Department of Health & Social Care

From Jo Churchill MP
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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 17 June to the Prime Minister on behalf of a number of your constituents, about cannabis-based products for medicinal use (CBPMs). Your query has been passed to the Department of Health and Social Care.

I deeply sympathise with your constituents' concerns and I am grateful to them for taking the time to raise this matter with you.

I have personally met patients and parents dealing with refractory epilepsy and other difficult-to-treat conditions, and I understand how demanding and distressing it is for them. Regarding Thomas Braun, I have invited his family to meet me in person, to discuss and understand their situation.

Decisions relating to the prescribing of CBPMs, which are unlicensed medicinal products whose quality, safety, and efficacy have not been assured by the regulators, need to be made on a case-by-case basis, weighing up the potential for benefit against the potential for harm. Whether to treat must remain a clinical decision. Since 1 November 2018, specialist doctors on the Specialist Register of the General Medical Council have been able to prescribe CBPMs where clinically appropriate and in the best interests of patients.

CBPMs are not routinely funded by the NHS in England. However, the licensed cannabis-based products Sativex, Nabilone, and Epidyolex, for which there is clear evidence of safety, clinical effectiveness and cost effectiveness, are provided routinely for their licensed indications. Most CBPMs have also not had their cost effectiveness determined by the National Institute for Health and Care Excellence (NICE). These are the foundations of NHS decisions about routine funding for medicines.

CBPMs are no different from any other drug, in that they have effects and side-effects. NICE conducted a review of the available evidence in 2019, concluded that more evidence is needed on the effectiveness of CBPMs for treatment-resistant epilepsy, and made research recommendations. The absence of routine practice recommendations does not, however, prevent healthcare professionals from considering the use of unlicensed CBPMs in individual cases, where clinically appropriate. Further information and the clinical guidelines can be found at www.nice.org.uk by searching for 'cannabis-based medicinal products'. The NHS has also issued guidance for clinicians, which can be found at www.england.nhs.uk by searching for 'process for prescribing cannabis-based products for medicinal use'.

It is well established that clinical trials represent the best way to develop robust evidence to support future NHS commissioning decisions. I am committed to working with NHS England and NHS Improvement (NHSE&I) and the National Institute for Health Research (NIHR) to ensure that we build a clearer evidence base to support decision-making in the NHS.

NHSE&I and the NIHR have confirmed support for two randomised controlled trials into early-onset and genetic-generalised epilepsy. These will compare medicines that contain cannabidiol (CBD) only and that contain CBD plus delta-9-tetrahydrocannabinol with placebos. I recognise that, like many projects during the pandemic, there have been delays in starting the trials. However, commercial discussions on the supply of products for the trials are nearing completion. Once a supply contract has been finalised, the study team will be able to initiate the formal trial set-up process and confirm a date for patient recruitment to start. This is a pioneering area of research, and we are keen to support patients by progressing these trials. I have written to the National Medical Director of NHS England, Professor Stephen Powis, to ask NHSE&I to keep the All-Party Parliamentary Group on Medical Cannabis under Prescription updated on its progress.

The NIHR has issued two calls for research proposals, alongside its highlight notice on medicinal cannabis, and welcomes applications for high quality research proposals in this area as a priority. Funding will be awarded according to the importance of the topic to patients and health and care services, value for money and scientific quality. To assist in the development of proposals, the Medicines and Healthcare Products Regulatory Agency is well equipped to provide independent advice to researchers and companies wishing to conduct clinical trials or submit applications for product licensing.

Whilst it will take time to generate further evidence and see the results of the clinical trials, I understand that patients and families continue to access these medicines privately, and that the cost of doing so has been and continues to be high. I know that there are no easy solutions, but I have committed that the department will reconsider what further action the Government might reasonably take regarding access to unlicensed CBPMs.

I hope this reply is helpful and demonstrates the department's commitment to developing a strong evidence base for these medicines.

JO CHURCHILL