All-Party Parliamentary Group
Medical Cannabis under Prescription

DISCUSSION PAPER ON UK MEDICAL CANNABIS

RECOMMENDATIONS FOR GOVERNMENT

A REPORT PREPARED FOR THE ALL PARTY PARLIAMENTARY GROUP ON MEDICAL CANNABIS UNDER PRESCRIPTION

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This report was originally prepared by Maple Tree Medical Cannabis Consultancy Ltd, specifically by Professor Michael Barnes MD FRCP (Chair of the Medical Cannabis Clinicians Society – MCCS) and Hannah Deacon (then Executive Director of the MCCS and secretariat of the APPG). Maple Tree received no payment for this work and no funding from any external source. Following the closure of Maple Tree, the Society now holds responsibility for maintaining and updating this report.

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EXECUTIVE SUMMARY

The recognition that cannabis has medical properties and a role in the mix of medical treatments has spread across the globe in recent years.

As a result, an increasing number of jurisdictions have legalised access to it to varying degrees. Currently, this comprises over 70 countries including Canada, Australia, Germany and over half of the US states. This increased recognition and legalised access has resulted in a global medical cannabis industry currently estimated to be worth £16.5 billion now and reaching to over £55 billion by 2027.[1]

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

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

This paper sets out recommendations that should be implemented if the UK is to play a part in this new global industry.

[1] Prohibition Partners – Global Cannabis Report 2019

INTRODUCTION

The APPG on Medical Cannabis under Prescription has produced this authoritative report on the need for a strong UK medical cannabis market.

Medical cannabis was legalised in the UK in November 2018 but although we have seen some growth in the last 7 years, the industry has not flourished. Medical cannabis in the UK has huge potential. There is world-wide interest in the use of cannabis for medical conditions with now over 70 countries having legalised the plant for medical purposes. Clinical trials and academic studies are expanding, and our understanding of the cannabis plant is continuously evolving. In parallel, market opportunities are developing in the industry as creativity, funding and technology expand.

The UK could lead the world on medical cannabis given our expertise in medicines, science and health technology. But it has not yet seen the opportunity and indeed has appeared reluctant to embrace the industry. We hope that Government will see and grasp the chance to promote medical cannabis, not only for the good of many thousands of people who may benefit, but for the good of the economy, for employment, tax income and export potential.

As it stands, there are many restrictions on full medical access due to unclear Governmental bureaucracy, a lack of medical education, and restrictive guidelines by The National Institute for Health and Care Excellence (NICE) and other bodies. Since the law change of 1st November 2018, the regulatory hindrance has had severe repercussions for the industry as well as for UK patients in need of medical cannabis.[2]

There are about 1.4 million people in the UK who currently use cannabis illegally for medical purposes.[3] However, in the seven years since legalisation, there have been only six NHS prescriptions for full-spectrum cannabis products and still only about 75,000 in the private sector[4] - less than 3% of the existing illegal medical users.

It is generally accepted that about 3-4% of the population may benefit from a medical cannabis product – about 2-3 million people in total. [4] The fully mature medical cannabis industry (and this paper does not deal with a recreational industry or the industrial hemp market or over-the-counter CBD market) is estimated to be worth at least £7-10 billion annually and employ over 100,000 people.

This Discussion Paper exposes gaps in the Government's policies on medical cannabis and details how the further development of a legal medical cannabis industry would help fill these gaps and stimulate the UK economy.

Our intention is to summarise concisely the complex issues cannabis businesses face in the UK whilst calling upon the Government to make meaningful, progressive changes to the laws and regulations that are currently hindering the industry

[2] Articles on UK cannabis issues
- Business of Cannabis
- Releaf
- Financial Times

[3] LEFT BEHIND: THE SCALE OF ILLEGAL CANNABIS USE FOR MEDICINAL INTENT IN THE UK

[4] https://www.statista.com/topics/6200/medical-cannabis-in-the-uk/#topicOverview

REPORT STRUCTURE

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

- **Chapter 1: The current state of play in the UK medical cannabis industry**
  - An outline of the current legal landscape and state of play for the industry as a whole.
- **Chapter 2: The potential value of an established medical cannabis industry**
  - This chapter investigates evidence of the value and growth of the medical cannabis market, exploring the potential benefits for the economy, not often considered in the mainstream discourse surrounding medical cannabis.
- **Chapter 3: Recommendations and calls to action for the Government**
  - A summary of the detailed recommendations for the Government to consider when discussing the medical cannabis industry
- **Appendix**
  - An explanatory introduction to medical cannabis and relevant terminology.

THE CURRENT STATE OF PLAY IN THE UK MEDICAL CANNABIS INDUSTRY

1.1 Medical Cannabis in the UK - current status

IMarc, a leading market intelligence firm has shown the current global medical cannabis market was worth around $34.4 billion in 2023 and should rise to over $66 billion by 2032 at a CAGR of 7.4% [5]. Other market intelligence firms predict even higher growth rates of up to 21.8% CAGR[6] If the Government supports the medical cannabis industry, the UK has the potential to take a significant percentage of this market.

