Citizen Participation and Public Petitions Committee

5th Meeting, 2022 (Session 6), Wednesday 23 March 2022

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

Note by the Clerk

Lodged on	19 August 2021
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. The Committee last considered this petition at its meeting on 22 September 2021. At that meeting, the Committee agreed to write to the Cabinet Secretary for Health and Social Care, seek further background information on the issues raised in the petition and write to the petitioner.

2. The petition summary is included in **Annexe A** and the Official Report of the Committee's last consideration of this petition is at **Annexe B**.

3. The Committee has received responses from the Cabinet Secretary for Health and Social Care and the petitioner which are set out in **Annexe C**.

4. The Committee requested a literature review from SPICe which is provided at **Annexe D**.

5. Written submissions received prior to the Committee's last consideration can be found on the petition's webpage.

6. Further background information about this petition can be found in the SPICe briefing for this petition.

7. The Scottish Government's initial position on this petition can be found on the petition's webpage.

Action

The Committee is invited to consider what action it wishes to take.

Clerk to the Committee

Annexe A

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

Petitioner
Steve Gillian

Date lodged
19/08/2021

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?

Annexe B

Extract from Official Report of last consideration of PE1884 on 22 September 2021

The Convener: PE1884, which has been lodged by Steve Gillan, calls on the Scottish Parliament to urge the Scottish Government to make whole plant cannabis oil available on the NHS, or to provide funds for private access for severely epileptic children and adults in cases in which all other NHS epilepsy drugs have failed to help.

In response to the petition, the chief pharmaceutical officer outlines that the regulation, licensing and supply of medicines remains reserved to the UK Government under the Misuse of Drugs Act 1971, and that includes the scheduling of cannabis-based products for medicinal use. The chief pharmaceutical officer states that specialist doctors across Scotland have a "clear and united view" that they would be unwilling to prescribe any CBPMs containing tetrahydrocannabinol—the longest word today— until there is clear published evidence available following a clinical trial.

The submission notes that there is currently a lack of data on dosage, toxicity, interactions and monitoring of long-term side effects. However, the chief pharmaceutical officer has been engaging with the development of clinical trials in refractory epilepsy. In addition, 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, to request an update on progress with clinical trials and to ask that manufacturers of CBPMs be encouraged to participate in those trials.

Do members have any comments or suggestions?

David Torrance: I would like us to keep the petition open. We should write to the UK Secretary of State for Health and Social Care to seek his views, especially on the clinical trials, and to find out what progress is being made. People say that whole plant cannabis oil helps them with a range of health complications. If it improves their quality of life, I would like to know whether it is going to be made available.

The Convener: Thank you for that. As someone who sat on the cross-party group on chronic pain, I know that there are individuals who will personally testify to evidence that they have heard or who are aware of somebody who has, under exceptional circumstances, benefited from use of the product. I ask the clerks to find out whether there is potentially a body of evidence from other countries where the use of whole plant cannabis oil may be an approved procedure. It is one of those issues on which we are told that the evidence does not exist, but it cannot exist within our own sphere. Various engagements are taking place in relation to potential trials. We should seek to find out what we can about those.

I am interested in the chief pharmaceutical officer's assertion that there is a "clear and united view" among specialist doctors that they would be unwilling to prescribe such products. Perhaps we could pursue that a bit more, because I would like to understand the reasoning for it.

Are members happy to pursue the petition on that basis?

***Members** indicated agreement.*

Paul Sweeney: I agree. There is a potential reconsideration of the regulations on cannabidiol—CBD—products, although they are currently legal, so the point about the Misuse of Drugs Act 1971 is a bit of a red herring. Further investigation of safe dosage levels is needed, and we could undertake potentially informative clinical trials in Scotland. Furthermore, a cross-party group on medicinal cannabis has recently been established, so it might be useful for the petitioner to consider participating in that as a way of furthering his objectives.

