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Dear Owen,

CANNABIS-BASED PRODUCTS FOR MEDICINAL USE (CBPMs) IN HUMANS

Thank you for your comprehensive reports dated 23 December 2019 (about the outline assessment framework setting out how the ACMD would assess the various impacts of the rescheduling, and the data sources that would be used), the 27 November 2020 report on Cannabis-Based Products for Medicinal use (CBPMs) in humans, which considered the impact of rescheduling CBPMs under the Misuse of Drugs Regulations 2001, ('the 2001 Regulations') and separate advice on whether the current scheduling of CBPMs remained appropriate. I am sorry for the delay in replying to you.

The thorough consideration of the issues concerning CBPMs, and other cannabis-based medicines by the Advisory Council on the Misuse of Drugs (ACMD) is greatly appreciated. From the outset the ACMD has been instrumental in ensuring that we provide the necessary access to CBPMs where clinically appropriate by assisting the Home Office to implement these legislative amendments. Nonetheless CBPMs are still a relatively new amendment and we continue to learn more as the time progresses. We appreciate the ACMD's consideration and work on this issue while we continue to navigate this complex area.

The Home Office and the Department of Health and Social Care (DHSC) have worked together to consider each proposed recommendation.

I would like to clarify from the outset, that the Government does not reject any of the proposed recommendations made by the ACMD. We agree with the purpose of each of the four recommendations, however we believe that some of the proposed outcomes could be delivered in a different way.

Recommendation 1

The ACMD should be commissioned to conduct a further assessment of the impact of the rescheduling of CBPMs in the two years following the publication of this report, as there is not yet sufficient evidence available to fully assess any and all consequences of the legislative change. Much of this evidence would not be expected to fully emerge for several years.

We agree with this recommendation, in principle, subject to the availability of sufficient data.

We would be grateful if the ACMD could consider the available data in autumn this year and set out any potential limitations to a further assessment. On receipt of this advice the Government will revisit this recommendation and provide a further re-commission if appropriate.

Recommendation 2

The availability of a CBPM patient registry should be recognised as crucial for future assessments of the impact of the rescheduling of CBPMs in November 2018. The Government should continue to support the development of an official CBPM patient registry. Depending on whether the official CBPM patient registry is developed to be able to collect all necessary CBPM private prescription data, the Government may wish to consider how the official registry can interact with those in development outside of Government.

We accept this recommendation. Following successful pilots in January 2021, NHS England and NHS Improvement (NHSE-I) has established a patient registry for patients prescribed unlicensed CBPMs and licensed cannabis-based medicines. As of 1 April 2021, completion of the patient registry is a requirement under the NHS Standard Contract. As such, it will be mandated by NHSE-I for use by commissioners for all contracts for healthcare services other than primary care contracts. In due course, the patient registry will be extended across the UK. The registry currently only covers NHS prescriptions and NHSE-I are conducting further work to explore how to capture data from private providers.

Recommendation 3

Research should be commissioned: a) to assess the impacts of the rescheduling of CBPMs in November 2018 on public knowledge and attitudes towards cannabis, unlicensed CBPMs, licensed CBPMs and licensed cannabis-based medicines; and b) to explore the safety, quality and efficacy of unlicensed CBPMs, licensed CBPMs and licensed cannabis-based medicines.

We agree with the ACMD on the importance of understanding public knowledge and attitudes towards cannabis, unlicenced CBPMs, licensed CBPMs and licenced cannabis-based medicines. As part of this we will continue to review the available evidence on the impact of the 2018 amendments.

As a starting point, the Government will consider how existing surveys can help with this. The Crime Survey for England and Wales (CSEW) provides the best dataset available on the prevalence of cannabis use and can help determine any changes in this since November 2018. The ACMD may also find the survey on Smoking, drinking and drug use among young people in England useful, although fieldwork for the 2020 survey was postponed until autumn 2021 (academic year 2021/22) due to the coronavirus (COVID-19) pandemic to help reduce the burden placed on schools. A report is due to be published in the summer.

In relation to Part a) we agree that it is necessary for the Government to consider what further research might help us better understand the effects of rescheduling CBPMs under the 2001 Regulations. The Government will consider this and will continue to update the ACMD with progress.

With regard to Part b) of the recommendation, like other medicines, it is the responsibility of manufacturers to produce evidence on safety, quality and efficacy and to put forward their products for scrutiny by the Medicines and Healthcare products Regulatory Agency (MHRA) before a marketing authorisation (licence) is granted.

Despite calls from DHSC Ministers, the industry has largely failed to invest in clinical trials to establish the safety, quality and efficacy of their products. The National Institute for Health Research (NIHR) and NHS England are developing a programme of 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 (THC) with placebos. The results of this trial will answer the critical question of whether adding THC to CBD improves anti-epileptic properties. Once commercial discussions on the supply of products for the trial are complete the study team will be able to confirm further details and when recruitment to the trials will commence. The NIHR has issued two calls for research proposals alongside its highlight notice on medicinal cannabis and remain open to research proposals in this area as a priority.

When prescribing an unlicensed medicine, it is the responsibility of the prescriber to be satisfied that there is sufficient evidence of using the medicine to demonstrate its safety and efficacy.

Recommendation 4

Government departments should conduct a full review of international approaches to legislation facilitating the medicinal usage of cannabis-based medicines.

We agree that there is clear merit in understanding the approaches being used internationally.

The United Nations Commission on Narcotic Drugs (CND) also provides a vital opportunity to discuss policies and legislation in various countries around the world. Since the last CND event in April 2021, the Home Office has hosted a number of bilateral meetings to discuss various drug policy issues. Since the introduction of CBPMs under the 2001 Regulations, the approach used in various countries on the use of cannabis-based medicines has been widely discussed.

If there are particular aspects of regulatory control of cannabis-based medicines that the ACMD would find helpful to explore further, such as those suggested in recommendation 3 a) of the ACMD's report, my officials could arrange some more focused bilateral meetings with relevant countries.

Review of the scheduling of products which currently fall under the definition of Cannabis-Based Products for Medicinal use (CBPMs) under the Misuse of Drugs Regulations 2001

Your letter of 27 November 2020 on the scheduling of CBPMs recommends that Schedule 2 of the 2001 Regulations remains appropriate for CBPMs, and that no further legislative amendments to the 2001 Regulations in relation to CBPMs are required at this point in time.

I accept the Council's advice that Schedule 2 of the 2001 Regulations remains appropriate for CBPMs and that there is a range of unlicensed products falling under the definition of a CBPM, which have not have been tested for safety, quality and efficacy to the same degree as licensed cannabis-based medicines. Therefore, there is no current evidence to support the rescheduling of CBPMs as a whole to Schedules 3-5 in the 2001 Regulations.

I would like to thank the Council once again for its continued valued advice. I would like to also recognise the valuable input from Maggie Throup MP, Minister for Vaccines and Public Health, to this Government response.

Rt Hon Kit Malthouse MP