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Medical use of cannabis

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Summary

Under the *Misuse of Drugs Act 1971*, Cannabis is a controlled drug. The Act makes it illegal for people to possess, supply, produce, or import/export controlled drugs. However, changes to the *Misuse of Drugs Regulations 2001* in November 2018 has meant that cannabis-based medicinal products can be prescribed under certain circumstances.

Review of the scheduling of cannabis medicinal products

There was increased debate on the medical use of cannabis in 2018. Much of this focused on the cases of children with rare and severe forms of epilepsy, whose families reported that they had benefited from the use of cannabis products.

In a statement on 19 June 2018, the Home Secretary said that the position in the UK on this issue was not satisfactory. He announced that the Government would review the scheduling of cannabis. There were two parts to the review:

- Part one was undertaken by the then Chief Medical Officer, Professor Dame Sally Davies, and looked at the evidence for the use of cannabis-based medicinal products. She reported that there was conclusive evidence of the therapeutic benefit of cannabis medicinal products for certain medical conditions and recommended that the whole class of cannabis-based medicinal products be moved out of Schedule 1; and
- Part two was undertaken by the Advisory Council on the Misuse of Drugs (ACMD) and provided advice on whether certain products should be rescheduled. Based on its short-term review, the ACMD advised that cannabis derived medicinal products of the appropriate medical standard should not be subject to Schedule 1 requirements. Once a definition of a Cannabis-derived medicinal product has been developed, the ACMD advised that products meeting that definition should be moved into Schedule 2 of the Misuse of Drugs regulations.

A change in the law

On 26 July 2018, the then Home Secretary announced that, following this advice from the ACMD and the Chief Medical Officer, he had decided to reschedule cannabis derived medicinal products.

In November 2018, the law changed to allow the prescribing of cannabis-based medicines in certain circumstances. The Regulations included a definition of cannabis-based medicines and set out that only doctors on the GMC specialist register could prescribe these. These doctors would predominately be prescribing unlicensed products since only two cannabis-based medicines have a marketing authorisation (often known as a 'licence') in the UK.

Prescriptions for cannabis-based medicines and concerns raised

It has been reported that there have been few prescriptions for cannabis-based medicines since the change in the law but only limited data on this is available. Patient groups and families have expressed concerns about prescribing and have called for more action in this area. Professional bodies and senior clinicians, however, have said there is a need for further evidence and have called for randomised controlled trials to look at the benefits and harms of these products.

A review into *Barriers to accessing cannabis-based products for medicinal use on NHS prescription*, was published by NHS England and NHS Improvement in August 2019. It found that clinicians were reluctant to prescribe medicinal based cannabis products to children with severe epilepsy, particularly in the absence of sufficient evidence to help

them balance potential benefits against potential harms. The Review recommended further research, including at least one randomised control trial (RCT), to address the lack of evidence into the safety and effectiveness of cannabis-based medicinal products.

In November 2019, the National Institute for Health and Social Care Excellence (NICE) published guidance on prescribing cannabis-based medicinal products for people with intractable nausea and vomiting, chronic pain, spasticity and severe treatment-resistant epilepsy.

1. What is the law on cannabis?

Cannabis is a controlled drug under misuse of drugs legislation. However, changes to the *Misuse of Drugs Regulations 2001* in November 2018 has meant that cannabis-based medicinal products can be prescribed under certain circumstances.

1.1 Controlling drugs in the UK

The *Misuse of Drugs Act 1971* is the main piece of legislation used to control illicit drugs in the UK. The Act makes it illegal for people to possess, supply, produce, or import/export controlled drugs.

The Misuse of Drugs Act 1971 separates illegal drugs into three classes: A, B and C. This aims to classify drugs according to their relative harmfulness when used and the classes carry different levels of penalty for possession and dealing. Cannabis is listed as a class B substance under the Act (it has been controlled under class C in the past –see Box 1 for further information).

Possession of cannabis carries a penalty of up to five years in prison, an unlimited fine or both. Supplying cannabis can result in up to 14 years in prison, an unlimited fine or both.[1]

Box 1: Changes to the classification of Cannabis

In October 2001, the then Home Secretary, David Blunkett, announced proposals to reclassify cannabis as a class C drug placing it in the same category as anabolic steroids and benzodiazepine tranquillisers.[2] Following a report of the Advisory Council on the Misuse of Drugs (ACMD) in 2002, the law was changed in 2003.

In 2007, the then Prime Minister, Gordon Brown, announced a review of the Government's drugs strategy, including whether or not to re-classify cannabis as a class B drug.[3] Following a request from the then Home Secretary, Jacqui Smith, the ACMD reviewed the evidence on cannabis and published a report in May 2008.[4] It recommended that cannabis remain a class C drug.

On 7 May 2008, Jacqui Smith made a statement on the classification of cannabis. While noting that *"cannabis use is falling significantly across all age ranges",* she was *"concerned to ensure that the classification of cannabis reflects the alarming fact that a much stronger drug – known as "skunk" – now dominates the cannabis market."*[5]

Ms Smith went on to state that she accepted all of the recommendations made in the ACMD report apart from the recommendation relating to classification (that cannabis remain a class C drug): she would reclassify cannabis as a class B drug, subject to Parliamentary approval. This decision took "*into account issues such as public perception and the needs and consequences for policing priorities"*.[6]

1.2 Allowing the legitimate use of controlled drugs

The *Misuse of Drugs Regulations 2001* allow for the legitimate use of certain controlled drugs. It defines the classes of persons who are

1 Sentencing Council, Drug Offences Definitive guideline, 2012
2 "Blunkett to focus on the menace of hard drugs", Home Office press release 255/2001, 23 October 2001
3 HC Deb 18 July 2007 c268
4 ACMD, Cannabis: Classification and Public Health, 7 May 2008
5 HC Deb 7 May 2008 c705
6 HC Deb 7 May 2008 c705

authorised to supply and possess controlled drugs while acting in their professional capacities and lays down the conditions under which these activities may be carried out.

In the Regulations, drugs are divided into five schedules each governing such activities as import, export, production, supply, possession, prescribing, and record keeping which apply to them. Details of the schedules are as follows:

> Schedule 1 to the 2001 regulations covers drugs that have no therapeutic value and are usually used mainly in research under a Home Office licence. Examples include cannabis, MDMA ('ecstasy') and lysergamide.
>
> Schedule 2 to the 2001 regulations covers drugs that have therapeutic value, but are highly addictive. These are strictly controlled and subject to special requirements relating to their prescription, dispensing, recording and safe custody. Examples include potent opiods, such as diamorphine and morphine.
>
> Schedule 3 covers drugs that have therapeutic value, but have slightly lighter control, special requirements relating to their prescription, dispensing, recording and safe custody (where applicable). Examples include temazepam, midazolam and buprenorphine, and methylphenobarbitone.
>
> Schedule 4 is divided in two parts. Part 1- benzodiazepines (examples include bromazepam, diazepam ('Valium') and triazolam) and Part 2 anabolic and androgenic steroids (examples include prasterone, testosterone, nandrolone and bolandiol), which is subject to lighter regulation with no possession offence.
>
> Schedule 5 covers weaker preparations of Schedule 2 drugs that present little risk of misuse and can be sold over the counter as a pharmacy medicine (without prescription). Examples include codeine, medicinal opium or morphine (in less than 0.2% concentration.[7]

Cannabis is listed in Schedule 1 of the Misuse of Drugs Regulations 2001 which generally applies to drugs that have been deemed to have no therapeutic value and are used mainly in research under a Home Office licence.

