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Health and Social Care Committee

Drugs policy: medicinal cannabis

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Health and Social Care Committee

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Summary

The plight of children affected by intractable epilepsy and the efforts of the families of Alfie Dingley and Billy Caldwell to access to medicinal cannabis led to a change in Government policy. In November 2018 medicinal cannabis was changed from Schedule 1 to Schedule 2 of the Misuse of Drugs Regulation 2001, allowing specialist doctors to prescribe it and for products to be available for further research to be conducted.

This rescheduling was widely welcomed but there was a failure to communicate what this would mean in practice for the availability of medicinal cannabis. Expectations were raised that these products would become widely available and there needs to be far clearer communication that this is not the case.

Very few prescriptions have been issued for medicinal cannabis since the rescheduling in November 2018. This is because most of these products are not licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA) and neither have they been approved by the National Institute for health and Care Excellence (NICE).

There are major gaps in the research base for medicinal cannabis in part because research was very difficult under the previous scheduling. There were restrictions on accessing products to conduct the robust clinical trials necessary to test efficacy and safety. Without a thorough research base products remain unlicensed and may only be prescribed if the individual prescribing doctor is satisfied that there is sufficient evidence for the product's safety and efficacy for an individual patient.

We are deeply sympathetic to families who want to be able to use medicinal cannabis to treat their children and who have seen individual benefit but are unable to obtain the product here in the UK. There needs to be a sense of urgency to explore the potential of medicinal cannabis in these conditions so that there is a robust research base on which to base future clinical decisions. We also call on the Government to desist from confiscating prescribed medicinal cannabis obtained overseas under specialist supervision.

Randomised double blind controlled trials (RCTs) are the gold standard for research and we are fully supportive of the need for patients to have the opportunity to take part in robust research trials. These trials are also important in order to provide evidence for licensing purposes and for NICE assessment. We also call on the NIHR to engage with patients and their representatives on additional suggestions for improving the evidence base.

Medical products are usually developed by industry as they stand to profit from investing in the research. However, in the case of medicinal cannabis, this is not happening in part because of the difficulty in obtaining patents for medicinal cannabis products. The call for research proposals by the National Institute for Health Research demonstrates that the public sector is taking the lead in this area but it is also important for industry to be more involved in developing medicinal cannabis products and supplying products for research.

There is potential medicinal benefit to cannabis-based products but the gaps in the research base mean that we do not know where this sits alongside other therapies. The Government should focus efforts in facilitating research especially in those areas where there is greatest patient need, as in the case of children with intractable epilepsy. We heard arguments that the small numbers of patients makes it difficult to conduct double blind RCTs but the Chief Medical Officer argued that if treatments are highly effective then this can be demonstrated with smaller numbers and that trials can be discontinued early in order that all participants can benefit.

The UK needs to do more to learn from international best practice. We reiterate the importance of the UK being able to take part in multi-centre international research and post marketing surveillance. Some have argued that double blind RCTs are inappropriate for cannabis research but we do not support making an exemption for this class of medicines.

Current and future patients could benefit greatly from a swift move to carry out robust research into medicinal cannabis products. We call on the Government to support the research community and industry to take this forward.

1 Introduction

1. Last year, the distressing cases of Alfie Dingley and Billy Caldwell caused a public outcry following the experience of their families in trying to obtain supplies of medicinal cannabis products. This prompted the Government to review the regulation of medicinal cannabis. Alfie and Billy both suffer from severe forms of epilepsy that are resistant to conventional treatments and their experiences with medicinal cannabis suggested that these products could help with reducing their seizures. Following expert medical advice, the Government rescheduled medicinal cannabis to relax some of the restrictions to its use. Where previously medicinal cannabis was kept under the strictest of regulations, which made research and obtaining these products difficult, medicinal cannabis products can now legally be prescribed by some specialist doctors.

2. These changes and the failure to be clear about who might then be able to access medicinal cannabis on prescription, raised public expectations and led to many groups feeling let down. Parents of other children suffering severe and intractable epilepsy have continued to face barriers in obtaining medicinal cannabis.

3. It was against that background—and with those children, and others hoping for new treatments for a variety of severe and debilitating illnesses, in mind—that we announced our inquiry into the use of medicinal cannabis.

The rescheduling

4. In November 2018 medicinal cannabis was rescheduled from Schedule 1 to Schedule 2 of the Misuse of Drugs Regulation 2001. The rescheduling recognised that medicinal cannabis has some therapeutic benefit. The rescheduling followed a two-part review conducted by the Chief Medical Officer (CMO) and the Advisory Council on the Misuse of Drugs (ACMD). The rescheduling of a drug under the Misuse of Drugs Regulation 2001 relates to the legality of certain activities with the drug such as manufacturing, supplying and possessing the drug. The rescheduling of medicinal cannabis allowed the products to be more available for research and prescribing.

5. The CMO conducted a review of the evidence base for medicinal cannabis and in June 2018 concluded that there is "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".[1] Those conclusions allowed her to recommend that medicinal cannabis be considered for rescheduling.

6. In July 2018 the ACMD recommended that a definition of "cannabis-derived medicinal product" be developed, and products meeting this definition be rescheduled. It was after this part of the review that the Government rescheduled medicinal cannabis on 1 November 2018 and provided a definition for cannabis-based product for medicinal use in humans (CBPM).

7. Medicinal cannabis is derived from the cannabis plant and contains more than a hundred chemical compounds called cannabinoids.[2] The two most widely-used

1 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/722010/CMO_Report_Cannabis_Products_Web_Accessible.pdf

2 House of Commons Library: Medical use of cannabis

cannabinoids are cannabidiol (CBD) and tetrahydrocannabinol (THC). Each medicinal product will have a different ratio of CBD to THC, as well as other cannabinoids.[3] Different compositions may be more effective for some individuals than single compounds.[4] Each product will have its own benefits and risks, and these are best established through further research.[5]

8. Medicinal cannabis has been used to try to treat a range of medical conditions and symptoms including chronic pain in adults; chemotherapy induced nausea and vomiting; multiple sclerosis spasticity syndromes; and intractable epilepsy.

9. Few CBPMs are currently available. Sativex, for the treatment of Multiple Sclerosis symptoms, is the only licensed CBPM in the UK, but it is not considered to be cost-effective by the National Institute for Health and Care Excellence (NICE). Consequently, Sativex is not a regularly prescribed product on the NHS in England but is available on prescription in Wales.[6] Epidiolex is close to being granted a licence by the European Medicines Agency, which would also grant it a licence in the UK.

10. Most CBPMs are unlicensed products. They have not been assessed by the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA) for their safety or efficacy. However, doctors can still prescribe these products if they believe it is medically appropriate. Under the current regulations, an unlicensed medicinal cannabis product can only be prescribed by a specialist doctor on the Specialist Register of the General Medical Council.

