



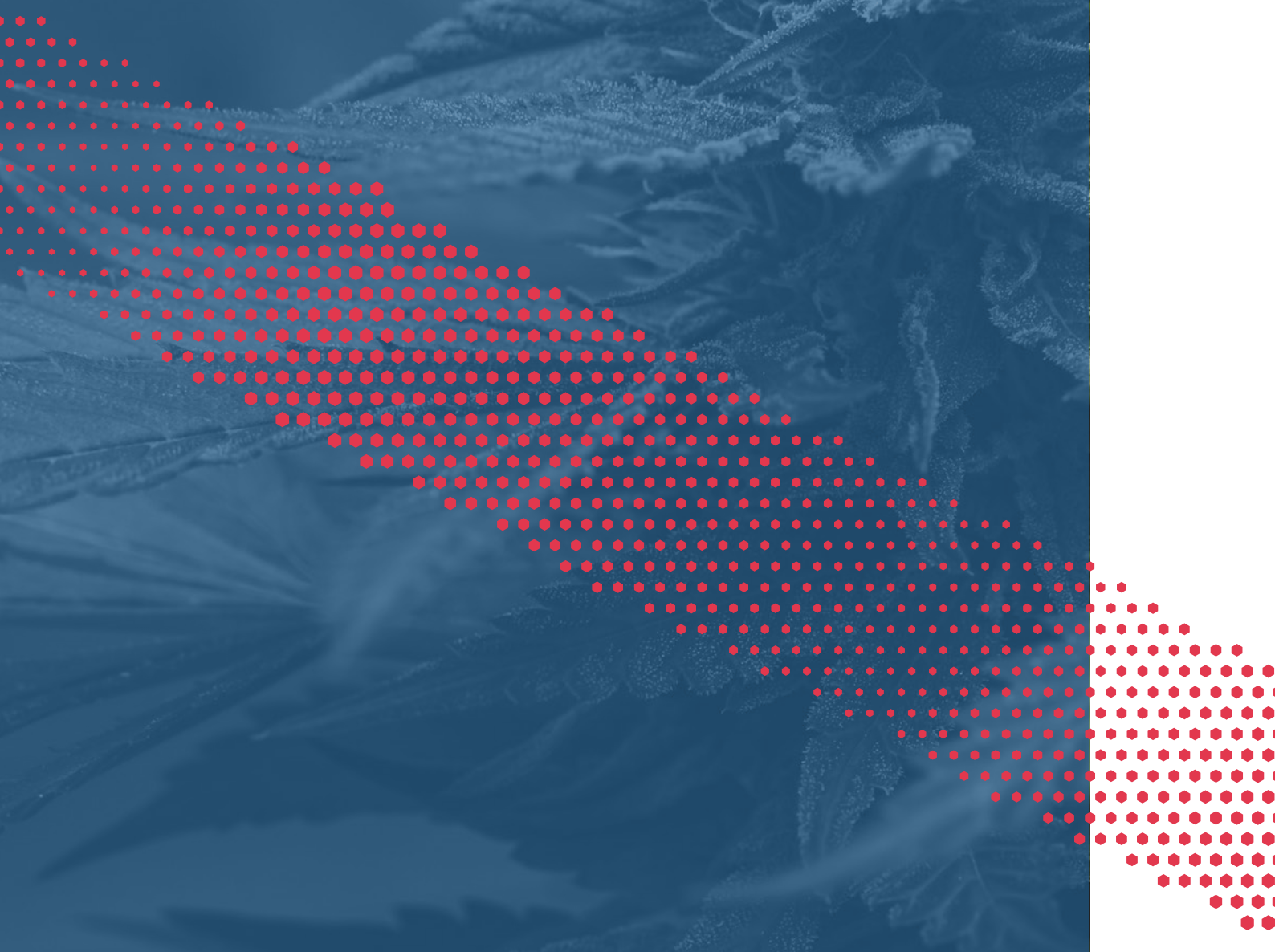
# The UK Cannabis Report™

DECEMBER 2019





# About Prohibition Partners



# Advancing the global cannabis industry.

## Data, analytics and business intelligence on the international cannabis industry.

### ABOUT US

Prohibition Partners is widely recognised as the world's leading provider of market intelligence, data driven solutions and corporate strategy for the emerging cannabis industry. Our knowledge, insight and network is unrivalled at the forefront of regulatory change and investor engagement across multiple global markets.

### SERVICES

#### Data

Bespoke Research, Polling, Consumer Insight, Pricing, Market Forecasting.

#### Intelligence

Policy & Compliance, Market Analysis, Supply / Demand.

#### Strategy

Market Entry / Expansion, Regulatory Guidance, Licensing, Partnerships, Business Development.

#### Marketing

Advertising, Promotion, Media Partnerships, Content Marketing.

## PROHIBITION PARTNERS TEAM:

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Our consultancy team works with investors, operators and regulators to identify and execute opportunities across multiple jurisdictions. We advise our private clients on licensing, regulatory and business opportunities.



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Co-Founder



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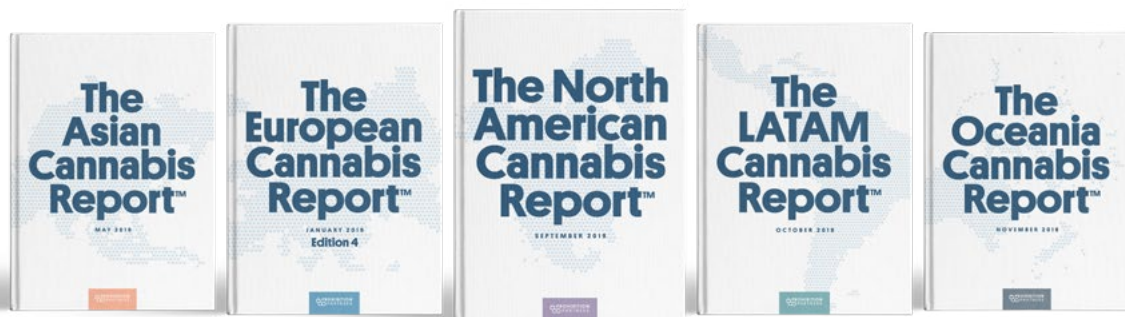
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Prohibition Partners is the number one source for data and information on established and burgeoning cannabis markets. Read by over 150,000 global cannabis investors and entrepreneurs, and creating more than 6 million social impressions annually, Prohibition Partners produces thought-leading industry reports. If you would like to partner with us and support independent data and research please contact our Sponsorship Manager [will.sloane@prohibitionpartners.com](mailto:will.sloane@prohibitionpartners.com)

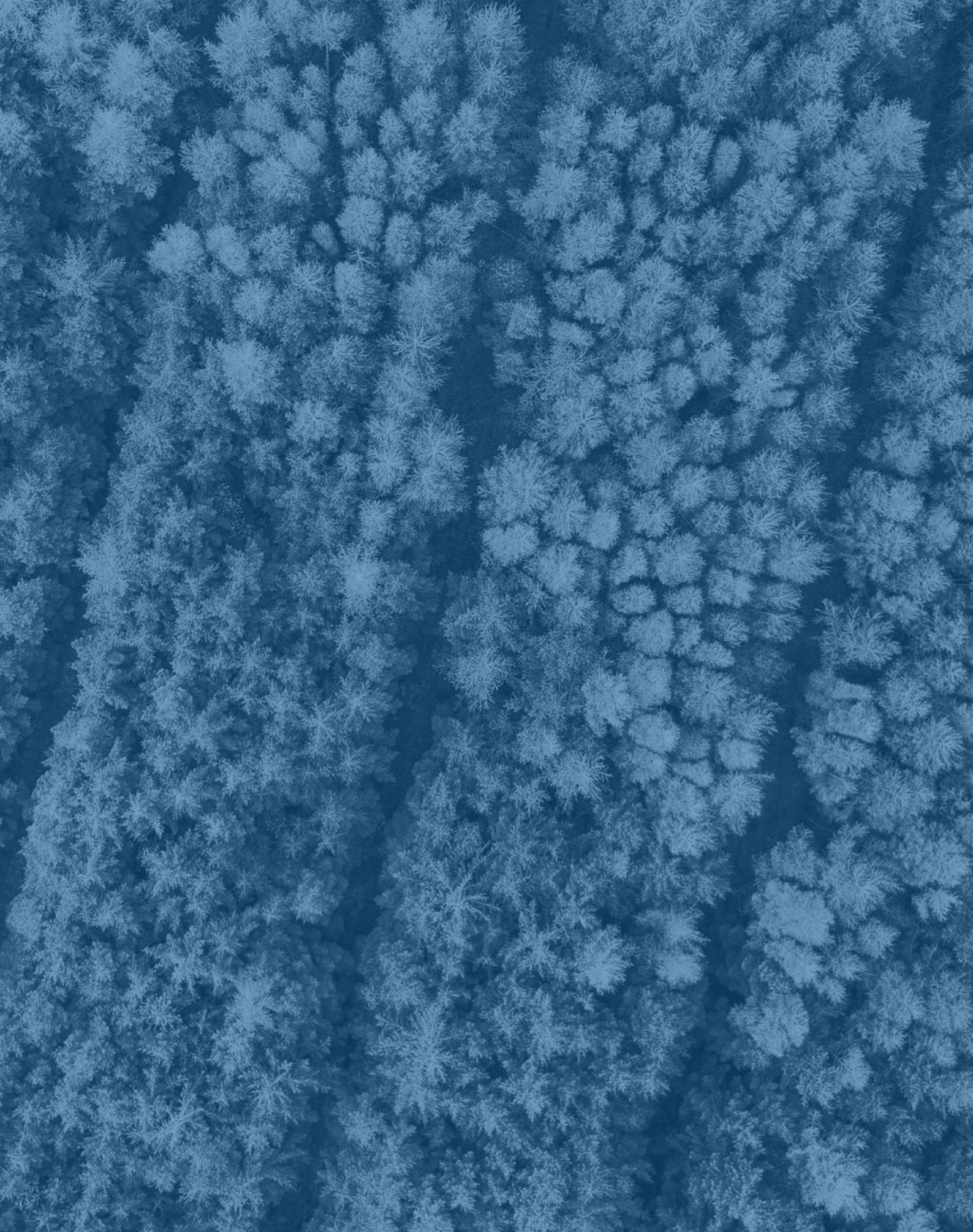
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**Will Sloane**  
Global Sponsorship Manager

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# INTRODUCTION

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**Stephen Murphy**  
Co-Founder,  
Prohibition Partners

**O**n 1 November 2018, the United Kingdom legalised medical cannabis. One year on, to mark the anniversary, Prohibition Partners has produced this report, which aims to provide an in-depth analysis of the unique aspects of the UK cannabis industry. Despite being the largest exporter of medical cannabis in the world, the UK currently imports 100% of its cannabis-based medicines prescribed to patients. This, combined with other factors, most notably a lack of education and training opportunities for medical specialists around prescribing, has resulted in a very limited number of prescriptions being issued, approximately 153, in England, since medical cannabis was legalised.

The opportunities in the sector remain immense, however. The numbers of consumers are likely to increase as access to medical cannabis improves, most recently evidenced by the licensing of Epidyolex, a cannabis-based medication for epilepsy soon to be reimbursed under the National Health Service (NHS). Furthermore, the CBD sector in the UK is thriving. There are approximately 7.3 million people in the UK using CBD products each year, giving rise to new and emerging opportunities, particularly in relation to beauty and skincare.

Our report aims to provide context and insights into the current cannabis market in the UK, as well as a detailed forecast for the future of the market, to equip, you, the reader, to understand both the challenges and opportunities that the UK cannabis market has to offer. We hope you enjoy reading this report.

**Stephen Murphy**  
**Co-Founder**  
**Prohibition Partners**

# MGC PHARMA FOREWORD

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**Roby Zomer**  
*Managing Director,*  
*MGC Pharmaceuticals*

**M**GC Pharma is an industry leading, European based 'Seed to Medicine' bio-pharma company supplying GMP certified phytocannabinoid-derived medicines to patients. MGC Pharma's founders are prominent figures in the Israeli medicinal cannabis Industry, supported by a Clinical Advisory Team with decades of experts. They believe that phytomedicines will influence public wellbeing across the globe by successfully treating formerly unmet medical requirements and improving the lives of patients. The medicinal cannabis medicine industry continues to grow, with the market expected to reach £48.3bn in 2024\*, and is rapidly picking up pace across USA, Canada, Europe, and Australia. MGC Pharma is well positioned in this growing market and has established a diversified business, with operations spanning the entire value chain.

MGC Pharma has two Investigational Medicinal Products in late stage development, targeting drug resistant epilepsy (CannEpil®), and dementia/Alzheimer's disease (CogniCann™). These formulations have been developed internally through the Company's

Research and Development division, and are undergoing clinical trials in Australia and Europe, while being provided to patients through early access schemes. This is in line with the Company's 'Seed to Medicine' strategy, controlling each stage of a product's development, from the genetics to finished pharmaceutical grade product.

MGC Pharma's goal is to facilitate the transformation of phytocannabinoids into true medicines, and to provide breakthrough solutions for prevalent global health issues such as epilepsy and dementia, improving the quality of patients' lives and contributing to better public health. MGC Pharma aims to build a responsible and profitable industry wherever the company operates.

**Roby Zomer,**  
**Managing Director,**  
**MGC Pharmaceuticals**



# Cutting-edge phytocannabinoid medical products



Seed to Pharmacy  
Pipeline



Global R & D



Patient Focus

Leading the way in  
Phytocannabinoid Derived Medicines  
with Seed-to-Pharmacy Strategy

[mgcpharma.com.au](http://mgcpharma.com.au)





# COUNTRY\* STATISTICS, 2018



POPULATION, 2018  
 **66.44 M**

GDP, 2018  
 **US\$2.65T**

ESTIMATED NUMBER OF  
CANNABIS USERS  
 **4.7M**

ESTIMATED NUMBER  
OF PEOPLE IN THE UK  
USING CANNABIS TO  
TREAT CHRONIC HEALTH  
CONDITIONS  
 **1.4M**

TOTAL NUMBER OF  
PRESCRIPTIONS FOR  
CANNABIS-BASED MEDICINES\*\*  
 **153**

\*The United Kingdom is made up of the following three countries: England, Wales and Scotland; and the province of Northern Ireland.