Regulation-making powers under the *Misuse of Drugs Act 1971* allow the Secretary of State to change the classification of a drug under the Act or the scheduling within the *Misuse of Drugs Regulations 2001* through regulations, introduced by Statutory Instrument. There is a duty under the *Misuse of Drugs Act 1971* on the Secretary of State to consult the Advisory Council on the Misuse of Drugs (ACMD) before making regulations. The ACMD is the statutory body which keeps under review drugs which are, or are likely to be, misused. It can appoint expert committees to consider specific issues and advises the Government on measures necessary for the prevention of drug misuse.

How is cannabis treated under these regulations?

Cannabis is generally listed in Schedule 1 of the *Misuse of Drugs Regulations 2001* which generally applies to drugs that have been deemed to have no therapeutic value.

However, in November 2018, The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018 rescheduled cannabis-based medicinal products to Schedule 2 of

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7 Home Office, Policy paper: 2010 to 2015 government policy: drug misuse and dependency, May 2015

the Misuse of Drugs Regulations 2001 which will allow prescription of these products in certain circumstances.[8] Separate regulations introduced this change in Northern Ireland.[9] More information about the change in the law and when these products can be prescribed is provided in section 2.

All other cannabis products remain under Schedule 1 of the *Misuse of Drugs Regulations 2001*.

1.3 Cannabinoids and cannabinoid containing products

There are more than a hundred different chemical compounds (cannabinoids) identified in the cannabis plant. As well as cannabis being controlled under the Misuse of Drugs Act, most cannabinoids are also controlled under the same regulations. These include tetrahydrocannabinol (THC) (the cannabinoid that gives cannabis its psychoactive effect) and cannabinol (CBN). So, if a product contains these controlled cannabinoids, it will be a controlled product. More information on this is provided in a Home Office factsheet, Cannabis, CBD and other cannabinoids.[10]

Some cannabinoids, however, are not controlled separately under the Act. Cannabidiol (CBD), for example, is a non-psychoactive cannabinoid that is not controlled under the *Misuse of Drugs Act 1971* and has been the subject of interest and research for potential medical uses.

Cannabidiol (CBD)

Pure CBD is not a controlled substance. The Home Office, however, reports that it is very difficult to isolate pure CBD and states that if a CBD product contains any THC or any other controlled cannabinoid it would be "highly likely" to be a controlled substance.[11]

In October 2016, the Medicines and Healthcare products Regulatory Agency (MHRA) advised retailers and manufacturers of CBD products that those products being sold for medical purposes should be regulated as medicines. Therefore, the products should have a marketing authorisation before being sold, supplied or advertised in the UK. It should be noted that this announcement made no assessment of the safety, quality or efficacy of CBD products. This would be assessed during the licencing process for these products.[12]

Novel foods

Some CBD products continue to be sold as food supplements or other types of products. In 2019, the European Commission listed CBD as a

8 *The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018*
9 *The Misuse of Drugs (Amendment No.2) Regulations (Northern Ireland) 2018*
10 Home Office, Drug Licensing Factsheet- Cannabis, CBD and other cannabinoids, January 2018
11 Home Office, Drug Licensing Factsheet- Cannabis, CBD and other cannabinoids, January 2018
12 MHRA, News story: MHRA statement on products containing Cannabidiol (CBD), October 2016 (updated December 2016)

'novel food' in the EU novel foods catalogue.[13] Novel foods are foods that do not have a history of consumption in the EU before May 1997. Before a novel food can be legally sold in the EU, it is required to have a pre-market safety assessment and authorisation under the Novel Foods Regulation (EU) No 2015/2283. More information on the regulation of novel foods is provided on the Food Standards Agency website. Concerns have been raised that this may mean that CBD will no longer be available as a food supplement in the UK.[14]

The Food Standards Agency (FSA) has said it will it will take action with local authorities, businesses and consumers in this area to clarify how to achieve compliance in the marketplace.[15] On the 13 February 2020 the FSA set the CBD industry a deadline of 31 March 2021 to submit valid novel food authorisation applications, stating that, otherwise, "the products will be taken off the shelves".[16]

Synthetic cannabinoids

There are three main groups of chemical compounds that fall within the broad category of 'synthetic cannabinoids'. NHS England describes the groups as follows:

- Group 1: Synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC) e.g. [as found in the drug] Dronabinol.
- Group 2: Synthetic compounds structurally related to naturally occurring cannabinoids that have been developed to mimic naturally occurring cannabinoids such as THC e.g [as found in the drug] Nabilone.
- Group 3: Synthetic compounds not structurally related to naturally occurring cannabinoids but which bind to cannabinoid receptors in the body.[17]

While compounds in group 1 (and some in group 2) have been developed as medicinal products, those in group 3 are generally illicit psychoactive substances. The Centers for Disease Control and Prevention (CDC) in the United States explains that the "chemicals are called cannabinoids because they act on the same brain cell receptors as tetrahydrocannabinol (THC), the main active ingredient in marijuana" but that these types of synthetic cannabinoids and THC are different chemicals.[18] In the UK, the *Psychoactive Substances Act 2016* makes it illegal to produce or supply synthetic cannabinoids and to possess them in a custodial setting.

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13 EU Novel Foods catalogue
14 MS-UK, New 'novel food' regulations could impact the availability of CBD products
15 FSA, Novel Foods, 20 May 2018
16 Food Standards Agency sets deadline for the CBD industry and provides safety advice to consumers, *Food Standards Agency news*, 13 February 2020
17 NHS England, Cannabis-based products for medicinal use: Frequently Asked Questions, 12 March 2020
18 Centers for Disease Control and Prevention, About synthetic cannabinoids, 21 August 2017

1.4 Marketing authorisations

Before a medicine can be sold or prescribed in the UK it must usually receive a marketing authorisation (medicines licence) either from the European Medicines Agency (EMA) or from the Medicines and Healthcare products Regulatory Agency (MHRA). Sativex and Epidyolex are the only cannabis-based medicines that have a marketing authorisation in the UK.

Sativex and Epidyolex are the only cannabis-based medicines that have a marketing authorisation in the UK

A marketing authorisation will only be issued if clinical trials have proved that the medicine:

- successfully treats the condition it was developed for;
- has acceptable side effects; and
- meets safety and quality standards.

Sativex

Sativex is an oral spray containing cannabis extracts which is licenced for use by the Medicines and Healthcare products Regulatory Agency (MHRA) to treat spasticity in adults with Multiple Sclerosis. This product was rescheduled in 2013 to Schedule 4 of the Misuse of Drugs Regulations 2001.[19] This means it can be prescribed by healthcare professionals. In November 2019, the National Institute for Health and Care Excellence (NICE) agreed that "THC:CBD spray [Sativex] could be recommended to treat moderate to severe spasticity in adults with multiple sclerosis if other pharmacological treatments had not been effective" (see section 3.1). Earlier NICE guidance did not recommend Sativex to this group on the grounds that it was not considered a cost effective treatment.[20] The change to the NICE guidance brought England in line with Wales, where Sativex has been recommended by the All Wales Medicines Strategies Group for MS patients with moderate to severe spasticity since August 2014.[21]

The MHRA has licensed one other cannabis product as a medicine: Epidyolex, discussed below. Nabilone, a synthetic cannabinoid medicine, is also licenced in the UK for use in treatment resistant nausea and vomiting caused by chemotherapy.[22]

Epidyolex

Epidyolex is a CBD containing medicine that has been developed for use as an adjunctive treatment for seizures associated with the severe and rare forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome. The European Medicines Agency (EMA) issued a marketing authorisation for the use of Epidyolex to treat patients who have Lennox-Gastaut syndrome or Dravet syndrome aged two years and over

