

Access to medicinal cannabis: meeting patient needs

All-Party Parliamentary Group for Drug
Policy Reform

Inquiry Report

“The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.”

Constitution of the World Health Organisation drawn up in 1946 in conformity with the Charter of the United Nations

Foreword

For six years, the All-Party Parliamentary Group for Drug Policy Reform has worked for an end to the “war on drugs” driven by the USA and supported by the UN. In our “Guidance on Interpreting the UN Drugs Conventions”, we called for three major changes:

1. evidence-based drugs policy;
2. policy that genuinely promotes the health and welfare of mankind driven by human rights and public health values;
3. flexibility for Member States to develop drug policy within the UN Conventions based on our four “Guidance” principles.

We have had meetings with the President of the UN Economic and Social Council (ECOSOC); the Executive Director of the UN Office on Drugs and Crime (UNODC); and the Deputy Secretary General of the UN. We have organised international meetings of Ministers and senior officials in Westminster and spoken at international meetings in New York, Brussels and Cartagena, Colombia.

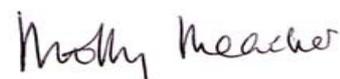
At the UN General Assembly Special Session (UNGASS) held in April 2016, we witnessed both the USA and the UN leadership reject a moralistic and prohibitionist approach to the global drug problem. Instead, the UN and US leaders called for all our proposed changes to global drugs policy.

As far as the UK is concerned, it seems clear that the legalisation of cannabis for medical use fulfils the above objectives. There is now a sound evidence base for such a policy. Legalisation and licensing will promote the health and welfare of very sick people and the policy respects human rights and public health values. The British Government needs to respond to the call from the UN for drug policies that comply with these principles.

We hope that this report will persuade Government Ministers and politicians of all Parties to support the proposed reforms. We hope that it will be useful to academics and others interested in advancing our knowledge and understanding of medicine, particularly for those with chronic conditions; to those concerned about drug policy; and, above all, to those for whom cannabis has provided some relief from suffering.



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We are also most grateful to everyone who gave written and/or oral evidence to the Inquiry and to APPG members who participated in the hearings (see Appendix 1).

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Disclaimer

This report has been approved by the officers of the APPG for Drug Policy Reform but does not necessarily represent the views of each individual member of the Group. It does not represent the views of the Houses of Parliament in general.

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Executive summary

Medicinal cannabis: the way forward

Many jurisdictions across the world have either already introduced systems that allow lawful access to medicinal cannabis or are in the process of so doing. At least 11 European countries already ensure access to it including: Austria, the Czech Republic, Finland, Belgium, Germany, Italy, the Netherlands, Romania, Portugal and Switzerland. Twenty-four States in the USA also ensure access, with more states due to vote on the matter. Canada, Israel, Jamaica and many Latin American countries, including Uruguay, Chile and Colombia join the countries that allow access to cannabis for medicinal purposes.

However, the UK lags behind. Indeed, in the UK cannabis and its derivatives are listed under Schedule 1, the Schedule for dangerous drugs with no medicinal value. At the same time, the UK Government has approved nabiximols (trade name Sativex) and nabilone (trade name Cesamet), which seems irrational and contrary to the Government's scheduling decision.

This issue matters to a substantial number of patients (and their families) across the UK. One estimate of current users of medicinal cannabis in the UK puts the figure at 30,000 daily. However, the campaign group End Our Pain (www.endourpain.org) puts the estimate at approaching 1,000,000 in total. This is based on the fact that Home Office figures put the number of UK cannabis takers (both recreational and medicinal) at 3,000,000, and figures from the USA suggest that approaching 1 in 3 will be for primarily medical reasons. If this figure seems high, it is interesting to note that Germany, which is currently introducing legislation to allow legal access to medicinal cannabis estimates that nearly 800,000 of its citizens may be eligible under their scheme.

Against this background, the APPG convened the most in-depth parliamentary inquiry into this issue ever undertaken. Alongside their inquiry, the APPG commissioned the most extensive review of evidence in the literature in modern times.

The inquiry

The inquiry learnt that the reputation of cannabis as a medicine, particularly for treating the symptoms of chronic conditions, and the failure of prescription medicines to relieve their symptoms, has led patients to try herbal cannabis even though access to it is not lawful and even though they cannot generally get expert medical guidance or supervision to cover its use. The APPG has heard and assembled compelling stories of the dramatic improvements to their health that some cannabis users have experienced. Many spoke of the ways in which cannabis had enabled them to stop using pharmaceutical drugs with serious side effects, or to "get their lives back". People without experience of medicinal cannabis told the Inquiry about the desperation they felt in experiencing the pain and suffering of a chronic illness. Many who were taking cannabis to help with their symptoms told of the added stress and worry induced by having to risk prosecution. They expressed sincere hope that cannabis might be made legally available and would prove effective for them.

As a part of this inquiry, we undertook a small online survey of health professionals with the help of the Chronic Pain Policy Coalition. They had prescribed or knew of prescriptions for cannabis-based treatments for chronic pain arising from many different conditions. The majority were positive about the role of cannabis-based medicines for reducing pain. At the very least, cannabis-based treatment can provide significant benefit for a small group of chronic pain patients where other treatments have failed.

We commissioned an online survey of medicinal cannabis use in the UK. This revealed cannabis use for a considerable range of conditions: for example, chronic and severe pain (24% of respondents); arthritis (12%); insomnia (21%); fibromyalgia (9%); post-traumatic stress disorder (PTSD) (7%); depression (30%); and anxiety (26%). Very similar results were found among cannabis users in Australia.

With regard to reported efficacy, cannabis was perceived to provide “great relief” overall by 86% of patients, and substantial relief of specific symptoms such as pain, nausea and insomnia. Over 90% reported no or mild side effects from cannabis treatment. By contrast, respondents experienced “significant”, “severe” and “very severe” side effects from prescribed medication.

A majority of respondents (63%) have discussed using a cannabis-based treatment with their GP or Consultant, but 72% of patients had obtained their cannabis on the street, directly or indirectly. Some respondents reported stress and anxiety associated with obtaining cannabis illegally.

Review of the evidence of the effectiveness of medicinal cannabis by Professor Mike Barnes and Dr Jennifer Barnes

The review was based on a literature search producing over 20 000 references. The evidence was graded according to the system used by the American Academy of Neurology (AAN), based on the robustness of the research methodology. The evidence for particular medical applications of cannabis was then grouped into three categories: “good”, “moderate” and “some”.

The theoretical basis for consideration of cannabis as a medicinal product is strong. The natural endocannabinoid system has a range of important natural functions, including modulation of pain, control of movement, protection of nerve cells and a role in natural brain adaptability, as well as a role in various metabolic immune and inflammatory processes and a possible role in the control of tumour growth.

The review found the following:

- There is **good** evidence for one or more of the cannabis products or “natural” cannabis in the management of chronic pain, including neuropathic pain; spasticity; nausea and vomiting, particularly in the context of chemotherapy; and in the management of anxiety.
- There is **moderate** evidence for the use of cannabis in sleep disorders; appetite stimulation in the context of chemotherapy; fibromyalgia; PTSD; and for some symptoms of Parkinson’s disease.
- There is **some** limited evidence of efficacy for a further list of disorders.

Potential downsides

As with the adoption of any substance in a medical environment, it is vital to consider any potential downsides and put them in context. The short-term side effects of cannabis are generally mild and well tolerated. There is probably a small link between cannabis and schizophrenia for those who start using cannabis at an early age and if the individual has a genetic predisposition to psychosis. There is a small dependency rate of around 9%. This compares with 32% for tobacco use and 15% for alcohol use. Researchers recommend caution in prescribing cannabis to younger people, given the possible susceptibility of the developing brain.

Overall, Professor Barnes concludes that “there is a considerable literature demonstrating the efficacy of cannabis and/or available cannabis products in a number of important indications. Much further research on cannabis is needed in relation to a range of diseases.” According to our survey of medicinal cannabis users, 54% of respondents reported significant to very severe side effects from prescription medicines compared to 8.5% reporting such side effects from their medicinal cannabis use.

The Drug Policy Alliance (DPA) in the USA has reviewed the evidence of the benefits of access to medicinal cannabis since its legalisation in many US States over recent years. Their findings included:

1. **Medical benefits.** The most obvious benefit is to patients. Cannabis has been shown to alleviate their symptoms.
2. **Crime.** Studies evaluating the effect on crime rates have concluded that the “legalization of marijuana for medical purposes is not predictive of higher crime rates and may be related to reductions in rates of homicide and assault”.
3. **Levels of social use.** Passing State medicinal marijuana laws does not affect marijuana use or perceived riskiness of use among adolescents or adults.
4. **Traffic safety.** A 2012 meta-analysis of 66 studies of drug-positive drivers and crash risk found that the risk of marijuana-positive drivers was “statistically comparable to that associated with penicillin, antihistamines and antidepressants”.
5. **Overdose prevention.** Recent studies document a relationship between medicinal marijuana laws and a significant reduction in opioid overdose fatalities.
6. **Alcohol substitution.** When people have access to marijuana through legal means, they consume less alcohol and the social consequences of alcohol use decrease.
7. **Reduction in suicides.** Medicinal marijuana “leads to an improvement in the psychological wellbeing of young adult males and fewer suicides”.

