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Chair of the Advisory Council on the Misuse of Drugs
Dr Owen Bowden-Jones

c/o Zahi Sulaiman
Secretary to the Advisory Council on the Misuse of Drugs (ACMD)
Home Office Science Secretariat
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21 September 2018

Dear Owen,

CANNABIS-BASED PRODUCTS FOR MEDICINAL USE

Thank you for your report dated 11 September regarding the consultation on *Cannabis-Derived Medicinal Products* (“CDMP”) and the subsequent discussion you had with the Home Secretary and officials from both our departments on 12 September. We understand the complexities of this issue and we appreciate the pace at which the ACMD have published their report. We are very grateful for the action that the working group and the rest of the Advisory Council on the Misuse of Drugs (ACMD) members took to deliver this.

The Government has been clear on its intention to reschedule cannabis-derived medicinal products. In the review of the Chief Medical Adviser to the UK Government published in July 2018 Dame Sally recommended that the whole class of cannabis based medicinal products be moved out of schedule 1. Dame Sally’s review highlighted conclusive evidence of the therapeutic benefit of cannabis based medicinal products for certain medical conditions and reasonable evidence of therapeutic benefit in several other medical conditions. Your advice in July 2018 was supportive of this approach, with the exception of rescheduling synthetic cannabinoids, which you committed to review ‘longer-term’. Given the evidence, the Government decided to act with pace and reschedule cannabis based products for medicinal use, within the current legal framework, as quickly as it could.

In light of the Chief Medical Adviser’s report, we think it is critical that we do not hinder the use of cannabis-based products for medicinal use for the relief of pain and suffering where medically appropriate and there is evidence. We acknowledge the risks involved in rescheduling any controlled drugs and it is right that we proceed with caution with such significant changes in drugs regulations.

We are confident that the definition and additional access restrictions that officials have recommended, alongside the checks and balances that exist in current medicines regulation, medical practice and the additional clinical guidance that is under development will provide a safe and supportive environment for both prescribers, patients and their carers to make informed decisions about treatment, whilst minimising the risks of harm and diversion.

This is an emerging field and many individuals and other jurisdictions are watching closely to see how this field develops, but it is important to reiterate that we are still at an early stage. We will continue to review and evolve our approach in the light of experience. We are clear, as we have set out in our responses to your recommendations that we will continue to work with you to ensure that our approach is carefully reviewed to inform the ACMD's long-term advice on the matter.

We look forward to receiving the ACMD's full report on cannabis-derived medicinal products in July 2019.

Thank you again for your work on the interim advice.

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Rt Hon Sajid Javid MP
Home Secretary

Rt Hon Matt Hancock MP
Secretary of State for Health and Social Care

Recommendation 1: The Home Office, DHSC and MHRA to refine the definition of a CDMP as a priority

We accept this recommendation and DHSC, MHRA and the Home Office will prioritise working with the ACMD to make further progress on this over the next year. Our priority is to make sure that the definition and associated access controls facilitate legitimate access to safe products while minimising the risk of diversion. We commit to working with you to ensure this is the case.

In the coming year, and as part of the longer-term review, we will have the opportunity to monitor the changes made to legislation as well as the anticipated domestic and international scientific and health developments and use that as an opportunity to refine the current definition proposed for cannabis based products for medicinal use. As we learn more about the products and compounds it might become appropriate to reschedule particular products, either back into schedule 1, or into other schedules (for example following evidence established through clinical trials etc). At this stage, the Government is keen to not inadvertently exclude a product of medicinal value, whilst agreeing that it is imperative that these substances are subject to the tightest controls on their distribution and use imposed by Schedule 2 of the Misuse of Drugs Regulations 2001. We have confidence in the good professional and prescribing practices of doctors to take a cautious approach in this novel field.

We believe that the current definition of cannabis based products for medicinal use should not be considered in isolation but as part of a package together with the restricted access routes and guidance that, where these products are unlicensed medicines, the decision to prescribe these products will only be made by a doctor on the Specialist Register of the General Medical Council (GMC) or otherwise used within the safeguards of a clinical trial. Our proposed definition brings cannabis-based products for medicinal use into the existing medicines framework. As part of this, like any other medicine, these products need to comply with the requirements of the Human Medicines Regulations 2012 ("the 2012 Regulations").