19 The Misuse of Drugs (Amendment No. 2) (England, Wales and Scotland) Regulations 2013
20 NICE, Multiple sclerosis in adults: management, October 2014
21 All Wales Medicines Strategy Group, delta-9-tetrahydrocannabinol/cannabidiol (Sativex®), Appraisal Information, 14 August 2014. The All Wales Medicines Strategy Group (AWMSG) provides advice to the Welsh Government on the clinical and cost-effectiveness of licensed medicines.
22 British National Formulary, Nabilone

on 19 September 2019.[23] NICE technology appraisals for the use of cannabidiol (Epidyolex) for Lennox-Gastaut syndrome and Dravet syndrome were subsequently published in December 2019 (see section 3.1).[24]

On 29 January 2020, the Chair of the Advisory Council on the Misuse of Drugs wrote to the Minister of State for Crime, Policing and the Fire Service, regarding the scheduling for Epidyolex. It recommended that "it would be most appropriate for Epidyolex to be placed in Schedule 5 under the Misuse of Drugs Regulations 2001" on the grounds that it "has a low risk of abuse potential, low risk of dependency and low risk of diversion".[25] The Minister replied on 4 May 2020 that he accepted the ACMD's recommendation.[26]

Prescribing unlicenced medicines

In certain circumstances, healthcare professionals can supply products without a medicines licence to meet the special clinical needs of a patient. The General Medical Council notes that the term 'unlicensed medicine' is used "to describe medicines that are used outside the terms of their UK licence or which have no licence for use in the UK".[27] Responsibility for deciding whether an individual patient has "special clinical needs" which a licensed product cannot meet is a matter for the prescriber responsible for the patient's care. See MHRA Guidance Note 14 for further information regarding the supply of unlicensed medicinal products.[28]

Since only two cannabis-based medicines have a marketing authorisation (licence) in the UK, the change in the law on cannabis-based medicinal products means that specialist doctors would predominately be prescribing unlicensed products.

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23 European Medicines Agency, "Epidyolex" (authorisation details), 4 October 2019 (accessed on 5 February 2020)

24 NICE, Cannabidiol with clobazam for treating seizures associated with Dravet syndrome, Technology appraisal guidance [TA614], 18 December 2019; NICE, Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome, Technology appraisal guidance [TA615], 18 December 2019

25 Letter from ACMD Chair, Prof Owen Bowden-Jones to Kit Malthouse MP, Minister of State for Crime, Policing and the Fire Service, RE: Epidyolex, 29 January 2020

26 Letter from Kit Malthouse MP, Minister of State for Crime, Policing and the Fire Service, ACMD advice: Epidyolex scheduling and definition under the Misuse of Drugs Regulations 2001, 4 May 2020

27 General Medical Council, Prescribing unlicensed medicines, 2019

28 MHRA, Guidance: Supply unlicensed medicinal products (specials), 2014

2. A change in the law for medicinal cannabis

2.1 A review on the medical use of cannabis

There was increased debate on the medical use of cannabis in 2018. Much of this focused on the cases of children with rare and severe forms of epilepsy, whose families reported that they had benefited from the use of cannabis products.

On 26 July 2018, the then Home Secretary announced that, following a two part review on cannabis-based medicinal products and their scheduling under the current law, he had decided to move these products to Schedule 2 of the Misuse of Drugs Regulations 2001, which would allow prescribing.[29]

This section provides background to the review on the medical use of cannabis and an overview of the findings.

Background

Prior to recent developments, there had been some support for a change in the law on medicinal cannabis, including from several political parties, as well as patient groups.[30] [31] [32] [33] Some countries already allowed the use of cannabis for medical purposes, including The Netherlands,[34] Germany,[35] and several US states.[36] In 2018, there was an increase in the debate on this issue. Much of this focused on the cases of two young boys – Alfie Dingley and Billy Caldwell.[37] Both of these boys have rare and severe forms of epilepsy and their families had reported that they have experienced improved control of their seizures with the use of medicinal cannabis outside of the UK. There had also been a number of other publicised cases of calls for access to cannabis for medical purposes.[38]

Billy Caldwell, who lives in Northern Ireland, had been receiving cannabis oil to manage his seizures through prescriptions from his GP until the Home Office advised that these prescriptions should cease.[39] On 11 June 2018, his mother Charlotte Caldwell, travelled to Canada to

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29 News story: Cannabis-derived medicinal products to be made available on prescription, Home Office, 26 July 2018
30 HC Deb 18 June 2018 c30
31 Plaid Cymru, 'Support Decriminalisation of Cannabis for Medicinal Use' – Plaid Cymru Leader Tells Welsh Government, February 2017
32 Policy Green Party, Drug Use [accessed 21 June 2018]
33 Liberal Democrats, Our plan: Rights [accessed 21 June 2018]
34 Office of Medicinal Cannabis [accessed 28 June 2018]
35 DW, German parliament legalizes cannabis for medical consumption, January 2017
36 Findlaw, Medical Marijuana - An Overview [accessed 28 June 2018]
37 For example, Home Office denies medical cannabis pleas for boy age six, BBC News Online, 18 February 2018; Billy Caldwell suffers seizure after cannabis oil confiscated, BBC News Online, 12 June 2018
38 For example, Mother in uphill struggle to secure son's cannabis remedy, The Times, 26 June 2018 and , Mother in call for legalised medical cannabis, BBC News Online, 23 March 2018
39 Mother who had son's medical cannabis confiscated warns he 'will surely pass away' if law does not change, The Independent, 11 June 2018

bring cannabis oil back to the UK but this was seized by customs officials at Heathrow Airport.

Following Billy's admission to hospital in London on 15 June 2018, the Home Secretary issued an emergency licence to allow the medical team to access medicinal cannabis to treat him.[40]

Announcement of the review

On 19 June 2018, the then Home Secretary, Sajid Javid, announced a review that would look at the scheduling of cannabis and the evidence for its use for medical purposes. He said that cases such as Alfie Dingley and Billy Caldwell had shown that there was a need to look closely at this issue and that it had become clear that:

> the position we find ourselves in is not satisfactory. It is not satisfactory for the parents, it is not satisfactory for the doctors, and it is not satisfactory for me.[41]

The Home Secretary stressed that this was not about legalising cannabis for recreational use and the penalties for offences under the law in this area would remain.[42]

He said the review would inform the Government as to whether cannabis-based medicines should be re-scheduled under the Misuse of Drugs Regulations to allow prescribing. As discussed in Section 1.2 of this paper, drugs listed in Schedule 1 of the Regulations cannot be prescribed but those in all other schedules can be prescribed under certain conditions. The Home Secretary said that the review would be in two parts:

- Part one would be under the remit of the then Chief Medical Officer, Professor Dame Sally Davies, and would involve a consideration of the evidence on the medicinal benefits of cannabis products. This would inform which forms of cannabis or cannabis-based medicines would be considered in part two of the review.
- Part two would be undertaken by the Advisory Council on the Misuse of Drugs (ACMD) and would involve an assessment of the balance of harms and public health need and provide advice on what, if any, cannabis products should be rescheduled.

He also confirmed the establishment of an interim expert panel to advise Ministers on applications for licences to prescribe medicinal cannabis. He said that this would ensure that this advice would be "clinically led, based firmly on medical evidence and as swift as possible".

He also reported that Alfie Dingley would receive a licence for cannabis for medical use that day.

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40 HC Deb 19 June 2018 c192
41 HC Deb 19 June 2018 c192
42 HC Deb 19 June 2018 c192

Part one of the review

On 3 July 2018, the then Chief Medical Officer, Professor Dame Sally Davies published the report of the first part of the review on medicinal cannabis.[43]

The remit of the report was limited to the assessment of the evidence on cannabis medicinal products; it did not look at recreational uses of cannabis and the harms associated with this. The report was also clear that it focused only on products developed for medical use, not other grown or street cannabis.

