HOUSE OF LORDS Library Briefing

Medical Cannabis: Recent Developments

Summary

According to the NHS, medical cannabis, also known as medicinal cannabis, is "a broad term for any sort of cannabis-based medicine used to relieve symptoms". The cannabis plant contains more than a hundred different chemical compounds called cannabinoids, some of which are the active ingredients in prescription medicines. The most well-known cannabinoids are tetrahydrocannabinol (THC) and cannabidiol (CBD).

Under the Misuse of Drugs Act 1971, cannabis (as well as most cannabinoids) is a controlled drug. Prior to September 2018, cannabis-based medicinal products could only be accessed through the granting of an individual licence. Following a review by the Chief Medical Officer and the Advisory Council on the Misuse of Drugs, the Home Office announced that from 1 November 2018 cannabis-based medicinal products would be rescheduled under the relevant regulations, meaning they could be prescribed by doctors on the Specialist Register of the General Medical Council.

Cannabis use for medicinal purposes is allowed in several countries and territories across the world. These include the Netherlands, Canada, France, Germany and some US states. In the Netherlands, for example, cannabis for medicinal purposes is available with a physician's prescription and can be prescribed by all doctors.

In December 2018, the House of Commons Health and Social Care Committee launched an inquiry into issues around medicinal cannabis. The committee stated that while the rescheduling of cannabis for medicinal purposes had been "widely welcomed", there had been a "failure" to communicate what this would mean "in practice". In September 2019, the Government responded to the recommendations set out in the committee's report. These included providing clearer information on availability and building the evidence base.

New National Institute for Health and Care Excellence (NICE) guidelines were published in November 2019 on the prescribing of cannabis-based products. The guidance recommends specific cannabis-based products in the treatment of intractable nausea and vomiting and for spasticity in Multiple Sclerosis (MS), but not for the treatment of pain. The guidelines did not recommend these products for severe treatment-resistant epilepsy, however NICE made research recommendations in this area.

Rebecca Watson | 9 January 2020

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1. Background

1.1 Definitions

According to the NHS, medical cannabis is "a broad term for any sort of cannabis-based medicine used to relieve symptoms".[1] The cannabis plant contains more than a hundred different chemical compounds called cannabinoids.[2] Tetrahydrocannabinol (THC) is the cannabinoid that gives cannabis its psychoactive effect. Cannabidiol (CBD) is a non-psychoactive cannabinoid that has been the subject of interest for medical use.

The relevant regulations define a cannabis-based product for medicinal use in humans as:

> […] a preparation or other product […] which—
>
> (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—
>
> (i) a medicinal product, or
>
> (ii) a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product.[3]

The NHS has cautioned that although many cannabis-based products are available to buy online, the quality and content is unknown and the products may be illegal and potentially dangerous.[4] In addition, products claiming to be medical cannabis such as "CBD oil" are available to buy legally from health stores. However, their quality and health benefits are unclear. Some cannabis-based products are available on prescription as medicinal cannabis. However, at present, the NHS states that "very few people in England are likely to get a prescription".[5]

1.2 UK Legislative Context

Change in the Law

Under the Misuse of Drugs Act 1971, cannabis, as well as most cannabinoids, including THC, is a controlled drug. The Act makes it illegal for people to possess, supply, produce, or import/export controlled drugs.[6] In 2018, new regulations under the Act were introduced to make cannabis-based

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[1] NHS, 'Medical Cannabis (and Cannabis Oils)', 1 November 2018.

[2] Home Office, *Drug Licensing Factsheet—Cannabis, CBD and other Cannabinoids*, accessed November 2019.

[3] Home Office, *Explanatory Memorandum to The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018*, 2018; Senedd Research, 'Medicinal Cannabis: What's the Situation Now?', 8 April 2019. In Northern Ireland the rescheduling of cannabis is a devolved issue, so it is not covered by the 2018 regulations in force in Great Britain. However similar regulations specific to Northern Ireland have been passed; and came into force on 1 November 2018.

[4] NHS, 'Medical Cannabis (and Cannabis Oils)', 1 November 2018.

[5] NHS, 'Medical Cannabis (and Cannabis Oils)', 1 November 2018.