\*\*Based on NHSBSA data gathered between November 2018 and August 2019 for England only.



# DEFINITIONS

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## MEDICINAL CANNABIS

Medicinal cannabis refers to both medical and pharmaceutical cannabis products. The definitions below give more detail.

### Medical cannabis

Medical cannabis refers to plant-based or plant-derived cannabis products prescribed by a medical practitioner for the treatment of a specific condition or disease (e.g. epilepsy, pain and multiple sclerosis (MS)). Medical cannabis uses the whole unprocessed plant, the processed plant or the chemicals contained within it. It can include high-CBD (cannabidiol) and low-THC (tetrahydrocannabinol) products, though CBD products may also appear as consumer goods. Medical cannabis products are currently prepared as plant materials, oils, tinctures, edibles and capsules

### Pharmaceutical cannabis

For the purposes of this report, pharmaceutical cannabis refers to products formulated using pure cannabinoids (either plant extracts or synthetic) that have been through full clinical trials and licensed as a medicine. Examples of products include Sativex, Epidiolex/ Epidyolex, Cesamet, Marinol and Syndros.

## Recreational cannabis

Recreational cannabis refers to any cannabis used for non-medical purposes, and this category includes black-market products. It ordinarily has a higher concentration of THC, the psychoactive properties of the cannabis plant, and is illegal in many countries and states. People tend to smoke recreational cannabis, or consume via edibles, or use oils or vaporised products. For the purposes of this report, users are assumed to be people aged 15 and over.

### CBD

Throughout this report, reference is made to CBD. While there is an emergent market for CBD-infused consumer goods, capsules and oils, these have been excluded from the market size calculations due to a lack of sales data. Although these products may be used for wellness purposes such as aiding sleep, or for pain or anxiety management, they do not require a prescription and have therefore been excluded from the medical market sizes..

# PROHIBITION PARTNERS' TOP 5 PREDICTIONS FOR THE UK CANNABIS MARKET

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## MEDICAL MARKET

# 1

**Supply chain:** the UK presents an anomaly at present. It is the world's largest exporter of plants for medical cannabis (44% of total global exports in 2016). Yet, all of the medical cannabis prescribed in the UK has been imported to date, posing a challenge to access for patients and companies alike, since supply to the UK is tightly regulated. As bulk imports increase, however, so too will patient access, driving down the cost of medicines to patients and the NHS, improving stability of access, while facilitating an exponential growth in patient numbers.

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# 2

**Education and training:** despite access to medical cannabis being legal for 12 months, patient access has been mired by the limited number of specialist doctors, based in hospital settings, permitted to prescribe the medicine. Lack of resources and support for these medical professionals, including access to tailored education and training opportunities, have done little to nurture their confidence in prescribing medical cannabis to patients. As greater access to education and training

emerges, like those provided by the Academy of Medical Cannabis or planned by the Drug Science initiative, confidence in prescribing practices are likely to improve, especially when coupled with an evidence base that supports the medicines' efficacy and official endorsements from bodies such as the National Institute for Health and Care Excellence (NICE), which will undoubtedly follow.

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# 3

**Evidence:** access to and promotion of medical cannabis in the UK to date have been hampered by a paucity of clinical evidence emanating from the UK, on the efficacy of medical cannabis to treat a variety of conditions, including chronic pain. As more clinical trials are carried out, boosted by endeavours such as Project Twenty21, which aims to recruit up to 20,000 patients to the UK's first ever medical cannabis registry by 2021, and research funding granted by the National Institute for Health Research (NIHR), the evidence base for medical cannabis is likely to grow and expand to include a greater number of conditions that benefit from the medicine. This, in turn, will influence NICE recommendations, promoting the use of medical cannabis and boosting confidence in prescribing cannabis among medical specialists.

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## RECREATIONAL MARKET

# 4

Attitudes towards cannabis among adults in the UK are softening. Two YouGov surveys, one in 2018, found that 51% supported liberalising policies on recreational cannabis, either legalising (24%) or decriminalising (27%). This increased to 53% of adults, who agreed they would tend to support (35%) or strongly support (18%) legalising cannabis, in 2019. This, coupled with a general relaxation of laws pertaining to medical cannabis across other countries in Europe and the imminent legalisation of recreational cannabis in Luxembourg in 2021, is likely to influence government policies in the UK and soften societal attitudes further, going forward. It is likely the UK will legalise recreational cannabis within the next five to ten years.

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## CBD MARKET

# 5

The ubiquity of CBD in health, wellness, and beauty and personal care (BPC) is well documented, with increasing numbers of consumers turning to brands promoting the benefits of CBD both online and in store in the UK. An estimated 7.3 million people use CBD in the UK every year. The growth of an edibles market will be hampered by the EU novel foods regulations. This may change, however, at such a time as the UK exits the European Union; at which point, the door may be opened to introduce edible brands, as seen in the burgeoning Canadian market.

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# LEAD SPONSOR INTERVIEW

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## ROBY ZOMER MANAGING DIRECTOR, MGC PHARMACEUTICALS

### Can you provide a brief overview of the company?

MGC Pharma is a global leader in the research and development of pharmaceutical grade phytocannabinoid-derived medicines within the biopharmaceutical industry. Our goal is to facilitate the transformation of phytocannabinoids into medicinal product pipelines, and to provide breakthrough solutions for prevalent health issues and to improve the quality of patients' lives. The company's activities revolve around an agenda consisting of three pillars – seed to medicine, global research and development, and patient focus. These three pillars have guided us to create a uniquely positioned company – producing pharmaceutical products from a phytocannabinoid-based pipeline, supported by experience and an understanding of the international industry that has continuously positioned us in a first mover both as far as standards, products and verticals.

Through our international distribution channels, we are already distributing products, the initial being CannEpil® into Australia and the United Kingdom under early access schemes. We also recently passed the 1,400 prescription milestones in UK, Australia and Brazil, with the number of prescribed products almost doubling month to month.

Through clinical research in Australia and Europe, we are on the pathway for both CannEpil® and CogniCann™ to be granted Conditional Marketing Authority in the EU, and approval in Australia, in the coming years.

### When was the business founded?

The business was founded in 2014, when the founders realised the limitations of the Israeli cannabis industry, of which they had been formative members. Shifting IP and basing operations in Slovenia created an opportunity for an RTO by an Australian Company, formerly known as Erin Resources, which then became MGC Pharma.

### What is the business strategy and what are you trying to achieve?

The Company's "Seed to Medicine" strategy comprises cultivation, to develop new strains of Cannabis spp, preclinical and clinical research product manufacturing, at the Group's facility in Slovenia, and distribution.

The Company's mission is to produce "cost effective, affordable, phytocannabinoid-derived medicines" to improve the lives of patients. This mission is cemented by the Company having established a GMP certified facility in Slovenia, which develops and manufactures GMP compliant phytocannabinoid-derived medicines following EU pharmacopeia standards.

Our main goal is to achieve product registration in various international territories,

allowing broader market access, while taking advantage of early access schemes.

#### **What are the main drivers behind the medical cannabis market?**

As more research is being conducted on an international scale, medical professionals and law-makers are becoming increasingly comfortable with prescribing phytocannabinoid-derived medicines. Alongside this, patients and carers are being educated on medicinal cannabis as a therapeutic option. This is not only driving legislation change around the world but driving demand for quality medicinal cannabis products.

#### **The cannabis market is becoming increasingly competitive. What are MGC's key strengths?**

Our key strength and differentiator is that MGC Pharma is a biopharma company, not a medicinal cannabis company. Our focus is on the goal of creating the pharmaceutical quality medicines for as many patients as possible, at an affordable cost. Unlike the vast majority of companies in the medicinal cannabis industry, MGC Pharma is not focussed on the recreational market, rather investing in GMP manufacturing and the clinical research required for product registration.

In addition, our flagship products are targeting addressable markets with unmet medical needs, targeting large patient populations who currently have limited therapeutic options. The Company has positioned itself as a bio-pharma manufacturer of phyto-

cannabinoid-derived medicines to a GMP certified pharmaceutical grade, under GMP certification. It is one of a few in Europe to manufacture and supply products to this level of quality, consistency, and safety.

#### **What products do you have in the pipeline?**

Implementing a "Seed to Medicine" core strategy, we currently have a pipeline of phytocannabinoid-derived medications and unique formulations, both proprietary and for third parties, all under GMP certified regulations and facilities. Pre-clinical products in the pipeline are for the treatment of neurological disorders (Cerebral Palsy), autoimmune diseases (Crohn's disease and colitis) and oncological disorders (glioblastoma, melanoma & prostate cancers) and cancer treatment side effects (cachexia).

In Australia, both CannEpi<sup>®</sup> and CogniCann<sup>™</sup> are available to patients through the special access scheme, while CannEpi<sup>®</sup> is also available in the UK as a 'specials' medicines prescribed by specialists. CannEpi<sup>®</sup> is for the treatment of drug resistant epilepsy, and CogniCann<sup>™</sup> is for symptom management associated with dementia and Alzheimer's disease.

Both these products are in late stage development, and on the path for Conditional Marketing Authority in the EU and approval in Australia. A Phase IIb clinical trial on CogniCann<sup>™</sup> is underway with the University of Notre Dame Australia, while approval is being sought for a Phase IIb for CannEpi<sup>™</sup> in Slovenia.

**The company looks to list on the UK stock exchange early next year. What will this mean for MGC?**

With our leading clinical and commercial position in Europe, and an increasing presence and patient uptake in the UK, it only makes sense to list on the LSE. This is an interesting time for us as MGC Pharma could soon be in the highly enviable position of being one of the first medicinal cannabis companies to be listed on the LSE, or any major stock exchange in the UK, following the country's introduction of medicinal cannabis legislation in November 2018. This has been an incredibly busy period for us where we have rapidly advanced the business, delivering material results through ground-breaking research and development, increasing our international distribution channels, opening new markets, strengthening our partnerships with academic institutions and widening our growing and manufacturing capabilities demonstrated by construction having been authorised on a state of the art 10,480m<sup>2</sup> manufacturing facility in Malta – the first of its kind. We definitely have exciting times ahead.





# METHODOLOGY

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The market forecasts provided in this report are based on Prohibition Partners' proprietary market sizing model, which received a major update in Q4 2019. These estimates are built with fully integrated statistical models for both recreational and medicinal cannabis, forecasted on a monthly basis for the next five years.

Key variables modelled at this level of granularity include: patient numbers, pricing, dosage, recreational cannabis usage rates and population growth, as well as the flow of customers between the legal and illegal recreational market. Calculations have then been made using quantitative analysis of socio-economic data, consumption trends, cannabis requirements and pricing, informed by a wide range of reputable datasets including, but not limited to, the United Nations Office for Drugs and Crime (UNODC), the World Bank, the Organisation for Economic Co-operation and Development (OECD), the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and the International Narcotics Control Board (INCB). Where UK specific data were not available, reputable data from the most comparable geography have been utilised (with appropriate statistical adjustments applied as necessary).

This represents the first iteration of our most complex market sizing model to date. The model methodology has been refined and standardised across regions to maximise the accuracy and comparability of forecasts. In addition, all input data have been revised to

align with most currently available market data. Due to the rapidly changing nature of the sector and the increasing amount of historical data coming onstream, it should be noted that these market sizing estimates will be further optimised with subsequent iterations.

Some key assumptions built into the market sizing model are outlined in the market forecast section of this report.

## MEDICINAL

The medicinal market-size estimates and forecasts contained within this report include both medical and pharmaceutical products. They represent monthly calculations of predicted price per gram of cannabis multiplied by the predicted monthly usage, multiplied by the predicted patient population. Price per gram of medicinal cannabis differs to street value prices, and the price per gram has been modelled based on post-legalisation pricing trends from a number of markets. This has been factored into the market-size calculations with price modelling incorporated into the year-on-year forecasts.

Patient numbers have been modelled on existing markets where medicinal cannabis has already been legalised and regulated. It is not calculated as the sum of patients who suffer from qualifying conditions, primarily because patients may suffer from multiple qualifying conditions for which cannabis can



be prescribed. Value forecasts can include pharmaceutical and CBD medical products.

## RECREATIONAL

Our recreational cannabis market sizes do not include the black market. They represent monthly predictions of recreational cannabis usage rates, multiplied by the predicted consumption amounts, multiplied by the predicted prices, with adjustments applied to account for the dynamics between the legal and illegal markets in terms of usage and pricing. The growth rate has been modelled on trends seen around the world, and pricing trends have been informed by research published in more mature markets on the impact of legalisation and regulation on the average cost per gram.



# MARKET OVERVIEW

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In 2018, the UK legalised medicinal cannabis, but government progress on access and prescribing recommendations lags behind much of Europe. In the past decade Germany, Italy, Spain, Switzerland and Ireland have all implemented medical cannabis access programmes. In fact, in 2019 to date, just a handful of doctors out of the UK's 180,000 have been trained in the endocannabinoid system.

In November 2018, an amendment to the *Misuse of Drugs Regulations 2001* and the *Misuse of Drugs (Designation) Order 2015* saw cannabis-based products moved from Schedule 1 to Schedule 2, making cannabis-based products available on prescription from doctors on the General Medical Council (GMC) Specialist Register under strictly controlled circumstances. However, the prescribing process is still nascent, severely restricting access and uptake, and the caution urged by a number of clinical representative organisations, notably the British Paediatric Neurology Association (BPNA), has contributed to uncertainty and confusion.

Around one hundred patients are thought to have successfully accessed medical cannabis in the UK to date (November 2019). However, this has largely been via private clinics rather than the NHS. Despite changes in the law, the barriers to access remain. These include:

- establishing exceptional clinical circumstances
- exhausting all lawful alternatives

- gaining agreement from an NHS Trust medical director
- engaging a specialist doctor to accept liability, meaning that patients are generally unable to secure this treatment via the NHS, while private prescriptions, costing as much as £2,500 for a three-month supply, are prohibitive to many.

