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

Findings and Recommendations

Gateway Reference number: 000842

NHS England and NHS Improvement

Contents

Summary of Recommendations

i. A UK-wide paediatric specialist clinical network should be established to provide specialist clinical expertise, support discussion of complex cases, provide support to clinicians and to assist in evidence generation.

ii. The National Medical Director and Chief Pharmaceutical Officer for England will write to doctors and pharmacists reminding them of General Medical Council (GMC) guidance on the prescribing and use of unlicensed medicines – and to clarify the procedure for prescribing and supplying cannabis-based products for medicinal use (CBPMs). Clinicians will also be made aware of how they can access the Health Education England (HEE) cannabis education package, commissioned by NHS England, and published alongside this report.

iii. NHS England and NHS Improvement and the Department of Health and Social Care (DHSC) should work together to develop clear information for patients and patient groups on the prescribing of cannabis-based products for medicinal use.

iv. The National Institute for Health Research (NIHR) should support research into the five priority research areas that have been identified by the draft National Institute for Health and Care Excellence (NICE) clinical guideline on the use of cannabis-based products for medicinal use.

v. For severe treatment-resistant paediatric epilepsy, evidence generation should be in two forms:

- Support one or more randomised control trials (RCTs) using a standardised approach with several comparative treatment arms.

- NHS England and NHS Improvement and NIHR in conjunction with the specialist network will work together to determine an appropriate alternative study design that will enable evidence generation for those patients who cannot be enrolled into a standard RCT. This scope of study should include those children and young adults who are currently in receipt of a CBPM.

vi. These should commence as soon as possible, pending ethical review, and if necessary the alternative study should commence in advance of the RCT.

vii. NHS England and NHS Improvement, DHSC and Devolved Administrations should work with industry and academia to scope the development of a national UK patient registry to collect a uniform data set, across all indications, for patients prescribed a cannabis-based product for medicinal use in the United Kingdom.

viii. NHS England and NHS Improvement will also explore how to update the National Genomic Test Directory so that whole genome sequencing would be offered to all children with severe treatment-resistant epilepsy under consideration for treatment with medical cannabis.

ix. DHSC and Medicines and Healthcare products Regulatory Agency (MHRA) should work to provide access to information on good quality products, manufactured to Good Manufacturing Practice standard and with consistent ratios of cannabidiol (CBD) to delta-9-Tetrahydrocannabinol (THC) between batches.

x. NHS England and NHS Improvement should work with suppliers to ensure that sufficient stock of good quality CBPMs are available and that the products available offer the best value for the NHS, including scoping options for UK manufacture.

Background

1. On 1st November 2018, cannabis-based products for medicinal use (CBPMs) were rescheduled under the Misuse of Drugs Regulations 2001 from Schedule 1 to Schedule 2. This change followed advice from the Chief Medical Adviser to the UK Government (3rd July 2018) and the Advisory Council on the Misuse of Drugs (19th July 2018). Both advised that the rescheduling of these products would facilitate the development of clinical evidence.

2. Since the change in regulations, subject to local governance arrangements, doctors on the Specialist Register of the General Medical Council (GMC) have been able to prescribe an unlicensed CBPM if clinically appropriate for their patients. In addition, there may be some circumstances in which GPs may be asked to prescribe under the direction of a specialist as part of shared care arrangements.

3. The government has defined "*a cannabis-based product for medicinal use in humans" as a preparation or other product, other than one to which paragraph 5 of part 1 of Schedule 4 applies, which*[1]*—*

    (a) *is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative (not being dronabinol or its stereoisomers);*
    (b) *is produced for medicinal use in humans; and—*
    (c) *is—*
        (i) *a medicinal product, or*
        (ii) *a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product;"*

4. If the three limbs are met, then the preparation or product is considered as a "cannabis-based product for medicinal use in humans" and a Schedule 2 drug under the 2001 Regulations.

5. Also set out in the legislation are three routes for accessing CBPMs:

    - either as a medicine with a marketing authorisation;
    - as part of a clinical trial; or
    - as a "special" medicine supplied through existing Medicines and Healthcare Products Regulatory Agency (MHRA) licensed routes.

