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 to submit 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.