It will certainly create Proceeds of Crime Act issues for any UK person or company holding any securities in German entities that profit from adult-use cannabis or contracting with said German companies. How the UK will become comfortable prohibiting transactions with a significant European trading partner will be interesting to watch. In any event, if the issue is not addressed, other European partners will inevitably surpass the UK in terms of maturity and sophistication – we will lose any competitive advantage we have had."

Dylan Kennett, Senior Associate, DLA Piper

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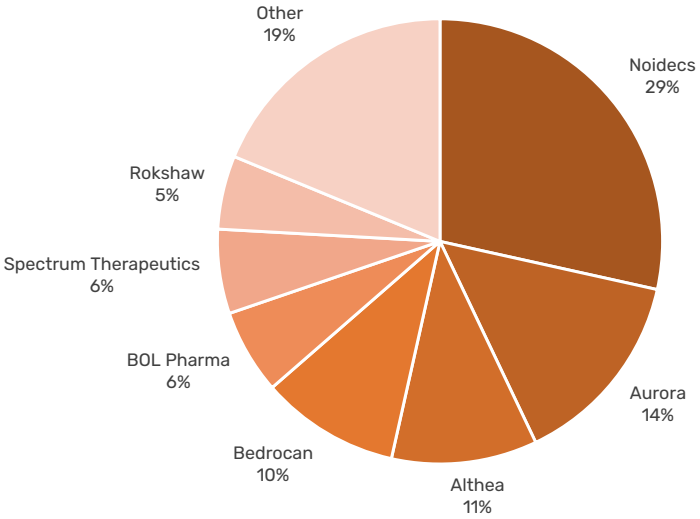
33 The Centre for Medicinal Cannabis (2022). Decalogue: Ideas to accelerating patient access & therapeutic understanding of medicinal cannabis. https://decalogue.info/wp-content/uploads/2022/03/Decalogue_final.pdf

34 The Centre for Medicinal Cannabis (2019). CBD in the UK: Towards a responsible, innovative and high-quality cannabidiol industry. https://hempindustrydaily.com/wp-content/uploads/2020/04/Report-_-CBD-in-the-UK-002.pdf

2.5 Ongoing reliance on imported product

A competitive market in this sector is made more difficult because of the dependence on imports. A market economy cannot thrive without mature trading links that facilitate import and export, but the UK's consumer cannabinoid sector is almost entirely reliant on imports of raw materials and finished CBD products from North America, Europe and other overseas markets – not as a product of market forces but rather domestic rules that outlaw activity that is the foundation of the supply chain itself. The outdated regulatory constraints that prevent domestic cultivation for CBD production combine with the dominance of international suppliers, who have understandably prioritised the UK market where domestic consumer demand is very high.

Percentage of all CBPM products prescribed to date, by supplier



Source: NHS Open Data Portal - FOI 22354 (2022)[35]

Manufacturer	Country of Origin	Country of Manufacture
Noidecs	Australia	UK
Aurora	Canada / Denmark	Canada / Denmark
Althea	Canada	Australia
Bedrocan	Netherlands	Netherlands
BOL Pharma	Israel	Israel
Spectrum Therapeutics	Canada	Canada
Rokshaw	Portugal	UK

35 https://opendata.nhsbsa.net/dataset/foi-23354

2.6 Lack of protection and incentives for the domestic industry

Most CBD oils /products on sale online or on the high street are imported into the UK, primarily from the US and Europe. The key question is whether all these imports go through the rigorous testing process that would be needed to confirm compliant levels of controlled substances, as per UK regulations. Testing standards, supply chain visibility and product labels of these CBD products are key for product quality and to boost consumer confidence. However, lack of clarity on regulations and testing methodology means many producers are, therefore, turning to self-regulation and independent verification to ensure compliance and a quality product.

Equally important, CBD consumers themselves are looking for guidance/education on products from the labelling, and for reassurance on safety standards, especially on psychoactive cannabinoids. As our opinion research shows (see Chapter 3), provenance matters to consumers, but so does a clear distinction between plant-derived CBD extracts (or hemp cold-press), or synthetic CBD products. Consumers deserve to know the difference and for products to explain what they include. What is the safe limit for daily intake of these psychoactive cannabinoids? Where did they originate? What extraction methods were used? All of these questions are not routinely answered in today's market, and imported products are not required to answer them by virtue of meeting any domestically imposed standards.

There is a lack of incentive for domestic firms to invest in the UK when there is no legal route to market under current licensing regimes, and most of the value is generated upstream in the cultivation, processing and finishing of retail products sold to British consumers. It is a reasonable assertion that had hemp farming regulations been updated prior to the upsurge in public interest in CBD, the UK economy would have benefited from UK growers moving into this sector in order to meet domestic demand. That early opportunity was missed, but it is still possible to make regulatory changes that will ensure that Britain's future CBD sector has a foundation of domestic cultivation or, at least, a critical mass of extraction and processing capacity so the consumer cannabinoid market can generate economic value in the UK as it matures and consolidates.

Some constraints have been eased in recent years. For example, prior to changes made to the import regime in 2020, suppliers of CBPMs were unable to import in bulk to supply patients and needed to incur the delay and expense of organising individual imports on a case-by-case basis. Now these licensed suppliers can import and hold a specified amount of CBPMs for onward distribution to pharmacies[36]. However, the recent changes to permit licensed companies to import larger quantities of cannabis-based products and hold supplies for future use by patients with prescriptions - while an important step to improve supply chain resilience and lower import costs - are still not enough to facilitate the growth of the UK CBPM market[37].

Other constraints have also been eased. For example, in previous years, farmers applying for a hemp cultivation licence had to abide by prescriptive rules on crop location, screening the crop and siting it away from schools and public rights of way. As of May 2021, the updated guidance removes this requirement, and on location of the licensed crop says: "In recognition of hemp fibre becoming a more widely used industrial crop, we do not wish to be prescriptive[38]." However, it is not the licence conditions on location of planted fields that are holding back the UK's hemp sector - it is the domestic rules that prevent farmers from extracting the maximum value from the crop. Incentives may one day be on offer to encourage farmers to grow hemp for its carbon benefit - although in replacing the CAP, this is still not an approach DEFRA has adopted explicitly. Regardless, without being permitted to exploit

36 Department of Health and Social Care (2020). Faster access to cannabis-based medicines as import restrictions are changed. https://www.gov.uk/government/news/faster-access-to-cannabis-based-medicines-as-import-restrictions-are-changed

37 Department of Health and Social Care (DHSC) (2020). Faster access to cannabis-based medicines as import restrictions are changed. https://www.gov.uk/government/news/faster-access-to-cannabis-based-medicines-as-import-restrictions-are-changed?utm_source=f2f53981-ef7c-4678-ba09-69e2c3398f96&utm_medium=email&utm_campaign=govuk-notifications&utm_content=immediate

38 Industrial hemp licensing: factsheet - GOV.UK (www.gov.uk)

hemp for CBD, there is no market incentive to grow more acreage. If those rules are not changed, then quite apart from the industrial commodity, the economics of hemp cultivation in the UK look poor.

2.7 Future regulatory evolution

The Role of the MHRA

The MHRA has already earned the status of one of the most innovative regulators in the world especially during the Covid-pandemic. The appropriate regulation of Medicinal Cannabis and consumer products presents a great opportunity for the UK to lead the world and be the architect of the most innovative SMART Regulatory Framework where key players want to be a part of this R&D innovation and economic development. Rather than create a separate agency for CBPMs, it is right that MHRA is recognised as the oversight organisation for these products. This however does not mean that there is no need to streamline and bring more order to the wider regulatory landscape.

Novel Foods: where next?

The Food Standards Agency (FSA) in England and Wales designated cannabidiol ('CBD') as a novel ingredient in 2020 and has issued guidance to the sector and the qualifying criteria for CBD products to be allowed to continue to be sold. A large number of CBD brands in the market in 2020-21 were unable to meet the requirements but many chose to seek full compliance by submitting a Novel Food dossier, either independently or as part of one of more consortias.

In the next 12-18 months, as full authorisation is pending for those qualifying consumer CBD products in England and Wales, the CBD sector is expected to consolidate as companies and brands that are on the Public List (comprising those qualifying applications received for products that can prove they were on the market before 13 February 2020) will continue to be permitted to trade. All other ingestible CBD products will gradually be removed from the market, using existing Trading Standards powers of enforcement.

The FSA's regulatory barrier has already driven a degree of rationalisation in the sector and has also discouraged new products from being launched, although some new products are still emerging in breach of the FSA rules. Those companies awaiting validation of their Novel Food dossier are likely to experience less competition from unregulated or 'grey' market products but given the size and nature of this sector, it is unlikely to dissipate without consistent and sustained enforcement. As the market solidifies, major FMCG businesses may choose to enter, however such corporate decisions are also awaiting regulatory certainty, and major consumer goods brands may enter the sector formally only if and when the FSA gives CBD products full authorisation based on the outcome of full assessment of their toxicity and stability at some point in 2023. If this occurs, it is expected that even more funding will flow into the sector and CBD market penetration will go 'mainstream', with household brands investing in innovative new products for consumers to integrate CBD into their daily routines.

The Novel Food process is entirely managed by the FSA and will be the first time they have regulated a new consumer product outside of the European Union's own EFSA process. In order to provide an efficient assessment process and clear, reliable terms of trade, it will be of wider benefit to the consumer cannabinoid industry if the FSA's own resources were increased to match the size and growth of the CBD sector, and to ensure that timely decisions on applications can be made in future. Because vaping and cosmetic products are not regulated by the FSA, the outcome of the Novel Food process for CBD will not impact the development of these two subcategories of CBD in the market.

2.8 Prospects for regulatory reform

The final report of the Prime Minister's Taskforce on Innovation, Growth & Regulatory Reform (TIGRR) report[39] sets out, inter alia, a new vision for the UK for regulatory innovation to encourage those sectors with high potential for future growth, for example through novel trial design and support measures that would make the country's life sciences sector the envy of the world, and to embrace new subsectors destined for rapid growth, like cannabis medicines, and the need for new pathways for products like nutraceuticals:

The pace of bioscience is creating a whole new sector of health enhancing 'superfoods' and supplements such as enriched broccoli or probiotics, which don't fit well in our traditional regulatory framework with its binary separation of medicines (MHRA) and food standards (FSA). A new regulatory pathway needs to be established to clarify the grey area between food and pharmaceuticals to allow this sector to realise its potential.

The possibility of a brand-new regulatory pathway for the fastest growing sector of health foods and supplements could be of huge importance for the consumer cannabinoid sector but it may also be complex to devise and codify and many years away from introduction. Nevertheless, in parallel, the global interest in the potential therapeutic value of CBPMs continues to stimulate basic research and clinical studies with several leading groups in the UK. Whilst recognising the strength of the UK's existing regulators, the TIGRR review urged a series of reforms to seize new clinical trial opportunities in dynamic sectors like cannabinoid medicines:

We recommend widening the MHRA's role, without in any way undermining its traditional expertise in assessing the efficacy and safety of new medicines and medical devices, to embrace a broader remit to promote UK leadership on Regulatory Innovation. The UK should build on the excellent 'Innovative Licensing and Access Pathway' model that the MHRA has launched in early 2021, and include the wider proposed reforms in this section.

Since innovation in this new sector of cannabinoid products is expanding fast - with the real potential of achieving verifiable medical benefits - this needs to be reflected in a modernised regulatory framework (see Chapter 4). General public awareness and interest is also showing signs of increasing (see Chapter 3), and indicates a degree of unmet need in the wider population that could benefit from cannabinoids.

39 Prime Minister's Office (2021). Taskforce on Innovation, Growth and Regulatory Reform independent report. https://www.gov.uk/government/publications/taskforce-on-innovation-growth-and-regulatory-reform-independent-report

2.9 International parallels and regulation of the sector after Brexit

Following the 2016 Brexit referendum, the United Kingdom left the European Union at the end of the transition period on 31 January 2021. In economic terms, this separation will continue to present certain administrative challenges to companies in certain sectors that rely on international trade, including the companies engaged in importing CBPMs and finished nutraceuticals or pharmaceutical ingredients from EU suppliers. However, aside from new trading arrangements and border friction, the policy implications of Brexit for the legal cannabinoid sector are ultimately more important. The repatriation of certain regulatory functions in terms of medical and pharmaceutical licensing and food safety are directly relevant to the future of the cannabinoid sector. Previously, these roles were primarily discharged by the European Medicines Agency (EMA) and the European Food Safety Authority (EFSA).

In theory, after Brexit a future UK government could decide to chart a distinctive course in terms of these regulatory arenas, however so far the goal has been to maintain high standards of consumer protection and not to dilute environmental safeguards. Even if there is no strategic policy to seek opportunities to diverge from inherited or existing EU-authored policies or regulations, it is now possible that such divergence could occur – both because of the independent decision-making that the MHRA and FSA undertake, according to their own timetables, and because of the unique circumstances of the UK's domestic market (for example, a much larger CBD food supplements sector, and a concentration of cannabinoid clinical trials at UK universities). In terms of Novel Foods, some products are seeking authorisation from both the FSA and the EFSA, in order to gain the right to sell their product in both the UK and EU markets, but each is now a separate process and authorisation (if it occurs), is unlikely to happen at the same time, especially as the EFSA announced in June 2022 that they have 'paused' CBD reviews pending more evidence. In the TIGRR report in 2021, the Brexit opportunity in the nutraceuticals space was set out:

Leaving the EU presents the UK with the opportunity to explore the potential benefits of regulatory reform in the nutraceuticals and emerging consumer wellness market, to enhance health promotion & disease prevention. This will help create a stronger research evidence base on which to develop a more proportionate, permissive and innovative approach to regulation, with the goal of providing better protection for consumers and enabling the UK to develop a stronger industrial base in this new sector.

The FSA have themselves acknowledged what Brexit means and this new role, and the opportunity it presents, in their board update for June 2022:

The UK food and agricultural regulatory system for almost half a century has been intrinsically linked to the UK membership of the EU. During this time, the FSA played a significant role in direct negotiations on technical agreements and directives. However, with the UK's withdrawal from the EU, the FSA has regained control over regulatory competencies which cover food and feed safety and has developed capacities, competencies and procedures (e.g., risk assessment of regulated products) that have not been required domestically for many years. For the FSA there is now an opportunity for the UK to assert itself more fully in the field of food safety on the global stage.

This all adds an additional layer of complexity in the regulatory environment for legal cannabinoid firms but it may also present future opportunities, for example in hemp cultivation and plant science, if UK authorities can be persuaded to adopt more progressive and pro-market policies to regulate the sector in a smart and proportionate way and help catalyse economic growth (see Chapter 5).

According to federal law in the United States, CBD is a narcotic. In Australia, CBD is classified as a medicine, not a food supplement. Other countries take similar approaches. This confusing and inconsistent regulatory landscape is unlikely to be simplified and clarified by any one country acting alone, and neither is there consensus on how a new regulatory framework for cannabis would work. This means that the UK, wherever possible in terms of the treaty commitments, must work to address deficiencies in its own regulatory approach, but also recognise how it can leverage the approach it has adopted, where its consumer

cannabinoid market is poised for strong growth. As legal approaches evolve, those countries that offer the most coherent and rational framework for regulating cannabinoids will attract the attention of policy makers and investors and could help shape the regulatory direction of travel in global forums like the United Nations.

Other jurisdictions have approached these same questions and adopted different but comparable regulations for their own industries. Some of these countries have important legal and structural differences to how they regulate cannabis, but almost all of them offer some inspiration for how defects in the UK's regulatory approach might be addressed. In the case of Canada and Australia, who both have a headstart on the UK in terms of their medicinal cannabis markets, the Common Law comparison is especially pertinent, and many of the issues that the UK is currently facing - in terms of poor patient access, reliance on imported products and limited domestic economic benefits - are all problems that both markets have faced and in some areas are still facing.

Case Study: Canada – where federal regulations depended on trust

Before the Cannabis Act was passed in 2018 and non-medicinal / adult-use cannabis was legalised, the Canadian policy framework had permitted access to cannabis for medicinal purposes in some form since 2001. The access pathway underwent a series of reforms over a ten year period and it was the last iteration, the Access to Cannabis for Medical Purposes Regulations (ACMPR), that was instructive. Under the governments of Stephen Harper, the lead federal ministry, Health Canada, created a regulatory framework that developed a domestic cultivation industry, national data gathering and surveillance, and direct supply of federally approved products to registered patients. Although certain patients from earlier periods were entitled to use their own supply through home-grow provisions (with registration of addresses and plant limits and restrictions on trade or sharing), most were registered customers of a range of Canadian-based Licensed Producers who would supply them directly via mail order upon receipt of a valid doctor's approval (not a prescription).

Licensed Producers had online dispensaries but no retail stores under this regime, although cannabis clinics were also permitted. Regulating the producers was a federal responsibility (not a provincial one), so the political risk fell to the government in Ottawa to ensure that only responsible businesses that qualified to supply medicinal cannabis could hold a licence. As patient numbers grew, so did the licensing activity of Health Canada, and patients could access medicinal cannabis confident that it was grown in Canada to specified quality production standards. Federal agencies inspected Licensed Producers and set mandatory testing, packaging and labelling requirements. The Canadian market for medicinal products grew to offer a diverse range of unlicensed cannabis medicines, with flower and oils dominating the market which by 2018 had expanded to over 130 licensed producers[40] of varying sizes.

The Canadian approach – though now superseded and conflicted with the roll-out of recreational cannabis in the last three years – was an example of government setting a clear regulatory framework based on centralised control, so quality could be assured and patients could access a reliable supply of domestically produced products at a reasonable price. Although not available on the public healthcare system, some insurance providers also covered cannabis prescription costs and many still do. Unlike the early years of the medicinal cannabis regime in the UK, the Canadian market was not dependent on imported products and neither were there rules that prevented domestic producers from exporting. In fact, it was Canadian Licensed Producers in 2018 (Tilray and later Aurora) who influenced the UK policy decision to reschedule cannabis when they supplied products for paediatric cases after consultations with those families in clinics in Ontario.

40 *Number of licensed cannabis producers in Canada in 2018, by province* https://www.statista.com/statistics/883644/licensed-cannabis-producers-canada-by-province/

The major advantage of the Canadian model, even though it had flaws and was criticised by patient groups at the time, was that it relied on building an ecosystem of trusted parties – namely the Licensed Producers – who were subject to inspection and audit and other Health Canada obligations, but were nonetheless free to exploit the new market and develop new products to meet patient needs. Instead of permitting only one access route, the Canadians – under a Conservative government – expanded access and enjoyed a regulated model that other countries have sought to emulate. Ministers decided that the public health benefits of a domestic, high quality supply chain was the best approach to providing safe, legal access at scale and their regulations created that opportunity. By June 2018 there were 330,00 registered patients[41] and dozens of research programmes and clinical trial studies underway at major Canadian universities.

This market-led approach involved collaboration with the private sector, but it was also balanced by a recognition of the risks, so the regulator focused attention and rule-setting predominantly on the producers and the supply chain, not on decisions by doctors and their patients about how and what products to use and the medicinal outcomes. Furthermore, there was a strategy behind the licensing activity that Health Canada undertook – it was about generating economies of scale to reduce costs to patients, providing a better and safer alternative to illicit street cannabis, while generating domestic jobs and investment in the new legal industry. The Home Office discharges an identical licensing function in a regime where similar products are now legally available, but there is no strategy to support and develop an ecosystem of domestic producers, no apparent concern about the over-reliance on imported products and the lack of quality controls, and many more constraints on the ability of doctors to recommend products that could benefit their patients.

Case Study: Australia – where regulation dictated the market's shape and scale

Australia is an important example of how a legal cannabinoid market develops, because although a medicinal access pathway was opened to patients two years earlier than the UK, policy and regulations differ in important ways.

Unlike the UK, Australia does not have a large, over-the-counter, regulated market in CBD products. In 2015, when the UK itself began to see the first signs of rising CBD trends in the consumer retail market, Australia took the decision to classify cannabidiol under their legislation as a Schedule 4 prescription-only medicine. This decision pre-empted the emergence of CBD as an unregulated ingredient in nutraceutical and other wellness products, and restricted access to those who could be prescribed it by a doctor.

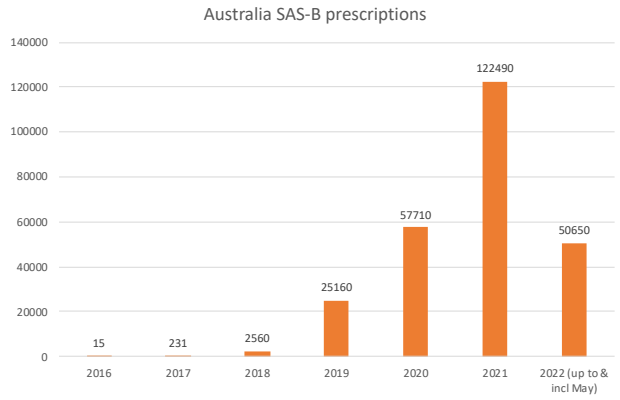
In 2016, the Federal government legalised the commercial cultivation and manufacture of medicinal cannabis and made prescriptions lawful. In 2018, they announced new permits for domestic producers to export those products, and some of those are now exported as CBPMs to British patients via suppliers in the UK. In 2017, the Federal government established the 'Australian Advisory Council on the Medicinal Use of Cannabis', as a body to advise and guide, although it did not decide policy.

Access to medicinal cannabis (as a Schedule 8 product) was controlled via regulations that required doctors to seek permission before prescribing such products. Initially this was largely done on a case by case basis using an existing pathway for unregistered (known in the UK as 'unlicensed') medicines – the Special Access Scheme (SAS). Suppliers of these medicines must comply with Therapeutic Goods Administration (TGA) rules on production, testing, marketing and end product labelling. In 2018, a single, streamlined application process was set up and managed by the TGA to make prescription requests quicker. Doctors still had to request TGA approval to prescribe products, and also navigate some State-level checks, but this made the process less bureaucratic.

Further changes in 2021 made the system easier to

41 *Quarterly number of medical marijuana clients registered in Canada between April 2015 and March 2021* https://www.statista.com/statistics/603356/canadian-medical-marijuana-clients-registered-by-quarter/

access, and prescribing controls relaxed. Such has been the growth in medicinal cannabis prescribing that the SAS is now dominated by unlicensed medicinal cannabis products. Australian doctors of all grades can prescribe these products and the single online portal launched in 2018 has enabled



quicker, easier access, with total prescriptions increasing significantly between 2019-21.[42] Federation meant two layers of government who could decide medicinal cannabis policy and access rules. This led to confusion for prescribers and patients over several years, but eventually, the States in Australia gradually became less involved. This dynamic also meant ongoing upward pressure on the Federal government and the TGA to iron out issues with access or supply. Even today, access procedures remain somewhat inconsistent depending on what State the patient lives in, but there is now a more unified approach to prescribing, and most of the barriers patients now face are to do with securing reliable supply, the attitudes of clinicians, or the cost of products that they do not have health insurance coverage for.

In addition to the market expansion of private clinics in the last five years, further changes in 2021 also seem to be delivering higher patient numbers, where now the rules no longer require doctors to seek prescription approvals on a named patient basis, and can now apply – within the clinical guidelines – to prescribe a type of unapproved SAS product for patients under their care. This liberalises the 'permissions' even further and will likely make the prescribing of unregistered cannabis medicines more widespread and routine.

Similarities with the UK

The Australian regulatory system was similar to the UK. No new institutional architecture was established – the law was changed to make it possible to use cannabis in a new way, but the production and import/export of any medicinal cannabis product was managed by the Office of Drug Control, and patient access to products and prescriptions was managed by the TGA, both within the Department of Health.

Like the UK, cannabis medicines were not fast-tracked for approval, and even now, there is very limited prescribing on the public system, reflecting the situation in the UK where hardly any NHS prescriptions have occurred. It is noteworthy that both Australia and the UK decided to open access to medicinal cannabis by utilising an existing exceptional medical prescription route, designed for any type of medicine that had not achieved marketing authority or licensed status.

The other similarity with the UK is the dominance of imported products in the early years after legalisation, where product standards are variable and domestic producers have not yet had time to establish their cultivation and manufacturing efforts. This was an opportunity for firms in Canada and elsewhere who were looking for export markets and who could partner with local importers and clinics to supply Australian patients before Australian licensed cultivators could.

Key differences from the UK

The UK and Australia have both seen activism to grant and then extend access to medicinal cannabis with outside pressure, media campaigns, and patient advocacy and litigation influencing

42 *MacPhail, S. L., Bedoya-Pérez, M. A., Cohen, R., Kotsirilos, V., McGregor, I. S., & Cairns, E. A. (2022). Medicinal Cannabis Prescribing in Australia: An Analysis of Trends Over the First Five Years.* https://www.frontiersin.org/articles/10.3389/fphar.2022.885655/full

policy design and political decisions. However, there are some key differences.

Australia took a more premeditated approach in response, and was able to put in place federal legislation that opened the door to economic benefits, with the creation of a clear licensing regime for domestic cultivators and producers. Licensing arrangements already existed in the UK, but they were not framed in the same way and designed to catalyse the creation of a domestic supply chain for medicinal patients.

Australian production was slow to come online, and the market is still dominated by unregistered medicinal cannabis imported from licensed producers in Germany, Canada, Israel and beyond, but there are now established Australian companies who are supplying domestic patients and customers in international markets, including Britain. Allowing such companies to export is also a key difference with the UK, where Specials manufacturers of CBPMs can only import their unlicensed products, not manufacture them in the UK and export to global customers. Australia also has a vibrant private clinic sector with chains and online clinics proving to be important players in the early years.

Unlike the UK, where CBPMs are governed by UK law (and so apply the same even in Scotland and Northern Ireland that have devolved healthcare systems), the Australian experience involved State governments also innovating their own laws to determine how medicinal cannabis would be made available. This made the situation more complex for doctors and their patients, but also generated many different targets for patient advocacy and lobbying, and exposed some jurisdictions for failing to deliver on political promises of access. And unlike the UK, Australia's drug control office and medical regulator were part of the Health Department.

The Australian regulators were also quicker to decide their preferred regulatory approach for CBD, classifying it as a medicine (unlike in the EU and UK), and doing so early. There is still a large grey market of imported CBD products, but it is not on the same scale as the very common OTC market in all manner of consumer cannabinoids in the UK. This regulatory decision was taken at least four years before the UK regulator announced their decision to adopt the Novel Food classification for CBD. The classification of CBD as a medicine does however make general patient access comparisons between the UK and Australian markets more difficult, because it is likely that some CBD users in Australia are classed as patients, accessing only purified CBD products, but would be retail consumers in the UK, albeit potentially using a CBD product at higher strengths.