[6] Crown Prosecution Service, 'Drug Offences', accessed 9 September 2019. Cannabis is a class B drug (GOV.UK, 'Drugs Penalties', accessed November 2019).

products available to be prescribed for medicinal use.[7]

Under the Misuse of Drugs Regulations 2001, made under the Misuse of Drugs Act 1971, controlled drugs are placed in one of five schedules. This relates to their therapeutic usefulness and potential for misuse. Prior to September 2018, cannabis-based medicinal products were categorised under schedule 1 of the 2001 Regulations.[8] Drugs in this schedule are tightly controlled and are deemed to have no therapeutic benefit. Schedule 1 drugs can only be accessed through the granting of an individual licence, which is controlled through the Home Office.[9] Following a review by the Chief Medical Officer and the Advisory Council on the Misuse of Drugs, the Home Office announced that from 1 November 2018 cannabis-based medicinal products would be moved to schedule 2. Drugs in schedule 2 are considered to have therapeutic benefit and can be prescribed by doctors. Therefore, since November 2018, doctors on the Specialist Register of the General Medical Council have been able to prescribe cannabis-based medicinal products.[10]

Unlicensed versus Licensed Products

At present in the UK, the majority of cannabis-based medicinal products are unlicensed. This means that a product has not been assessed by the relevant licensing authority against criteria for safety, quality and efficacy.[11] There may only be limited information available about dosing. The exceptions to this are Sativex and nabilone, which are licensed products. The change to legislation in 2018 did not affect these products. Furthermore, cannabidiol (CBD) is unlicensed in the UK, but it is not classed as a controlled drug.

1.3 International Context

Under international laws, the cultivation, supply and possession of cannabis should be allowed only for medical and scientific purposes.[12] In January 2019, the Director General of the World Health Organisation (WHO) sent a letter to the Secretary General of the United Nations recommending that cannabis and associated substances be rescheduled in the international drug control framework in order to facilitate the trade of substances for medicinal and scientific purposes.[13] Proposals from the WHO were expected to be voted on by the Commission on Narcotic Drugs at its March 2019 session, but the vote was postponed as the recommendations were delayed.

At a country level, cannabis use for medicinal purposes is allowed in several countries and territories

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[7] Home Office, *Explanatory Memorandum to The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018*, 2018.

[8] Senedd Research, 'Medicinal Cannabis: What's the Situation Now?', 8 April 2019.

[9] ibid.

[10] General Medical Council, 'The Specialist Register', accessed November 2019.

[11] NICE, *Cannabis-Based Medicinal Products: Evidence Reviews for Prescribing Cannabis-Based Medicinal Products*, November 2019.

[12] European Monitoring Centre for Drugs and Drug Addiction, 'Cannabis Policy: Status and Recent Developments', accessed November 2019.

[13] European Monitoring Centre for Drugs and Drug Addiction, 'WHO Recommends Rescheduling of Cannabis', 25 March 2019.

around the world, including: Canada, France, Germany, the Netherlands and some US states.[14] In contrast, it remains a prohibited substance in much of the world.

The Netherlands: Case Example

The Netherlands is known for its "toleration policy" regarding soft drugs.[15] In the Netherlands, cannabis for medicinal purposes is available with a physician's prescription and can be prescribed by all doctors.[16] The Dutch Office of Medical Cannabis (OMC) states that medical cannabis dispensed by a pharmacy must meet "stringent quality requirements". Cannabis growers appointed by the OMC cultivate the substance under strict, controlled conditions. Five different types of medical cannabis are available which vary in compositions of THC and CBD. Products range from Bedrocan, which is 22% THC and less than 1% CBD, to Bedrolite, which is less than 1% THC and 9% CBD. The OMC states that the type of medical cannabis "most suitable" for a patient depends on their condition. For example, Bediol (6% THC and 8% CBD) is often the first step for treating chronic nerve pain. The OMC states that THC is an important ingredient for "pain reduction".

CBD oil is also available on prescription as a pharmaceutical compound from several pharmacies. However, it is also available to buy via other channels, with the source of the product unknown or unregulated. Despite established government guidance on medical cannabis use and prescription in the Netherlands, issues have been raised around legal access to medical cannabis and the practice of patients paying for medication.[17] For example, the Dutch Care Institute has stated that there is "insufficient evidence" for the effectiveness of medicinal cannabis to include it in basic health insurance.