Where is the UK medical cannabis industry now – 7 years after the law change? There are presently about 75,000 people prescribed full-spectrum medical cannabis but sadly only 6 patients are funded by the NHS (excluding the small numbers prescribed the two first-generation licensed products – Epidyolex and Sativex). Everyone else is prescribed privately and as the insurance industry does not yet cover cannabis medicine then all these patients are self-funding. This costs an average of about £300 per month plus consultation fees, so over £4,000 pa, which is simply not affordable for most people. Parents of children with resistant epilepsy (for whom the law was changed) are forced to pay even more to help their children – up to £2000 per month. This is iniquitous and presumably not what Parliament intended when the law was changed. At an average annual spend of £4,000 per person the current market of 75,000 patients generates about £300 million revenue per annum.

The UK has over 40 specialist cannabis clinics, some being specialist cannabis-only clinics and others being more generic clinics which can prescribe cannabis as part of a wider medical programme, such as a pain clinic or a psychiatric clinic. There are about 160 prescribers in the UK serving the needs of about 75,000 private patients. Those numbers are increasing at approximately 1,500 per month.

The commonest condition prescribed is chronic pain (about 53%) followed by anxiety and related conditions, like PTSD, (33%), neurological conditions (10%) including MS, Tourette's, epilepsy and ADHD and then small numbers of people with end-stage cancer, gastrointestinal problems and substance use disorder.

A major issue has been reliability of the supply chain. Products regularly go out of stock and clinicians are frequently forced to rewrite prescriptions for another product – which makes for poor medicine. Production within the UK was, pre-law change, confined to one main grower – British Sugar – and one main producer – GW Pharmaceuticals (now Jazz Pharmaceuticals). In 2018, GW was supplying 44.9% of the reported world total of cannabis-based products for medical use (CBPM), related almost solely to their two licensed products, Sativex and Epidyolex.[5]

These two products are licensed for use in the UK, to treat the common MS symptom of spasticity and specific forms of epilepsy. However, they are rarely used by the internal UK market – medical cannabis patients are nearly always prescribed full-spectrum products in the private sector for the good reason that such products are usually more efficacious and with less side-effects and are cheaper.

Since the law change there are now a few new growers (about 12) who have a high THC cultivation license on mainland UK or in the Channel Islands and Isle of Man. They are now beginning to produce for the UK market.

If they were allowed more readily to export to the larger markets abroad (see Recommendations) then the UK producers should thrive and those growers would benefit from economies of scale, as well as making a larger contribution to the UK economy.

[5] Medical Cannabis Market Report

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

1.2 The UK's legal position and general guidance on medical cannabis

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

General Practitioners were not allowed to be primary prescribers but can prescribe under the guidance of a specialist for follow-up prescriptions – as can Independent Prescribing Pharmacists and Nurses. Clinicians can prescribe for any condition but are hampered, particularly in the NHS, by restrictive guidance issued by the National Institute for Health and Care Excellence (NICE) and some medical establishment bodies.[7]

Prescriptions need approval by a peer panel, which can be a useful training and mentoring exercise for less experienced clinicians.

Clinicians do not have to undergo mandatory training, which is a pity as cannabis medicine is somewhat different from more mainstream medicine and, in our opinion, training should be a pre-requisite for prescribing. The CQC now seems to support this as they prefer clinicians to be trained and have required to see certificates of training during their inspections.

The Medical Cannabis Clinicians Society offers a monthly 3-hour training course to members, with over 800 clinicians now having passed through this course.

Prescribers need to work under the umbrella of a CQC registered entity, usually a clinic. The CQC has been supportive of the industry and produced useful guidance.[8]

The Medical Cannabis Clinicians Society has also recently produced an update to its useful Good Practice Guide[7] to assist clinics and clinicians to work to a high standard.

1.3 Growing high-THC cannabis in the UK

1.1 Specific licences are required for companies that wish to grow cannabis containing a controlled cannabinoid for medical use, and further licences will be required to produce and market the active ingredients, and the final cannabis-based medicines. The main controlled cannabinoid is THC but cannabinol (CBN) is also controlled, as are several other cannabinoids.[9]

The application process is long and complex. It requires an application for a Controlled Drugs License and although the Home Office has granted these licences, they are few and far between.[10] The applicant will need to register with the MHRA to manufacture, import or distribute (as appropriate) an Active Pharmaceutical Substance (API), and if the applicant wishes to produce the cannabis-based medicines themselves, they will also need a Manufacturer's Specials License. The MHRA will want to ensure that the product complies with EU GMP standards.[11]

To sell or supply medicines to anyone other than the patient using the medicine, a wholesaler licence – also known as a Wholesale Dealer's Licence or Wholesale Distribution Authorisation will be needed to ensure that applicant complies with good manufacturing and distribution practice (GMDP).[12]

[7] UKMCCS Good Practice Guidance - Updated

[8] Cannabis-based medicinal products: further guidance and information

[9] Drug licensing factsheet: cannabis, CBD and other cannabinoids

[10] Controlled drugs: domestic licences

[11] Apply for manufacturer or wholesaler of medicines licences

[12] Medicines: good manufacturing practice and good distribution practice

There are many requirements in these applications. For example, all movements and transactions concerning the cultivated crop must be accounted for, as well as how and when the destruction of excess produce will occur. Security is often a chief concern and must also be considered within the proposal.