Under pressure from lobbying groups, government action has resulted in a clear consensus on the need for more clinical evidence to ease the restrictions on access and support the use of cannabis-based products for medicinal use (CBPMs) in the treatment of a wider variety of illnesses.

NHS England has stated that cannabis-based products would be prescribed only where there was 'clear published evidence of benefit' that could not be achieved by a licensed medicine. With particular regard to CBPMs that are to be supported by public funding, the NIHR is taking action, with a call for research to produce evidence that will inform further decisions on the use of CBPMs. England's Chief Medical Officer, Professor Dame Sally Davies, has called for more research into the plant's benefits so that any future guidance on prescribing cannabis-based medicines has a 'more solid scientific basis'. In November 2019, NICE published further guidelines concerning all cannabis-related medications. Draft guidelines were released for public consultation on 8 August 2019; they made no direct recommendation for treatment with

## Despite UK-based company GW Pharmaceuticals being the largest exporter of medicinal cannabis in the world, currently all CBPMs are imported.

cannabis medication other than Nabilone for intractable nausea. The draft called for further research on clinical efficacy and cost-effectiveness of cannabis-based treatments for pain conditions, epilepsy, MS spasticity and nausea (see 'Regulatory Environment' section for further details). The guidelines issued in November 2019 extended this list to include Epidyolex for the treatment of epilepsy and Sativex for the treatment of spasticity in MS patients.

Despite UK-based company GW Pharmaceuticals being the largest exporter of medicinal cannabis in the world, currently all CBPMs are imported. Medical cannabis was made legal in the UK on 1 November 2018, but it wasn't until

February 2019 that a shipment arrived in the UK from the Netherlands. Importers need to apply to the UK Home Office for a licence to bring cannabis in from overseas. The process can take up to 28 days, so by the time it has been imported the prescription may have expired. According to the United Nations International Narcotics Control Board, in 2016 the UK produced 44% of global cannabis plants intended for medicine and scientific research. Restrictions on imports to the UK mean that companies like the German Cannamedical could profitably sell medicinal cannabis to domestic pharmacies in Germany at €10 a gram, but would need to sell for £30 a gram in the UK to achieve the same profit margin.

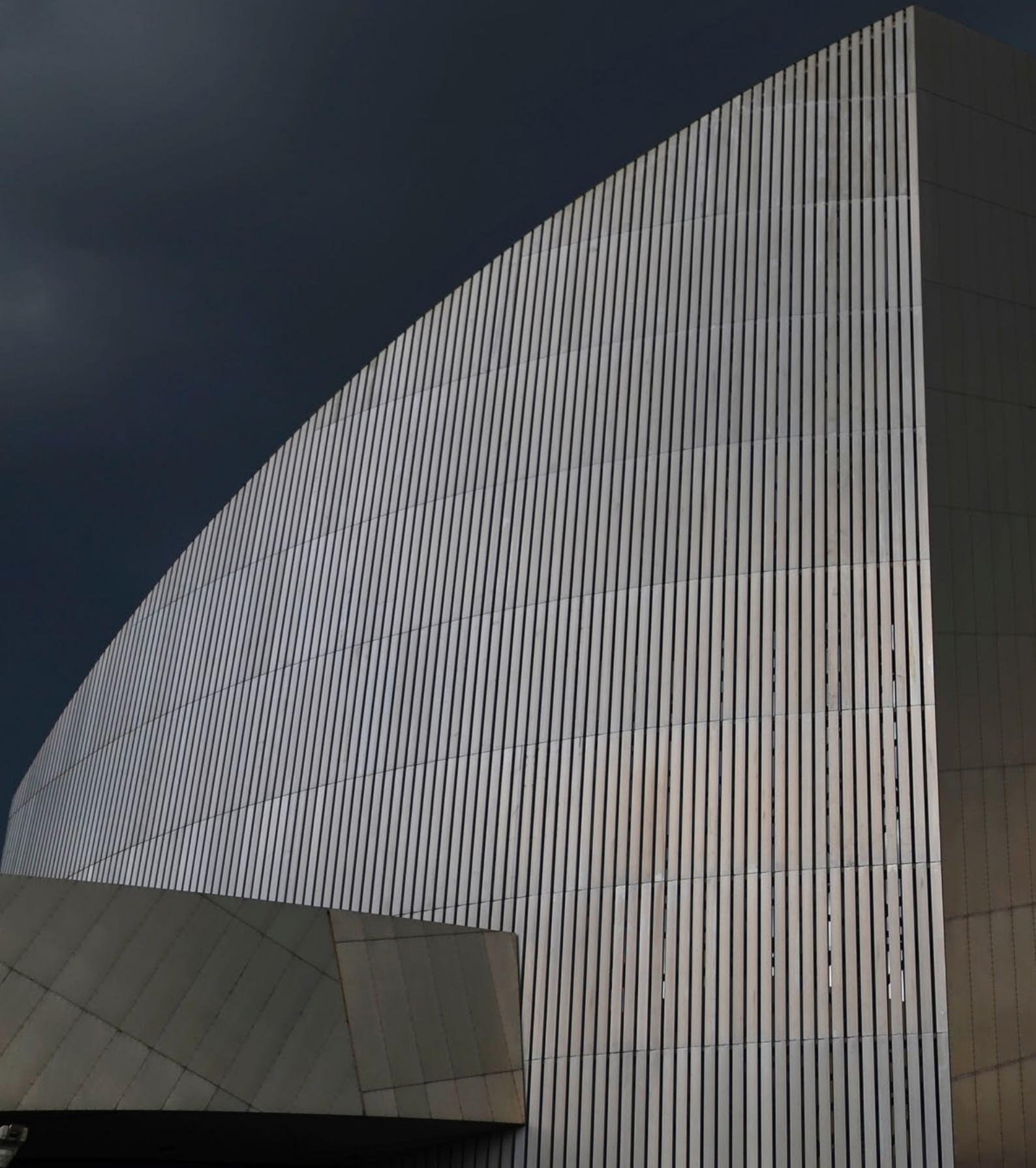
There is evidence that the cannabis investment sector is beginning to gain traction in Europe. Throughout 2019 investment groups have been turning their attention towards the UK market, with banking groups and private investors setting up and investing in partnerships in the European market for medical cannabis and CBD, including the nascent dispensary and clinic sector. For example, on 12 September 2019 High Life plc, an investment vehicle focused on CBD and medical cannabis in the UK, floated on the Nex Exchange stock market in London. The company opened with an initial £2.4 million in raised funds, and since then has attracted investment from Canadian groups, including Victory Resources Corporation and Codebase Ventures. Of further interest is the decision by Cannacord, the largest underwriter of cannabis stocks in Europe, to deal specifically

## **In 2016 the UK produced 44% of global cannabis plants intended for medicine and scientific research.**

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with investment banking in European cannabis stocks. The company has a UK branch and assets in two companies in the UK – Ananda Developments and Sativa Investment plc, which is one of the largest players in the UK. This example is illustrative of a broader trend in the growth of ancillary services within the cannabis sector in the UK, with London set to become a central hub for cannabis-related banking services going forward.

Consumer industries, including cosmetics, food and drinks, are capitalising on the purported therapeutic applications of CBD oil. Depending on their product, producers of CBD-infused goods need to look to a variety of other industry regulations in the UK, set out by the Medicines and Healthcare Products Regulatory Agency (MHRA), the Food Standards Agency, Trading Standards and the Cosmetics Toiletry and Perfumery Association. How these parameters and guidelines apply to CBD-infused products is often unclear or inconsistent.



# UK REPORT INDUSTRY EXPERT INTERVIEW



**Barbara Pastori**  
*Head of Consultancy,  
Prohibition Partners*

## **Please introduce yourself and tell us what you do for Prohibition Partners.**

I currently manage the Consulting team at Prohibition Partners. We are a strategic consultancy specialising in the legal cannabis sector. Our mission is to open up the international cannabis industry through reliable data and intelligence. We provide a broad range of services around strategy setting, market intelligence, regulatory analysis and lobbying support, as well as branding. We leverage our broad network of contacts to provide our clients with solid insights and connect them with reliable partners to expand their business.

## **Medical cannabis has been legal in the UK for over a year, but access is still limited; why is that and what needs to happen to improve the current situation?**

Reportedly, there may be as many as 1.4 million people in the UK using black-market cannabis to manage chronic pain conditions. These people are primed and ready to switch to legal high-quality medical cannabis, as soon as the current price (the highest in Europe) comes down, and access and prescriptions are issued not only by private clinics, but also by the NHS. We forecast that the UK will experience the highest growth in Europe over the next five years to 2024, but explicit approval from the relevant authorities (NHS, NICE) and some level of reimbursement, as well as training in the endocannabinoid system for doctors, will be essential to ensure large-scale patient access.

## **How do you see the current state of the medical cannabis market in the UK?**

Promising but slow. The UK boasts an extremely active cannabis sector, with a number of notable pharmaceutical players willing to join the sector. This, coupled with relatively liberal regulations, which allow substantial involvement of private companies in the supply chain, led to a few import shipments as well as a number of partnerships signed between producers and distributors. These companies are now best placed to benefit from the probable relaxation of current Conservative policies. When the National Institute for Health and Care Excellence (NICE) assessed medical cannabis and medicinal cannabis products for its November 2019 guidelines, one of the criteria to be met is “value for money”; and, therefore, a reduction in price, linked to a decrease in either the cost of cultivating, importing and distributing medical cannabis, or a change in taxation and fees, could really make a substantial difference to sales.

## **What are the biggest opportunities in the cannabis industry in the UK?**

Cultivation is not an option for medical cannabis at this point, as all the medicinal cannabis produced in the country is used for pharmaceutical production and there are no licences available for the production of medical cannabis (as an unlicensed medicine). Currently, the best opportunities are within the import/distribution sector (either through partnerships with local established pharma players, or through the creation of specialised start-up businesses). Moreover, since we expect the UK to

remain a private market for the next few years, private health care should be considered as an opportunity to gain patient base and, at the same time, educate specialists.

**What would you say to a business owner or investor, looking to operate in the UK cannabis market?**

Be patient. Preparation is key. Plan your strategy carefully and invest in long-term partnerships, as well as raising the profile of your company and the industry in general, with regulators.

**What is the best piece of advice you would give to a business looking to expand into the cannabis market, having never worked in the space before?**

Choose wisely and strategically when it comes to positioning your company in the value chain. The regulatory system can be tough to navigate without appropriate expertise; when companies have this in place, it gives them an advantage over their competitors. Focus on quality over volume and emphasise the evidence base over misinformation.

**How have you helped other businesses in the cannabis market?**

The Consulting team at Prohibition Partners have facilitated countless clients to define their market entry strategy to Europe, taking into account current and future global market balance, as well as in-depth analysis of potential import or cultivation markets. We have provided market intelligence and strategic advice to established pharma and FMCG play-

ers, tailoring our support to help them better understand the potential of cannabis for their specific sector. We have also helped clients to maximise their lobbying and fundraising efforts, by structuring successful communication strategies with investors and regulators, whilst focusing on a compelling rebranding of the company. In addition, we have supported international LPs with their offtake strategy, establishing the best options for their particular needs and connecting the client to credible distributors open for long-term partnerships.

# REGULATORY ENVIRONMENT

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- 1 Regulation reform is buoyed by highly visible patient cases.**
- 2 Medical legalisation is not yet supported by provisions for patient access. Official recommendations for prescribing CBPMs changed in November 2019, however, with access increased to include Sativex and Epidyolex.**
- 3 While the CBD market thrives, the laws governing THC limits and the definitions of novel foods remain legally obscure.**





## BACKGROUND AND CONTEXT

### 1913

Cannabis becomes criminalised in occupied territories ('Ganja' Law introduced in Jamaica).

### 1928

Cannabis prohibited in the UK.

### 1971

Cannabis classified as a Class B drug under the Misuse of Drugs Act 1971.

### 1998

House of Lords calls on the government to reschedule cannabis and allow doctors to prescribe it for patients with MS.

### 1998

UK government green-lights a cannabis research facility operated by GW Pharmaceuticals, a subsidiary of the Capital Group.

### 2004

Cannabis rescheduled from Class B to Class C.

### 2009

Cannabis rescheduled back to Class B.

### 2017

**OCTOBER 2017** — Bill calling for the legalisation of cannabis for medical purposes was introduced to parliament.

### 2018

**OCTOBER 2018** — first hearing.

**JULY 2018** — second hearing.

**APRIL 2018** — The Dingley family applied for a licence to use medical cannabis oil to

treat their six-year-old's severe epilepsy. Two months later the Caldwell family attempted to 'openly smuggle' cannabis oil from Canada to the UK to treat Billy, 12, also an epilepsy sufferer. The two incidents mobilised mainstream media support and created public awareness around the urgency for medical cannabis reform.

**JUNE 2018** — The Home Office began reviewing its legislative stance on medical cannabis. Home Secretary Sajid Javid announced that the Home Office would provide 20-day licences to use medical cannabis for both Billy Caldwell and Alfie Dingley.

**JUNE 2018** — The government announced it would be undertaking a two-part review to examine the scheduling of cannabis-related medicinal products under the *Misuse of Drugs Regulations 2001*.