2. Recent Developments in the UK

2.1 Health and Social Care Committee Inquiry: Drugs Policy Medicinal Cannabis

In December 2018, the House of Commons Health and Social Care Committee launched an inquiry into issues around medicinal cannabis.[18] The backdrop to the inquiry was that, although changes in the scheduling of medicinal cannabis from schedule 1 to 2 under the relevant regulations had been "widely welcomed," there had been a perceived "failure" to communicate what this would mean "in practice".[19] The committee described the need for a "sense of urgency" to explore and build a "robust" research base in order to make future clinical decisions. Furthermore, the committee argued that the UK needed to "learn" from international best practice.

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[14] European Monitoring Centre for Drugs and Drug Addiction, *Cannabis Legislation in Europe*, June 2018; Canada Department of Justice, 'Canada Legalization and Regulation', accessed November 2019; and Congressional Research Service, *The Marijuana Policy Gap and the Path Forward*, 10 March 2017.

[15] Government of the Netherlands, 'Toleration Policy Regarding Soft Drugs and Coffee Shops', accessed November 2019.

[16] Office of Medicinal Cannabis, 'Office of Medicinal Cannabis', accessed November 2019; and Office of Medicinal Cannabis, *Medicinal Cannabis Information Brochure for Patients*, accessed November 2019.

[17] DutchNews.nl, 'Medical Cannabis Users Left High and Dry by Dutch Tolerance Policy', 13 March 2019.

[18] House of Commons Health and Social Care Committee, *Drugs Policy: Medicinal Cannabis*, 3 July 2019, HC 1821 of session 2017–19, p 5.

[19] ibid p 3.

The committee identified that the "high-profile" nature of the rescheduling had led to "misinformation", with the public believing that cannabis-based products worked as a treatment where the evidence to support this was "lacking". Its report stated:

> The reality of the change in law was that medicinal cannabis products were rescheduled, which allowed them to be prescribed. However, most medicinal cannabis products are unlicensed, and therefore remain governed by a restrictive prescribing process. The Government failed to communicate this point, and unduly raised the hopes and expectations of patients and their families.[20]

Based on the evidence it collected, the committee supported proposed Randomised Control Trials (RCTs) into cannabis-based products for medicinal use (CBPM). The committee called on the National Institute for Health Research (NIHR) to engage fully with parents and clinicians' proposals to use observational trials, as well as RCTs, to improve the evidence base. The committee also identified current barriers to research. These included in industry, where corporations were "not always prepared" to supply products to clinicians or organisations proposing to carry out research trials.

Furthermore, the committee recommended that the Department of Health and Social Care (DHSC) should take the following steps:

- investigate instances where pharmaceutical companies do not provide their medical product for research and take appropriate action where necessary;
- encourage and focus research into specific conditions where the Chief Medical Officer's report found good evidence for the use of cannabis-based medicinal products;
- set out in its response to the report how it will work with research organisations in the UK and internationally to ensure research is being co-ordinated and encouraged in the most appropriate areas; and
- look at how medicinal cannabis is made available to patients in other EU member states such as the Netherlands.[21]

Government Response

In September 2019, the Government responded to the recommendations set out in the Health and Social Care Committee's report on medicinal cannabis.[22] The Government agreed with the committee's recommendation on providing "clear information" about the availability of cannabis-based medicinal products, and stated that NHS Improvement and the DHSC would "work together" to develop clearer information on prescribing.

In response to recommendations around the current evidence base, the Government stated that there was a "clear consensus on the need for more clinical evidence", restating that two calls for research had been made by the NIHR.[23] Further to this, the Government responded that the NIHR

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[20] House of Commons Health and Social Care Committee, *Drugs Policy: Medicinal Cannabis*, 3 July 2019, HC 1821 of session 2017–19, p 9.

[21] ibid pp. 19 – 20.

[22] Department of Health and Social Care, *Government Response to the Health and Social Care Select Committee report on Drugs Policy: Medicinal Cannabis*, September 2019, CP 171.

[23] ibid.

was working with industry to promote research calls and encourage participation. The Government agreed that industry needed to "play its part" in being more transparent in publishing data from all clinical trials.

Following issues raised by the committee around making resources "immediately available" for intractable epilepsy, the Government stated that "a legal route now exists to prescribe and supply CBPM in the UK" and "there is no need for patients to travel abroad to seek treatment".[24] In light of questions on "the future of European multi-centre clinical trials" post-Brexit, the Government stated that as part of the EU negotiations they were working "to ensure the best possible" environment in which to support clinical trials. In terms of developing policy, the Government stated that it had "engaged" with authorities and regulators in a number of other countries. More specifically, the Government highlighted that the UK system was "very similar" to the Dutch system, so both countries were "grappling with many of the same issues and challenges".