Tess White: I support that suggestion and keeping the petition open. Confidentially, a constituent of mine has said that they are taking CBD for pain relief but, because it is not regulated and not on prescription, they are having to pay extortionate costs. It is much better for a product to be examined and clinical trials to be undertaken. There is also a suggestion that the petitioner's family member could take part in a clinical trial. Keeping the petition open, having clinical trials and exploring the matter further is a good way forward.

The Convener: We should certainly, as Paul Sweeney suggests, draw the petitioner's attention to the new cross-party group that has been established. I take note of Tess White's suggestion. We could write to the chief pharmaceutical officer about the petitioner's family member potentially being eligible to participate in the clinical trial that is being talked about. That is a useful, productive and proactive suggestion.

Do we agree to keep the petition open and wait to hear back from those we wish to write to?

***Members** indicated agreement.*

Annexe C

Cabinet Secretary for Health and Social Care submission of 28 January 2022

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

Thank you for your letter of 23 September 2021 relating to the above petition about access to Cannabis Based Products for Medicinal Use (CBPMs) on the NHS. I apologise for the length of time it has taken to respond.

In your letter, you seek information about the progress of clinical trials connected to CBPMs. The National Institute for Health Research (NIHR) and NHS England are developing a programme of two randomised controlled trials into early-onset epilepsy, and these trials will be open to patients in Scotland. The trials will compare medicines that contain cannabidiol (CBD) only and that contain CBD plus delta-9-tetrahydrocannabinol (THC) with placebos. Commercial discussions about the supply of products to the trial are underway, and it is only after they concluded that it will be possible to confirm details of the trials, including when recruitment will commence and other timetable details.

The trials will examine the quality, safety and efficacy of the use of CBPMs in epilepsy, and crucially will help answer the question of whether adding THC to CBD improves anti-epileptic properties. Building this evidence will enable the manufacturers of these products to apply for marketing authorisation (also known as a license) for their products from the Medicines and Healthcare products Regulatory Agency (MHRA), depending on the outcome of the trials, and products could potentially be made more widely available.

My officials have engaged with NHS England and NHIR about trial delivery matters, including contacts with Scottish clinicians and discussions about Scottish patient recruitment.

Your letter also seeks information about the progress of discussions with the UK Government on this matter. I have written to the Secretary of State for Health and Social Care, Sajid Javid MP, to discuss the need to build the evidence base connected to CBPMs and the ways in which Governments might cooperate on this matter. In response to my letter, the Secretary of State invited me to meet with the Minister for Patient Safety and Primary Care, Maria Caulfield MP, in early February. We will discuss this matter and in particular will consider together ways in which the clinical trials can be expedited in order to benefit as many patients as possible.

I acknowledge this is not an immediate solution to patients seeking to access these products on the NHS. However, it is I think the lack of evidence on the quality, safety and efficacy of CBPMs that remains the main barrier to these products being prescribed by NHS clinicians. Therefore, the Government continues to support the development of clinical trials to enable clinicians to have the assurances they need to consider prescribing these products on the NHS.

Petitioner submission of 15 March 2022

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

The Cabinet Secretary for Health and Social Care said: “I acknowledge this is not an immediate solution to patients seeking to access these products on the NHS. However, it is I think the lack of evidence on the quality, safety and efficacy of CBPMs that remains the main barrier to these products being prescribed by NHS clinicians. Therefore, the Government continues to support the development of clinical trials to enable clinicians to have the assurances they need to consider prescribing these products on the NHS.”

I don't accept or agree that there is a lack of evidence for the NHS to be allowed to prescribe CBPM's with THC to patients.

I have repeatedly pointed out that there are currently three prescriptions given out to date, these prescriptions have also been handed out for more than 3 years so there's at least this amount of reliable evidence through the NHS.

Furthermore, if there was such a lack of evidence why do these NHS prescriptions exist?

Below is a submission made to Petition PE1884 from the Chief pharmaceutical Officer Alison Strath.