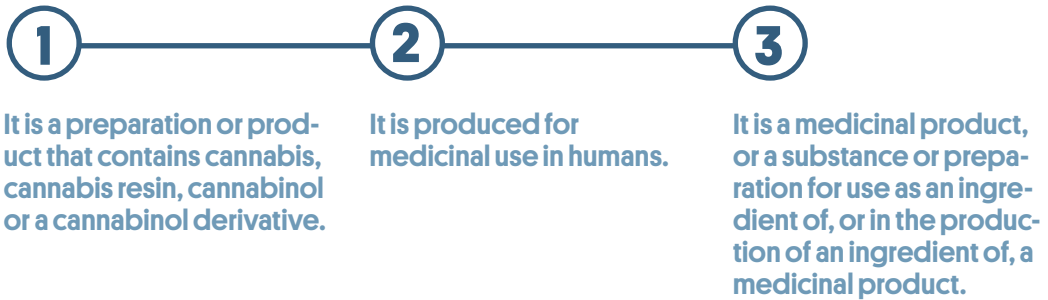
**NOVEMBER 2018** — Medical cannabis legalised. New regulations introduce a definition of 'cannabis-based products for medicinal use in humans' (CBPMH). Only products meeting this definition would be moved to Schedule 2. Products that failed to satisfy the definition would remain Schedule 1 drugs and be available only under a Home Office licence.

### 2019

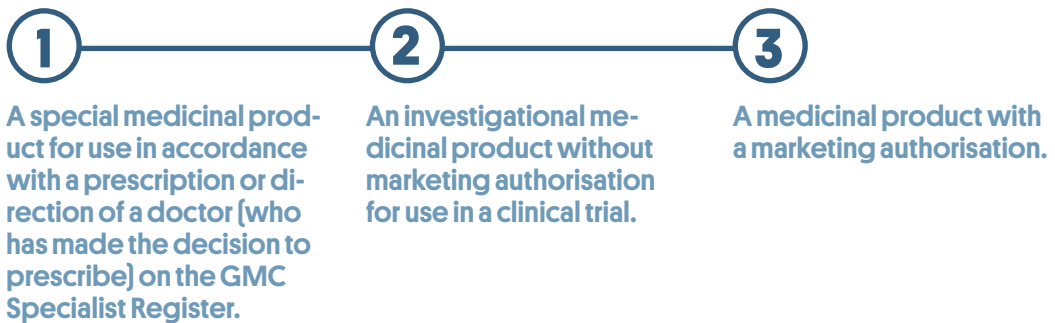
**FEBRUARY 2019** — The first major shipment of medical cannabis arrives in the UK from the Dutch Office of Medical Cannabis. The delivery was facilitated by Grow Biotech, European Cannabis Holdings and pharmaceutical importer IPS Specials.

**MARCH 2019** — A new panel was convened by the Health & Social Care Committee (HSCC) to explore the issues that underpinned the November 2018 ruling and to assess how well the new regulations are working.

## To be considered a CBPMH, a product must satisfy three requirements.



## The new regulations also allow just three access routes for the order, supply and use of these products by patients.



This change in regulation brought medicinal cannabis products in line with the existing medicines framework, folding it into well-established mechanisms for the supply of unlicensed medicines to patients with exceptional needs. Currently there is no government policy pertaining to the conditions for which medical cannabis can be prescribed; the implication is that doctors have the freedom to use their clinical judgement. Medicinal cannabis can only be prescribed by doctors on the GMC Specialist Register (an estimated 80,000 doctors) where the cannabis-based product is an unlicensed ‘special’ medicinal product for use by a specific patient. Once a product is licensed by the MHRA, it will be available for prescription in the same way as any other Schedule 2 drug.

In an open letter to clinicians, sent on the eve of the rescheduling of certain cannabis-based

products for medicinal use, NHS England criticised the new regulations for raising more questions than they answered, as no CBPMs are routinely commissioned by NHS England.

Restrictive NHS prescription guidelines (cannabis products may be used only as a last resort) and the lack of guidance for NHS doctors on how to prescribe cannabis have meant that many of the doctors on the GMC Specialist Register have refrained from prescribing cannabis due to a lack of infrastructure to support them. The only guidance available takes the form of new continuous professional development e-learning platforms, such as that operated by the Academy of Medical Cannabis (chaired by Professor Mike Barnes, Academy Director of Education and one of Europe’s most respected experts in medical cannabis and related policy).

The publicity around the law change in November 2018 resulted in a surge in patient requests for medical cannabis treatments. With no formal training on medical cannabis as a treatment option, healthcare professionals were unprepared for this influx.

The draft NICE guidelines, published in August 2019, which set out guiding principles for physicians prescribing medicinal cannabis for spasticity in MS, chemotherapy-induced nausea and vomiting, severe treatment-resistant epilepsy in children (specifically Dravet syndrome and Lennox-Gastaut syndrome), chronic pain in adults, and appetite and weight loss associated with HIV/AIDS, were

criticised for being overly restrictive. While the legislation technically allows medical cannabis to be taken for any condition, lack of clarity due to insufficient training on medical cannabis means doctors are more likely to follow the guidelines in the narrowest sense and are therefore less likely to prescribe it for conditions other than those listed. NICE further reformed its guidelines on cannabis prescriptions in November 2019, approving reimbursement for the licensed cannabis-based medication Epidyolex, available through the NHS. NICE recommendations issued in November 2019 are summarised below.

## NICE recommendations for prescribing CBPMs

Condition	Recommended cannabis-derived medicine	Reason
<b>NAUSEA</b>	Nabilone, where other medications have not been efficacious	Some evidence of efficacy for treatment-resistant nausea; some side effects cited
<b>CHRONIC PAIN</b>	None	Treatment effect exists, but it was deemed 'modest' and not cost-effective for the NHS
<b>MS SPASTICITY</b>	Sativex, where other medications have not been efficacious	Some evidence of efficacy for reduction in spasticity. However, evidence was considered 'low quality'
<b>RESISTANT EPILEPSY</b>	None. However, the Committee did not recommend against the use of cannabis-based medications for severe epilepsy, of which Epidyolex is the only licensed product available in the UK	'No clear evidence' pertaining to the efficacy and safety of cannabis-based medication in the treatment of severe epilepsy; adverse side effects cited

Source: NICE guidelines, November 2019

NICE initially reported receiving significant feedback on the draft recommendations. The Royal Pharmaceutical Society criticised the draft publicly, and called on NICE to consider case studies and real-world data in place of lengthy randomised controlled trials (RCTs) for patients who require treatment urgently and whose doctors deem cannabis-based treatments the only viable option in the short term. The public consultation is likely to have influenced the final guidelines issued in November 2019.

The regulatory environment is rendered even more complicated by the guidelines issued by patient/category-specific governing bodies.

The BPNA is especially cautious in its approach. It advises against working with unprescribed CBD oil, and does not recommend that doctors prescribe products that contain THC (for example, Bedrolite). On the basis that ‘the evidence base for the efficacy and safety of most of the CBPMs is extremely limited’, the BPNA has drafted guidelines indicating that cannabis should be prescribed only as a last resort or for children who meet the following three criteria:

- 1 have epilepsy that has proven intractable to treatment with conventional, licensed anti-epileptic drugs given at therapeutic doses
- 2 have not responded to a ketogenic diet, or for whom the diet is inappropriate
- 3 are not candidates for epilepsy surgery.

The current system for prescribing medicinal cannabis remains inadequate. The people who benefit the most from the new regulations are those who can afford private healthcare. When Professor Mike Barnes made the point that ‘not one patient has yet managed to obtain a cannabis prescription on the NHS’ (British Medical Journal, February 2019) and the first private prescription of cannabis reportedly cost £2,500 for a three-month supply, it was clear that there would be a backlash to privatisation of cannabis medicines. It was not until September 2019 that the NHS referred its

first patient to The Medical Cannabis Clinics, private clinics based in the UK.

## MAIN REGULATORY BODY GOVERNING CBPMs

The involvement of a large number of regulatory bodies (government, industry and Trading Standards) is a defining feature of the challenges affecting medicinal cannabis. The UK MHRA is responsible for controlling and regulating medicines, but it has not published any statements regarding the regulatory status of CBD and cannabinoid-containing products since December 2016.

Our primary concern is patient safety and we wish to reiterate that individuals using cannabidiol (CBD) products to treat or manage the symptoms of medical conditions should discuss their treatment with their doctor.

The MHRA works with individual companies and trade bodies to ensure products containing CBD, which are used for a medical purpose and can be classified as medicines, satisfy the legal requirements of the *Human Medicines Regulations 2012*.

The Department of Health and Social Care (DHSC) issued its most recent statement on medicinal cannabis in June 2018:

It is unlawful to prescribe, possess, supply, produce, import or export any other cannabis product containing THC for medicinal purposes, except under a Controlled Drug (CD) licence. An application for a CD licence to use a THC-containing product for medicinal purposes would only be considered for use in bona fide research or a clinical trial, with appropriate clinical support. No such applications have been received by the Department. No licences have therefore been granted by the Department.

## CURRENT LAWS AND REGULATIONS GOVERNING CBD

Approximately 7.3 million people are currently using CBD products each year in the UK. Products ranging from cosmetics to supplements and cannabis flower are being sold both online and in specialty and high-street retail stores. The laws governing hemp supply are clear: licences are granted to grow hemp with THC levels below 0.2% for fibre, stalk and seed. The laws governing CBD products are somewhat vague. Despite the apparent ban on CBD products indicated by legal instruments such as the Misuse of Drugs Regulations 2001, laws are enforced lightly and inconsistently and, as a result, the market is currently thriving. Industry leaders, medical professionals and patient bases are all calling for clarification on the current laws surrounding CBD supply and possession, with hopes that the government will consider the potential medical and financial benefits of bringing clarity to the market by legalising it.

**Approximately 7.3 million people are currently using CBD products each year in the UK.**

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## Focus on hemp

Historically, industrial hemp was cultivated for its fibre for use in clothing and paper manufacturing, as well as in construction. More recently, in part due to a better understanding of its therapeutic properties, industrial hemp is being grown to harvest CBD for use in consumer goods such as BPC, pet care, drinks, food, food supplements and vape products.

A key condition for granting a hemp cultivation licence is that only the fibre and hemp seeds can be processed for commercial purposes (as seed, fibre or oil). The rest of the plant, including the bud and flower, must be destroyed. The bud and flower fall under the generic term of 'cannabis' (and are within the scope of the *Misuse of Drugs Regulations, 2001*), and thus cannot be sold in shops. Home Office guidance issued in November 2018 made it very clear that British farmers would not be permitted to harvest the flower for CBD oil, restricting permission to growing seeds and cultivating the stalk. Industry operators point out that this highly punitive decision puts UK hemp farmers at a distinct disadvantage, with the most valuable part of the crop (which can be used to extract CBD in other countries) rendered worthless in the UK market.

## HEMP SUPPLY

To grow hemp in the UK a licence from the Home Office is required. The process is as follows:

- Apply using the online application form (MD 29) on the Home Office Drugs Licensing website.
- Register with the Home Office and submit the application form electronically.
- Provide contact details along with field location numbers, names/grid references, hectare details, farm map with a marked growing area, seed type, THC content and confirmation of whether this is an EU-approved seed.
- The fee must be paid with the application. New licences usually cost £580, while licence renewals cost £326.
- Eligibility for a licence is subject to a Disclosure and Barring Service check.
- Applications are generally considered by assessment of the electronic documents,

although the applicant may be subject to a compliance visit.

- The licence must be in place before the planting of hemp commences.
- The Home Office may impose restrictions on where the crop is planted. It may also request that the crop is screened off or 'sensitively' located, for example, not near schools or in areas of public access.
- The Home Office must be notified of any changes to the licence holder's growing season or planting location. Full details of the changes must be supplied.

Licences typically last for three growing seasons, and an 'annual licence review statement' must be submitted in advance of the new season, which is typically in March. Local police must also be informed where hemp will be grown. Only EU-approved seed varieties may be sown, and only in 'sensitive' locations (away from schools, hospitals and public rights of way). The price of each licence type is shown in the table below.

### LICENCE REQUIREMENT

### COST

Licence renewal

» **£326**

First-time cultivation licence

» **£580**

Licence requiring compliance visit (uncommon)

» **£1,371**

Licence for 'high-THC' cannabis cultivation (for comparison)

» **£4,700**

## Focus on Hempen

In July 2019, not-for-profit Oxfordshire-based company Hempen Co-operative was ordered to destroy its crop, as the Home Office belatedly denied it a licence to grow hemp in the UK. Hempen had reportedly submitted clear statements over three consecutive years to the Home Office detailing how the plant was to be used, and stressing that the CBD oil to be extracted from the hemp was well within the Home Office's legal limit of 0.2% THC. No issues were raised by the Home Office with regard to the intended use of the plant until a sudden U-turn in July 2019, which saw the full licence revoked mid-season.

This decision had a far-reaching impact, with an estimated financial loss to the company of £200,000 expected as a result of destroying the crop. To continue to supply customers with certified-organic fully traceable CBD products (including organic hemp seed oil, hemp tea and moisturising oils), Hempen now imports CBD from partners in Europe. Hempen has indicated that it will continue to work with the Home Office on the appeals process.

A national campaign has been launched to have the decision reversed and urge the Home Office to grant licences to British farmers who want to cultivate the crop for CBD oil and other extracts.



## OTHER INDUSTRY REGULATIONS

Depending on the product, producers of cannabis-infused goods may also need to meet and adhere to a variety of other industry regulations (on cannabis, food safety, food supplements, vape and cosmetics) issued by various government departments.

### CBD as a novel food

Member states of the EU already regulate the supply of cannabis and its extracts at the national level. In the UK, for example, the Misuse of Drugs Regulations 2001 regulates cannabis and extracts of cannabis, along with other controlled substances.

However, authorities in EU member states have to regard food, drink and food supplements with CBD as a 'novel food' on the basis of the European Commission definition: 'food that had not been consumed to a significant degree by humans in the EU before 15 May 1997, when the first Regulation on novel food came into force'. As such, the rules of the European Food Safety Agency have to be adhered to. Technically, food and supplements in the UK that contain CBD should be classed as a novel food and should require a novel foods licence. However, in reality, CBD products are sold as food and supplements in mainstream retail stores out in the open. The authorities are operating a 'light touch' policy, and this allows the market to thrive.

## CBD: TRADING STANDARDS/ IMPORTS

Trading Standards has the authority to oversee the UK CBD retail market. However, there is a need for further clarity from the UK regulatory authorities on the legal status of CBD.

- In September 2018, police officers, supported by Trading Standards, confiscated cannabis and CBD products from a shop in Plymouth.