Our inquiry

11. In December 2018 we set out to look at the issues around medicinal cannabis. Our terms of reference asked for evidence on:

- The current evidence base for medicinal cannabis
- Plans and challenges for future research
- Current prescribing procedures
- Guidance and knowledge of practitioners regarding medicinal cannabis
- Public opinion and behaviours in the UK.

We heard of a number of issues from different groups. Campaign and patient groups told us about the issues around obtaining products, conducting trials and the various forms of evidence for medicinal cannabis. We also heard that the key issue for clinicians was the lack of a research base into medicinal cannabis products and the issues around off licence prescribing. The research and evidence gap needs to be addressed to determine whether and if so which patients could benefit from CBPMs, and their place in treatment options.

3 Q33
4 Q33
5 GW Pharmaceuticals (DMC0090)
6 MS Society (DMC0064)

2 Public opinion and communications

12. The rescheduling of cannabis-based products for medicinal use in humans (CBPM) on 1 November 2018 from Schedule 1 to Schedule 2 has been welcomed by patients and their families.[7] The rescheduling recognises that there is a therapeutic benefit to cannabis-based products.

13. Following the change from Schedule 1 to Schedule 2, it is now easier to carry out research into such products.[8] Products in Schedule 1 are deemed to have no therapeutic benefit and cannot be obtained and stored by researchers without a Home Office licence. Medicinal cannabis is now in Schedule 2, which allows researchers access to medicinal cannabis products without a Home Office licence. The products in Schedule 2 are still strictly controlled and subject to special requirements relating to their prescription, dispensing, recording and safe custody.[9]

14. Medicinal cannabis is not readily available as the vast majority of products are unlicensed. Patient and families' expectations were raised when medicinal cannabis was rescheduled.[10] The rescheduling was influenced by high-profile cases,[11] but there was poor communication from the Home Office and Department of Health and Social Care about who would be able to access CBPMs in practice. Many people believed that CBPMs would be easily available for a wide range of conditions.[12] The media attention around the subject added to these expectations. The Cambridge University Trust Hospital said:

> Following changes in the scheduling of CBMP in November 2018 we have observed a noticeable increase in requests for CBMP that we receive in our clinical practice. Parents of children with a variety of epilepsies and/or spectrum of disease burden have requested the drug. Unfortunately, parents often have a number of misperceptions about the effectiveness and tolerability of CBPMs. In many cases this seems to reflect the gaps in the media attention around CBMPs.[13]

15. The high-profile nature of the rescheduling and well-known cases have led to misinformation, whereby the public believe CBPMs work in several areas where the evidence to support this is lacking. As the Royal College of Physicians told us, "there is a perception that CBMPs work in areas where there is little or no evidence and some patients feel they are being denied access to an efficacious drug."[14]

16. The raised expectations also had an impact on patient-doctor relationships, as patients expected ready access to prescriptions. The expectations have led to increasingly difficult relationships between doctors and patients where, as consultant psychiatrist Dr Imran Malik told us, doctors are having to "thrash" patients' hopes.[15] Doctors are having to spend time clarifying misconceptions about access to CBPMs, which has led to both

7 Epilepsy Action (DMC0061)
8 Q222
9 House of Commons Library: Medical use of Cannabis
10 All-Party Parliamentary Group on Medical Cannabis under Prescription (DMC0050)
11 Q210
12 Royal College of Physicians (DMC0034)
13 Cambridge University Hospitals NHS Trust (DMC0053)
14 Royal College of Physicians (DMC0034)
15 Q100

public mistrust in the regulatory system and angry patients.[16] We heard Professor Helen Cross, The Prince of Wales Chair of Childhood Epilepsy at UCL Institute of Child Health, Great Ormond Street Hospital, say that:

> With the initial announcement in July last year, and then the subsequent change in legislation and the announcements in November, there came a real expectation on the part of the families, and not just the 16 families we have heard about but every family in my clinic, that we could just prescribe it. It was a natural treatment, and therefore that is what they wanted because it was different from what they were on. Probably 70% to 80%, if not more, of my clinics now are taken up with explaining the position.[17]

17. The NHS website is a resource for information on CBPMs. However, it is not always easy for clinicians to refer patients to a website. We heard that clinicians do not have a comprehensive patient information leaflet summarising accurate information, as the previous British Paediatric Neurology Association (BPNA) leaflet has been withdrawn.[18] It would be helpful if doctors had an agreed and consistent resource to hand out to patients.

18. We heard that the Government needed to communicate the reality of the rescheduling better. Professor Finbar O'Callaghan, president of the British Paediatric Neurology Association, told us:

> When the Home Secretary announced the intention to reschedule the products, there was a lot of good publicity surrounding that statement. What was then needed was communication with the public about exactly what that meant; that it did not mean that these products were now going to be freely available to be prescribed on the NHS, because that is not the case, and it did not mean that clinicians in particular areas were necessarily going to think it appropriate to prescribe these products, given the evidence base. There could have been some management of how that was dealt with at the time.[19]

19. It is apparent that the Government did not have a communications plan to ensure that the public and patients were not misinformed about the availability of CBPMs. The Government should have recognised the high-profile nature of the rescheduling and the possibility for the move to be misinterpreted. Whilst the Home Office Minister said he " … would be very sensitive to any charge that we over-egged expectation as a Government",[20] it is apparent that the Government did not manage the expectations of the public. The Government made a concerted effort to emphasise that recreational cannabis was not being legalised but failed to communicate important points about the availability of what it *was* rescheduling. Patients and their wellbeing should be at the forefront of considerations when decisions are made and in this case, it was patients and their families who felt the repercussions of the Government's poor expectation management.

20. There has also been poor communication since the rescheduling. Once it became apparent that there was a degree of misunderstanding about the rescheduling, it would

16 Royal College of Physicians (DMC0034)
17 Q104
18 Cambridge University Hospitals NHS Trust (DMC0053)
19 Q140
20 Q211

have been feasible for the Government to step in to clarify the situation. Whilst clinicians have been issued guidance in the interim by their professional bodies, the Government has done little to correct the widespread misconceptions regarding CBPMs. Patients have had their expectations raised unfairly and doctors are handling the backlash of poor Government handling.[21]

21. The situation remains that the vast majority of CBPMs are unlicensed and are therefore subject to stringent prescribing regulations. Under the current regulations, CBPMs can only be prescribed by a specialist doctor on the General Medical Council's (GMC) register. Prescribing unlicensed products is often referred to as "off-licence" or "specials". The GMC's guidance on prescribing unlicensed products requires doctors to:

a) Be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy

b) Take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so

c) Make a clear, accurate and legible record of all medicines prescribed and, where they are not following common practice, their reasons for prescribing an unlicensed medicine.[22]

In the first instance, doctors must be satisfied that there is a sufficient evidence base for prescribing the unlicensed product. If there is an insufficient evidence base, doctors are reluctant to prescribe knowing that they are taking personal responsibility for doing so and that there could be serious professional and legal consequences if there are adverse outcomes for their patient. Prescribing a product without a clear evidence base and on the basis of anecdote can be harmful to patients and the history of medicine has numerous examples of interventions that were introduced with the best of intentions but later turned out to be harmful.