Guidance on the content of the security plan is sparse. Until recently there was a 'catch 22' situation in that a Controlled Drug License issued by the Home Office could not be granted until the Home Office was satisfied that all procedures and facilities were in place.

However, all procedures could not be in place until the applicant was able to handle Controlled Drugs, which required a license! Fortunately, the MHRA and Home Office have now issued guidance to get around this impasse.[13]

The Home Office reiterate that they do not wish to be too prescriptive in the requirements to apply for the various cultivation and controlled drugs licences. However, the MHRA and Home office need to issue clear and simple guidance on the whole process.

1.4 Medical cannabis imports

Most prescribed CBMPs in the UK are currently Most prescribed cannabis in the UK is currently imported.

There are now over 50 producers with product in the country from diverse places, including Israel, Australia, Canada, Portugal and North Macedonia.

There is a good choice of product (over 800 individual products) which are mainly flower (about 75% of imports) and oil but so far with very limited other formats, such as pastilles, suppositories, patches and creams.

There are about six specialist importers with a few of them having a Schedule 1 Controlled Drugs License and a Manufacturing Specials License which would allow them to import in bulk and then package product or extract or make other formats. The import is relatively straightforward, as long as the grower has an euGMP certificate.

A Certificate of Analysis is required as well as a Clinical Letter of Need from a specialist prescriber, confirming an unmet need in the UK. Imported product is moved to a retail pharmacy (about 28 specialist cannabis pharmacies in the UK) awaiting dispensing against a prescription.

The prescriber has the right to prescribe any available product from any pharmacy. The prescription top copy still has to be posted to the pharmacy as e-prescribing is not yet permitted (see Recommendations). The product is then couriered to the patient.

[13] MHRA Process for approving Manufacturing Authorisations or API Registrations in relation to unlicensed Cannabis-Based Products for Medicinal Use

THE BENEFIT OF AN ESTABLISHED UK MEDICAL CANNABIS MARKET: WHY IT MATTERS

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

2.1 Medical benefit

There is now a significant literature on the safety and efficacy of medical cannabis. Most evidence is of benefit to those with chronic pain and neurological indications such as epilepsy, symptoms of multiple sclerosis, as well evidence for chronic anxiety and related conditions, such as PTSD.

The Medical Cannabis Clinicians Society is producing a series of evidence guides on the different indications. The first Introductory booklet is available, as is the 2nd in the series on cannabis and epilepsy.

Just as an example, the epilepsy evidence guide summarised all 90 papers now published on cannabis and epilepsy since 1949. The studies involved over 8600 patients, mainly children, with many types of epilepsy and using many different cannabinoids, most often CBD. The studies overall showed that about 80% of those prescribed improved their seizures and 40-50% improved seizures by at least 50% and 10-15% achieved seizure freedom.

Other benefits were improved mood, sleep, behaviour, communication, emotional stability, motor skills and cognition. Side effects were few and entirely compatible, and indeed less, than licensed anti-convulsants. These findings are remarkable given that most of the subjects, by definition, had epilepsy resistant to all prior medication.

Comments from some bodies, such as the British Paediatric Neurology Association, that there is insufficient evidence for treatment of epilepsy are ridiculous and entirely unsustainable.

Similar strength of evidence exists for the other main indications, as long as Real-World literature is accepted as valid evidence. The problem with the NICE recommendations was that they did not consider such evidence (nor evidence not written in English). Cannabis does not lend itself to the classic pharmaceutical model of the double-blind, placebo-controlled study and Real-World studies are essential to assess the strength of evidence (see Recommendations).[14]

2.2 Potential market

There are approximately 1.4 million people in the UK (just over 2% of the population) using cannabis illegally for medical reasons[15], due to the inaccessibility of the drug.

This figure may seem high, but there are significant numbers of people in potential need of medical cannabis; people with epilepsy, MS, people with mental health disorders, such as anxiety and those suffering with any kind of chronic pain. Also, there are potentially many more people who would benefit but have not wished to criminalise themselves by buying products on the black market.

The total market, by extrapolation from existing and longer-established jurisdictions, is around 3% - 4% of the population who may benefit from cannabis as a medicine. That would equate to about 2 to 2.5 million people.

These are people who are taking up much NHS resource, clinical time and hospital beds and are also those who often require formal and informal care, benefit support and many of whom cannot work. The health economic benefit of helping these people is potentially immense.