Until these products have gone through the necessary MHRA marketing authorisation process and received confirmation of their quality, safety and efficacy, they will be regulated as unlicensed medicines for human use, commonly known as "specials". As such, it will be for prescribers to decide whether prescribing these products is in the best interest of the patient taking into account a variety of factors, including consideration of prescribing licensed products first. There is extant guidance from the GMC on prescribing specials and from the MHRA on their manufacture, including manufacturing site standards (Good Manufacturing Practice), import, supply, distribution, storage, labelling and pharmaco-vigilance. Further to this there is a legal requirement that such products are not advertised. The MHRA is currently updating this guidance specifically to support the rescheduling of cannabis-based medicinal products. The Guidance will be available when the legislation is laid.

In parallel, NHS England is developing interim clinical guidance to ensure that prescribers have the necessary information about cannabis-based products for medicinal use and the process for prescribing unlicensed medicines by the time that the changes are implemented. NICE guidance on prescription of cannabis-based products for medicinal use is expected by October 2019.

As Schedule 2 controlled drugs, cannabis-based products for medicinal use will also need to comply with the requirements set out under the Misuse of Drugs Regulations 2001 ("the 2001 Regulations") and supporting legislation. There are strict arrangements in place in relation to Schedule 2 drugs such as safe custody, prescription requirements, record-keeping, destruction and requisitioning. Controlled Drug Accountable Officers have a statutory duty to secure the safe management and use

of controlled drugs both within and outside of the NHS. This includes monitoring patterns of use, prescribing, supply and administration, working closely with other agencies and regulators, including the police, to identify and tackle diversion and poor prescribing practice.

We accept that there are further steps that could be taken in relation to the information provided to clinicians and patients concerning the content and quality standards that should be met by medicinal products. We will work closely with the ACMD to understand the specific concerns and the best approach to address this.

Recommendation 2: CDMPs meeting appropriate safety and quality standards under Schedule 2 should be exempted from the general designation of Cannabis, Cannabis resin, cannabinal and cannabinal derivatives under the Misuse of Drugs (Designation) Order 2015.

We accept this recommendation and we will reschedule cannabis-based products for medicinal use from Schedule 1 to Schedule 2.

In order to ensure that access to cannabis-based products for medicinal use is possible through prescription without a Home Office licence, we will exempt these from the Misuse of Drugs (Designation) Order 2015. However, those products falling outside of the proposed definition of cannabis-based products for medicinal use will continue as Schedule 1 drugs to the 2001 Regulations and will remain designated under the Misuse of Drugs (Designation) Order 2015.

Until the medicines market develops, we accept that the re-scheduled products will be unlicensed medicines. As such, quality standards will be set out in guidance including the need to have a declared content of THC and CBD which is routinely verified.

Recommendation 3: The DHSC and NHS England (and their equivalents in Scotland, Wales and Northern Ireland) to lead the development of interim guidance for clinicians considering prescribing a CDMP and pharmacists who will be required to source and dispense CDMPs (including unlicensed 'special medicinal products' and products with MHRA marketing authorisation). The ACMD supports the involvement of NICE in developing substantial guidance to replace the interim guidance in due course.

We accept this recommendation.

NHS England is developing interim clinical guidance to support prescribers. This and MHRA guidance, which will detail the controls on production and importation of special unlicensed medicines (including requirements for supply, distribution, storage, labelling and pharmacovigilance), will be available ahead of the rescheduling legislation coming into force.

NICE has started developing clinical guidance expected by October 2019 and have started recruiting for posts on the guideline committee.

Recommendation 4: The DHSC (and its equivalent in Scotland, Wales and Northern Ireland) to develop, with stakeholders, a competency framework and training pathway for the prescribing of CDMPs to support safe and effective prescribing.

We accept this recommendation.

We will explore with the professional bodies and Health Education England (and their equivalents) what additional training/competence may be required to support safe and effective prescribing.

As a start the NHS England guidance and guidance from the Royal College of Physicians and the British Paediatric Neurology Association, followed by the more extensive guidance from NICE will provide support for the doctors on the specialist register authorised to prescribe these products.

Recommendation 5: The ACMD recommends that all CDMPs should have a clear content description. The description should, as a minimum requirement, state the content of CBD and THC (in mg per unit dose or volume) in a manner that would inform the prescriber when making a clinical decision. Consideration should be given to what additional information would be helpful to prescribers.

We accept this recommendation.

We understand the importance of ensuring that prescribers are aware of the THC and CBD content in all cannabis-based products for medicinal use. MHRA guidance will recommend that all cannabis-based products for medicinal use have a declared content of THC and CBD and that this is routinely verified. MHRA does not envisage permitting the importation of such products without a declaration of content. The expression of content needs to be appropriate to the presentation of the product so in the case of herbal material this declaration may be as percentage.

