

Citizen Participation and Public Petitions Committee

4th Meeting, 2021 (Session 6), Wednesday
22 September 2021

PE1884: Make whole plant cannabis oil
available on the NHS or alternative funding
put in place

Note by the Clerk

Petitioner Steve Gillian

**Petition
summary** Calling on the Scottish Parliament to urge the Scottish Government to make whole plant cannabis oil available on the NHS, or provide funds for private access, for severely epileptic children and adults where all other NHS epileptic drugs have failed to help.

Webpage <https://petitions.parliament.scot/petitions/PE1884>

Introduction

1. This is a new petition that was lodged on 22 July 2021.
2. A SPICe briefing has been prepared to inform the Committee's consideration of the petition and can be found at **Annexe A**.
3. Whilst not a formal requirement, petitioners have the option to collect signatures on their petition. On this occasion, the petitioner elected to collect this information. 411 signatures have been received.
4. The Committee seeks views from the Scottish Government on all new petitions before they are formally considered. A response has been received from the Scottish Government and is included at **Annexe B** of this paper.
5. A submission has been provided by the petitioner. This is included at **Annexe C**.

Scottish Government submission

6. The Chief Pharmaceutical Officer (CPO) outlines that the regulation, licensing and supply of medicines remain reserved to the UK Government under the Misuse of Drugs Act 1971, and this includes the scheduling of Cannabis Based Products for Medicinal Use (CBPMs).
7. In response to the call for funds to be provided for private access, the submission states that it is “solely a decision for the patient or the patient’s carer whether or not to seek private treatment” and that they are responsible for paying the costs incurred.
8. The submission explains that only specialist doctors on the General Medical Council (GMC) specialist register can prescribe cannabis-based products where there is clear, published evidence of benefit. It highlights that the majority of specialist doctors have concerns around its safety and efficacy because CBPMs are unlicensed products.
9. With regards to increasing prescribing of CBPMs on the NHS, the CPO outlines that specialist doctors across Scotland have a “clear and united view” that they would be unwilling to prescribe any CBPMs containing tetrahydrocannabinol (THC) until there is clear, published, evidence available following a clinical trial. It was noted that they were willing to participate in clinical trials to build the required evidence base. A lack of published data was noted on the following issues:
 - Dosage ranges;
 - Toxicity;
 - Interactions; and
 - Monitoring or long-term side effects (in particular in the developing brain)
10. On the issue of identifying an evidence base, the submission notes that cannabis clinical trials in refractory epilepsy to assess the efficacy of CBPMs are in development. The CPO suggests that the petitioner discuss the possibility of his family member participating in a clinical trial.
11. The submission concludes by stating that the Cabinet Secretary for Health and Social Care will be writing to the UK Secretary of State for Health and Social Care to see what additional leverage can be brought to bear on potential solutions, including an update on the clinical trials progress and seeking to encourage manufacturers of CBPMs to participate in these trials.

Petitioner submission

12. In his submission, the petitioner responds to CPO and states that the issue is with availability of CBPMs, rather than a reluctance to prescribe.

13. The submission also points to the three NHS prescriptions to address GMC concerns about the lack of published data and questions whether this information could be used as an evidence base.

Action

14. The Committee is invited to consider what action it wishes to take on this petition.

Clerk to the Committee

PE1884: MAKE WHOLE PLANT CANNABIS OIL AVAILABLE ON THE NHS OR ALTERNATIVE FUNDING PUT IN PLACE

Petitioner

Steve Gillan

Date Lodged

19 August 2021

Petition summary

Calling on the Scottish Parliament to urge the Scottish Government to make whole plant cannabis oil available on the NHS, or provide funds for private access, for severely epileptic children and adults where all other NHS epileptic drugs have failed to help.

Previous action

I have emailed my local MSP Mairi McAllan for help. I have also emailed my MP David Mundell, the Health Secretary for Health and Social Care and the First Minister for help to secure access to whole plant cannabis oil for children with severe epileptic conditions.