Models of regulation of cannabis for medicinal purposes

We have considered different models of regulation for cannabis. Examples from elsewhere in Europe, Australia, Canada, Israel, Uruguay, the USA and other countries show that there is a place within state health programmes for making herbal cannabis available for a designated number of conditions based on the best available evidence, to be reviewed regularly.

There are challenges in terms of ensuring the strength, quality and purity of herbal cannabis for medicinal purposes. These seem to be best met by controlling supply via regulated outlets,

such as pharmacies, and cultivation by licenced growers. However, cost and a limited variety of strains being made available in such outlets may restrict patient access to the best medicinal cannabis product to meet their needs. This is why some jurisdictions have opted for programmes where patients can grow a limited amount for their own use.

Conclusions

- There is a sizeable population of patients in the UK who have found that medicinal cannabis works for them. For many, it is the *only* substance that brings them relief from their symptoms.
- As access to medicinal cannabis is not lawful in the UK, these patients have to suffer the added stress of breaking the law to obtain what for them is a medicine.
- The review of the literature clearly shows that there is a broad range of evidence that medicinal cannabis works for a range of conditions, which means that the continued listing of cannabis under Schedule 1 is irrational.
- The fact that so many countries now have or are introducing a form of cannabis regulation to ensure access to herbal cannabis to help those with serious chronic conditions, where prescription medicines have been ineffective, further undermines the UK Government's current position.
- The issue of medicinal cannabis should be treated as a matter of compassion and be viewed separately from the wider issue of drug policy reform.

Recommendations

That the government:

1. accepts the evidence from this inquiry, from the associated Barnes report and from around the world that medicinal cannabis works and has a role to play in the treatment of a range of conditions;
2. moves to introduce a system that allows lawful access to medicinal cannabis in the UK. This will involve the relisting of cannabis from Schedule 1 to Schedule 4;
3. carries out an assessment of the various models used across the world to allow lawful access to medicinal cannabis and draw up options for consultation;
4. notes our preference for a system based on the proposed German model which we believe has characteristics that ensure much wider availability of medicinal cannabis to patients; and
5. that the Government decriminalises home growing of small quantities of cannabis for medicinal purposes as witnessed in Uruguay and some US state

1. Introduction

The UN context

The recent UNGASS meeting on global drug policy held in New York in April 2016 marked the beginning of the end of the “war on drugs”. Although the Drugs Convention framework remains in place for the time being, the rhetoric of UN leaders and organisations now reflects an entirely new interpretation of the Conventions. In New York, they emphasised human rights, sustainable development, the primacy of health and the need for policy to be based upon evidence. This breakthrough at the UN reflects actions taken by Member States in Europe, South America, the Caribbean and States within the USA to find better and more humane ways to respond to drug use. This report proposes that law reform relating to medicinal cannabis should be the first UK response to the new UN focus on the need for evidence-based drug policies.

History of the medicinal use of cannabis

The medical use of cannabis dates back to about 4000 BC. More recently, in the 19th century cannabis was used throughout Europe for migraine, neuropathic and musculoskeletal pain and as an aid to childbirth. At that time, the noted physicians of the age supported its medicinal use. Indeed, Sir John Russell Reynolds recommended it for various conditions ranging from insomnia to dysmenorrhea and prescribed it to Queen Victoria.

In the UK, cannabis remained clinically available until 1971 when it was banned under the Misuse of Drugs Act. This Act made possession and supply of controlled drugs, including cannabis, unlawful.

The Act introduced three classes of controlled drugs: Class A drugs (including morphine, diamorphine (heroin), cocaine and LSD) are deemed the most harmful with the highest penalties for possession or sale; Class B (including cannabis, amphetamines and barbiturates) are an intermediate category; Class C are deemed the least harmful and carry lesser penalties. These include anabolic steroids, benzodiazepines and growth hormones. There is no consistent scientific basis for these classifications.

This has remained the case to this day, although cannabis was reclassified as a Class C drug for five years in 2004 on the advice of the Advisory Council on the Misuse of Drugs. For no good reason, it was reclassified to the more serious Class B in 2009.

In 2006, the UK Parliamentary Science and Technology Select Committee produced a report that concluded that the present classification was arbitrary and unscientific and suggested improvements. There has not yet been a change in the law as a result of their recommendations.

Box 1: What are cannabis and medicinal cannabis?

Cannabis

Cannabis is a very hardy plant that grows throughout the world. The plant produces over 10 natural cannabinoids called phytocannabinoids. These are found in the greatest concentration in the unfertilised flower heads. The main psychoactive component of cannabis, tetrahydrocannabinol (THC), was isolated and synthesised in Israel in 1964. Of the other phytocannabinoids, cannabidiol (CBD) has along with THC been identified as having strong medical potential. As our knowledge of phytocannabinoids and the human endocannabinoid system develops, the medical use of some of the other cannabinoids may also be recognized. There is interaction between phytocannabinoids. CBD can reduce the psychoactive effects of THC.

The ratio of THC to CBD appears to be important in terms of medicinal use and has a bearing on the side effect profile. It is also possible that the overall efficacy of the natural plant in medicinal terms depends not only on THC and CBD and the other phytocannabinoids, but also on the “entourage effect” of the other plant chemicals.

Medicinal cannabis

There are a range of interpretations of the term “medicinal cannabis”. It can mean a specific medical intervention from a healthcare professional using a pharmaceutical grade drug, containing a synthesised cannabinoid, licenced by a national health authority. Alternatively the term can refer to self-medication by individuals using street herbal cannabis or resin. These two interpretations and others within that range are examined in this report.

Schedules of drugs for medical use

The Misuse of Drugs Regulations 2001, which amend and update the Misuse of Drugs Regulations 1985, currently define the categories of people authorised to supply and possess controlled drugs for medicinal use. Schedule 1, which includes drugs such as cannabis, are not conventionally used for medicinal purposes and are deemed to have no medicinal value. Possession and supply is prohibited without specific Home Office approval. Schedule 2 includes morphine and diamorphine and those drugs are subject to special requirements relating to their legal prescription, including safe custody and the need to maintain registers. Nabiximols (Sativex) is marketed under Schedule 4. These drugs are available on prescription in certain circumstances and are not subject to the strictest safe custody requirements. CBD in isolation is not proscribed (see Section 6 – Results of survey of health professionals).

In the UK, even the established medicinal applications of cannabis are only partly recognised. Dronabinol has never been licenced. Nabilone was licenced in 1982 as a hospital-only prescription indicated by the National Institute for Health and Care Excellence (NICE) for nausea and vomiting caused by cytotoxic chemotherapy, unresponsive to conventional anti-emetics (under close observation, preferably within a hospital setting).¹ Sativex has only been approved by the Medicines and Healthcare Products Regulatory Agency (MHRA) as an extra treatment for patients with spasticity due to multiple sclerosis. It is not indicated as a

recommended treatment by NICE partly because of its high cost, although it is available on prescription in Wales.

It is very difficult, although not impossible, to undertake studies of cannabis because of its Schedule 1 status. Clearly, at least in the UK, this has hampered research.

2. Developments in the regulation of medicinal cannabis elsewhere in the world

The list of countries that have some form of regulation for medicinal use now includes 24 States in the USA with more due to vote on the issue; Canada, Israel and in Europe, Austria, Belgium, the Czech Republic, the Netherlands, Romania and Portugal. Bedrocan, herbal cannabis grown under licence for medical use in the Netherlands, is available on prescription in a number of European countries including: Finland, Germany, Italy and Switzerland. Countries that have recently decided to introduce a system of regulation include Australia and Jamaica, and in South America, Chile, Colombia and Uruguay. In a number of other South American countries, personal use is decriminalised.

Uruguay

Uruguay is the only country in the world to regulate cannabis supply for social use at the national level. Its system has not yet been fully implemented and the impact has not been assessed. The Uruguayan law has introduced a system of licences for individuals and clubs to grow their own. The law refers to a limit of six plants for individuals, more for clubs. It is also intended to grant licences to commercial growers whose product will then be sold via registered pharmacies. It is expected that cannabis will begin to be sold in pharmacies in 2016 and will be exempt from VAT.² Cannabis for medicinal purposes will be grown under licence separately and under stricter conditions to ensure purity and quality. This will be reflected in its price.

It is likely that the Uruguayan initiative has encouraged the schemes for medicinal cannabis in Colombia and Chile.

USA

In the USA, California was the first State to approve a regulatory system for cannabis in 1996. This has been regarded as a loose model of regulation. Since then, 24 States, as well as the District of Columbia and the Island Territory of Guam have regulated medical use. More recently, States have tended to follow tighter models of regulation that include restrictions on the conditions for which a cannabis prescription can be provided and the systems for authorising and supervising dispensaries.³

In those States where medicinal cannabis is available, systems vary but the common elements include:⁴

1. Physicians can recommend rather than prescribe cannabis if they think it will be beneficial. As cannabis remains within the US Schedule 1 at federal level (which determines that it has no medicinal value) it cannot be prescribed.
2. An identity card is issued to the patient and/or “caregiver”. A caregiver can be a dispensary or someone who undertakes to grow cannabis for a patient under a more informal arrangement.
3. Many states, although not all, have a system of approved dispensaries for cannabis.

4. Most states restrict the conditions for which cannabis can be recommended. The list of conditions can vary considerably between states.⁵ A quite short and specific list has been drawn up by the State of Maine:

“Epilepsy and other disorders characterized by seizures; glaucoma; multiple sclerosis and other disorders characterized by muscle spasticity; nausea or vomiting as a result of AIDS or cancer chemotherapy; and PTSD.”