Conclusions and recommendations

22. 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.

23. **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.**

21 Royal College of Physicians (DMC0034)
22 General Medical Council (DMC0071)

3 Current evidence base

24. The Chief Medical Officer's (CMO's) report reviewed the evidence on the therapeutic benefits of CBPMs. She found that there is evidence, though contested, for the use of CBPMs in the following conditions: chronic pain in adults; chemotherapy induced nausea and vomiting; multiple sclerosis spasticity syndromes; and intractable epilepsy. The report also found areas where there is limited or no evidence that CBPMs are effective.

25. The CMO's report contains a number of caveats and nuances because of conflicting conclusions about the evidence. For example, the CMO's review records that the US National Academies of Sciences, Engineering and Medicines do not think there is sufficient evidence for the use of CBPMs in intractable epilepsy, whereas the Australian and Irish studies did find sufficient evidence.[23]

26. Based on her report, the CMO recommended that cannabis-based medicinal products be moved to Schedule 2 of the Misuse of Drugs Regulations 2001, which allows research to be carried out into these products, and enables them to be prescribed by specialist doctors. The CMO's report sets the background to the dilemma for those clinicians who are not confident to prescribe these products off-licence.

Research into CBPMs

27. A more appropriate summary of the of the evidence base of CBPMs within each discipline is available in the clinical guidance produced by the Royal College of Physicians, Association of British Neurologists and British Paediatric Neurology Association.[24] The evidence has not led to more products being licensed as the evidence is not robust enough to demonstrate safety and efficacy for licencing purposes and companies have not used the existing evidence to make successful licensing applications.

28. For licensing purposes, companies who carry out the research present the findings of the research as evidence for the benefits and safety of the product, after which the medicines regulator will decide whether or not it is safe and efficacious enough to be licensed. GW Pharmaceuticals outlined what a licensed product ensures:

> Approval from a medicines regulator ensures the safety, quality and efficacy of a medicine. This will provide prescribers with a robust evidence base (on which its approval is based) to inform clinical decisions and includes: safety data to protect human exposure; strong efficacy and safety data from clinical trials in the target patient populations; and a medicine of a consistently high quality which has been produced in an audited manufacturing plant, to reliable manufacturing and quality standards, with clear guidance on labelling and dosing.[25]

Licensing medicinal cannabis products would bring forward important information for clinicians to consider when prescribing.

23 Q5

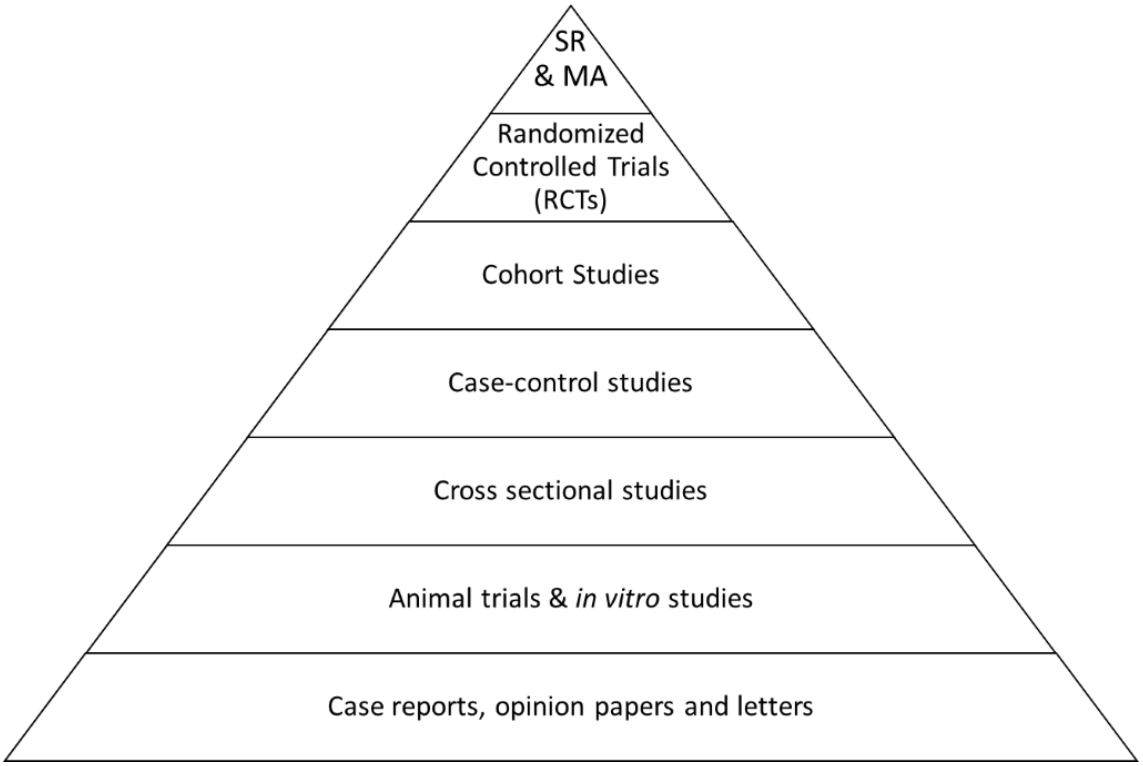
24 https://www.rcplondon.ac.uk/projects/outputs/recommendations-cannabis-based-products-medicinal-use https://www.theabn.org/media/Documents/ABN%20publications/ABN%20guidelines%20Use%20of%20cannabis-based%20products%20in%20neurology%20December%202018%20v2.pdf https://www.bpna.org.uk/userfiles/BPNA_CBPM_Guidance_Oct2018.pdf

25 GW Pharmaceuticals (DMC0090)

29. Products that are licensed are also required to undergo assessment for cost-effectiveness by NICE if they are to be routinely prescribed by the NHS. If a product is assessed to be cost-effective, NICE will recommend it, after which these products will usually be available on NHS prescription. The research into and evidence for the efficacy of a product are important factors in NICE's appraisal system.

30. One of the debates we heard throughout our inquiry was what type of evidence should be accepted to demonstrate the efficacy and safety of CBPMs. The CMO told us that "the only way we can get it licensed is through doing randomised controlled trials."[26] There is a clear hierarchy of evidence when it comes to licensing. It is accepted that randomised controlled trials are one of the best forms of evidence from a clinical trial and the "gold standard" in evidence.[27]

Figure 1: Pyramid of hierarchy of scientific evidence.[28]



SR: Systematic review

MA: Meta-analysis

31. A double-blind randomised controlled trial is a study in which a number of similar people are randomly assigned to groups to test a specific treatment. One group has the intervention being tested, while the other group takes a dummy treatment (placebo). The groups are assessed at specific times and any differences are recorded statistically. In such a trial, the researchers and the patients do not know who is on what treatment, therefore reducing bias. Randomised controlled trials are also important in understanding the place of a new treatment alongside existing treatments. An open-label trial is that where the researchers and the patients are aware of the treatment being given. Randomised controlled trials are necessary for licensing purposes as they are objective measures of

26 Q10
27 Q33
28 GW Pharmaceuticals (DMC0090)

safety and efficacy.[29] While other methods of evidence in the graphic above can provide valuable information for clinicians making a judgement, these forms of evidence do not suffice for a licence.