Background information

Whole plant cannabis oils was approved for use in the UK for medicinal purposes in 2018 but unfortunately not one person in Scotland has been able to receive a prescription for this. However, there are 3 prescriptions awarded to 3 children on the NHS in other parts of the UK. I have been told that the Scottish Government does not intervene on individual prescription given out on the NHS or intervene on clinical decisions. I was also advised that parents should seek advice from the clinical team in charge of their children about CBD (Cannabidiol) with THC (Tetrahydrocannabinol). However, can I make clear that we have been told that CBD oil with THC isn't available to the NHS to prescribe so here stands the problem. How can the NHS clinical teams make prescriptions for people when these aren't available for them to make?



Briefing for the Citizen Participation and Public Petitions Committee on petition [PE1884](#): Make whole plant cannabis oil available on the NHS or alternative funding put in place, lodged by Steve Gillan.

Background

Medicinal cannabis refers to any sort of cannabis-based medicine used to relieve symptoms. Cannabis has many active chemical constituents. Two of these, tetrahydrocannabinol (THC) and cannabidiol (CBD), have been investigated for their medicinal value. Medicinal cannabis may be available in a range of forms, including as the actual plant material or an extract such as oils and capsules.

From 1 November 2018, changes to [Misuse of Drugs legislation](#) has enabled cannabis-based products to be prescribed by some doctors for medicinal use, where there is a special clinical need.

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

In certain circumstances, healthcare professionals can supply products without a medicines licence to meet the special clinical needs of a patient. The General Medical Council (GMC) notes that the term ‘unlicensed medicine’ is used “to describe medicines that are used outside the terms of their UK licence or which have no licence for use in the UK”. Responsibility for deciding whether an individual patient has “special clinical needs” which a licensed product cannot meet is a matter for the prescriber responsible for the patient’s care.

Only specialist doctors on the [General Medical Council's Specialist Register](#), for example neurologists and paediatricians can prescribe unlicensed cannabis-based products for medicinal use. These doctors should only make the decision to prescribe in their own area of practice and training. In addition, the decision to prescribe should be agreed by a multidisciplinary team.

The [National Institute of Clinical Excellence \(NICE\)](#) has published a [guideline on prescribing of cannabis-based medicinal products](#) for people with intractable nausea and vomiting, chronic pain, spasticity and severe treatment-resistant epilepsy.

[Clarification guidance](#) was published in March 2021. This relates to the interpretation of the guideline in relation to the use of cannabis-based medicinal products to treat severe treatment-resistant epilepsy in children. This noted that, whilst no population-wide recommendation was made in the guideline, healthcare professionals can prescribe cannabis-based medicinal products if they consider that that would be appropriate on a balance of benefit and risk, and in consultation with the patient, and their families and carers or guardian.

The [British Paediatric Neurology Association](#) has published [Guidance on the use of cannabis-based products for medicinal use in children and young people with epilepsy](#).

Scottish Government Action

In 2018, the [Chief Medical Officer \(CMO\) wrote to clinicians about the use of cannabis-based products](#).

NHS England and NHS Improvement have published a review of [Barriers to accessing cannabis-based products for medicinal use on NHS prescription](#). This reviewed 20 cases, 18 from England and two cases from Northern Ireland were included at the request of the Northern Ireland Executive. A response to a [FOI request on why Scottish patients were not included in the review](#) has been published by the Scottish Government.

The review [made several recommendations](#) including that 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.

Scottish Parliament Action

The use of medicinal cannabis has been discussed in the Scottish Parliament on several occasions.

[First Minister's Questions Time: 10 January 2019](#) – discussion of the case of child with epilepsy,

[Debate on the Supply and Demand for Medicines: 24 November 2020](#)

[Written question S5W-25972: 19 November 2019](#) – “Prescription levels or numbers for information on unlicensed cannabis based products for medicinal use (CBPMs) is not collected by the Scottish Government.”