Dame Sally reported that there was conclusive evidence of the therapeutic benefit of cannabis medicinal products and recommended that the whole class of cannabis-based medicinal products be moved out of Schedule 1 (bold retained from original):

> There is now however, conclusive evidence of the therapeutic benefit of cannabis based medicinal products for certain medical conditions and reasonable evidence of therapeutic benefit in several other medical conditions. This evidence has been reviewed in whole or part, and considered robust, by some of the leading international scientific and regulatory bodies, as well as the World Health Organization (WHO). As Schedule 1 drugs by definition have little or no therapeutic potential, it is therefore now clear that from a scientific point of view keeping cannabis based medicinal products in Schedule 1 is very difficult to defend. Moreover, I believe that it would not make sense to move cannabis and its derivatives out of Schedule 1 whilst leaving synthetic cannabinoids, which the evidence suggests have potentially greater therapeutic benefit and less potential for harm, in Schedule 1**. I therefore recommend that the whole class of cannabis based medicinal products be moved out of Schedule 1**.[44]

Part two of the Review

On 3 July 2018, the Home Secretary commissioned the Advisory Council on the Misuse of Drugs (ACMD) to undertake the second part of the review on medicinal cannabis.[45]

He asked the ACMD to undertake a short-term review within three weeks to provide advice on whether a number of cannabis and cannabinoid substances should be moved to a different schedule under the *Misuse of Drugs Regulations 2001* (which would allow prescribing of these products).[46]

The Home Secretary also asked the ACMD to undertake a fuller 12-month review to look at these substances and assess whether changes to the listing of the substances under the regulations should take place. He asked the ACMD to look at whether there were further provisions

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43 Professor Dame Sally Davies, Cannabis Scheduling Review Part 1: The therapeutic and medicinal benefits of Cannabis based products – a review of recent evidence, June 2018

44 Professor Dame Sally Davies, Cannabis Scheduling Review Part 1: The therapeutic and medicinal benefits of Cannabis based products – a review of recent evidence, June 2018, para 1.4

45 Home Office, Medicinal cannabis review part 2 commissioned, 3 July 2018

46 Home Office, Part Two - Commission to the ACMD – Scheduling under the Misuse Of Drugs Regulations 2001, 3 July 2018

that could be made to reduce the risk of potential harms of any rescheduling.[47]

On 19 July 2018, the Chair of the ACMD, Dr Owen Bowden-Jones, wrote to the Home Secretary with the findings of the short-term review on the rescheduling of cannabis-based medical products.[48] The report made a number of conclusions, including that:

- Cannabis derived medicinal products of the appropriate medicinal standard should not be listed in Schedule 1 of the 2001 Regulations and clinicians should have the option to prescribe these for certain medical conditions;
- There remains uncertainty around the definition of a cannabis derived medicinal product and work should be undertaken to develop a clear definition for this. Once the definition has been developed, only those products that meet this should be moved to Schedule 2 of the Regulations;
- There are potential risks relating to the inappropriate prescribing of cannabis derived medicinal products that should be considered and addressed. In addition to the provisions of Schedule 2 of the Regulations, the Department of Health and Social Care (DHSC), the Medicines and Healthcare products Regulatory Agency (MHRA) and the Home Office should "develop additional frameworks and clinical guidance for 'checks and balances' to maintain safe prescribing of Cannabis-derived medicinal products;"
- Clinical trials are urgently required to establish the effectiveness and safety of cannabis derived medicinal products; and
- In light of the harms associated with use of synthetic cannabinoids (such as Spice), these should remain under Schedule 1 of the regulations but further research should look at the potential therapeutic uses of certain synthetic cannabinoids.[49]

Home Office response

On 26 July 2018, the then Home Secretary announced that he had decided to reschedule cannabis-based medicinal products following advice from the Chief Medical Officer and the ACMD. The Home Office stated that this meant "that senior clinicians will be able to prescribe the medicines to patients with an exceptional clinical need."[50]

In a letter to the Chair of the ACMD, Mr Javid said that he accepted in principle the recommendations to establish a definition for cannabis derived medicinal products, and to only add products within this definition to Schedule 2 of the Regulations.[51] The DHSC, MHRA and the

47 Home Office, Part Two - Commission to the Acmd – Scheduling under the Misuse Of Drugs Regulations 2001, 3 July 2018
48 ACMD, Advice on scheduling of cannabis-derived medicinal products, 19 July 2018
49 ACMD, Advice on scheduling of cannabis-derived medicinal products, 19 July 2018
50 Home Office, Cannabis-derived medicinal products to be made available on prescription, 26 July 2018
51 Home Office, Government response to the ACMD: Cannabis-derived medicinal products, 26 July 2018

Home Office would work to develop a definition for these products. The intention was to make amendments to the Regulations by autumn 2018.

He also agreed with the ACMD's recommendation in relation to additional 'checks and balances' and said that the Home Office was working with the DHSC to "discuss any legal amendments and clinical advice which should be developed to maintain appropriate prescribing whilst minimising the risk of diversion".[52]

The announcement that the Government intend to reschedule cannabis-based medicinal products was welcomed by health charities and campaigners.[53]

Longer term review of cannabis-based products for medicinal use in humans

In February 2019, the then Home Secretary wrote to the ACMD asking it to commence the longer term review of cannabis-based products for medicinal use. The Home Secretary commissioned the ACMD to undertake work in three areas. These broadly covered:

- monitoring/assessment of the impact of the change in legislation on cannabis-based products for medicinal use;
- an updated harms assessment to the ACMD's previous reports on synthetic cannabinoids;
- whether the scheduling of products which currently fall under the definition of cannabis-based products for medicinal use is appropriate.[54]

A full report by the ACMD is expected to be published by November 2020. In the interim, the Chair of the ACMD wrote to the Home Secretary in December 2019, in response to the first component of the commission. The letter includes the ACMD's "outline assessment for cannabis-based products for medicinal use (CBPM) framework". The purpose of the framework is to set out:

- how the ACMD will assess the various impacts of rescheduling CBPMs to Schedule 2 under the Misuse of Drugs Regulations 2001 (MDR) and;
- the data sources that might be used in an assessment.[55]

2.2 The rescheduling of cannabis-based medicinal products

On 1 November 2018, The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018 came

52 Home Office, Government response to the ACMD: Cannabis-derived medicinal products, 26 July 2018
53 The Reader: We must get it right deciding the law on medicinal cannabis, Evening Standard, 26 July 2018
54 Home Office, Policy paper: Cannabis-based products for medicinal use in humans: commission to the ACMD, 15 February 2019
55 Advisory Council on the Misuse of Drugs, ACMD framework for the assessment of the various impacts of rescheduling Cannabis-based Products for Medicinal use in humans (CBPMs) to Schedule 2 under the Misuse of Drugs Regulations 2001, 23 December 2019

into force to reschedule cannabis-based medicinal products to schedule 2 of the Misuse of Drugs Regulations 2001 and allow prescribing of these products. Separate regulations introduced this change in Northern Ireland.[56]

Definition of cannabis-based medicinal product

The definition of cannabis-based medicinal products is set out in regulation 3. Products must satisfy three conditions to be defined as 'cannabis-based product for medicinal use in humans:'

> a) is or contains cannabis, cannabis resin, cannabinol, or a cannabinol derivative (not being Dronabinol or its stereoisomers);
>
> b) is produced for medicinal use in humans; and
>
> c) is a medicinal product or a substance or preparation for use as an ingredient of, or in the production of a medicinal product.[57]

The Explanatory Memorandum to the Regulations sets out that this definition makes treatment options available but with safeguards, because there was no marketing authorisation for the treatment as yet:

> The Government has been clear in its commitment to ensuring that cannabis-based products are available for medicinal use where clinically appropriate. However, it is not customary to reschedule a controlled drug which has not yet received a marketing authorisation from the MHRA or European Commission (such products are also known as an unlicensed medicine or 'special'). This is because controlled drugs are known to be dangerous or otherwise harmful, and the medicines licensing process provides assurances of a product's quality, safety and efficacy. In line with the UK Chief Medical Adviser's report, there is an imperative to reschedule cannabis-based products for medicinal use due to evidence of their therapeutic benefits. However, without the assurance of a marketing authorisation it is right that access to cannabis based products for medicinal use is strictly controlled.[58]

Who can prescribe cannabis-based medicines?