32. Other witnesses took a different view and told us that they felt randomised controlled trials were not the most appropriate method of approaching CBPMs. Peter Carroll, Campaign Director at End Our Pain, told us:

> We have to take a broader view of the evidence, because there is a point where multiple anecdotal stories build up to a pattern of evidence, and it seems absurd to me that we have to wait three, four or five years for trials to be produced when there are real-life cases now.[30]

Anecdotes or isolated stories of success do not amount to evidence that can be used to license a product. However, anecdotes may be useful in identifying areas where more thorough research could be carried out.[31]

33. However, we also heard that anecdotal and open-label trials do not provide a rigorous enough evidence base. Professor O'Callaghan told us:

> 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.[32]

34. Anecdotes do not allow researchers to assess the true impact of the products and their place compared to existing treatments. The most efficient way of ensuring that patients in the future have access to CBPMs is for them to be subject to research and to be licensed.

35. One of the explanations provided for the lack of randomised controlled trials in CBPMs is that it is inherently difficult to carry out such trials into medicinal cannabis products. Professor Mike Barnes, Chair of the Medicinal Cannabis Clinicians Society, said:

> Cannabis is a plant and it does not lend itself very well to the standard pharmaceutical approach. It is not a single molecule that we can compare against a placebo. There are over 2,500 varieties of cannabis, each with a different structure of cannabinoids and terpenes, each with subtle differences. Which one would you pick for the standard pharmaceutical model?[33]

36. We heard that trials do not necessarily have to have a large number of patients for the trial to produce good quality evidence.[34] We further heard from the CMO that *if* a drug performs very well in a trial, the trial does not have to continue. She said:

29 Q160
30 Q33
31 Q161
32 Q149
33 Q33
34 Q95

> Modern, good trials have a blinded data management committee who regularly review the data, and if it is clear that it is harmful, or that it is an advantage, you break it and you stop there, and then you, of course, ethically provide the drug to the rest of the people who were in the trial and not taking it. I would think that was the right way to do the trial and the best way to get to the right answer.[35]

If medicinal cannabis products are trialled and found to be clearly efficacious, the trial can be concluded quickly. This should provide encouragement to those who believe they can demonstrate clear advantages of medicinal cannabis to conduct trials.

37. We also heard that the side effects of cannabis are generally well known as cannabis has been used for a sustained period. Professor Mike Barnes told us:

> […] cannabis is rather different in the sense that it has rather a lot of experience over thousands of years. It is not something that has come on to the street in the last few decades. In this country today, about 3 million people take cannabis, of which 1 million take it for medical purposes—1 million people. That is an accumulated great experience, so we know an awful lot about potential side-effects. If some awful side-effect was going to emerge, it probably would have emerged by now.[36]

38. Whilst illegal street cannabis may have been used for many years, medicinal grade cannabis-based products have not been used for a substantial period of time. Street cannabis is generally high in tetrahydrocannabinol (THC) and of inconsistent quality.[37] Street cannabis high in THC is known to damage the developing brain.[38] While street cannabis may have a long history, medicinal grade cannabis has a relatively short history of being used to target specific medical conditions and side effects should be evaluated in the context of medicinal use.

39. The history of medicine contains many examples of products and procedures assumed to be so beneficial that they should be introduced without rigorous research, only for them to be later withdrawn because they turned out to be harmful.

40. The CMO pointed to an example: there had been a widespread assumption that steroids would help reduce brain swelling (oedema) and reduce harm after head injury. Doctors regularly gave steroids to head trauma patients before a randomised controlled trial was eventually conducted "and the outcomes were worse if you give steroids."[39]

41. There is ongoing controversy around the evidence base for CBPMs. One argument put forward during our inquiry was that there is plenty of research and evidence across the world which the UK should take account of. Professor Mike Barnes told us:

> At the moment, there are 128 trials of cannabis ongoing worldwide. We should not forget that other jurisdictions—sensible jurisdictions, if I can use that word—Canada, Australia, Germany and other European countries, such as Denmark, have introduced cannabis legislation and allowed doctors

35 Q7
36 Q35
37 Q34
38 Q34
39 Q19

> to prescribe, and they are prescribing with more freedom than we are here. I think we are a little bit obsessed with UK-based evidence. We need to take into account global evidence.[40]

42. We welcome the large number of trials being undertaken. Whilst the CMO's review and the professional guidance did take account of the existing international evidence, we endorse the call for further research to be prioritised. It is the quality of the trial and the evidence that is being presented by the company which influences licensing decisions rather than the country in which it is conducted. The Government should work with other countries to facilitate and encourage research that demonstrates the safety and efficacy of medicinal cannabis.

43. The British Paediatric Neurology Association told us that there is no randomised controlled trial data within childhood epilepsy that demonstrates that the addition of THC confers any added medical benefit and there is no adequate safety data concerning products that contain THC.[41] The Association of British Neurologists said that there is good evidence for the use of cannabidiol (CBD) in two complex epilepsy syndromes - Dravet and Lennon-Gastaut syndrome.[42] The Royal College of Physicians told us that there is also good evidence that CBPMs are effective in preventing chemotherapy-induced nausea and vomiting, but they have a high side effect profile and there are more efficacious agents available.[43] In the treatment of chronic pain, Professor Andrew Goddard, President of the Royal College of Physicians, told us there is a "weak" suggestion of its efficacy. He told us:

> You would need to treat 24 people in order to see benefit in one person. When it comes to the harms of those drugs, you only need to treat six people to see significant harms.[44]

44. The vast majority of evidence that we have received from clinicians told us that there is a weak evidence base for CBPMs in general.[45] We cannot ignore the conclusions that clinicians have come to. If clinicians feel that the evidence base is not strong enough for them to prescribe the product, the focus must be on generating sufficient evidence.

