

From Jo Churchill MP Parliamentary Under Secretary of State for Prevention, Public Health and Primary Care

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The Rt Hon Sir George Howarth MP By email to: george.howarth.mp@parliament.uk

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Dear Sir George,

Thank you for your correspondence of 1 December to the Prime Minister on behalf of one of your constituents about cannabis-based products for medicinal use (CBPMs).

I was very sorry to read of the emotional and financial difficulties experienced by families caring for children with intractable epilepsy. I understand how incredibly distressing it must be for patients and their families to resource funding for private prescriptions.

The change in law to allow prescriptions for medicinal cannabis is intended to transform the care received by patients with severe epilepsy.

However, most CBPMs are unlicensed medicines and have not had their quality, safety or efficacy assured by medicines regulators, nor their cost-effectiveness determined by the National Institute for Health and Care Excellence (NICE). These concerns are echoed by the Royal College of Physicians, the Association of British Neurologists, the Royal College of Paediatrics and Child Health and the British Paediatric Neurology Association.

Currently, the NHS in England does not routinely commission funding for CBPMs. The treatment and funding for patients with epilepsy is considered carefully by clinicians and the NHS. Therefore, decisions relating to the prescribing of CBPMs need to be made on a case-by-case basis, and whether to treat must remain a clinical decision. We firmly agree that patients must be able to access CBPMs when they are appropriately prescribed.

As your constituents may be aware, the Secretary of State for Health and Social Care commissioned a review into the barriers being faced by patients seeking access to CBPMs. This followed his meeting with families of patients on 19 March 2019. The report has now been published, and can be found at www.england.nhs.uk by searching for 'barriers to accessing cannabis-based products for medicinal use'. The NHS is working closely with the Department and other delivery partners to implement the recommendations.

It is well established that we do not yet know enough about the benefits and potential harms of using these products as medicines. The use of Sativex, Epidyolex and nabilone is supported by clear evidence of their safety, clinical and cost effectiveness for the specific indications for which they are licensed. These products have marketing

authorisations and are being prescribed on the NHS; however, other cannabis-based products are currently unlicensed medicines.

The NICE clinical guidelines do not make practice recommendations for the use of unlicensed CBPMs in the management of severe treatment-resistant epilepsy. The guidelines conclude that more evidence is needed on the effectiveness of CBPMs in these cases, but state that specialists, people with epilepsy and their carers should continue to make treatment decisions in the best interests of each patient, in line with the General Medical Council's guidance for doctors. The NICE guidelines can be found at www.nice.org.uk by searching for 'cannabis-based medicinal products'.

In addition to this, the NHS report and the NICE guidelines both recognise that there is not yet enough evidence to allow decisions to be made regarding the routine funding of these products on the NHS. The NHS has been clear that guidance is just that, and decisions on the treatment of individual patients are for treating clinicians to make. Further information can be found at www.england.nhs.uk by searching for 'process for prescribing cannabis-based products for medicinal use'.

The NHS and the Chief Medical Officer have disseminated information to clinicians to clarify the procedure for prescribing and supplying CBPMs, including how to access resources such as Health Education England's medicinal cannabis education package published on 8 August 2019. As recommended in the NHS report, a UK-wide paediatric specialist clinical network has been established to provide specialist clinical expertise, support discussion of complex cases, provide support to clinicians and assist in generating evidence.

It is important that prescribing decisions for CBPMs are based on clear evidence. The Department has called on the industry to take action to produce this evidence in a form that will support decisions about public funding. CBPMs are no different from any other drug, in that they have effects and side effects. That is why it is so important to develop firm evidence and increase our knowledge about the safety and efficacy of these products when they are used as medicines.

To further our understanding in this area, we are promoting high-quality research through the publicly funded National Institute for Health Research (NIHR). The NIHR has issued two calls for research proposals, alongside its highlight notice on medicinal cannabis, and remains open to additional proposals for research in this area as a priority. The Department, the NHS, the NIHR and the specialist network are considering how these clinical trials should be set up, after which the usual processes for research will need to be undertaken.

The Secretary of State and I have met Sir Mike Penning and Tonia Antoniazzi, the Joint Chairs of the All-Party Parliamentary Group (APPG) on Medical Cannabis under Prescription, Hannah Deacon, the mother of Alfie Dingley, and Peter Carroll, the Campaign Director of End Our Pain, to discuss access to CBPMs. Sir Mike and Mr Carroll have also recently met Professor Stephen Powis, National Medical Director of NHS England, and Dr Keith Ridge, Chief Pharmaceutical Officer for England, to discuss the progress in the establishment of the clinical trials. The trials have not progressed as quickly as we had originally hoped, and the Department remains committed to working with NHS England and NHS Improvement (NHSE&I) to ensure the trials commence as

soon as practically possible. I have asked NHSE&I to keep the APPG updated on progress. I am certain that these trials represent the best way to develop robust evidence to support future NHS commissioning decisions.

We strongly agree that it is vital that a sustainable system is set up under which CBPMs are available to patients in need, where they are clinically appropriate.

I hope this reply is helpful to your constituents and clarifies the Department's approach in improving access to treatment for patients and families with severe epilepsy.

JO CHURCHILL