In terms of current guidance and education, the Government stated that both it and NICE had "actively encouraged" all interested parties to engage in the consultation process for new draft NICE guidelines on medicinal cannabis.[25] The committee "welcomed" the e-learning modules being prepared by Health Education England, and in response to the committee, the Government stated that the modules could be "easily" updated to take into account new evidence. In response to the committee's recommendation that steps should be taken to secure long-term international deals that "ensure a consistent supply of CBPM", the Government stated that the DHSC and the Medicines and Healthcare products Regulatory Agency had met with several producers to establish supply in the UK. The Government also stated that following publication of a forthcoming NHSE-I process review report, doctors and pharmacists would be reminded again of the General Medical Council guidance on prescribing and use of unlicensed medicines.

2.2 NHS: Barriers to Prescribing

In 2019, the Secretary of State for Health and Social Care, Matt Hancock, requested that NHS England and NHS Improvement undertake a "rapid process review" into any barriers to prescribing on the National Health Service, where clinically appropriate.[26] The resulting report, published in August 2019, stated that the "vast majority" of clinicians saw lack of good quality RCT data as a "major hurdle" to prescribing. This was particularly pertinent to the issue of prescribing products containing THC. Findings suggested there was a "spectrum" in clinicians' willingness to prescribe on an individual case-by-case basis. "Unique factors" were identified when considering use of CBPM in severe treatment-resistant epilepsy. Recommendations included:

- establishing a UK-wide paediatric specialist clinical network;
- developing clear information for patients on prescribing;
- conducting NIHR research on priority areas including severe treatment resistant epilepsy; and
- providing access to information on good quality products.

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[24] Department of Health and Social Care, *Government Response to the Health and Social Care Select Committee report on Drugs Policy: Medicinal Cannabis*, September 2019, CP 171, p 9.

[25] ibid.

[26] NHS England and NHS Improvement, *Barriers to Accessing Cannabis-based Products for Medicinal Use on NHS Prescription*, August 2019.

On 1 November 2019, in response to a written question on the progress made on the provision of medical cannabis on the NHS, the DHSC highlighted the rapid process review on barriers to prescribing on the NHS produced by NHS England and NHS Improvement.[27] The response stated that the Government was "working closely" with NHS England, NHS Improvement and other delivery partners to implement the report's recommendations.

2.3 NICE Guidance

In 2019, NICE was commissioned to develop updated clinical guidance on the prescribing of cannabis-based medicinal products. Draft NICE guidelines on the prescribing of cannabis products were published for consultation in August 2019.[28] The consultation period ended on 5 September 2019 and final guidelines were published on 11 November 2019.[29] Products covered by the final guidance included:

- cannabis-based products for medicinal use as set out in the 2018 regulations;
- the licensed products delta-9-tetrahydrocannibinol combined with cannabidiol (Sativex) and nabilone;
- plant-derived cannabinoids such as pure cannabidiol (CBD); and
- synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example, dronabinol.[30]

NICE guidelines for prescribing cannabis-based medicinal products were as follows:

- **Intractable nausea and vomiting**: consider the cannabis-based product nabilone as an "add-on treatment" for adults, however also consider potential adverse drug interactions.
- **Chronic pain:** cannabis-based products should not be offered to manage chronic pain in adults. CBD should not be offered unless part of a clinical trial. Individuals who started taking cannabis-based medicinal products before the guidance was published should be able to continue.
- **Spasticity**: offer a four-week trial of the THC:CBD spray cannabis-based product to treat moderate to severe spasticity in adults with multiple sclerosis (MS). This should be offered if other treatments are not effective and when the company provides the spray according to its pay-for-responders scheme.[31]
- **Severe treatment-resistant epilepsy**: recommendations for prescribing are currently not provided, however NICE has made research recommendations for its use. Technology appraisal guidance is being developed by NICE on cannabidiol with clobazam for treating seizures associated with Lennox-Gastaut syndrome and Dravet syndrome. [32]

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[27] House of Commons, 'Written Question: Cannabis: Medical Treatments', 1 November 2019, 5043. See also House of Commons, 'Written Question: Cannabis: Medical Treatments', 5 November 2019, 7143.