[14] Using real world evidence to optimize care – the case of medical cannabis.

[15] Around 1.4m people in Britain using 'street cannabis' to treat chronic health conditions, poll finds

One child - the original child prescribed, Alfie Dingley - has saved the NHS about £130,000 annually due to now having no seizures, taking no time on paediatric intensive care and coming off expensive medication. He has returned to school and this has allowed his parents to return to fruitful employment.

It is important to look at the social and economic value of treating these very hard-to-treat patients successfully not only for their benefit but that of the parents and wider family which in turn benefits wider society and the UK economy. To put into context there is currently over 37,000 children who do not have effective treatments for their epileptic conditions.

The current way of licensing medications also means that researching these very rare conditions is not financially viable for pharmaceutical companies which is why this specific research rarely happens.

One recent study on the health economics of treating chronic pain with cannabis[30] has shown a saving of £1,037 per patient per annum if cannabis is used, as opposed to normal treatment. Given the number of people with chronic pain in the UK then the potential savings amounted to over £23.6 billion.

Clearly, not everyone with chronic pain would be prescribed cannabis and some would not be suitable but nevertheless the savings to the economy as a whole would be highly significant.

Further health economic studies are needed. The potential UK market is huge and the economic benefits significant (see Recommendations).

2.3 Potential market revenue

At current spend (average £300 per month) treating a population of between 2 and 2.5 million would equate to a revenue of between £7-9 billion pa.

A conservative estimate of revenue, given cost reductions on economy of scale when more people are prescribed and the fact that cannabis does not suit everyone (about 80% repeat prescription rate), is that the industry could comfortably and conservatively generate about £5 billion in income per annum.

This figure is compatible with the estimated medical cannabis revenue from the United States adjusted for the States in which it is legal.[16]

For an interesting comparison, look to Australia. The country's medical cannabis industry is generating significant amounts of money.

Recreational cannabis is still illegal (except for the Canberra region), but medical cannabis was made legal in 2016. Since then, the industry has taken off and is expected to be worth $1 billion within Australia by the end of this year.[17] The Australian population is about 40% of the UK. In the first 4 years after legalisation, 92 licences had been granted to cultivate cannabis in Australia, including 31 for commercial cultivation, 20 for research and 41 for production of medical cannabis products.[18]

The UK Government should learn from the Australian example.

[16] Medical cannabis revenue in the United States from 2016 to 2029

[17] AUSTRALIAN MEDICINAL CANNABIS INDUSTRY REPORT

[18] The Oceania Cannabis Report: Second Edition

2.4 Creating a domestic producer industry

2.4.1 Securing the supply chain

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

Furthermore, if patients are affected by poor product availability through a disrupted supply chain, there is risk they will be pushed to the black market, which continues to provide an accessible alternative.

Patients are therefore left with a choice – wait in pain for the legal market to fix its supply issues or turn to unlicensed and potentially dangerous products.

2.4.2 Investment opportunities and POCA 2002

In September 2020, medical cannabis companies were cleared by the UK's financial regulator (Financial Conduct Authority) to float on the London Stock Exchange.[19] This gives many investors a significant opportunity to invest in the UK Market, which is welcome news for investors looking for new viable forms of investment revenue. There are 5 "pure-play" companies now listed.

However, there is a serious obstacle for overseas producers making a profit from their own legal, recreational market – they must demonstrate that their operations comply with the UK's Proceeds of Crime Act 2002 (PoCA), even though making a profit from the recreational market is legal in their own jurisdiction.

This is currently hindering cannabis investment opportunities on the UK stock market (see Recommendations).

This is currently hindering cannabis investment opportunities on the UK stock market.

Compare the UK situation to Australia, which has over 30 medical cannabis companies currently listed on the Australian stock exchange (ASX), despite medical cannabis only being legalised in 2016.[20] This is considerably more than the number of publicly listed cannabis companies in all of the countries of Europe combined.

2.4.3 Job opportunities

There is a potentially huge job market for cannabis related industries, which require farmers, production workers, chemists, accountants, lawyers, IT specialists, financial experts, researchers, retail workers, pharmacists and lab technicians, to name a few. With unemployment currently at 4.5%, with around 1.5 million people out of work, the need for new employment streams is significant.[21]

In the USA, ZipRecruiter highlighted that over the course of 2017 that the number of cannabis industry jobs grew by 445%, outpacing both the technology (254%) and healthcare (70%) industries.[22] As more States move towards legalisation and nascent markets become more established, this trend has continued. In 2020 the number of medical cannabis jobs in Arizona, for example, was 15,059[23] and in Oklahoma was 9,412.

Correcting this for the UK population equates to an equivalent of 135,000 jobs from the Arizona data and 157,000 jobs from the Oklahoma data. This is from the medical market alone and does not account for jobs in the industrial hemp industry and the over-the-counter CBD industry. It does not account for any jobs in the recreational market, as those states had no recreational legalisation at that time. There will be economies of scale but it is reasonable and realistic to presume at least 100,000 UK jobs in the mature medical cannabis market.

