



Government Response to the Health and Social Care Select Committee report on Drugs Policy: Medicinal Cannabis

Presented to Parliament by the Secretary of State for Health and
Social Care by Command of Her Majesty

Sept 2019



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ISBN 978-1-5286-1587-7

CCS0819924472 09/19

Printed on paper containing 75% recycled fibre content minimum

Printed in the UK by the APS Group on behalf of the Controller of Her Majesty's Stationery Office

Introduction

1. This paper sets out the Government's response to the conclusions and recommendations made in the Health and Social Care Select Committee's report on Drugs policy: medicinal cannabis.

Overview

2. The law was changed on 1 November 2018 to allow clinicians on the General Medical Council's (GMC) Specialist Register to prescribe unlicensed cannabis-based products for medicinal use (CBPM), where it is clinically appropriate and in the best interest of patients. No licences are required to prescribe CBPMs.
3. Whilst cannabis and cannabis-based products remain a Class B drug under the Misuse of Drugs Act 1971, there is now a legitimate route to access these products for medicinal use as set out in the Misuse of Drugs Regulations 2001: either as a medicine with a marketing authorisation; as part of a clinical trial; or as a "special" medicine prescribed on a case by case basis by a specialist doctor on the GMC's specialist register. Whether or not to treat a patient with CBPMs must remain a clinical decision.
4. Currently all CBPMs are imported. A proportionate and long-established licensing regime is in operation which enables the import of CBPMs (and other controlled drugs) or their domestic production, possession and supply, to support access to these medicines where a prescription has been lawfully written. Products imported in contravention of these arrangements are unlawful.
5. Guidance and training have been developed for clinicians and is currently being refreshed. On 8 August 2019 a Health Education England e-learning package was published alongside draft guidelines from the National Institute of Health and Care Excellence (NICE). The NICE guidelines will replace the interim clinical guidance that was issued by the Royal College of Physicians (RCP), the British Paediatric Neurology Association (BPNA) and more recently the Association of British Neurologists (ABN) when the legislation first came into force.
6. The National Institute for Health Research (NIHR) has put out two calls for proposals to enhance our knowledge in this area. Further proposed action to stimulate research and the development of evidence is detailed in this response.

Response to the Committee's recommendations

Public opinion and communications

Recommendation 1 - The Home Office, Department of Health and Social Care and NHS England should consult relevant patient and professional organisations and form a communications plan to relay clear information to patients and the wider public about the availability of CBPMs and the need for further research. (Paragraph 23)

7. Recommendations from the Committee, NHS England & NHS Improvement (NHSE-I) in their review on the barriers to accessing cannabis-based products for medicinal use on NHS prescription (NHSE-I Review) and NICE draft guidelines on medicinal cannabis, support the Government position that more research is required on the clinical and cost effectiveness of CBPMs, before decisions on public funding can be made.
8. The Government is committed to the following actions to provide clear information to the public and patients on the availability of CBPMs and the need for further research:
 - a. NHSE-I and the Department of Health and Social Care (DHSC) will work together to develop clear information for patients and patient groups on the prescribing of CBPMs. Patient groups were consulted as part of the policy development process. NHSE-I has liaised with patient and professional organisations to inform the findings set out in the NHSE-I Review and has discussed its recommendations and implementation plans in detail.
 - b. The public and patient facing information on Gov.uk and NHS.uk will be expanded 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.
 - c. Explore using the Science and Media Centre to help promote and disseminate accurate and evidence-based information about CBPMs.
 - d. Regular meetings and dialogue between professional organisations, NHSE-I, MHRA, Home Office and DHSC will continue to help ensure consistent communication.
9. In addition, on 8 August 2019, Health Education England published an e-learning package to further support healthcare professionals in their discussions with patients. This is available to all healthcare professionals across the UK.