Cannabis-based medicinal products are only to be prescribed by a doctor who is on the General Medical Council's (GMC) specialist register. Almost all cannabis-based medicines in the UK prescribed by specialist doctors are unlicensed medicines and are therefore prescribed as 'specials'.

The Explanatory Memorandum to the regulations sets out that due to concerns around the risks of harm, misuse and diversion of cannabis-based products for medicinal use, special measures for the prescribing and supply of cannabis-based medicines would be introduced. It states that, until evidence develops in this area there are only three ways in which these medicines can be supplied:

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56 *The Misuse of Drugs (Amendment No.2) Regulations (Northern Ireland) 2018*

57 Explanatory memorandum to The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018

58 Explanatory memorandum to The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018

1 Where a product is unlicenced, the decision to prescribe should be made by a doctor who is on the GMC specialist register. The medicines would be prescribed as a 'special.' The explanatory memorandum sets out why this is the case, and the responsibility on doctors:

> In the absence of the reassurance that the product licensing system provides about product safety, quality and efficacy, a greater burden of responsibility falls on the specialist doctor making the decision to prescribe. That doctor will need to look to other sources of reassurance and ultimately, it will be for the specialist doctor, making the decision to prescribe, to decide whether prescribing these products is in the best interest of the patient. The limitation on the decision to order/prescribe, to doctors on the Specialist Register of the GMC, replicates the principle used in the Interim Expert Panel on cannabis-based medicines. The Expert Panel had been put in place by the Home Secretary to allow for special licences to be issued where there was an exceptional clinical need.[59]

2 Where a cannabis-based medicines is unlicenced, it can still be used in clinical trials so long as the legislation regulating clinical trials is complied with.

3 If a cannabis-based medicine has a marketing authorisation, it can be prescribed by any doctor, such as a GP.[60]

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59 Explanatory memorandum to The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018

60 Please note that while the Explanatory Memorandum to the regulations states that GPs can prescribe licenced cannabis-based medicines, guidance published by NHS England and NHS Improvement in December 2019 states that the prescribing of these medicines is limited to doctors on the GMC specialist register.

3. Prescriptions for cannabis-based medicinal products

The NHS website provides information on how someone may be able to get a prescription of cannabis-based medicines:

> **How do I get a prescription?**
>
> You cannot get cannabis-based medicine from a GP – it can only be prescribed by a specialist hospital doctor.
>
> And it is only likely to be prescribed for a small number of patients.
>
> A hospital specialist might consider prescribing medical cannabis if:
>
> - your child has one of the rare forms of epilepsy that might be helped by medical cannabis
> - you have spasticity from MS and treatments for this are not helping
> - you have vomiting or feel sick from chemotherapy and anti-sickness treatments are not helping
>
> The specialist will discuss with you all the other treatment options first, before considering a cannabis-based product.
>
> A prescription for medical cannabis would only be given when it was believed to be in your best interests, and when other treatments had not worked or were not suitable.
>
> It's expected this would only apply to a very small number of people in England.
>
> If the above does not apply to you, do not ask a GP for a referral for medical cannabis.[61]

3.1 Clinical guidance on prescribing

On 31 October 2018, NHS England sent guidance to clinicians about medicinal cannabis products. This linked to clinical guidelines produced by the Royal College of Physicians, which provides guidance on the prescribing of these products in the treatment of pain and chemotherapy induced nausea and vomiting, and by the British Paediatric Neurology Association which provides guidance on the use of cannabis-based medicine in children and young people with epilepsy.

In March 2019, the Medical Cannabis Clinicians Society (an organisation for clinicians with an interest in medicinal cannabis) and the APPG for Medical Cannabis under Prescription published guidelines for prescribers on cannabis-based medicines.[62]

National Institute for Health and Social Care Excellence (NICE) prescribing guidelines

The National Institute for Health and Social Care Excellence (NICE) subsequently published guidance on the prescribing of cannabis based

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61 NHS, Medical cannabis (and cannabis oils), November 2018

62 Corinne Burns, Medical Cannabis Clinicians' Society publishes guidance for prescribers, The Pharmaceutical Journal, 21 March 2019

medicinal products in November 2019.[63] The guidance was commissioned by the Department for Health and Social Care and covers the following products:

- cannabis-based products for medicinal use as set out by the UK Government in the 2018 Regulations
- the licensed products delta-9-tetrahydrocanaibinol combined with cannabidiol (Sativex) and nabilone
- plant-derived cannabinoids such as pure cannabidiol (CBD)
- synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC – the cannabinoid that gives cannabis its psychoactive effect), for example, dronabinol.

For adults aged 18 and over, the guideline suggests that nabilone can be considered as an add-on treatment for those with chemotherapy-induced nausea and vomiting "which persists with optimised conventional antiemetics" (drugs to manage/treat nausea and vomiting). To treat moderate to severe spasticity in adults with multiple sclerosis, the guideline also recommends offering a 4-week trial of THC:CBD spray (Sativex), though only if other pharmacological treatments for spasticity are not effective.

NICE did not recommend any of the products listed above to manage chronic pain in adults, "unless as part of a clinical trial". In addition, NICE did not recommend, nor make a "recommendation against the use of cannabis-based medicinal products [for epilepsy]". This approach was taken on the grounds that advising against their use "would restrict further research in this area and would prevent people who are currently apparently benefiting from continuing with their treatment".

NICE also made several "research recommendations" as part of its guidelines, predominately covering:

- Fibromyalgia or persistent treatment-resistant neuropathic pain in adults
- Chronic pain in children and young people
- CBD for severe treatment-resistant epilepsy
- THC in combination with CBD for severe treatment-resistant epilepsy
- Spasticity

For further details see Cannabis-based medicinal products, NICE guideline [NG144]: Recommendations for research.

NICE Technology Appraisal

NICE technology appraisal guidance makes recommendations for the NHS on whether drugs represent a clinically and cost-effective use of NHS resources. Under the NHS Constitution, the NHS is legally obliged

63 National Institute for Health and Care Excellence, Cannabis-based medicinal products, NICE guideline [NG144], November 2019

to fund and resource medicines and treatments recommended by NICE's technology appraisals.

In December 2019, NICE published Technology Appraisals for the use of cannabidiol (Epidyolex) for Lennox-Gastaut syndrome and Dravet syndrome.[64] Both appraisals recommend cannabidiol with clobazam (a benzodiazepine) as an option for treating seizures associated with these syndromes in people aged 2 years and older, subject to adequate monitoring and supply arrangements.

NHS England and NHS Improvement subsequently published a letter providing updated guidance on the *Process for prescribing Cannabis-based products for medicinal use* in December 2019. The letter also stated that "for those patients that fulfil the criteria, funding for cannabidiol has been fast-tracked and will be in place from the 6th January 2020".[65] Health Education England published an e-learning package in August 2019 to support healthcare professionals in their discussions with patients and to ensure appropriate access to cannabis-based medicinal products. NHS England and NHS Improvement's

64 NICE, Cannabidiol with clobazam for treating seizures associated with Dravet syndrome, Technology appraisal guidance [TA614], 18 December 2019; NICE, Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome, Technology appraisal guidance [TA615], 18 December 2019

65 NHS England and NHS Improvement, Guidance on prescribing cannabis based products for medicinal use, 20 December 2019

Box 2: How many prescriptions for cannabis-based medicines have there been?