[19] Listings of cannabis-related businesses
[20] The Oceania Cannabis Report: Second Edition
[21] UK Labour Market Statistics
[22] Will Cannabis Job Growth Continue to Outpace Tech Job Growth?
[23] Leafly Jobs Report 2022

2.4.4 Tax income

An industry employing 100,000 people and generating an income of at a least £5 billion will in turn generate significant tax income for the government. There will income tax from employees, national insurance, corporation tax, dividend tax, etc.

There should, of course, be no VAT on the medical product. It is difficult to estimate accurately this income but it should conservatively amount to several hundred million pounds per annum.

RECOMMENDATIONS FOR GOVERNMENT

The regulatory landscape for medical cannabis is currently fraught with problems. Although we are coming up to the seventh anniversary of it becoming legal in the United Kingdom, many issues remain prominent in the sector.

Namely, the lack of accessible pathways to patient access, a lack of confidence offered to physicians in prescribing medical cannabis and an incredible amount of latent economic value that has yet to be tapped.

The previous Government also neglected to update the Police, Border Force and other agencies and patients still struggle to be prescribed medical cannabis without coming across many issues in society. With estimates that the UK medical cannabis market could be worth over £5b when mature,[24] almost double the value of the UK's fishing industry, medical cannabis has the potential to revolutionise patient care and assist the UK economy.[25]

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

We make the following Recommendations to Government which should stimulate a new medical cannabis industry:

1. **Childhood epilepsy (existing patients)**
   - Establish a central Government fund to allow the children with drug-resistant epilepsy already prescribed to continue accessing cannabis medicine which has been shown to have a seizure reduction effect
2. **Childhood epilepsy (new patients)**
   - Establish a central approval system for cannabis prescription for children with drug-resistant epilepsy
3. Commission new NICE guidelines recognising that cannabis is a botanical and not a pharmaceutical product
4. Ensure the CQC is aware of the Good Practice Guidelines[26] produced by MCCS when approving and inspecting cannabis clinics and compare practice against those guidelines.
5. Commission a proper and thorough health economic analysis of medical cannabis in regard to the UK economy
6. Roll out the electronic prescribing of controlled drugs to the private sector
7. Ease the ability to export medical cannabis products
8. Review the medical cannabis sector

[24] The UK Cannabis Report
[25] Brexit: The fisherman's tale
[26] Good Practice Guide 2025

1 Childhood epilepsy (existing patients)

Establish a central fund to allow the children with drug-resistant epilepsy already prescribed to continue accessing cannabis medicine which has been shown to have a seizure reduction effect

The law was changed in 2018 to recognise the need of one child – Alfie Dingley. The needs of similar children have simply not been met since the law change with only four children now prescribed on the NHS (and two adults). Only about 50 other children have been prescribed cannabis medicine privately (except the first-generation cannabis medicine, Epidyolex) at a personal cost of about £1,500 - £2,000 per month.

There is an urgent need to address this issue as children could be left without a prescriber (only two prescribers in the UK currently) with consequent risk of return of seizures and even a small (about 5%) risk of death. The situation is intolerable.

Some medical bodies, such as the BPNA, state that there is insufficient evidence to support prescription. This stance is outdated and incorrect. A recent evidence review (outlined in chapter 2 above) clearly refutes this allegation. The anti-medical cannabis stance of some medical bodies is astonishingly ignorant of the facts and shows a deep-seated prejudice. We call urgently on the Government to establish a fund to pay for the medicine for these children.

The Medical Cannabis Registry which was set up after Matt Hancock's NHS review of barriers to access could be used to collect the data retrospectively. This Registry currently has no entries.

2 Childhood epilepsy (new patients)

Establish a central approval system for CBMP prescription for children with drug-resistant epilepsy

Recommendation 1 will assist those already prescribed but for those who have been unable to access the private system we recommend establishing a clear central commissioning pathway. There is already a precedent of a central commissioning for specialist services.[27]

We suggest that children with drug-resistant epilepsy who have tried and failed with at least three licensed AEDs should be able to have their consultant present a case to a central panel.

This panel must include medical cannabis specialist clinicians as well as senior neurologists in the UK. This will help with peer support and build confidence for naïve prescribers.

These medications should be funded in the same way as any other unlicensed medication.

[27] NHS Specialised services

3 Commission new NICE guidelines recognising that cannabis is a botanical and not a pharmaceutical product

The most restrictive aspect of medical cannabis regulation comes from the guidelines provided by The National Institute for Health and Care Excellence (NICE). At present, NICE guidelines approve the prescription of the three first-generation cannabis-based drugs, those being Epidyolex, Nabilone and Sativex[28]. No full spectrum products are recommended, and thus unlicensed medicines are effectively not allowed. Whilst the NICE guidelines are not mandatory, they are treated as such by doctors and hospital Trusts who are reluctant to allow prescription against those guidelines.