Current evidence base

Recommendation 2. We call on the National Institute for Health Research to engage fully with parents and clinicians [who have argued for observational trials] to discuss their proposal and explore all ways to improve the evidence base. (Paragraph 50)

10. Patients, carers and the public are central to NIHR work. All NIHR programmes involve public contributors at each step of the research process. We would expect researchers to involve patients in both the design and delivery of the research.
11. NIHR has engaged with industry, researchers and clinicians to encourage high quality research in this priority area. Randomised Control Trials are the gold standard, but other well-designed studies are encouraged to further the evidence base.
12. The NIHR has issued two calls for research to further the evidence base in this area. The second call for applications to the NIHR closed on 31st July. Applications are being assessed and will be judged on scientific merit. For any successful applications, the research would be expected to start around Autumn 2020.
13. This topic is an on-going priority for the Government and NIHR and researchers that missed the earlier calls are being encouraged to submit applications under other NIHR research calls.
14. The Government and NIHR continue to encourage high quality research proposals on CBPMs. It is important for the evidence to be developed in a way that will inform decisions on the use of CBPMs that are to be supported by public funding. NHSE-I and NIHR are also considering the best options for developing alternative research approaches to assist children who are currently receiving CBPMs.

Recommendation 3. The Department of Health and Social Care should investigate those instances where pharmaceutical companies do not provide their medicinal cannabis product for research and take appropriate action where necessary. The Department should not be afraid to ‘name and shame’ companies who are not doing all they can to make their products available for research. The Department should also set out a plan to encourage industry to take a more active role in research itself and should present this plan in response to this report. (Paragraph 67)

15. NIHR are working with the industry to promote the research calls and encourage industry participation in clinical trials. The participation of manufacturers in these trials is vital, not only in supplying products, but also in providing data to help improve the

evidence of clinical and cost effectiveness. Without an improved evidence base, CBPMs will not be routinely commissioned on the NHS.

16. Randomised clinical trials are the gold standard to test whether medicines are safe and effective. The industry needs to play its part and be more transparent in publishing data from all clinical trials that it conducts, to ensure that a full and proper assessment of the research outcomes can be made. In May 2019, the NIHR published its policy on clinical trial registration and disclosure of results. This policy applies to all clinical trials actively recruiting on or after 20 May 2019, ensuring all research funded by the NIHR is registered, with timely disclosure of research findings. In addition, on 17 June 2019 the Health Research Authority (HRA) launched a consultation on their 'Make It Public' research transparency strategy, which aims to improve and promote research transparency. The strategy focuses on clinical trials involving Investigational Medicinal Products, devices, public health and surgical interventions, where registration and disclosure across all areas of trials are still not 100%. The HRA are intending to publish their final strategy by the end of the year to provide clear direction on how to make sure that patients, the public and professionals can easily access useful information about health and care research studies.

Recommendation 4. We welcome the broad call for research proposals into medicinal cannabis products by the National Institute of Health Research (NIHR). The Department of Health and Social Care and the NIHR should encourage and focus research into those specific conditions where the Chief Medical Officer's report found good evidence for the use of cannabis based medicinal products. (Paragraph 68)

17. There is a clear consensus on the need for more clinical evidence. The NIHR is supporting the industry to take action to produce evidence across these areas in a way that will inform decisions on the use of CBPMs that are to be supported by public funding. The NIHR has issued two calls for research proposals on CBPM across the range of indications where the evidence is most developed. NICE, in its draft guidelines, also recommend that the NIHR should support research in five priority research areas:
 - Cannabidiol (CBD) as an add on treatment for adult patients with fibromyalgia or persistent treatment-resistant neuropathic pain;
 - CBPMs in chronic pain in children and young people
 - CBPMs for people with spasticity

- CBD for severe treatment-resistant epilepsy in children, young people and adults; and
- The effect of adding Tetrahydrocannabinol (THC) in combination with CBD on seizure frequency, brain structure and neurophysiological performance when compared with both CBD alone and placebo.

18. The NIHR is continuing to strongly signal to the research community that this is a priority area for funding and that it would like to receive further research proposals. The NIHR is also actively engaging with researchers who have shown an interest in applying for relevant NIHR funding. This recognises that the original highlight notice that called for proposals was relatively recently launched and that we expect further research proposals to be forthcoming. NIHR is also considering launching some more focused commissioned workstreams, being more directive with the research community on which areas have the greatest need and where the existing evidence supports further work.