The New Hampshire list of conditions is more detailed:

“(1) Cancer, glaucoma, positive status for human immunodeficiency virus, acquired immune deficiency syndrome, hepatitis C currently receiving antiviral treatment, amyotrophic lateral sclerosis, muscular dystrophy, Crohn’s disease, multiple sclerosis, chronic pancreatitis, spinal cord injury or disease, traumatic brain injury, epilepsy, lupus, Parkinson’s disease, Alzheimer’s disease, or one or more injuries that significantly interferes with daily activities as documented by the patient’s provider; AND

(2) A severely debilitating or terminal medical condition or its treatment that has produced at least one of the following: elevated intraocular pressure, cachexia, chemotherapy-induced anorexia, wasting syndrome, agitation of Alzheimer’s disease, severe pain that has not responded to previously prescribed medication or surgical measures or for which other treatment options produced serious side effects, constant or severe nausea, moderate to severe vomiting, seizures, or severe, persistent muscle spasms.’

A number of States allow that other conditions, not specified, may be treated subject to the approval of the State health authorities. A few allow for physician discretion in recommending cannabis as a treatment. For example, in Massachusetts this is set out as follows:

“Cancer, glaucoma, positive status for human immunodeficiency virus, acquired immune deficiency syndrome (AIDS), hepatitis C, amyotrophic lateral sclerosis (ALS), Crohn’s disease, Parkinson’s disease, multiple sclerosis and other conditions as determined in writing by a qualifying patient’s physician.”

5. Fourteen states specify a possession limit for medicinal cannabis which includes a specific number of cannabis plants indicating that private growing of cannabis plants is within their laws. Other states set out possession limits that are couched in terms of the usable weight of cannabis or in terms of supply over a fixed time period. For example, Massachusetts specifies a limit of a 60-day supply which is set at 10 ounces.⁶

What has been the impact of medicinal marijuana legislation in the USA?

The most obvious impact of developments in the USA is much improved access to medicinal cannabis by patients; cannabis has been used to treat a range of conditions. However, there have been a number of other benefits to communities in those States where cannabis is legally available for medical use. The APPG sent a call for evidence to the DPA, the leading organisation in the USA promoting drug policies that are grounded in science, compassion,

health and human rights. The response from the DPA included a review of research into the wider impacts of medicinal cannabis regulation. This covered issues of crime, overall cannabis consumption, driving, overdose, alcohol and suicide and is reproduced below.⁷

DPA: Review of wider impacts from the regulation of medicinal cannabis

Crime rates: Studies evaluating the association between state medical marijuana laws and crime rates have found that legalization of marijuana for medical purposes “is not predictive of higher crime rates and may be related to reductions in rates of homicide and assault.”⁸ Recent studies have specifically examined the location of medical marijuana dispensaries and violent or property crime rates and concluded that “robbery and burglary rates were unaffected by medicinal marijuana legislation.”⁹

Youth and adult use of marijuana: Studies demonstrate that the passage of state medical marijuana laws does not affect “marijuana use or perceived riskiness of use among adolescents or adults.”^{10,11} Specifically, research shows that youth marijuana use rates typically decrease in the year following medical legalization¹² and that in the subsequent next few years, youth do not significantly increase the prevalence or frequency of their marijuana use.¹³

Traffic safety: The issue of marijuana consumption and road safety has received considerable scrutiny, particularly in the last decade. The preponderance of evidence indicates that the risks of further reforming marijuana laws are quite low. The largest review of the scientific data by far—a 2012 meta-analysis of 66 studies of drug-positive drivers and crash risk—found marijuana-positive drivers’ risk among the lowest of any drugs; the risk was statistically comparable to that associated with penicillin, antihistamines and antidepressants.¹⁴ (See also Alcohol substitution.)

Overdose prevention: A striking study published last year in the *Journal of the American Medical Association* documents a relationship between medical marijuana laws and a significant reduction in opioid overdose fatalities. “States with medical cannabis laws had a 24.8% lower mean annual opioid overdose mortality rate compared with states without medical cannabis laws,” an association that “generally strengthened over time.”¹⁵ The authors hypothesize this relationship results from patients successfully substituting marijuana for analgesic opioids, which is particularly noteworthy as opioid overdose has surpassed auto accidents as the leading cause of accidental death in the country.¹⁶ (More recently, academics at the University of Georgia have found that between 2010 and 2013, for Medicare Part D enrollees (seniors), the use of prescription drugs for which marijuana could serve as a clinical alternative fell significantly once a medical marijuana law was implemented. They calculate that on a national level this saved an estimated \$165.2 million per year in 2013.)¹⁷

Alcohol substitution: A recent review of research has demonstrated that marijuana is a substitute for alcohol—when people have access to marijuana through legal means, they consume less alcohol and the social consequences of alcohol decrease.¹⁸ The potential implications of marijuana-for-alcohol substitution are further illustrated by a study that

associated marijuana use with lower incidents of intimate partner violence.¹⁹ And multiple traffic safety studies demonstrate that drivers under the influence of THC are able to compensate for their impairment, while drivers under the influence of alcohol are not.²⁰

Suicide: A recent Colorado study demonstrated that there is no known association between marijuana use and suicide rates.²¹ Meanwhile a national study concluded that medical marijuana “leads to an improvement in the psychological wellbeing of young adult males, an improvement that is reflected in fewer suicides.”²²

Canada

Canada introduced a system for the regulation of cannabis in 2001. The system allows for medical professionals to prescribe cannabis at their own discretion under two broad categories. The categories cover any symptoms treated as part of providing compassionate end-of-life care or the symptoms associated with the following medical conditions (Category 1):

- severe pain and/or persistent muscle spasms from multiple sclerosis, from a spinal cord injury or from spinal cord disease;
- severe pain, cachexia, anorexia, weight loss, and/or severe nausea from cancer or HIV/AIDS infection;
- severe pain from severe forms of arthritis; or
- seizures from epilepsy.

They also cover patients who have debilitating symptoms from conditions, other than those listed above (Category 2).

Israel

Medical use has been permitted since the early 1990s. In 2013, 13 000 patients had been given a state license to use cannabis for medical purposes.²³ It is currently being used to treat the following conditions:

- Parkinson’s disease;
- multiple sclerosis;
- Crohn’s disease;
- other chronic illnesses; and
- PTSD.

Europe

In Europe, a clear distinction needs to be made between systems for the regulation of herbal cannabis as a medicine and those for cannabis synthetics and derivatives that have gone through the clinical trials normally necessary for a medicine to be approved. Sativex (nabiximols), which has gone through this process, is currently approved for medical use in 17 countries.²⁴

The Netherlands

The Netherlands has the longest-standing scheme for medicinal cannabis in Europe. Medicinal herbal cannabis in the form of florets or powder has been available since 2001 on prescription from pharmacies. Its production is controlled by the Office for Medicinal Cannabis which is responsible for ensuring supply and quality control. Cultivation is licenced and monitored by the Office and the products should contain no pesticides, heavy metals, fungi or bacteria. The Office supplies a variety of strains of cannabis as shown in Table 1.²⁵

Table 1: Strains of cannabis supplied by the Office for Medicinal Cannabis

Variety	THC content	CBD content
Bedrocan	About 19%	<1%
Bedrobinol	About 12%	<1%
Bediol	About 6%	About 7.5%

The Dutch health authorities have carried out an extensive review of the scientific literature and consequently made a limited list of the conditions where the use of medicinal cannabis can be indicated. This includes:

- pain and muscle spasms or cramps associated with multiple sclerosis or spinal cord damage;
- nausea, loss of appetite, weight loss and debilitation due to cancer or AIDS;
- nausea and vomiting associated with chemotherapy or radiotherapy used in the treatment of cancer, hepatitis C or HIV infection and AIDS;
- chronic pain (mainly pain associated with the nervous system, for example, that caused by a damaged nerve, phantom pain, facial neuralgia or chronic pain that remains after the recovery from shingles);
- Tourette syndrome;
- therapy-resistant glaucoma.²⁶

The reason for this limited list of indications is that the efficacy of the medicinal use of cannabis for other medical conditions has not yet been properly studied in convincing clinical trials. The list is subject to change based on the findings of new studies. In terms of cost, medicinal cannabis is not automatically covered by healthcare insurers. Some will provide limited cover through supplementary insurance. The number of people using herbal cannabis supplied by the Dutch authorities has increased from 1300 patients in 2010 to 4000 patients in 2015.²⁷

Germany

In Germany, the Federal Institute for Drugs and Medical Devices has authorised the medicinal use of cannabis for special “compassion” cases, mainly patients with terminal cancer. There are currently a few hundred such cases who can purchase, at their own cost, cannabis imported from the Netherlands primarily for pain relief. The issues for patients have included:

- availability of cannabis from the Netherlands;
- quality of the cannabis on offer;

- cost (palliative cannabis treatment can cost between €800 and €1,000 per month,²⁸ and is not covered by the health insurance system).