Key Organisations and relevant links

- [NICE](#)
- [MHRA](#)
- [SMC](#)
- [GMC](#)
- [Professor Stephen Powis, National Medical Director of NHS England](#)
- [Boy's plea to Nicola Sturgeon for medical cannabis for his brother - BBC News](#)

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18/08/21

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Chief Pharmaceutical Officer submission of 19 August 2021

PE1884/A – Make whole plant cannabis oil available on the NHS or alternative funding put in place

Thank you for your email of 23 July seeking the Scottish Government's views on the actions called for in [Petition PE1884](#) on behalf of Steve Gillan: *Make whole plant cannabis oil available on the NHS or alternative funding put in place*. I was deeply sorry to learn from previous correspondence about the difficulties which Mr Gillan and his family face and I have enormous sympathy for the family's circumstances.

As the Committee may be aware, the decision on whether to prescribe any medicine for a patient, and which medicine to prescribe, is entirely one for clinicians to make – it would be inappropriate for Scottish Ministers to make or influence individual prescribing decisions. It is also solely a decision for the patient or the patient's carer whether or not to seek private treatment. Where they do so then they are responsible for paying the costs incurred.

The regulation, licensing and supply of medicines remain reserved to the UK Government under the Misuse of Drugs Act 1971, and this includes the scheduling of Cannabis Based Products for Medicinal Use (CBPMs). Accordingly, the Scottish Government has no power to alter this while responsibility remains reserved to the UK Government.

Under the current rules, only specialist doctors on the General Medical Council (GMC) specialist register can prescribe cannabis-based products where there is clear, published evidence of benefit. While CBPMs can be prescribed on the NHS, the majority of specialist doctors have concerns around the safety and efficacy of CBPMs, and the lack of robust evidence on their use, particularly the long-term side effects. The only evidence for efficacy and safety of products containing cannabis extracts in childhood epilepsies relates to Epidyolex®, an isolated cannabidiol which received a licence in September 2019, from the European Medicines Agency. The Scottish Medicines Consortium (SMC) accepted Epidyolex for routine use in conjunction with clobazam

for both Lennox-Gastaut Syndrome and Dravet Syndrome in September 2020. This is because CBPMs are unlicensed products, which means that they have not been tested for safety, efficacy and quality through the marketing authorisation (licensing) process in the way that a licensed medicine would have. A doctor is professionally and clinically responsible for any medicine they prescribe and the responsibility that falls on them when prescribing an unlicensed product is greater than when prescribing a licensed medicine. This means that whilst the evidence base remains limited and there is not better clarity of the risks and benefits, specialist doctors will be cautious about prescribing unlicensed CBPMs. It is only by building this evidence base that doctors will gain the confidence to prescribe them.

With regards to increasing prescribing of CBPMs on the NHS, the Scottish Government is fully aware of the importance of a robust evidence base in reaching a long-term solution. On 8 April 2020, the former Chief Pharmaceutical Officer for Scotland chaired a teleconference with key paediatric neurologists from the specialist centres across Scotland. The specialist doctors had a clear and united view (which I understand to be a UK-wide view) that following GMC and British Paediatric Neurology Association (BPNA) guidelines, they would be unwilling to prescribe any CBPMs containing tetrahydrocannabinol (THC) until there is clear, published, evidence available following a clinical trial.

Some of the main concerns that they highlighted were that there were no published data on dosage ranges, toxicity, interactions, monitoring or long-term side effects (in particular in the developing brain). They were also concerned that they could not guarantee the quality or efficacy of the products due to the variable quantities of THC in dosages. They advised that while they use many medicines 'off-label', they knew of no other medicine where it was prescribed without a licence at all, unless part of a clinical trial. They did, however, indicate that they were willing to participate in clinical trials to build the evidence base.

Therefore, the only way to give clinicians the confidence to support NHS prescribing of CBPMs is by building the evidence base relating to their use. To this end, I have been engaging with the development of cannabis clinical trials in refractory epilepsy, which are led by the National Institute for Health Research (NIHR), where the effectiveness of CBPMs can be assessed. Mr Gillan may wish to discuss the possibility of his family member participating in a clinical trial with her clinical team.

While these clinical trials will not offer a short-term solution to the families currently seeking private prescriptions for CBPMs, they are nevertheless critical to developing the evidence base for a long-term solution and the Scottish Government is determined to support their development. To this end, the Cabinet Secretary for Health and Social Care will be writing to the UK Secretary of State for Health and Social Care to see what additional leverage can be brought to bear on potential solutions, including an update on the clinical trials progress and seeking to encourage manufacturers of CBPMs to participate in these trials. I expect this letter to be issued in the next couple of weeks.