Sadly, they are written as though cannabis is a pharmaceutical product. They are heavily reliant on the pharmaceutical concept of the double-blind placebo-controlled study. However, cannabis is a botanical product and needs assessment using the full panoply of evidence, including some controlled trials but also case studies and observational data - so called "real world" evidence. There are thousands of such studies that are all currently ignored by NICE. Astonishingly, NICE also discounted studies not written in English.

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

The NICE Guidelines are not just a barrier to patient access. They have far-reaching implications for the commercial viability of the medical cannabis market. If there are significant barriers to patients accessing medical cannabis, then a thriving medical cannabis market will simply not be created.

4 Ensure the CQC is aware of the Good Practice Guidelines produced by MCCS when approving and inspecting cannabis clinics and compare practice against those guidelines.

It is essential that the private cannabis clinics are run in an ethical and professional manner. The MCCS Best Practice Guidelines cover such matters as appropriate eligibility criteria, patient referral pathways, peer approval panels, clinician training and dosing and dose approval guidance.

The public, Government, regulatory bodies and the prescribing community must be reassured that cannabis prescribing is conducted in a transparent, professional and ethical fashion and the APPG feels that these guidelines ensure that this is the case.

[28] Cannabis-based medicinal products

5 The Government should commission a proper and thorough health economic analysis of medical cannabis in regard to the UK economy

Cannabis is basically a cheap product and in some parts of the globe can be produced for around 10 US cents per gram of dried flower. The average UK prescription for dried flower is about 1.3 gram per day and thus, at the cheapest, the constituent product costs only about $4 per month. Obviously, producer, importer and retailer profit margin, and license costs, need to be factored in.

A proper and comprehensive health economic analysis of the financial impact of providing medical cannabis widely in the UK through the NHS is urgently required. The medicine cost can be offset by savings in other drug costs, such as less opioid prescription (and less opioid deaths). Evidence from the USA indicates reduced opioid prescriptions of about 29% and a similar reduction in opioid dosage amounting to a Medicaid saving of also 29%. This equates to an overall saving of many millions of dollars.[29]

Additionally, there would be less anticonvulsant prescribing for those with resistant epilepsy and less anti-anxiety drug prescribing for those with resistant anxiety and PTSD. Other savings could be generated due to less associated therapies, such as physiotherapy for pain and, for example, less epilepsy emergency hospital admissions. It is entirely possible that carer costs can be reduced for those severely disabled by relevant conditions. And some patients, currently on benefits, may even return to work.
The improved quality of life for those on a successful prescription should be factored into a full health economic report. One recent study showed that the cost saving of using cannabis for chronic pain amounted to £1037 pa per person and given the many millions of people with chronic pain in the UK then that would amount to many millions of pounds saved to the health economy.[30]

6 The Government should roll out the electronic prescribing of controlled drugs to the private sector

This has recently been allowed in the NHS[31] and we see no reason why this could not also be allowed in the private sector. At the moment, the need for prescribers to send top copy prescriptions to the pharmacy is a major factor in slowing down prescription and increases risk of security breaches.

The NHS has already documented the advantages of electronic prescribing:
“Benefits include

- Fewer patients with both paper and electronic prescriptions, making it easier for them as all their prescriptions can be sent electronically to their nominated pharmacy
- Sending more prescriptions electronically will reduce the administrative burden on both GP practice (and the private practice) and pharmacy staff
- Prescriptions will be sent securelyand electronically, and so can’t be lost or misplaced
- Being able to see everything that has been prescribed helps pharmacists make the right decisions to safely and effectively dispense the right drugs for patients Patient safety is increased as errors are less likely”

If re-writes are required these can be done quickly and do not require posting to the pharmacy. Re-writes are often needed and occur mostly due to supply issues.

[29] Medical cannabis legalization and opioid prescriptions: evidence on US Medicaid enrollees during 1993-2014
[30] An early economic analysis of medical cannabis for the treatment of chronic pain
[31] Electronic Prescription Service

7 Ease the ability to export medical cannabis products

At present, it is very difficult for cannabis companies in the UK to export their products. Investment is hampered as the industry does not see the return on capital from the limited UK Market. Cannabis in the UK is produced to a very high standard – euGMP. Quality is not an issue. Ironically, the UK remains the biggest exporter of cannabis flower in the world.

In 2021 production of cannabis in the UK was reported by INCB to be 329.1 tons, or 43 per cent of global production. Most of that production was exported but by one company - Jazz Pharmaceuticals for production of their two licensed first-generation cannabis medications - Sativex and Epidyolex. This flower is made to the same standard as the flower destined for production of unlicensed medicine.

It is illogical to allow export of the product from one company and not allow export from other companies, as long as those products are made to the same standard. The same principle applies to other cannabis products such as tablets, vape cartridges, cream, suppositories, patches, etc. Allowing export of these products will attract investors in the knowledge that excess production, not yet able to find a UK market, will find a foreign market – and thus generate income for the UK.