Legislation is now being introduced by the Federal Government into Parliament which addresses these issues by setting up a system to license the production of herbal cannabis on German soil and to ensure that its provision to patients is covered by the German health insurance scheme. The initial number of beneficiaries from this legislation is likely to be small. They will be limited to those judged to have no other treatment options or where existing treatments have been ineffective. However, it has been estimated that in due course 800,000 patients may gain access to cannabis under the scheme.²⁹

Italy

Since 2013, it has been possible for those in possession of a valid prescription from a licenced physician to be treated with medicinal cannabis. Patients can obtain medicinal cannabis from licenced pharmacies, which have imported cannabis from the Netherlands. This is expensive at up to €38 per gram.³⁰

In response, Italy has recently licenced the production of herbal cannabis at a facility within a military compound in Florence, which is expected to produce up to 100 kg of cannabis per year. About half of Italy's regions have agreed to supply medicinal cannabis free or at low cost. Even if charges are imposed, the price would be in the region of €5–15 per gram.³¹

Spain

A limited amount of cannabis that is used for therapeutic purposes is available via Spain's Cannabis Social Clubs. Although Nabilone and nabiximols (Sativex) are authorised for prescription, herbal cannabis is not. The Cannabis Social Clubs operate in a legal grey area. A successful defence against prosecution by individuals and members of Cannabis Social Clubs has been that the cultivation of cannabis has not been for sale but is available to members for therapeutic purposes. This has not stopped crackdowns on the Clubs and the attitude of the authorities can vary region by region.

3. Conducting the Inquiry and taking evidence

In January 2016, the APPG began its Inquiry to clarify:

- whether switching the medical status of cannabis from Schedule 1 to a less restrictive schedule would be beneficial;
- the range and extent of the unofficial use of cannabis for medical purposes;
- the impact of the current Schedule 1 status on research into the medical uses of cannabis;
- whether useful evidence is emerging from the regulation of cannabis in over 20 US States and elsewhere (the implications of licensing cannabis for medical use following a change in Schedule).

The Inquiry has taken evidence in the following ways:

- a call for evidence to a range of bodies and individuals including government agencies, experts in the field of medicinal cannabis, voluntary organisations and individuals who use cannabis to treat a medical condition;
- a series of four hearings held at the Houses of Parliament to probe some of the written evidence received and to hear oral evidence on the main issues;
- the commissioning of a systematic literature review of medical applications of cannabis by Professor Mike Barnes, Honorary Professor of Neurological Rehabilitation, Newcastle University and Dr Jennifer Barnes, DPsych, Clinical Psychologist, Northumberland, Tyne & Wear NHS Foundation Trust. Professor Barnes has been Clinical Director of Rehabilitation North within the NHS, President of the World Federation for NeuroRehabilitation, Chairman of the Royal College of Physicians Rehabilitation Committee. He is currently Clinical Director of Neurological Rehabilitation with the Christchurch Group;
- carrying out two online surveys:
 - one of users of cannabis for medicinal purposes who were contacted by Jonathan Liebling, Political Officer from the United Patients Alliance (UPA), and a representative body for medicinal cannabis users. Jonathan analysed the results;
 - also, a survey of health professionals who were alerted to the survey by the Chronic Pain Coalition, a forum for patients, professionals and parliamentarians who are concerned with the issue of chronic pain.

The work of the Inquiry was carried out between January and the end of May 2016. The APPG received 12 formal responses to its call for evidence and had many more exchanges with other interested parties about the issues involved. It held hearings on the 10 and 24 February and on the 2 and 9 March 2016. Sixteen experts gave evidence to a panel of APPG members. Between six and nine panel members were present at each hearing. For details of those giving evidence and panel members see Appendix 1.

4. Medicinal cannabis: the evidence

The medicinal cannabis environment is bedevilled by claim and counterclaim about the benefits or dangers of using cannabis. To assess the evidence and bring a dispassionate view of what is known about current and potential applications of cannabis-based treatments, the APPG commissioned Professor Mike Barnes³² and Dr Jennifer Barnes to prepare an up-to-date review of the current evidence and to grade the evidence in terms of its quality. Specifically they were asked to:

- examine those diseases and conditions where cannabis is identified as having an established or credible potential treatment application;
- assess and grade the quality of the research related to each of those diseases and conditions;
- document the side effects of cannabis; and
- comment on the impact of the potential legalisation of cannabis in the UK on potential medicinal use and supporting research.

The work was carried out in April and May 2016. It involved a literature search producing over 20 000 references. The results are summarised here.³³ Evidence was graded according to the system used by the American Academy of Neurology (AAN), particularly in the systematic review of medicinal marijuana for neurological conditions by the Academy (Koppel et al., 2014; www.ncbi.nlm.nih.gov/pmc/articles/PMC4011465/). The AAN grading scheme (paraphrased) divides the quality of research into four classes depending on how robust the research methodology is. The classes range from 1 to 4, Class 1 being a randomised, controlled clinical trial with a masked or objective outcome assessment, in a representative population. Class 4 includes trials that may not use controls. The evidence for particular medicinal applications of cannabis was grouped into three categories: “good”, “moderate” or “some” where:

- **good** represents at least two Class 1 studies plus studies in Class 2/3/4;
- **moderate** represents one Class 1 or at least two Class 2 studies backed by Class 3/4 studies; and
- **some** represents one Class 2 study backed by Class 3/4 studies.

A lack of a categorisation for a particular or potential medicinal application of cannabis may simply mean that further research is necessary.

Cannabis has been used as a medical product for many centuries. In recent decades, it has been discovered that the human brain and other organs contain naturally occurring cannabinoid receptors and chemicals that bind to those receptors. This is called the endocannabinoid system. The endocannabinoid system has a range of important natural functions, including modulation of pain, control of movement, protection of nerve cells and a role in natural brain adaptability (plasticity), as well as a role in various metabolic, immune and inflammatory processes and a possible role in the control of tumour growth.

Plant cannabis probably works in man by “mimicking” the effects of the human endocannabinoid system. The main plant cannabinoids (phytocannabinoids) studied and

thought to be the most important in terms of efficacy, are THC and CBD, although many others exist and a role for them may become clearer with time.

The paper has provided an analysis and has graded the evidence for the efficacy of cannabis and various licensed cannabis products for a number of different indications. The findings are that there is:

- **good** evidence for one or more of the cannabis products or “natural” cannabis in the management of chronic pain, including neuropathic pain, spasticity, nausea and vomiting, particularly in the context of chemotherapy, and in the management of anxiety;
- **moderate** evidence in sleep disorders, appetite stimulation in the context of chemotherapy, fibromyalgia, PTSD, and for some symptoms of Parkinson’s disease;
- **some** limited evidence of efficacy, but further studies are required, in the management of agitation in dementia, epilepsy, particularly drug-resistant childhood epilepsies, bladder dysfunction, glaucoma and Tourette’s syndrome. There is a theoretical basis, but so far **no** convincing evidence, of efficacy for the management of dystonia, Huntington’s disease, headache, brain protection in the context of traumatic brain injury, depression, obsessive compulsive disorder, gastrointestinal disorders, psychoses (CBD), and a role in cancer/tumour control.

In summary, the review found that the short-term side effects of cannabis are generally mild and well tolerated. An assessment of the evidence for a causal link between cannabis use and schizophrenia indicates that there is probably a link in those who start using cannabis at an early age and also if the individual has a genetic predisposition to psychosis. There should be caution with regard to prescription of cannabis for such individuals. There is a small dependency rate with cannabis at around 9%, which needs to be taken seriously but compares to around 32% for tobacco use and 15% for alcohol use. There may be a, as yet unproven, risk of respiratory cancer for smoked cannabis. This route of administration is not recommended. The evidence for cognitive impairment in long-term users is not clear but it is wise to be cautious in prescribing cannabis to younger people, given the possible susceptibility of the developing brain.

Overall, there is a considerable literature demonstrating the efficacy of cannabis and/or available cannabis products in a number of important indications. Clearly much further work is needed with regard to the formulation of cannabis and the best THC:CBD ratio for different conditions. Better and further studies are also needed on both its short- and, more particularly, longer-term effects.

5. The use of medicinal cannabis in the UK

The extent of cannabis use for medicinal purposes in the UK is unclear. Much of it, necessarily and regrettably, involves obtaining cannabis from illegal sources so it is, as a rule, hidden. Estimates of the level of cannabis use suggest that 30,000 patients in this country are using cannabis each day.³⁴ If medicinal cannabis were legalised, we might expect the number of users to increase to over 1,000,000.³⁵ The 1,000,000 estimate is based on the proportion of those using cannabis for medicinal compared with overall use within US states where medicinal use is legal and regulated.

Alongside evidence presented to the Inquiry from individuals and experts on what medicinal cannabis users have faced and risked to use it for treatment, the APPG commissioned an online survey in the UK of those who use cannabis medicinally. The survey was administered and analysed by Jonathan Liebling from the UPA, a body representing those who use cannabis medicinally. It was completed between March and April 2016 by those who were contacted through social media and a number of medically focused cannabis support groups and health support groups.

Respondents were given the choice to submit their answers anonymously and the analysis was carried out after the answers had been anonymised. The questionnaire comprised 25 questions which sought to capture the experience of using cannabis medicinally. (The questionnaire used is shown in Appendix 2.) Six hundred and twenty-three questionnaires were received. Those using the survey were self-selecting in that they had to be in a position to know about the survey, principally via the UPA, and to be motivated to spend the time completing it. We do not claim that the sample is representative. Those who responded to the survey are more likely to be those who have had a positive experience of cannabis treatment. Finally, the descriptions of conditions and the impact of medicines including cannabis are those of the respondents and not independent clinical diagnoses.

