Citizen Participation and Public Petitions Committee

13th Meeting, 2022 (Session 6), Wednesday 28 September 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 23 March 2022. At that meeting, the Committee agreed to write to the Cabinet Secretary for Health and Social Care and the Minister for Drugs Policy.

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 a new response from the Cabinet Secretary for Health and Social Care which is set out in **Annexe C**.

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

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

6. The Scottish Government's initial position, provided by the Chief Pharmaceutical Officer, on this petition can be found on the petition's webpage.

7. Members may wish to note that the Cabinet Secretary for Health and Social Care elected to respond on behalf of the Minister for Drugs Policy.

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 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?

Annexe B

Extract from Official Report of last consideration of PE1884 on 23 March 2022

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

When we last considered the petition, we agreed to write to the Cabinet Secretary for Health and Social Care to seek information about the progress of clinical trials and further information on his discussions with the UK Government. The cabinet secretary's response stated that he thinks that "the lack of evidence on the quality, safety and efficacy" of cannabis-based products for medicinal uses is "the main barrier" to them being prescribed by NHS clinicians, and he stressed the importance of development of the trials. He outlined plans to undertake two randomised and controlled trials of their use in early-onset epilepsy. The trials will compare medicines that contain only cannabidiol with ones that contain CBD and tetrahydrocannabinol and with placebos. That is to help answer the question of whether adding THC to CBD improves anti-epileptic properties. He also indicated that commercial discussions about the supply of products to the trial are under way, and that further details of the trials, including the timetable, will be dependent on the conclusion of those discussions.

The cabinet secretary stated that a meeting was scheduled for early February with the UK Minister for Patient Safety and Primary Care, Maria Caulfield MP. It was to include a consideration of ways in which the trials can be expedited.

The committee also requested information on existing evidence from other countries from the Scottish Parliament information centre. Its review is included in your papers pack at annex D. It provides information on current guidelines from Australia, America, Ireland and Canada. It highlights that a review on medicinal cannabis in Australia was examined by the UK Government. The UK Government stated that the review showed "limited but high quality evidence for the use of medicinal cannabis products" to treat epilepsy.

The use and efficacy of THC treatments is addressed in the guidance from Australia, Ireland and Canada. It indicates that the evidence base for THC is complex in that it may have either pro or anti-epileptic properties.

Much of the guidance in other jurisdictions acknowledges that limited evidence is available for the use of cannabis-based products for medicinal use and frequently advises that such products should be prescribed as an add-on treatment with existing anti-epileptic drugs.

The petitioner points to three existing prescriptions across the UK, and reiterates that he does not accept that there is a lack of evidence for prescribing. He explains that

the prescriptions have been in place for three years, and he considers that to be an example of “reliable evidence” for its use by the NHS.

Again, that was quite a long introduction. Do colleagues have any comments that they wish to add?

David Torrance: In light of the meeting with Minister for Patient Safety and Primary Care, Maria Caulfield, having been held in February, could we write to the cabinet secretary to ask him for an update on how that went? Can we also ask when commercial discussions about the supply of the products to trials are likely to conclude; whether the trials will include patients, including children, with severe epileptic conditions and whether patients in Scotland will be recruited for the trials? Can we also ask for further information on the timescales for trials and how they can be expedited, and, depending on the outcome of the trials, the timescales for achieving authorisation?

The Convener: Thank you. Again, that is quite a comprehensive series of recommendations. Would anybody like to add to that, or is the committee content to support that?

Paul Sweeney: I think that it is also important to raise the fact that people are self-medicating with THCs already, where they have got a supply from unofficial sources. It might be worth engaging with the Minister for Drugs Policy, Angela Constance, about the pattern of illicit access to substances that are cannabis-derived products.

That might also illustrate that, where health and social care partnerships have introduced programmes such as herb-assisted treatment, it is actually seen as a public health benefit that people are medicating themselves in that way, as it is much more satisfactory that people do that in a controlled environment. Perhaps there is an angle that is not simply about the context of prescribing by a general practitioner or a clinician but about instances in which people are already selfmedicating, and recognising that there is a public health interest in ensuring that harms are reduced in that situation.

The Convener: Are members content to add those recommendations to our actions?

Members *indicated agreement.*

Annexe C

Cabinet Secretary for Health and Social Care submission of 26 April 2022

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

Thank you for your letter of 5 April 2022 in relation to the above petition, and in particular regarding clinical trials on the use of Cannabis Based Products for Medicinal Use (CBPMs).

Following my meeting with the Minister for Patient Safety and Primary Care, Maria Caulfield MP, I understand that NHS England remain in commercially sensitive discussions around the establishment of two clinical trials to further the evidence base for CBPMs. These trials will focus on CBPMs in early onset and genetic generalised epilepsy in adults and children. Due to the commercially sensitive nature of these discussions, I am limited in what I can say publicly so as to not jeopardise or prejudice any outcomes.

That said, I can confirm that patients in Scotland will be eligible to take part in the trials once they are live. The study team will announce the timeline plans for the trial as soon as possible, this will include details on when patient recruitment is expected to commence.