The most important difference between the two Common Law jurisdictions however, is not a legal one or even a political one – as acceptance of medicinal cannabis is similar and patient advocacy continues to be influential in both countries. The most important difference is the regulatory contrast on prescribing. The ability of family doctors and GPs to prescribe has, in the words of cannabis researcher Rhys Cohen, been 'especially impactful':

In 2018, changes were made to the Federal approval process to streamline and speed up application processes, at the same time as many State governments began permitting General Practitioners to prescribe medicinal cannabis without the involvement of a condition specialist. This was the turning point for patient access in Australia. The Federal Department of Health's submission to a 2020 Senate Inquiry into barriers to accessing medicinal cannabis paints this picture very clearly. Data cited in their submission showed that from 2017 to 2019, the number of medicinal cannabis prescribers in Australia grew from 108 to 1,465, with approximately 55% of those being general practitioners. From 2017 to 2019, the cumulative number of SAS approvals for medicinal cannabis access grew from 457 to over 18,000. As of May 2022, there have now been over 4,000 unique

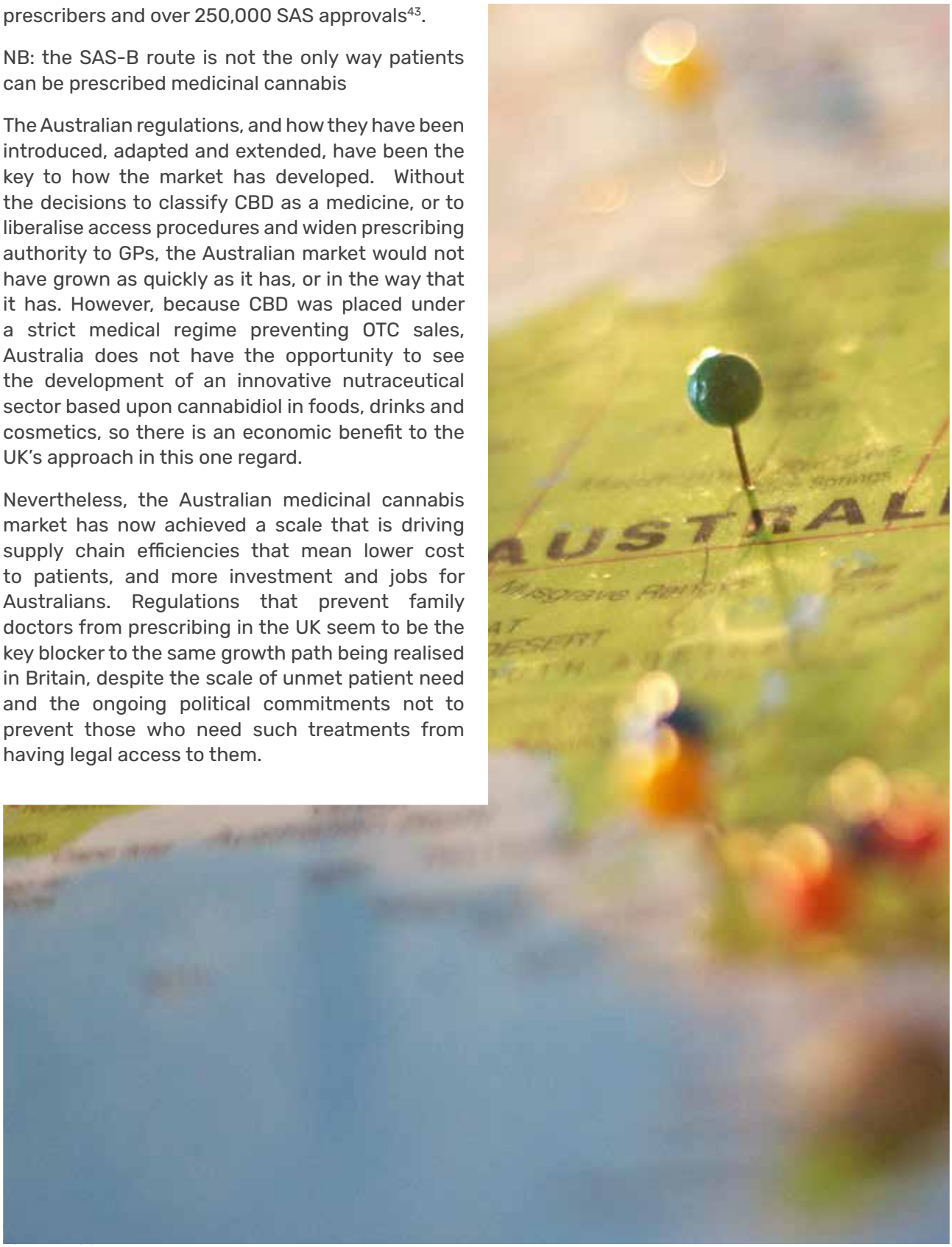
Year	UK Prescriptions	Australian Prescriptions
2016	0	15
2017	0	231
2018	0	2560
2019	278	25,160
2020	4469	57,710
2021	33,778	122,490

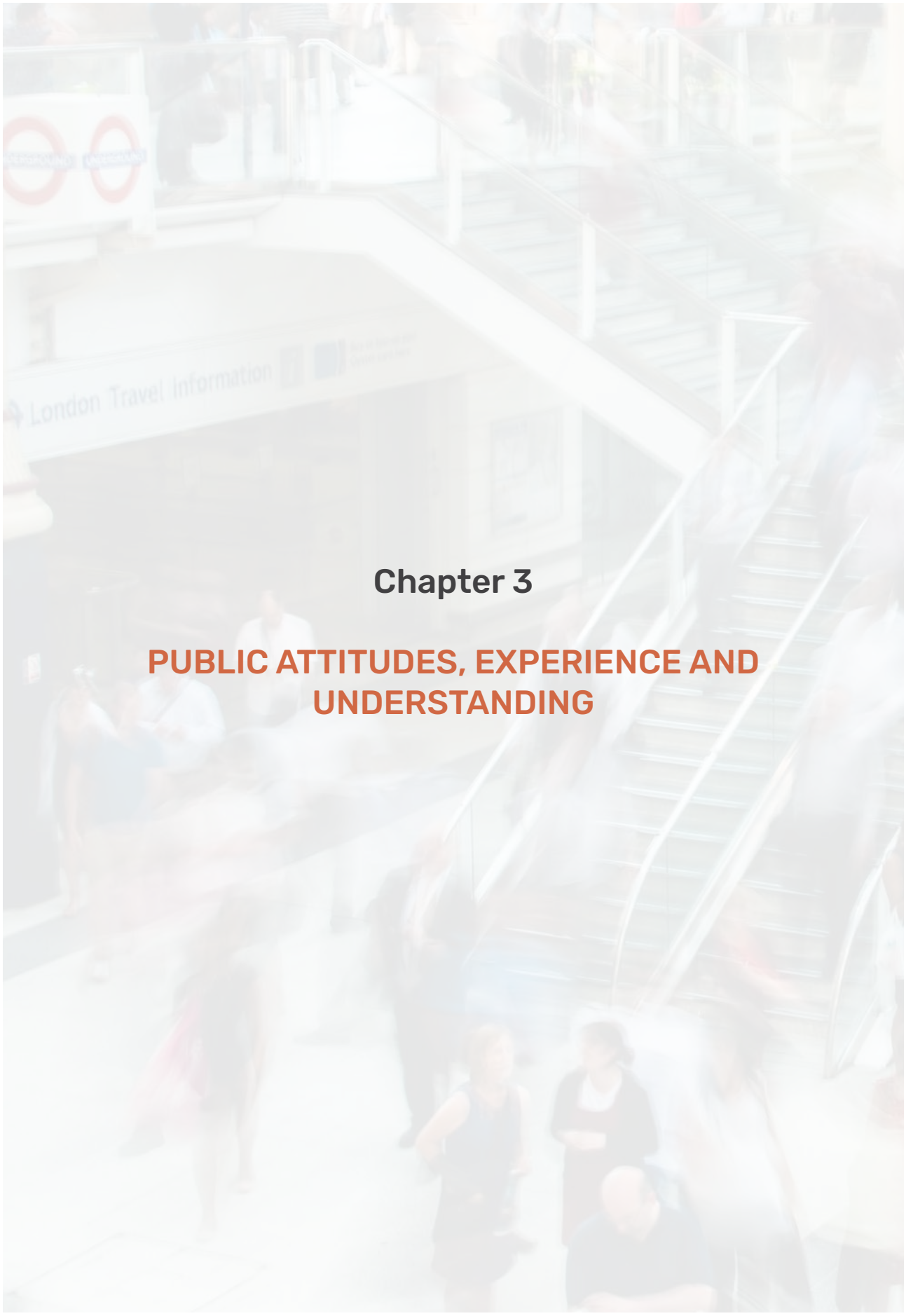
prescribers and over 250,000 SAS approvals[43].

NB: the SAS-B route is not the only way patients can be prescribed medicinal cannabis

The Australian regulations, and how they have been introduced, adapted and extended, have been the key to how the market has developed. Without the decisions to classify CBD as a medicine, or to liberalise access procedures and widen prescribing authority to GPs, the Australian market would not have grown as quickly as it has, or in the way that it has. However, because CBD was placed under a strict medical regime preventing OTC sales, Australia does not have the opportunity to see the development of an innovative nutraceutical sector based upon cannabidiol in foods, drinks and cosmetics, so there is an economic benefit to the UK's approach in this one regard.

Nevertheless, the Australian medicinal cannabis market has now achieved a scale that is driving supply chain efficiencies that mean lower cost to patients, and more investment and jobs for Australians. Regulations that prevent family doctors from prescribing in the UK seem to be the key blocker to the same growth path being realised in Britain, despite the scale of unmet patient need and the ongoing political commitments not to prevent those who need such treatments from having legal access to them.





Chapter 3

PUBLIC ATTITUDES, EXPERIENCE AND UNDERSTANDING

3.1 Knowledge and support for the sector

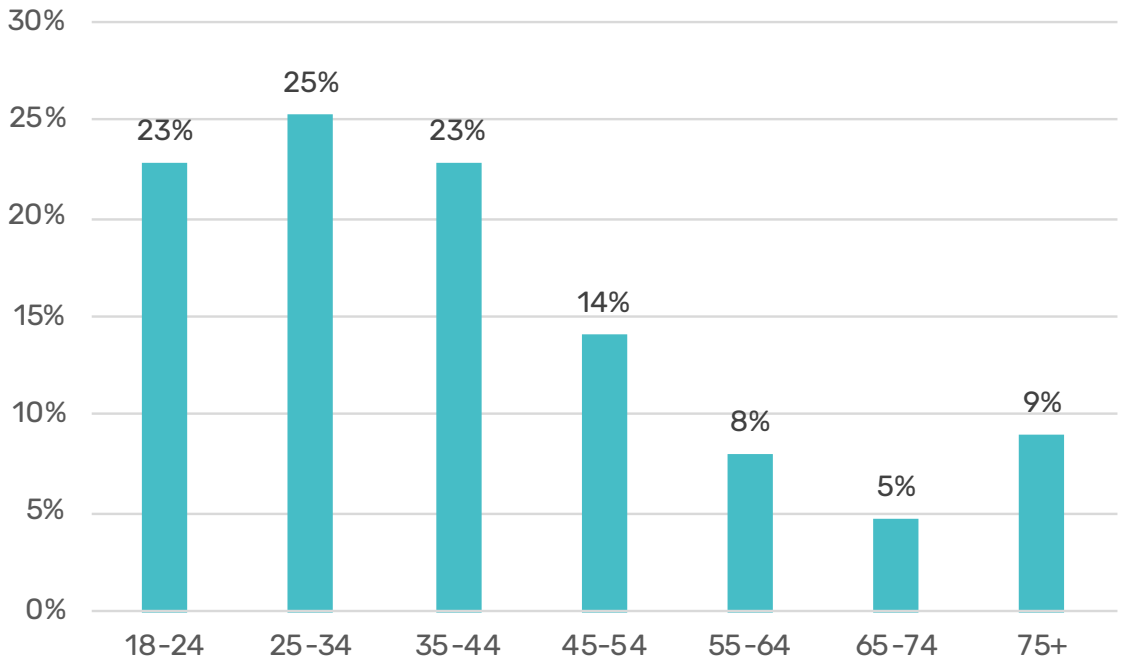
The extent to which a new industry can develop and expand its economic footprint ultimately depends on whether it is serving the end-user: patients and retail customers. There are many surveys of public attitudes designed to demonstrate public opinion on political questions around legalisation, or to gauge rates of past cannabis use. For this project, the focus was more on the experience, attitudes and understanding of the British public regarding the legal sector that exists today - not their view on what might be a very different world at some point in the future.

To gather a representative survey of public attitudes, The Centre of Medicinal Cannabis commissioned STACK Data Strategy to run a large opinion poll of British adults. The results of this research are summarised in this chapter. They are important results for the issues we have explored and the fundamental choices that need to be made about how best to regulate this sector.

The UK's legal cannabinoid sector is a relatively new industry, and yet the public do seem to show a high level of experience and/or awareness of some of its elements, especially medicinal access and the general availability of CBD.

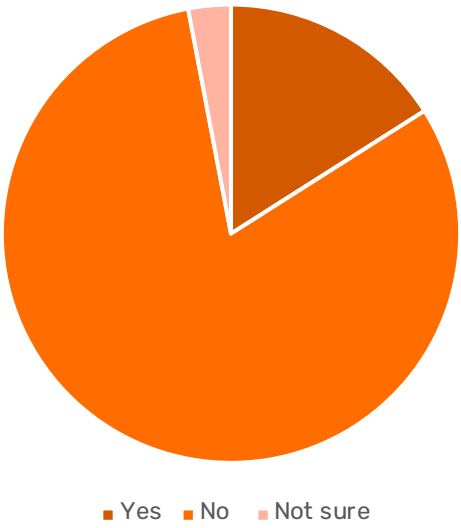
According to the STACK survey, almost 1-in-6 people (16%) have used CBD/cannabis oil for medicinal reasons ('oil' being more widely understood than just 'CBD'). This high level of experience was more widespread among younger respondents, but education level showed no distinction.

Have used CBD/cannabis oil for medicinal reasons?



Of those that have used CBD for medicinal reasons, more than a quarter (28%) said they had not used CBD/cannabis oil in the past year, while 42% reported using it 1-3 times in the same period. Meanwhile, 16% said they had used CBD/cannabis oil 4-11 times, and 15% reported monthly use.

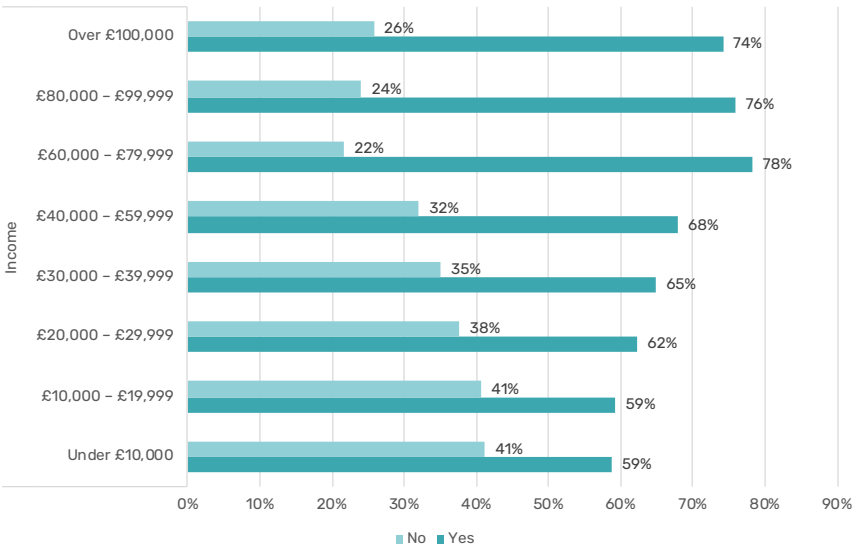
Have you ever used CBD/cannabis oil for medicinal reasons?



Our findings suggest that 16% of Brits have previously used CBD-based products for health-related reasons. And almost the same number, 1 in 6, have previously used cannabis for health-related reasons. Young people are considerably more likely to have used these products, with 24% of 18-34s having used CBD and 25% having used cannabis for medical reasons. Notably, Londoners and respondents who reported having one of our listed set of medical conditions are particularly likely to have used CBD and/or medicinal cannabis.

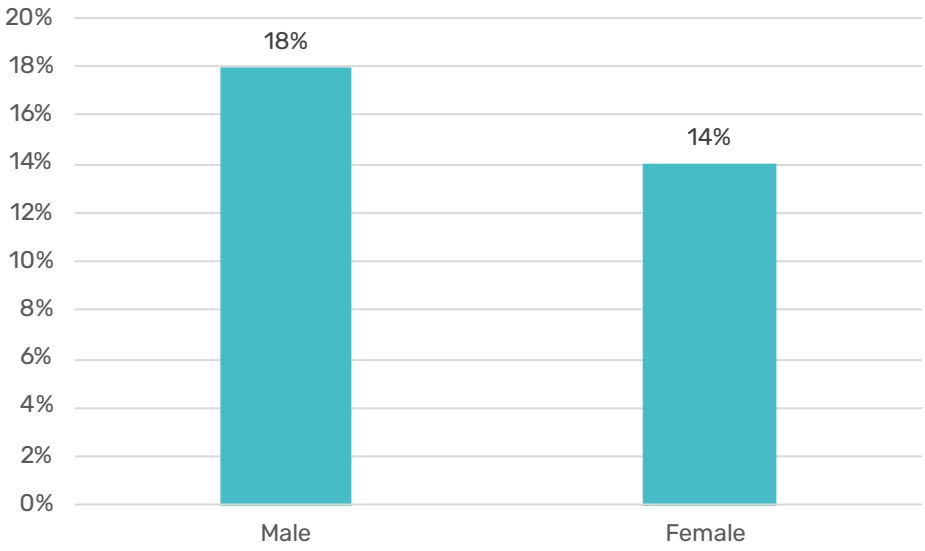
Almost two-thirds of people were aware of CBD products before taking the poll, with women showing generally higher levels of awareness than men, and the highest levels of awareness among 25-34 year olds (80%) and 35-44 year olds (77%), which is a very high level of consumer market penetration.

Before taking this survey, were you aware of any cannabidiol (CBD) based products?



In line with these results, and supporting the research by Public First on market sizing of the CBD sector conducted in 2021 for the Greenshoots report[44], 1-in-10 people said they had 'tried, used or purchased' CBD in the last year.

Have used CBD/cannabis oil for medicinal reasons?



44 Association for the Cannabinoid Industry (2021). Green Shoots: Sowing the seeds of the new UK cannabinoid market. https://theaci.co.uk/wp-content/uploads/2021/05/Green-shoots-Sowing-the-seeds-of-the-new-UK-cannabis-market-ACI-_-CMC-report.pdf

3.2 Medicinal cannabis: awareness, experience and benefits

The challenges that many families have faced in seeking to get a legally prescribed cannabis medicine after the law changed in 2018 appears to have registered with the public: a large majority (60%) of respondents believe that many families with sick children who could benefit from cannabis medicines cannot access it easily. This suggests that media coverage of patient access issues has started to drive wider awareness.

When thinking about the law on cannabis, do you think the following statements are true or false?
Many families with sick children who benefit from cannabis medicines cannot access it easily

60% **of respondents felt many families with sick children who benefit from cannabis medicines cannot access it easily**

Medicinal cannabis is also entering wider public consciousness as a result of patient experiences. One-in-five (19%) respondents said they personally know someone whose health has benefited from medicinal cannabis, which in practice could be relatives or friends who have accessed it in other countries where they live.

Since medicinal cannabis was made legal for a doctor to prescribe in 2018, do you know anyone personally who has had a medicinal cannabis prescription?

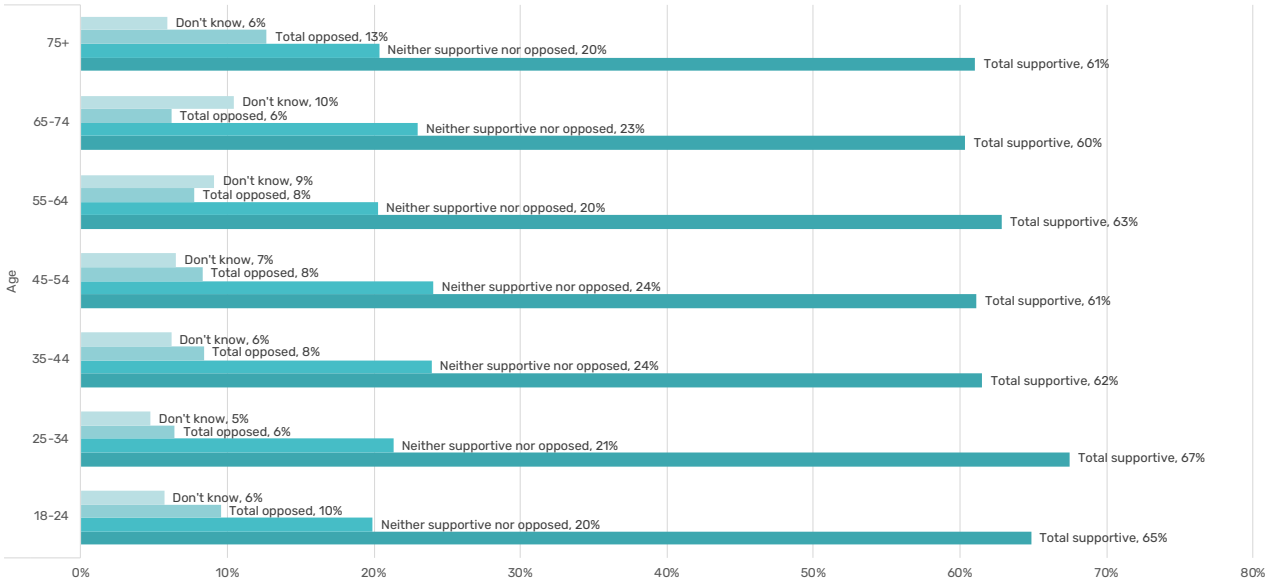
18% **of respondents know someone personally who has had a medicinal cannabis prescription**

Do you personally know anyone whose health has benefited from medicinal cannabis?

19% **of respondents know someone whose health has benefited from medicinal cannabis**

There is also a deep and broad level of support for the idea that cannabis can be an effective medical treatment. When asked 'How would you feel if a family member of yours was taking medicinal cannabis to address a health condition?', there was overwhelming majority support from 63% of respondents, with only 8% saying they would be somewhat or very opposed to it.

How would you feel if a family member of yours was taking medicinal cannabis to address a health condition?



By and large, there is also not much scepticism about the motives or purpose behind medicinal cannabis. When asked to what extent they agreed with the following statement - 'Medicinal cannabis is not a serious clinical treatment and is just used by people who want to consume cannabis legally' - a quarter of respondents agreed, but 37% disagreed, and a third neither agreed nor disagreed while 11% were unsure.

To what extent do you agree with the following statements? *In ten years time, there will be widespread understanding and acceptance of the medical benefits of cannabis*

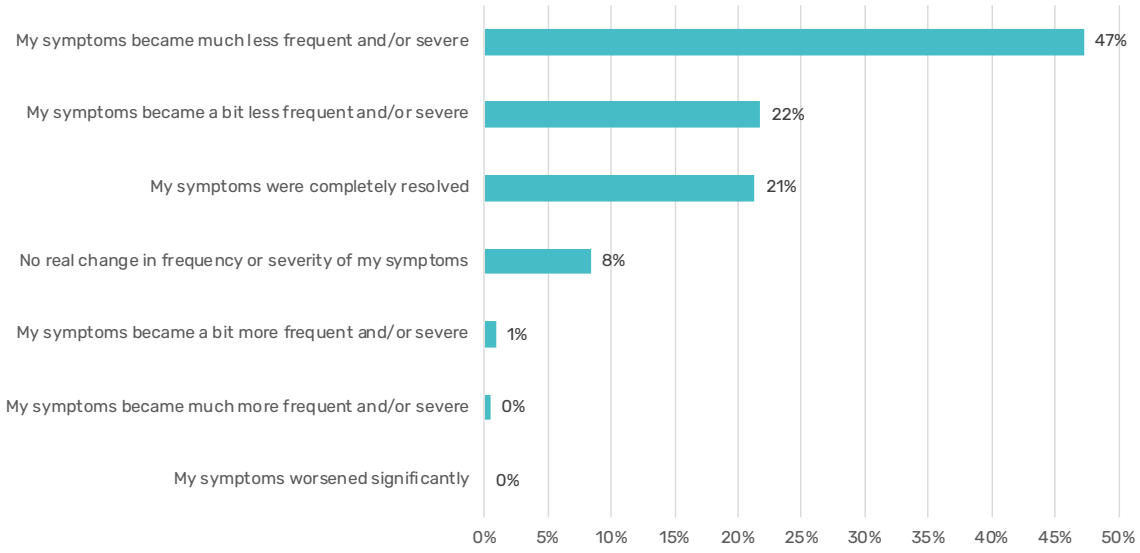
59% **of respondents think that in ten years time, there will be widespread understanding and acceptance of the medical benefits of cannabis**

This is probably the reason why almost 1-in-7 people (14%) admitted that they have used cannabis 'for health reasons or to treat a medical condition' at some point in their lives.

Medicinal cannabis users are very positive about its impact on their health. Overall, 90% of users report that it made their symptoms less frequent and/or severe, with reduced anxiety, pain relief, better mood, and better sleep most frequently cited as its advantages. In terms of concerns, large proportions of respondents worry about addiction risks (37%), long-term mental health impacts (34%) and its impact on other activities like driving a car (29%).

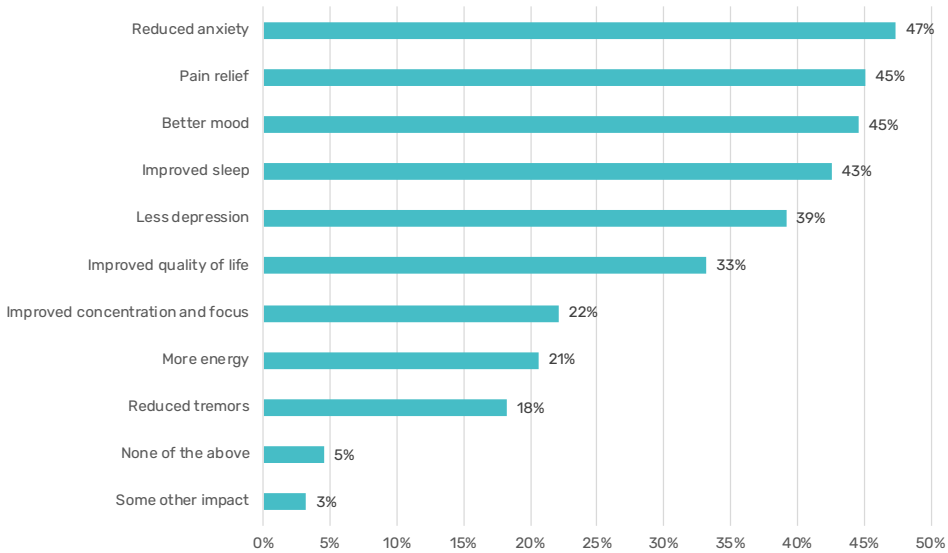
For those with personal experience, the reported benefits were notable. Of those who had used cannabis for medicinal reasons whether prescribed by a doctor or not (a smaller sample of 215), the vast majority (90%) experienced positive benefits, including a fifth (21%) whose symptoms were 'completely resolved'.

For your particular health issue, what was the effect you experienced from using cannabis?
(sample size: 215)



Of the reported benefits, the most common were reduced anxiety, followed by pain relief, better mood, and improved sleep.

In terms of some of the reported health benefits, which of the following have you personally experienced *(sample size: 215)*

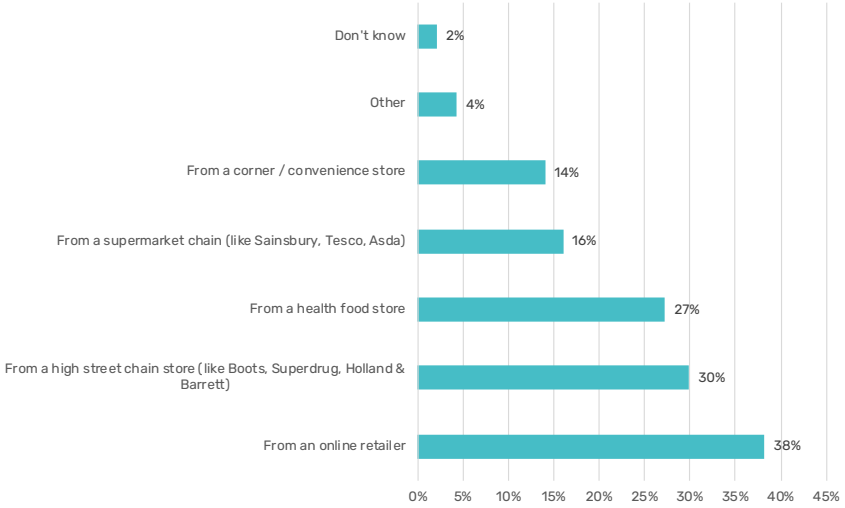


3.3 Consumer cannabinoids: CBD usage and purchaser priorities

One of the features of the UK's large and diverse consumer CBD sector is its reliance on imports and its dependence on low-cost online retail channels. Not only are medical claims on these websites harder to police, they are also often hosted and owned by individuals and parent companies registered overseas. This is how the nascent CBD sector started in the UK, with CBD products on the shelves of high street stores following later.

However our polling clearly shows that the dominance of online channels continues, with 38% of respondents to the STACK survey saying they buy their CBD products online, and 30% in high street shops.

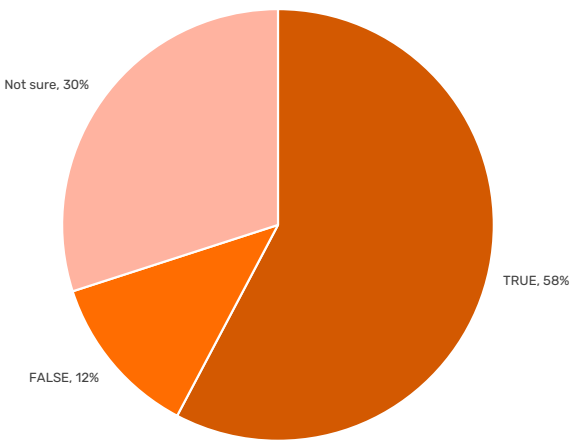
Where participants who had recently purchased CBD-based products usually buy from
(sample size: 270)



When asked if they had ever purchased CBD products themselves, 28% said they had. Of those that had, half (51%) had purchased CBD in the past six months. Parents with dependent children are significantly more likely to have purchased CBD products than those who do not (34% to 24%).

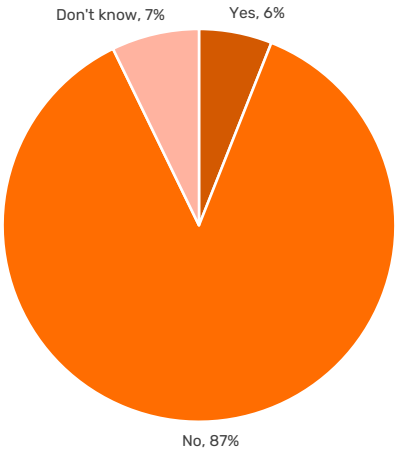
When asked about its benefits, a majority (58%) said CBD had 'proven health benefits' with women more likely to say this (63%) than men (52%), and around a third of people (30%) were unsure. This shows that the motivating factors for CBD purchasing for many consumers are tied to perceived health benefits that science has established.

CBD has proven health benefits - *True of False*



When asked how they had used CBD, a higher than anticipated number - 6% of all those surveyed - said they had given it to their pet. If this were applied across the population, it would suggest there is already widespread use of CBD by hundreds of thousands of UK pet owners, on their pets (cat, dog, horse), which the relevant regulator - the Veterinary Medicines Directorate (VMD) - has prohibited from being prescribed by a licensed veterinarian. A search of online CBD stores also shows companies offering CBD for use on pets and willing to ship this to UK-based customers.

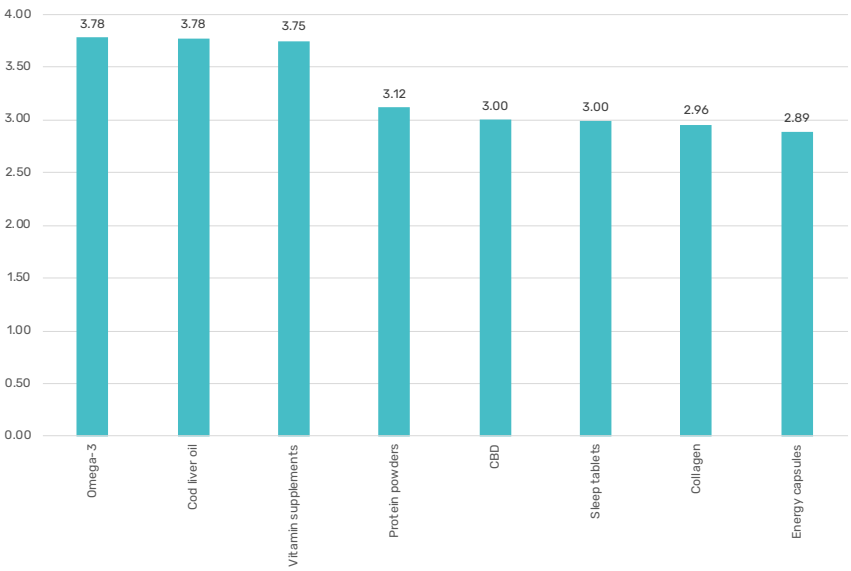
Do you currently or have you ever given any type of CBD products to your pet (dog, cat, horse)?