6. Cannabis has many active chemical constituents and two of these constituents, delta-9-Tetrahydracannabinol (THC) and cannabidiol (CBD) have been investigated the most with respect to their medicinal value. THC is the major psychoactive constituent of cannabis and is considered responsible for giving so called "highs" to users of cannabis. CBD on the

[1] Home Office Regulations

other hand, is not psychoactive. Products falling within Schedule 2 contain varying quantities and ratios of THC and CBD.

7. Recent data on cannabis use in recreational users (March 2019) is consistent with previous evidence suggesting that the use of cannabis with a high concentration of THC has harmful effects on mental health[2]. Whilst the evidence base continues to develop, on balance, the use of high strength THC regularly and over the longer term, would appear to put people at higher risk of harm.

8. Currently almost all CBPMs prescribed by specialist doctors are unlicensed medicines and are therefore prescribed as 'specials'. This situation will remain the case until other products have received a marketing authorisation from either the European Medicines Agency or the MHRA. The MHRA defines a 'special' as a product which "has been specially manufactured or imported to the order of a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber for the treatment of individual patients".

9. Unlike licensed medicines, CBPMs have not undergone rigorous tests for quality, safety and efficacy. Therefore, local medicines governance arrangements will always include robust arrangements to safeguard patients where there is a clinical need to use an unlicensed medicine. These arrangements will consider the evidence base, and the risks and benefits of using the medicine before allowing its use. If necessary, funding arrangements are subsequently considered.

10. The exceptions to the above are the cannabis-based products dronabinol, Sativex® and nabilone, all of which have been individually rescheduled under the Misuse of Drugs Regulations 2001 and have been granted a marketing authorisation from the MHRA or equivalent medicines regulatory body. Another product Epidyolex® is currently in the process of being considered for a European marketing authorisation. Epidyolex® is a CBD-only product which is available through compassionate use and extended access programmes prior to licensing.

11. There are other products which are also derived from the cannabis plant that were never scheduled as they do not contain controlled substances and therefore are not covered by the change in the regulations. An example is CBD oils sold through health shops. These products are classed as food supplements and are not sold for medicinal use.

12. Following the rescheduling the Chief Medical Adviser to the UK Government, National Medical Director and Chief Pharmaceutical Officer wrote to clinicians to set out expectations of what the regulatory change would mean in practice for clinicians working in the NHS and in private practice. This letter published on 31st October 2018 contained links to the interim clinical guidance developed by the Royal College of Physicians (RCP)and the British

[2] The contribution of cannabis use to variation in the incidence of psychotic disorder across Europe (EU-GEI): a multicentre case-control study. Di Forti, Marta Amoretti, Silvia et al. The Lancet Psychiatry, Volume 6, Issue 5, 427 - 436

Paediatric Neurology Association (BPNA). Guidance from the Association of British Neurologists (ABN) was issued subsequently. Similar letters were issued in the Devolved Administrations.

13. A further UK-wide letter was issued. The second letter, published on 20th November 2018, clarified the status of the interim clinical guidance, and provided further clarification in relation to synthetic cannabinoids for medicinal use.

14. Since the change in regulations, there has been an increase in the prescribing of CBD products, but there has been no increase in NHS prescriptions of THC-containing products:

    - 111 patients have accessed Epidyolex® through compassionate use and early access programmes ahead of a licensing decision by the European Medicines Agency.

    - Intelligence from NHS England Controlled Drugs Accountable Officers is that, up until the end to March 2019, five patients have had private prescriptions issued for a CBPM in an independent secondary/tertiary care setting in England.

    - According to data from the NHS Business Services Authority (March 2019) there have been fewer than 10 NHS prescriptions for CBPMs issued in primary care since November 2018.

15. The Secretary of State for Health and Social Care met a number of families on 19 March 2019 to listen to their concerns about access to CBPMs. Following the meeting, he asked NHS England and NHS Improvement to review NHS system processes to identify and recommend any action necessary to address any barriers to clinically appropriate prescribing on the NHS.