However, despite these limitations, it is important to consider the results of this survey as an indication of the experience of some cannabis user patients. Also, the number of questionnaires received has allowed for both a range of experiences to be described and for a number of common issues within those experiences to be identified.

Results of the survey

Characteristics of the respondents

Respondents included 447 (71%) males and 176 (28.3%) females. Their ages ranged from 16 to 75 years with a mean age of 37.1 years. The majority of male respondents were between 20 and 40 years old (61.3%), while less than half (43.8%) of female respondents were from that age group. Respondents came from all regions of the UK.

Conditions for which medical cannabis is used as a treatment

According to respondents, cannabis was used medicinally to treat a wide range of conditions, for example, chronic and severe pain (24.1%), arthritis (12%), insomnia (21%), fibromyalgia (9%), PTSD (7%), depression (30%) and anxiety (26%).

This compares with some previous studies. For example, a 2005 study of medicinal cannabis users in Australia³⁶ found that:

“Long term and regular medical cannabis use was frequently reported for multiple medical conditions including chronic pain (57%), depression (56%), arthritis (35%), persistent nausea (27%) and weight loss (26%).”

How long had patients suffered from these conditions?

Over half of respondents (53.1%) had suffered the conditions described for between 10 and 30 years. This indicates that cannabis is being used to treat and provide relief, in most cases, from the symptoms of long-term, chronic conditions. Even for those reporting that they had had their condition for between 1 and 5 years the majority (64.8%) had suffered from it for at least 3 years.

At what point did patients start treating themselves with cannabis?

Although some respondents had treated themselves with cannabis before or at the same time as they had been treated with conventional medicines, the majority (67.1%) only turned to cannabis after being prescribed conventional medicines. Nearly half (48.1%) persevered with prescription medicines for at least one year before beginning a cannabis treatment. The list of medications prescribed includes some significantly intrusive and in some cases, addictive preparations. The list includes: analgesics (23% of cases), antidepressants, sedatives, antipsychotics, steroids and anticonvulsants. One witness heard by the group listed 34 medications prescribed for their condition before they tried treating their condition with cannabis. (See Appendix 4 for an example of the kind of prescription medicines that have been used.)

What had been the experience with prescribed medicines and with cannabis treatment?

Many patients responding to the survey clearly suffer from conditions that are resistant to prescribed medicines: 41.9% of respondents reported that their condition was not relieved or in some way their situation was worse after taking prescribed medication; 45.9% reported a modest improvement in their condition while the proportion of respondents reporting some improvement in their condition was 10.9%. Only 1.4% felt that their prescribed medication had been completely effective.

The experience reported for cannabis treatment was far more positive. A strong majority of respondents (89.9%) reported some improvement in their condition and no zero or negative effects were reported. Cannabis was perceived to provide “great relief” overall (86%), and

substantial relief of specific symptoms such as pain, nausea and insomnia. Again this compares very closely to the Australian study cited earlier which found that:

“Cannabis was perceived to provide ‘great relief’ overall (86%), and substantial relief of specific symptoms such as pain, nausea and insomnia.”³⁷

What were the side effects reported for prescribed medicines and for cannabis treatment?

Fifty-four per cent of respondents experienced significant, severe and very severe side effects from prescribed medication. To describe their side effects respondents used terms including “sickness, nightmares, severe headaches” (significant); “a number of negative effects, suicidal thoughts, vomiting” (severe); and “severe suicidal thoughts, seizures, blackouts” (extremely severe).

By comparison, 8.5% of respondents reported significant or severe side effects from cannabis treatment. That is, over 90% of respondents report no or mild side effects. Those patients who experienced side effects from cannabis reported drowsiness, the munchies, being “too-high”, nausea and dizziness, paranoia, anxiety and a dry mouth. Cannabis is a thoroughly researched drug in terms of its potential harms, so this list is not surprising. However, it is important to note that these side effects were considered mild compared with many of those reported for prescribed medicines and were to some extent mitigated by patients learning which strains of cannabis and which combinations of cannabinoids worked best for them.

However, there was an effect reported which resulted from the illicit status of cannabis; 35.6% of respondents reported illegality as being a concern arising from their use of cannabis as a treatment. In some this led to experiences of paranoia and anxiety; others were concerned about the stigma associated with taking a controlled substance or the problems of obtaining cannabis on the illicit market. Finally, there were issues around not being able to guarantee quality or safety in a product obtained on the illicit market combined with a high cost.

The problems with obtaining illicit cannabis can also affect the family. In giving oral evidence to the Inquiry, representatives of Law Enforcement Against Prohibition (LEAP) described the situation of many people in their 20s, 30s and 40s.

“They still have to live with their parents. Whoever’s roof you are living under, they face the same level of prosecution as you. Not only are you putting yourself at risk, but you are putting your family and support groups at risk. That of course causes stress and a whole other realm of family fallout from criminalisation.” (Neil Woods, LEAP)

What was the view of the medical profession to cannabis treatment?

Not all but a majority of respondents (63%) have discussed using a cannabis treatment with their GP or Consultant. Of this group, only a small proportion of prescribers (28%) have taken a negative view of their cannabis treatment with a higher proportion (41.3%) being actively positive. Over one-third of respondents (37%) had not discussed using cannabis to treat their condition with their GP or Consultant. This group are likely to have been put off doing so by

the current illegal status of cannabis which thus acts as a barrier to finding the most effective way to meet their health needs.

Where do people using cannabis as a treatment obtain it?

Of the 80.9% of respondents who answered this question, a clear majority (72%) obtained their cannabis on the street or from a friend. As a friend will almost certainly obtain cannabis from the street, this ultimately amounts to the same thing.³⁸ Other sources involved “grow your own” either by the patient themselves or by their friends or Clubs. Alternatively, the cannabis was obtained via the internet (Table 2).

Table 2: Sources of cannabis supply

Did not answer	19.1%
Street	52.6%
Friends	19.4%
GYO	10.7%
GYO-Friends	6.7%
GYO-Club	2.0%
Internet	7.3%
Abroad	1.2%

Users who presently access cannabis for medicinal purposes receive significant advice and guidance from their suppliers, including instructions on strains, dosage and indications.

Proposals for change

Not surprisingly, none of the respondents were happy with the status quo in terms of the current schedule and control of cannabis as a Class B drug. They split into three groups either calling for legalisation of cannabis with regulation of supply, its legalisation for medicinal use or the decriminalisation of users of cannabis. The proportion supporting each option is given in Table 3.

Table 3: Proportion supporting each option

Law change	Respondents
Full legalisation	58.9%
Legalise for medicinal use only	31.6%
Decriminalise use	9.5%
Grand total	100.0%

The emerging market in CBD oil

The Inquiry has also heard evidence of a cannabis-based product which has emerged recently: CBD oil. CBD oil is extracted from hemp plants which are a form of cannabis grown legally as they contain a minimal amount of THC (<2%). CBD oil is sold mainly over the internet. Nick Ellis, the Chief Executive of CBDUK Ltd, himself a user of CBD oil medicinally for ulcerative colitis and fibromyalgia, described to our Inquiry what was involved.

His company sells a range of cannabis oil products which are classed as dietary supplements and the company is not allowed to give medical advice or make any claims as to the medicinal efficacy of the products. It seemed, however, that 90 % of customers are buying the products for health reasons.

There are concerns from government agencies that the trade in CBD oil is not strongly regulated. In 2015, the US Federal Food and Drug Administration wrote to six companies selling CBD products.³⁹ The problems they cited included medicinal claims being made for the CBD oil product being sold and an absence of any CBD content. They informed one company:

“Your product is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use this drug safely for its intended purposes.”⁴⁰

Another issue with CBD oil is the cost. Although the medicinal use of legally sold CBD is obscured, and details of the cost of medicinal use are anecdotal, an example of the daily cost of using CBD oil medicinally is \$18 per day.⁴¹ For a chronic condition continued use for over two months could cost more than \$1000.

The results of research into the efficacy of medicinal cannabis are increasingly known. It is reasonable to assume that the market in CBD oil in the UK is driven at least in part by the fact that herbal cannabis is not legally available for medicinal use. A regime of regulated herbal cannabis as available in Europe would seem to offer the best prospect for patients to access medicinal grade cannabis at a reasonable cost and with the benefit of professional advice from a doctor.

Conclusions

The survey has identified users’ experiences with medicinal cannabis taken to treat a wide range of conditions. For some of these conditions, our review of evidence suggested that there is a good evidence base for the effectiveness of cannabis. For others the evidence base is not so strong but the respondents have reported positive results.

Those using medicinal cannabis are not doing so lightly. Typically, they will have been prescribed a range of medications for at least a year before trying cannabis.

Respondents report a generally positive experience with cannabis by contrast with their mixed experience of previously tried prescription drugs. The positive experience includes an experience of the side effects of cannabis relatively less serious than those of prescription drugs. However, a “side effect” of cannabis that needs to be acknowledged is the stress and anxiety caused by having to obtain it illegally.

In the main, respondents’ experience with the medical profession is that in their main doctors are not opposed to self-medication with cannabis. However, it is a matter of concern that an exchange between health professionals and cannabis users does not take place in 37% of cases.

Not surprisingly, respondents are in favour of a change in the law. It is a reasonable assumption that they speak for the estimated 30 000 who use medicinal cannabis daily. Such

a change would also benefit those who are currently seeking treatment from the legal, but costly and poorly regulated, CBD oil market.