When asked to rate a range of common OTC products on trust, CBD scores well, with the same levels of trust as protein powders, collagen, energy capsules and sleep tablets.

Trust levels in CBD products are average, with young people reporting slightly higher levels of trust than older people. With an average trust level of 3 on a scale from 1-to-5, CBD products enjoy levels of trust that are comparable to energy capsules, sleep tablets, and collagen, whilst vitamin supplements and omega-3 are trusted significantly more. Major factors that could drive trust include Food Standards Agency approval and clear labelling/product information. This highlights the information gap that many potential consumers seemingly experience.

Level of trust in consumer wellness or nutraceutical bought off the shelf (*Mean average rated on a scale from 1 to 5, 1 is "very low trust" and 5 is "very high trust")*

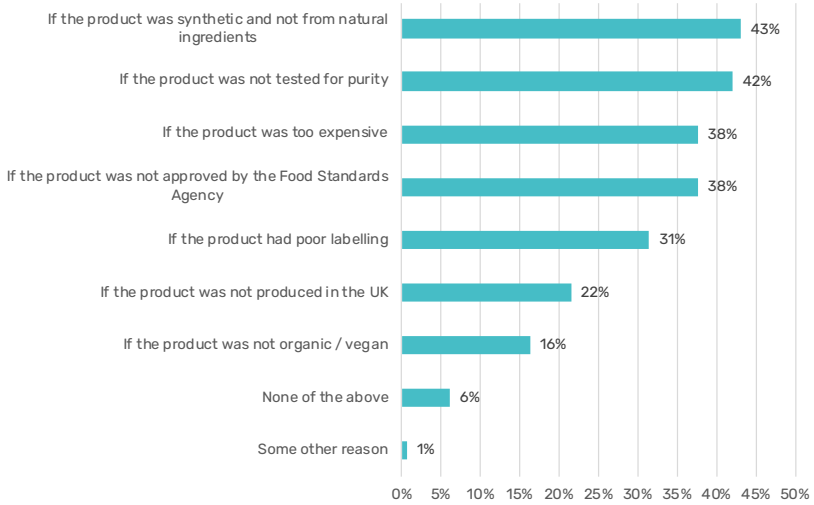


In terms of factors that CBD consumers look for, the survey results support the need to level up the quality of the CBD market and give consumers a better product. When asked what would concern them about a CBD product, respondents showed a preference for naturally-derived CBD where the purity was assured.

The most concerning thing for 43% of respondents was if the product was synthetic and not from natural ingredients, or if the product was not tested for purity (42%). This was followed by 'if the product was too expensive' (38%) or 'if the product was not approved by the Food Standards Agency' (38%) or 'had poor labelling' (31%). This suggests that quality, and the badge of compliance that the FSA can provide, would be influential factors for consumer's buying decisions.

When it comes to purchasing CBD, which of the following would you find most concerning?

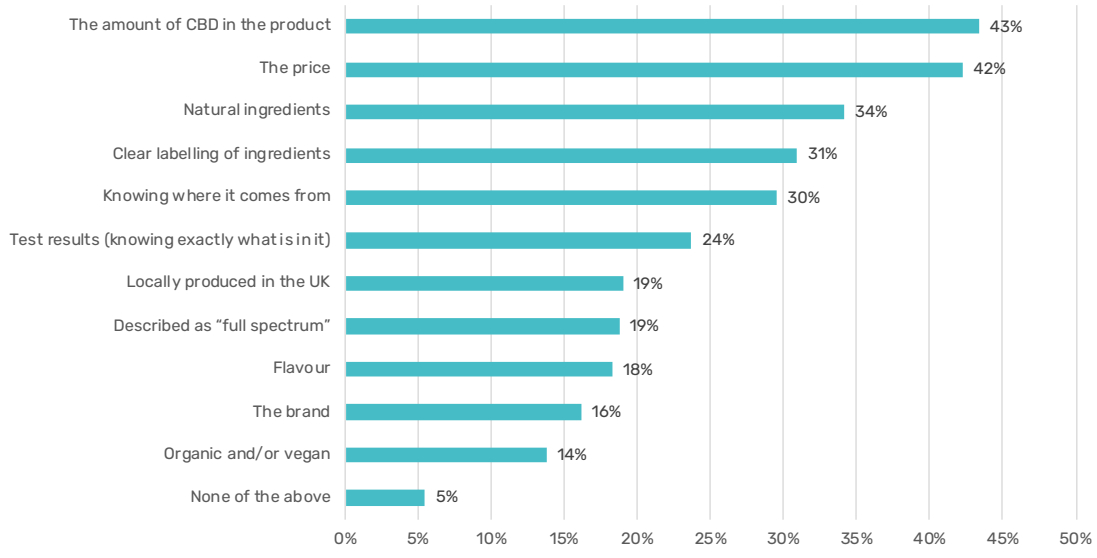
(sample size: 270)



When asked what the most important things were when purchasing CBD products, in order of importance: the amount of CBD (43%); the price (42%); natural ingredients (34%); clear labelling of ingredients (31%) and knowing where it comes from (30%). This again shows a public demand for quality, affordable CBD that is well labelled and gives the consumer key information, like country of origin. Currently, a large number of CBD products do not meet these clear expectations.

What is important to you when purchasing CBD-based products?

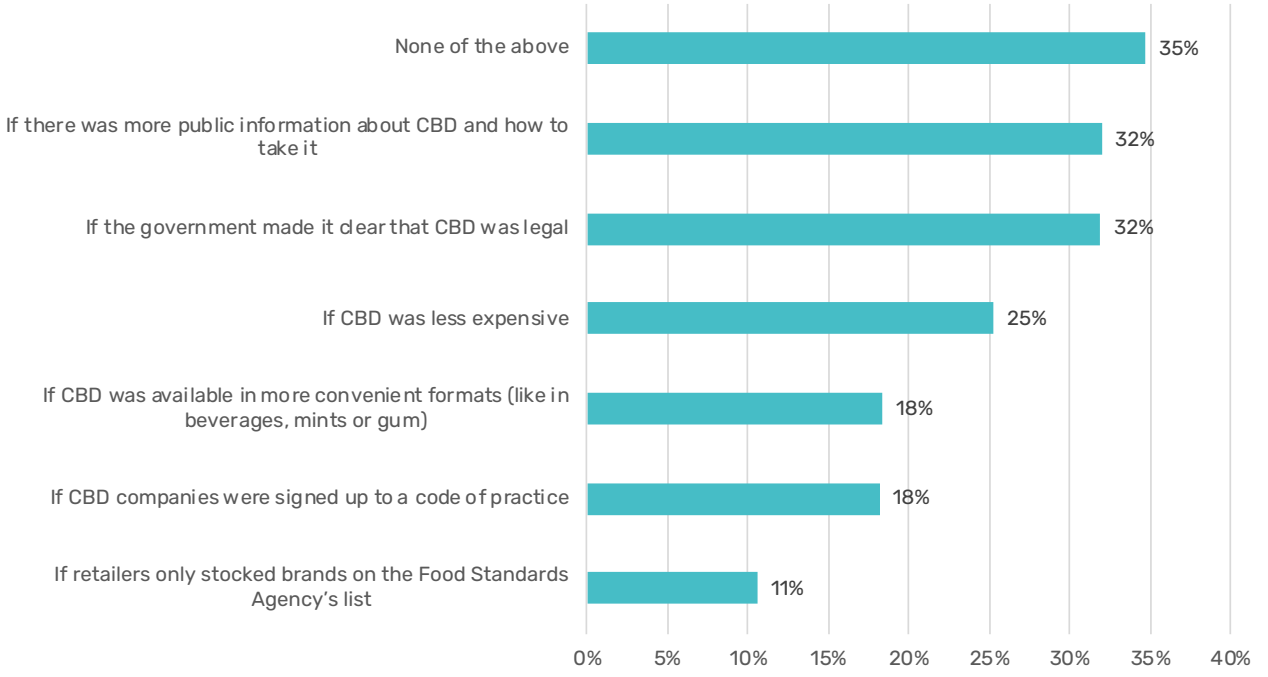
(sample size: 270)



The STACK survey also asked respondents who had not used CBD what factors were most likely to make them try CBD in the future. This revealed an educational imperative, but also a hesitancy tied to the uncertainty people have about the law and what makes for a compliant cannabinoid product. In order of most important, hesitant CBD consumers would be most likely to try a CBD product if there was more public information about CBD and how to take it (32%), and if the government made it clear that CBD was legal (32%).

Other factors that could be influential to encourage more CBD consumers were if CBD was less expensive (25%); if CBD was available in more convenient formats (like in beverages, mints or gum) (18%) and if CBD companies were signed up to a code of practice (18%).

For respondents who have not purchased CBD before the following would make them more likely to try CBD in the future

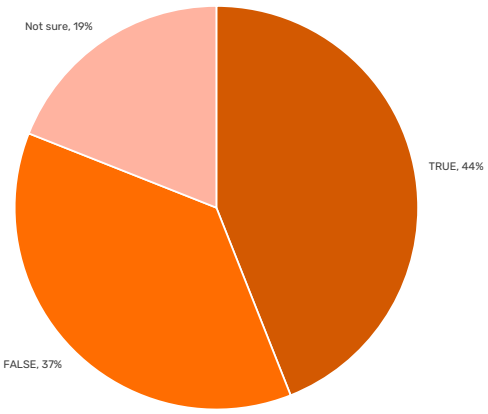


3.4 Consumer cannabinoids: CBD usage and purchaser priorities

The issue of legality and consumer behaviour being influenced by uncertainty and confusion over the law was also picked up in the STACK survey.

More than half (54%) of respondents know that CBD is legal to consume in the UK. But responses to other statements clearly show the public generally does not understand the law on cannabis products. This was demonstrated most clearly in the responses to the following statement: 'it is legal for adults to possess small amounts of cannabis for their own personal use, but they cannot sell it or supply to under 18s'. More people thought this statement was true (44%) than thought it was false (37%).

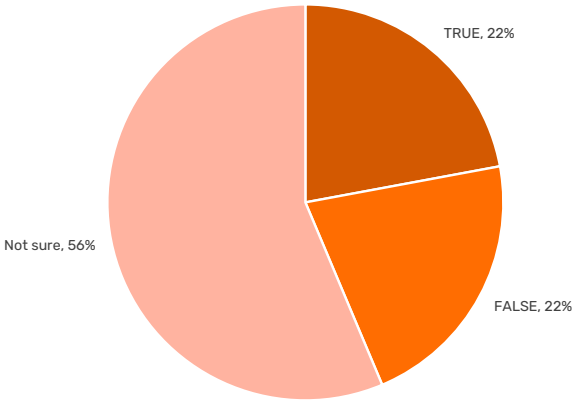
It is legal for adults to possess small amounts of cannabis for their own personal use, but they cannot sell it or supply to under 18s - *True of False*



Whilst most Brits are fairly well-informed about rules and regulations on cannabis, levels of information on hemp and CBD are considerably lower. Respondents were often split 50-50 when asked to judge the veracity of statements on hemp and CBD, with between 30% and 60% of respondents reporting that they were unsure about the factual nature of statements on i.e. hemp licensing, the country of origin of CBD products, and the legality of cannabis prescriptions by private clinics.

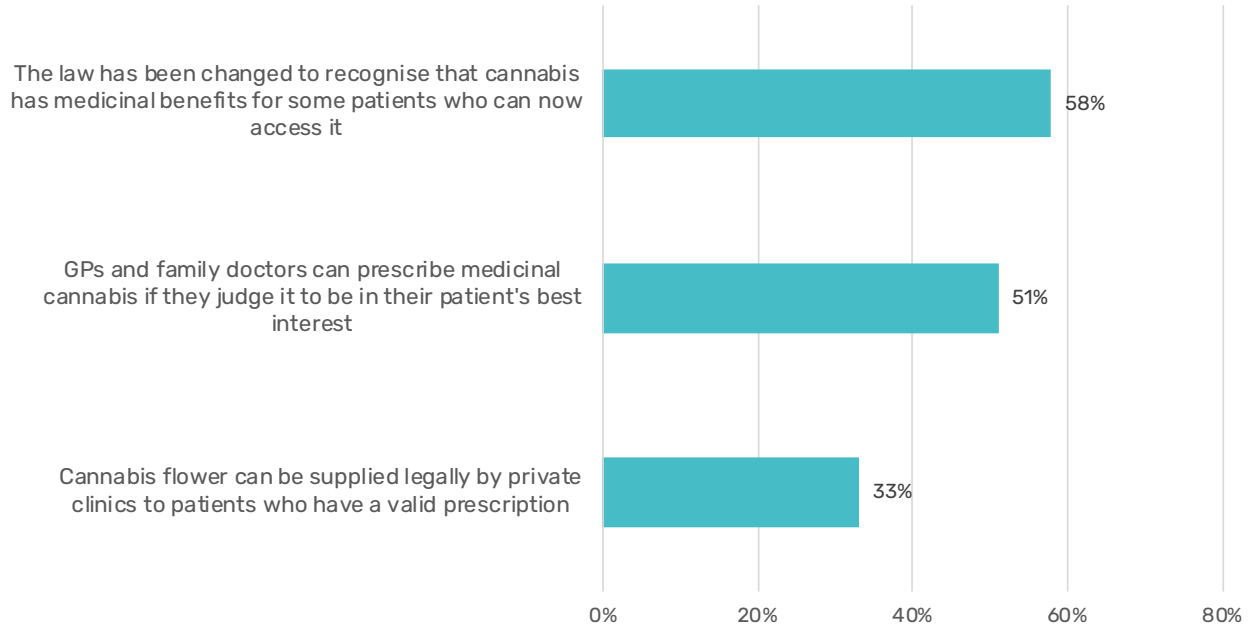
There is also clear evidence of uncertainty about the origins of the CBD that many people buy. Respondents were split equally on whether it was true or false that 'Most of the CBD / cannabis oil sold in shops comes from hemp grown in Britain' and a majority (56%) were unsure. In reality, this is false and no CBD is sourced in the UK currently.

Most of the CBD / cannabis oil sold in shops comes from hemp grown in Britain - *True of False*



A majority of respondents were aware that the law had changed to allow some patients to be prescribed medicinal cannabis by a doctor (58% said true), and that it can be accessed via private clinics for those with a valid prescription.

% of respondents that felt the following statements were true



The public were broadly aware of the need to have a licence to do anything with cannabis legally, and of the criminal justice penalties, but on many of the other questions, there were high levels of uncertainty, and no big majorities correctly judging a statement to be true or false.

These results reinforce our argument that the current regulatory landscape is confused and complex and ordinary people could be excused for not understanding it. There is a large amount of confusion about the basic state of the law on cannabis, such that many citizens simply do not have a clear sense of what is legal and what is not. This has a read across to the regulatory debate: a large consumer marketplace relies on engaged, interested consumers making informed decisions about products. The continuation of a 'grey market' in illegal, unregulated CBD products, relies on the opposite - ongoing confusion about legality and what products can and cannot be sold. If there was this much confusion on the part of consumers about alcohol products, the industry and government together would be motivated to move quickly to address it.

3.5 Consumer cannabinoids: CBD usage and purchaser priorities

One perspective on the legal cannabinoid sector is to focus on its future potential, and the sense that there is scientific progress that is building our understanding and giving the sector momentum to expand into the future.

The STACK survey asked respondents to think about the future:

A large majority (64%) of respondents believe the government should do more to support scientific research into cannabis in the UK, which suggests that the plant is no longer seen as being without medicinal or social value, and that Britain could make important scientific discoveries by researching it more fully.

To what extent do you agree with the following statements? The government should do more to support scientific research into cannabis in the UK

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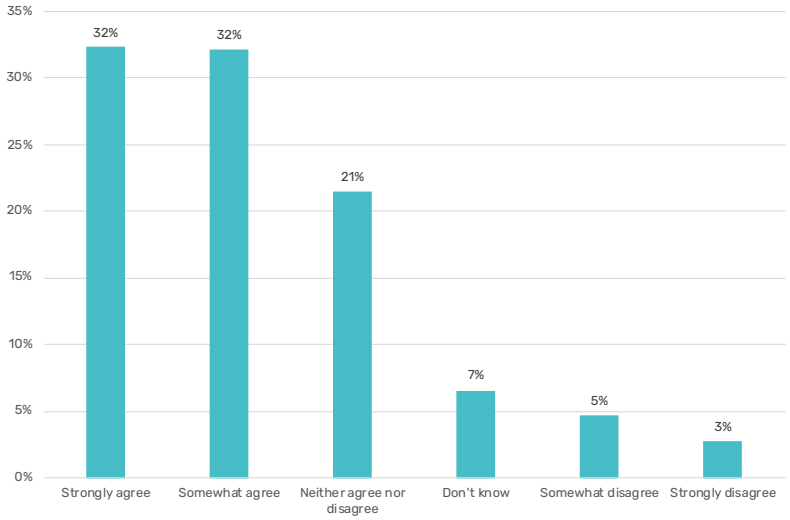


At (23%), respondents thought cannabis medicines rank as an important future industry where Britain could try and become a global leader, alongside green technology and sustainable energy (carbon capture and storage, nuclear fusion, sustainable aviation fuels) and health innovations like new vaccine development.

Respondents were also asked whether they thought in ten years the medical benefits of cannabis would be more widespread and accepted, with a majority (59%) agreeing and only 8% disagreeing.

To what extent do you agree with the following statements? *In ten years time, there will be widespread understanding and acceptance of the medical benefits of cannabis*

59% **of respondents think that in ten years time, there will be widespread understanding and acceptance of the medical benefits of cannabis**

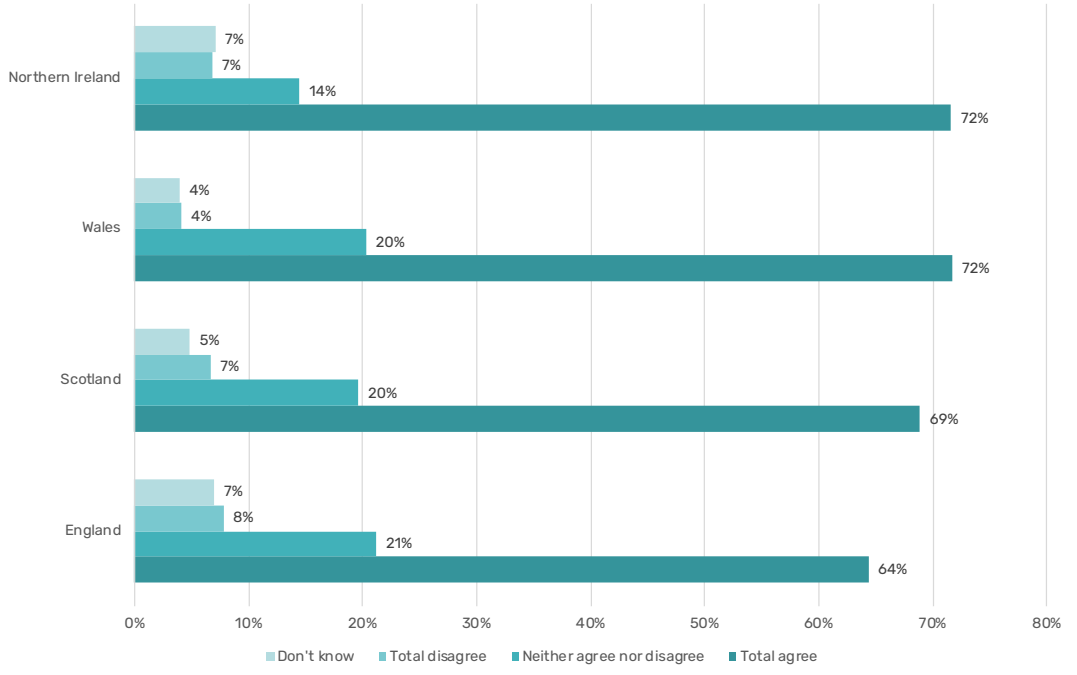
In both examples, when asked to consider their place in Britain's future, respondents seemed confident that cannabis medicines would be important. However 44% also believe that in the future, there will be new evidence about the harms and risks of cannabis. This shows that the public is not naive about cannabis.

Being accustomed to the idea that cannabis medicines are here to stay, the STACK survey asked about trust in how they are prescribed, and what reforms they would support.

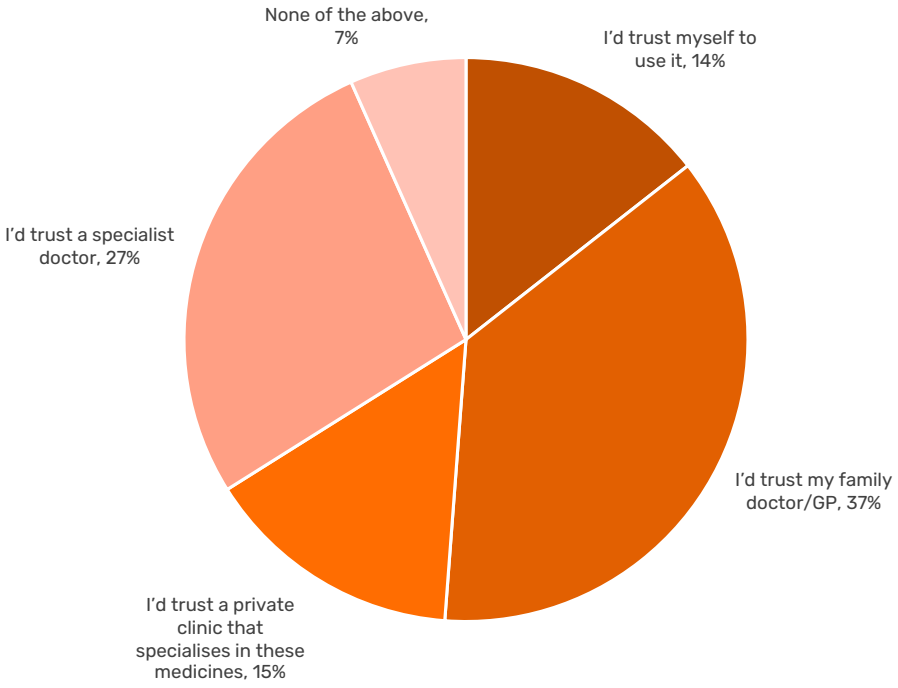
There was strong support for allowing all doctors to prescribe cannabis as a treatment. Two-thirds of respondents (65%) believe GPs should be allowed to prescribe medicinal cannabis and family doctors/ GPs scored highly on who would be trusted to prescribe it to you - more than a third (37%) of respondents would trust their GP to prescribe them medicinal cannabis.

Although public awareness of medicinal cannabis is lower than of CBD, we find evidence to suggest that public levels of trust are higher. Specifically, 65% of Brits agree that "the government should allow GPs to prescribe medicinal cannabis". Notably, whereas we find that young people are more open to the use of CBD, old people are more likely to report positive views towards medicinal cannabis than young people. By contrast, young people are more likely to think that medicinal cannabis is not a serious clinical treatment.

To what extent do you agree with the following statements? *The government should allow family doctors and GPs to prescribe medicinal cannabis*

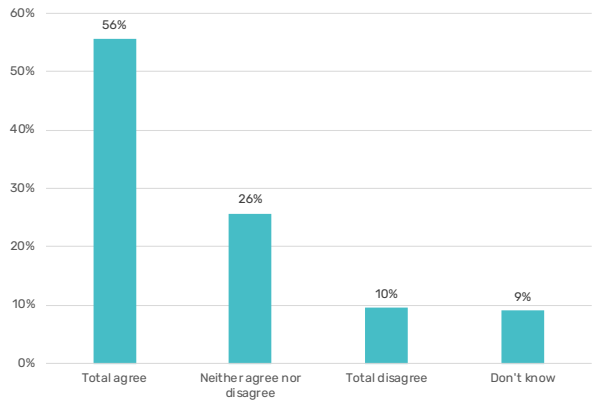


If you had a health need, who would you trust to prescribe medicinal cannabis to you?

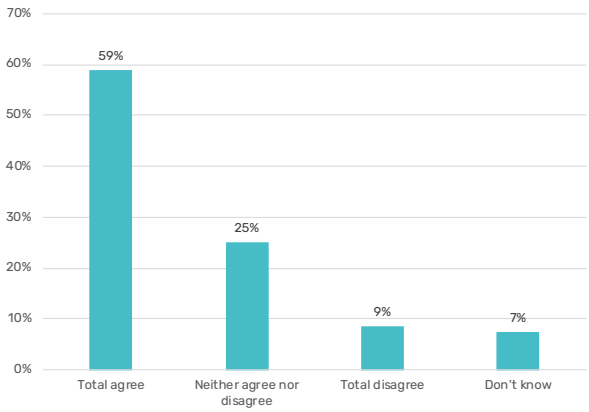


More people believe the government should help lower the cost of cannabis supplied by private clinics (59%) so more people can afford it, than believe cannabis should be granted an 'exemption' from licensing rules to be made free on the NHS, although 56% support this approach also.

To what extent do you agree with the following statements? *The government should make an exception to drug licensing rules and make medicinal cannabis flower available on the NHS*



To what extent do you agree with the following statements? *The government should help lower the cost of medicinal cannabis prescribed in private clinics so more people can afford to buy it privately*

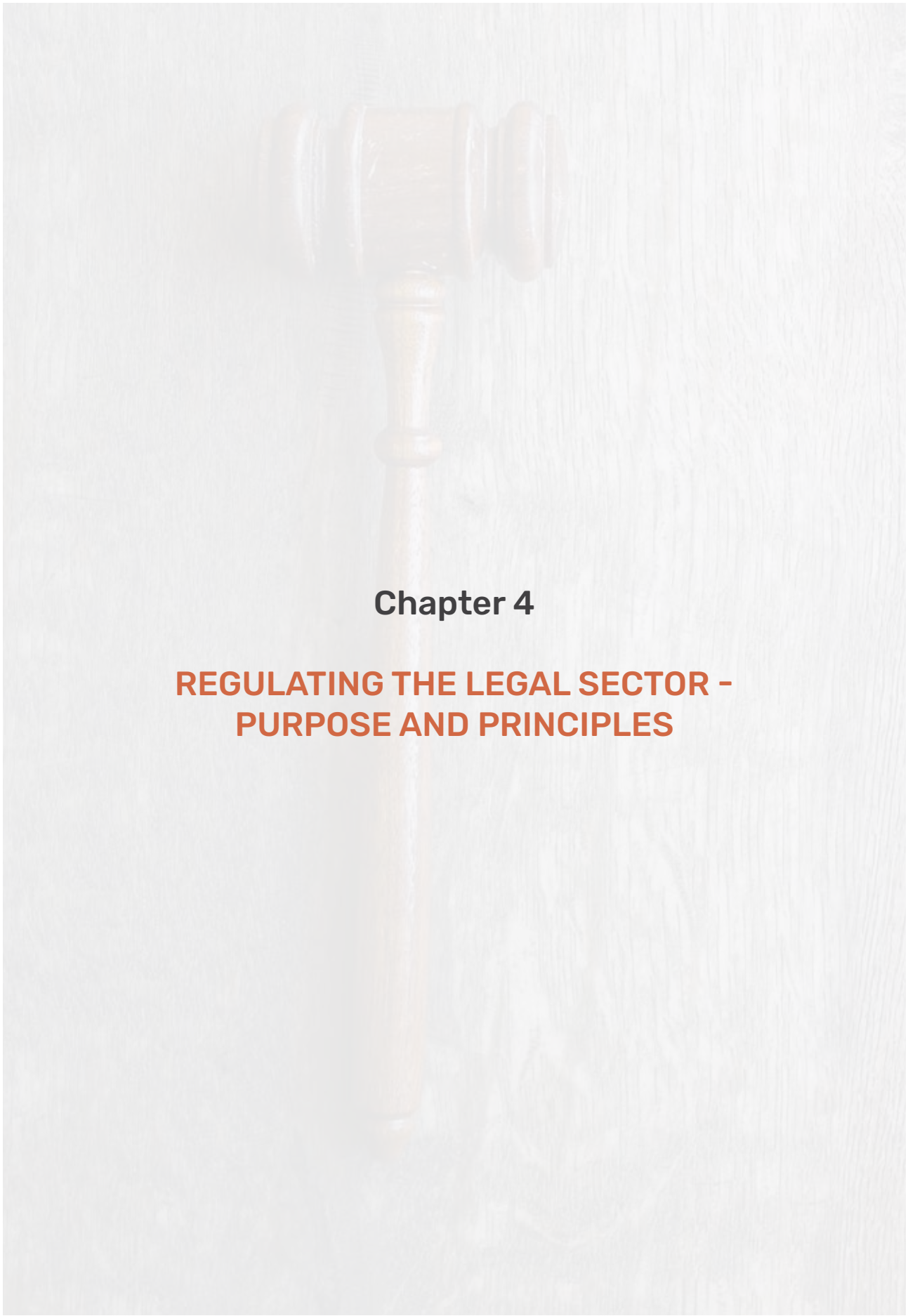


Also lending support to some other themes in this report, and where new regulations could help improve supply chain efficiencies and cut costs for patients, there was clear support for changing rules to permit export. Almost half of respondents (46%) agreed that the government should allow British companies with a licence to grow cannabis here to export it overseas, and only 13% disagreed (30% were agnostic, and 11% did not know).

The opinion research for this report should give the industry and those benefiting from the legal cannabinoid sector renewed confidence that the British public are on their side. Clear majorities support medicinal cannabis as a healthcare concept, and a sizable minority claim to either personally know someone who has benefited, or admit that they have self-medicated and derived a clear benefit from using cannabis.

The same is true of CBD, which is seen as having clear health benefits, and of being both legal and a trusted product, with high levels of awareness and a large minority of people using it frequently. This general positive attitude to the issues also feeds into attitudes about the future and what reforms they would support, but respondents are also clearly still somewhat confused and unsure about the status of the law on cannabis, and want better information on the content and origins of CBD and better labelling on consumer products.