16. The review was led by the National Medical Director and the Chief Pharmaceutical Officer for England and the focus of the review was severe treatment-resistant paediatric epilepsy, as most cases were for this condition and it is the condition for which there are the strongest arguments for improving access. Two cases were for chronic neuropathic pain indications with other associated conditions.

Aims and Objectives

17. The review was aimed at addressing the following question:

    - *Where they exist, what are the barriers to patients accessing cannabis-based products for medicinal use within the NHS where they are clinically appropriate for the patient, and how might these barriers be overcome?*

18. The review sought to:

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

19. NHS England and NHS Improvement worked with the *All-Party Parliamentary Group (APPG) on Medical Cannabis under Prescription* and with patient groups, to identify patient cases which should be included in the review. Twenty-one cases were put forward. Twenty cases were reviewed, as consent was not received for one case. Eighteen of the cases were in England. A further two patients from Northern Ireland were included at the request of the Northern Ireland Executive.

20. The review was undertaken through:

    - Face-to-face or telephone meetings with patients and their families and/or carers, who were invited to share their experiences and give their views;
    - Structured interviews with the relevant NHS staff for each case being reviewed; and
    - A short survey of clinical commissioning groups (CCGs) in each of the case study local areas.

21. Key lines of inquiry for the review were developed based on the existing process for the prescribing of unlicensed medicines. The key lines of inquiry were used to test this process by considering the prescribing decision, the commissioning decision and the availability of supply.

22. Terms of Reference for the review are attached at **Annex A**.

Findings and Key Themes

Clinical Evidence

23. The vast majority of the clinicians we spoke to told us that the lack of good quality randomised control trial (RCT) data demonstrating adequate safety and clinical-cost effectiveness of CBPMs for all indications is a major hurdle to prescribing.

24. Most clinicians told us that products containing THC would not be prescribed in their trusts, primarily because of the lack of evidence, a lack of knowledge about the products and a lack of long-term safety data. Several clinicians referenced the higher risk of impaired mental health from longer term exposure to THC and the need to proceed with caution.

25. In contrast we heard that RCTs do exist for some CBD-only products and because of this, clinicians are using these products for the conditions specified in the BPNA guidance, as part of the compassionate or extended access schemes.

26. The interviews indicated that clinicians are very cautious in prescribing CBPMs due to the lack of any data on efficacy and long-term adverse effects in children. However, the interviews suggested a spectrum in clinicians' willingness to prescribe, with some clinicians more willing to prescribe on an individual case-by-case basis.

27. We heard clearly from parents and carers that whilst they acknowledge that the evidence base is limited, they feel that clinicians are not adequately considering the international observational study data.

28. Parents and carers told us that their children are already prescribed several other antiepileptic medicines, including some that are off-label or unlicensed, many of which have significant adverse effects and that they want a cannabis-based medicinal product to be prescribed either in addition to, or instead of, existing treatment.

29. Many of the clinicians we interviewed told us that, as with all unlicensed medicines, the potential risks of using a CBPM should be assessed against the effect of continued seizures (in some cases up to 300 per week) on the development of the child.

30. CBPMs are used in a variety of conditions. Parents, carers and clinicians told us that there are unique factors in considering the use of CBPMs in cases of severe treatment-resistant paediatric epilepsy.

31. We heard that the primary issue is that severe treatment-resistant paediatric epilepsy carries with it a risk of sudden death. Dravet syndrome-related

mortality is estimated to be around 20%[3], with most deaths occurring before 10 years of age. Sudden unexpected death in epilepsy and status epilepticus cause around 80% of deaths in this condition; and in approximately a third of cases, patients with epilepsy do not respond to other anti-epileptic medicines. We heard that patients with severe treatment-resistant epilepsy have typically tried most other licensed medicines, often with little obvious benefit and an increased risk of adverse effects.

32. The children included in our review had complex aetiologies and had tried multiple combinations of antiepileptic medicines and other treatments (e.g. surgery or vagus nerve stimulation) which had limited impact on reducing seizure frequency. Clinicians noted that CBPMs are not a 'miracle cure' for all patients with severe treatment-resistant epilepsy. However, when patients do respond, there is some observational data showing that CBPMs can reduce seizure frequency for some patients leading to better control, fewer A&E attendances and a better quality of life for both the patient and the family.