The recent law change allows specialist doctors to prescribe cannabis-based medicines. However, while there have been reports that the products have proved difficult to access, we do not know for sure how many new prescriptions have been enabled since the law change. Detailed NHS publications on prescribing only cover prescribing in primary care, i.e. prescriptions dispensed in the community. However, since GPs are not covered by the law change – only specialist doctors can prescribe the newly-permitted medicines – not all new prescribing would be visible in this data.

In a response to a written question the Government published the following table setting out the number of prescriptions issued for licensed and unlicensed cannabis-based medicines between January 2019 and October 2019. It noted that Epidyolex was unlicensed prior to September 2019 and that no NHS prescriptions for Epidyolex had been submitted at the time the data was produced.

	Licensed Cannabis-based medicines			
Month	Nabilone	Sativex	Epidyolex *	Unlicensed cannabis-based medicines
January 2019	44	167		2
February 2019	36	159		1
March 2019	51	171		2
April 2019	49	156		2
May 2019	59	176		2
June 2019	47	187		2
July 2019	54	158		2
August 2019	46	174		1
September 2019	58	179	0	1
October 2019	46	173	0	1
Total	490	1,700	0	16
Grand Total	2,206			

The response to the PQ states that "NHS England and NHS Improvement is using extant systems to monitor the use of unlicensed cannabis-based products for medicinal use in England. In England, these systems monitor the number of items dispensed and associated costs in primary care and the volume of products used and associated cost in secondary care. NHS England and NHS Improvement Controlled Drug Accountable Officers are also collecting local intelligence in both the National Health Service and independent sector".[66]

It should be noted that while the data sets out the number of prescriptions, it does not state how many patients have received prescriptions. The Government has also confirmed in response to a different PQ that neither Nabilone nor Sativex falls within the scope of the definition of a 'cannabis-based product for medicinal use' under the recent change to the law: both have had marketing authorisations from the MHRA since February 1995 and June 2010 respectively, for use in defined circumstances.[67]

66 PQ 3830 [on Cannabis: Medical Treatments], 23 January 2020
67 PQ 251366 [on Cannabis: Medical Treatments], 13 May 2019

3.2 Comment on cannabis-based medicine prescribing

There has been some criticism that the rules and guidance on the prescribing of cannabis-based medicinal products are too restrictive and that as a result there have been very few prescriptions for these products.[68] Parents of children with severe epilepsy, and patient groups such as End Our Pain and the United Patient's Alliance, have said that that despite the change in the law, doctors are not prescribing these products.[69] Speaking to *The Guardian* newspaper after the NICE guidance had been published, Millie Hinton from End Our Pain stated that the guidelines were "a massive missed opportunity", adding that it was:

> particularly devastating that there is no positive recommendation that the NHS should allow prescribing of whole-plant medical cannabis containing both CBD (cannabidiol) and THC in appropriate cases of intractable childhood epilepsy.[70]

Commenting on a draft version of the NICE guidelines in August 2019, the Director of the Centre for Guidelines at NICE, Paul Chrisp, stated:

> We recognise that some people will be disappointed that we have not been able to recommend the wider use of cannabis-based medicinal products. However, we were concerned when we began developing this guidance that a robust evidence base for these mostly unlicensed products was probably lacking. Having now considered all the available evidence it's therefore not surprising that the committee has not been able to make many positive recommendations about their use.
>
> In most cases, the draft guidance recommends that more research is carried out, echoing the recent call by the National Institute of Health Research for research proposals for these products. To that end NICE welcomes the recent suggestion from the House of Commons Health and Social Care Committee that companies should be encouraged to undertake or enable research into their medicinal cannabis products.[71]

3.3 Health and Social Care Select Committee report – Drugs Policy: Medicinal Cannabis

Criticisms of the rules and guidance on the prescribing of cannabis-based medicinal products were also raised during the Health and Social Care Select Committee's (HSCC) inquiry into Medicinal Cannabis. The inquiry was launched in December 2018 following the rescheduling of cannabis-based medicinal products a month earlier.

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68 Richard Hurley, Medical cannabis: no NHS patients have benefited from law change, say campaigners, BMJ, 15 February 2019

69 See for example, Esther Webber, Parents of epileptic children criticise guidance on medical cannabis, The Times, 12 November 2018, and Harry Sumnall, Medicinal Cannabis: Legal yet impossible to access, 14 May 2019

70 "First cannabis-based medicines approved for use on NHS", *The Guardian*, 11 November 2019

71 NICE, 'NICE Draft Guidance and NHS England Review Highlight Need for More Research on Cannabis-based Medicinal Products', 8 August 2019

Peter Carroll, Campaign Director of the group End our Pain, gave evidence to the HSCC in March 2019. He was critical of the implementation process and told the Committee that families were seeking prescriptions of medicinal cannabis, but that it was not being prescribed:

> The Government did the right thing. The Home Secretary listened, and there was a consultation on the evidence—the high-profile cases of Billy Caldwell, Alfie Dingley and Sophia Gibson. They were genuine cases and the Government, for once, did the right thing and did it quickly. No, I do not think they were raising expectations.
>
> What has happened is that hopes have been correctly raised, because this offers a lot of hope and benefit to a lot of people, but we have now moved across to implementation and the honest reality is that it is a disaster. It is just not working. The families sitting behind me now should be getting prescriptions, going home and watching their children, hopefully—it might not work for everyone—improving day after day. I do not think it was wrong to raise the expectation: it is wrong not to implement it.[72]

He said that the families were devastated and that his organisation would continue to campaign for access to cannabis-based medicines for these children.[73]

Professor Mike Barnes, Interim Chair of the Medical Cannabis Clinicians Society, told the Committee that he thought barriers to prescribing of these products included a lack of education for doctors and that the guidelines produced by the Royal College of Physicians and the British Paediatric Neurology Association were too restrictive.[74] He said there were things that could be learnt from other country's approaches, such as the teaching programmes provided in the United States, and alternative approaches to licensing, such as the Office of Medicinal Cannabis in the Netherlands.[75]

Witnesses to the Committee, including representatives of professional organisations and other healthcare professionals, raised concerns about the existing evidence base on cannabis-based medicines and stressed the need for further research, and specifically randomised controlled trials on these products which are required for a medicines licence. Professor Finbar O'Callaghan, President of the British Paediatric Neurology Association, described their assessment of the current evidence base on the use of medicinal cannabis in treating childhood epilepsies and how the research should be developed in the future:

> […] the evidence base for cannabis-based medicinal product use in childhood epilepsies is remarkably thin, with the exception of investigating the use of pure cannabidiol in the two rare epilepsy syndromes that I just mentioned. Other than that, there are no

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72 Health and Social Care Committee, Oral Evidence: Drugs Policy: medicinal cannabis, HC 1821, 19 March 2019 Q77