- In 2019, the restaurant Canna Kitchen in Brighton, which offered foods infused with hemp-derived CBD, was raided and shut down by police despite the restaurant owner's claims that both the police and the Trading Standards Agency had declared the business legal. As the restaurant used hemp-derived CBD products, it was thought to have met the Home Office guidelines for legality up to that point.

### THC limits

Confusion remains regarding the legal limit for THC in CBD oils and other products, and this results in open trade of CBD products in high-street stores like Holland & Barrett and CBD-focused stores such as Hemp Life.

Police raids are carried out occasionally, with a view to prosecuting suppliers of CBD stores who are suspected of distributing cannabis flower that exceed the 0.2% THC limit on cannabis substances or the 1 milligram THC limit on vessels containing cannabinoids. These laws are laid out in government guidelines: 'Drug licensing fact sheet – Cannabis, CBD and other cannabinoids.'

Clarification on the laws has been provided by the Home Office in response to freedom-of-information requests, indicating that any product containing controlled cannabinoids, such as THC in excess of 0.2% concentration, will be classified as a controlled substance. Low-THC flower is sold openly in the UK, online and in retail stores. The senior compliance officer of the Drugs & Firearms Licensing Unit within the Home Office has confirmed that any flower produced from cannabis plants is defined as a cannabis substance, indicating that possession or supply of cannabis flower may be prosecuted similarly, regardless of THC content.

In summary, the law is clear that 'no one component part of the product or preparation may contain more than one milligram of controlled drug' (Misuse of Drugs Regulations 2001). Inconsistent application of the laws under the 'light touch' approach used by the authorities throws into confusion whether CBD products are fully covered by the law. In either case, the market for CBD is booming,

## Market for CBD is booming, with a YouGov survey indicating 11% of UK inhabitants used CBD products in the last year

with a YouGov survey indicating 11% of UK inhabitants used CBD products in the last year, amounting to roughly 7.3 million people. While the market is one of the largest in Europe, UK inhabitants are not reaping the full benefit, as the vast majority of products are imported and bought online. Three quarters of respondents to the YouGov survey stated support for allowing CBD to be grown and processed freely in the UK. If and when the government responds to such opinion, the UK could see the growth of a new source of revenue, jobs and investment opportunities in the country.

### Licences and availability

- The prescription process in the UK now represents the tightest bottleneck to patient access and the cannabis value chain.
- Removing the requirement to obtain prescriptions from specialists and allowing a patient's GP to prescribe CBPMs directly would improve patient access considerably.

### Licensed products

Sativex, Nabilone and Epidyolex are currently the only licensed pharmaceutical cannabis products in the UK. Sativex is used to treat spasticity associated with MS. Nabilone is prescribed to treat nausea as a result of chemotherapy. Epidyolex was approved for use by the European Medicines Agency (EMA) for two rare forms of epilepsy, Dravet and



Lennox-Gastaut syndromes, in September 2019, but it was not until November 2019 that NICE issued guidelines which stopped short of recommending the use of Epidyolex. Instead, the agency chose not to recommend against cannabis-based medication for severe epilepsy, this while cautioning specialists and patients about the ‘lack of evidence’ to support claims on the efficacy or safety of cannabis-based medication for the treatment of severe epilepsy. NICE recommends the cost of the medication be covered by the NHS. Shares in GW Pharma, the manufacturer of Epidyolex, rose by more than 2% following the announcement.

All other CBPMs fall into the category of ‘Specials’: unlicensed medicine that may be prescribed by consultants in exceptional patient cases. The current licensed products and use of those products severely limit the potential therapeutic benefits that UK inhabitants obtain from CBPMs. Pain conditions such as chronic pain and fibromyalgia are the most common reason for use of medical cannabis in most countries such as the USA, Germany and Australia. People in the UK suffer from a particularly high rate of chronic pain (defined as pain lasting more than three months) at 43% for all levels of such pain and approximately 12.4% or 7.9 million people with moderate or severe pain. Yet, CBPMs are not available to this large population suffering pain-related conditions. If products such as cannabis flower and Nabixols were licensed in the UK, this would represent a major opportunity for not only improving patient lives but also benefiting investors.

## Access routes

There are three access routes to medicinal cannabis under the new regulations introduced in November 2018. The most relevant is ‘specials’: a special medicinal product can be prescribed by a doctor on the GMC Specialist Register for patients with exceptional needs.

In September 2019, the government responded to the Health and Social Care Select Committee’s report on drugs policy with the following points.

- The DHSC and the MHRA have met with a number of producers of CBPMs to establish a supply of ‘special’ medicines that meet quality standards in the UK.
- Lists of licensed UK wholesalers and products were made available by the NHS to procurement pharmacists. These will be updated as new products become available.
- Further work on establishing a stable UK supply is being undertaken. NHS England and NHS Improvement are working with suppliers to ensure that sufficient stocks of good-quality CBPMs are available and that these products offer the best value for the NHS. This work includes scoping options for UK manufacturers.

## Import licensing and supply chain

The supply of medicinal cannabis to the UK is tightly regulated.

Importers of medicinal cannabis must:

- apply to the Home Office for a licence,
- each licence automatically expires after three months.
- while the Home Office states that applications are usually processed within 10 working days, reports of delays of anywhere from twenty-eight days to three months are common.
- a new import licence is required for each individual shipment.
- licence holders are required to submit annual statistical returns to the Home Office
- licence holders must submit online endorsements for actual shipment amounts immediately after they have been shipped

Following legalisation, it took three months to source enough medical cannabis to treat thirty patients for one month. Initially, specialist wholesalers applied for licences on a prescrip-

tion-by-prescription basis. This created a bottleneck in supply of CBPMs with patients waiting up to three months for their medicine, which is not viable for many patients, especially those in palliative care.

Since February 2019, there has been some improvement in the supply of medicinal cannabis in the UK with the first licensed bulk imports of CBPMs. The first-ever bulk shipment of medicinal cannabis came from the Netherlands. This was facilitated by the Astral Group (now part of Lyphe Group). Canadian company Tilray is now facilitating bulk imports of cannabis oil to the country. In October 2019, Canopy Growth began bulk imports of medical cannabis from its distribution centre and greenhouses in Denmark. They also have storage facilities in Buckinghamshire, UK, meaning that a more stable supply of medicinal cannabis can be made available to UK patients. With the awarding of the first bulk import licence, the supply of medication should improve significantly. This may in turn improve access to prescriptions if specialists feel more assured of the medicine's availability.

### Prescription process holding back patient access and investor opportunity

Two factors that could massively improve patient access and investor opportunities in the UK would be:

- 1 allowing GPs to prescribe a wider range of CBPMs without consultant input and
- 2 issuing comprehensive guidelines for prescribing cannabis based on evidence from international as well as domestic clinical trials.

At the moment, patient access is slowed by the requirement to obtain a prescription for any unlicensed products from a specialist consultant. However, many leaders in the industry as well as medical and political groups are calling on the government to license more CBPMs, which could be prescribed by a patient's regular GP. A report by the cross-party Health and Social Care Committee advised

that the government risked 'failing' patients who have 'distressing and life-threatening conditions' if more consideration was not given to licensing products. If UK leaders are not ready to accept evidence from international sources, the outcome of clinical trials within the country will largely determine the outcome of these issues. The other factor that will eventually unlock cannabis access in the UK is the issuing of guidelines in November 2019 by NICE for prescriptions issued by the NHS. These are likely to play a large role in determining patient access and investor opportunities.

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**Prohibition Partners' estimates that up to 1% of the UK population could potentially be medical cannabis patients by 2028.**



# INDUSTRY EXPERT INTERVIEW



**Jonathan Nadler**

Group Managing Director,  
Lyphe Group

## Tell me about Lyphe Group and its role in the medical cannabis market in the UK.

We have spent the past 18 months developing a patient focused ecosystem of medical cannabis companies, with a focus on building the infrastructure for the UK market.

We have spent the past 18 months developing a patient-focused ecosystem of medical cannabis companies, with a focus on building the infrastructure for the UK market.

Our strategic approach has been to design logistics and services that comply with CQC, MHRA and the Home Office's compliance and regulatory requirements, whilst ensuring we remove friction from patient access.

Our business portfolio includes:

- The Medical Cannabis Clinics – the UK's first chain of clinics is focused on medical cannabis treatments, provides patient access and captures scripts
- Dispensary Green – the UK's first cannabis-focused pharmacy, fulfils our patients' scripts as well as the broader market and more general NHS scripts
- Astral Health – handles the import and distribution of EU-GMP certified medical cannabis into the UK and other European markets
- The Academy of Medical Cannabis – online education platform on medical cannabis for health professionals

## One year after legalisation, supply remains a significant stumbling block for patients wishing to access medicinal cannabis. How would you like to see this addressed going forward?

Yes, it has been slow to get going. However, the last two months has shown us that the market is finally opening. We have seen a surge in script numbers, a surge in doctor numbers, and a surge in patients receiving their medicines.

We have to remember that whilst the re-scheduling happened on 1 November 2018, doctors were not ready and the health sector was catching up. Of course, we recognise the market is not where we would like it to be; we are where Australia was in January 2018, but look at that market now, more than 20,000 patients approved and growing at about 4,000 per month.

The room for UK growth is phenomenal; demand is through the roof from both those looking to obtain medicine on the private market and those waiting to receive it on the NHS, and consequently we will be one of the top medical cannabis markets in Europe by the end of 2021.

## Education and training of specialist doctors is another obstacle. The Academy of Medical Cannabis was established to combat this. What can be done to ensure more doctors are educated in the endocannabinoid system? Do you think that the education of doctors would have a significant impact on

### **the number of prescriptions being written for cannabis?**

Yes, education is key. It's something said daily by pretty much everyone in the industry but it's true.

Doctors have to understand the biology of how the endocannabinoid system (ECS) works. It's complicated and without proper training it might seem alien to some doctors. Thankfully, universities are beginning to look at introducing modules around the subject of medical cannabis and the ECS, the evidence and the phytocannabinoids, so the generation of healthcare professionals coming through will have a very different perspective.

It is for the current doctors to take the time and use their CME/CPD credit requirements to investigate medical cannabis. We have a library of more than 45 hours of online education as a starting point, and the most established offline training in the UK as well.

Our training programme is consistently rated highly by doctors that have taken it. We have designed it around giving the doctors the tools they need to go into their clinic the following day (or work in one of our clinics) and write prescriptions confidently.

Plant medicine and preventive medicine will be one of the most significant shifts in Western medicine over the coming decade. Those doctors that don't take action to keep up will get left behind – after all, patients are smart, they see what is happening in other Europe-

an and global health sectors and they do not want to feel they are not getting the same care and access to the same medicines.

### **What are the other factors hindering patient access and how might these be resolved?**

The guidelines from NICE we all know are mainly economically driven and based on their rigid approach to only following RCT evidence, the gold standard in the UK. But NICE make it clear that it is down to the circumstances of the consultation that the doctor is having with the patient as to what they decide is best to prescribe. And doctors are taking note of this and the other solid evidence that exists and that is used by other legal medical markets, and from this they are now starting to prescribe medical cannabis a lot more.

Price is not helping the market – it is still way too high for the NHS to agree to this medicine being handed to patients for free. Even the drug Sativex which has a marketing authorisation in the UK has a scheme whereby they reimburse for patient scripts, taking the pressure off the NHS balance sheet.

### **The vast majority of cannabis prescriptions to August 2019 were written by private cannabis clinics; how long do you think it will take for the NHS to increase its share of cannabis prescriptions and what is the key obstacle to this?**

Probably up to 24 months. Price is the main obstacle.

**The medicine for UK cannabis patients is imported, but do you see an opportunity for cannabis grown on home-soil to help reduce the prohibitive prices and speed up access?**

Price will fall dramatically next year as imported product becomes easier to bring in and the LPs bring their price down as the raw API becomes even more commoditised.

Yes, there will be a domestic market but we are a long way off this and it is still yet to be seen what the price point might be.

**There has been a lot of discussion around CBD lately about product quality and content, even when sold through trusted high-street retailers. What can be done to reassure consumers of product provenance, and quality?**

We need to wash out some of the CBD businesses that are giving the industry a bad name. We also need to do something about the inconsistent efficacy of the product from brand to brand. If it doesn't work, it is not going to be highly regarded and we as an industry cannot allow this to happen.

More needs to be done to create a market that is driven by a clear supply chain for reasons of consumer safety – there are a few businesses and concepts that are driving this change but it will take time and needs more input from the regulators.

**Which medical cannabis model employed internationally do you believe the UK has**

**the most to learn from?**

Australia have some challenges but their growth has been good and the ease for patients to get approval has seen a recent step change that should be admired.

Germany, obviously, being the largest medical cannabis market in Europe, gets everyone's tongues wagging, but I like to look at those coming through – Czech Republic, with its recent change of reimbursement seems like a very interesting market and the system in Denmark has given it kudos around the world. France has a lot of work to do but the potential for a successful and well-orchestrated trial from early next year could see it becoming one of the key European markets in 2022.

**Despite trials being done overseas, it seems that the British medical community are looking for British research into the efficacy of cannabis as a medicine. What is the role of research in helping to unlock the potential of the UK market?**

It is everything. Ten years from now there will be so much more known about the medicine, the chemical and therapeutic uses of the plant, and clear pathways for a number of conditions which will give certain brands/strains/ratios marketing authorisation for those conditions. The industry today will be gone and a pharma-led one will exist in its place. Purists will hate to hear this but it is the reality of the health market.

**What will the cannabis landscape in the UK look like in five years' time?**

Green.

**7.18%** of UK  
adults have used  
cannabis in the past  
year. This accounts  
for approximately  
**4.7 MILLION**  
adults, which  
gives an estimated  
black-market  
value of up to  
**£6 BILLION**  
per year.