Guidance to Support Clinicians

33. Most of the clinicians we spoke to stated that they found the interim clinical guidance drafted by the specialist bodies useful, as it provided a framework to work within and outlined the available evidence.

34. However, the interim clinical guidance was cited by all the parents and carers as a key barrier to prescribing CBPMs in cases of severe treatment-resistant paediatric epilepsy. Other patients felt the same. They feel that clinicians often stick rigidly to the guidance and are not considering each case on an individual basis, as per the GMC guidance on prescribing off-label or unlicensed medicines.

35. Many clinicians told us that they would not prescribe any product other than a pure cannabidiol and that they would not prescribe a CBPM outwith the indications of Dravets syndrome and Lennox-Gastaut syndrome. In only a few cases did we hear that CBPMs containing THC were considered for the patient.

36. Many review meetings with carers and/or families also demonstrated that their knowledge of CBPMs is good and continuing to develop. Some carers have undertaken extensive research into the properties of CBPMs, the limitations and the potential side effects. They have used a variety of evidence sources to inform their opinions and have brought that evidence with them to discuss with their clinicians.

37. Trust Medical Directors and Chief Pharmacists told us that without the necessary evidence base, and given the cost of CBPMs, it was unlikely that these medicines would be routinely funded.

[3] https://www.nice.org.uk/guidance/gid-ta10274/documents/final-scope

38. Patients with indications related to neuropathic pain told us they felt that the NICE Clinical Guideline 186: Management of Multiple Sclerosis in adults was too restrictive as it did not recommend the use of the licensed cannabis-based medicinal product due to a lack of cost effectiveness data.

39. We consistently heard from all parties that the rapid re-scheduling of CBPMs in Autumn 2018 led to a very high expectation from patients and their families that they would be able to access these medicines on the NHS.

40. Several patients and their families reported that they have very good relationships with their specialist clinicians, especially where they have been in the care of a clinician for many years. However, other families and patients reported that trying to persuade clinicians and Trusts to prescribe CBPMs, both before and after the legislative change, had been very frustrating and on occasion led to tension.

41. Clinicians also told us that in some circumstances, these high expectations, coupled with a lack of high-quality clinical evidence and no licensed products has strained the relationships with families.

42. Clinicians reported that whilst the regulatory change was intended to facilitate more research into the use of CBPMs and allow limited access for patients based on individual clinical need, there was little time to consider the impact on well-established NHS medicines policies, governance systems and clinical practice.

43. Many families raised concerns around the lack of involvement in decision-making. They also told us that information provided by NHS organisations was inadequate, particularly in written communications concerning governance processes or decisions made relating to CBPMs. In many cases, patients thought the explanations given to them for declining to prescribe CBPMs were incomplete or insufficient. Patients and their families or carers fed back that whilst communications with specialist clinicians are often good, the relationship with the NHS Trust was not felt to be open.

Cost and Supply

44. All parties told us that, should the clinician agree that a prescription for a CBPM is clinically appropriate, the next key barrier is cost of the product and funding. In normal circumstances for unlicensed medicines, NHS Trusts would be responsible for identifying funding for individual patients. However, in practice, NHS Trusts tend to fund medicines for many indications but generally for lower cost products, and for short term use only.

45. Several NHS Trusts have therefore made Individual Funding Requests to either their local CCG or NHS England depending on the commissioned indication.

46. Some families fed back that due to a lack of clarity around the availability of NHS funding or a delay in obtaining it, they have obtained a private

prescription, imposing a very considerable and often unsustainable financial burden on themselves.

47. Some Trusts are currently funding – or would be willing to fund – CBPMs in indications of intractable paediatric epilepsy, but they have told us this is unsustainable in the long term, particularly as some specialist NHS Trusts may be responsible for the care of several patients over the longer term. In several instances, NHS Trusts stressed that whilst funding was a factor in their decision making, the lack of clinical evidence for the use of CBPMs was the primary determinant of the prescribing decision.