6. Results of the survey of health professionals

In order to get a picture of how medicinal cannabis is viewed by health professionals, a short online survey was undertaken with the assistance of the Chronic Pain Policy Coalition. The Coalition is a forum established in 2006 to unite patients, professionals and parliamentarians in a mission to develop an improved strategy for the prevention, treatment and management of chronic pain and its associated conditions.⁴² The Coalition notified the health professionals with whom it is in touch that we had set up an online survey. Between 26 February and 13 April 2016, 126 replies were received. This is a strong response from busy and senior health professionals. It indicates a lot of interest in the issue by a group of health professionals working in the field of chronic pain, a field where our evidence review has demonstrated that there is good evidence for the use of cannabis to contribute to treatment plans. How far the comments of this group represent the medical profession as a whole is untested.

The majority of respondents were Consultants, mainly working in the field of pain management. The full breakdown of respondents is shown in Table 4.

Table 4: Breakdown of respondents

Breakdown of respondents		
Academics	5	4%
Consultants	86	68%
Doctors	8	6%
Nurses	12	10%
Physiotherapists	5	4%
Other	10	8%
Total	126	100%

Knowledge of cannabis being used by patients to treat their condition

Ninety-seven (77%) of those responding were aware of patients being prescribed or making use of cannabis or cannabis-based medicines to treat their condition, either in the form of synthetic cannabinoids or cannabis derivatives such as nabilone or Sativex (nabiximols); or imported from the Netherlands (Bedrocan); or cannabis obtained by other means.

Of these, half described the prescription of Sativex for pain management. Specialist pain consultants are one of the groups within the medical profession that can prescribe Sativex although not all prescribing committees authorise its prescription. A smaller group had made use of synthetic THC in the form of nabilone. Such drugs are licenced for the reduction of spasticity in multiple sclerosis sufferers but in some cases were being prescribed off licence for the treatment of pain. Some health professionals have anything up to 100 patients being treated with Sativex. The numbers reported as being treated with nabilone are much lower, under 10.

It was clear from the responses that many health professionals are aware of patients taking cannabis obtained from the street in addition to prescriptions of Sativex or nabilone. The numbers involved could be as many as 150 per respondent, but the number varies from this

figure to a very few. This can depend on whether patients feel confident to talk to their Consultant or other health professional.

As the health professionals were pain specialists they reported their experience of cannabis-based treatments in this area. The types of pain where they had either prescribed or had knowledge of the prescription of cannabis-based treatment included: pain associated with multiple sclerosis, neuropathic or nerve pain, severe musculoskeletal pain from degenerative changes, back pain, cancer pain, pain due to spinal cord injury, fibromyalgia, chronic migraine and cluster headaches, atypical facial pain, chronic visceral and pelvic pain syndromes, post-amputation phantom pain, failed back surgery syndrome, nociceptive pain (caused by damage to body tissue), demyelinating polyneuropathy, complex regional pain syndrome and deafferentation pain (based on interruption of nerve impulses).

In summary, as one respondent put it, “every kind of pain you can mention” and according to another “pain resistant to other treatments”.

Perceived effectiveness of cannabis based medication

One hundred and eight replies were obtained to the question “What in your experience has been the impact of using cannabis medicinally on the conditions listed?” Of these, 72 were positive about the role of cannabis-based medicines for the conditions they were involved in researching. For example:

Nabilone

“Nabilone seems to be a useful drug, generally well tolerated and does not seem to suffer from problems with tolerance and analgesic (pain causing) side effects like opioids.”

Sativex

“Sativex is a very useful addition to the menu of treatments for spasticity and neuropathic pain.”

“Street” cannabis

“Those who report using cannabis report that they find it either reduces pain or helps them to tolerate pain.”

Negative comments often referred to applications of a particular cannabis-based treatment for particular conditions where very limited or no benefit had been observed, for example, in a trial for the treatment of diabetes. Other reports included observations that benefits were short term or that cannabis-based medicines can have negative psychoactive effects. But other patients reported to respondents that the relaxing experience from taking cannabis was helpful to them in managing their condition.

A number of positive comments were qualified by comments that cannabis-based treatment did not work for all patients and could have less of an impact on some patients than other drugs. However, health professionals were clear that cannabis definitely works for some people and according to one respondent, it works *“in the most difficult cases”*. For another

respondent, cannabis-based treatment *“can provide significant benefit for a small group of chronic pain patients where other agents have failed”*.

Also the fact that a drug does not work for all patients is not, in itself, a reason to exclude it from the formulary. As one respondent commented, *“I probably see an equal number of patients who report that they tried cannabis but found that it didn't help. (This is true for prescribed pain meds too.)”*

Conclusion

A group of senior health professionals have given their views on the current and potential use of cannabis-based treatment in the treatment of chronic pain.

While some have been negative about the value of any of the cannabis treatments available, a much larger group have been positive about the role of cannabis, mainly in terms of nabilone and Sativex (nabiximols) but in some cases in terms of herbal “street” cannabis as well.

There were a number of calls among respondents for cannabis-based treatment to be more widely and more easily available. Typical examples were:

“Some patients claim to have benefited significantly but at present we cannot legally support the use of illicit substances, therefore potentially stopping patients getting their perceived benefit.”

“Not magic, safe, well worth a try in these awful chronic pain problems where we have few options.”

7. Case studies

Chronic neuropathic pain – Jacob

Jacob is 28 years of age. He has been battling chronic and neuropathic pain for eight years, having been born with a diaphragmatic hernia and initially needing life-saving corrective surgery. He had surgery on several occasions and in 2007 was found unconscious due to extreme pain and internal bleeding. Surgery was again necessary to remove adhesions and scarring of his abdomen and bowel. But he continued to struggle with intense pain, spasms and digestion and mobility problems. After trying various antispasmodics and opiates, including oxycodone (OxyNorm), pregabalin (Lyrica) and amitriptyline which all caused very severe side effects, he was given nabilone and Sativex (nabiximols). Neither of these medications was effective in combating his symptoms. He is currently trying to obtain Bedrocan legally and relies on herbal and extracted cannabis as his sole source of relief.

Multiple sclerosis – Clark

Clark was diagnosed with multiple sclerosis in 2010 at the age of 24. He took many prescription medications to control his symptoms, but they all had severe side effects, leaving him feeling worse than without them.

Clark had watched his stepfather slowly deteriorate from the same disease. Clark does qualify for Sativex but his primary care trust/ clinical commissioning group refused to pay for it. Clark has two doctors' recommendations from the USA after a recent trip there and now consumes cannabis almost exclusively to treat his multiple sclerosis, saving the NHS the cost of medications which is about £30k per year. The benefits he experiences include: reduced spasticity, pain relief, increased appetite, reduced bladder and bowel problems, less nausea and very little side effects and means he can walk further and does not need the aid of a wheelchair.

Degenerative disc disease/osteoarthritis and stenosis in lumber and cervical spine, and arthritis in knees and right hip – Anonymous

This anonymous patient is a 42-year-old mother of three and former paediatric nurse. Last year she underwent major spinal surgery to replace two discs in her neck. She suffers constant pain and is unable to work. Indeed, the neuropathic pain is much worse than before the operation.

Over the past 15 years she has been prescribed over 34 different medications, including opiates, anti-inflammatories, anti-epileptic medication, antispasmodics, antidepressants and anti-emetics. Most of the medications have had intolerable side effects including nausea, vomiting, sedation, arrhythmia, dizziness, severe headaches and a marked reduction in appetite; also severe withdrawal symptoms when she stopped taking opiate medication. She has also had epidural and facet joint injections.

Today she relies on Bedrocan, a licenced cannabis medicine, which she buys in the Netherlands. This involves a painful journey four times a year to get a Dutch prescription and to purchase the cannabis medication in person from a pharmacy. She pays £2130 a year for

her cannabis. This dose of Sativex would cost more than £49 000 per year. Her consultant has discussed increasing her dose, but she cannot afford it.

She is clear that cannabis has not cured her but it alleviates her neuropathic pain, spasms and stiffness. It also helps reduce the nausea which she experiences when in pain and improves her appetite. She says that for those in severe pain, cannabis does not cause a “high”. It simply restores the patient to a normal mental state. She is not aware of any adverse side effects.

Brain tumour and seizures – Mark

Mark had 24/7 headaches for seven years and had five or more seizures per day. He had lost the sight in his left eye and lost his driving license. He was prescribed a long list of medications which were generally not effective and caused a number of severe side effects. (See Appendix 4 for list of medications and side effects.) He spent a year researching the endocannabinoid system and the use of cannabis oil to treat cancers and seizures. He finally made some cannabis oil and took it. Within 10 minutes he says his headache stopped. After three days, he noticed that his seizures had also stopped, along with the pain behind his left eye. His eye then began to focus. He told his neurologist about these changes. He has since stopped all other medications and has his driving license back. He continues to take cannabis and cannabis oil.

Neuropathic pain – Caroline

Caroline has not had one night of sound sleep in the UK in 15 years, due to neuropathic pain and spasms. She describes her neuropathic pain as “covering all of her body. It is burning, scalding pain. Neuropathic pain does not respond to usual pain killers due to its aetiology and yet cannabinoids have been proven to work.”