45. A further issue with the current evidence base for CBPMs is that there is limited evidence on how they interact with other drugs. Professor Helen Cross told us that "even a small amount of cannabidiol may interact with liver-metabolised drugs."[46] Dr Imran Malik from the Royal College of Psychiatrists also explained:

> For example, day in, day out, I see patients who have epilepsy but have mood disorders associated with that. When we are to prescribe whatever form of medicinal cannabis we get approval for, we do not have any drug interaction information available to us. In real life, they are on multiple drugs, so they would be on antidepressants, antipsychotics or a number of

40 Q65
41 British Paediatric Neurology Association (DMC0087)
42 Association of British Neurologists (DMC0017)
43 Royal College of Physicians (DMC0034)
44 Q152
45 Association of British Neurologists (DMC0017) Faculty of Pain Medicine of the Royal College of Anaesthetists (DMC0032) Royal College of Physicians (DMC0034) Dr Ruth Williams (DMC0039) Cambridge University Hospitals NHS Trust (DMC0053) Dr Sophia Monica (DMC0063) Professor J Helen Cross (DMC0065)
46 Q105

> other physical health-related medications. As a clinician, when I stick my neck out to prescribe something that does not have a licence, I still do not know what the interactions are.[47]

It is explicit in the GMC's guidance Good Medical Practice 2013 that in providing clinical care a doctor must "check that the care or treatment you provide for each patient is compatible with any other treatments the patient is receiving, including (where possible) self-prescribed over-the-counter medications".[48] Until data on how CBPMs interact with other drugs is available, it would contradict the GMC's guidance if clinicians were encouraged to prescribe CBPMs without being confident about the way the prescribed products interact with other drugs.

Current evidence base: conclusions

46. It is clear there is not a firm evidence base for those CBPMs which were rescheduled in November 2018. It is critical that the Government and industry should work to further the evidence base in order to improve the confidence of doctors who can begin to prescribe CBPMs and also allow the products to be licensed. Specialist centres can play an important role as they are a valuable resource in bringing together expert clinicians and patients with complex conditions. We support the case for specialist centres to be able to lead on building the evidence base.

47. We are very mindful of the plight of children living with severe and intractable epilepsy, who are already on powerful drugs which may not be licensed in the age groups or for the specific conditions where they are being used. We heard about the specific case of Jorja Emerson, who is receiving medication that her father told us was not appropriate for her age at the time it was first prescribed.[49] We are deeply sympathetic towards the struggle of patients and their families who see others being treated with CBPMs whilst not being able to obtain it themselves.

48. There needs to be a sense of urgency on the part of the Government, industry and clinicians in responding to children with severe and intractable epilepsy. We are aware of research proposals submitted and being prepared.[50] These proposals need to be prioritised so that all children with these conditions can access clinical trials of CBPMs through specialist centres. Additional trials have a dual benefit of furthering the evidence base and allowing patients in the trials to access therapies which may treat their condition. We encourage paediatric neurologists and other specialists to help families access appropriate clinical trials. Patients and their families are remarkably well informed with regard to the publicly available information and published research in this subject area.[51] Clinicians should take advantage of their knowledge and keenness to be involved in furthering the evidence base.

49. While we fully support the proposed Randomised Control Trials and calls for them to be started as a matter of urgency, we believe that other means of gathering evidence must also be investigated. RCTs can take up to 4 years to complete. Furthermore, the nature of RCTs is that some patients may be required to take a placebo, which, in some

47 Q101
48 General Medical Council (DMC0071)
49 Mr Robin Emerson (DMC0098)
50 Professor J Helen Cross (DMC0065)
51 Mr Robin Emerson (DMC0098)

cases, could mean existing patients being taken off their current treatment with CBPMs which are giving them relief from their symptoms. It is unlikely that a patient or parent would be willing to accept this. Nor should they have to.

50. The parents and clinicians who supported them made an impassioned argument for observational trials to be conducted alongside RCTs. **We call on the National Institute for Health Research to engage fully with these parents and clinicians to discuss their proposal and explore all ways to improve the evidence base.**

51. It is important that clinicians and researchers retain the confidence of patients and their families. Faith in the role and importance of research will be undermined if clinicians are unwilling to participate and to make sure that children can take part in clinical trials. The rarity of some of the conditions that medicinal cannabis is used to treat makes it additionally important that all those who could take part are facilitated to do so. Clinicians and relevant bodies should endeavour to keep patients and their families informed of the importance of research trials in ensuring their safety, whilst making every effort to update patients about trials they can participate in.

Barriers to research

52. As mentioned previously, we welcome the Government's decision to move medicinal cannabis from Schedule 1 to Schedule 2. This will help facilitate much needed research. Products in Schedule 1 are judged to have no therapeutic benefit and used mainly in research under a Home Office licence. Moving CBPMs to Schedule 2 allows the product to be more available for researchers and prescribers, but still under special requirements. We also welcome the National Institute of Health Research's (NIHR) call for research proposals. The call for proposals was initiated alongside the rescheduling. Successful applications could be expected to start trials in Summer 2020.[52]

53. Whilst we welcome the call, we call on those involved to prioritise and aim to expedite this process for clinical trials into intractable childhood epilepsy. There needs to be a greater sense of urgency in the response to the plight of those children living with intractable epilepsy and to make sure that their families can all access clinical trials of CBPM. The evidence gathered by our inquiry highlighted a number of additional barriers facing research in this area that need to be recognised if research is to be carried out widely and quickly.

54. There are a number of conditions where research is needed to establish the place of CBPMs. These include, but are not limited to: epilepsy; chronic pain; chemotherapy induced nausea and vomiting; multiple sclerosis; fibromyalgia; Tourette syndrome; anxiety and posttraumatic stress disorder; and palliative care. The Chief Medical Officer's review identifies these, along with other conditions where the value of medicinal cannabis has been explored.

55. One of the barriers to research is that industry is not always prepared to supply products for research trials to those clinicians or organisations proposing to carry out those trials. We heard throughout our inquiry that some pharmaceutical companies were not willing to provide their product for trial.[53] Professor Helen Cross told us of her

52 Department of Health and Social Care (DMC0020)
53 British Paediatric Neurology Association (DMC0087)

experience of being in discussion with one particular company where it has taken six months to persuade them to supply, and the company have been known to pull out of trials early.[54]

56. Professor Helen Cross suggested a possible reason why some companies do not submit their products to randomised controlled trials:

> I think there is a plan for some of them to engage in trials but there is also a belief that there is lots of money, and that they do not need to do the trials because it is just going to be prescribed and therefore it is going to be okay. There are one or two companies that are discussing with us about doing the trials, but they cost a lot of money, and are they going to get their licence at the end? If it is going to be prescribed anyway, they may or may not need to. If they are based in countries where it is all legalised, they may not feel that they need to do that.[55]

57. We appreciate that it is not all pharmaceutical companies who bring this attitude, but it is unacceptable that some are behaving this way. Industry's lack of engagement is one of the reasons why there is a lack of robust international evidence. The British Paediatric Neurology Association suggested that:

> The manufacturers of the CDMPs may not be willing to provide their product for analysis in robust RCTs. There is evidence from other countries that manufacturers have been reluctant to facilitate RCTs in the past and this may be why there are no RCTs of these products (with the exception of Epidiolex) in the scientific/medical literature.[56]

58. A further barrier to research is that pharmaceutical companies do not want to carry out the necessary research themselves to achieve a licence. In part, this reflects the difficulties in obtaining a patent for CBPMs as the chemical compound can be difficult to patent. However, there are few incentives for drug companies to go through the licensing process, especially if any products they produced could be rapidly produced and sold by other companies. Companies may also not want to carry out research because randomised controlled trials can be expensive to carry out. The National Institute for Health Research (NIHR) call for research proposals demonstrates that public money is being invested into research. This is against the norm as it is private companies who stand to profit from conducting research and achieving a licence. The Chief Medical Officer told us:

> Randomised controlled trials are the only way to get these drugs licensed and they would normally be funded by the industry. It is time that the industry started to say what they are going to do about funding trials to get the licences so that patients can have access. This cannot be just left to the public sector.[57]

As suggested above, it may be that industry does not want to invest the money into research itself as they believe their products will soon be prescribed anyway.