[28] NICE, *Draft Guidance–Cannabis-based Medicinal Products*, 8 August 2019.

[29] NICE, 'Cannabis-based Medicinal Products', accessed 21 November 2019.

[30] ibid.

[31] For more information read: Sativex, 'Pay for Responders Scheme', accessed 25 November 2019.

[32] ibid.

Key recommendations for research included the use of cannabis-based medicinal products in the following conditions:

- 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; and
- spasticity.

Other recommendations included further research into the clinical and cost effectiveness of intractable nausea and vomiting both caused, and not caused, by chemotherapy in babies, children, young people and adults.

Analysis by NICE on the rationale and impact of its guidance suggested that recommendations could result in an increased number of prescriptions for intractable nausea and vomiting, and spasticity in MS.[33] However, the guidance does not recommend the use of medicinal cannabis to treat chronic pain. According to NICE, this "might reduce the number of these prescriptions".

Reaction

Following publication of the draft NICE guidelines, Paul Chrisp, Director of the Centre for Guidelines at NICE, 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.[34]

In response to the final NICE guidance, Millie Hinton from the campaign group End Our Pain stated that the guidelines were a "massive missed opportunity".[35] Particularly "devastating" to the campaign was the absence of positive recommendations for prescribing whole-plant medical cannabis, which contains CBD and THC. She stated that the "whole plant extract" had been shown to be "life-transforming" for a "significant" number of children, including those involved in high-profile cases which had "led to" updated medical cannabis legalisation.

Genevieve Edwards, Director of External Affairs at the MS Society, stated that approval of the licensed product Sativex to treat muscle spasms was "brilliant" but did not go far enough.[36] Furthermore, no recommendations were made for using medical cannabis to treat pain in MS, despite this being a "common symptom" of the condition. Limited accessibility was also highlighted, as "Sativex will be funded by local bodies—who might not have the resource they need to prescribe it—even more people could miss out".

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[33] NICE, 'Rationale and Impact', November 2019.

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

[35] Sarah Marsh, 'First Cannabis-based Medicines Approved for Use on NHS', *Guardian,* 11 November 2019,

[36] ibid.

2.4 Potential Developments in the New Parliament

In August 2019, the Home Secretary, Priti Patel, stated that "any form of drug use […] has a corrosive impact on people and communities".[37] Following the Queen's Speech in October 2019, Baroness Blackwood of North Oxford, Parliamentary Under Secretary of State at the Department of Health and Social Care, wrote to Members of the House of Lords on matters raised during one of the days of debate on the address. In respect of medicinal cannabis, she wrote:

> NHS England and the Chief Medical Officer have made it clear that cannabis-based products can be prescribed for medicinal use in appropriate cases. The Process Review commissioned by the Secretary of State has now been completed, and my department is working closely with NHS England and other partners to implement the recommendations. The department has also been clear that the National Institute for Health Research is ready to fund additional research on medicinal cannabis in order to improve the clinical evidence base for its use.[38]

The Conservative Party general election manifesto made no specific reference to medical cannabis.[39] In contrast, the Labour manifesto stated that the party would have "progress[ed] clinically appropriate prescription of medical cannabis".[40] Meanwhile, the Liberal Democrats' manifesto stated that the party would have "reform[ed] access to cannabis through a regulated cannabis market in the UK".[41] The document suggested that this approach would have supported and encouraged more clinical trials of cannabis for medicinal use to establish a clear evidence base. Furthermore, the party would have allowed "those who feel that cannabis helps to manage their pain" to do so without "fear" of criminal prosecution.

3. Further Reading

- House of Commons Library, *Medical Use of Cannabis*, 17 May 2019
- NICE, *Cannabis-Based Medicinal Products: Evidence Reviews for Prescribing Cannabis-Based Medicinal Products*, November 2019

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[37] Damien Gayle, 'Home Secretary Priti Patel Criticised Over Wish for Criminals to "Feel Terror"', *Guardian,* 3 August 2019.

[38] Department of Health and Social Care, *Letter from Baroness Blackwood of North Oxford to Members of the House of Lords*, 31 October 2019, p 2.

[39] Conservative Party, *Conservative Party Manifesto 2019*, accessed November 2019.

[40] Labour Party, *Labour Party Manifesto 2019*, November 2019, p 35.

[41] Liberal Democrats, *Liberal Democrat Manifesto 2019*, November 2019, p 61.