Caroline refers to the repeated GP and hospital appointments and hospital admissions, all of which are very costly and could be avoided if cannabis were available on prescription, she says. Caroline is critical of the limitation on prescribing of cannabis medications to multiple sclerosis sufferers. She argues that this discriminates against others with similar symptoms but with a different diagnosis. Caroline has had to give up work as a dual qualified nurse 10 years before retirement because of her symptoms. She tried cannabis in Amsterdam and is clear that she could have continued working if she were able to access cannabis in the UK. She experienced her first night of sound sleep in Amsterdam. There, she did not have to get up 10 times in the night because of bladder spasms which keep her awake for hours.

“I also suffer from emotional problems” says Caroline. This is because of her multiple sclerosis lesions that are so severe that when they start she has to drive her car to somewhere secluded and scream for up to 3 hours until they subside, not to disturb others.

“This issue is about the morality of the government, and how it defends and cares for those it represents”, says Caroline. “I want my life back – it’s simple.”

8. Current scheduling of cannabis: implications for research

The implications for research of the current Schedule 1 status for cannabis are that to obtain the necessary permissions remains a costly obstacle course. Getting a Schedule 1 licence for research in the UK takes about a year and costs around £5000. This sum includes £3000 for the licence and £2000 for the other requirements (extra security for the drug cabinets, police checks, etc.). For cannabis trials involving a placebo, cannabis placebo is held to be a Schedule 1 substance so these costs are reproduced again.⁴³

Import licences are only granted for 12 weeks by the Home Office and can expire before all the arrangements (e.g. export licence from the Netherlands and approval by the Dutch Medical Cannabis Office) are made. As a result of these restrictions, it has been calculated that research involving Schedule 1 drugs takes significantly longer and costs about 10 times that of research into other drugs. Researchers not only have to consider the cost but also the uphill administrative struggle if they are to pursue their studies.

A further consequence of Schedule 1 status is that only four hospitals have been granted a licence to hold stocks of cannabis although all of them can hold heroin.⁴⁴ Only a handful of UK universities hold a Home Office Licence to do research on cannabis.

Research into cannabis can take place in a number of different ways with different objectives. It can explore the characteristics and impact of the many different cannabinoids and terpenes. (Terpenes are organic molecules which are understood to contribute to the smell and taste of plants, e.g. the distinctive smell of *turpentine* derived from pine resin.) It can involve pre-clinical trials of individual cannabinoids or particular combinations of one or two cannabinoids conducted *in vitro* or by means of animal testing. As the review conducted by Mike Barnes has shown, there is a lot of documentation from these pre-clinical trials. However, many of the results are yet to be tested in a full clinical trial.

The experience of conducting clinical trials was described in evidence given by representatives of GW Pharmaceuticals who developed Sativex (nabiximols). They argued that in this process the demands of the clinical trials pose more of a challenge than overcoming the difficulties presented by Schedule 1 status. This point of view was also put forward by Gerald Heddell from MHRA. The situation of GW Pharmaceuticals may have been made easier after they were able to establish the cultivation of their own supply of cannabis which others who engage in cannabis research in the UK cannot do. But the initial negotiations with the Home Office to establish their own supply were extensive, and the installation of the necessary security equipment took five months.

While it is accepted that as far as medicine development is concerned, for those with considerable infrastructure and resources, the schedule question may not be so acute, it still seems to be a major obstacle for academic and pre-clinical research in the UK. And as our evidence review indicates, there are still some major gaps in our understanding of the medical potential of cannabis.

In order to resolve some of the problems, a rescheduling of cannabis is recommended. Rescheduling to Schedule 2 puts cannabis on a par with heroin where there is a recognised therapeutic application, although heroin is characterised as being highly addictive. Accordingly, Schedule 2 drugs are subject to strict controls about the security of stocks kept for medicinal purposes. Our evidence review found that cannabis has a “*small*” dependency rate compared to tobacco and alcohol and the experience of the regulation of medicinal cannabis in the USA involves little leakage of cannabis stocks into the illegal market. A more appropriate schedule, given these factors, would be Schedule 4 alongside Sativex (nabiximols). The requirements for the security of medical stocks would then be less strict, more proportionate to any risk and less expensive.

9. Models of regulation for medicinal purposes

The models of regulation for medicinal cannabis currently in operation fall into three broad groups:

1. the licensing of cannabis-based drugs which have been shown in clinical trials to pass the appropriate tests for a medicine to be approved by national health authorities for treatments;
2. models which allow herbal cannabis to be prescribed for a limited number of conditions and where cannabis is supplied via regulated outlets, such as pharmacies, and cultivated by licenced growers. This is the model adopted or being proposed by many European countries, Australia, Canada and Israel.
3. models similar to model 2 but with the added provision that individuals and/or informal caregivers can grow a limited number of cannabis plants for medical use. This is the model in place in a number of the States within the USA and in Uruguay.

Model 1

Most countries in Europe, Australia, Canada, the USA and many others have approved the use of cannabis-based drugs including Dronabinol and Sativex (nabiximols). The process by which these drugs have been developed and approved has been the standard one for the development of medicines with an additional struggle to get government consent and licences to carry out the tests. The clinical trials properly involve stringent tests over a period of time and are very expensive. They require major investment, the cost of which is reflected in the price of the drugs. Importantly, these drugs have been developed while cannabis and cannabis derivatives remained within the UN Schedules 1 and IV.

The UN Schedule 1 is for *“substances that are highly addictive and liable to abuse ... and which have no medicinal value”* and Schedule IV is for *“certain drugs with particularly dangerous properties and little or no therapeutic value”*.

The national scheduling of cannabis in Europe and elsewhere generally follows the UN position. This has led to anomalies where the particular approved cannabis-based drugs have been rescheduled to recognise their status as medicines while cannabis and its derivatives remain in the *“no medicinal value”* category. As described above, it also means that further research into the medicinal properties of cannabis is restricted.

A change in the medicinal schedule of cannabis would free up a wide range of research and could lead to the development and approval of further medicines. As recommended earlier, the change of schedule should be from Schedule 1 to Schedule 4. Schedule 2 is for high harm drugs, such as opiates, which nonetheless have a medical application but where the security of medical stocks needs to be at the highest level. Schedule 4 acknowledges that drug harms are at a lower level and the same level of security is not necessary.

Rescheduling cannabis with no other reform would continue to leave the majority of patients needing medicinal cannabis with a number of problems:

1. The availability of medicinal cannabis will not improve in the short term and it is questionable whether any new cannabis-based drugs which might be developed and approved sometime in the future will be easily available. As in the case of Sativex (nabiximols) a NICE recommendation for availability on prescription is not guaranteed.
2. Many will not be able to afford a private prescription. The costs will be prohibitive.
3. Many will continue to have problems with the approved cannabis-based drugs. For some, the strength is too low. For others, the form of administration of the drug (such as the Sativex spray) is problematic.
4. For others, the proportion of THC and CBD will not be right for their condition.

In order to meet the needs of this large group of patients we need to consider other models.

Model 2

In Europe, the system of regulation where herbal cannabis can be made available on prescription to patients was initially adopted by the Netherlands. The key features are:

- the creation of a special cannabis agency (a requirement of the UN conventions);
- the cultivation of cannabis restricted to licenced growers; and
- a list of conditions for which herbal cannabis can be prescribed. The Netherlands has based this list on a literature review of the evidence and their system allows for the list of approved conditions to expand should the evidence justify it.

A number of other countries in Europe including Finland, Germany and Italy have set up systems where particular conditions can be treated with herbal cannabis. However, there is considerable room for improvement. Eligibility criteria can vary considerably. In Israel, the scheme has granted licences for cannabis treatment to over 13 000 patients. Finland's system is so restricted that there are less than a hundred registered patients. The registration procedure can be complex and difficult to navigate. In Europe, the supply from the Netherlands has not kept up with the demand. The range of herbal cannabis strains is too limited and there are concerns about quality. Another issue is cost. Although the cost of herbal cannabis from the Netherlands is significantly lower than Dronabinol and Sativex (nabiximols), it could be cheaper to grow it under licence in each country.

Some of the drawbacks to this model will be removed in Germany if its scheme for medicinal marijuana becomes law:

- Treatment will be based on a doctor's prescription. Registration will not be required.
- Over 60 conditions will be eligible for medicinal cannabis treatment.⁴⁵
- While in the first instance herbal cannabis will be imported, Germany intends to produce a range of pharmaceutical grade products.
- The cost will be at least partly covered by the German health insurance scheme.⁴⁶
- The cost of herbal cannabis is considerably less than that of Sativex. In the UK, the cost of Sativex, where available, is over £150 per week whereas the weekly cost of Bedrocan (supplied from the Netherlands and having a comparable balance of THC and CBD) is £20.⁴⁷

- A particular feature of the German proposal is a requirement for patients receiving medicinal cannabis paid for by the health insurance scheme to agree to take part in research trials. It is not proposed that this practice be replicated in the UK.

One of the drivers of this model is that the State concerned is trying to reduce patient reliance not only on street cannabis but also “grow your own”. This is based on a perspective that the state should not be sanctioning or condoning use of a treatment product where quality, impurities and dosage cannot be controlled. The other concern is that there may be an overlap between “grow your own” and the illicit drugs trade. All current examples of the regulation of forms of medicinal cannabis apart from Uruguay, some American States and perhaps Spain, retain laws where trade in cannabis for recreational use is illegal. Concern about quality where the cultivation of cannabis for personal use is permitted was expressed by one of the expert witnesses giving evidence to the hearing.