In practice, prescribers, as with any other unlicensed medicine, will need to ensure they are fully cognisant of the quality and composition of the products that they prescribe, and to monitor clinical outcomes and adjust medication as necessary. Pharmacists and specialist importers will also need to be clear about the composition and identity of the products being prescribed to ensure that the right product is supplied against the prescription/direction i.e. a prescription simply stating “cannabis” would not result in the prescription being dispensed.

Guidance from the MHRA on the supply of cannabis-based products for medicinal use, supplied as “specials”, will include how prescribers and those involved in the supply chain might provide assurance that only products with defined contents, produced to defined quality standards (GMP), are supplied to patients.

Recommendation 6 The DHSC and NHS England (and their equivalents in Scotland, Wales and Northern Ireland) to ensure that the route of administration is stated on prescriptions to help to ensure patient safety and reduce diversion. Producers of CDMPs should be required to state the appropriate route of consumption of their product. CDMPs should not be administered by smoking.

We accept this recommendation.

The Human Medicines Regulations 2012 require that dispensed medicines are labelled with instructions for use so that patients are clear how products should be administered, how often and in what strength. Pharmacists can seek advice from the prescriber if this is not clear from the prescription/direction. In sourcing products, the pharmacists or importers will wish to make sure the product is suitable for the specified route of administration.

We share the ACMD’s concerns about the smoking of these cannabis-based products for medicinal use due to the known harms of smoking and the potential operational impact on misuse and diversion this could have due to its close association with recreational cannabis. As such, we have decided to include this restriction within the amendment to the 2001 Regulations which means that the administration of cannabis-based products for medicinal use by smoking will remain prohibited.

Recommendation 7: The ACMD recommends that the DHSC (and its equivalents in Scotland, Wales and Northern Ireland) establishes mechanisms to capture and publish the clinical outcomes of the prescription and use of CDMPs.

We accept this recommendation providing it does not compromise patient confidentiality.

We will explore what additional monitoring of clinical outcomes may be required to inform research on the therapeutic benefits of cannabis-based products for medicinal use and further consideration on rescheduling (beyond the systems that are already in place for other unlicensed medicines that are controlled drugs).

Recommendation 8: The National Institute for Health Research (NIHR) to work with DHSC and NHS England (and their equivalents in Scotland, Wales and Northern Ireland) to coordinate and support a programme of clinical trials to establish a credible evidence base for short and long-term safety and clinical indications.

We accept this recommendation.

The National Institute for Health Research (NIHR) intends to publish a 'highlight notice' to coincide with the rescheduling of cannabis-based products for medicinal use. Highlight notices are intended to stimulate research proposals under specified themes /strategic priorities to rapidly advance thinking or collaboration in these areas. The NIHR has worked with NHSE to ensure the content of the highlight notice will attract research proposals that address NHS priorities as well as proposals that will enable the generation of evidence across a broad range of indications and themes.

Recommendation 9: The Home Office, DHSC (and its equivalents in Scotland, Wales and Northern Ireland) and MHRA to develop a robust communications strategy for the public, clinicians and law enforcement to ensure that coherent messages are conveyed prior to and following the proposed rescheduling. This should clarify when these products are likely to be prescribed and the route by which they can be prescribed.

We accept this recommendation.

We have developed a communication plan to ensure that all members of the public, clinicians and law enforcement are informed of the changes to legislation. We will also be issuing a Q&A to provide further details on what this will mean in practice.

Recommendation 10: The DHSC and MHRA to consider methods to encourage pharmaceutical companies to apply for MHRA marketing authorisation for CDMPs

We accept this recommendation to consider what further could be done to make sure that organisations feel able to apply for market authorisations where appropriate.

The MHRA already offers a range of advice services (some of which are paid for services) covering regulatory and scientific advice at all stages of product development including applying for market authorisation. However, as the medicines licensing authority, the MHRA cannot initiate clinical trials nor can it require companies to apply for a marketing authorisation, which is ultimately a commercial decision.

Recommendation 11: The Home Office and DHSC (and its equivalents in Scotland, Wales and Northern Ireland) to commit to undertaking an evidence based review of the proposed interim approach. The ACMD looks forward to the findings of this review being made available to inform our longer-term work.

We accept this recommendation.

We are confident that the governance and assurance systems already in place or committed to in response to the above recommendations will enable the Home Office and DHSC (and equivalents) to gather evidence and share with the ACMD on how the rescheduling and proposed controls have worked in practice. We aim to do so in sufficient time to inform the ACMD's final advice.

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Rt Hon Sajid Javid MP
Home Secretary

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Secretary of State for Health and Social Care