Overall, the key observation from the STACK survey might be that amidst a booming CBD consumer sector and growing familiarity with the notion of cannabis as a medicine just three years after the law was changed, the British are optimistic about the potential for the cannabinoid sector, and not fearful, cynical or dismissive. There are also signs that as a result of both medicinal and consumer sectors, the normalisation of the conversation about cannabis is occuring, and it no longer elicits the same oppositional responses as similar surveys might have done a decade ago.



Chapter 4

REGULATING THE LEGAL SECTOR - PURPOSE AND PRINCIPLES

4.1 Purposes of regulation

The core purpose of regulation is to provide protection from harm to consumers, bystanders, communities, competitors, markets and so on. Regulation exists in various forms, such as to ensure safety, economic activity (fair pricing, fair market behaviour and fair markets that have level playing fields), integrity (privacy, corruption, accountability, transparency and electoral rules) and social morality (use of illegal drugs, smoking, drinking, gambling and gun control) - and may take a number of forms - but all of these revolve around a society's goal of ensuring protection from harm and reduction in risk.

Regulation is typically intended to ensure that those who engage in the relevant activities do so in a way that they control against risks of harm occurring, by taking appropriate steps to undertake their activities in such a way that avoids or reduces risk. Viewed in this way, good regulation should be akin to a checklist of how a well-run commercial or other enterprise should run itself, if it wants to maximise its own investment, expenditure and effort. However, it is easy to see how a perception may arise that rules and requirements 'get in the way' of people trying to do things. In fact, that is precisely what regulation should be doing, so that a good business runs itself well and controls its own risks. But one can see how misleading or contested impressions may arise, through lack of understanding or balance on one side or the other, or a situation where levels of intrusive control may be disproportionate.

Regulation usually has the consequence that it has some effect on the economic activity of an actor, and hence of all actors in a market. Indeed, the objective or consequence is that the economic activity of all actors should be affected, so that they are all subject to the same constraints and costs, thereby producing a level playing field. It is important that the requirements are observed by all, to avoid free-riding. This is typically achieved through techniques such as auditing, inspection, verification, testing, market surveillance and so on, coupled with coercive action to ensure observance. The traditional model of 'enforcement', however, although remaining relevant in some contexts, has widened to concepts like providing information, support, training, intervention, and so on.

4.2 Harms to avoid or mitigate in this sector

In order to set out some outcomes and shared goals that those in the legal cannabis sector might adopt, it is important to also clarify what harms we are collectively trying to avoid or mitigate. The discussion of cannabis 'harms' is often understood to mean the physical, psychological and neurological impact of the drug on those who consume it, and the science surrounding these questions continues to advance. For this report, by 'harms' we mean the broader question of how regulated activity involving cannabinoids can present risks – either to users or to wider public interests – that ought to be recognised and where possible addressed.

Not all of these harms are avoidable, and some of the risks associated with this new legal sector require regulations that are stricter at first, but which can be relaxed or moderated later as behaviour is monitored and best practices become established and trust demonstrated. The sector also reflects some of the risks that any regulated industry faces, where the harms are easily understood and there are well established ways to mitigate them - for example, damage to consumer's rights, exploitation of vulnerable patients, monopolistic practices in supply chains, and misleading marketing, along with criminal activity such as breaching licence conditions, diversion into the illicit market, money laundering, fraud in analytical reporting, and the sourcing of illicit ingredients.

The harms of cannabis as a drug

At the core of these questions about what harms regulation is trying to avoid is the controlled status of the plant itself, which reflects a legal codification of a harm assessment originally adopted over fifty years ago – that is, that cannabis, when not classed as a CBPM prescribed by a specialist according to evidence-based guidelines (as of 2018 in the UK), is a harmful drug with some addiction potential and a risk to youth. The premise of the 1971 Act and the ongoing prohibition of cannabis for adult use is that the plant and its key active compounds like THC have a negative (and no potential positive) psychoactive effect on the user when consumed recreationally, with societal harms that result, including impairment and possible injury to others via child neglect or drug driving. In addition, the UK debate is still influenced by the opinion that early use, and especially habitual use of high strength cannabis among adolescents can cause permanent damage to brain development. As evidence emerges from legal regulated regimes such as Canada, and better longitudinal data emerges around mental health and legal consumption by young adults, it will be possible for policy-makers to judge whether these arguments are still valid. Emerging evidence of the therapeutic benefits of cannabis may moderate some of the public anxiety about any link that they might perceive between cannabis consumption and psychosis or other mental health issues. Given the complexity of these issues it is unlikely that the public or politicians will agree with the assertion that cannabis presents no harms. It is a question of balance and of adopting proportionate regulations that are designed with the risks in mind, but also taking into account the strict medicinal access channel that has been created and the trusted actors (specialist doctors, registered pharmacists, licenced suppliers and transport companies) that are permitted to handle and supply it.

4.3 Principles of effective regulation

Today's legal cannabis sector is a regulated industry. The law governing the plant's use and the regulations that dictate permitted activity are all designed to control and direct behaviour. It is therefore essential that how it is regulated is determined by reference to the evidence base on what makes for effective regulation that works to affect behaviour.

The science supports the following basic ideas:

1. People achieve more when they cooperate.
2. Cooperation is based on partners having trust in each other. Trust is a mental attitude that helps us act in the face of uncertainty and risk – especially lack of knowledge about the future. It gives us confidence in our expectations of how others are going to behave, on the basis of which we can base our actions.
3. Trust is based on evidence of a person/organisation's behaviour, intentions, outcomes, competence (including the ability to manage systems), resources, culture and so on. The evidence typically builds up over time to form a consistent and comprehensive picture.
4. Humans evaluate evidence based on their internal values, which are applied through our ability to know the difference between right and wrong – i.e. we have an inherent ethical compass. The vast majority of humans do this all the time, automatically. We all have the same basic set of values, although the set comprises opposing values, and circumstances and mood etc can trigger some values to be dominant at particular times (e.g benevolence/altruism or defensiveness/aggression). A sense of fairness/justice is a fairly constant value, although people interpret what they think is fair based on their own character, experiences and environment.
5. The ideal approach is for a person/organisation itself to produce relevant, reliable and convincing evidence that it is trustworthy, rather than for an evaluer to have to form a judgement based on incomplete or unreliable information.
6. The nature and scope of that evidence will depend on the circumstances. In organisational and regulatory contexts, some of it is familiar and standard, and some less so (and novel), such as:

a. An organisation's mission statement, setting out its values and core purposes.

b. An organisation's level of sophistication in operating management, quality, and safety systems.

c. Application of technical standards and rules, auditing, and demonstrating their regular results.

d. An organisation's culture (which is difficult to measure but can be evidenced by surveys and sophisticated tools). An openness to challenge and evaluation are important, as opposed to unengaged following of procedures or rules – but this depends on the nature of the tasks.

e. Outcomes. It's usually much easier to produce metrics on outputs than outcomes, but it's outcomes that matter – are we producing good or harm? And are we improving performance or not?

7. Trust is difficult and slow to build, and easy and quick to undermine. So supporting strong trust takes constant effort.
8. People always perform better and achieve more when they have strong intrinsic motivation. There are various psychology theories, which show that supporting individuals' needs for feeling competent, autonomous, and related (per Self-Determination Theory), are particularly important.[45]
9. Thus, managers, colleagues, regulators, leaders etc will all be more or less effective depending on the extent to which they succeed in supporting these needs. Acting in

45 *Deci, E. L., Olafsen, A. H., & Ryan, R. M. (2017). Self-determination theory in work organizations: The state of a science. Annual review of organizational psychology and organizational behavior, 4, 19-43. https://mycourses.aalto.fi/pluginfile.php/1633529/mod_folder/intro/Self-determination%20theory__Deci%20et%20al.%2C%202017%20%281%29.pdf*

a way that supports a person's need to feel competent, autonomous and related to others will be effective, whereas the opposite is true of acting in a way that diminishes those needs. Thus, both the substance and the mode (how it is done) are important in delivering leadership, direction, criticism, control, restrictions, sanctions and so on.

10. This analysis shows why dictatorial or deterrent behaviours are consistently found to have little if any effect on others' behaviour and motivations – and sometimes provoke reactions that are entirely the opposite of achieving the external 'control' that was intended. It shows that how regulation (and especially enforcement) is done, and how staff are incentivised and remunerated, can have profoundly powerful effects on whether outcomes are successful or otherwise.

11. The same ideas also show the importance of the level of trust people feel in leaders, institutions and systems.

12. Social mechanisms affect behaviour to a considerable extent. We like to conform to the values, behaviours and culture of the group(s) in which we find ourselves.

13. Humans also have a mechanism, based in maintaining a sense of self-worth, by which we rationalise having done something that does not conform to our (or others') values, after the event, as in fact being ethical (when objectively it isn't – cognitive dissonance).

14. There is a limit on the number of humans who can work well in a group. The Dunbar number limits the number of people with whom humans can effectively inter-relate (based on comparing the sizes of brains in monkeys and humans, and the numbers in their social groups) and the solution is to create multiple ideal-sized groups that interconnect within a wider organisational and trust-based framework.

15. People will cooperate if they trust and respect each other. This is more likely where (a) they are treated like responsible autonomous adults, rather than like children, and (b) where they share the same values, purposes, intended outcomes and undesired outcomes, and ability to evaluate relevant evidence that builds trust.

16. These considerations suggest that cooperative mechanisms are needed to discuss, debate and monitor all these issues. Hence, the mode should ideally be horizontal rather than vertical – a community of all stakeholders rather than an authoritarian structure.

17. One would not push too far or too fast in implementing that ideal, as this would produce instability. Representative structures such as parliament, governments, managers, regulators and so on remain fully relevant. But some surprising reforms can be (and have been) implemented effectively to build greater trust, involvement, accountability, evaluation and so on.

4.4 Outcome Based Cooperative Regulation

Global developments in practice and theory of regulation have been occurring that offer considerable opportunities for the regulatory regimes of both new and existing products and services. Regulation is essentially about delivering protection of people, the environment and markets from harm. But it has sometimes been seen as constituting barriers in terms of too many rules and complex processes ('red tape') which are disproportionate for businesses, especially small businesses.

Thirty years ago, a change in orientation started to occur to align the activities of regulators to be more engaged with businesses[46], and to be more responsive to the situation and needs of those businesses with whom they interrelate or who break rules[47]. Developments have continued to occur along these lines, with barriers to the introduction of new regulation (such as requirements for Impact Assessments that show positive cost and benefit calculations)[48] and a Regulators' Code, under which regulators are, since 2014, required to consider the impact of their activities on growth.[49]

A 2017 review of the future direction of regulation involving leasing regulators concluded that the best organisations achieve compliance partly through 'effective self-assurance' and that a general shift towards 'earned recognition' and 'regulated self-assurance' would be productive and efficient[50].

Related developments have occurred in the approach of businesses towards effective management, and the broadening out of corporate purpose and governance from the goal of solely maximising shareholder value to encompass social and environmental purposes and longer-term sustainability goals (Corporate Social Responsibility; Environmental, Social and Governance; and the UN Sustainable Development Goals). Business leaders now focus on Stakeholder Capitalism, taking account of achieving the interests of their various stakeholders[51], and on strengthening trust[52]. Research into effective organisational management and operations has consistently highlighted the importance of ethical values in leadership, organisational culture, and treatment of customers and staff[53].

Recent research has brought together all the above issues around achieving better regulation[54] and delivering more effective outcomes based on the achievement of the basic purposes of prosperity and protection[55]. The Outcome-Based Cooperative (OBC) model is being applied in various contexts, such as communities, organisations, regulation and dispute resolution. In the regulatory context, the OBC model[56] suggests that stakeholders should cooperate to co-create:

a. their purposes, objectives, outcomes;

b. harms to be avoided, and their root causes, barriers and solutions;

c. their mode of engagement, supporting intrinsic motivation[57] based on actors producing evidence that they can be trusted, by producing relevant evidence of ethical

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46 Hampton, P., (2005). Reducing administrative burdens: effective inspection and enforcement. HM Treasury.

47 Ayres, I., & Braithwaite, J. (1992). Responsive Regulation: Transcending the Deregulation Debate. Oxford; Braithwaite, J. (2002). Restorative Justice and Responsive Regulation. Oxford.

48 First introduced under Better Policy Making: A Guide to Regulatory Impact Assessment (Cabinet Office, 2003).

49 Regulators' Code (Department for Business Innovation & Skills, 2013), made under the Legislative and Regulatory Reform Act 2006, s22 (2) and (3).

50 Regulatory Futures Review (Cabinet Office, 2017). This drew on Hodges, C. (2016). Ethical Business Regulation: Understanding the Evidence. Better Regulation Delivery Office.

51 See statement by the U.S. Business Roundtable at www.opportunity.businessroundtable.org/wp-content/uploads/2019/09/BRT-Statement-on-the-Purpose-of-a-Corporation-with-Signatures-1.pdf

52 See Strengthening Trust in Business. OECD Business and Finance Outlook 2019 (OECD, 2019).

53 Hodges, C., & Steinholtz, R. (2017). Ethical Business Practice and Regulation: A Behavioural and Values-Based Approach to Compliance and Enforcement. Hart.

54 See Russell, G., & Hodges, C. (eds) (2019). Regulatory Delivery. Hart.

55 The goal of achieving outcomes was specified in Regulatory Futures Review (Cabinet Office 2017); Sir Michael Barber, Delivering better outcomes for citizens: practical steps for unlocking public value (HM Government, 2017); Primary Authority: Statutory Guidance (Department for Business Energy and Industrial Strategy 2017), para 1.27. See Impacts and Outcomes Toolkit: Summary (Local Better Regulation Office, 2010)

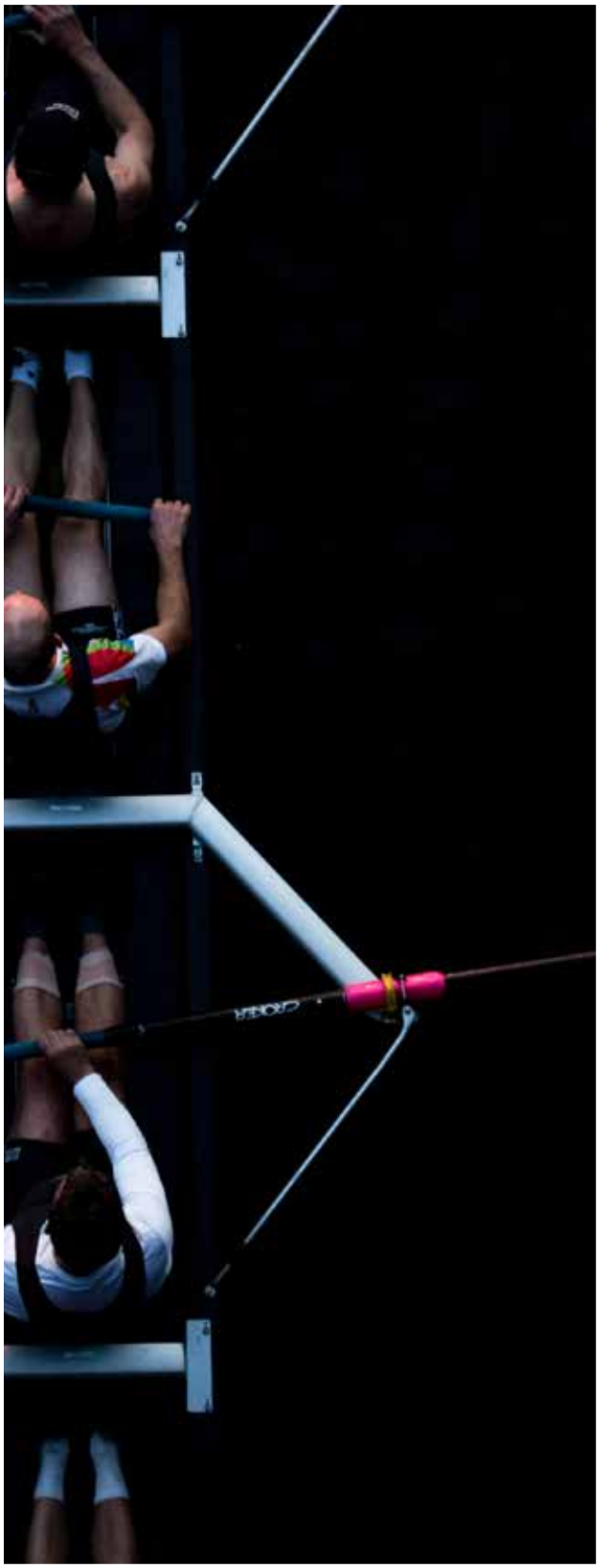
56 Hodges, C. (2022). An Introduction to OBCR at www.indr.org.uk

57 Ryan, R. M., & Deci, E. L. (2017). Self-Determination Theory. Basic Psychological Needs in Motivation, Development, and Wellness. Guilford Press.

motivation, competence[58],resource, behaviour, culture and outcomes;

d. metrics and evidence that will demonstrate trustworthiness, involving identifying specific ethical values and operational management systems, and evidence of improvements in performance in achieving the right outcomes.

The essence of OBC is to focus on how people and organisations (including markets) best inter-relate, rather than just on a system based on rules, identifying breaches of rules, and enforcement. The system and institutions of a rules-based approach (standards, contract, requirements, state enforcement) remain relevant but will not be adequate on their own to maximise the level of effective cooperation needed to achieve well-functioning outcomes – whether in terms of investment, research, product regulation, safe and appropriate use, strong markets. But those objectives can be achieved if other approaches are adopted – through OBC.



58 *Bandura, A. (1977). Self-efficacy: Toward a unifying theory of behavioral change, Psychological Review 84(2) 191-215.*

4.5 Current state of Outcome Based Cooperative Regulation

In essence, what is occurring is the application of the findings of modern science to social, managerial, regulatory and dispute/conflict situations. This science can be challenging in at least two major ways. First, some of it may be counterintuitive to many, for example, those who say things like 'Who's to blame for this disaster?' and 'They need to have a heavy sanction, that will teach them'. The science shows that people do not share information or collaborate unless they have psychological safety, so blame impedes learning and improving – a lesson that aviation safety has been able to apply very successfully but many other services have not (such as the NHS).

Second, the inherited structures of institutions and the way they are governed and operate are based on centuries of philosophy and academic theory on law and economics that turn out to have some important flaws when measured against the empirical scientific evidence. Thus, ideas around authoritarian structures, enforcement, deterrence and sanctions are embedded but flawed. If we want to be more successful in achieving more good outcomes, and in avoiding bad outcomes, we need to apply the science to how we organise our institutions and how we behave.

Many large companies have made very significant shifts in the past fifty years in their management practices and culture, based on scientific and empirical studies from Business Schools, producing clear improvements in culture, performance, behaviours and outcomes. Debates on continuing this shift are currently seen in corporate governance, a broadening of business goals to encompass Environmental, Social and Governance purposes as well as profits (business theory has moved from maximising shareholder value as the sole rationale to ideas that profits are outcomes rather than goals).

Changes have been slower in governmental and regulatory contexts. But some, such as the industry-wide adoption of performance and culture-based approaches to aviation safety and its regulation, have been outstandingly successful. Case studies involving elements of purposes, outcomes, trust, ethics, cooperation, and performance have produced encouraging results in contexts such as regulation of medical technology, water pricing, SMEs in energy, and human tissues.

The sheer quantity of scientific studies is now very extensive, and academic consensus amongst those who are aware of it is clear about the findings and implications (there has been a succession of books and articles recently by professors of socio-legal studies – but traditional disciplines remain largely unaware). However, a couple of models have been produced on how to apply the science in concrete form. Hodges and Steinholtz suggested Ethical Business Practice and Ethical Business regulation in a 2017 book, and Hodges has now transcended and broadened the model with OBCR – also showing that it can be applied equally in communities, organisations and dispute resolution contexts.

The science indicates that OBCR will be the most effective way of achieving objectives and good outcomes through cooperative means. OBCR ideas are catching on quickly in multiple contexts – examples include Just Energy Transition; medical technology; behaviour and regulation in the social housing and private rented/leasehold/commonhold property sectors; the rail sector; supporting SMEs; unregulated legal services; food; Artificial Intelligence (AI) and internet platforms; construction products; and measurement.

Widespread adoption of OBCR would be transformative for organisations, markets, regulatory systems and so on, since the interactions between multiple discrete OBCR networks would be mutually supportive, each being based on trust and producing relevant evidence. However, the elements and approach may be more of a challenge to apply in some contexts than others, and may take time to apply in some contexts. It's certainly true that adopting a generic approach (such as a national policy) would generate speed in achieving better outcomes.

In a positive sign, all of the basic concepts of OBCR (working together, cooperation, collaboration, trust) formed the basis of the UK Government's policy on the future of regulation in the January

2022 paper The Benefits of Brexit[59], as well as the June 2022 Regulatory Horizon's Council report[60].

Stages of Creating OBCR

The basic stages in the development of the core elements to support OBCR are:

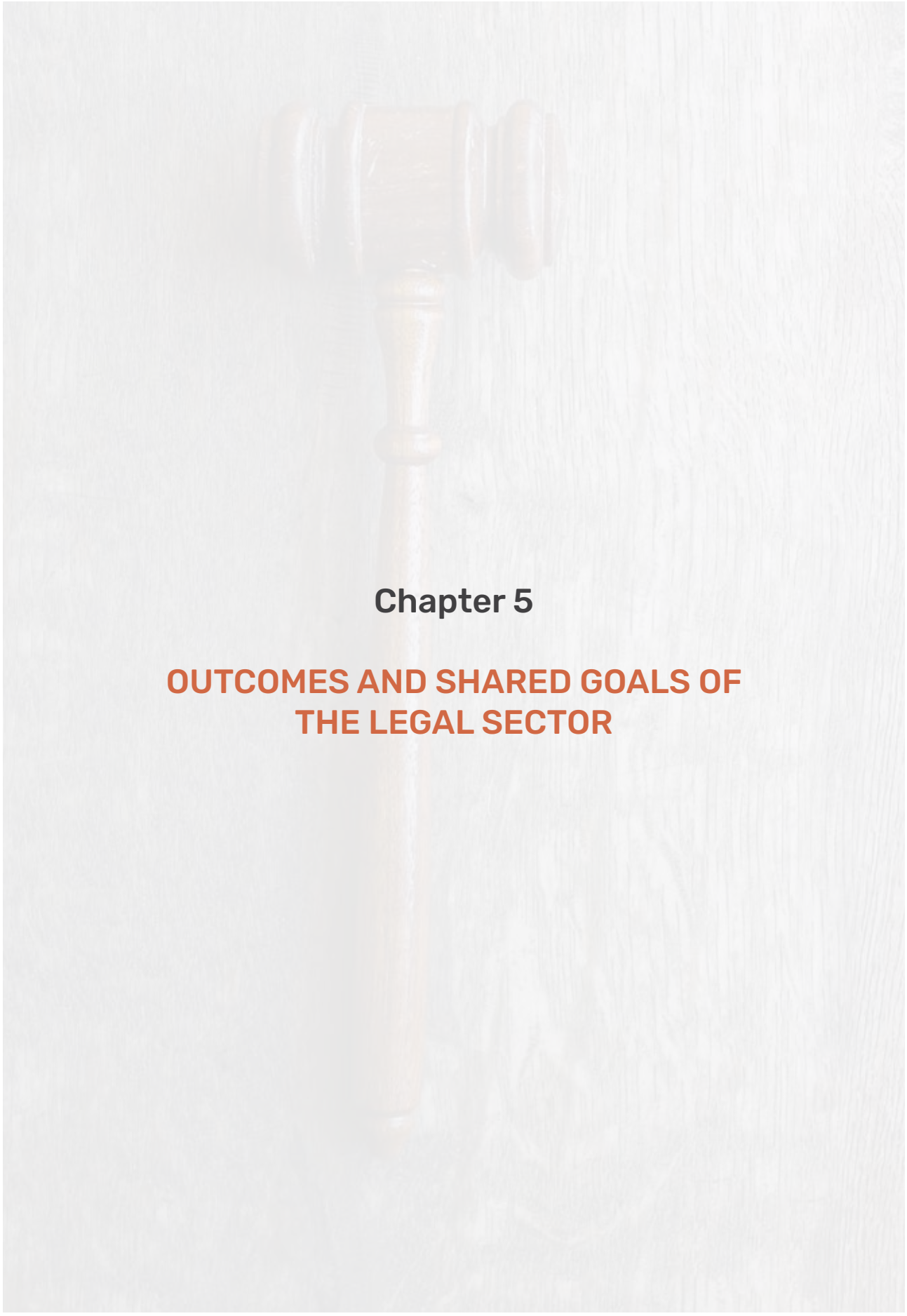
a. Agreeing amongst all stakeholders the purposes, intermediate strategic objectives, and outcomes that are desired (and not desired). Agreeing the evidence and metrics that should identify the desired and undesired outcomes.

b. Actors produce evidence that they are trustworthy. Trust should be based on evidence produced by each actor that they can be trusted (to behave so as to achieve the right outcomes by doing the right thing). The evidence should distinguish those who can be trusted, and so should qualify for trust-based relationships.

c. All stakeholders should be offered the opportunity to be involved in cooperatively achieving the agreed purposes, objectives and outcomes - i.e. to take responsibility for their actions in this delivery, and to be accountable for delivering the agreed outcomes. This accountability will be measured by metrics on whether the outcomes are achieved, and on improvements in performance in achieving them.

59 HM Government (2022). The Benefits of Brexit: How the UK is taking advantage of leaving the EU. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1054643/benefits-of-brexit.pdf

60 Department for Business, Energy & Industrial Strategy (2022). Closing the gap: getting from principles to practice for innovation friendly regulation. https://www.gov.uk/government/publications/closing-the-gap-getting-from-principles-to-practice-for-innovation-friendly-regulation



Chapter 5

OUTCOMES AND SHARED GOALS OF THE LEGAL SECTOR

The principles of ethical and trust-based regulation provide a valuable framework for thinking about how the legal cannabinoid sector can develop in the UK. Our approach is entirely consistent with the principles for innovative regulation set out in a the Regulatory Horizons Council's latest report[61] which discusses four strong overarching themes that appear in a range of UK and OECD papers:

1. Collaboration
2. Retaining a degree of proportionality, and adaptability
3. Outcomes focused
4. Future facing.

From these, they call for regulation and regulators to:

1. Be proportionate and balance potential benefits and risks;
2. Integrate ethical considerations and outputs from public and relevant stakeholder dialogue;
3. Take account of commercial considerations and the need to attract investment;
4. Include alternative forms of regulation;
5. Get the timing right;
6. Cultivate a culture of openness and a growth mindset.

All of these are key to how the government and regulators should see their regulatory mission when it comes to cannabinoids. Government Ministers and officials should take onboard this framework as it is a very balanced and evidence-based approach, and completely applicable in this context.

In addition to getting the right kind of approach adopted by regulators, along with the key pillars that make up any well regulated market (competition, clear rules, transparency, informed buyers/users, feedback mechanisms etc), the regulation of the legal market also needs to include some clear outcomes.

By outcomes we mean social, environmental or economic results that go beyond outputs - so they are measurable changes that the industry is able to strive towards and document progress against. Agreement on the outcomes we are all working towards is essential when we come to adopting an OBCR approach to the legal cannabinoid sector, and these are explored further below.

61 *'Closing the Gap' Getting from Principles to Practices for Innovation Friendly Regulation* https://www.gov.uk/government/publications/closing-the-gap-getting-from-principles-to-practice-for-innovation-friendly-regulation

5.1 OBCR applied to this sector and market

When considering how to apply the OBCR approach to this sector, it is important to consider how it should be implemented, and then what aspects of that the current sector would struggle to adopt.

Steps to Implement OBCR:

Helpful rules that support good performance: the principles of good practice in a code of ethical practice, and technical rules, mainly in guidance/ standards (regularly updated); legally enforceable rules triggering a right to intervene, and especially formal enforcement, should be designed as a long-stop to protect against really unacceptable behaviour.

- A commitment by traders and regulators (and others like assurance bodies or regional hubs) to observe the ethical and technical rules. the basis on which people engage should be agreed and should conform to society's values and norms, i.e. ethical values. Codes of ethical practice will be central documents.
- A data system that identifies performance, problems and risks. The data can be contributed by traders from their trust/technical sources, from feedback by certification & assurance audits and inspections, from customers and suppliers (e.g. complaints), or anything else. It will identify both generic issues and issues with specific traders. A sectoral Ombudsman is a good host for this portal and database.
- A feedback system to identify actual levels of performance, including comparisons with the market average (e.g. the Drinking Water Inspectorate's risk and issue system). Traders would be given their own aggregated data and anonymised comparative performance data. Regulators would have more specific access. This allows traders to institute their own action to improve performance. Platforms operated by Ombudsmen will be particularly effective here.
- A support and intervention system that provides targeted support or intervention, and if necessary formal enforcement. This can be organised on a national basis in some sectors, but often will be an integrated regional Authority/Business Hub/Chamber of Commerce. The possibility of enforcement will be necessary but will be a backstop in many sectors, whereas most actors will be supported in improving their performance. This will rely on an ecosystem of information, advice, training, support and intervention.