“My personal view is that growth should be controlled, as opposed to some of the States in the United States where you can grow your own in your backyard. That is not satisfactory, because it allows so many different varieties, types and impurities to be incorporated. I would like to see growth controlled, such as the Bedrocan initiative and Sativex. It allows for quality control.” Professor Mike Barnes

In order to ensure much wider availability of pharmaceutical grade herbal cannabis, it is recommended that a scheme incorporating the main features of the proposed German legislation are introduced into the UK.

Model 3: availability of herbal cannabis for medicinal purposes including provision for individuals to grow their own supplies

Schemes allowing individuals to grow their own medicinal supplies are present in Uruguay and some American States; here, the option for “grow your own” can operate alongside models 1 and 2 and in some cases within the context of the regulation of cannabis for recreational use. In Spain, Cannabis Social Clubs are the only way in which medicinal cannabis users can access herbal cannabis. There is some evidence that those jurisdictions intending to introduce a scheme for regulating herbal cannabis by means of a licenced supplier are doing so, in part, because of concerns that there is more of a risk that a “grow your own” scheme will leak into the illicit recreational market. Germany and the regional government in Catalonia, Spain who have been considering a scheme for licenced commercial growers on behalf of the State are two examples of this approach.

A key issue that patients may consider is cost. Even at £20 a week the cost of herbal cannabis for the treatment of a chronic condition where the patient is not able to work is a significant financial burden. In Uruguay, medicinal cannabis sold via pharmacies is likely to be more expensive than recreational cannabis as it is grown under stricter conditions and will have a greater variety of strains. This may well encourage the numbers registering to grow their own. An important feature of any state scheme for regulated access to herbal cannabis will be to subsidise it through a state health insurance scheme.

Testimony from the users of medicinal cannabis at the hearings, case studies and the survey of users of medicinal cannabis suggests that some at least try different strains of cannabis until they find the ones that work best for them. Decriminalisation of home growing of medicinal cannabis would allow more flexibility in determining the type of cannabis used.

A system of state-controlled, licenced production can guarantee quality, ensure the product is free from pesticides and other impurities and ensure specified levels of the main cannabinoids in the particular strains selected. However, lower cost, avoiding the illicit market and flexibility for users in experimenting with the strain and dosage that works best for them are more easily achieved in a system of decriminalised “grow your own”. A state-sponsored resource could be made available to growers advising on growing methods and quality control.

10. Conclusions and recommendations

Conclusions

This Inquiry has produced strong evidence from Mike Barnes, Professor of Neurological Rehabilitation; senior health professionals; patients taking cannabis to control chronic pain and other debilitating symptoms; the MHRA and others to prove that policy reform in this field is long overdue.

The Inquiry Panel concludes that:

1. Patients suffering chronic severe conditions should not risk arrest if they obtain cannabis as a treatment, when other treatments have failed or generate unacceptable side effects.
2. The inclusion of cannabis in Schedule 1 (the schedule for substances with no medicinal value) is no longer sustainable. There is now a sound evidence base showing cannabis to be effective for a range of chronic conditions.
3. Some estimated 30,000 patients in the UK use cannabis or cannabis-based products as medicines on a daily basis. This could entail as much as 1,000,000 in total.
4. Cannabis-based medicines have an established place in the management of chronic pain in the UK.
5. Many countries now have or are introducing a form of cannabis regulation to ensure access to herbal cannabis to help those with serious chronic conditions, where prescription medicines have been ineffective.

Recommendations

1. Cannabis should be included in Schedule 4 rather than Schedule 1, thus promoting research.
2. A scheme incorporating the main features of the proposed German legislation should be introduced into the UK to ensure much wider availability of medicinal cannabis. Herbal cannabis would thus be available on prescription for the treatment of specified conditions, paid for by the NHS for those conditions. Medicinal cannabis would be produced by licenced producers and sold through licenced outlets, such as pharmacies.
3. The Government should decriminalise home growing of small quantities of cannabis for medicinal purposes as is the case in Uruguay and some American States.

Appendix 1: Those giving evidence and the APPG panel

Written evidence

Written evidence was received from the following organisations and individuals:

The National Police Chiefs' Council

The Medicines and Health Care Products Regulatory Agency (MHRA)

GW Pharmaceuticals (developers and suppliers of Sativex)

The Drug Policy Alliance (DPA), a US-based organisation

The United Patients Alliance (UPA)

The UK Law Enforcement Against Prohibition (LEAP) organisation

Cannabis Law Reform UK (CLEAR)

Professor Val Curran

Professor Les Iverson, Chair of the Advisory Council for the Misuse of Drugs (in a personal capacity)

Patients: LS, CS and NE

Oral evidence

Four hearings were arranged on the 10 and 24 February and the 2 and 9 March 2016 in Committee Rooms at the House of Lords. At each hearing, those giving oral evidence were:

10 February 2016

Professor Val Curran, Professor of Psychopharmacology, University College London

Professor Les Iverson, Chair of the Advisory Council for the Misuse of Drugs (in a personal capacity)

Jonathan Liebling, Political Officer of the UPA

LS – a user of medicinal cannabis for treatment

CS – a user of medicinal cannabis for treatment

24 February 2016

Professor Mike Barnes, Honorary Professor of Neurological Rehabilitation, Newcastle University

Dr David Potter JP, Director of Botanical Research and Cultivation, GW Pharmaceuticals

Dr Stephen Wright, the Chief Medical Officer of GW Pharmaceuticals

Nick Ellis, Chief Executive UKCBD Ltd

Lisa-Marie, Francom UKCBD Ltd

Jason Reed, Chief Executive LEAP

Neil Woods LEAP

2 March 2016

Tom Lloyd (former Chief Constable of Cambridgeshire), Chair of the National Cannabis Coalition

Roland Gyallay-Pap, Chief Executive CLEAR

Peter Reynolds, President, CLEAR

9 March 2016

Gerald Heddell, MHRA

Bernadette Sinclair-Jenkins, MHRA

APPG members present at hearings

APPG members present at hearings included:

Caroline Lucas MP (Co-chair)

Baroness Meacher (Co-chair)

Baroness Walmsley

Baroness Hamwee

Lord Rea

Lord Walton

Jeff Smith MP

Lord Dear

Lord Howarth

Lord Ramsbotham

Lord Norton

Lord MacLennan

Mary Glendon MP

Paul Monaghan MP

Baroness Afshar

Appendix 2: Survey of those who use medicinal cannabis

All-Party Parliamentary Group for Drug Policy Reform

Inquiry into medicinal cannabis

This questionnaire is intended to look at the extent and range of use of cannabis for medicinal purposes in the UK. This questionnaire was administered by the United Patients Alliance. Responses were taken in the strictest confidence.

Questionnaire for those using cannabis medicinally

1. What is your age?
2. What is your gender? Male/Female
3. What is your ethnicity? White/Asian/African/Afro-Caribbean
4. What is your medical condition?
5. How long have you had this condition?
6. What medicines have you been prescribed for this condition by your doctor or a consultant?
7. How effective has this medication been? (Please give details)
8. What are the side effects of this medication? (Please give details)
9. How long after you had been prescribed other medicines did you decide that cannabis was a viable medicine for your condition?
10. How did you come to this decision?
11. What was the view of your GP or Consultant about this?
12. How long have you been taking cannabis?
13. In what form do you take cannabis?
14. Can you describe the effect that taking cannabis has had on your condition?
15. What have been the side effects of taking cannabis?
16. How do you obtain your cannabis? (Please do not feel obliged to answer this question)
17. How difficult is this?
18. How risky is it in terms of compliance with the law?
19. If there are risks involved in obtaining your cannabis what do you feel about this?
20. What do you think should happen in terms of the law to make it easier/less risky to obtain cannabis for your condition?

21. Have you had any advice about using cannabis for your condition from a person or organisation other than your GP or doctor?
22. What was that advice?
23. How helpful has it been?
24. Do you have any other comments that you would like to make?

Appendix 3: Brief Survey for health professionals on the medicinal use of cannabis

1. Can you briefly describe in general terms your role?
2. Have you experience of patients who are using cannabis for their condition either prescribed in the form of Sativex or Dronabinol or imported as Bedrocan from the Netherlands or obtained by other means? Yes/No
3. If yes can you estimate the number of such patients in a year?
4. What conditions is cannabis being used for? Please list
5. What in your judgement has been the impact of cannabis use on the condition/s described above?

Would you be willing to be contacted further on this issue? (If so please enter email and/or phone number and name)

Appendix 4: Mark's medications prior to starting treatment with cannabis

- Phenytoin (to reduce fits): tripled dose when ineffective, then stopped due to side effects (judders);
- Carbamazepine (to reduce fits): tripled dose then changed medication. Ineffective and reduced memory;
- Gabapentin (for headache): stopped. It was ineffective and caused side effect of night terrors;
- Omeprazole (for vomiting);
- Lamotrigine (to reduce fits). Helped but did not stop them completely;
- Clopidogrel (to thin the blood) post-heart attack for one year;
- Bisoprolol (to improve heart function post first heart attack);
- Ramipril (to reduce blood pressure after first heart attack). Stopped after two weeks due to very low blood pressure. Caused postural hypotension;
- Aspirin (to thin the blood). Still on this following second heart attack;
- Simvastatin (to lower cholesterol). In fact cholesterol is normal;
- Amitriptyline (to control headaches and assist with sleep). Ineffective.

Endnotes

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