8 Review the medical cannabis sector

It is now nearly 7 years since the law change and the APPG feels it is time to review the sector and analyse what has gone right and what has gone wrong and what could be improved.

Medical cannabis regulation mainly falls under the jurisdiction of the Home Office, Department of Health and Social Care, Medicine and Healthcare products Regulatory Agency (MHRA) and the Care Quality Commission (CQC). Coordination between these bodies is essential and clearer regulatory pathways are needed.

The entire sector could usefully be reviewed and recommendations for improved support be made. The APPG supports such a review, as long the industry and expert clinicians are properly consulted and involved in the process.

SUMMARY

The recommendations outlined above should be underpinned by a comprehensive review of the UK medical cannabis industry.

We urgently need to explore ways to improve patient access and develop an industry which will not only be of benefit to many millions of patients but also contribute significantly to the UK economy.

The review should extend beyond improving NHS access to include encouraging investment in an industry that could create tens of thousands of jobs, generate significant tax revenue, and enhance the quality of life for many - all contributing further to the national economy.

WHAT IS CANNABIS?

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

Medical cannabis is a term used when prescribing the cannabis plant. In general, the prescribed medical product will be proportionally higher in CBD, minor cannabinoids and terpenes and proportionality lower in THC than the cannabis used recreationally. It is also produced to a high quality and more consistent standard and be free of contaminants, compared to the illegal "street" product. All UK products are produced to the EU GMP (Good Manufacturing Practice) standard which ensures quality, consistency and safety.

CANNABIS OVERVIEW

Second generation CBMPs

These are the products that are now legal to prescribe as Schedule 2 medicines and the great majority are currently unlicensed medicines as they have not yet been through the marketing authorisation process. They are usually full spectrum products (see below).

- **CBD**: This is a psychoactive cannabinoid, but it is non-intoxicating and non-euphoric, meaning it will not get you 'high'. The production, sale and use of CBD is not controlled in the UK, subject to certain restrictions regarding the THC content of the final product. It is widely available as an over-the-counter health supplement, although producers can make no medical claims about their product. Nevertheless, it has clear and scientifically accepted medical properties. It can be used, for example, to help reduce inflammation and pain. It may also, amongst other properties, ease nausea, migraines, seizures, and anxiety. CBD counteracts the "high" effect of THC to a large extent, partly by binding to the brain receptors to which THC is bound.
- **THC**: This is the principal psychoactive compound in cannabis. THC is responsible for the 'high' that most people associate with cannabis. Any compound or product containing THC, or a derivative thereof, is controlled in the UK except when it is a second generation Cannabis Based Medical Product (CBMP) prescribed by a doctor on the specialist register or is an "Exempt" product. The exceptions are two first generation licensed products – Sativex and Epidyolex made by Jazz Pharmaceuticals - and a synthetic THC – nabilone - which can be prescribed by any registered doctor. THC can also be used in a recognised and approved research study under licence. It has well recognised medical properties including being analgesic, anti-inflammatory, anti-emetic, is a muscle relaxant and is anti-oxidant.
- "**Minor" Cannabinoids**: The cannabis plant is currently known to contain 147 cannabinoids. Whilst we know little about many of them, we do know that many have medical properties. The "mother" cannabinoid is CBG (cannabigerol), which has anti-inflammatory, anti-cancer and anti-bacterial properties, amongst other benefits. Others have medical possibilities like CBC (cannabichromene), which may have the potential to act as an anti-depressant and has benefits for acne and psoriasis; CBN (Cannabinol - a breakdown product of THC), which is anti-convulsant, anti-bacterial, appetite stimulant and helps sleep; and THCV (tetrahydrocannabivarin), which is strongly appetite suppressant and may have a role to play in diabetes and Alzheimer's disease.