# HEALTHCARE ANALYSIS

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- 1 Due to a paucity in education and training opportunities in cannabis-based medication, medical professionals lack the confidence to prescribe the medicine for conditions other than those listed in the NICE guidelines or for symptoms other than those narrowly defined within the same guidelines.**
- 2 With up to 52 conditions potentially treatable with medical cannabis, Prohibition Partners estimates that the total patient base in the UK could potentially reach four million.**
- 3 The cost of cannabis based products has been prohibitive for many patients to date and has acted as a disincentive for businesses entering the UK market. The**

**addition of two new licenced cannabis based medications for reimbursement under the NHS in November 2019, has not gone far enough to satisfy patient advocacy groups, which have called for an expansion of the list of conditions to be treated with cannabis based medications, along with greater access to these medications.**



## OVERVIEW

Healthcare in the UK is a devolved matter, with England, Northern Ireland, Scotland and Wales each having its own NHS of publicly funded healthcare, funded by and accountable to separate governments and parliaments. A smaller private sector and voluntary provision supplement the publicly funded healthcare. This means that the approach to medical cannabis differs by nation. In August 2014, Wales became the first UK nation to authorise the funding of Sativex on the NHS. The All Wales Medicines Strategy Group took the decision, despite NICE guidelines to the contrary stating that the drug was not cost-effective.

In other geographies a wider range of illnesses and disorders benefit from treatment with medicinal cannabis. For example, in the US state of Connecticut doctors can recommend medical cannabis for 29 conditions in adults

Data from the British Medical Journal on patient numbers for 52 conditions potentially treatable with medical cannabis indicate a potential patient base of over 4 million people. Prohibition Partners' estimates that up to 1% of the UK population could potentially be medical cannabis patients by 2028. Cannabis researchers are currently exploring the likelihood of a wider range of conditions qualifying for treatment with medical cannabis, including neurological conditions such as Alzheimer's and Parkinson's. Currently, the EU Clinical Trials Register shows 18 cannabis studies being conducted in the UK, and a further two examining the impact of THC on dementia.

## MAIN CONDITIONS TREATED

When cannabis-based products were moved to Schedule 2 of the *Misuse of Drugs Regulations 2001* in November 2018, clinicians made it clear that, in the short term at least, they were focusing on the following five conditions set out in the government's review:

- 1 » MS (specifically pain or muscle spasticity)
- 2 » chemotherapy-induced nausea and vomiting
- 3 » severe treatment-resistant epilepsy in children (specifically Dravet syndrome and Lennox-Gastaut syndrome)
- 4 » chronic pain in adults
- 5 » appetite and weight loss associated with HIV/AIDS.

## Conditions for which medical cannabis is legal in other countries, by number of sufferers in the UK, 2018–2019



**Anxiety and depression**



**1 IN 4 PEOPLE**

(Mental Health Foundation)



**Fibromyalgia**

**1.5–2 M**

(Fibromyalgia Action UK)



**Cancer**

**360 K**

new cases per annum  
(Cancer Research)



**HIV/AIDS**

**100 K**

(National AIDS Trust)



**Crohn's disease**

**146 K**

(Crohn's & Colitis UK)



**Parkinson's:**

**145 K**

(Parkinson's UK)



**Dementia  
(including Alzheimer's)**

**850 K**

(Alzheimer's Society)



**Rheumatoid  
arthritis:**

**400 K**

(National Rheumatoid  
Arthritis Society)



**Epilepsy**

**< 500 K**

Epilepsy Society UK



**Spinal cord  
injuries:**

**50 K**

(Back Up Trust)

## EFFECTING CHANGE

Several groups in the healthcare sector, including patient non-governmental organisations, medical societies and government bodies, have been instrumental in progressing cannabis legislation in recent years.

Organisations representing patients, in particular, have lobbied for change in government policy on qualifying medical conditions and contributed to debates in the House of Commons. Data from the British Pain Society highlight the large number of people in the UK suffering from a variety of painful conditions: an estimated 28 million adults are experiencing pain that has lasted for three months or more. In October 2018, the society released a position paper acknowledging the potential of medicinal cannabis in treating certain types of pain, but stated that more research would be helpful in determining whether legalising medicinal cannabis was the right path to take.

Around 100,000 people live with MS. At present, only some physical symptoms qualify for treatment with medicinal cannabis, meaning that not all MS patients are eligible. In 1998, the House of Lords called on the government to reschedule cannabis and allow doctors to prescribe it for patients with MS. A 2014 survey from the UK MS Society suggested that around one in four people use cannabis to ease their MS symptoms, particularly stiffness and muscle pain. In 2018, the society launched a national campaign for better access to medicinal cannabis for patients, and continues to push for patient access to cannabis treatment for MS. Through 2019, the society has lobbied the government to improve product availability and the competence of GPs in prescribing cannabis.

In a review published in June 2018, the Chief Medical Officer of England stated that she had found 'conclusive evidence of the therapeutic benefit of cannabis-based medicinal products for certain medical conditions and reasonable evidence of therapeutic benefit in several other medical conditions'. Following this, Professor Davies

recommended that medicinal cannabis be moved from Schedule 1 to Schedule 2. The UK government implemented this recommendation in November 2018. The Royal Pharmaceutical Society, which has been a consistent lobbying force for patient access to medical cannabis in the UK, declared the reform a 'great step forward for patients'.

In May 2019 the NIHR issued two calls for research proposals on CBPMs across a range of conditions where the evidence is most compelling. NICE, in its draft guidelines, also recommends that the NIHR supports research in five priority research areas:

- CBD as an add-on treatment for adult patients with fibromyalgia or persistent, treatment-resistant neuropathic pain
- CBPMs for chronic pain in children and young people
- CBPMs for spasticity
- CBD for severe treatment-resistant epilepsy in children, young people and adults
- the effect of combining THC and CBD on seizure frequency, brain structure and neurophysiological performance when compared with CBD alone and a placebo.

In response to government pressure, in its report of 8 August 2019, NHS England committed to working with the NIHR and specialist clinical networks to determine appropriate alternative study designs for children and young adults, including those who are currently receiving a CBPM, to ensure evidence is generated for the benefit of these patients and future generations.

## PRODUCTS

Cannabis-based medicines come in the form of whole cannabis flower, oils or capsules, or a single compound which can be isolated and

extracted. The two main active ingredients in cannabis are CBD and THC.

Up to November 2019, Sativex and Nabilone were the only licensed pharmaceutical cannabis products in the UK, and are used to treat spasticity associated with MS and

nausea resulting from chemotherapy. The latest NICE guidelines, published in November 2019, added Epidyolex to the list of licenced pharmaceutical products as a treatment for two rare forms of epilepsy.

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### **Sativex (Nabiximols)**

A cannabis-based sublingual spray, which is a 50–50 combination of THC and CBD.

Sativex has been approved for use in the UK by the MHRA as a treatment for MS. It is licensed in the UK for people with MS-related muscle spasticity that does not respond to other currently authorised treatments, but its availability on the NHS has been limited to patients in Wales. In 2014, NICE, which issues guidance to NHS doctors, recommended against prescribing Sativex because it was not considered a cost-effective treatment. However, from November 2019, the medicine has been made available to NHS patients in England and Northern Ireland.

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### **Nabilone**

A synthetic non-natural cannabinoid taken in capsule form. Nabilone can be prescribed as a treatment of last resort by a specialist to help relieve the symptoms of chemotherapy-induced nausea and vomiting.

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### **Epidiolex/ Epidyolex**

A prescription CBD medication, approved for use by the EMA in September 2019 for the treatment of Dravet and Lennox-Gastaut syndromes, both rare forms of epilepsy. In draft guidelines on cannabis prescriptions issued in August 2019, NICE stopped short of making a recommendation on prescribing CBD medicines, citing the need for more RCTs. NICE guidelines updated in November 2019 chose not to recommend against prescribing cannabis-based medicines for the treatment of severe epilepsy but cautioned medical professionals and patients about its safe use. However, following negotiations with GW Pharmaceuticals, the manufacturer of Epidyolex, agreement was reached to provide the medicine to the NHS at a discounted rate.

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*Source: Prohibition Partners*

## COST OF PRODUCTS

Strict laws around licensing result in the costs associated with accessing CBPMs in the UK being high relative to other medications. Current NICE guidelines advise doctors against prescribing cannabis on the NHS, so many patients opt to use private insurance providers and foot the medical bills themselves. Patients wishing to access CBPMs other than Sativex and Nabilone must visit a specialist consultant, which can cost in the vicinity of £250 per visit. Patients are usually prescribed a single month's supply, in order to deter abuse of

the medicine. Repeated consultant visits also push up treatment costs. The second factor that currently increases the cost of CBPM in the UK is the limited supply of products. Up until 2019, no bulk imports of products were allowed, and a low supply and frequent small imports of products pushed up costs; however, costs associated with importation can be expected to lessen with the authorisation of the first ever bulk imports in the year 2019 by companies such as Lyphe Group, Tilray and Canopy Growth. The costs associated with each product can be seen in the table below.

DRUG NAME	AVERAGE DAILY COST* (£)	AVAILABLE IN UK/IMPORT	FORMAT
Sativex	9.03	Available	Oromucosal spray
Nabilone	39.2	Available	Capsules
Epidiolex/ Epidyolex	27.11	Import	Oral Solution
Dronabinol	28.36	Import	Capsules
Dronabinol SYNDROS	234.675	Import	Oral solution
Bedica THC 2.0%	0.6	Import	Oil
Bedrolite CBD 10%	19.92	Import	Oil
Tilray 2:100 THC:CBD	11.515	Import	Oil
Avidekel™ 1:15 THC:CBD	40.945	Import	Oil

\*Daily costs vary from patient to patient based on source of medication and dosage. Costs associated with importation, doctor visits and VAT not included.

Source: Prohibition Partners/National Institute for Health and Care Excellence

# INDUSTRY EXPERT INTERVIEW

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**Michael Barnes**

*Chair,  
The Medical Cannabis  
Clinics*

**Ever since the UK legalised medical cannabis in 2018 there have been very few pre-prescriptions issued through the NHS. We are observing people turning to private clinics in order to access their medication. What are the factors hindering patient access and how could they be resolved?**

There are many reasons. Foremost, I think, is the lack of understanding about the medicine amongst doctors. We can educate them (such as through the Academy of Medical Cannabis – taomc.org) but it will take time. Second is the perceived lack of evidence of efficacy. The Royal College of Physicians and now NICE have said there is insufficient evidence to warrant prescription but there is credible evidence from many senior bodies, such as the National Academies of Science, Engineering and Medicine in the USA. They are too focused on double blind trials and ignore thousands of observational trials and “real world evidence”. There are other reasons such as bureaucracy and poor supply chain but these issues should fall away as more doctors prescribe.

**Perhaps influenced by the status of cannabis as an illegal/recreational drug there appears to be a lack of understanding amongst some UK nationals and healthcare professionals regarding cannabis-derived products and medication. Is there a case to be argued for better education of the public in anticipation of easier access to cannabis as medication and prescriptions?**

We certainly need better education not only for doctors but also for the public so that the

full tide of public opinion turns in favour of having access to medicinal cannabis.

**A recent article stated that Alfie Dingley has begun to suffer seizures again due to his epilepsy, despite being seizure-free for the past 11 months. The article states that Alfie has developed a tolerance to his medication. What role, if any, might dosing play in relation to Alfie’s case? Do you believe that there is sufficient understanding of the importance of optimum dosing among medical practitioners when it comes to medical cannabis?**

There is not sufficient knowledge amongst doctors about what to do when a tolerance develops in patients. In some patients the dose needs to be increased but in others it needs to be decreased. Having an alternative strain is also important and we need other types of cannabinoids to be available such as THCA. It is very early days in terms of knowledge and supply of products into the UK.

**There is talk of a need for a Royal Commission to oversee and evaluate current drugs policy in the UK, including the easing of the process to achieve the earliest possible and safe access to medicinal cannabis. Given the complexity of the issues and the number of regulatory bodies involved, would the establishment of a Royal Commission help to expedite a licensed, regulated cannabis market?**

That is potentially a good idea as long as it doesn’t take too long and thereby delay the introduction of this valuable medicine.

**How can the correct balance be struck between opening up the medical cannabis market to better respond to the needs of some patients and making sure that there is sufficient evidence of the efficacy of these treatments?**

That's not difficult. We need evidence, of course, but by enrolling patients on an audit study, for example, we can start prescribing now and learn as we go along. The twenty21 project is a perfect example of how this could be achieved.

**Which medical cannabis model employed internationally do you believe the UK has the most to learn from?**

We need to learn from all countries that have made cannabis legal medically. I think Australia and New Zealand seem to be getting it right but there is so much to learn from 50 other countries that are ahead of us.

**How do you imagine the cannabis landscape in the UK will look in five years' time?**

I hope in five years that we will see full prescription of cannabis as a medicine on the NHS for all who need it. I think by then we will be wondering what all the fuss was about in 2019!

# CONSUMPTION

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Prohibition Partners' European Cannabis Report (fourth edition) estimated that medical cannabis can treat up to 2.9 million patients in the UK. This demonstrates the volume of the consumer base in waiting, indicating the extent to which the UK could capitalise and flourish within the legal cannabis industry. However, the current situation allows access to very few patients despite regulatory change and with no dedicated cannabis agency in place to facilitate access. A year after legalisation, just 18 prescriptions have been issued on the NHS in England and a further 135 were issued via private medical cannabis clinics in the country. Exact figures for the rest of the UK have not been made public.

- 1 **FEBRUARY 2019**  
Bulk shipment of cannabis (to treat 30 patients for one month) arrives in the UK from the Netherlands.
- 2 **MARCH 2019**  
First cannabis clinic at The Beeches Centre in Manchester opens after it was widely reported that a total of just four prescriptions for medical cannabis had been issued on the NHS.
- 3 **SEPTEMBER 2019**  
Private medical cannabis clinics receive the first referral from the NHS.
- 4 **NOVEMBER 2019**  
Sativex and Epidyolex made available for reimbursement on the NHS



Private-sector prescriptions are more likely to be filled, but there is still a blockage in the NHS despite medical cannabis now being legal and available in the country.

opened in London, where the existing multi-disciplinary approach will extend to neurology and psychiatry in addition to the treatment of chronic pain. Birmingham is also mooted as a possible future location.