48. As most CBPM products are not manufactured in the UK, the NHS is reliant on importing the products. The NHS needs to adhere to the export procedures of other countries, which can cause delays and difficulties with sourcing the correct product.

49. Pharmacists reported that they have systems in place to import the products but raised concerns around the difficulty in knowing which products are of good quality and if the batches ordered have consistent ratios of CBD and THC (thereby ensuring a standardised dose of each component).

Conclusions and Recommendations

Guidance to support clinicians

50. Clinical understanding of CBPMs is variable, and this variability in understanding can have an impact on relationships with patients, parents and carers.

51. The complexity of the cases involved and the speed in which Controlled Drugs legislation changed in 2018 has left some clinicians, and particularly those with a generalist role, feeling that they do not have the specialist professional education needed to make fully informed prescribing decisions in cases where a CBPM may be appropriate.

52. It will be important for clinicians dealing with cases for which CBPMs may be a clinically appropriate treatment option to ensure that they are aware of the research and evidence available for a wide range of indications. They also need to be prepared to discuss the clinical appropriateness of CBPMs with the patient, and/or their parent or carer in an open and consultative manner.

53. We also heard that patient expectation around access to a CBPM is high following the rescheduling, and clinicians asked for support to manage this expectation.

54. The National Institute for Health and Care Excellence (NICE) was asked by the Department of Health and Social Care to produce a clinical guideline on the prescribing of cannabis-based products for medicinal use in humans. This guidance will be available in October 2019, however NICE has issued a draft for consultation.

55. In the interim period, until the NICE Clinical Guideline is finalised, advice was commissioned from the specialist medical societies (ABN, BPNA and RCP) to support specialist clinicians with their prescribing decisions. This guidance was published, alongside the NHS England letter, on the 31st October 2018. The NICE clinical guidance will update and replace the interim clinical guidance issued by the specialist medical societies.

56. Specialist Clinical Networks are a well-established way of working in complex disease areas. These already occur at a regional level and have been used to facilitate a second opinion process in this area. Development of a UK-wide network will provide both improved specialist care to children and provide the basis on which to provide clinical expertise into complex and difficult to manage cases. All clinicians should be able to easily access specialist support which will be provided as part of the specialist clinical network which we intend to establish.

57. On the 3rd July 2019, the Health Select Committee (HSC) published a report on medicinal cannabis and recommended that 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.

Recommendations:

i. **A UK-wide paediatric specialist clinical network should be established to provide specialist clinical expertise, support discussion of complex cases, provide support to clinicians and to assist in evidence generation.**

ii. **The National Medical Director and Chief Pharmaceutical Officer for England will write to doctors and pharmacists reminding them of GMC guidance on the prescribing and use of unlicensed medicines – and to clarify the procedure for prescribing and supplying CBPMs. Clinicians will also be made aware of how they can access the Health Education England (HEE) cannabis education package, commissioned by NHS England, and published alongside this report.**

iii. **NHS England and NHS Improvement and the Department of Health and Social Care (DHSC) should work together to develop clear information for patients and patient groups on the prescribing of cannabis-based products for medicinal use.**

Clinical Evidence

58. Our review has highlighted that the lack of evidence into the safety and effectiveness of CBPMs has weighed heavily on prescribing decisions in cases of severe treatment-resistant paediatric epilepsy. In many cases, patients have not been considered for or prescribed a CBPM because of the lack of high-quality evidence.

59. One of the key themes was the availability of RCT evidence, but there were also concerns the evidence would take time to develop.

60. If CBPMs are to be routinely commissioned across the NHS, the science and the evidence base supporting use needs to be significantly better developed. The NHS needs robust evidence on the effectiveness of CBPMs, as well as clear insight into the risk and prevalence of any side effects and must approach the issue with care. This will also need a reliable supply of high quality, consistent products.

61. The published studies for use of THC-containing products have tended to be observational, have lacked a control group and had low patient numbers.

These studies are important and can contribute to the evidence base but are lower quality sources of evidence compared to RCTs and are not routinely used to make population prescribing decisions or recommendations.