73 Health and Social Care Committee, Oral Evidence: Drugs Policy: medicinal cannabis, HC 1821, 19 March 2019 Q78

74 Health and Social Care Committee, Oral Evidence: Drugs Policy: medicinal cannabis, HC 1821, 19 March 2019 Q51

75 Health and Social Care Committee, Oral Evidence: Drugs Policy: medicinal cannabis, HC 1821, 19 March 2019 Q67

> randomised controlled trials of cannabis-based medicinal products in childhood epilepsies, so you would have to say that the evidence base is thin.
>
> There are a number of open-label, observational studies, including some from Canada, Israel and so on, which suggest evidence of efficacy for the cannabis-based medicinal products they were investigating. In Israel, they were looking at whole-plant extract, which was cultivated to have a certain proportion of cannabidiol versus THC. In Canada, they were using a pharmaceutical grade product, which was a cannabidiol THC product called Tilray. As I say, they suggest evidence of efficacy.
>
> The problem with open-label, non-randomised, non-blinded studies is that they almost invariably overestimate efficacy. That is why, when we are licensing medicines, we demand randomised controlled trials as the level of evidence we need for efficacy. There are severe biases that could be at play in open-label studies that could distort the results.
>
> Safety is a big issue that needs to be talked about. In terms of cannabidiol, we have evidence of short-term safety data; adverse events were relatively common in people treated with cannabidiol. We do not have long-term safety data yet, but that is not unusual in a new medicine coming on to the market.[76]

Both Professor O'Callaghan and Professor Goddard, President of the Royal College of Physicians, said that the guidance that had been produced for clinicians on the prescribing of cannabis-based medicines represented the evidence base in this area. They said that whilst some patient groups had said the guidance had been a barrier, the feedback from professionals had been positive.[77]

Professor Whitty, the then Chief Scientific Advisor at the Department for Health and Social Care, advised that now the barrier of the products being in Schedule 1 had now been removed, the next stage was to undertake trials to look at the benefits and harms of the products:

> Basically, there were four barriers to people getting cannabis products before the change in the law. The first and most important one at that stage was that all of those drugs were in schedule 1, which made it difficult to build an evidence base, because, although it is possible to do trials under those conditions, it is extremely difficult. Removing that barrier is the single most important thing that could be done by Government at this stage. That has now happened, and it is a lot easier to do stuff on a schedule 2 basis.
>
> The next stage is to do the trials. The point the previous two witnesses made, which has been made by pretty well all your other medical witnesses, either in writing or in front of you, is that it is very dangerous to have a kind of cannabis exceptionalism. These are drugs; they have side-effects and positive effects. That is clear. What we have to do is to balance the two, but they are no different from any other drug in that sense. The history of medical development is littered with people rushing things through and ending up regretting it or, in a few cases—thalidomide is probably the best known—having an absolute disaster on their hands. It is

[76] Health and Social Care Committee, Oral Evidence: Drugs Policy: medicinal cannabis, HC 1821, 26 March 2019 Q149

[77] Health and Social Care Committee, Oral Evidence: Drugs Policy: medicinal cannabis, HC 1821, 26 March 2019 Q178

> really important that we balance throughout this a responsible look at the side-effects of the drugs and the positive effects of the drugs. We all completely accept that there are both.[78]

Professor Whitty added that he thought there would be faster movement now, because:

> quite a lot of people have been thinking about what they would do if the drugs were out of schedule 1, which is different from the situation with many other drugs […] it will go faster in conditions where there are quite a lot of people—let us say spasticity in multiple sclerosis than other rarer diseases—because it is easier to do trials in that situation.[79]

Another issue raised by witnesses was that companies producing cannabis-based medicines should be involved in clinical trials. In evidence, the then Parliamentary Under-Secretary of State for Health and Social Care, Baroness Blackwood, said that the Government had put out a statement to encourage industry to conduct randomised controlled trials:

> We have also put out a significant statement in which we encourage industry to conduct randomised control trials, because we think that cannabis should not be different from any other drug. This is a very lucrative market; there are some very successful companies in the sector, and there is no particular reason why they should not be conducting trials, just as any other pharmaceutical company would.[80]

The HSCC's report concluded that there were "major gaps in the research base for medicinal cannabis in part because research was very difficult under the previous scheduling".[81] Six of its 11 recommendations were focused on ways to improve the evidence base, particularly through addressing existing barriers to research. The Committee also concluded that there had been a failure to communicate to patients what the rescheduling would mean in practice for the availability of medicinal cannabis. "Expectations", it stated, "were raised that these products would become widely available and there needs to be far clearer communication that this is not the case".[82]

Medicines funding

The funding of prescriptions of cannabis-based medicinal products was also raised in the Committee evidence sessions. As almost all cannabis-based medicines continue to be unlicensed, they are not routinely funded by local clinical commissioning groups. Clinicians that wish to prescribe these would need to apply for an individual funding request for a patient. More information about medicines funding is provided in Box 3.

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78 Health and Social Care Committee, Oral Evidence: Drugs Policy: medicinal cannabis, HC 1821, 26 March 2019 Q222
79 Health and Social Care Committee, Oral Evidence: Drugs Policy: medicinal cannabis, HC 1821, 26 March 2019 Q222
80 Health and Social Care Committee, Oral Evidence: Drugs Policy: medicinal cannabis, HC 1821, 26 March 2019 Q219
81 Health and Social Care Committee, Drugs policy: medicinal cannabis, 18 June 2019, HC 1821, p3
82 Health and Social Care Committee, Drugs policy: medicinal cannabis, 18 June 2019, HC 1821, p3

Box 3: Commissioning and medicines funding in England

Clinical commissioning groups (CCGs) have statutory responsibility for commissioning the majority NHS services in England, which includes policy decisions on the funding of medicines. NHS England is also responsibly for the commissioning of specialised services.

Commissioners must fund a medicine that has been recommended by NICE in a technology appraisal. In the absence of NICE guidance, NHS organisations can determine their own policy on funding but cannot have a blanket policy to refuse particular treatments and must consider exceptional individual cases where funding should be provided. They have to have procedures in place for deciding what are known as Individual Funding Requests (IFRs).

Doctors, on behalf of patients, can make an IFR for treatment to NHS England for treatments that are not routinely be funded. Patients cannot apply directly to the NHS. Decisions will be considered by an IFR panel in NHS England. Patients can appeal against the decision of an IFR panel but if a review panel upholds an IFR panel's decision, the patient and his/her clinician will usually be advised that no further considerations can be made through the IFR process. NHS England has published information on Individual funding requests - A guide for patients.

An October 2018 NHS England letter on Cannabis-based products for medicinal use stated that trusts would meet the costs of specialist prescribing of cannabis-based medicines, where necessary. It said that the "current position is that no cannabis-based products for medicinal use are routinely commissioned by NHS England. When licensed they will become subject to normal NHS appraisal and commissioning processes."

More information on the commissioning of NHS services is provided in the Commons Library paper, The structure of the NHS in England.

Witnesses representing patient groups described funding as a barrier to supply for patients. Genevieve Edwards, Director of External Affairs at the MS Society said that the situation was currently unclear:

> At the moment, NHS England has said that trusts need to fund it. To take a step back, there is no clear and secure supply chain for these medicines. When people go to see their neurologist, they are told, "I have no idea where to get this from or who pays for it." There is a lot of confusion at clinic level. In order for trusts to fund it, they need a budget line in place and there isn't one at the moment. It will take a while to get the system in place and sorted, but what we would like to see quickly—there is a cross-departmental working group on it—is a strategy that starts to unpick some of this stuff so that people get the further research that we need, and professionals know how they can do it, what they can prescribe, how it is being paid for and who is paying for it. At the moment, that is really unclear.[83]

Professor Goddard set out the process he would undertake to apply for funding for a medicine that is not routinely funded:

> I am used to dealing with medicines that I want to prescribe to my patients in clinic that are either not licensed or are licensed for other uses. The mechanisms and steps that I have to go to in order to prescribe that medicine or any new medicine—leaving cannabis aside—are quite lengthy, require a lot of information, and often do not allow me to prescribe it in the long run because of funding issues and because the evidence is not there. While it is a good thing to move it into medicine scheduling, the prescription of unlicensed medicines is very difficult for good reasons, and the