These paragraphs below are taken straight out Alison Strath's submission.

"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."

This is the reason I don't agree that there is not enough evidence to prescribe CBPM's with THC, because if this were to be the case the NHS has gone against all guidelines and laws set out for prescribing unlicensed medications and are producing three prescriptions on the NHS.

Annexe D

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.

Brief overview of issues raised by the petition

Introduction

SPICe has published a briefing for this petition. This briefing provides Members with an overview of some of the current international legislation and policy on the use of cannabis-based products for medicinal use (CBPM) containing THC (tetrahydrocannabinol) to treat epilepsy in children and adults.

Cannabis has many active chemical constituents. The two that have been investigated the most for their medicinal value are THC (tetrahydrocannabinol) and CBD (Cannabidiol).

The CBPMs which contain THC include:

- Sativex (contains both THC and CBD)
- Nabilone (synthetic cannabinoid similar to THC)
- Dronabinol (synthetic form of THC)

The Chief Pharmaceutical Officer for Scotland's written submission of 19 August 2021 on this petition outlines some of the barriers to prescribing CBPMs in Scotland. The Chief Pharmaceutical Officer for Scotland states that the 'majority of specialist doctors have concerns around the safety and efficacy of CBPMs' and, specifically, the lack of 'robust evidence' regarding their use.

These concerns reflect the findings of a review by NHS England (August 2019), which suggested that weak clinical evidence has prevented the prescription of CBPMs by clinicians.

Three products have been licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) following the changes to the Misuse of Drugs legislation in 2018. These are Epidyolex, Sativex, and Nabilone. Epidyolex received marketing authorisation in September 2019.

However, only Epidyolex is recommended for prescription by the NHS in Scotland.

The Scottish Medicines Consortium (SMC) accept Epidyolex (CBD) for use within NHS Scotland as an add-on therapy with clobazam for seizures associated with Lennox Gastaut syndrome and Dravet syndrome, both severe forms of epilepsy, in patients aged 2+. Epidyolex is currently under consideration by the SMC as an add-on therapy for seizures associated with Tuberous Sclerosis Complex in patients aged 2+.

Sativex is currently not recommended for use in NHS Scotland as an add-on treatment for patients with treatment-resistant moderate to severe spasticity caused by Multiple Sclerosis (MS). The SMC states that this is due to the holder of the NHS marketing authorisation not making a submission to the SMC regarding this product. Individual doctors may be willing to prescribe Sativex without SMC recommendation. Sativex can also be accessed on a private prescription.

All cannabis-related products for medicinal use that do not have market authorisation (i.e. those other than Sativex, Nabilone, and Epidyolex) are unlicensed medicines. Unlicensed medicines can be legally prescribed in some cases if there is a special clinical need. However, unlicensed medicines create further concerns for clinicians due to the responsibility of care that prescribing clinicians have.

Medicines with a market authorisation have been submitted to and authorised by a regulatory authority, which implies that the medicine has went through extensive clinical trials and tested for its safety, efficacy,

and side effects. A briefing paper by the House of Commons Library in May 2020 stated that 'almost all' cannabis-based medicines in the UK prescribed by specialist doctors are unlicensed medicines

Relevant UK Guidance

The National Institute for Health and Care Excellence (NICE) published guidance on prescribing CBPMs in November 2019. The guidance focused on using CBPMs to treat intractable nausea and vomiting, chronic pain, spasticity, and **severe-treatment resistant epilepsy**.

NICE have released evidence-based recommendations on Epidyolex, which does not contain THC, for seizures associated with Lennox-Gastaut syndrome and for seizures associated with Dravet syndrome. NICE have acknowledged that most of the current evidence for severe treatment-resistant epilepsy has evaluated the use of pure CBD products, rather than THC-containing products.