54 Q96
55 Q110
56 British Paediatric Neurology Association (DMC0087)
57 Q3

59. We heard throughout our inquiry that there are a vast range of CBPMs. It would not be feasible to attempt research into every single product. Professor Goddard told us:

> As I said earlier, we need to focus on a very small number of products. If you are trying to choose from 50-odd different types of cannabis, it will get confusing and will take much longer to get some answers. You look at some pure CBD, CBD with a little bit of THC, and CBD with a bit more THC; then you focus on specific areas. That might be, for example, looking at pain in patients with fibromyalgia or patients with multiple sclerosis. If you try to do too many things, it is going to take much longer and we will not get a clear answer, so we have to be very focused.[58]

By focusing research on certain products, there is a greater likelihood of these products rapidly gathering an evidence base, thereby improving the availability for patients.

60. It is unfair on patients and their families if they are asked to wait years for research to be conducted and for clinicians to prescribe. Families are seeing CBPMs being used in others and feel that they are being denied potentially efficacious treatment. This sentiment is driving families abroad to source these products themselves. Peter Carroll told us:

> Dame Sally Davies herself said that we have to wait maybe three or four years before that kind of high-quality, gold-standard data is with us. How do you explain that to the parent sitting behind me now who is—and you may disapprove of this—sourcing a full plant extract cannabis, bringing it into the country and treating her child with it, and the child has improved dramatically?[59]

We should not be treating patients or their families who are resorting to bringing medication here from abroad because they cannot obtain it on prescription here as if they are committing a criminal offence. Neither should patients have their medication confiscated, as happened recently to the mother of Teagan Appleby. We are pleased that following the outcry in Parliament and beyond, the medication was subsequently restored to Teagan's family. This cruel practice must not happen again.

61. We were told of examples where the use of CBPMs has benefitted a patient. Peter Carroll said:

> I showed them [BPNA] the story of Alfie Dingley, who had 150 seizures a week, each potentially life threatening, and now goes 300 days without a single seizure, rides a bike and goes to school. Does he have to wait for a randomised controlled trial?[60]

Conclusions and recommendations

62. The current evidence base for the safety and efficacy of CBPMs is not extensive or robust but there are compelling examples in some particularly distressing and dangerous

58 Q172
59 Q33
60 Q33

conditions such as intractable childhood epilepsy which highlight the urgent case to clarify their place in treatment. Good quality research is required and circumventing this is unhelpful in the long run to future patients.

63. Individual cases highlight the potential benefit which CBPMs might bring, but individual cases do not amount to a strong enough evidence base for licences, or give clinicians and families the information on the best combinations of CBMPs and their place in treatment or allow an informed discussion of potential risks. Robust randomised controlled trials must be carried out as soon as possible. For highly effective treatments we heard that randomised controlled trials can demonstrate this with smaller numbers of patients and in a shorter time frame than is required for treatments with less marked benefits.[61]

64. We do not agree that randomised controlled trials should be set aside for cannabis. There are well rehearsed dangers in using anecdotal evidence. The Government and relevant organisations should focus on expediting and encouraging clinical trials. Carrying out clinical trials is the safest and most effective way of ensuring that patients gain access to the most appropriate medication.

65. There are a number of barriers to research into CBPMs. Industry's lack of willingness to provide their product and to carry out research themselves is a great concern. We also recognise that the chemical compounds and how patients with the same condition can react differently can make research challenging but not insurmountable.

66. We reiterate concerns expressed in our previous report, *Brexit: medicines, medical devices and substances of human origin*, about the future of collaborative research between EU member states. Now that the UK has changed the scheduling of cannabis to facilitate research it would be helpful to be able to participate in multi-centre pan European trials. The Government needs to set out how it will ensure that Brexit does not jeopardise opportunities for patients to participate in international clinical trials and post marketing surveillance.

67. **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.**

68. **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.**

69. **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**

61 Q95 Q7

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.

70. **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.**

71. **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.**

4 Current guidance and education

72. After the rescheduling in November 2018, the Government asked three professional organisations to issue clinical guidance to their practitioners. In line with the Chief Medical Officer's report, the Royal College of Physicians, the British Paediatric Neurology Association and the Association of British Neurologists were asked to issue guidance to their members. This guidance summarises the evidence base for the relevant areas and advises clinicians on how to proceed. The guidance is interim, and the National Institute for Health and Care Excellence (NICE) is expected to publish full guidance in October 2019.

73. We have heard that some see the guidance as a barrier to prescribing, arguing that it is too restrictive. Professor Barnes told us:

> The second barrier is the guidelines. I am sure that the Royal College of Physicians and the British Paediatric Neurology Association felt they were doing a good job in providing those guidelines. Personally, I think they are too restrictive, rather negative and focused on double-blind placebo-controlled studies, as we have heard, so I think producing guidelines that are a little bit more balanced is necessary.[62]

74. The Royal College of Physicians, British Paediatric Neurology Association and the Association of British Neurologists disagreed. They argued that their guidance is evidence-based and not a barrier to prescribing. Professor O'Callaghan said:

> Our guidance is evidence-based guidance. The evidence says what it says. You cannot expect us to distort the evidence or come to a different conclusion. We have just given you the evidence.[63]

75. The interim guidance, as well as the forthcoming guidance created by NICE, is advice, and not an instruction to prevent prescribing. Clinicians on the Specialist Register of the GMC are able to use their clinical judgement along with the guidance in making a decision on whether or not to prescribe CBPMs. If a clinician believes that prescribing a medicinal cannabis product will help their patient, they should not be discouraged by the guidance from doing so.

76. We heard that one of the barriers to prescribing CBPMs is the lack of familiarity with the product among clinicians. Professor Barnes said:

> The main barrier, to be honest, is education. There are bureaucratic barriers, but I think they can be overcome. I think most doctors do not want to prescribe because they do not understand the nature of cannabis. They do not understand what dose to give or in what format to give it. We can overcome that with an educational programme; there are one or two around at the moment.[64]

77. The British Paediatric Neurology Association felt that paediatric neurologists were well informed about medicinal cannabis. Professor O'Callaghan told us:

62 Q51
63 Q199
64 Q51

> In terms of childhood epilepsy, the paediatric neurology group are pretty well educated about the evidence that is out there. They are very interested in the area and have read just about all the papers that are out there. It is not a question of their not knowing what the evidence is, or that they are unaware that cannabis-based medicinal products may potentially be helpful.[65]

Professor Goddard of the Royal College of Physicians, on the other hand, told us that more education is welcome and will help doctors understand their patients' needs better.[66]

78. Whilst some specialist groups of doctors may be confident in their knowledge of medicinal cannabis and the evidence, other doctors in various fields may not be as well versed. The interim guidance gives specialist clinicians the basics of what they need to know regarding medicinal cannabis. However, patients may ask any doctor about medicinal cannabis, and it will be helpful in managing expectations if all doctors have a degree of knowledge about the subject.