5.2 Missing elements of OBCR in the UK market

The legal cannabinoid market in the UK has a hill to climb when it comes to these important implementation steps for OBCR, even if some progress is happening:

- Rules are in place to define the regulated activity but guidance is not always coherent and is not issued in any comprehensive format. This means rules are not as clear as they need to be, and technical guidance where it is asked for by industry is still absent. A major step forward will be when the Home Office decides to define (by a revision to the MDR2001 regulations), the tolerable trace limit of controlled cannabinoids in consumer products, which resulted in an ACMD commission and final recommendation to Ministers in 2021. The CMC/ACI urged them to adopt their own proposal to ensure a safe and workable limit that would give clarity to industry and enable a focus for enforcement[62], and the Cannabis Industry Council (CIC) has recently proposed an alternative approach based on ratios of THC to CBD, but no decisions have been taken.
- Individual companies have adopted vision statements or ethical codes but these do not yet exist as collectively agreed standards adopted industry-wide. We describe what this might look like for the legal cannabinoid sector in Chapter 6.
- Data on the sector and how it is operating is a major deficit at present, with far less data published in the UK than in other peer group countries, and no commitment by regulators or government departments to be more transparent about this sector and its operations. The number, nature and conditions of licences issued are not in the public domain, and even regular monthly counts of CBPM prescriptions were only obtained following a Freedom of Information request and published by the NHS Business Services Authority (NHSBSA) for the first time in May 2022. Much of this data is already held, but is not collated in a single place and is not shared routinely. Data on number and identity of Home Office licensees (not locations) is in the public interest and should not be subject to exemption on grounds of commercial confidentiality.
- These issues are also reflected in a lack of a feedback system for problems, other than the established consumer or patient complaint or alert mechanisms (e.g. MHRA's Yellow Card scheme for adverse effects of medications), which means that aside from individual testimony and anecdote, the industry struggles to understand where it is facing friction or not delivering what is expected of it.
- Lastly there is also no systematic support or intervention system, with the enforcement tools being used sparingly and no interim measures being considered for how to bring the sector into compliance by adopting supportive interventions and behavioural science 'nudges'. At present, the law and regulations in each sub-sector require certain behaviours, but the only tool on offer to police this industry is the threat of enforcement. Regulators like the FSA, in partnership with Trading Standards, need a more sophisticated range of compliance tools that encourage engagement and provide them with a graduated set of sanctions to warn non-compliant companies before enforcement is initiated.

62 *The Association for the Cannabinoid Industry (2021). Health Guidance Levels for THC in CBD Products.* https://theaci.co.uk/aci-and-cmc-recommend-home-office-clarify-thc-limit-for-cbd-products/

5.3 Trust and the cannabis sector

The history of social use of cannabis and its contested legality clearly raise issues of trust. But it is important to distinguish those aspects that may remain contentious from those that should not be, given differing goals and situations, and the likely consequences of specific changes. Some people are suspicious of the lifestyle and values of those who take cannabis or of the motives of those involved in the industry.

The current elements of illegality that cover many aspects of manufacturing, delivery, prescription and use for other legal medicines and consumer products, unavoidably raise questions of involvement in illicit activities and the illegal market (previously or currently). These factors clearly erode trust and can make every argument for reform to make medicinal access easier look like a slippery slope to full legalisation. The reality, however, is that full legalisation is not the goal or an unavoidable consequence of the objective of making valued therapeutic benefits available to patients. Questions of the wider wisdom or inevitability of recreational legalisation simply do not arise here. The idea of full legalisation is not in fact the goal of many people who came to cannabis later in life via their awakening to its medical benefits.

Nevertheless, those in the legal cannabinoid sector have to work especially hard to counter misconceptions and stigma, and the same goes for working to demonstrate that they are to be trusted. A trust-based and cooperative approach should be a powerful model for adoption in a new market or regulatory context, since it should not require pre-existing structures or approaches to be modified, but can be established relatively unimpeded.

Contrary to some assumptions, the legal cannabinoid sector in fact offers a powerful opportunity for applying a trust-based approach. This can be achieved by adopting the following framework:

a. Commitment by industry, and verified observance, of a system based on evidence that all elements of the production, research, manufacture, marketing, distribution and use of regulated products are subject to all legal regulatory requirements and ethical practices.

b. This will involve oversight mechanisms such as governance by an independent council comprising the full range of stakeholders and independent consumer and medical voices, as well as regulatory and scientific expertise. The system would agree and oversee validation and accountability of requirements and ethical values that would support (and not undermine) high levels of trust in all relevant activities. It would include mechanisms for blockchain-based verification in the manufacturing chain, full inputting of relevant data up to patient use, enabling continuous monitoring and swift feedback on any aspect of use or safety. It would identify areas requiring further investigation and research, and enable gaps in knowledge to be swiftly filled.

c. Industry and regulators/NHS authorities would engage on the basis of a ‘trust track’ that supports more effective, comprehensive and efficient engagement and achieves desired outcomes.

d. The clarity and confidence around such a system would simplify the existing jungle of regulatory constraints and support rational use, an ethical marketplace and appropriate investment.

If all actors in the established system are assumed to be “trustworthy” then it makes perfect sense that to preserve both their own ease of operating in a new OBCR environment and their commercial position, that they would ensure anyone not operating to the principles of OBCR are first addressed directly to modify their behaviour. If this fails then the rogue actor should be reported to the relevant regulatory body to take further action. This has worked extremely well in the pharmaceutical industry with the Association of the British Pharmaceutical Industry (ABPI) and Prescription Medicines Code of Practice Authority (PMCPA) handling the majority of infringements within the sector, with companies and individuals often reported by peer companies, patients or doctors.

5.4 Defining 'trusted actors'

Trust needs to exist in relation to everyone involved in relevant activities, both as individuals and in relevant organisations and institutions. Thus, one would aim to construct relevant evidence of trustworthiness - which might differ in each case - for producers (seed suppliers, farmers, other scientific producers, those involved in processing, manufacturing, distributing, marketing), regulators, professionals (doctors, pharmacists, researchers) and even end-users and consumers.

Almost all traditional mechanisms remain relevant as providing potential evidence of trustworthiness, such as mission statements, codes of conduct, application of standards, management and production control systems, auditing, inspection reports, monitoring, feedback of all kinds, the ability to implement crisis plans (and even more, the fact that people behaved quickly and well when problems actually occurred) and so on.

In addition, recent realisation that behaviour and culture are important to outcomes give rise to the need to demonstrate the state of good (ethical, fair, respectful) cultures in human and management relations, equality, human rights, an absence of abuse of all kinds, and so on. The nature and extent of relevant evidence should vary depending on an organisation's activities and its scale (providing proportionality). The list may potentially be long, but modern IT systems involving efficient monitoring and feedback, and building up a convincing body of evidence over time, should enable efficiencies to be realised.

CASE STUDY: Regulations that constrain trusted parties are increasing costs to patients

Regulations in the private medical sector are vital for safety, patient trust and for public confidence in healthcare services. However certain regulations – when not proportionate to risk and when too proscriptive – can result in unnecessary costs being imposed on the sector, which can in turn lead to higher end-user costs, or in this example, higher prescription costs for medicinal cannabis patients.

The most common route for patients to access medicinal cannabis currently is via a specialist prescription issued in the private sector. This may be the only route for UK patients to legally obtain a cannabis medicine outside the NHS for the foreseeable future, and so the cost and other barriers inherent in this private health route need examining.

Regulations governing the supply of CBPMs are not specific to these products, insofar as they require certain security standards to be met for the supply of a scheduled drug to a patient's home address. This is required of all drugs in this category that pharmacies dispense via the postal system and are not unique to medicinal cannabis products. In addition the regulations for CBPMs restrict prescribing authority to specialist doctors, and limit supply in most cases to 30-days per prescribing episode. The limitations on bulk imports also constrain the ability of the industry to stockpile products domestically for faster and cheaper dispensing via licensed partners.

The combination of these factors mean that patients must undertake more consultations (an average of eight per annum) with a doctor, and those consultations are more expensive for clinics to deliver, even via a telehealth channel. The cost of the product itself is then inflated by the import procedures and again by the need for pharmacies to use only a select group of courier companies who hold a controlled drugs licence. The inflated cost to the end-user is the consequence of this arduous access route in addition to GDP (good distribution practice) and compliance with storage regulations due to the controlled nature of CBPMs.

A medicinal cannabis prescription is less expensive today than it was in 2019 or 2020 and in particular, the shift to virtual appointments during Covid-19 and the increase in providers offering telehealth consultations has enabled some cost reductions. Future downward pressure on prices will result from increased patient demand as awareness grows, and from general market competition between clinics and their licensed suppliers. However, this alone will not make CBPMs significantly more affordable for patients because certain compliance costs in

the current system cannot be avoided.

If regulations were updated in any of the following ways, the regulatory burden on the private businesses operating in this sector could be reduced, and the financial access barriers for patients also addressed:

- **Expanding prescribing authority to family doctors** who can provide less expensive consultations;
- **Further relaxing the import controls on CBPMs so licenced companies could hold larger quantities in secure UK settings** and reduce their transportation and import costs;
- **Authorising licensed clinics to offer a 90-day supply of CBPMs** for registered patients through registered clinics;
- **Removing the requirement for CBPMs to be mailed to patients via a courier firm holding a controlled drug licence**, and requiring only a track-and-trace / signed-for delivery option.

Building a responsible medicinal cannabis sector requires regulation, but inline with the principles of OBCR, it should also be based upon a level of trust with the parties involved in dispensing and supplying the product to patients. Through existing licensing rules, and the inspection regime of the CQC, the companies importing and distributing CBPMs as well as the doctors and pharmacists prescribing and dispensing such medicines already occupy a position of trust. It therefore adds unnecessary cost to their operations to treat them like they are not already trusted members of a professional, certified, licenced (and inspected) supply chain.

Trusting the medicinal cannabis sector and relaxing the regulations in any of the ways described would support a reduced cost to the end-user and help to widen access to CBPMs for many more patients who may benefit from them. If all the above measures were adopted, more sizable reductions in cost could be achieved and medicinal cannabis could become affordable to millions of people. This would also support a key outcome for the sector, which is to reduce harm and the appeal of the illicit cannabis market and provide a safe, affordable and well regulated pathway for patients to access a quality CBPM, where it is determined to be a worthwhile treatment option.

"Our price in the UK for patients for the oil products is £199. In Australia, the price is £80-£90.

The cost of supplying product to the UK is roughly 3.2 times higher than supplying product to Australia. We can only import small amounts of product into the UK at a time. The cost of shipping is therefore very high, because we have to do small, frequent shipments via air travel in order to ensure a steady supply into the country. Other countries allow us to import larger amounts, thereby reducing the cost of bringing products in. Even if we set up a domestic supply, we will need to import in the interim and potentially after as well to meet patient demand. But if we can increase the efficiency of the supply chain, we can effectively scale.

There are also fundamental differences in patient access between the UK and Australia. Since only specialists can prescribe in the UK, our total addressable market is largely restricted to patients who are going to medical cannabis clinics. Allowing GPs to prescribe and widening patient access may increase sales. It would also reduce the costs of consultations for private patients since they could see a GP rather than a specialist consultant. If volumes increase, companies will be able to reduce the cost of manufacture and shipping which will reduce the cost to the patient."

Hazel Neavyn-Neita, Medical Information Lead, Althea UK

5.5 Proposed outcomes for the UK sector

Whether the focus is cultivation, consumer products, or health and wellbeing, and irrespective of whether the parties are growers, manufacturers, CBD brands, private clinics or suppliers of cannabis medicines, there are certain overarching outcomes that the legal cannabis sector should strive for:

- **Reducing harm** - defined as the personal and social harm that can arise from unregulated activities involving cannabis
- **Improving health and well-being** - defined as the personal and societal benefits of cannabinoid use on individuals and their families
- **Expanding knowledge and evidence** - defined as both the level of expertise among key actors such as prescribers and regulators, as well as wider societal understanding
- **Increasing confidence** - defined as the scientific, corporate and governmental confidence to invest resources in cannabinoid science and new commercial ventures
- **Securing competitive advantage** - defined as the relative appeal of the UK as a place for conducting business and research involving cannabis, as compared to similar jurisdictions
- **Delivering collaboration** between industry, end-users and regulators - defined as the means by which each of these parties can formally interact in an open and informed way about challenges and opportunities.

These outcomes reflect the shared agenda to work on improving the economic and social impact of legal cannabinoids, but they also speak to a mutually beneficial desire to pursue pro-growth objectives that can set an example for the world. Many other jurisdictions are working to regularise the legal sector and achieve some competitive advantage to attract investment and the human capital involved in scientific research and product innovation. If the UK could base a new strategy for its legal cannabinoid sector on these six outcomes, it would give the industry a crucial edge and could help to set the standard for other countries.

Outcomes suggested here have the benefit of being measurable, and because they apply across all categories, they would incentivise cooperation and build up trust within the sector and also between the sector and the government and its regulators. Some common metrics for each of these outcomes are suggested in the following table but these ought to be decided independently and there might be other measures that would be more suitable. The sector is generating measurable outputs - and we still need better data to truly understand these (for example, annual hemp acreage in the UK, or accurate prescription by category and product type) - but beyond outputs are the broader outcomes we want the legal sector to deliver. If it is successful, the legal sector achieving these outcomes should invariably result in the illicit market being squeezed and its market share being replaced.

The UK's legal cannabis sector: OBCR 'outcomes'					
	REDUCING HARM & IMPROVING HEALTH	***EXPANDING KNOWLEDGE***	***INCREASING CONFIDENCE***	***SECURING COMPETITIVE ADVANTAGE***	***COOPERATION & SUSTAINABILITY***
Definition	The personal and social harm that can arise from unregulated activities involving cannabis, and the therapeutic benefits that can be realised	The level of expertise among key actors such as prescribers and regulators, as well as wider societal understanding	The private sector and governmental confidence to invest resources in cannabinoid science and new commercial ventures	The relative appeal of the UK as a place for conducting business and research involving cannabis, as compared to similar jurisdictions	Decisions based on understanding the Input from all the stakeholders involved and ensuring plant CBMPs are leading to sustainable circular economy
Supporting Activity	Working together to reduce the appeal of the existing illicit market in unsafe and unlicensed cannabis products; Providing a safe, affordable and well regulated pathway for patients to access a CBPM, where it is determined to be a valid treatment option by a qualified clinician Reducing costs imposed by regulation on CBPMs which impact affordability of legal access	Generating more research in the UK that contributes to an expanded evidence-base for the clinical efficacy and patient benefits of medicinal cannabis; Supporting a transparent industry by maximising the information available to users of legal cannabinoid medicines/products Empowering users by providing free educational resources locally to help inform them about the science and the lawful access routes for cannabinoids	Contributing to the expansion of a domestic (British Isles) cannabinoid industry through economic investments in local universities and innovation grants to companies / joint ventures Setting up official, permanent dialogue mechanisms with the participants in the legal industry at all levels Creating a trusted single source portal for consumers and patients to access guidance and data on all aspects of the sector	Increasing the UK's relative appeal for global companies and investors as the best place in Europe for innovation in cannabinoid products and treatments (e.g. adopting a sovereign list of approved strains, relaxing rules on R&D, and clarifying law and listing requirements re: POCA / FCA) Adopting revised regulations that encouraged on-shoring of the consumer cannabinoid supply chain (e.g. mandatory testing of products in UK ISO accredited labs; permission to extract from domestically cultivated hemp)	R&D for innovative clinical trials for CBMPs All sectors; R&D(Pharma, wellness & agriculture/genome), Medicinal product development, Delivery devices Product packaging Patient feedback Regulator's continuous involvement to ensure each sector gets the desired outcome
Possible metrics	*Number of people who admit to sourcing cannabis from the illicit market for a medical condition* *Number of patients receiving a CBPM from a private source* *Average monthly cost of a CBPM to patients*	*Volume of published research in peer-reviewed outlets of UK-based trials involving cannabinoids* *Survey evidence on the level of public awareness of legal cannabis and how to access it*	*Proportion of products meeting best quality standards, such as offering information to confirm Country of Origin and supply chain traceability, and batch specific certificates of analysis* *Published documents or strategies from the four UK governments that recognise the economic contribution that the cannabinoid sector can make*	*Number of UK-based jobs in the cannabinoid sector* *Market assessment of the percentage of the value of the consumer and medicinal cannabinoid sector supply chain captured by the UK* *Number of companies in these categories listing on UK public exchanges* *Patents granted for cannabinoid innovations*	*Assistance in overall risk based approach* *More cooperation from all sectors increased frequency of formal venues and events to engage with HMG and regulators* *Circular sustainable economy in UK defined as delivering quantifiable, verifiable gains such as CO2 reduction etc.*
Key actors	Prescribers Private clinics Home Office Trading Standards	DHSC/NHS NIHR FSA BEIS/Office for Science	HM TREASURY BEIS / InnovateUK FSA MHRA	BEIS / InnovateUK DIT FCA HO DEFRA	NIHR HO MHRA FSA

5.6 Shared goals of the legal cannabinoid sector

Hemp farmers, CBD cosmetic brands, Specials manufacturers, and cannabinoid pharmaceutical companies may not have much in common in terms of their customers and operations, but they do all derive their activities from a plant that is closely regulated. It is therefore possible to define a number of shared goals or a common purpose that the sector as a whole represents, and might be able to subscribe to, supporting as it does the ecosystem for the growth and development of cannabinoids as a regulated sector:

Six shared goals for the legal cannabinoid sector:

1. The sector demonstrates that it is trustworthy, legitimate and responsible
2. The evidence base improves and new insights are generated in the UK
3. Health and well-being outcomes are improved and access to these benefits is maximised
4. The scientific and social value of the whole cannabis plant (and synthetic derivatives) can be fully explored and exploited
5. A world standard for regulatory and scientific best practice can be set, embracing innovation and a level playing field for producers
6. New models of collaboration between regulated actors, policy-makers, legislators and ultimately producers, patients and consumers can be achieved.

Chapter 6

THE PATH TOWARDS A TRUSTED, COOPERATIVE INDUSTRY

6.1 For government: setting the strategic path

Together the CMC and ACI have already urged ministers to develop and adopt a single, cross-government strategy for this sector, and the regulatory approach we propose would benefit from that. Parties in a regulated environment can more readily cooperate with, and be trusted by, the government if they understand and see the part they play in the strategy:

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.

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.

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).

This strategy, while overdue, is important to get right. It should not be generated without proper consultation with the industry. Even larger and more mature markets like Canada have shown that relations between regulators and industry can break down when the mechanisms to cooperate, to share insights and market intelligence, and to listen to the experiences of businesses and end users are not in place. More than three years after cannabis was legalised for adult use in Canada, the Trudeau Government announced in Spring 2022[63] that it was moving to address this lack of engagement in an effort to repair the gulf that had developed between the politicians and policy-makers in Ottawa, with the burgeoning industry and the growing pains they had been experiencing. In the Federal Budget, the government said:

As a relatively new sector of the Canada economy, it is important that the federal government and all stakeholders have a clear understanding of the challenges and opportunities that are facing Canada's legal cannabis sector. Budget 2022 proposes launching a new cannabis strategy table that will support an ongoing dialogue with businesses and stakeholders in the cannabis sector. This will be led by the Department of Innovation, Science and Economic Development, and will provide an opportunity for the government to hear from industry leaders and identify ways to work together to grow the legal cannabis sector in Canada.

The UK Government should learn this lesson and move early to create a cooperative relationship with industry via a formal structure like this (see 'Quick Wins').

63 Government of Canada (2022). Budget 2022. https://budget.gc.ca/2022/report-rapport/toc-tdm-en.html

When the UK government rescheduled cannabis for medicinal use, it was already following major economies like Germany, Holland, Australia and Canada which had already done the same. Although patient numbers in all these countries were much lower in 2018 than they are today, there was a clear head start for producers in these jurisdictions when it came to supplying the clinics and suppliers in the UK who were now able to cater to UK patients via the unlicensed Specials pathway in the private sector.

Three years on and the UK market – measured by prescriptions issued per month – is significantly larger, but the market is still dominated by imported CBPMs from overseas producers, especially European and Canadian suppliers. Data from the NHSBSA details every make and product type prescribed as a CBMP so far, and the dominance of a few foreign suppliers is noteworthy. Licensed cultivators in the UK, including Celadon Pharmaceuticals and Glass Pharms, expect to be in a position to supply into this market within the next 12 months, so the percentage of products sourced from overseas can be expected to fall (along with prices for the end-user).

It is not unusual for a new market to be exploited in the early years by established foreign companies that can navigate the import procedures and partner with local distributors to reach domestic patients more quickly than new licensed firms can stand up their production and do the same. Nevertheless, even after issuing more licences in recent years, there appears to be no coordination or strategy about what such licences are designed to achieve, and no apparent concern about the over-reliance on imported products that are not inspected or tested on arrival.

The sensible approach is to ensure that imported products are not able to evade production requirements that apply to domestic producers – as they were in Australia for many years – who may already be at a unit price disadvantage because of the higher costs of cultivating an approved cannabis crop in the UK (land, labour and energy costs being the principal drivers). Without a set of quality controls and production, testing and labelling standards that all CBPM suppliers must abide by (equivalent to the Rule 93 provision set down by the TGA in Australia[64]), foreign suppliers have an unfair advantage and patients cannot be assured of a competitive market where local producers can compete.

The strategic advantage of more local production is both the issue of trust, but also about the capacity to monitor the supply chain, and also to collaborate with industry based on companies that are invested in the UK and have a stake in local economic growth as well as the welfare of users and patients. Without systems of track-and-trace, and the complicated global supply arrangements between overseas producers and their import partners, the traceability of products is harder to determine for regulators, and almost impossible to discern for prescribers and patients. These problems will increase as the market expands and more clinics open, with foreign companies also now involved in establishing new clinic chains tied to overseas suppliers.

In addition to levelling the playing field, so the key outcome of 'Securing a Competitive Advantage for the UK' can be realised, the government's strategic aim should be a regulatory framework that encourages domestic production, incentivises on-shoring of current activity in this space (both medicinal, and consumer cannabinoids/CBD), and sees a growing proportion of prescriptions issued for domestically produced CBPMs. Quality and price will drive product growth in this sector like all others, but the UK's own licensed parties should be trusted, and encouraged, to expand their capacity to serve the British population, instead of the UK's medicinal cannabis market being seen as a commercial free for all for any licensed company that can make the logistics work.

An on-shoring of cultivation, processing and production of finished medicinal cannabis products would not only generate UK jobs and permit more efficient surveillance of the market and the supply

64 *Therapeutic Goods Administration (2022). Guidance on quality requirements for medicinal cannabis product. https://www.tga.gov.au/sites/default/files/guidance-on-quality-requirements-for-medicinal-cannabis-products.pdf*

chain, it would also provide ancillary opportunities for laboratories for analytical and quality control testing, and for academia for patient trials and public health research.

Even in consumer cannabinoids, where more value accrues to FMCG companies investing in brands and retail product innovation, a move to encourage the on-shoring of the CBD sector would also offer clear advantages: improving traceability and reducing dependence on raw ingredients from unregulated sources overseas; bringing benefits of sustainable, local production and provenance for the environment and the ethical supply chain desired by many consumers, as well as enabling more investment in manufacturing and R&D ventures involved in devising new products and refining and finishing retail CBD products in the UK.

Some freeports could even become the place where such activity could be encouraged, serving as the basis of successful UK-based suppliers who could save on taxes and customs duties, by creating and finishing CBD products under a Home Office licence, for onward export into the EU and global markets. Other commercial activity in the CBD market would be catalysed by easing restrictions on domestic hemp cultivation (see Recommendations, Chapter 7), so raw materials would not need to be imported but could be grown and utilised for extraction here in the UK – with export also permitted to foreign markets.

A strategy of keeping more of the supply chain, and the value of the industry, at home, would directly support the OBCR goals of having a regulatory framework for the legal cannabinoid sector that enables and is built upon trust, with high levels of transparency and cooperation between the regulator and the industry. So long as the majority of the value of the sector is generated outside of the UK, the harder it will be to advance the agenda of trust and cooperation and the more that UK producers will struggle to compete, thus undermining wider goals of helping a post-Brexit UK to pioneer new scientific and regulatory approaches.

6.3 Target support for the sector in today's more benign funding environment

The UK has recently made major commitments to boosting investment in R&D overall, and to invest more in high-growth sectors like life sciences. Both moves have a direct bearing on the opportunities for grant and subsidy support for many parts of the legal cannabinoid industry. Increased public spending will lead to new opportunities to access competitive grant schemes in healthcare research and other sectors that are a political priority, such as Net Zero.

Since the 2021 Comprehensive Spending Review, the Department for Business, Energy and Industrial Strategy - the lead department for life sciences - has made a number of key funding commitments. These include:

Funding amount	For what
£7m	National Space Innovation Programme
£26m	Biofuels funding
£100m	Three 'Innovation Accelerators' in Glasgow, Manchester & West Midlands
£60m	Boost UK medicines manufacturing, diagnostics and med tech

In time, such funding schemes should provide opportunities for new and existing firms in the legal sector to have early stage research as well as translational development supported. In addition to current InnovateUK grants to some R&D plant science research (for example, in Aberystwyth University, in conjunction with funding from the Welsh Government), new UK-wide competitions can be expected to be opened by BEIS for applications in 2022-23 that could support new cannabinoid initiatives in the UK.

Innovative Medicines Fund: an opportunity for cannabis medicines?

In June 2022, following the success of the Cancer Drugs Fund, the Department for Health and Social Care launched the Innovative Medicines Fund (IMF), allocating £680M of ring-fenced NHS funding to accelerate the deployment of promising new medicines[65]. One of the biggest barriers to the widespread prescribing of cannabis medicines is the lack of positive clinical trial data generated in the UK, and the IMF appears to be geared towards trying to address such challenges: "The primary function of the Innovative Medicines Fund is to operate as a managed access fund while evidential uncertainty is resolved in medicines that otherwise show significant clinical promise". However, according to the scope of the fund, promising non-cancer medicines that could be candidates to benefit from this faster route to market would need an initial positive determination by NICE (in advance of full approval) before being made available on the NHS as part of a managed access arrangement. At present, no unlicensed cannabinoid medicines have been subject to NICE evaluation, and the IMF principles are clear that "Managed access does not displace or replace the need for good quality clinical trials[66]". The terms of the funding scheme also state: "Given the centrality of the NICE process to the Innovative Medicines Fund, it is highly unlikely that products that are not evaluated by NICE will gain entry into the Innovative Medicines Fund." In light of this, current unlicensed CBPMs which have not managed to generate late-stage trial data or sufficient real world data (due to low patient numbers) that enables them to undergo a NICE evaluation are unlikely to be able to access this fund. This should spur a wider debate among the NHS and health policymakers about how cannabis medicines – given the increasing overseas evidence base of their efficacy – can move more quickly into conventional clinical trials in the UK.

There are other recent examples of certain subsectors of the economy receiving dedicated support to catalyse growth, especially in areas where there is already domestic strength in research institutions and human capital, and where new science is lowering costs and making new innovations cheaper to bring to market. One clear parallel is the commitment by multiple

65 NHS England (2022). Innovative Medicines Fund. https://www.england.nhs.uk/medicines-2/innovative-medicines-fund/
66 National Institute for Health and Care Excellence (2022). The Innovative Medicines Fund Principles. https://www.england.nhs.uk/wp-content/uploads/2022/06/B1686-the-innovate-medicines-fund-principles-june-2022.pdf

governments in the last decade or more to nurture the UK's space industry.

CASE STUDY: UK Space – an emerging industry parallel

The UK space sector now employs 46,995 people and is growing fast – with income of £16.5bn in 2021 and exports making up almost a third of this total[67]. The first industry-specific legislation for the civilian space sector in recent decades was published in 2018[68]. The latest strategy, published in 2021, committed to investing £5 billion over 10 years in satellite communications and £1.4 billion in new technologies and capabilities, combined with a clear regulatory architecture, and the commitment to build out domestic infrastructure, such as two new space ports in Cornwall and Scotland[69].

Today's space sector has been able to exploit the UK's scientific expertise in computing, satellites, and robotics, and with government support alongside private investment, the country has been able to leverage the value of the new market in space technology and services that was only just emerging two decades ago.

These inherent strengths – in human capital and research excellence – had been dormant for many decades after much of the government-funding for an independent British space programme was withdrawn in the 1960s. However, a small cadre of experienced engineers and scientists managed to develop innovative satellite technology in the late 1990s that seeded the rebirth of the civilian space sector, outpacing European competitors and capturing a disproportionate share of an expanding global market by the 2010s.

With world class researchers and a network of universities involved in cannabinoid research, the parallels with the UK space industry twenty years ago are clear. Developments in medical technology and therapeutics are likely to make healthcare an increasingly valuable global market for Britain to access, and novel treatments involving cannabinoids can be expected to play more of a role in two decades' time than they do now.

However the UK space sector would not have grown so successfully if successive governments had not been willing to invest in and nurture British-based companies and research initiatives in the civilian space sector, long before the large global opportunity was evident. If the legal cannabinoid sector were able to access the same support from government, including not just grant funding but a clear strategic agenda to nurture and grow the sector domestically, then it could one day generate more jobs and tax revenue and wider societal benefits than today's space industry.