Second generation CBMPs continued

- **Terpenes and Flavonoids:** The cannabis plant also contains over 100 terpenes (that give cannabis its characteristic smell) and flavonoids, which give colour.These also have potential medical application. The terpene myrcene, for example, is sedating and helps sleep. Linalool is anti-convulsant and the flavonoid, quercetin, appears to have anti-viral and anti-cancer properties.
- **Hemp**: The hemp plant is a variety of cannabis sativa but differs from most cannabis strains in that it has very low levels of THC and fewer of the other "minor" cannabinoids. It has been bred over centuries for its strong stem to produce many goods, including paper, rope, canvas, clothing, building materials and agricultural products. The hemp seeds are healthy to consume and nutrient rich and are used to produce many consumer products like salad oils and soap, industrial products like paints and vanishes, and animal feeds. Strict conditions and fees apply to the cultivation of industrial hemp, which requires an Industrial Hemp license from the Home Office – and even then, only certain parts of the plant can be used and the flowers, ridiculously, have to be destroyed in the fields. That means that all CBD for over- the-counter use has to be imported.
- **Chemovars**: Refers to the breakdown of the plant according to its chemical composition. There are thousands of cannabis chemovars with varying proportions of THC, CBD and the other cannabinoids, terpenes and flavonoids. Each chemovar may have subtly different medical properties. We have barely scratched the surface of our knowledge of this remarkable plant.
- **Entourage effect**: This refers to the known (and now scientifically generally accepted) phenomenon that the whole plant has a better medical effect than the individual components. In other words, an isolate (such as a pure CBD isolate) will have less benefit than the full spectrum plant for, for example, epilepsy.
- **Cannabis Types**: Most cannabis products for prescription are either Full Spectrum, Broad spectrum, or Isolate. These definitions are used to describe which cannabinoids are in the product.
- **Full Spectrum:** An extract that contains all compounds that occur naturally in the plant, including essential oils and other cannabinoids. These are the prescribed products used in the UK for most patients and have to be prescribed due to their THC content being above the legal limit for an over-the-counter product.
- **Broad spectrum**: This is similar to full spectrum, whereby most compounds within the plant are preserved. However, THC and the other controlled cannabinoids are removed. These products could be sold over-the-counter in the form of CBD oils, edibles, etc. in the UK as long as they fully comply with the definition of an "Exempt Product" as defined in the Misuse of Drugs Regulations (MDR) 2001 as it pertains to the level of controlled substances in the product.
- **Isolate**: The purest form of cannabinoid, which is produced by removing all other compounds found in the plant. CBD isolate is typically extracted from Hemp, due to its low to non-existent THC-content.
- **Flowers (sometimes called flos)**: These are also prescribed in the UK. The dried flower will require grinding before being vaped. In the UK, the smoking of any cannabis flower (be it hemp or higher THC cannabis) is not allowed by law.

First Generation Licensed products

First generation products are those licensed medicines listed below. They are largely isolates, although Epidyolex contains a small amount of THC. They were on the market before the current second generation CBMP products. Currently, only Sativex and Epidyolex and the synthetic nabilone (marketed by Valeant) have marketing authorisations in the UK and can be prescribed in the normal way.

- **Sativex:** : A mouth spray containing two cannabinoids (THC and CBD) in broadly equal proportion. It is licensed in the UK for people with MS-related muscle spasticity that is resistant to other treatments.
- **Epidyolex:** A highly purified liquid containing mainly pure CBD (1000mgs CBD per ml and 3mgs THC per ml), and thus has no intoxicating effects. Currently, it can be prescribed for patients with Lennox-Gastaut syndrome and Dravet syndrome and in some jurisdictions Tuberous Sclerosis (all rare forms of epilepsy) in combination with a licensed anti-convulsant – clobazam.
- **Nabilone:** A synthetic capsule medicine, which has been developed to act in a similar way to THC. It is used to help relieve the symptoms of nausea caused by chemotherapy – but it is only prescribed when other treatments have not worked. Although licensed in the UK for adults, due to 'limited evidence' considered by NICE, it is not currently available to most patients.

The Medical Cannabis Clinicians Society

The Medical Cannabis Clinicians Society (MCCS) is the UK's independent, not-for-profit network for clinicians with an interest in cannabis-based medicinal products (CBMPs). Founded in 2019, the Society provides practical, evidence-based support for doctors, nurses, pharmacists, and other healthcare professionals involved in or exploring this emerging field.

It offers CPD-accredited training, prescribing guidance, a 24/7 peer support network, and expert-led educational resources to help clinicians practise safely, lawfully and confidently. The MCCS is the largest community of medical cannabis healthcare professionals in the UK, and serves as a trusted point of reference for safe prescribing standards.

The Society is chaired by Professor Mike Barnes and governed by a multidisciplinary committee of leading clinicians. It plays a key role in national advocacy, provides the secretariat of the Medical Cannabis under Prescription All-Party Parliamentary Group (APPG), and regularly contributes to policy and regulatory discussions. Its members are at the forefront of clinical practice, and the Society is widely recognised for its commitment to improving patient access and clinical standards.

All its work is funded through membership fees and unrestricted educational grants, ensuring it remains independent of commercial influence.

Professor Mike Barnes
MD FRCP
Chair, MCCS

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

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

Hannah Deacon
Former Executive Director, MCCS

Hannah Deacon was the UK's most recognised and award-winning medical cannabis campaigner. Her tireless fight secured her son Alfie the first Schedule 1 licence granted to doctors to prescribe whole-plant cannabis on the NHS. Internationally respected for her ability to achieve real change, her work was instrumental in the landmark law reform of 1 November 2018.

Hannah went on to become a driving force in shaping the medical cannabis sector. As a Director of the Medical Cannabis Clinicians Society and Maple Tree Consultants, she championed the development of an ethical, patient-focused industry. She was deeply committed to building a system where patients' needs came first and where access to medical cannabis on the NHS was a reality for all who could benefit. Hannah's dedication and advocacy created lasting change. Her legacy continues to influence policy, practice, and public understanding of medical cannabis in the UK and internationally.