While individual patients have reported having fewer seizures when using unlicensed CBPMs for epilepsy, NICE states that current evidence for these medicines is 'limited and of low quality'. NICE feels unable to assess how affective these medicines are and therefore recommends further research on:

- The clinical and cost effectiveness of CBD in epileptic disorders in children, young people, and adults.
- The impact of THC in combination with CBD for severe treatment-resistant epilepsy in children, young people, and adults.

NICE released a clarification of guidance in March 2021. NICE stated that, while there was 'insufficient evidence of safety and effectiveness to support a population-wide practice recommendation' of CBPMs for severe treatment-resistant epilepsy, healthcare professionals are not prevented from considering the use of unlicensed CBPMs where clinically appropriate.

The British Paediatric Neurology Association (BPNA) released guidance in October 2018 on the use of cannabis-based products for medicinal use in children and young people with epilepsy:

- While the BPNA found ‘good clinical evidence’ that CBD has an anti-epileptic effect in Dravet Syndrome and Lennox-Gastaut Syndrome, two severe epilepsy syndromes, the evidence for THC was mixed.
- The BPNA noted that there was less data on the effectiveness and safety of products containing THC in treating epilepsy in children and young people.
- The BPNA found that one study suggested some effectiveness, but it did not consider this study to be ‘high quality’ evidence.
- The BPNA also had concerns about the possible impact of THC on the development of children and young people.

International Evidence

This briefing provides information on current guidelines from Australia, America, Ireland, and Canada. It is not intended to be a comprehensive review of all research and literature in the area.

Ireland

The Health Products Regulatory Authority (HPRA) is the Irish equivalent of the UK Medicines and Healthcare Regulatory Authority. Under a request by the Minister for Health, the HPRA reviewed the potential medical uses of cannabis. Following the review’s publication in February 2017, a 5-year Medical Cannabis Access Programme (MCAB) was established.

The MCAB permits patients with three medical conditions, defined in the review, to be treated with cannabis or cannabinoids. One of these conditions is **severe, treatment-resistant epilepsy that has failed to respond to standard anticonvulsant medications whilst under expert medical supervision.**

With regards to the use of THC for severe, treatment-resistant epilepsy, the HPRA found the evidence to be complex. While THC appeared to function as an anti-convulsant in some circumstances, it also appeared as a pro-convulsant in others.

The HPRA’s review covered the **differences between THC and CBD**. A distinction must be made between cannabis products containing THC and those which contain no THC. **The review reported that data is not**

sufficient for THC-containing cannabis products in many cases. The evidence does not currently support their authorisation as medicines.

The HPRA provided an opening statement to the Oireachtas Joint Committee on Health's evidence session on the Medical Cannabis Access Programme, in September 2021. It acknowledged that the scientific evidence considered by the review was 'extremely limited and fell well short of the standard and level required for a medicine to receive market access.'

America

As of May 2021, 36 American states and 4 territories allow for the medical use of cannabis products. In January 2017, the National Academies of Sciences, Engineering, and Medicine (NASEM) published The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research. NASEM convened a committee of experts to conduct an evidence review of the short and long-term impacts of cannabis and/or its constituents. The committee considered recently published systematic reviews and good-quality primary research.

Key conclusions included **no or insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for epilepsy.**

In their 2018 assessment of NASEM's publication, the Chief Medical Officer for England and the Chief Medical Adviser to the UK Government concluded that 'the review of this committee can be considered the most rigorous and wide ranging to date' on medicinal cannabis.

Australia

The Department of Health of the Australian Government completed a review on medicinal cannabis, published in 2018. The Chief Medical Officer for England and the Chief Medical Adviser to the UK Government also examined this review in their assessment. This said that the review

showed limited, but high-quality, evidence for the use of medicinal cannabis products in the treatment of epilepsy.

The Therapeutic Goods Administration (TGA) within the Department of Health released guidance for the use of medicinal cannabis in Australia (December 2017). The TGA are responsible for regulating therapeutic goods in Australia. The guidance acknowledges that, in many cases, there is 'very limited data' from which to draw specific recommendations for the use of CBPMs.