## DISPENSARIES/CLINICS

It is very early days for dispensing in the UK, but Lyphe Group (formerly European Cannabis Holdings) is pioneering the effort with the first Medical Cannabis Clinic. Led by Dr David McDowell, a consultant in pain management, it opened at The Beeches Consulting Centre in Manchester in March 2019. Professor Mike Barnes, a consultant neurologist and one of the world's foremost experts in medical cannabis, has been appointed clinical director. His 2016 report, Cannabis: The evidence for medical use, is credited with helping pave the way for legalisation of medical cannabis. Read Prohibition Partners' interview with Professor Mike Barnes in this report. It is anticipated that additional clinics will be

## RECREATIONAL CANNABIS

Government statistics indicate that 7.18% of UK adults have used cannabis in the past year. This accounts for approximately 4.7 million adults, which gives an estimated black-market value of up to £6 billion per year. There is an observable decrease in the prevalence of cannabis use among youth, which suggests success of local education around the potential harms of cannabis for the mental health of youth. The millions of cannabis users in the UK, with numbers increasing over the past six years, belies the massive opportunity for investors if recreational cannabis were to be made legal in the UK.

### Cannabis consumed in the previous year, adults aged 16–59

YEAR	PERCENTAGE OF POPULATION (%)	TOTAL NO. PEOPLE (M)
2012	» 6.4	» 4.1
2013	» 6.6	» 4.2
2014	» 6.7	» 4.3
2015	» 6.5	» 4.2
2016	» 6.6	» 4.3
2017	» 7.18	» 4.7

# MARKET FORECASTS



- 1 **Medicinal cannabis market value in the UK is forecast to reach almost US\$1.3 billion by 2024.**
- 2 **Almost 400,000 patients are forecast by 2024.**
- 3 **Total cannabis market value is estimated to reach US\$3 billion by 2024.**

## MARKET SIZE AND FORECASTS

The market forecasts here have been adjusted downward from previous forecasts based on the fact that accessibility of medical cannabis post-legalisation has been significantly lower than expected based on historical data from other markets. Pressure is currently being placed on the government to increase accessibility, and a number of politicians have been outspoken in their support for legalising recreational cannabis. Key assumptions factored into the model include:

- 1 there will be a significant increase in accessibility of prescription cannabis in mid-2020 (making the UK more closely aligned with

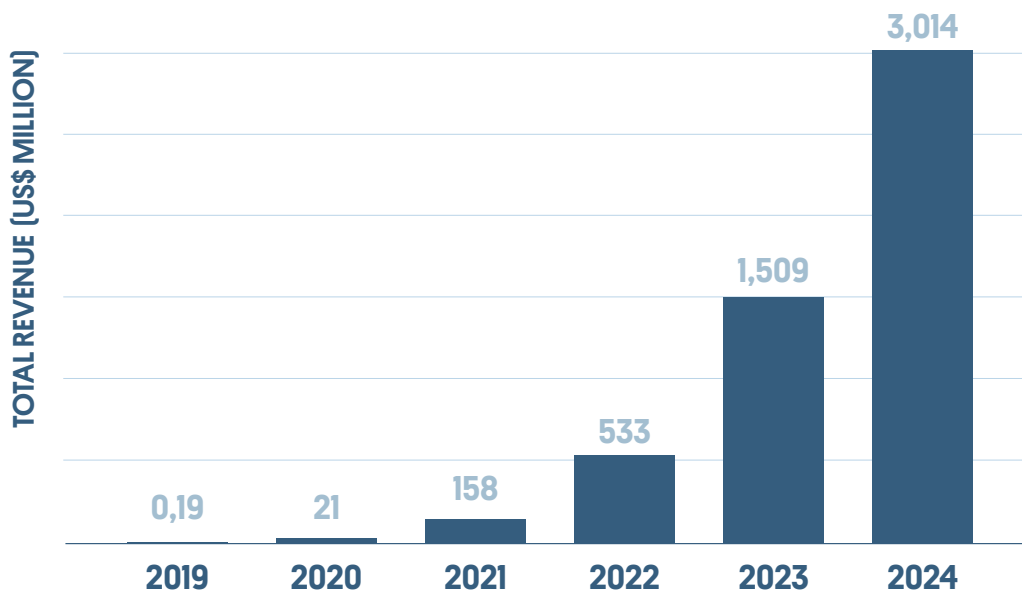
Canada in terms of growth rates) the UK will legalise recreational cannabis in mid-2021.

2 It should be noted that the impacts of a deal/no-deal Brexit have not been factored into this model due to the complexity of potential scenarios and their associated effects.

### Legal cannabis market

Prohibition Partners estimates the UK legal cannabis market will be worth US\$3.0 billion (£2.3 billion) by 2024, rapidly growing from an estimated starting point of approximately US\$190,000 (£147,200) in 2019. Key drivers behind this growth are the events mentioned above – a significant increase in accessibility of medical cannabis in mid-2020 and recreational cannabis being legalised in mid-2021.

### Total UK legal cannabis market, 2019 – 2024 (estimated)



Source: Prohibition Partners

### Medicinal cannabis market

#### UK medicinal cannabis market, 2019 – 2024

	2019*	2020	2021	2022	2023	2024
<b>Total Revenue (US\$ million)</b>	0.19	21	87	269	749	1,293
<b>Number of Active Patients at Year End</b>	242	13,076	32,784	106,784	244,685	337,886

Source: Prohibition Partners

\*In the early stages of growth, patient numbers change significantly on a monthly basis. Patient numbers could be as low as approximately 150 at year end, corresponding with estimated total revenues of approximately US\$98,256

**ALTHOUGH MEDICINAL CANNABIS HAS BEEN LEGAL IN THE UK SINCE NOVEMBER 2018, THE MARKET HAS PROGRESSED AT A FAR SLOWER PACE THAN WOULD BE EXPECTED FROM OBSERVING TRENDS IN PATIENT NUMBERS FROM OTHER GEOGRAPHIES.**

We anticipate a significant increase in accessibility for patients in the second half of 2020, igniting a period of exponential growth, leading to a total medical cannabis market value of approximately US\$1.3 billion (or just over £1 billion) in 2024 with 337,886 active patients at year end, representing ~0.5% of the total population.

**Recreational market forecast**

**UK legal recreational cannabis market, 2019 – 2024**

	2019*	2020	2021	2022	2023	2024
<b>Total Revenue (US\$ million)</b>	—	—	71	264	760	1,721
<b>Number of Regular Recreational Cannabis Customers at Year End</b>	0	0	62,799	177,360	500,766	773,334

Source: Prohibition Partners

**THE TOTAL ESTIMATED VALUE OF THE LEGAL RECREATIONAL CANNABIS MARKET IN 2024 WILL BE US\$1.7 BILLION (£1.3 BILLION)**

based on a legalisation date of June 2021. Due to the later date of legalisation, the value of the recreational market will be lower than the medicinal market until 2024, when recreational is likely to surpass medical by a significant margin.

**FORECASTED REGULAR RECREATIONAL CANNABIS CUSTOMERS AT YEAR END 2024 WILL REACH 773,334, REPRESENTING AN ESTIMATED 1.2% OF THE TOTAL POPULATION.**



# COMPANY ACTIVITY

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The cannabis investment sector is beginning to gain traction in Europe, and over the last year or so has turned its attention towards the UK market. Banking groups and private investors are setting up and investing in partnerships in the European market for medical cannabis and CBD, including the nascent dispensary and clinic sector. A number of consultancies, market research and cannabis-focused finance groups have established themselves in London. Two such companies are European Cannabis Holdings and Canaccord.

As a sign of the keen interest in the development of the commercial, regulatory and scientific landscape for cannabis products in the UK and Europe, the inaugural Cannabis Europa conference debuted at the Barbican in London in May 2018, and returned to London in June 2019 after a Paris-based event earlier in the same year. The focus is on public policy, regulatory frameworks, scientific research and commercialisation of the emerging European medical cannabis market.

## KEY PLAYERS

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UK company GW Pharmaceuticals is the largest exporter of legal medical cannabis in the world, cultivating cannabis for the production of medicines such as Epidiolex (US)/Epidyolex (EU) and Sativex. In October 2018, the company sold almost two million shares on the US stock market, raising US\$345 million (£267 million). This move came four months after Epidiolex, manufactured by GW Pharmaceuticals' subsidiary Greenwich Biosciences, became the first cannabis-derived medicine approved for use in the US for the treatment of seizures caused by Lennox-Gastaut and Dravet syndromes. Epidiolex (trading as Epidyolex) was approved by the European Commission in September 2019.

In August 2019, GW Pharma's Epidyolex was rejected by NICE for use as a treatment for rare childhood epilepsy. Following extensive randomised placebo-controlled trials, NICE has recommended two of GW Pharma's cannabis-based medicines. However, In November 2019, Epidyolex for Lennox-Gastaut Syndrome and Dravet Syndrome became the first cannabis-derived medicine to be recommended for NHS funding in England. In addition, the NICE guidelines were also updated to recommend funding for GW Pharma's Sativex drug.

## LYPHE<sup>1</sup> GROUP

Lyphe Group has developed a patient focused ecosystem of medical cannabis companies, with a focus on building infrastructure for the UK market. The group manages a portfolio which helps to build out a number of firms focused on access, imports, education and distribution, including:

- The Medical Cannabis Clinics - UK's first chain of clinics focused on medical cannabis treatments, providing patient access and captures scripts
- Dispensary Green - UK's first cannabis-focused pharmacy, fulfilling patient's scripts as well as the broader market and more general NHS scripts
- Astral Health - Import & distribution of EU-GMP certified medical cannabis into the UK and other European markets.
- The Academy of Medical Cannabis - Online education platform on medical cannabis for health professionals.



MGC Pharma is a European-based ‘seed to pharmacy’ biopharmaceutical company specialising in the production and development of phytocannabinoid-derived medicines. Having progressed CannEpil and MXP100 from the research and development stages through to commercialisation, MGC Pharma reached another milestone when, in September 2019, specialist doctors in the UK were able to prescribe these products under the Early Access to Medicines Scheme. MGC Pharma is looking to the UK, alongside Australia, for its growing patient base and is evolving a network of distribution and commercial partners to help achieve its goal.

## CANNABIS GIANTS MOVE INTO THE UK MARKET

Interest in the UK medicinal cannabis and CBD markets is currently rocketing skyward. Companies from Australia, the US and Canada are all putting down roots in the market either directly or, in the case of companies like Althea, through a UK subsidiary. Many of the international groups have come together to form a lobbying voice for the industry in the shape of the Centre for Medical Cannabis. Members include industry goliaths like Aurora and Spectrum Pharmaceuticals, a subsidiary of Canopy Growth. Cam Battley, chief corporate officer of Canada-based Aurora Cannabis, has publicly called on the UK to be ‘a leader not a laggard’ in one of the world’s fastest-growing industries, and has urged the government to authorise GPs to prescribe medical cannabis.

Many of the major industry players have already made their first move into the UK. In February 2019, Althea acquired a UK subsidiary, Althea MMJ UK, whose oil was first prescribed in the UK in June. Similarly, in February 2019, Aurora announced its first successful product shipment to the UK and

the first successful dispensing of its product in a UK pharmacy. In August 2019 Zoetic, a subsidiary of Highlands, announced it would be selling CBD products in the UK for the first time from its online platform, mostly CBD oils and tinctures. In October 2019, Spectrum Pharmaceuticals obtained the first licence granted by the MHRA and the Home Office, which will allow the company to supply pharmacies from its European network without the need for intermediary suppliers. This could pave the way for Spectrum Pharmaceuticals and its parent company Canopy Growth to gain a very competitive foothold in the UK market. The table opposite gives details of the companies currently operating in some form within the UK.



## Cannabis companies operating in the UK, December 2019

COMPANY NAME	SHARE PRICE	MARKET CAPITALISATION (£ MILLION)	STOCK PERFORMANCE (3 MONTHS)
<b>SATIVA GROUP PLC</b>	£ 5.20	27.8	-13.76
<b>WORLD HIGH LIFE</b>	£ 11.50	17.6	-4.35%
<b>ZOETIC INTERNATIONAL</b>	£ 6.85	10	-27.78%
<b>SPINNAKER OPPORTUNITIES PLC</b>	£ 4.65	1.4	NA
<b>ANANDA DEVELOPMENTS PLC.</b>	£ 0.24	1	-17.24%
<b>FREYHERR INTERNATIONAL GROUP</b>	£ 97.50	25.1	-43.48%
<b>GW PHARMA</b>	£ 0.23	2354.59	-28.%

Source: Prohibition Partners



## CBD COMPANY ACTIVITY

The CBD market in the UK is thriving. A YouGov poll published in October 2019 estimated that 11% of UK adults had tried a CBD product (this equates to approximately 6 million people), with higher consumption among younger adults (15% of 25- to 34-year-olds compared with just 8% of the over 65s) and among females (at 13% compared with 9% of males).

The size of the UK CBD market in 2019 was £300 million, making it larger than the markets for vitamins C (£119 million) and D (£145 million) combined. This figure is expected to reach £1 billion by 2025. The CBD market in the UK has begun to attract international investment. One of the largest suppliers of hemp and CBD products is Love Hemp, with over 40 products retailing in more than 1,200 stores in the UK. World High Life plc, a UK-based company with international backers, acquired Love Hemp for a reported £9 million in September 2019.

Consumer packaged goods industries, including cosmetics, and food and drinks, have started to capitalise on the many perceived therapeutic applications of CBD. However, to make health claims, manufacturers have to apply for a product licence from the EMA. In the UK, any CBD products making medicinal claims must first receive marketing authorisation from the MHRA, but this is not consistently enforced. However, the MHRA has reportedly contacted 180 stockists since 2016 over concerns about unauthorised health claims on CBD products.

Companies offering CBD products categorised as food supplements are exempt from this rule. Significantly, there is no legal requirement for these products to be tested, though some companies submit their products for rigorous testing.