62. We heard repeatedly from parents, carers and clinicians that they would welcome the availability of RCT evidence, but parents and carers fear this would take too long to ensure their child received a CBPM in a timely manner.

63. The National Institute for Health Research (NIHR) has issued two calls for research proposals to rapidly advance knowledge in this area. The first call closed on the 19th March 2019, and the current call closed on 31st July 2019.

64. To further support the generation of new evidence, a detailed and consistent set of data on those most affected is needed, including children who are currently in receipt of a CBPM.

65. Structured collection of data will add to the underlying evidence base. It can also provide information upon which to base RCTs, as already happens in normal clinical practice.

66. From the small number of patients with other conditions interviewed, many of the same issues – lack of evidence, reluctance to fund and unreliable supply – apply.

67. For epilepsy, NICE recommends further research into CBD for severe treatment-resistant epilepsy in children, young people and adults, and the effect of adding in THC in combination with CBD on seizure frequency, brain structure and neurophysiological performance when compared with CBD alone.

68. NICE has issued five priority research recommendations in the draft Clinical Guideline, which cover the following:

    I. CBD as add on treatment for adult patients with Fibromyalgia or persistent treatment-resistant neuropathic pain;
    II. CBPMs in Chronic pain in children and young people;
    III. CBPMs for people with spasticity;
    IV. CBD for severe treatment-resistant epilepsy in children, young people and adults; and
    V. The effect of adding THC in combination with CBD on seizure frequency, brain structure and neurophysiological performance when compared with both CBD alone and placebo.

69. For patients who cannot be enrolled into standard RCTs, we need a mechanism that will further support the generation of new evidence and that draws together a detailed and consistent set of data on the most affected, including those children and young adults who are currently in receipt of a CBPM.

70. Offering genome sequencing to all children with severe treatment resistant epilepsy will allow better data collection and enable a quicker diagnosis

which may in the future lead to matching people to the most effective medications and interventions and thereby reducing the likelihood of adverse drug reactions.

Recommendations:

iv. **NIHR should support research into the five priority research areas that have been identified by the draft NICE clinical guideline on the use of cannabis-based products for medicinal use.**

v. **For severe treatment-resistant paediatric epilepsy, evidence generation should be in two forms:**

- **Support one or more RCTs, using a standardised approach with several comparative treatment arms.**

- **NHS England and NHS Improvement and NIHR in conjunction with the specialist network will work together to determine an appropriate alternative study design that will enable evidence generation for those patients who cannot be enrolled into a standard RCT. This scope of study should include those children and young adults who are currently in receipt of a CBPM.**

xi. **These should commence as soon as possible, pending ethical review, and if necessary the alternative study should commence in advance of the RCT.**

vi. **NHS England and NHS Improvement, DHSC and Devolved Administrations should work with industry and academia to scope the development of a national UK patient registry to collect a uniform data set, across all indications, for patients prescribed a cannabis-based product for medicinal use in the United Kingdom.**

vii. **NHS England and NHS Improvement will also explore how to update the National Genomic Test Directory so that whole genome sequencing would be offered to all children with severe treatment-resistant epilepsy under consideration for treatment with medical cannabis.**

Cost and Supply

71. Clinicians and patients or their carers have highlighted cost and supply of the currently available products as a barrier to access.

72. Subject to Marketing Authorisation and outcome of the NICE Technology Appraisal, any CBD product or CBPM would be routinely commissioned in the usual way for licensed indications.

73. CBPMs by definition are unlicensed and will therefore need to be obtained from specialist wholesalers. We understand this process for obtaining

CBPMs can be a time-consuming process with import/export forms needing to be filled in, often by clinicians or pharmacists. UK-based wholesalers have told us that they are unable to guarantee stock as market demand in the UK is so uncertain. Patients should not be expected to travel abroad in order to obtain a suitable product as there are lawful routes of supply that can be utilised.

74. Concerns were raised by pharmacists around the difficulty in assessing quality and consistency of product and they asked for support with this.