The TGA also released specific guidance for the use of medicinal cannabis in the treatment of epilepsy in paediatric and young adult patients.

The TGA's guidance to health professionals is that the use of CBPMs should only be considered in cases where conventional treatments for epilepsy in paediatric and young adult patients have been unsuccessful in managing the patient's symptoms. Medicinal cannabis or cannabinoids should only be prescribed as an **add-on treatment** with existing anti-epileptic drugs.

The guidance states that most published clinical and pre-clinical data on the efficacy of CBPMs in treating epilepsy relates to CBD.

The guidance therefore focused mainly on CBD, but did evaluate the efficacy of some THC treatments:

- There is currently insufficient evidence to show the efficacy of CBD:THC (administered orally as an oil) as a treatment for epilepsy. Under the guidelines, the TGA define 'efficacy as the proportion of patients experiencing a 50% or greater reduction in seizure frequency'.
- There is currently insufficient evidence to suggest that CBD:THC/THCA may achieve complete freedom from seizures for the patient.
- There is currently insufficient evidence to suggest that CBD:THC can improve quality of life outcomes.
- There is currently insufficient evidence to suggest that THC can contribute to overall improvements in the patient's quality of life outcomes.

Canada

The Government of Canada outlines guidance for health care professionals on the use of cannabis and cannabinoids for medical purposes. The guidance was updated in Spring 2018. The guidance reviews the current evidence for CBPMs as a treatment for various conditions, including epilepsy.

The guidance states that there is 'anecdotal evidence' to suggest the anti-epileptic effect of cannabis (THC- and CBD- predominant strains). **The available evidence from pre-clinical studies suggests that certain cannabinoids (CBD) may have anti-epileptic and anti-convulsive properties. However, THC may have either pro- or anti-epileptic properties.**

Observational studies also suggest an association between CBD and a reduction in seizure frequency, as well as an increase in quality of life, among adolescents with rare and serious forms of drug-resistant epilepsy.

The guidance detailed the current evidence on the potential impact of CBPMs, particularly in THC-predominant cannabis:

- The early on-set use of high-potency, THC-predominant cannabis has been associated with an increased risk of some brain structural changes and cognitive impairment.
- Epidemiological studies suggest an association between THC-predominant cannabis use and the onset of anxiety, depressive, and bipolar disorders and the persistence of symptoms related to PTSD, panic disorder, depressive disorder, and bipolar disorder. This association is higher if the THC-predominant cannabis use is chronic and heavy.
- Epidemiological studies suggest an association between THC-predominant cannabis use and psychosis and schizophrenia. This association is higher if the THC-predominant cannabis use begins at an early age, is chronic, and heavy.

Current trials

- Project Twenty21 aims to create the UK's largest body of evidence for the effectiveness and tolerability of medicinal cannabis. Adults with epilepsy who have a used at least two licensed medications and

found them ineffective at managing their condition are eligible to participate.

- Schneider Children's Medical Centre of Israel and University Children's Hospital, Ljubljana University Medical Centre (Slovenia) - Study of the safety and efficacy of MGCND00EP1 (each ml solution contains 100mg of CBD and 6mg of THC) as an add on treatment in children and adolescents with resistant epilepsies.

- The Hospital for Sick Children, Toronto (Canada) – Cannabinoid Therapy for Paediatric Epilepsy. All participants will receive the study drug 'Cannabidiol-Rich whole Plant Extract (TIL-TC150)'. The active ingredients in TIL-TC150 are THC and CBD.

- University of British Columbia (Canada), University of Manitoba (Canada), Universite de Montreal (Canada), University of Saskatchewan (Canada) – Cannabidiol in Children with Refractory Epileptic Encephalopathy. Participants will receive CanniMed® 1:20, a CBD:THC 20:1 ratio product.

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