67 UK Space Agency (2022). 3,000 jobs created in one year by 'resilient' UK space sector. https://www.gov.uk/government/news/3000-jobs-created-in-one-year-by-resilient-uk-space-sector

68 HM Government (2018). Space Industry Act. https://www.legislation.gov.uk/ukpga/2018/5/contents/enacted/data.htm

69 HM Government (2021). National Space Strategy. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1034313/national-space-strategy.pdf

6.4 Seek international convergence on CBD regulations

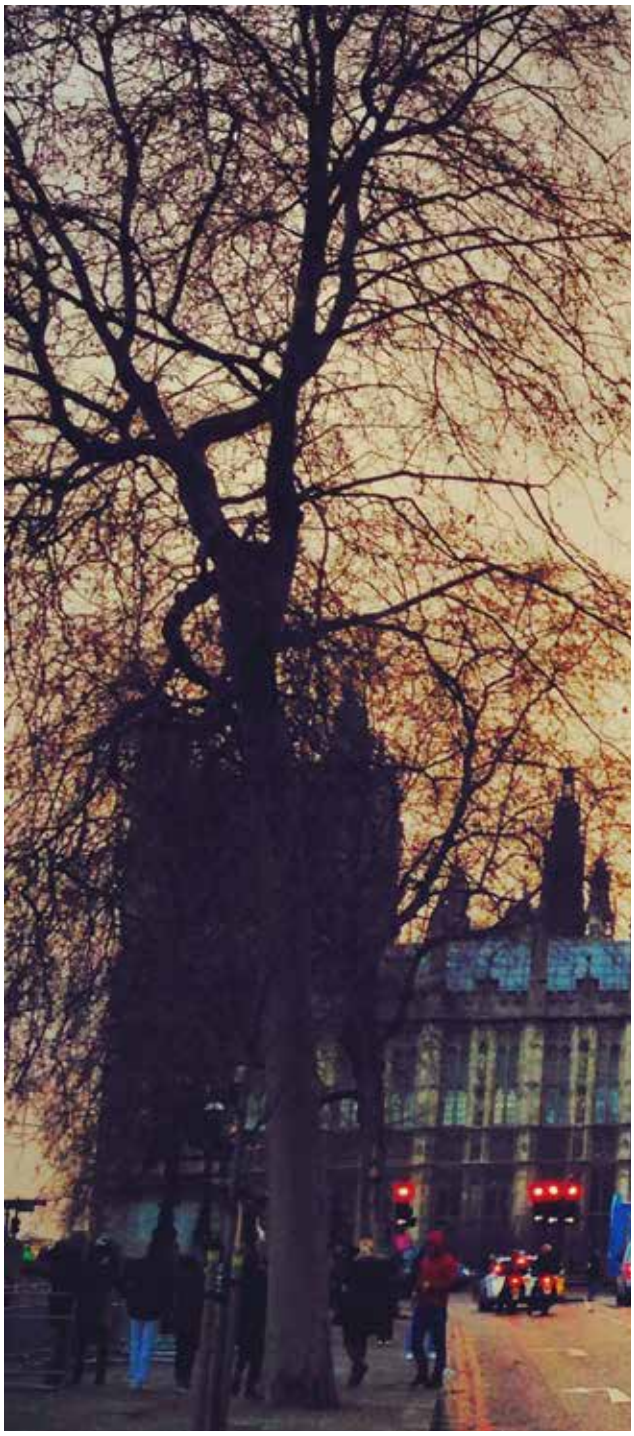
The UK's confusing regulatory landscape is mirrored in many other countries. Politicians and policy-makers may share the aim of simplifying regulations and providing greater clarity, but such an agenda must also account for international factors, and the extent that the UK's trading and political partners would move in the same direction with broadly the same approach.

Future regulations for cannabinoids are unlikely to be simplified and clarified by any one country acting alone, and neither is there consensus on how a new regulatory framework for cannabis would work. The USA remains the most influential country in this regard and even a firm decision on the legal framework for CBD (still awaited from the FDA) would help inspire a regularisation of the international approach in many allied countries. Currently the regulatory approaches of Common Law countries with shared economic and political interests are quite starkly different. According to federal law in the United States, CBD is a narcotic. In Australia, CBD is classified as a medicine, not a food supplement. Other countries take similar approaches.

This means that the UK, wherever possible in terms of the current treaty commitments, must consider these factors as it works to address deficiencies in its own regulatory approach, but also recognise how it can leverage the approach it has adopted, where its consumer cannabinoid market is the first to be properly regulated and poised for strong growth.

As legal approaches evolve, those countries that offer the most coherent and rational framework for regulating cannabinoids will attract the attention of policy makers and investors and could help shape the regulatory direction of travel in global forums like the UN. In the meantime, the UK Government should begin exploratory conversations with peer group countries that also share a similar legal framework to discuss how a common approach to the classification and trade in cannabis products can be achieved, in order to facilitate trade and investment and also the scientific exchange and research collaboration in this new frontier for healthcare.

Policy alignment discussions at this governmental level should start with Common Law countries including Canada, Australia, New Zealand and South Africa that have adopted reforms to their own drug laws in recent years and which all have permitted legal cannabis access and international trade in products to a greater or lesser extent.



6.5 For industry: cooperation and building trust

There are many responsible industries where regulators can afford to tread gently, and enforcement is a long stop and not a routine and widespread activity. However even in industries that present risks of consumer exploitation and public health harms, the players in the market typically take it upon themselves to organise around a set of commitments that they pledge to uphold, and which is the basis for self-regulation, over and above what is strictly required of them by law. These codes or principles can take a variety of forms, but they have some common features, including a commitment to compliance and very often, a statement around shared goals that go beyond profit, and mechanisms like transparency, collaboration and fair adjudication of complaints.

6.6 An industry commitment

The code that was developed by the Portman Group for the UK drinks industry is a good example of an approach that the legal cannabinoid sector could seek to emulate. The Portman Group's Code of practice on Alcohol Sponsorship[70] was first adopted in 2014 and is consumer-facing, giving a clear set of commitments about how complaints and other feedback will be dealt with. In addition, the same industry body produced a separate code on the marketing and labelling of drink products which it is possible to imagine the consumer cannabinoid sector adopting[71].

Other examples include The EU Code on Responsible Food Business and Marketing Practices[72] talking about 'responsible businesses' uniting behind a common aspirational path towards sustainability, aligning with a common agenda and contributing to tangible actions to help achieve the objectives set out; working with 'positive values….'. The Guiding Principles of the EU code (adopted in summer 2021) could have clear application and relevance to the UK's legal cannabinoid sector as they encompass the following:

- Legal compliance
- Positive collaboration
- Good faith and collegiality
- Inclusivity
- Science- and evidence-base
- Food safety
- Transparency and accountability
- Active participation

In the international sphere, there are a range of examples of these quality standards and industry codes, for example the Cannabis Quality Assurance project in Canada that is pioneering a model of best practice around cannabis production, supply and marketing for adult use products where those are legal[73].

These examples vary in their approach and the level of detail and codification they adopt, but they also reflect the relative maturity of the sector and the scale and nature of the market. For an emerging industry like legal cannabis in the UK, where certain product and supply chain standards are yet to be codified and widely promulgated, the high level ethical format is most appropriate.

The very nature of OBCR requires such an ethical standard or code to be devised collaboratively with input from users, patients, producers, prescribers and regulators, in discussion with government. The exact shape or terminology for such a project cannot therefore be determined, however analogous examples in parallel industries like food or alcohol provide some inspiration.

An example of a draft industry code:

We support cooperation aimed at achieving desired outcomes.

We commit to cooperating on the basis of trust to achieve positive outcomes for the consumers and patients who use legal cannabis products.

We wish to adopt a cooperative approach with trusted partners in delivering good/ethical benefits for end users, prescribers and their patients.

We support advancing the health and well being of patients and consumers in an open and ethical manner.

We share a belief in the value of the cannabis plant, determined by scientific enquiry, and will work to support a safe and responsible industry that can exploit that value in the interests of society.

To take proactive steps to show that UK companies in the cannabinoid sector commit to

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70 Portman Group (2019). Code of Practice on Alcohol Sponsorship. https://1kp8gk3a0fdl3qf9kb2wo9ei-wpengine.netdna-ssl.com/wp-content/uploads/2019/09/Code-of-Practice-on-Alcohol-Sponsorship-First-Edition.pdf

71 Portman Group (2019). Code of Practice on the Naming, Packaging and Promotion of Alcoholic Drinks. https://1kp8gk3a0fdl3qf9kb2wo9ei-wpengine.netdna-ssl.com/wp-content/uploads/2019/09/Code-of-Practice-on-the-Naming-Packaging-and-Promotion-of-Alcoholic-Drinks-Sixth-Edition.pdf

72 European Commission (2021). EU Code of Conduct on Responsible Food Business and Marketing Practices. https://ec.europa.eu/food/horizontal-topics/farm-fork-strategy/sustainable-food-processing/code-conduct_en

73 CQA Canada (2021). Introducing the Gold Standard Cannabis Quality Assurance. http://cqacanada.org/home/

be as compliant and trustworthy as any other legal industry would improve the dialogue with policy-makers and legislators, and give the whole sector a rallying point to demonstrate trust and the fruits of genuine cooperation - the foundations of a well functioning, regulated market.

6.7 Labelling and product standards

One of the most important areas where there is a trust deficit at present is in supply chain transparency and end product compliance. Regulators such as the FSA and MHRA are alive to the risks in the current supply chain and its often opaque and complex overseas elements, as well as the variability in quality and compliance of end products, whether those are retail items or prescribed CBPMs.

Responsible manufacturers and Specials suppliers have an interest in ensuring their own products are able to maintain high quality standards and already invest in screening processes to identify supply chain problems or issues that could pose risks to end users (for example product contamination, variable cannabinoid content levels, and the controlled elements of finished consumer products). However there is no industry consensus on what 'good' looks like, and traceability is a challenging concept in an emerging market with jurisdictional requirements that are not consistent.

In this context, technology can be a tool of trust, by providing companies in this sector with a robust means to demonstrate compliance, but also as a track-and-trace method to prove where products originate from - whether that is a CBPM produced domestically or one imported from the EU or further afield. Blockchain offerings in the market are the most promising example of this technology and allow for bottom up and top down scrutiny - from customers and ultimately patients and retail customers wanting more information to verify the source of a cannabinoid product, and to empower regulators to improve their surveillance of the industry to ensure companies are compliant.

Some companies are already adopting this approach, and in future, the reduced costs of these software platforms should make them appealing products for cannabinoid companies who want to demonstrate a level of trust in a marketplace that has often been reliant on self-assurance of compliance, without a way to verify the activities that can generate risks in the supply chain. The show-not-tell approach to trust in this sector going forward would leverage technology like blockchain to build trust where currently it is lacking.

Supply chain visibility and traceability assists in mitigating risks related to operations, stock management and tracking batch to batch variations and risks to the business as a result of supply chain variations. This automatically leads to a harmonised and standardised platform by tracking any non-conformities and formulating corrective and preventative actions. The supply chain transparency and visibility leads to continuous improvements in streamlining testing methodology, labelling & certificates of analysis. This increases consumer and investor confidence and also enables regulators to take a more 'light touch' and permissive approach, knowing that the whole process can be audited efficiently and on-demand when required.

6.8 Testing and assurance

In the absence of mandatory production and product quality standards for CBPMs, the UK sector is not required to adopt consistent approaches, and variability can result, and is often unavoidable. The health risks and other imperatives make it more important that raw materials and finished products undergo robust analytical assessment at several stages. Laboratory testing is widespread in this sector already, but robust testing practices are not adopted everywhere, and regulators have good reason to doubt the testing marketplace and how it operates - especially with reference to laboratory reports from products tested overseas.

This is not a novel or complex question to address. Testing to recognised standards is common in the pharmaceutical and food manufacturing sectors. The UK already has some of the highest standards in the world, and some of the most advanced testing organisations - several of whom have begun to service the cannabinoids market. The voluntary adoption of a shared set of industry-wide standards for systematic testing of all products should be happening, and as the market expands and consolidates, the time is right to reinforce the importance of testing and the vital role that the ancillary industry of laboratories can play in ensuring the highest quality standards are being achieved.

There is currently no Home Office, DEFRA or DHSC/MHRA guidance on the testing of hemp crops, CBPMs or consumer/CBD finished products, and unlike Australia, no mandatory testing obligation on manufacturers. To close this gap and further reinforce moves to encourage an on-shoring of the legal cannabinoid sector and regulations that allow the UK to capture more of the value of the international supply chain, the government could mandate independent third-party testing of all materials destined for the consumer or medicinal markets using only ISO-accredited laboratories based in the UK. There is already a competitive market of testing organisations who would operate in this field, and it would generate direct investment into UK labs that have the trust and expertise to support the industry to achieve compliance and high quality outputs.

6.9 Labelling and product standards

For products themselves, how they are marketed is a commercial decision so long as the language used and claims made do not convene MHRA rules, or breach guidelines laid down by the ASA. However the end products that this sector produces are not subject to specific rules that would guarantee better protection for the consumer and reduced risks to the public. In two related areas, the current system is flawed - packaging rules for CBPMs, and labelling requirements for CBPMs and consumer cannabinoids / CBD retail products.

Suppliers of CBPMs in the UK – whether imported or those that might be produced domestically in the years ahead – have a shared interest in establishing their reputation for high quality products. In order to safeguard patients and to provide a trusted product that prescribers and clinics can have confidence in, certain basic requirements are necessary that go beyond the conditions demanded of Specials providers (for example, meeting GMP standards in production). As new companies enter the sector and the market expands, a common set of product standards would ensure a level playing field and also help manage risk. It is unacceptable that CBPMs must be despatched from pharmacies by a controlled drug courier, but flower can be supplied in foil packets with no detailed labelling and oil products containing THC can be sent out to patients with no standardised label format or health warnings.

A better model is the medicinal cannabis market in Australia, which is also operating in the unlicensed space, but which has to comply with national requirements, set out by the TGA. These rules apply specifically to unregistered (or unlicensed) cannabis medicines. The latest version of those regulations (Order 93, published in March 2022[74]) is a model that the UK should adopt, covering manufacturing standards, testing protocols, and product labelling and packaging rules.

At present, medicinal cannabis dispensed by pharmacies can also be supplied without links to Certificates of Analysis that can give details on the composition of the product, which is especially pertinent to patients using flower products to smoke or vaporise their medication. In addition, Specials manufacturers are not required to use child-safe packaging for oil products containing THC, which may pose a risk to under-18s in a household where a patient lives. Regulations require an expensive courier to deliver a signed-for prescription product dispensed by an online pharmacy, but regulations to protect the end-user at the point of receipt and the end product itself could be made safer.

Within the CBD sector, companies have adopted some examples of best practice in giving their customers detailed information on the product's source and ingredients, but this is not widespread, and the level of detail is highly variable. Terminology is also inconsistent and there is no guidance on what words or phrases are potentially misleading. This is one area where it seems irresponsible for the government to set no packaging requirements for food supplements containing cannabinoids - despite the size and diversity of this novel category - and so have only a minority of responsible companies adopt transparent labelling, amongst thousands of retail branded products, when it would be simple for every company on the FSA's public list to do so.

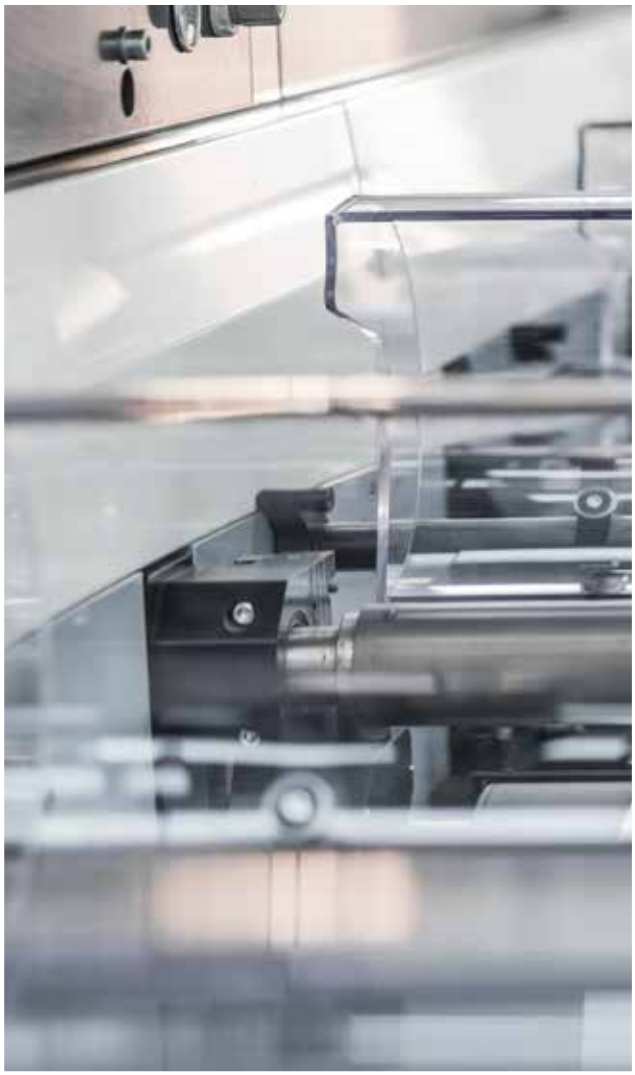
It is also unjustifiably lax, given the strict constraints around licensing of cultivators and manufacturers, for the government to set no rules on finished product packaging or labelling, such that some CBD products have information on the labels that far exceeds that of CBPM products containing controlled substances prescribed to patients. There ought to be obligations around packaging and labelling for both sectors, but the medicinal cannabis sector should be under tighter requirements as they now are in Australia - with information that patients receive required to be consistent and more detailed than food supplements, given the nature of the medicinal product and patients' need to trust what medication they are relying on.

74 *Therapeutic Goods Administration (2022). Guidance on quality requirements for medicinal cannabis products: TGO 93. https://www.tga.gov.au/sites/default/files/guidance-on-quality-requirements-for-medicinal-cannabis-products.pdf*

The 'Gateway' review commissioned by the former Health Secretary[75] made two key recommendations on availability and supply of quality CBPM products and these should be taken forward without delay:

DHSC and MHRA should work to provide access to information on good quality products, manufactured to GMP standard and with consistent ratios of cannabidiol (CBD) to delta-9-Tetrahydrocannabinol (THC) between batches.

NHS England and NHS Improvement should work with suppliers to ensure that sufficient stock of good quality CBPMs are available and that the products available offer the best value for the NHS, including scoping options for UK manufacture.



75 NHS England & NHS Improvement (2019). Barriers to accessing cannabis-based products for medicinal use on NHS prescription: Findings and Recommendations. Barriers to accessing cannabis-based products for medicinal use on NHS prescription (england.nhs.uk)

6.10 Compliance and Enforcement

The UK's sector is already operating within a legal framework, even if at times the regulations are not always clear and some organisations have needed to seek specialist legal counsel and consultancy advice to understand what to do to become compliant. In the next few years, as the FSA's authorisation process unfolds, and more clarity is offered by the Home Office on trace limits for consumer CBD products, we can expect a consensus to emerge around what compliance looks like.

Most companies are already responding to compliance by self-regulating using current good manufacturing practices (cGMP), good laboratory practices (GLP) and British retail consortium (BRC) standards. The use of supply chain track & trace technology will help the industry to assist in standardisation and harmonisation in each sector of the supply chain, laying the foundation for regulator, investor confidence and ready for enforcement as and when it happens.

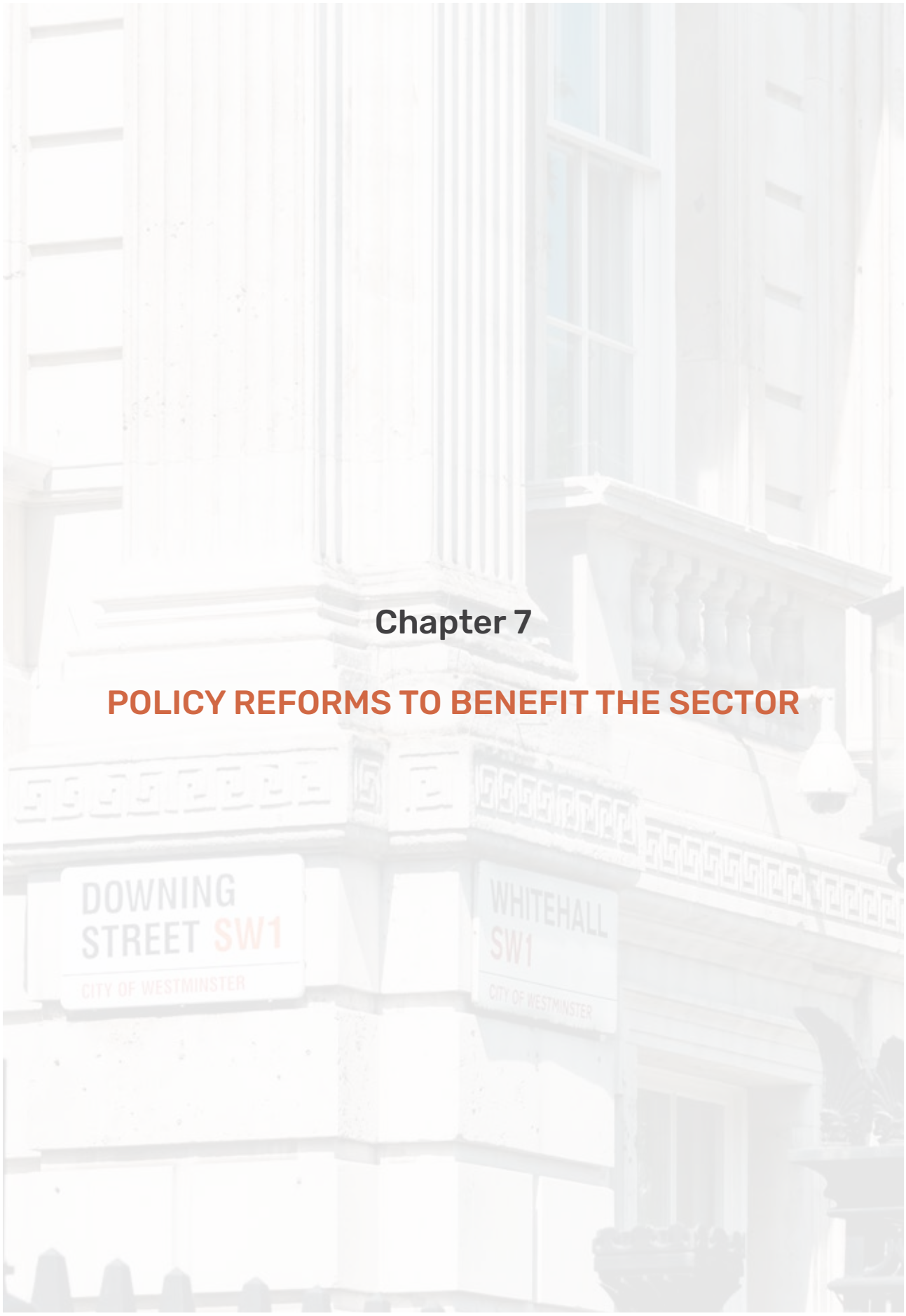
Conventionally, regulatory enforcement activities in this sector have been reactive, often in response to complaints, but regulators can now use technology, including AI-led surveillance of online content, to fulfil their enforcement role. This includes misleading advertising (ASA), unwarranted medicinal claims (MHRA) and the active pursuit of CBD products not on the FSA's public list (Trading Standards).

All these authorities and regulators understand that the sector - principally the consumer cannabinoid sector - includes some non-compliant activity, and some ongoing breaches of public guidelines. Examples include import of unregistered seed varieties, the sourcing of cold-press extracts from low-THC cannabis flowers grown under licence in the UK (not permitted by law), or the launch of new retail CBD products when these were not on the market prior to the 13 February 2020, as per the FSA's deadline.

For activities like these to be discouraged they need to be addressed and proportionate enforcement needs to happen. Regulators must decide the level and nature of enforcement that is warranted in each case, and it is not a policy question of what type of enforcement method is most applicable. The law already provides Trading Standards, food safety inspectors, healthcare regulators and the police with the powers they need to sanction breaches of the law. However, given the limited and sporadic nature of enforcement to date, it will become more important over time that the basic standards for the industry are upheld.

The regulatory philosophy we support is one that places an emphasis on trust and cooperation, with mutual incentives for the industry to self-regulate, rather than a reliance on top-down enforcement where traditional sanctions are used to deter and punish malpractice. Occasionally that will be necessary and it is in the interests of the legal cannabinoid sector that flagrant breaches are responded to promptly. But short of formal sanctions, there are also a range of warnings and advisory efforts that can be made to ensure rules are followed. The equivalent Irish regulator to the FSA does not have enforcement powers itself, but it does take a proactive approach when unlawful CBD products are brought to their attention - sending warning letters to the companies concerned and publicising the fact. In the US, the FDA has done the same, signalling to the wider market what breaches are deemed serious and giving those companies a chance to bring themselves into compliance.

Even if enforcement is not widespread or heavy-handed, building trust with regulators and improving the reputation of the industry does depend on demonstrating compliance and also cooperating to root out bad practices. If the CBD retail sector continues to be undermined by a proliferation of products that are not permitted to be sold in the UK, then the industry itself has a duty to support regulators and Trading Standards to identify non-compliant products and help protect the consumer. Any systematic reporting of breaches by consumers or companies should receive a response from the regulator and what industry supplies can assist them in the surveillance of the market.



Chapter 7

POLICY REFORMS TO BENEFIT THE SECTOR

7 Policy reforms to benefit the sector

The analysis in this report and the principles we have outlined lead us to recommend a series of policy changes to help bring about the positive and shared goals that we articulate. The recommendations are directed both at regulators and industry, with the understanding that both parties have an obligation to cooperate to steward this new industry and support it to develop in an innovative but also safe and responsible way.

Some of the following 20 recommendations have been called for before by The Centre for Medicinal Cannabis in 2019 and 2021, and at other times by the Conservative Drug Policy Reform Group, and by numerous reports by All Party Parliamentary Groups, and other industry bodies. Some recommendations are entirely new, and flow from the findings of our research, where it was clear to us that reforms are needed to support trust and cooperation. Other recommendations reflect those made in one or more government reports, which have yet to be acted upon.

The UK has a really good opportunity to build off some solid foundational policy work that has been done particularly in places like Canada, and better it….

For example, by not allowing for all GPs to prescribe, we're effectively putting people into the black market, because people are going to try to access this whichever way they can, so if they're not going to be able to get it through the legal market they're going to go to alternate channels, and that is not in the public health approach. In fact that is contrary to the public health interest. Arguably not only are you stifling access for patients, you are also willingly putting them into the black market. That is a serious and abject policy failure from a public health perspective by the government.

Once we start to see GPs prescribing, you will see a real opening up of the industry in the UK.

Deepak Anand, Principal, ASDA Consultancy Services

Legislative or Structural Reforms

The following policy recommendations require changes to law or regulations and/or involve devoting taxpayer funding towards new initiatives that need parliamentary approval.

1. **Establish a single 'steward' authority to govern and guide the entire sector, at arms length from ministers.** This new agency would require legislation to set up but it would inherit clear responsibilities and could become the home for developing a specialist agency with expert staff recruited from a range of sectors.

2. **Provide long-awaited legal clarity in respect of trace amounts of controlled cannabinoids in retail products and revise the 2001 MDR to set the permitted 'zero THC' level**. This will give industry the confidence to invest in a high quality supply chain with robust analytics to support proof of compliance, and clear up any remaining confusion among retailers and ultimately consumers. Along with the ACMD recommendations it is advisable to introduce British Pharmacopoeia monographs on CBD & Cannabis extracts to assist industry to maintain self-compliance.

3. **Encourage the creation of a UK 'Centre of Excellence' to advance the evidence base for cannabinoids and their applications**. Drawing on the strength of the UK's higher education sector, this institute could be established with the support of major universities.

4. **Roll-out a national trial for GP prescribing of CBPMs based on an opt-in model for doctors' consent and systematic data collection to inform future guidelines**. Another dimension could be that such prescriptions, when issued in the private or public system, would need to involve patient enrollment in a national registry to help gather real world evidence.

5. **Update hemp farming rules to permit licensed growers to extract the controlled parts of the cannabis plant on site under the right conditions.** Farmers would need to partner with an approved transport provider or third party

distributor to move controlled substances to market and maintain more detailed records of their seasonal yields.

6. **Modernise the Proceeds of Crime Act provisions to create an explicit exemption for private enterprise by entities operating in legal jurisdictions**. Modelled on the changes already incorporated into law in Jersey, the UK government should update POCA to permit investment by entities involved in cannabinoid commerce, insofar as those entities are engaged in lawful activity in a jurisdiction where a regulated regime exists. This would remove the chilling effect associated with concern over exposure to unlawful recreational cannabis and give new confidence to investors to consider UK ventures. With this change, institutional investors can be expected to look again at opportunities to invest in the legal cannabinoid market, supporting new start-ups and established companies to expand.

7. **Permit licensed suppliers to export CBPMs in bulk outside the UK where their customer is a licensed party in the overseas jurisdiction**. This would help UK-based CBPM companies with new customer acquisition in foreign markets and supply chain efficiencies such that medicinal patients in the UK could benefit from reduced costs for their treatment.

8. **Consult with patient groups and police forces to introduce Home Office guidance for frontline officers to check and verify patients** who have a valid, current CBPM prescription, potentially linked to a national patient registry when this is introduced.

9. **Take forward commitments for a national patient registry** and begin coordinated data collection efforts for real world evidence emerging from CBPM use among British patients accessing treatment privately (and in time, on the NHS). As recognised by the DHSC review in 2019: "NHS England and NHS Improvement, DHSC and Devolved Administrations should work with industry and academia to scope the development of a national UK patient registry to collect a uniform data set, across all indications, for patients prescribed a cannabis-based product for medicinal use in the United Kingdom."

A single strategy and a single steward: a dedicated and expert authority to control, guide and licence the industry

We propose that the government should legislate to create a Non-Departmental Public Body (constituted as a Non-Ministerial Department) called the Cannabinoid Control and Licensing Agency or CCLA. This new body would have a UK-wide remit and would take the lead on all aspects of natural and synthetic cannabinoid research, production, distribution and sale, adopting all of the roles currently discharged by the UK Home Office.

This new body would:

- Assume all existing functions of the Home Office in respect of licensing for cultivation, transport, production and handling, along with an inspection function;
- Develop its own in-house expertise and formalise academic links with UK higher education drawing from scientists and officials working in the Home Office, DEFRA, BEIS, DHSC and relevant regulators (MHRA and FSA);
- Build and promote a single public-facing portal for commercial, public and academic audiences where guidance would be published, reports and data hosted, licensing details published and news on the industry in the UK collated;
- Establish formal links with the respective regulators (MHRA, CQC, FSA and FCA) and also funding bodies (InnovateUK, NIHR) to communicate information on projects and licences, and to advise them on applications underway and also to direct applicants to the correct channel for their business or academic needs.
- Host an incubator and cannabinoid innovation fund for UK pilot studies in areas aligned with the government's R&D strategy to support

key areas like life sciences and new agri-tech opportunities.