It may be helpful if I explain the process for new medicine licensing. In the UK, medicines need to have a marketing authorisation (also known as a licence) before they can be marketed for use. To get a licence, the manufacturer of the medicine has to provide evidence to the Medicines and Healthcare products Regulatory Agency (MHRA) that shows that the medicine is effective enough and safe enough to be used for a specific condition and for a specific group of individuals, and that they can manufacture the medicine to the required quality. This is followed up by a system of inspection and testing which continues throughout the lifetime of the medicine. The evidence for safety and efficacy comes from clinical trials. Clinical trials are carried out in three phases which must all be completed before an application can be made to market a new medicine.

In Phase I studies the medicine will be tested in healthy volunteers or closely-monitored patients to collect information about the metabolism of the medicine in human subjects. The information is used to establish the dose which will be used at the next stage of testing.

Phase II studies involve patients who are affected by the target disease. The efficacy of the medicine will be studied in terms of its effects on symptoms and signs of the disease, and further information obtained regarding the safety of the medicine. In some trials, the new medicine is compared with the best currently available treatment, in others it is compared with a placebo. In either case, the trial will often be carried out in a ‘double blind’ manner, meaning that neither the patient, nor the doctor, knows whether they are taking the new medicine or not. This helps to differentiate between the physical effects of a medicine and any other effect that might occur as a result of a patient believing a medicine will produce a particular effect and consequently actually experiencing it (placebo effect).

Phase III trials are carried out on a much larger scale. A decision to begin this stage is made once the results from the previous phases have been documented and have been seen to indicate that the medicine is potentially efficacious, and its safety profile has been established as far as possible. Phase III trials are designed to gather evidence of efficacy in specific indications and to more fully understand the safety profile of the medicine. Patients are allocated to the treatment they will receive through a randomised code, some will receive the new medicine, others an existing treatment or placebo. The numbers required are dictated by statistical considerations so that a comparison of the new medicine with existing medicines or placebo is placed on a sound footing. The results of these trials provide support for claims concerning efficacy and safety and the pivotal evidence required by the regulatory authorities before the new medicine can be licensed.

Unlicensed products are not routinely available on the NHS, and going through the licensing process is the only way to be sure of the safety, quality and efficacy of any medicines, including CBPMs. The MHRA has advised that the licensing process for any medicine, once a submission is received, typically takes 210 to 230 days. Furthermore, the decision to make a submission to the MHRA is one for the manufacturer to make.

In Scotland, the Scottish Medicines Consortium (SMC) appraises the clinical and costeffectiveness of newly-licensed medicines. The decision to submit a medicine to the SMC and the timing of that decision tosubmit

is one entirely for the manufacturer to make. Notably, a company may choose to make a submission for a medicine to the SMC before final approval from the MHRA. Following receipt of a submission from the manufacturer, the SMC carries out an appraisal of the medicine and then determines whether it should be accepted for routine use within the NHS in Scotland. The SMC appraisal is undertaken independently of Scottish Ministers and the Scottish Parliament and is based on the clinical and cost-effectiveness of the medicine at a population level. The usual assessment timeline is 18 weeks, from the scheduling of a submission to the publication of advice. A longer timeline of 22 to 26 weeks, is sometimes required for medicines used to treat end of life and/or rare conditions if the submitting company requests a Patient and Clinician Engagement (PACE) meeting which gives patient groups and clinicians a stronger voice in SMC decision making.

Following the appraisal process, the SMC publishes advice for Health Boards to consider. Once a medicine is submitted to the SMC for appraisal, Health Boards have procedures in place through the Peer Approved Clinical System “PACS Tier Two” process which allows clinicians to consider prescribing licensed medicines to individual patients on a case by case basis in advance of the SMC completing the appraisal process and issuing its advice.

I hope that the above information has been helpful in addressing the points you have raised.

Cabinet Secretary for Health and Social Care submission of 8 June 2022

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

Thank you for your letter of 16 May addressed to Angela Constance MSP, Minister for Drugs Policy in regards to the above petition, and specifically in relation to people accessing cannabis, and Cannabis Based Products for Medicinal use (CBPMs), for medicinal purposes. As CBPMs are within my portfolio area I have been asked to respond.

By way of context, the Scottish Government recognises that there are genuine limitations in our public health approach to drug use whilst the

Misuse of Drugs Act 1971 is maintained in its current form. We are therefore looking at measures which have been successfully implemented across the world which are designed to decrease the social and physical harm caused by drugs. To that end, we continue to urge the UK to amend the Misuse of Drugs Act 1971 to make more public health measures possible or to devolve the necessary powers to the Scottish Government to allow us to make much needed amendments to drug legislation.

The Scottish Government is aware, from correspondence received, that there are people accessing cannabis through both legitimate and illicit routes for medicinal purposes. We are aware of a number of conditions for which people may access illicit cannabis, including chronic pain, multiple sclerosis and fibromyalgia. We encourage anyone who is self-medicating with illicit cannabis to discuss their treatment options with the clinicians in charge of their care.

We do not hold any information on the number of people accessing illicit cannabis for medicinal purposes, and data on this subject are not routinely collected. Information on prescriptions dispensed for CBPMs in Scotland is collected by Public Health Scotland.

Furthermore, we are not aware of any current or planned programmes run by Health and Social Care Partnerships to allow people to self-medicate with cannabis in a safe and controlled environment. It is important to note that any such programme would be in breach of the Misuse of Drugs Act 1971, hence why we continue to call on the UK Government to make suitable amendments to the Act.