79. We therefore welcome the e-learning modules being prepared by Health Education England. These modules are designed to raise awareness of the rules and evidence around CBPMs and build confidence in appropriate use and prescribing of CBPMs.[67] These modules begin the process of educating all healthcare professionals about medicinal cannabis.[68] This is a step in the right direction from the Government, which has recognised that it is important for all doctors to have a basic working understanding of CBPMs.

Prescribing procedures

80. There is a lack of clarity amongst some as to the procedure for prescribing unlicensed products. As most CBPMs are unlicensed, it is important that clinicians are able to navigate the governance structure to ensure that patients can access a product if it is prescribed. Robin Emerson, the father of Jorja Emerson, who has obtained a cannabis-based medicinal product, described some of the practical difficulties of obtaining a product:

> Once I got the prescription the next issue was getting the product imported into the country, as no one had done it before in a pharmacy. The hospital pharmacy had to get guidance in order to understand how to put the product on to their system. I knew the wholesalers who had brought medical cannabis in for Alfie Dingley and Billy Caldwell, so I was able to link them with the pharmacy. Unfortunately, I cannot yet get it to a community pharmacy as it has to be written on a different type of prescription! All of which has never been explained to the consultants, and does not appear on any guidance to inform them.[69]

81. Under the Medicines and Healthcare products Regulatory Agency (MHRA) guidance for the supply and prescription of unlicensed products, an unlicensed product may only be made available in response to an unsolicited order—that is, one where the clinician has made a judgement free from pressures of patients or manufacturers. The product must

65 Q181
66 Q182
67 Department of Health and Social Care (DMC0020)
68 Q232
69 Mr Robin Emerson (DMC0098)

also be manufactured and assembled in accordance with the specification of a doctor, whilst the supplier must hold all the relevant supplier and manufacturing licences. The product must be for a patient whose treatment the doctor is directly responsible for and for the patient's special needs.[70]

82. Unlicensed products are funded differently from regular prescriptions. Although procedures vary across each provider, an unlicensed prescription usually goes to a local prescribing committee within the Trust or local Clinical Commissioning Group (CCG) for approval. Unlicensed drugs are paid for from local NHS budgets, which can create a difficult situation for those approving the application. Professor O'Callaghan told us:

> The problem then is who is going to pay for that product, which we have already heard may cost in the region of £25,000 to £30,000 per patient per year. If I put an individual funding request to my local trust to use the product, a drug and therapeutics committee would look at it and ask, "What is the evidence for efficacy, safety and benefit?" I have competing demands for my budget, and they are probably going to say that there is not enough evidence of efficacy and safety to pay out that amount of money.[71]

83. We also heard that the unlicensed nature of the products means that there is inconsistency between trusts as it is a decision taken within local organisations rather than at a single national level. Dr Malik told us:

> However, at local NHS trust levels, medicine management committees assess the cost-effectiveness, and they have to look at the other medications that are being used and how much budget is being spent on them. In line with that, they may or may not allow it to be prescribed at different NHS hospitals, so one particular NHS hospital may allow it, but down the road another may decline it.[72]

84. The most effective way of overcoming these issues is to ensure that the products are licensed, which can only be done by carrying out further research. Cases for unlicensed prescriptions are usually strengthened if there is a strong evidence base which demonstrates that it will be cost effective in how much benefit the product brings to the patient. Further research will help at this stage of prescribing as it should enable a stronger case to be made for benefit and cost-effectiveness.

85. Professor Helen Cross pointed out to us that even if she were to prescribe a CBPM, she would face difficulty. She said:

> When it comes to other products, because I want to know about clinical trials and how I move forward, I inquired with my pharmacy. I have been told that, if I decided I wanted to prescribe the product with THC tomorrow, I could not get it through standard procedures even if I prescribed it tomorrow. There are many different barriers. It has been put forward that it

70 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products__specials_.pdf
71 Q173
72 Q120

> is the doctors who are stopping this, when actually a multitude of things are putting the barriers in place. That has made relationships between us and some patients quite difficult.[73]

86. During our evidence session, Baroness Blackwood and Dr Keith Ridge spoke about a "process review" that NHS England were asked to carry out, intended to assess the barriers to prescribing CBPMs. We welcome this review, and note with approval that NHS England will hear from patient voices in the course of it. This review should address the bureaucratic barriers to appropriate prescribing.

Supply of medicinal cannabis products

87. Another issue we heard was that there is currently no UK supply of CBPMs. Baroness Blackwood said:

> One of the problems with cost is, obviously, that there is no UK supply. That is something we are working with industry to try to address, because the import cost is significant. That is another issue that we would like to encourage industry to help us to address. The supply chain is a barrier in that context.[74]

The import costs increase the price of the product, which makes it more difficult for local prescribing committees to approve applications. It is important that the UK has a consistent supply to ensure that any patient who has been prescribed a medicinal cannabis product is not delayed in receiving it.

88. A further challenge which remains is the cost-effectiveness of any CBPM. The MS Society highlighted the case of Sativex, which has been licensed to treat spasticity in multiple sclerosis (MS), but has not been recommended by NICE as it is not deemed cost effective. Given that this product is not widely available on the NHS, some MS patients feel they are being driven to illegal street cannabis to treat their symptoms.[75] Other patients have spent thousands of pounds obtaining the product through a private prescription.[76] It is an unfortunate circumstance that patients are not able to access Sativex easily. Ultimately, the question of cost-effectiveness is one that is considered by NICE. The case for cost-effectiveness can be improved if more research is carried out demonstrating the efficacy of the product. This is another illustration of why robust evidence is so important.

Conclusions and recommendations

89. The role of the current interim guidance in being a barrier to prescribing CBPM is contested. The BPNA claim it is not a barrier, but the patients, their families and the clinicians who support them say it is. The BPNA says their guidance is based on the available evidence. They also say it should not be a barrier to prescribing and is only advisory. Specialist clinicians should use their own judgment, along with the evidence, when judging whether prescribing CBPMs would be in the best interests of their individual patients.

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73 Q104
74 Q229
75 MS Society (DMC0064)
76 MS Society (DMC0064)

90. There are several issues in the prescribing procedure. The unlicensed nature of CBPMs requires local decision-making, which inevitably leads to a degree of inconsistency. We look forward to the process review conducted by NHS England which will look at these issues and address them.