Functions of a UK Cannabinoid Control and Licensing Agency (CCLA)			
Law and guidance	Licensing and inspection	Ecosystem development	Pilots and innovation
The CCLA would author all relevant guidance for the sector and publish law updates on the application of the 1971 Act and the MDR2001 (or its successor) to provide legal clarity to the sector and to support organisations to be compliant.	The CCLA would evaluate and approve all licence applications in all categories along with leading on inspection of licence holders and maintaining a public database of licensees setting out the details of the licence holder and the terms of the licence.	The CCLA would signpost organisations to the correct regulatory pathway for their business or product and develop academic partnerships to broker connections between cannabinoid science and commercial initiatives	The CCLA could manage an innovation fund for translational research and award funds annually for mercialisation of cannabinoid science and innovation in UK settings, complimenting NIHR/ InnovateUK grants

Market & Industry Reforms

These reforms do not necessarily require amendments to law and can be adopted more quickly by regulators and the existing players in the market:

Create and mandate a consistent set of manufacturing and labelling standards for CBPMs that provides more information to patients and links to a batch-specific Certificate of Analysis (CoA). Modelled on the Rule 93 Guidance imposed by the TGA in Australia, these production standards and testing and labelling requirements would create the 'floor' that is currently missing from CBPMs, other than their need to adhere to generic GMP rules. This would require CBPM suppliers to adopt best practice around product safety with, for example, child-proof containers and standardised warning messages.

Require end-product testing for all CBPM and consumer cannabinoid products (imported or locally produced) using independent ISO accredited laboratories in the UK. This would also stimulate expansion in ancillary services like laboratories for ensuring the industry standards are adhered to. In time the sector should adopt an industry-wide set of benchmarks for cannabinoid testing quality, potentially utilising the protocols adopted by those laboratories operating in other legal jurisdictions.

10. **Permit licensed CBPM suppliers to utilise mainstream, trackable, signed-for delivery options to reduce the cost to patients of private CBPM prescriptions**. With auditable records of licensed pharmacists and new rules requiring child-safe packaging, it is no longer necessary to require expensive controlled drug couriers for delivering CBPMs to patients.

11. **Create a single formulary of available CBPMs which provide doctors with an up-to-date list of medicinal cannabis products available in the UK market**. This would enable patients to request certain types of product and for prescribers to have a wider view of what types of quality assured products are currently available. The most used CBMPs under specials are Cannabis dried flowers, and there is now enough information to introduce a British Pharmacopoeia monograph on Cannabis flowers to uphold British quality standards.

12. **Provide clarity on the legal status of CBD vaping products and issue guidance on the permitted ingredients in a vaporizer used for cannabinoids, either as a consumer CBD or CBPM delivery device**. Consider additional research on the long-term health impact of vaping, and the safe ingredients for e-liquids.

13. **Establish an expert committee to review the approach of the Veterinary Medicines Directorate to explore options for a more proportionate approach to CBD use by veterinarians**. A rethink on the approach announced in 2019 would reflect how pet owners and farmers are already using CBD unofficially, and would bring consistency with the pragmatic approach of the FSA.

14. **Examine and integrate policy on hemp cultivation activity into broader Net Zero efforts**. DEFRA should commission an assessment of the contribution hemp

cultivation could make to the UK's Net Zero goals and begin a policy development process to devise incentives within the new post-Brexit agricultural subsidy regime that rewards farmers for carbon sequestration and soil remediation using hemp cultivated domestically, with the possibility of such licensed activity generating tradable carbon credits for off-setting.

15. **Develop and roll-out more comprehensive surveillance of the UK border to detect illicit imports and non-compliant CBD products entering the UK by sea or air freight**. UK Border Force should resource a suite of methods to discourage the importation of illicit cannabinoid material and deter the grey market from seeking to exploit the UK's consumer market.

16. **Clarify with guidance that any product derived from synthetic cannabinoid synthesis is by definition novel** and must follow the conventional risk-based route for approval as a medical treatment or as an ingredient in food.

17. **Proactive and proportionate enforcement from regulators to pursue breaches of food law**. The FSA, working with Trading Standards, needs to develop a strategy for enforcing the Novel Food regime based on a proportionate approach that involves a range of graduation sanctions, beginning with the type of activity that their equivalent body has adopted in Ireland, by using published warning letters to notify consumers and retailers of a product's status.

18. **Collaborate on an education initiative to improve general understanding among distinct professional and public audiences**. Institutional partners in respective sectors could partner with industry bodies to support education and training of lawyers, accountants, doctors, pharmacists and farmers. In addition, public-facing resources could be developed for ordinary citizens to support them to learn about cannabinoids and use their knowledge to make informed choices.

Taken together, the reform recommendations are the tactical steps that the UK needs to take in order to realise the strategy that we recommend. They vary in complexity and controversy, but all of them are possible to implement if the political and industry will is there, and many are inspired by or based upon international precedent or changes adopted in comparable jurisdictions who have wrestled with the same challenges. And while they support each other in helping move the legal cannabis sector forward, some recommendations are clearly more important than others in terms of removing constraints, addressing outstanding barriers, and properly calibrating regulation so that it is tighter in some areas and more proportionate in others.

First steps on the road of reform

The regulatory framework we advocate cannot come about overnight - it will require collaboration between government and industry over many years. Some changes would require legislation or extensive consultation in order to be implemented effectively, and other reforms are only possible subsequent to some priority changes taking place first.

The CMC's submission to the Prime Minister's 2021 Taskforce on Innovation, Growth and Regulatory Reform (TIGRR) made a number of explicit asks of government, and they align with the basic approach we think is needed for the sector, to level up the quality and reputation of the legal cannabinoid sector, and to complement what the industry and regulators can do themselves.

For this to happen, multiple government departments would need a coordinated plan that was properly sequenced so the sector could cooperate and the direction of travel is clear. This is why we believe the creation of the UK's first cross-government strategy for the legal cannabinoid sector is so necessary now. The following actions are those that only the government can take, and after consultation with the sector and with patients and consumers, they could form the basis of the pillars of a new UK strategy to cultivate the world's leading cannabinoid sector:

Pillars of a new government strategy

- **New regulations that encourage on-shoring of the consumer cannabinoid supply chain** (e.g. mandatory testing of products in UK ISO accredited labs; permission to extract from domestically cultivated hemp; schedule 1 licences for domestic CBD manufacture)
- **More encouragement for regulators (e.g. FSA and Trading Standards) to be proactive** and lean in to shape the market's development, using their soft power to issue published warning letters and encourage retailers to adopt only CBD companies/suppliers, and deploy tools like new AI analysis of online commerce to identify rule breaking
- **More proportionate regulation of the medicinal cannabis / Specials market to avoid adding unnecessary cost** on to private patient prescriptions, for instance in terms of product shipping
- **Encourage a shift towards true traceability** by requiring data to verify source material for imported products and mandate standardised labelling of all CBPM products
- **Using existing R&D support mechanisms (InnovateUK etc) to catalyse the start up ecosystem in cannabinoid life sciences**, with some future calls and RfPs devoted to this sector specifically
- **Exploit post-Brexit regulatory freedoms to generate competitive advantages** (a sovereign permitted hemp variety list) so that the UK can distinguish itself from EU and USA (EFSA/FDA) markets
- **Devote more research funding (NIHR and agtech grant schemes) to the cannabinoid sector** and encourage university partnerships with the commercial sector to expand scientific study in the UK
- **Create a dedicated agency to coordinate, sign-post and act as steward and expert authority on the whole cannabinoid sector**, responsible for licensing, guidelines, and sector updates, and insulated from direct ministerial control
- **Trust those actors who are already professionally accredited (NHS, NIHR research initiatives, doctors and pharmacists) and adopt proportionate regulations** where their activity is already monitored, e.g. prescribing and dispensing
- **Establish a standardised medicinal cannabis ID card scheme for registered patients** and issue supporting NPCC guidance to police forces to give bonafide patients better legal protection from arrest and harassment
- **Increase enforcement where the sector has weak spots** and can be exploited by non-compliant and illicit actors at key touchpoints or in harder to police domains (e.g. border control, the grey market of online CBD retail)
- **Baseline and begin systematic data collection on the size, nature and economic contribution of the three legal cannabinoid sectors** (cultivation, consumer and medicinal) and publish these
- **Encourage promotion of the sector by overseas agencies/trade organisations (Department for International Trade, and Trade Commissioners etc)** to sell the advantages of the legal, well regulated UK cannabinoid sector to foreign companies and investors.

Three Quick Wins

The following 'quick wins' would give the legal cannabinoid sector confidence that the government was prepared to move in the right direction, opening up dialogue and public debate about the sector and among stakeholders, fostering further changes.

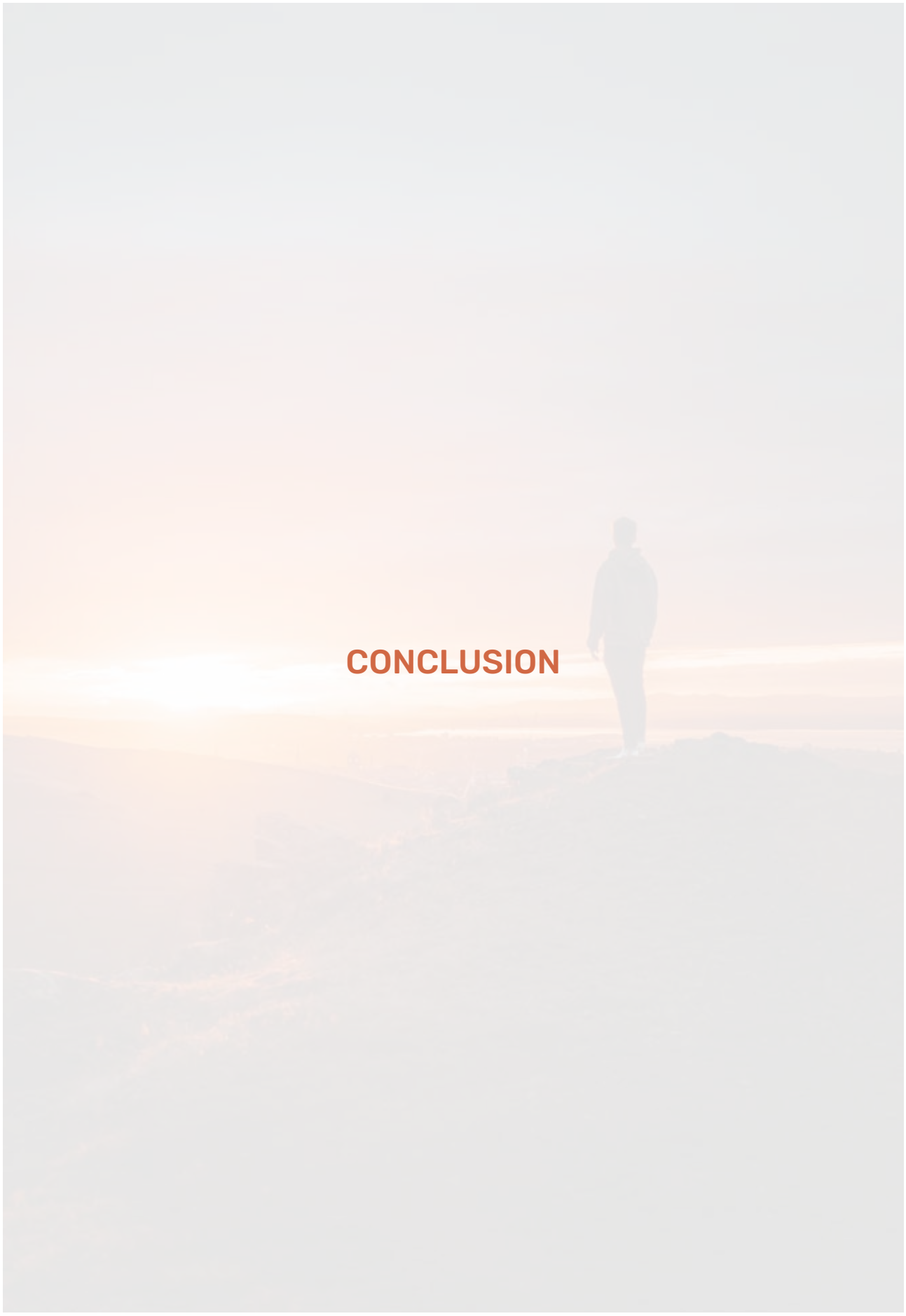
In the next 12 months, the following would represent the first steps on the road of reform:

Set up a single online portal - designed to bring together all government advice and guidance in a single place, covering the three distinct sub-

sectors - industrial hemp, consumer cannabinoids, and medicinal - and in advance of the creation of any dedicated agency, the portal would help inform the market and guide applicants, as well as hosting the most recent published data relevant to the industry

Establish a legal industry roundtable - taking inspiration from the Canadian Government's commitment to do the same in 2022, this new arrangement would give the legal sector a conduit to policy-makers and provide a single forum for raising issues, and offering constructive proposals to government. It could also act as the venue for deliberating on a future industry-wide Ethical Code or equivalent to help foster trust.

Publish more and better data - on prescribers, licence holders, prescriptions, and enforcement, so that the political and policy debate can be informed with real data on the current state of the sector. Prescriber and prescription data should be published quarterly, on an anonymised basis, in line with current GDPR requirements.



CONCLUSION

Conclusion

The primary purpose of this report was to explore the right regulatory approach to the UK's legal cannabis sector, informed by original market and policy research, consultation with stakeholders, and new data around public attitudes. Based on this analysis, the report has described a regulatory approach that could support the legal sector to expand and develop in a way that achieves some shared purposes that are widely perceived to have economic and social value.

In addition to setting out this framework, we describe a vision for a legal cannabis sector that moves beyond a policy of control and containment, so that the UK can maximise the potential it has to advance scientific discovery and innovation, improve well-being, create jobs and investment in local economies, and enhance the health outcomes of potentially millions of people. In addition to these goals, we also outline key pillars of a well-regulated legal cannabis sector, and based on these, have drawn together policy recommendations to support this direction of travel.

The cannabinoid industry has a very bright future ahead but all stakeholders - industry, government and regulators - must work together, and end-users like patients and consumers have a key role too. Our main conclusion from this research is not that the UK's legal cannabis sector is over-regulated, or merely suffering from outdated rules, or simply needs red tape and unwarranted regulations to be stripped back. In some specific areas that was our conclusion. However, overall we recognise that the value that accrues to the UK from exploiting the cannabis plant in all its legal forms is largely the result of Britain's legal and regulatory framework which itself engenders compliance and trust, or should do. There is no advantage for the UK in a race to the bottom in product standards or quality controls around cannabis and how it is utilised. It is a question of how to optimise the right kind of regulations.

"We have everything in place to make the UK the global go-to hub for cannabinoid scientific excellence, all we need now is the regulatory environment to support it; now is the time to use it or lose it."

Dr Andrew Yates, Chief Scientific Officer, Artelo Biosciences

The approach we took was to decide what the right outcomes were, and to apply OBCR principles to determine how regulations should be best calibrated, or introduced where they currently did not exist. The OBCR model remains the best example of how to regulate effectively. Everyone engaged in this industry should consider its merits and the way it would change how they operate today. As an approach it would also improve on the current jungle of regulations that lack coherence, and which are often unnecessarily restrictive or unclear, and in areas replete with constraints and almost entirely devoid of incentives for people to enter the market or do the right thing when they are in it.

In some areas, such as hemp farming, not only are there almost no meaningful incentives to participate, but existing regulations are far too restrictive and have not kept pace with the economic opportunity that the UK's consumer cannabinoid market now presents. Not only are laws around hemp cultivation disproportionate and anti-competitive, they are antithetical to the development of a UK industry and the economic opportunity hemp cultivation could offer to rural economies. This is not to mention the benefits to the soil and wider environment.

In other areas, such as consumer cannabinoids like CBD, we have seen the result of too little regulation. This has led to the emergence of a large, unprofessional grey market, which now needs tighter rules to safeguard consumers. This tightening of the rules is essential if we are to build and sustain public trust, backed by targeter, sustained enforcement for those who do not comply. And in the arena of medicinal cannabis, the picture is more complex, with regulations too onerous and restrictive in some areas, and too lax (or entirely absent) in others, despite the greater need to ensure patients are protected and able to access quality, reliable products.

The goal throughout was to ensure that the regulations or guidance can be justified in terms of risk and protection of the public from harm, without depressing economic growth and scientific and technological innovation. Overall, this calls for a coordinated assessment of the rules we have, and a single, coherent cross-government

strategy for the sector built upon a modern set of regulations. In tune with the principles of OBCR, this new regulatory framework should encourage collaboration between the government, the regulators and the regulated parties, and ultimately foster trust through engagement, openness and self-regulation wherever possible.

From containment to nurturing

This report is the CMC's attempt to bring some coherence to how the government, Parliament, the NHS, regulators and other key stakeholders should see this diverse, novel and dynamic sector, especially given how quickly it is evolving and the potential it represents in terms of health, well-being and prosperity. Ultimately, our suggestions for how it can thrive in future are designed to improve the sector for the benefit of consumers, patients, prescribers, suppliers, and our academic and investor communities.

If adopted, the right regulatory framework outlined in this report will achieve three important strategic objectives for the UK as a whole:

- **Competitive advantage for the UK post-Brexit**, helping the country to leverage its historic and economic strengths in a rapidly growing and unprecedented global industry;
- **Regulatory best practice giving early mover advantage**, helping to pioneer new approaches to regulating a novel industry that other jurisdictions on a similar path can choose to emulate;
- **Scientific advances and innovations**, with pioneering new treatments, manufacturing methods, and end-user products, helping the UK to reinforce its reputation as the home of world-leading discoveries that improve our environment, our health and our quality of life.

In the appendix, we summarise the policy and law in other comparable jurisdictions, to highlight how other countries are approaching some of these issues. However, there is no one country's model that is an exemplar, and the cultural and political contexts of each nation have shaped their own approaches and will continue to dictate how legal cannabis sectors develop there.

It is our belief that the law and rules that govern a regulated industry like the legal cannabis sector are fundamental to how that sector develops (or even if it develops), and its ultimate trajectory of growth. Those laws and rules are more important than public attitudes or media opinion, but they are influenced by these factors, and they will be different everywhere. However none of them are fixed in stone, and they can be adjusted in light of experience and new data, or in response to political or industry pressure. However they emerge and evolve, regulations should be crafted by politicians and their civil servants in a way that at least attempts to be coherent and consistent. The UK's cannabis regulations are not in that place currently.

And so while the UK must chart its own course, and the development of the legal sector here will have distinctive British dimensions, there are also important country parallels that policy makers and ministers should be learning from in order to ensure a level playing field and to give the UK the best possible chance of creating and sustaining a thriving new industry.

The Australian market is the closest parallel to our own, and offers both inspiration for what reforms might be sensible, and also some warnings for what the UK should look to avoid. The German market is also an example where there were many of the same barriers, but patient numbers and the industry overall has scaled much more than the UK:

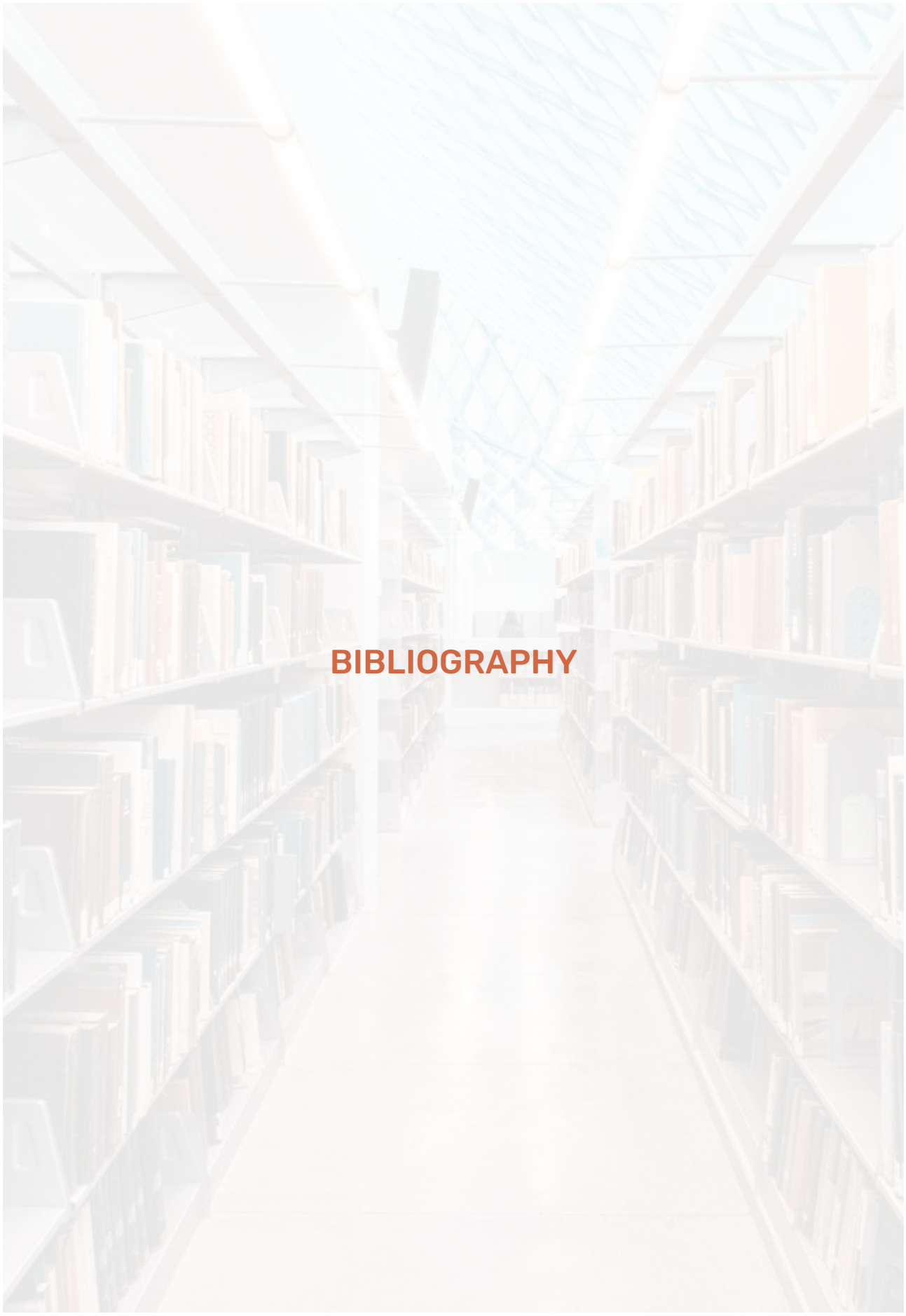
"The need for more research is often touted as the key to broadening access to medical cannabis. Without minimising the importance of research, stakeholders in the UK interested in broadening access to medical cannabis should also look at the structural differences between the German and UK medical cannabis programs. More research is needed both in the UK and in Germany, but it is not the volume or quality of scientific research or clinical trial results that explains why Germany has a much larger population

of medical cannabis patients than the UK five years after the law changed. The most important of these pillars being public health insurance coverage; that any doctor – not just specialists – be allowed to prescribe unlicensed CBPMs; and a policy emphasis on authorised in-country cultivation to limit the dependency on imported products, possibly making cannabis-based end-products more affordable."

Alfredo Pascual, Investment Analyst, Seed Innovations

It would be a missed opportunity for this government to continue to take an uncoordinated, disinterested or laissez faire attitude to the sector as a whole, and to have no strategy – publicly articulated or otherwise – about how the UK should shape and steer this new legal sector to capture the opportunities it presents. The legal cannabinoid sector is like the UK's space industry twenty years ago. The seeds are there for rapid growth but it cannot happen without a clear strategy built upon coordinated government stewardship and the ambition to not just tolerate, but actively nurture the sector to expand and mature, so it attracts more investment, jobs and innovations, and secures widespread support and public recognition.

The UK's legal cannabinoid sector is already making progress but its potential has not yet been unleashed. We propose that a strategy close to the one proposed here would help to deliver on that potential. Such steps would not just be politically responsible and many years overdue, they would also be welcomed by the growing number of people in the UK whose lives, health or livelihoods are touched by cannabis, or might be in the years ahead.



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APPENDICES

APPENDIX I - Legal sectors

The following provides additional information on the current law and regulations governing activity in the legal cannabinoid market in the UK and some of the outstanding policy and scientific challenges:

Medicinal

"Any substance or combination of substances presented as having properties for treating or preventing disease in human beings."

MHRA: A guide to what is a medicinal product[76]

For a defined medicine, we need to know:

What is the composition and ratio of all the components with respect to each other?

Consistency of the final product for each batch manufactured

The plant derived CBPMs contain a mixture of plant matrix and other cannabinoids. CBPMs containing tetrahydrocannabinol (THC) come under schedule 2 but the use of CBPMs containing THC for any R&D activities or clinical development comes under schedule 1. This imposes overwhelming restrictions on the cannabinoid developments in all sectors.

Moreover, there are currently no CBD products which are authorised in the UK for veterinary use. A veterinary surgeon may prescribe a legally obtained human CBD product under the provisions of the prescribing cascade[77] [78]. However, there is widespread use of CBD products for animal use.

Challenge:

- Ratio of other components & batch-to-batch consistency
- R&D/innovation work and need for schedule 1 licence requirements and complexities
- CBMPs or consumer cannabinoids used for humans are not allowed to be used for animals without a veterinary surgeon prescription in the UK as compared to most countries.
- Use of CBD products for animal use

Specials

'**Specials**' are products which have been specially manufactured or imported for the treatment of an individual patient after being ordered by a: doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber[79].

As per MHRA guidance, a Wholesale Dealer's Licence holder must only supply Specials to:

- The Wholesale Dealer's Licence holder
- The holder of an authorisation granted by the competent authority of another European Economic Area (EEA) State authorising the supply of those products by way of wholesale dealing
- Any person who may lawfully supply medicinal products in circumstances corresponding to retail sale
- Any person who may lawfully administer those products

The complexities of the above regulations lead not only to logistical costs but also to significant time delays.

Challenges:

- **Prescribing restriction**: Due to the limited evidence base and their unlicensed nature, only Specialist Registered clinicians of the General Medical Council (GMC) may prescribe a CBPM, although in rare cases a GP may be able to under 'Shared Care' protocols. This condition was laid out in the amendment in 2018 to the UK MDR2001, so it cannot be varied by the devolved governments who administer their

76 *Medicines & Healthcare products Regulatory Agency (2020). A guide to what is a medicinal product. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/872742/GN8_FINAL_10_03_2020__combined_.pdf*

77 *NOAH (2016). Controls of veterinary medicines. https://www.noah.co.uk/briefingdocument/controls-on-veterinary-medicines/*

78 *Veterinary Medicines Directorate (2018). Veterinary medicines guidance: a Collection. https://www.gov.uk/government/collections/veterinary-medicines-guidance-notes-vmgns*

79 *Medicine & Healthcare products Regulatory Agency (MHRA) (2018). Supply unlicensed medicinal products (specials): Guidance. https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials*

own health systems. Guidelines also require that such specialists only prescribe in their own area of practice & training.

- **GP referral**: GPs may make a referral to a specialist doctor on the GMC's 'Specialist Register' once the patient reaches the appropriate point in their treatment pathway, but cannot initiate treatment themselves or continue it without the ongoing engagement of a specialist.
- **Private doctors**: Only those on the GMC's specialist register are now legally able to prescribe CBPMs for medicinal use and most do so via a private clinic or cannabis clinic chain.
- **Prohibition on export of CBPMs**: the UK's medicines regulations mean the UK is allowed to import specials, including CBPMs, but is not allowed to export them. This hinders the UK-based suppliers of CBPMs from expanding into overseas markets and achieving economies of scale.

Hemp and 'Herbal Medicine'

The term Herbal Medicine (HM) automatically implies that it can contain one Active ingredient or more than one active ingredient…. or the whole plant. Further, this may be a mixture of individual, isolated, active Ingredients or a plant extract containing one or more ingredients.[80]

According to Pharmaceutical linguistic rules, herbal drugs are dried or processed plants or parts of plants used for the manufacture of pharmaceutical preparations.[81]

It is important that when herbal equivalent synthetic APIs are used that their purity and comparability with the natural product is established using validated analytical methodology. This has been a key area of concern since CBD was declared as Novel Food in January 2019.

In very general terms, the MHRA does not usually regard products containing culinary herbs to be medicines unless included for their medicinal properties or claims to treat or prevent disease are made for them. Some herbs, however, have well-known medicinal effects and would usually only be found in products for a medicinal purpose.[82]

Challenge:

- No controlled plant parts are allowed to be used under industrial hemp licence
- Analytical analysis requires validated methodology
- Comparison and bioequivalence of plant derived and synthetic
- Limited availability of pharmacopeial reference markers or published standards for industry to follow in UK to ensure quality

CONSUMER

Novel Foods

The Regulation (EC) 1169/2011, contains provisions for both the labelling and advertising of food. Any claim that a food has the property of preventing, treating, or curing human disease is not permitted. This covers any implication that a foodstuff can protect against or relieve the symptoms of disease, infection, or other adverse conditions.

The MHRA must therefore be mindful of the primary purpose of the product when investigating whether medicinal claims which are made for food products (including food supplements) should be subject to the Regulations.

In addition, any nutrition or health claims made on food must now be authorised before use in the EU. The Nutrition and Health Claims Regulation (Regulation (EC) 1924/2006) sets out the requirements for authorisation of claims for foods and the European Commission has established a register of permitted, rejected and pending

80 *National Health Service (NHS) (2018). Herbal medicines. https://www.nhs.uk/conditions/herbal-medicines/*
81 *Gaedcke, S. (2003). Herbal Medicinal Products. CRC Press. p.2*
82 *Medicine & Healthcare products Regulatory Agency (MHRA) (2020). A guide to what is a medicinal product, MHRA Guidance Note 8. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/872742/GN8_FINAL_10_03_2020__combined_.pdf*

nutrition and health claims.

Many different terms and definitions are used by regulators and suppliers, which result in regulatory compliance confusion. Moreover, being part of a food product it is governed by food safety regulations in the UK, but if there are any claims then the Nutrition and Health Claims Regulations (Regulation (EC) 1924/2006) need to be followed.

Challenges:

- Regulatory clarity required for food products/ labels & respective claims
- ACMD recommendations (2021) and next steps in amending MDR2001 has not been agreed by relevant authorities
- THC limits & Home Office regulations
- Regulatory clarity required for nutraceutical, cosmeceutical and vape products
- Compatibility and convergence of approach with global regulations

APPENDIX II - Comparative models

Australia

Only Epidyolex and Sativex have received approval from the Therapeutic Goods Administration (TGA) and are registered on the Australian Register of Therapeutic Goods (ARTG).