In the meantime, I would encourage the petitioner to continue to engage with the specialist doctor and clinical team about any treatment options.

Petitioner submission of 12 September 2021 PE1884/B - Make whole plant cannabis oil available on the NHS or alternative funding put in place

The paragraph below it taken out of the submission received from the Chief Pharmaceutical Officer:

"The regulation, licensing and supply of medicines remain reserved to the UK Government under the Misuse of Drugs Act 1971, and this includes the scheduling of Cannabis Based Products for Medicinal Use (CBPMs). Accordingly, the Scottish Government has no power to alter this while responsibility remains reserved to the UK Government. "

My response is who actually is responsible for the licensing supply of medicines including scheduling of CBPM for medicinal use? As both Governments are saying each other has the right

I have previously contacted the MP for my constituency David Mundell. Who in turn asked the UK Health Secretary at that time, Matt Hancock, to look into the case for CBPMs being prescribed to children on the NHS and I was told this was a matter for the devolved Government. Which in my case is the Scottish Government.

The Chief Pharmaceutical Officer goes on to say:

"Under the current rules, only specialist doctors on the General Medical Council (GMC) specialist register can prescribe cannabis-based products where there is clear, published evidence of benefit. While CBPMs can be prescribed on the NHS, the majority of specialist doctors have concerns around the safety and efficacy of CBPMs, and the lack of robust evidence on their use, particularly the long-term side effects. This is because CBPMs are unlicensed products, which means that they have not been tested for safety, efficacy and quality through the marketing authorisation (licensing) process in the way that a licensed medicine would have. A doctor is professionally and clinically responsible for any medicine they prescribe and the responsibility

that falls on them when prescribing an unlicensed product is greater than when prescribing a licensed medicine.

This means that whilst the evidence base remains limited and there is not better clarity of the risks and benefits, specialist doctors will be cautious about prescribing unlicensed CBPMs. It is only by building this evidence base that doctors will gain the confidence to prescribe them"

This is not the case that specialist doctor have concerns and so we are unable to get CBPMs with THC, it is the case that these are not available to them to prescribe on the NHS. We personally have learned this first hand. Again, it's not the concern it's the fact they are not there to give out.

The paragraphs that follows on from the submission in which I have a response to are:

"With regards to increasing prescribing of CBPMs on the NHS, the Scottish Government is fully aware of the importance of a robust evidence base in reaching a long-term solution. On 8 April 2020, the former Chief Pharmaceutical Officer for Scotland chaired a teleconference with key paediatric neurologists from the specialist centres across Scotland. The specialist doctors had a clear and united view (which I understand to be a UK-wide view) that following GMC and British Paediatric Neurology Association (BPNA) guidelines, they would be unwilling to prescribe any CBPMs containing tetrahydrocannabinol (THC) until there is clear, published, evidence available following a clinical trial.

Some of the main concerns that they highlighted were that there were no published data on dosage ranges, toxicity, interactions, monitoring or long-term side effects (in particular in the developing brain). They were also concerned that they could not guarantee the quality or efficacy of the products due to the variable quantities of THC in dosages. They advised that while they use many medicines 'off-label', they knew of no other medicine where it was prescribed without a licence at all, unless part of a clinical trial. They did, however, indicate that they were willing to participate in clinical trials to build the evidence base"

The GMC and BPNA said they would be unwilling to prescribe CBPMs containing THC until there is clear published evidence. There are currently 3 NHS prescriptions handed out.

Why can 3 children have CBPMs containing THC on the NHS when there are a lot more looking to have this luxury? I can only describe it as a luxury as most other patients are having to pay out vast amounts of money each month for private prescription

In terms of evidence why can't the patients on private and NHS prescription provide their details of current studies?

The first NHS prescription was handed out 2018 that alone is 3 years worth of reliable evidence.

To finish of my submission I also asked if the Government would be willing to provide funding to help out with private prescription cost, I still await an answer to any help that could be given.