Recommendation 5. The National Institute of Health Research should make resources immediately available for a programme of clinical trials for the treatment of intractable epilepsy. This will allow many more patients to access treatments in specialist centres. These trials should be facilitated as a matter of urgency. Families of children suffering from these distressing and life-threatening conditions should not have to travel abroad to seek treatment, but we will fail future patients if we do not establish the evidence base for the place of medicinal cannabis in treatment. (Paragraph 69)

19. A legal route now exists to prescribe and supply CBPMs in the UK, where it is clinically appropriate to do so. There is no need for patients to travel abroad to seek treatment.

20. All good quality proposals will be assessed by NIHR. NIHRs funding is not ring-fenced and treatment-resistant epilepsy is one of the priority areas in which the NIHR is encouraging good quality proposals.

21. In addition, in its report of 8 August 2019, NHSE-I committed to work with the NIHR and specialist clinical networks to determine appropriate alternative study designs to help those children and young adults, including those who are currently receiving a CBPM, and ensure evidence is generated in way that will not only benefit these patients, but future generations.

Recommendation 6. The Department of Health and Social Care should set out in its response to this report how it will work with research organisations here in the UK and internationally to ensure that research is being co-ordinated and encouraged in the most appropriate areas. Government should also set out how it will ensure that the future of European multi-centre clinical trials and the post marketing surveillance that protects patient safety are not put at risk by Brexit. (Paragraph 70)

22. NICE has issued recommendations on five priority areas for research in the draft Clinical Guideline, as outlined above. The NIHR is further considering how best to encourage further good quality research proposals across the range of priority conditions identified by NICE in its draft guidelines.
23. As part of EU Exit negotiations, we are working to ensure that we continue to have the best possible environment in which to support clinical trials. Our overall aim is to ensure that patients in the UK and across the EU continue to be able to access the best and most innovative medicine.
24. As part of preparations for leaving the EU, the UK Government is working across several areas to ensure that the UK has the best possible environment for basic, biomedical, health, and life sciences research. This includes access to, and mobility of the research leaders and the technical and research delivery workforce; access to EU research funding; the regulation of clinical trials, data and devices; rare diseases research; and clinical trials supplies in a no-deal scenario.
25. The UK and the EU have a long track record of jointly tackling global challenges with strong existing links already in place between our research and innovation communities. We want to continue this collaboration in areas of shared interest through a partnership with the EU covering research, science and innovation.

Recommendation 7. The Department of Health and Social Care should look at how medicinal cannabis is made available to patients in other EU member states such as the Netherlands and see whether lessons might be learnt which could be helpful. (Paragraph 71)

26. In developing policy on CBPM, the Government engaged with authorities and regulators in a number of EU and other countries, including the Netherlands. Our system is very similar to the Dutch, and we are both grappling with many of the same issues and challenges.
27. The Dutch model is based around controlling the domestic production and supply of standardised cannabis-based medicines to licenced pharmacies that dispense flos

(flowers) or compound oils to patients. The same standards of production are applied to the products imported to fulfil UK prescriptions.

28. As in the UK –

- prescriptions are on a name patient basis only and prescriptions are only written when other licensed medicines have not been effective.
- prescribing is a decision for clinicians and the Office of Medicinal Cannabis (OMC) states in guidance for clinicians that there is insufficient evidence to support use in many conditions, including epilepsy.
- prescriptions are largely privately funded and are not covered by standard health insurance in the Netherlands¹.

29. The OMC was set up to control the quality of cannabis used for medicinal use and to promote the development of licensed medicines. It now uses income from export and the sale of products to fund further research. In the UK, we have also set standards for medicinal products and are encouraging research through the NIHR calls.

30. The OMC provides a two-hour training course and guidance. In the UK, Health Education England has issued a training package, which is available to all UK healthcare professionals and NICE has been asked to develop further clinical guidelines, which is expected by November 2019.

31. We consider the current UK regulatory regime is a proportionate one which allows for patient access to medicinal cannabis where there is a clinical need that has not been met by licensed medicines.