91. **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.**

92. **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.**

93. **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.**

94. **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.**

List of recommendations

Public opinion and communications

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)

Current evidence base

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)

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)

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)

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)

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)

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)

Current guidance and education

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)

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)

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)

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)

Formal minutes

Tuesday 18 June 2019

Members present:

Dr Sarah Wollaston, in the Chair

Mr Ben Bradshaw	Diana Johnson
Rosie Cooper	Andrew Selous
Angela Crawley	Dr Paul Williams

Draft Report (*Drugs policy: medicinal cannabis*), proposed by the Chair, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 94 read and agreed to.

Summary agreed to.

Resolved, That the Report be the Sixteenth Report of the Committee to the House.

Ordered, That the Chair make the Report to the House.

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

[Adjourned till Tuesday 25 June at 2 pm.

Witnesses

The following witnesses gave evidence. Transcripts can be viewed on the inquiry publications page of the Committee's website.

Tuesday 19 March 2019

Professor Dame Sally Davies, Chief Medical Officer for England, **Alette Addison**, Head of Pharmacy Development and Regulation, Department of Health and Social Care	Q1–29
Genevieve Edwards, Director of External Affairs, MS Society, **Professor Mike Barnes**, Interim Chair, Medical Cannabis Clinicians' Society, **Peter Carroll**, Campaign Director, End Our Pain	Q30–91
Professor Helen Cross, Head of Developmental Neurosciences, UCL GOS Institute of Child Health, **Dr Imran Malik**, Committee member, Royal College of Psychiatrists, **Professor Sanjay Sisodiya**, Chair of the ABN Epilepsy Advisory Group, Association of British Neurologists	Q92–133

Tuesday 26 March 2019

Professor Andrew Goddard, President, Royal College of Physicians, **Professor Finbar O'Callaghan**, President, British Paediatric Neurology Association	Q134–208
Baroness Blackwood, Parliamentary Under Secretary of State, **Professor Chris Whitty**, Chief Scientific Advisor, Department of Health and Social Care, **Nick Hurd MP**, Minister of State for Policing and the Fire Service, Home Office, **Dr Keith Ridge**, Chief Pharmaceutical Officer, NHS England	Q209–255

Published written evidence

The following written evidence was received and can be viewed on the inquiry publications page of the Committee's website.

DMC numbers are generated by the evidence processing system and so may not be complete.

1 All-Party Parliamentary Group on Medical Cannabis under Prescription (DMC0050)

2 Alta Flora (DMC0085)

3 Althea MMJ UK Ltd (DMC0083)

4 Association of British Neurologists (DMC0017)

5 Association of British Neurologists (DMC0094)

6 Aurora Cannabis Inc. (DMC0041)

7 Bayer (DMC0082)

8 Beckley Canopy Therapeutics (DMC0027)

9 The Beckley Foundation (DMC0024)

10 The Brain Tumour Charity (DMC0059)

11 Brain Tumour Research (DMC0058)

12 British Paediatric Neurology Association (DMC0087)

13 British Paediatric Neurology Association (DMC0095)

14 British Pharmacological Society (DMC0047)

15 Cambridge University Hospitals NHS Trust (DMC0053)

16 Centre for Medicinal Cannabis (DMC0092)

17 Centre for Medicinal Cannabis (DMC0073)

18 The Christian Institute (DMC0060)

19 CLEAR Cannabis Law Reform (DMC0066)

20 Cross, Professor J Helen (DMC0065)

21 D'Ambroiso, MD, Dr Francis G (DMC0023)

22 Department of Health and Social Care (DMC0020)

23 Department of Health and Social Care (DMC0091)

24 Department of Health and Social Care (DMC0093)

25 Department of Health and Social Care (DMC0101)

26 Drugscience (DMC0079)

27 Emerson, Mr Robin (DMC0098)

28 End Our Pain (DMC0030)

29 Epilepsy Action (DMC0061)

30 Faculty of Pain Medicine of the Royal College of Anaesthetists (DMC0032)

31 Frary, Ms Kavita (DMC0086)

32 General Medical Council (DMC0071)

33 GW Pharmaceuticals (DMC0090)

34 GW Pharmaceuticals (DMC0102)

35 International Drug Policy Consortium (DMC0004)

36 Liberty Herbal Technologies Ltd (LHT) (DMC0080)

37 Medical Cannabis Clinicians Society and APPG on Medical Cannabis under Prescription (DMC0088)

38 Monica, Dr Sophia (DMC0063)

39 MS Society (DMC0064)

40 MS Society (DMC0097)

41 National Pharmacy Association (DMC0084)

42 The Neurological Alliance (DMC0062)

43 Okuleye, Ms Yewande (DMC0081)

44 Royal College of Nursing (DMC0033)

45 Royal College of Physicians (DMC0034)

46 Royal College of Physicians (DMC0099)

47 The Royal College of Psychiatrists (DMC0054)

48 Royal College of Psychiatrists (DMC0096)

49 SUDEP Action (DMC0057)

50 Suprex (DMC0100)

51 Surterra Wellness (DMC0078)

52 Transform Drug Policy Foundation (DMC0067)

53 UK Fibromyalgia (DMC0008)

54 United Patients Alliance (DMC0026)

55 University of York (DMC0001)

56 Williams, Dr Ruth (DMC0039)

57 Young Epilepsy (DMC0051)

List of Reports from the Committee during the current Parliament

All publications from the Committee are available on the publications page of the Committee's website. The reference number of the Government's response to each Report is printed in brackets after the HC printing number.

Session 2017–19

First Report	Appointment of the Chair of NHS Improvement	HC 479
Second Report	The nursing workforce	HC 353 (Cm 9669)
Third Report	Improving air quality	HC 433 (HC 1149)
Fourth Report	Brexit: medicines,medical devices and substances of human origin	HC 392 (Cm 9620)
Fifth Report	Memorandum of understanding on data-sharing between NHS Digital and the Home Office	HC 677
Sixth Report	The Government's Green Paper on mental health: failing a generation: First Joint Report of the Education and Health and Social Care Committees of Session 2017–19	HC 642 (Cm 9627)
Seventh Report	Integrated care: organisations, partnerships and systems	HC 650 (Cm 9695)
Eighth Report	Childhood obesity: Time for action	HC 882 (CP23)
Ninth Report	Long-term funding of adult social care	HC 768
Tenth Report	Appointment of the Chair of NHS England	HC 1351
Eleventh Report	Antimicrobial resistance	HC 962
Twelfth Report	Prison health	HC 963 (CP 4)
Thirteenth Report	First 1000 days of life	HC 1496 (CP112)
Fourteenth Report	Sexual health	HC 1419
Fifteenth Report	NHS Long-term Plan: legislative proposals	HC 2000
First Joint Special Report	Children and young people's mental health—the role of education: Government Response to the First Joint Report of the Education and Health Committees of Session 2016–17	HC 451