In November 2016, the federal government legalised cannabis cultivation for medical and scientific purposes. Patients can access unapproved medicinal cannabis products through an authorised prescriber or the Special Access Scheme (SAS) for any indication if the medical practitioner deems it appropriate following a thorough assessment[83]. Any medical practitioner can apply to become an authorised prescriber, or the SAS allows for medicinal cannabis products to be imported on a case-by-case basis. The TGA retains a list of all unapproved medicinal cannabis products to assist prescribers and pharmacists in prescribing and supplying, although this list is not prescriptive or indicative of availability[84]. Medicinal cannabis is not considered a first-line treatment option for any indication, and there is currently no subsidy available from the Pharmaceutical Benefits Scheme (PBS). Over 250,000 SAS applications have been approved, the majority of which have been for chronic pain, anxiety, or cancer pain and symptom management[85].

As of 2021, a single and perpetual licence has been adopted for cultivation, research and manufacturing[86]. Rather than duplicating applications, applicants apply in one go for the specific activities they require. Additionally, there is no requirement to renew licences - they last until the company surrenders it, or it is revoked. This single and perpetual licence scheme has reduced the regulatory burden. There is no limit on the number of licences that can be handed out.

In December 2020, the TGA announced its decision to down-schedule certain low-dose CBD preparations with a THC limit of 2% to Pharmacist Only Medicines. Adults can legally buy a maximum of 150mg of CBD per day without prescription. Although it is now legal, any CBD-containing products must be approved by the ARTG, and thus far no product has been approved for over-the-counter sale. Therefore in practice, CBD is not available in Australia.

Canada

In Canada, all phytocannabinoids are regulated under the Cannabis Act of 2018[87]. This act legalised cannabis for 'adult use' in those over the age of 21, but does not permit health claims for any cannabis products (other than prescription drugs containing cannabis compounds) as evidence of therapeutic benefit is yet to have been determined by the regulator. This should be taken into account when considering the context of the legislation of medicinal cannabis and CBD.

Only two health products containing cannabis have been authorised - Sativex and Nabilone. There are currently no authorised veterinary drugs containing cannabis. In an effort to provide stakeholders with consistent information on the current regulatory requirements, the Health Products and Food Branch of Health Canada has created a single window for questions related to health products with cannabis. This single window manages and responds to all enquiries associated with the development of submissions and applications for health products containing cannabis or for use with cannabis, including human drugs, natural health products, medical devices as well as clinical trials. This system is highly transparent and accountable, providing detailed guidance as well as information on the number of applications and licensing process status[88].

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83 *Therapeutic Goods Administration (2021). Accessing medicinal cannabis for a patient. https://www.tga.gov.au/accessing-medicinal-cannabis-patient*

84 *Therapeutic Goods Administration (2022). Medicinal cannabis products by active ingredient. https://www.tga.gov.au/medicinal-cannabis-products-active-ingredients*

85 *Therapeutic Goods Administration (2021). Medicinal cannabis Special Access Scheme Category B data. https://www.tga.gov.au/medicinal-cannabis-special-access-scheme-category-b-data*

86 *The Office of Drug Control (2021). Medicinal cannabis single licence and permit reforms. https://www.odc.gov.au/medicinal-cannabis-single-licence-and-permit-reforms#:~:text=The%20amendments%20to%20the%20Narcotic,and%20provide%20benefits%20to%20businesses.*

87 *Government of Canada (2018). Cannabis Act. https://laws-lois.justice.gc.ca/eng/acts/c-24.5/*

88 *Health Canada (2022). Health products containing cannabis or for use with cannabis: Guidance for the Cannabis Act, the Food and*

All healthcare practitioners can prescribe cannabis for medical use by providing a medical document which authorises the patient to purchase cannabis from a licensed producer. The patient is then required to apply to a specific licensed producer with their medical document, and can henceforth purchase cannabis from said producer[89]. Patients can also apply for permits to grow their own cannabis for their own medical purposes, provided they have confirmation of their medical requirement from their doctor and no previous cannabis-related offences[90]. They may also designate a third party as their grower if they themselves are not capable of growing the plant due to their health. The number of active patients accessing cannabis through federal licence holders peaked at 377,024 in September 2020, but as of September 2021 has fallen to 264,686[91]. Conversely, there has been a steady upward trend in the number of active personal/designated production registrations, increasing from 25,945 in October 2018 to 47,147 in September 2021[92].

CBD and products containing CBD are subject to all of the same rules and requirements that apply to cannabis under the Cannabis Act and its regulations. You must have a processing licence to manufacture products containing CBD for sale, no matter the source. CBD and products containing the cannabinoid, such as cannabis oil, may only be sold by a provincially or territorially-authorised cannabis retailer, or federally-licensed seller of cannabis for medical purposes[93]. CBD-containing products cannot make health claims as this requires approval for the product as a prescription drug under the Food and Drug Regulations[94]. There is a growing demand for access to regulated cannabis products which are approved for therapeutic use and that would not require practitioner oversight. The Canadian government is currently engaged in a stakeholder review to introduce these 'Cannabis Health Products'[95].

Farmers need a federal licence to grow cannabis for the commercial sale of CBD, and an industrial hemp licence to grow hemp. Hemp must not contain more than 0.3% THC, and there is a list of approved cultivars (varieties)[96]. Hemp farmers must apply for a cannabis processing or research licence if they wish to extract CBD from their crop. Under the Cannabis Act, it is prohibited to export or import cannabis (apart from hemp) for any purposes other than medical or scientific purposes.

It is worth noting that the 'guiding principles' and 'compliance and enforcement activities' of Canada's cannabis regime[97] seem very in line with OBCR.

Denmark

Denmark is currently attempting to cement itself as a European hub for medicinal cannabis research and innovation.

Sativex, Epidiolex, Dronabinol and Nabilone are approved for medicinal use and can only be prescribed by specialists. The current medicinal cannabis pilot programme running in Denmark

Drugs Act, and related regulations. https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/guidance-cannabis-act-food-and-drugs-act-related-regulations/document.html

89 *Health Canada (2021). Accessing cannabis for medical purposes from a licensed producer.* https://www.canada.ca/en/health-canada/services/getting-cannabis-from-licensed-producer/accessing-from-licensed-producer.html

90 *Health Canada (2021). Registering to produce or possess cannabis for your own medical purposes.* https://www.canada.ca/en/health-canada/services/registering-produce-cannabis-own-medical-purposes.html#a2a

91 *Health Canada (2022). Data on cannabis for medical purposes.* https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/research-data/medical-purpose.html

92 *Ibid.*

93 *Health Canada (2020). Cannabidiol.* https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/about/cannabidiol.html

94 *Government of Canada (1985). Food and Drugs Act.* https://laws-lois.justice.gc.ca/eng/acts/F-27/

95 *Health Canada (2022). Forward Regulatory Plan 2022-2024: Proposed Approach to the Regulation of Health Products Containing Cannabis that would not require practitioner oversight.* https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/forward-regulatory-plan/plan/regulation-cannabis-products-health-claim.html

96 *Health Canada (2021). List of Approved Cultivars for the 2022 Growing Season: Industrial Hemp Varieties Approved for Commercial Production.* https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/producing-selling-hemp/commercial-licence/list-approved-cultivars-cannabis-sativa.html

97 *Health Canada (2018). Health Canada Compliance and Enforcement Policy for the Cannabis Act: Summary.* https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/laws-regulations/compliance-enforcement-policy-cannabis-act.html

commenced in 2018 and will now continue to December 2025 after an extension to its duration[98]. Under this scheme, some companies have been granted permits for growing, cultivating and distributing medicinal cannabis in the country, and all general practitioners can prescribe unlicensed herbal cannabis but are not obligated to do so. The Danish Medicines Agency has supplied a list of relevant indications for consideration, but doctors are permitted to prescribe for any illness if they believe the treatment to be clinically appropriate. The Danish Medicines Agency retains a list of the cannabis products that can be prescribed which is subject to change[99]. Products dispensed under the pilot program are subject to reimbursement, with terminally ill patients receiving full reimbursement and other patients a 50% subsidy amounting to up to DKK 10,000 (£1,150) a year[100].

CBD laws in Denmark align with EU regulations - ingestible products containing CBD are defined as novel foods and must contain less than 0.2% THC. Likewise, industrial hemp production is legal, with the EU supplying a list of certified strains[101]. Hemp flower containing CBD is prohibited.

Germany

Germany's 2017 medicinal cannabis law reform[102] can be loosely compared to the UK's 2018 reform, but the markets in the two countries have evolved quite differently during their first years of the new regimes for several reasons[103]. Any physician, excluding dentists and veterinarians, can now prescribe medical cannabis for any condition. Cannabis products without marketing authorisation also fall under statutory health insurance (SHI) coverage, meaning SHI is expected to cover the cost of medication for almost 90% of Germany's population (although over a third of applications are rejected[104]). This has resulted in the subsidised medicinal cannabis market in Germany growing year on year, totalling €123m in 2019, €165m in 2020, and €185m reimbursed in 2021[105]. This does not include private prescription sales, which is increasingly believed to be a significant proportion of the market. These numbers far outstrip any prediction that has been made about the size of the UK market, even accounting for the one year difference between regulatory change.

Germany seems on the cusp of legalising cannabis for recreational or 'adult' use, with the new coalition government announcing its plans to introduce draft legislation in late 2022[106].

Israel

Israel is considered a global pioneer of medical cannabis research and development over the past 30 years. It also has a very specific and successful medical cannabis regime. A patient and a specialist in the field for which the patient is being treated must submit applications in tandem to the Medical Cannabis Unit of the Ministry of Health. The unit examines these applications on a case-by-case basis and decides whether or not to issue a permit. Patients must typically have attempted other medical treatments, and cannabis is only approved for the following conditions: Crohn's disease, ulcerative colitis, AIDS (HIV), multiple sclerosis, Parkinson's disease, epilepsy, Tourette's Syndrome,

98 Danish Medicines Agency (2022). Medicinal cannabis pilot programme. https://laegemiddelstyrelsen.dk/en/special/medicinal-cannabis-/medicinal-cannabis-pilot-programme/
99 Danish Medicines Agency (2022). Overview - cannabis products. https://medicinpriser.dk/Default.aspx?id=422
100 Danish Medicines Agency (2022). Questions and answers on medicinal cannabis. https://laegemiddelstyrelsen.dk/en/special/medicinal-cannabis-/questions-and-answers-on-medicinal-cannabis/
101 European Commission (2022). EU Plant variety database: SPECIES A - 85 - HEMP - CANNABIS SATIVA https://ec.europa.eu/food/plant/plant_propagation_material/plant_variety_catalogues_databases/search/public/index.cfm?event=SearchVariety&ctl_type=A&species_id=240&variety_name=&listed_in=0&show_current=on&show_deleted=
102 Federal Law Gazette (2017). Law to amend narcotics law and other regulations. https://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&start=//*%5b@attr_id=%27bgbl117s0403.pdf%27%5d#__bgbl__%2F%2F*%5B%40attr_id%3D%27bgbl117s0403.pdf%27%5D__1654692985929
103 Pascual, A. (2022). Drivers of patient growth in Germany. https://decalogue.info/drivers-of-patient-growth-in-germany/
104 Pascual, A. (2020). German medical cannabis applications for insurance reach 100,000. https://mjbizdaily.com/german-medical-cannabis-applications-for-insurance-reach-100000/
105 Brandt, M. (2022). 185 million euros for medical cannabis. https://de.statista.com/infografik/27137/umsatz-und-verordnungen-vom-medizinischem-cannabis-in-deutschland/
106 Sabaghi, D. (2022). Germany Speeds Up The Process To Legalize Recreational Cannabis. https://www.forbes.com/sites/dariosabaghi/2022/05/09/germany-speeds-up-the-process-to-legalize-recreational-cannabis/

PTSD, chronic pain, or patients undergoing chemotherapy, immunotherapy or radiology treatment[107].

Once approved, the department issues an ID card identifying the patient as being able to purchase medical cannabis from authorised pharmacies or dispensaries. This product is subsidised and is much cheaper than on the illicit market, with prices ranging from about 9 shekels to 40 shekels per gram (£2.15 - £9.50)[108]. The preliminary monthly allowance is 20 grams, but applications can be made to increase the prescription allowance. The number of medical cannabis patients has doubled over the last few years, and as of 2021 over 110,000 patients have medical cannabis licences[109]. To handle such a large number of patients, a computerised interface has been established in which doctors and the patients can update and directly feed their medical documents, allowing applications, approvals, licences and prescriptions to be quickly accessible all in one place[110].

Despite the great number of patients accessing cannabis, Israel's production of cannabis is limited, and in 2020 it overtook Germany as the largest importer of medical cannabis flower[111].

Despite the booming medical cannabis system, CBD had for a long time been prohibited due to its inclusion in the Dangerous Drugs Ordinance. In 2017 it was made available in pharmacies, and as of 2022 the Health Ministry will remove it from this list, allowing its use and import into Israel[112]. Their research concluded that there is a lack of sufficient evidence regarding CBD's safety for use in food and cosmetic products, meaning that no CBD products will be approved for use as an ingredient for the next two years. During this time, additional research on usage, safety practices and profile will be undertaken.

New Zealand

In 2018 the government introduced amendments to the Misuse of Drugs Act to create a medical cannabis industry[113] and in 2020 these regulations came into force. Under the new regime, the commercial cultivation of cannabis for medical purposes is permitted, and cannabis-based medicines can be prescribed by any general practitioner for any medical condition if they believe it clinically appropriate. These medicines are not subsidised, and so are paid for by patients. Despite these changes to legislation, many doctors do not have the training they feel is necessary to prescribe these products and the scale of the industry is limited, so there are fears cannabis-based medicines may still be inaccessible for some years[114]. CBD is currently a prescription-only medicine, with a THC limit of 2% for CBD products.

New Zealand has set up a government body named the Medicinal Cannabis Agency to deal with all things cannabis-related[115]. This body is the access point for cultivation, research, manufacturing and distribution licences, as well as an information hub for patients, health professionals and the general public. Moreover, it acts as the quality standards regulator and has published a list of cannabis products that have met the minimum quality standards - essentially a national formulary of available oils[116].

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107 *Kol Zchut (2022). Obtaining Medical Cannabis. https://www.kolzchut.org.il/en/Obtaining_Medical_Cannabis_(medical_marijuana,_medical_grass)*

108 *Hartman, B. (2021). Is cannabis legal in Israel? https://cannigma.com/regulation/cannabis-laws-israel*

109 *The Medical Cannabis Unit (2021). Licences status: November 2021. https://www.health.gov.il/Subjects/cannabis/Documents/licenses-status-november-2021.pdf*

110 *The Medical Cannabis Unit (2022). Cannabis for Medical Use and for Research. https://www.health.gov.il/English/Topics/cannabis/Pages/default.aspx*

111 *Pascual, A. (2020). Israel passes Germany as world's largest importer of medical cannabis flower. https://mjbizdaily.com/israel-passes-germany-as-worlds-largest-importer-of-medical-cannabis-flower/*

112 *Silkoff, S. (2022). Israel will remove CBD from Dangerous Drug Ordinance. https://www.jpost.com/health-and-wellness/article-698917*

113 *Parliamentary Counsel Office (2018). Misuse of Drugs (Medicinal Cannabis) Amendment Act 2018. https://www.legislation.govt.nz/act/public/2018/0054/latest/whole.html#whole*

114 *NZ Drug Foundation (2022). Medicinal Cannabis.https://www.drugfoundation.org.nz/policy-and-advocacy/medicinal-cannabis/*

115 *Ministry of Health (2021). Medicinal Cannabis Agency. https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicinal-cannabis-agency*

116 *Medicinal Cannabis Agency (2022). Medicinal cannabis products that meet the minimum quality standard. https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicinal-cannabis-agency/medicinal-cannabis-agency-information-health-professionals/*

Switzerland

Sativex is the only licensed cannabis medical product in Switzerland, prescribed in certain cases of multiple sclerosis. From 2011 general practitioners could also apply to the Federal Office of Public Health (FOPH) for approval for the prescription of cannabis-based medicinal products (magistral formulations) on an individual patient basis, as long as the practitioner believed it to be clinically appropriate. Patients covered the cost of these unlicensed magistral formulations, with a month's supply of high-THC oil costing anywhere between €300 and €500. This system was cumbersome and time-consuming for both the patient and the physician, resulting in a bottleneck at the FOPH due to its limited bandwidth in dealing with excessive paperwork and bureaucracy[117]. This effectively limited the number of medical cannabis patients to 3,000. However, after taking stock of this situation and the growing levels of demand, the government has introduced new regulations coming into effect in 2022 which will allow all practitioners to prescribe without making individual applications.

CBD products, including CBD flower with a THC level lower than 1%, can be sold legally as novel foods. In order to comply with European regulation for medical products, all CBD products are not labelled as medicines.

In 2011, an amendment was made to the Swiss Narcotics Act 1951 to make a distinction between hemp and cannabis[118], which came into effect in 2017. The result was that cannabis with a THC content of less than 1% does not qualify as a 'narcotic' as it is deemed non-intoxicating, and so can be produced, imported, sold and consumed legally for recreational use. While legally not a narcotic, this hemp is still subject to the regulation under which the product is brought to the market (tobacco substitute, food stuffs, cosmetics etc.).

While many expected this change in legislation to create a flourishing market for low-THC cannabis, this has not exactly been the case. Anyone wishing to grow hemp must still notify the authorities, and since 2018 there has been a downward trend in the number of these notifications[119]. Supply has exceeded demand for raw, smokable inflorescences, and instead producers now mainly focus on processed hemp products such as supplements, cosmetics and pharmaceutical-standard products.

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medicinal-cannabis-products-meet-minimum-quality-standard

117 McCusker, P. (2021). New Era Beckons For Swiss Medical Cannabis Patients After Ten Years In Slow Lane. https://businesscann.com/new-era-beckons-for-swiss-medical-cannabis-patients-after-ten-years-in-slow-lane/

118 The Federal Department of the Interior (2016). EDI ordinance about the lists of narcotics, psychotropic substances, precursors and auxiliary chemicals. https://fedlex.data.admin.ch/filestore/fedlex.data.admin.ch/eli/cc/2011/363/20161201/de/pdf-a/fedlex-data-admin-ch-eli-cc-2011-363-20161201-de-pdf-a.pdf

119 Zocatelli, Z. (2020). Swiss cannabis market - a delicate balancing act. https://www.swissinfo.ch/eng/swiss-cannabis-market-a-delicate-balancing-act/46193410

	Australia	Canada	Denmark	Germany	Israel	New Zealand	Switzerland	United Kingdom
Can general practitioners prescribe licensed cannabis products?	✅	✅	❌	✅	✅	✅	✅	❌
Are licensed cannabis products free to access?	❌	❌	❌	✅	❌	❌	✅ (all prescriptions are covered by insurance, but patients always pay 10%)	✅
Number of indications for which licensed cannabis products can be prescribed	1	2	2	Any medical condition, if practitioner believes it is clinically appropriate	2	Any medical condition, if practitioner believes it is clinically appropriate	1	3
Can general practitioners prescribe unlicensed cannabis products?	✅ (through application to the TGA's Special Access Scheme)	✅	✅ (under current pilot scheme, running until Dec 2025)	✅	❌	✅	✅	❌
Are unlicensed cannabis products free to access?	❌	❌	❌	✅	❌	❌	❌	❌
Number of indications for which unlicensed cannabis products can be prescribed	Any medical condition, if practitioner believes it is clinically appropriate	Any medical condition, if practitioner believes it is clinically appropriate*	Any medical condition, if practitioner believes it is clinically appropriate*	Any medical condition, if practitioner believes it is clinically appropriate	11	Any medical condition, if practitioner believes it is clinically appropriate	Any medical condition, if practitioner believes it is clinically appropriate	Any medical condition, if practitioner believes it is clinically appropriate
Medicinal cannabis ID scheme?	❌	❌	❌	❌	✅	❌	❌	❌
CBD regulated as a consumer product?	❌	❌	❌	❌	❌	❌	❌	✅
THC limit for CBD	2%>	N/A	0.2%>	0.2%>	N/A	2%>	1%>	0.2%>
Dedicated cannabinoid authority?	❌	❌	❌	❌	✅	✅	❌	❌
Unlicensed cannabis products imports?	✅	✅	✅	✅	✅	✅	✅	✅
Unlicensed cannabis products exports?	✅	✅	✅	✅	✅	✅	✅	❌
Government-sponsored medical ID card / database schemes?	❌	❌	❌	❌	✅	❌	❌	❌
CBD legal in pet food?	❌	❌	❌	✅	✅	✅	✅	❌

*Health agencies have provided a list of indications for which cannabinoid prescriptions might be considered, but this list is not exhaustive and practitioners can prescribe beyond the remit of this list.

APPENDIX III - Orphan diseases & cannabinoid indications

CBMPs can play an important role in rare disorders. The UK's rare disease framework has established four key priorities:

1. Helping patients to get a final diagnosis faster
2. Increasing awareness of rare diseases among healthcare professionals
3. Better coordination of care
4. Increasing access to specialist care, treatment & drugs

The UK has well-established processes and procedures in place for clinical trials but given the poor response to the 2019-20 NIHR initiative[120], where applications were sought for medicinal cannabinoid trials but none were taken forward, a different approach is now required.

There are also some key lessons to be learned from the COVID-19 pandemic that could apply to CBPMs. The establishment of the RECOVERY trial by UKRI's Medical Research Council and NHIR proved to be an efficient process in identifying and validation of key COVID-19 therapeutic agents in months rather than years. A similar initiative is required for identifying and evaluating CBPMs for unmet needs[121].

The Orphanet Report Series details the incidence of rare diseases, listing them in descending order of prevalence[122]. Of the most common 50 diseases, cannabis and its constituents have demonstrated therapeutic potential in 16 (33%), and there is anecdotal evidence for multiple others. All of the below conditions require further study vis-a-vis cannabinoids.

120 https://www.nihr.ac.uk/documents/themed-call-cannabis-based-products-for-medicinal-use/24043
121 https://decalogue.info/wp-content/uploads/2022/03/Decalogue_final.pdf
122 https://www.orpha.net/orphacom/cahiers/docs/GB/Prevalence_of_rare_diseases_by_decreasing_prevalence_or_cases.pdf

Rare Disease	Incidence per 100,000	Cannabinoid indication	Source	
Pneumonia caused by Pseudomonas aeruginosa infection	50	Cannabis can help relieve and reduce many of pneumonia's symptoms	Endogenous cannabinoid anandamide in rodents strongly hindered a capsaicin-induced cough and bronchospasm. Long COVID, the Mysterious Disease: a Role for Cannabidiol?	https://pubmed.ncbi.nlm.nih.gov/11081515/ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2828614/
Rare cutaneous lupus erythematosus	50	Cannabinoids can help reduce pain and inflammation in skin conditions like Lupus	Yale doctors currently investigating synthetic CBD and Lupus	https://www.yalemedicine.org/news/cbd-and-lupus
Ovarian cancer	49	CBD may be useful in relieving some of the uncomfortable side effects of ovarian cancer and its treatments	Dramatic response to Laetrile and cannabidiol (CBD) oil in a patient with metastatic low grade serous ovarian carcinoma Cannabinoids: Current and Future Options to Treat Chronic and Chemotherapy-Induced Neuropathic Pain	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6535622/ https://link.springer.com/article/10.1007/s40265-019-01132-x
B-cell chronic lymphocytic leukaemia	48	Cannabinoid receptors type 1 (CB1) and type 2 (CB2) are tentative treatment-targets in cancer	A Clinical Trial of Cannabis As Targeted Therapy for Indolent Leukemic Lymphoma	https://www.sciencedirect.com/science/article/pii/S0006497118634135
Congenital hydrocephalus	46.5	Medical cannabis can be helpful in relieving some of the long-term symptoms associated with this condition, including: sleep apnea chronic seizures; panic attacks or bipolar outbursts; chronic or weakening pain; frequent headaches and severe nausea	Cannabinoid receptor 2 activation restructs fibrosis and alleviates hydrocephalus after intraventricular haemorrhage	https://pubmed.ncbi.nlm.nih.gov/27769788/
Diffuse large B-cell lymphoma	43	CBD has great potential in cancer treatment by eradicating cancer cells by inhibiting cell viability and minimising relapse	Synergistic effect of cannabidiol with conventional chemotherapy treatment Does CBD Induce Apoptosis in Diffuse Large B Cell Lymphoma?	https://ashpublications.org/blood/article/132/Supplement%201/5382/265911/Synergistic-Effect-of-Cannabidiol-with http://www.theyoungresearcher.com/papers/xu.pdf
Scleroderma	42	CBD is helpful in reducing inflammation and suppressing fibrosis and tissue scarring	Clinical trials currently underway The use of cannabidiol in the treatment of pain related to scleroderma digital ulcers	https://www.projectcbd.org/medicine/cannabinoids-scleroderma https://ard.bmj.com/content/80/Suppl_1/672.2
Renal cell carcinoma	42	Cannabis may have medicinal benefits for treating symptoms of advanced chronic kidney disease and end-stage renal disease including as a pain adjuvant	The nephrologist's guide to cannabis and cannabinoids	https://journals.lww.com/co-nephrolhypertens/fulltext/2020/03000/the_nephrologist_s_guide_to_cannabis_and.15.aspx

Genetic peripheral neuropathy	40	Cannabis provides benefits for peripheral neuropathy, including pain reduction, better sleep, and improved function, even in patients with symptoms refractory to standard therapies	Cannabis for peripheral neuropathy: the good, the bad, and the unknown	https://www.ccjm.org/content/85/12/943
AL amyloidosis	40	The common treatment is chemotherapy, for which cannabis can reduce the side-effects. THC can also reduce formation of amyloid plaques, while CBD is beneficial for inflammation reduction	Cannabidiol promotes amyloid precursor protein ubiquitination and reduction of beta amyloid expression in SHSY5YAPP+ cells through PPAR involvement	https://pubmed.ncbi.nlm.nih.gov/24288245/
Uveitis	38	CBD exerts anti-inflammatory and neuroprotective effects by a mechanism that involves blocking oxidative stress and activation of p38 MAPK and microglia	Neuroprotective effects of cannabidiol in endotoxin-induced uveitis Anti-inflammatory effects of cannabinoid CB2 receptor activation in endotoxin-induced uveitis	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2592995/ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3954484/
Moderate and severe traumatic brain injury	38	Cannabinoids have neuroprotective and psychotherapeutic properties,and mortality is severely decreased in patients with a THC screen in adult patients sustaining TBI	Use of medical cannabis to treat traumatic brain injury Recovery from traumatic brain injury following treatment with Δ9-tetrahydrocannabinol is associated with increased expression of granulocyte-colony stimulating factor and other neurotrophic factors Effect of marijuana use on outcomes in traumatic brain injury	https://pubmed.ncbi.nlm.nih.gov/33256496/ https://www.liebertpub.com/doi/abs/10.1089/can.2020.0119 https://journals.sagepub.com/doi/abs/10.1177/000313481408001015
Follicular lymphoma	37	Cannabinoids demonstrate anti-cancer potential and synergistic cytotoxic effects with traditional chemotherapy drugs	Cannabinoid: A potential anti-cancer agent for non-Hodgkin lymphoma Expression of cannabinoid receptors type 1 and type 2 in non-Hodgkin lymphoma: Growth inhibition by receptor activation	https://etd.auburn.edu/handle/10415/7864 https://sativaisticated.com/wp-content/uploads/2017/04/Expression-of-cannabinoid-receptors-type-1-and-type-2-in-non-Hodgkin-lymphoma-Growth-inhibition-by-receptor-activation-Cannabis-Research-for-Non-Hodgkin-Lymphoma-.pdf
Non-papillary transitional cell carcinoma of the bladder	37	Cannabidiol induces apoptosis, reduces cell migration, and acts as a chemotherapy sensitizer in various human tumour types	Cannabidiol Effectively Promoted Cell Death in Bladder Cancer and the Improved Intravesical Adhesion Drugs Delivery Strategy Could Be Better Used for Treatment Bladder cancer cell growth and motility implicate cannabinoid 2 receptor-mediated modifications of sphingolipids metabolism Combination therapy with cannabidiol and chemotherapeutics in canine urothelial carcinoma cells	https://www.mdpi.com/1999-4923/13/9/1415/pdf https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5304189/ https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0255591

Uremic pruritus	35	Endocannabinoids appear to be effective in reducing both pruritus and xerosis in hemodialysis patients	Efficacy and Tolerance of the Cream Containing Structured Physiological Lipids with Endocannabinoids in the Treatment of Uremic Pruritus: A Preliminary Study	https://hrcak.srce.hr/file/131497
Fragile X syndrome	32.5	Therapeutic potential for CBD: patients exhibited functional benefit, including noticeable reductions in social avoidance and anxiety, as well as improvements in sleep, feeding, motor coordination, language skills, anxiety, and sensory processing	A phase ½, open-label assessment of the safety, tolerability, and efficacy of transdermal cannabidiol (ZYN002) for the treatment of paediatric fragile X syndrome Treatment of fragile X syndrome with cannabidiol: a case study and review of the literature Pharmacotherapeutic Effects of Cannabidiol (CBD) in Fragile X syndrome (FXS) and Autism Spectrum disorder (ASD)	https://jneurodevdisorders.biomedcentral.com/articles/10.1186/s11689-019-9277-x https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6446166/ https://www.fraxa.org/pharmacotherapeutic-effects-of-cannabidiol-cbd-in-fragile-x-syndrome-and-autism-spectrum-disorder/

ANNEX - Survey methodology

Stack Data Strategy surveyed a representative sample of 1,500 individuals across the UK between 9 and 13 June 2022. Respondent quotas were used to ensure the representativeness of the sample, specifically with regard to age, gender, education, and region. In the post-processing phase of the fieldwork, the data was weighted to age/gender (interlocked), education, and region. Due to weighting and rounding, percentages may not add up to 100%. When interpreting the results, numbers based on samples of below 50 respondents should not be seen as representative of the demographic group as a whole. The full data sheets are available at https:/hodgesreview.com.

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