32. As with all new laws, we will keep its impact under review and we will continue to learn from the Netherlands and other countries that have legalised cannabis for medicinal use.

¹ Health insurers in the Netherlands are not automatically allowed to provide cover for any new medicine that comes onto the market. The Ministry of Health, Welfare and Sport and the Healthcare Institute of the Netherlands decide what drugs fall under the standard health insurance package. Registered medicines have to be assessed (in Dutch) before they can be included in the Medicines Reimbursement System (GVS). Medicines listed in the GVS are fully or partially reimbursed by health insurers.

Current guidance and education

Recommendation 8. The National Institute for Health and Care Excellence (NICE) should take account of patient voices in its creation of guidelines for medicinal cannabis by allowing patient groups the opportunity to comment on the draft guidelines and receive a response to those comments from NICE. (Paragraph 91)

33. The NICE Guideline Committee consists of practitioners, professionals, care providers, commissioners and lay members and is tasked to review the evidence and make recommendations. The Government and NICE has actively encouraged all interested patients and patient groups to engage with the consultation process and register as stakeholders.
34. NICE has consulted and received comments from a range of stakeholder, including patient groups on all stages of development of its guidelines on cannabis-based medicines. Responses to these comments are published on the NICE website. NICE ran a public consultation on its draft guidelines and evidence review between 8 August - 5 September 2019. NICE will carefully consider all responses with a view to publishing final guidelines in November 2019. Further information is available on the NICE website at: <https://www.nice.org.uk/guidance/indevelopment/gid-ng10124/documents>

Recommendation 9. We welcome the e-learning modules being prepared by Health Education England (HEE). HEE should keep the e-learning modules under review and ensure that they take feedback from clinicians and relevant organisations on their impact and make sure that clinicians are aware of the modules. (Paragraph 92)

35. The Health Education England (HEE) e-learning module was published on 8 August 2019. This is available to all healthcare professionals in the UK. Healthcare professionals can register on the HEE website at: <https://www.e-lfh.org.uk/programmes/cannabis-based-products-for-medicinal-use/>
36. The modules can easily be updated to take account of new evidence or information and it is intended that this will be done on at least a quarterly basis. A communications plan to accompany the publication of the modules was developed to raise awareness of this important new resource.

Recommendation 10. We recommend that the Department of Health and Social Care should take steps to secure long-term international deals to ensure a consistent supply of CBPMs so as to ensure that patients are not delayed in receiving their prescriptions and the cost of the medicinal cannabis products are kept as low as possible. Baroness Blackwood has indicated that the Department is working with industry on establishing supply. We welcome this work and further recommend that the Department work with other governments, devolved and abroad, to make a more collaborative and attractive deal for industry. We expect to hear from the Department what success it has had in this area by the beginning of 2020. (Paragraph 93)

37. DHSC and Medicines and Healthcare products Regulatory Agency has met with a number of producers of CBPMs to establish supply in the UK. There are a range of producers and products available as imported 'special' medicines that meet the quality standards we rightly expect in the UK.
38. A list of licensed UK wholesalers and products has been made available to NHS Procurement Pharmacists and will be updated as new products become available.
39. Further work on establishing a stable UK supply will be undertaken. NHSE-I will work with suppliers to ensure that sufficient stock of good quality CBPMs are available and that these products offer the best value for the NHS. This work will include scoping options for UK manufacturers.

Recommendation 11. NHS England should encourage providers to make their prescribing structures known and transparent to ensure that clinicians are aware of the possible barriers they face and how to tackle them. We recommend that following its process review, NHS England should issue targeted guidance to practitioners and pharmacists explaining the procedure for prescribing and supplying cannabis-based products for medicinal use in humans. (Paragraph 94)

40. Following publication of the NHSE-I process review report, the National Medical Director and Chief Pharmaceutical Officer for England will write again to doctors and pharmacists reminding them of the General Medical Council guidance on the prescribing and use of unlicensed medicines - and to further clarify the procedure for prescribing and supplying CBPMs.

CCS0819924472

978-1-5286-1587-7