[83] Health and Social Care Committee, Oral Evidence: Drugs Policy: medicinal cannabis, HC 1821, 19 March 2019 Q60

> regulation is there for good reasons, and perhaps that needed to be communicated.[84]

Baroness Blackwood said that the (then upcoming) NICE guidance would be of great assistance to Clinical Commissioning Groups (CCGs) and other funding bodies.[85]

The Government Response to the HSCC report stated that "more research is required on the clinical and cost effectiveness of CBPMs [*cannabis-based products for medicinal use*], before decisions on public funding can be made".[86] The Government also committed to expand the public and patient facing information on Gov.uk and NHS.uk "to include more detailed questions and answers to dispel some of the myths concerning what the law says and availability of CBPMs in the UK".[87]

3.4 Recent developments

On 8 April 2019, Mike Penning tabled an Urgent Question on the prescribing of medicinal cannabis products.[88] This was prompted by a case where the family of a girl with severe epilepsy, Teagan Appleby, had attempted to bring medicinal cannabis (prescribed in the Netherlands) to the UK. The medicinal cannabis had been confiscated from them by Border Force staff on the grounds that an import licence for the drugs was required.[89] A number of Members raised concerns about access to cannabis-based medicines on behalf of their constituents.

In response to the debate, the Secretary of State for Health and Social Care, Matt Hancock, expressed sympathies with the patients and families seeking to use medicinal cannabis but stated that the decision to prescribe must remain a clinical one which takes into account the clinical evidence, and the circumstances of the patient.

He set out that had asked NHS England to undertake a review of barriers to prescribing and introduce measures to encourage further research in this area:

> First, I have asked NHS England rapidly to initiate a process evaluation to address barriers to clinically appropriate prescribing. Secondly, to improve the evidence base and to get medicinal cannabis to patients in need, I have asked the National Institute for Health Research and the industry to take action to produce that evidence in a form that will support decisions about public funding. The NIHR has issued two calls for research proposals on

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84 Health and Social Care Committee, Oral Evidence: Drugs Policy: medicinal cannabis, HC 1821, 26 March 2019 Q140
85 Health and Social Care Committee, Oral Evidence: Drugs Policy: medicinal cannabis, HC 1821, 26 March 2019 Q229
86 Department of Health and Social Care, Government Response to the Health and Social Care Select Committee report on Drugs Policy: Medicinal Cannabis, CP 171, September 2019, p6
87 Department of Health and Social Care, Government Response to the Health and Social Care Select Committee report on Drugs Policy: Medicinal Cannabis, CP 171, September 2019, p6
88 HC Deb 8 April 2019 c 26
89 Teagan Appleby's seized medicinal cannabis returned, BBC News Online, 15 June 2019

> medicinal cannabis and I look forward to the responses to those consultations. That is in addition to the training package being developed by Health Education England to provide support to clinicians to enable them to make the best decisions with their patients.[90]

Barriers to accessing cannabis-based products for medicinal use on NHS prescription

The Review was led by the National Medical Director and the Chief Pharmaceutical Officer for England and looked at barriers to accessing cannabis-based products on NHS prescription for severe treatment-resistant paediatric epilepsy.[91] The review sought to:

- identify the potential barriers to the appropriate prescribing of Cannabis-based products for medicinal use in humans (CBPMs);
- identify any changes that would need to be put in place to support appropriate prescriptions of CBPMs in future; and
- identify ways to facilitate the building of an evidence base for the use of CBPMs.

As part of the review, NHS England and NHS Improvement worked with the All-Party Parliamentary Group on Medical Cannabis under Prescription and with patient groups, to identify patient cases which should be included in the review.[92] A total of 20 cases were reviewed: 18 from England and 2 from Northern Ireland.

The feedback received from clinicians was that:

> That products containing THC [Tetrahydracannabinol the cannabinoid that gives cannabis its psychoactive effect] would not be prescribed in their trusts, primarily because of the lack of evidence, a lack of knowledge about the products and a lack of long-term safety data. Several clinicians referenced the higher risk of impaired mental health from longer term exposure to THC and the need to proceed with caution.[93]

Parents and carers told the review that while they "acknowledge that the evidence base is limited, they feel that clinicians are not adequately considering the international observational study data".[94] In particular, they cited the interim specialist prescribing guidance produced by specialist bodies (see section 3.1) as a key barrier to prescribing cannabis-based products for medicinal use (CBPMs) in cases of severe treatment-resistant paediatric epilepsy. This was on the grounds that:

> Clinicians often stick rigidly to the guidance and are not considering each case on an individual basis, as per the GMC guidance on prescribing off-label or unlicensed medicines.[95]

The Review concluded that clinical understanding of CBPMs is variable with some clinicians feeling that "they do not have the specialist

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90 HC Deb 8 April 2019 c 26
91 NHS England and NHS Improvement, Barriers to accessing cannabis-based products for medicinal use on NHS prescription Findings and Recommendations, 8 August 2019, para 16
92 ibid, para 19
93 Ibid, para 24
94 Ibid, para 27
95 Ibid, para 34

professional education needed to make fully informed prescribing decisions in cases where a CBPM may be appropriate.[96] Patient expectation around access to a CBPM was also found to be "high following the rescheduling, and clinicians asked for support to manage this expectation".[97]

A total of 10 recommendations were made in the review, including the following:

> i. A UK-wide paediatric specialist clinical network should be established to provide specialist clinical expertise, support discussion of complex cases, provide support to clinicians and to assist in evidence generation.
>
> ii. The National Medical Director and Chief Pharmaceutical Officer for England will write to doctors and pharmacists reminding them of General Medical Council (GMC) guidance on the prescribing and use of unlicensed medicines – and to clarify the procedure for prescribing and supplying cannabis-based products for medicinal use (CBPMs). Clinicians will also be made aware of how they can access the Health Education England (HEE) cannabis education package, commissioned by NHS England, and published alongside this report.
>
> iii. NHS England and NHS Improvement and the Department of Health and Social Care (DHSC) should work together to develop clear information for patients and patient groups on the prescribing of cannabis-based products for medicinal use.[98]

The Government has not published a formal response to the review conclusions and recommendations. It has, however, indicated in a response to a PQ that it is working with partners towards addressing all 10 recommendations:

> Guidelines published by the National Institute for Health and Care Excellence (NICE) demonstrate a clear need for more evidence to support prescribing and funding decisions of cannabis-based medicines (whole-plant extract or otherwise) across all conditions covered in the report. We are working hard with the health system, industry and researchers to improve the knowledge base available. Central to this, NHS England and NHS Improvement are working closely with partners to deliver all recommendations from the NHS process evaluation report entitled 'Barriers to Accessing Cannabis Based Products for Medicinal Use'.[99]

In early March 2020, the Government announced that import restrictions on cannabis-based products for medicinal use had been changed, to help ensure people with prescriptions "do not have their treatment delayed or interrupted".[100] Licensed wholesalers will now be able to:

- import larger quantities of cannabis-based products

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96 Ibid, para 51
97 Ibid, para 53
98 NHS England and NHS Improvement, Barriers to accessing cannabis-based products for medicinal use on NHS prescription Findings and Recommendations, 8 August 2019, para 57
99 PQ 3152 [on Cannabis: Medical Treatments], 22 January 2020
100 Department of Health and Social Care; Home Office, News story: Faster access to cannabis-based medicines as import restrictions are changed, 2 March 2020

- hold supplies for future use by patients with prescriptions.[101]

The new measures will be implemented by the Home Office and the Medicines and Healthcare products Regulatory Agency (MHRA) from 2 March.

[101] Department of Health and Social Care; Home Office, News story: Faster access to cannabis-based medicines as import restrictions are changed, 2 March 2020

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