- While British high-street mainstay Body Shop has been selling its Hemp range for 20 years (founder Anita Roddick confirmed that the products contained trace elements

of THC), in recent years there has been a swell in cosmetic companies coming to the market with products infused with hemp-derived CBD extracts.

- In October 2019, Holland & Barrett's website advertised seven brands of CBD oil, ranging in price from £15 to £80. The company makes it clear that these products contain the active substance found in hemp oil and extracted from the leaves and flowers of the hemp plant
- In June 2018, Love Hemp Water (the first functional CBD oil-infused water product to be sold in Europe) 'infused with CBD hemp droplets' was available in Waitrose stores.
- In June 2019, the variety store chain B&M launched a range of CBD oil products, with prices starting at £1 (Total CBD Tongue Shots 100mg). Its Revuele Hemp Me! skin-care products (starting at £2.99) are made from cold-pressed hemp seed oil.
- Boots, the high-street chemist, has also embraced CBD brands, suggesting that it believes in CBD as a significant trend rather than short-term novelty. Its concept store has a dedicated area for CBD products and there are several brands on boots.com, including Ambience CBD skincare and body products, Revolution Skincare CBD, BYBI CBD Booster, Green Stem CBD lip balm and EcoStyle Hair Oil.



# POLITICAL PARTIES AND INTERVENTION

Since the beginning of 2018 there has been a notable increase in political involvement in the cannabis debate, with the party-specific campaigning groups (for example the Labour Campaign for Drug Policy Reform) as well as cross-party panels such as the All-Party Parliamentary Group on Drug Policy Reform gaining more traction. Alongside regional parties, MPs in Wales and Scotland have been vocal about their support for a regulated medical cannabis system.

The turning point came in the wake of the long-fought campaigns for Alfie Dingley, a six-year-old epilepsy patient, and Billy Caldwell, a 12-year-old with the same condition, and in November 2018, regulations came into force to reschedule cannabis-derived medicinal products to Schedule 2 of the Misuse of Drugs Regulations 2001 and allow prescribing of these products, but only by a doctor who is on the GMC Specialist Register. This raised expectations for families who have children living with severe forms of epilepsy and also for sufferers of other medical conditions who may be helped by cannabis. During Prime Minister's Questions in February 2019, Welsh Labour MP Tonia Antoniazzi took the government to task for the lack of access to cannabis on the NHS.

In March 2019, a new panel was convened by the HSCC, appointed by the House of Commons and chaired by Dr Sarah Wollaston, to explore the issues that underpinned the November 2018 ruling and to assess how well the new regulations are working.

The panel comprises a significant number of leading figures from key organisations, which serves to highlight the increasing focus on medical cannabis as a mainstream political issue and the quest for improvements in understanding and regulations.

- Professor Dame Sally Davies, Chief Medical Officer for England/DHSC
- Alette Addison, Head of Pharmacy Development and Regulation/DHSC
- Genevieve Edwards, Director of External Affairs, MS Society
- Professor Mike Barnes, Interim Chair, Medical Cannabis Clinicians' Society
- Peter Carroll, Campaign Director, End Our Pain
- Professor Helen Cross, Head of Development Neurosciences, University College London, Great Ormond Street Institute of Child Health
- Dr Imran Malik, Committee member, Royal College of Psychiatrists
- Professor Sanjay Sisodiya, Chair of the ABN Epilepsy Advisory Group/Association of British Neurologists

In June 2019, the HSCC agreed a way forward on the basis that the November 2018 ruling was 'widely welcomed but there was a failure

to communicate what this would mean in practice for the availability of medicinal cannabis. Expectations were raised that these products would become widely available and there needs to be far clearer communication that this is not the case.'

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### **The conclusions and recommendations were numerous and wide-ranging. In particular, the HSCC recommended the following.**

- The Home Office, the DHSC and NHS England should consult relevant patient and professional organisations, and form a communications plan to relay clear information to patients and the wider public about the availability of CBPMs and the need for further research.
- The NIHR is to engage fully with parents and clinicians who have argued for observational trials to discuss their proposal and explore all ways to improve the evidence base.
- The DHSC should investigate those instances where pharmaceutical companies do not provide their medicinal cannabis product for research and take appropriate action where necessary, and should also set out a plan to encourage industry to take a more active role in the research itself.
- The NIHR should put out a broad call for research proposals into medicinal cannabis products, and the DHSC and the NIHR should encourage and focus on research into those specific conditions where the Chief Medical Officer's report found good evidence for the use of CBPMs.
- As a matter of urgency, the NIHR should make resources immediately available for a programme of clinical trials for the treatment of intractable epilepsy, which will allow many more patients to access treatments in specialist centres.
- The DHSC should set out in its response to the report how it will work with research organisations in the UK and internationally to ensure that research is being coordinated and encouraged in the most appropriate areas. The government should also set out how it will ensure that the future of European multicentre clinical trials and post-marketing surveillance to protect patient safety are not put at risk by Brexit.
- The DHSC should look at how medicinal cannabis is made available to patients in other EU member states, such as the Netherlands, and see whether lessons might be learnt which could be helpful.
- NICE should take account of patient voices in its creation of guidelines for medicinal cannabis by allowing patient

groups the opportunity to comment on the draft guidelines and receive a response to those comments from NICE.

The e-learning modules being prepared by Health Education England are welcome. Health Education England should keep the e-learning modules under review, ensure that it takes feedback from clinicians and relevant organisations on their impact and make sure that clinicians are aware of the modules.

The DHSC should take steps to secure long-term international deals to ensure a consistent supply of CBPMs so that patients are not delayed in receiving their prescriptions and the cost of the medicinal cannabis products is kept as low as possible. The DHSC is working with industry on establishing supply. It is further recommended that the DHSC work with other governments, devolved and abroad, to make a more collaborative and attractive deal for industry. The DHSC is expected to report on its progress at the beginning of 2020.

NHS England should encourage providers to make their prescribing structures known and transparent, to ensure that clinicians are aware of the possible barriers they face and how to tackle them. Following its process review, NHS England should issue targeted guidance to practitioners and pharmacists explaining the procedure for prescribing and supplying cannabis-based products for medicinal use in humans.

Pressure has been mounting for more clarity at EU level. Legislation in the member states varies widely on the subject of cannabis for medicinal purposes, and further clarification at EU level is being sought.

In a resolution adopted in February 2019, members of the European Parliament called on the European Commission and national authorities to draw a clear distinction between medical cannabis and other uses of cannabis. The resolution urges the European Commission and the member states to:

- address regulatory, financial and cultural barriers which burden scientific research and sufficiently fund research
- undertake more research to stimulate innovation with regard to medicinal cannabis projects
- allow doctors to use their professional judgement in prescribing cannabis-based medicines and, when effective, for health insurance schemes to cover these medicines in the same way as other types of medicine
- embrace the notion that the regulation of cannabis-based medicines would translate into additional revenue for public authorities, ensure quality and accurate labelling, limit the black market and limit minors' access to these substances.

## LOBBY GROUPS

There are a great number of lobby groups, and this reflects the growing call for a drugs policy review.

The All-Party Parliamentary Group on Medical Cannabis Under Prescription was vociferous in demanding change and calling 'on the Government immediately to act to ensure that medical cannabis is available to appropriate patients and in particular to children suffering from severe intractable epilepsy'. In April 2019, the spokesperson for the group criticised the treatment of the Appleby family, who travelled from Kent to the Netherlands to buy cannabis oil for their daughter but the product was later seized by Border Force staff at Southend Airport.

Former Minister for Prisons and Youth Justice Crispin Blunt launched the Conservative Drug Policy Reform Group to push for a government review of policy on medicinal and recreational cannabis in the UK. The aims of the not-for-profit organisation (which comprises a panel of clinicians, politicians and law enforcement leaders) are stated to be the achievement of the earliest possible safe access to medicinal cannabis, the examination of the evidence for

a licensed and regulated cannabis market and the establishment of a Royal Commission to evaluate current drugs policy in the UK.

The patient access group United Patients Alliance is an organisation serving cannabis patients in the UK. Carly Barton, believed to be the first recipient of a medicinal cannabis prescription in the UK, began campaigning on behalf of the United Patients Alliance for increased access to medical cannabis.

Parents of Hope, a group of parents of 35 epileptic children, wrote an open letter to the BPNA in February 2019 urging it to reconsider the guidelines issued on prescribing medical cannabis. 'We are not asking anyone to do anything that is illegal, we are simply asking that rather than dismissing medicinal cannabis based on lack of knowledge, scaremongering neurologists into fearing for their jobs if they do help, that you do the proper research and review or remove the guidelines you have released.'

## EVIDENCE INFORMED POLICY

Drug Science, an initiative founded by Professor David Nutt, is an independent and nonpartisan evidence based drugs charity in the UK. It advocates for science informed drug policy and has established an ambitious project to recruit 20,000 patient to a medical cannabis registry by 2021 (Project twenty21). The Conservative party in the UK also established a Drug Policy Reform Group which emphasises the importance of scientific evidence in shaping drug policy which reduces harm and is consistent with the party's core values. The Centre for Medicinal Cannabis is a membership body for stakeholders in the medicinal cannabis sector. It aims to improve access to high quality medicinal cannabis products and assist patients to make informed decisions by advancing the scientific evidence base. CMC promotes the sector, in the interest of its members and to advance access for patients.

## CHANGING ATTITUDES AMONG LEADING MEDICAL INSTITUTIONS

Among members of the Royal Colleges (general practitioners, emergency medicine and psychiatrists) it is widely felt that, given the association of cannabis with mental health problems and its members' key role in advising ministers on mental health issues and the misuse of drugs, the views of the Royal College of Psychiatrists should hold particular sway.

Following the Royal College of Psychiatrists' announcement in October 2018 that it would review its opposition to the legalisation of cannabis, a debate was held in July 2019 at the annual meeting of the college on whether cannabis supply should be legalised. One outcome of this debate was the launch of a survey 'asking those with expertise and personal experience of medicinal cannabis and cannabis for recreational use to contribute to its review by providing relevant evidence'. The survey seeks the opinion of a wide range of stakeholders from patients and providers of mental health services to charities and the criminal justice system. As the college's position appears to be central to the government's approach to reform, the results of this survey are eagerly awaited.

*The British Medical Journal's* current position is that it 'will be developing information and education for doctors and their patients. We welcome research on the effects of medicinal cannabis, and we will continue to campaign for wider reform of drug policy.'

Lobby groups also represent the interests of companies seeking to trade in the cannabis industry. The Cannabis Products Directive is the proposed framework for CBD regulation in the EU drawn up by the UK-based Cannabis Trades Association. Although the directive was reportedly developed in conjunction with the Food Standards Agency and the MHRA, neither the MHRA nor the Food Standards Agency has made a public statement on the framework.

## INFLUENCERS

Credited with obtaining the first prescription for cannabis for Alfie Dingley in June 2018, neurologist and professor of neurological rehabilitation Professor Mike Barnes (member of the Executive Committee of the Medical Cannabis Clinicians' Society and author of *A Brief History of the UK's Cannabis Laws*) is a clinician with a high and influential profile in the medical cannabis debate.

Urging Theresa May to be 'bold' and legalise cannabis, former Tory leader William Hague was vociferous in June 2018 when he condemned cannabis laws that were 'inappropriate, ineffective and utterly out of date'.

In October 2018, former Metropolitan police chief Bernard Hogan-Howe urged the government to review the evidence that justifies the ongoing criminalisation of cannabis use. While he stopped short of advocating an immediate law change, he called for an 'urgent commission of experts to look at the evidence about what's happening about cannabis in North America'.

In August 2019, a delegation of cross-party MPs (Labour's David Lammy, the Liberal Democrats' Sir Norman Lamb and Conservative MP Jonathan Djanogly) went on a fact-finding trip to Canada, which was recorded for a Radio 1 Newsbeat documentary called 'Legalising Weed: Canada's Story'. Broadly speaking, they returned with the belief that the UK would follow Canada's lead and legalise cannabis for recreational use in the next decade. The most significant shift was experienced by David Lammy, who now backs legalisation. Jonathan Djanogly was the most conservative with his predictions: 'I think we have got a lot to learn before the legalisation of recreational cannabis ... I think we're on a 10-15-year cycle, which would mirror what has happened in Canada.'





# GLOSSARY

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<b>ABN</b>	Association of British Neurologists
<b>BPC</b>	beauty and personal care
<b>BPNA</b>	British Paediatric Neurology Association
<b>CBD</b>	cannabidiol
<b>CBPM</b>	cannabis-based product for medicinal use
<b>CBPMH</b>	cannabis-based products for medicinal use in humans
<b>CD</b>	controlled drug
<b>DHSC</b>	Department of Health and Social Care
<b>ECH</b>	European Cannabis Holdings
<b>EMA</b>	European Medicines Agency
<b>EU</b>	European Union
<b>GMC</b>	General Medical Council
<b>HSCC</b>	Health and Social Care Committee
<b>MD 29</b>	hemp cultivation licence application form
<b>MHRA</b>	Medicines and Healthcare Products Regulatory Agency
<b>MS</b>	Multiple Sclerosis
<b>NHS</b>	National Health Service
<b>NHSBSA</b>	National Health Service Business Services Authority
<b>NICE</b>	National Institute for Health and Care Excellence
<b>NIHR</b>	National Institute for Health Research

<b>RCT</b>	randomised controlled trial
<b>THC</b>	tetrahydrocannabinol
<b>UK</b>	United Kingdom
<b>Class A</b>	Crack cocaine, cocaine, ecstasy (MDMA), heroin, LSD, magic mushrooms, methadone, methamphetamine (crystal meth)
<b>Class B</b>	Amphetamines, barbiturates, cannabis, codeine, ketamine, methylphenidate (Ritalin), synthetic cannabinoids, W synthetic cathinones (for example methedrone, methoxetamine)
<b>Class C</b>	Anabolic steroids, benzodiazepines (diazepam), gamma hydroxybutyrate (GHB), gamma-butyrolactone (GBL), piperazines (BZP), khat

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