Recommendations:

ix. DHSC and MHRA should work to provide access to information on good quality products, manufactured to Good Manufacturing Practice standard and with consistent ratios of CBD to THC between batches.

x. NHS England and NHS Improvement should work with suppliers to ensure that sufficient stock of good quality CBPMs are available and that the products available offer the best value for the NHS, including scoping options for UK manufacture.

Annex A: Terms of Reference

Cannabis Based Products for Medicinal Use – Process Review

Aims

The purpose of the review is to answer the following overarching question:

Where they exist, what are the barriers to patients accessing cannabis-based products for medicinal use within the NHS where they are clinically appropriate for the patient and how might these barriers be overcome?

The aims of the process are threefold:

- to identify the potential barriers to the appropriate prescribing of Cannabis Based Products for Medicinal use (CBPMs);
- to identify any changes that we may want to put in place to support appropriate prescriptions of CBPMs in future; and
- to identify ways in which we might facilitate the building of an evidence base for the use of CBPMs.

Scope

The review considered indications for which the Association of British Neurologists (ABN), the British Paediatric Neurology Association (BPNA) and the Royal College of Physicians (RCP) produced interim guidance, however the main focus of the review will be on those with an indication of severe treatment-resistant epilepsy.

The review will be conducted internally and will be based on evidence primarily collected through interviews with the Trust personnel involved in the identified cases and the patients and/or their carers.

Out of Scope

Clinical appropriateness of whether a cannabis-based product for medicinal use is suitable for individual patients.

Methodology

The review will seek views from patients and/or their carers as well as structured interviews with key clinical staff, and other relevant staff within the Trust and/or CCG as relevant.

Patients who should be involved in the review will be identified by working closely with the All-Party Parliamentary Group (APPG) on Medical Cannabis under Prescription and through them the patient representative group End Our Pain. The patients identified are diagnosed with indications covered by the interim guidance produced by the ABN, BPNA and RCP.

We are reviewing 21 cases in total. We have agreed to include cases from Northern Ireland at the request of the Northern Ireland Executive.

Consent will be obtained from each patient to allow us to conduct the review and to allow NHS England and NHS Improvement to speak to the patient's clinical team as part of the process review.

The following people are expected to be interviewed (as appropriate) for each case reviewed:

- Specialist Clinician
- Trust Drug and Therapeutics Chair
- Trust Medical Director and/or Chief Finance Officer
- Trust Chief Pharmacist
- NHS England Regional teams or CCG staff

The interview will take the form of structured interviews, which will consider the key decision-making points of the prescribing pathway for cannabis-based medicinal products that have been identified.

Based on experience of governance arrangements for prescribing unlicensed medicines, it is expected that any potential barriers will arise at these key decision-making points and our questions will need to investigate and probe these points.

The interviews will be used to identify and test any barriers to access and the potential ways to overcome those barriers.

Medical Directors at the Trust will be contacted via telephone to inform of them of the need for the review and to arrange the interviews. Patients/Carers will also be contacted.

Interviews will take place at the relevant Trust. Patients and/Carers will be invited to discuss their experiences either via telephone or at a convenient location.

Expected Outputs

The resultant output will be a summary report, including:

- Potential barriers at each stage of the process from decision to prescribe, to supply.

- Any other key cross-cutting themes, where they have been identified
- Potential options for addressing the barriers

The findings and any potential changes will be considered by NHS England.

Reviewers

The review is being led by Professor Stephen Powis, National Medical Director, who will share the report with Secretary of State for Health for England.

The interviews will be led and undertaken by Dr Keith Ridge, Chief Pharmaceutical Officer, supported by Dr Bruce Warner, Deputy Chief Pharmaceutical Officer, and Celia Ingham Clark, Medical Director for Professional Leadership and Clinical Effectiveness.

Secretariat

The reviewers will be supported by Alexander Williams and Bhavana Reddy, Medicines and Diagnostics Policy Unit, in NHS England and NHS Improvement. The secretariat will provide policy, analytical and delivery insight to support the reviewers.

Timing

The review will start in May and will aim to conclude by the end of June.

Information Governance

No personalised information will be put into the public domain or released under freedom of information unless written content is provided by the patient.