Rt. Hon. Sajid Javid MP
Home Secretary
2 Marsham Street
London, SW1P 4DF

19 July 2018

Dear Home Secretary,

RE: Scheduling of *Cannabis-derived medicinal products*

Thank you for your commission of 3 July 2018, which the Advisory Council on the Misuse of Drugs (ACMD) has accepted. This report presents our short-term advice on the scheduling of *Cannabis*-derived medicinal products.

1. *Cannabis-derived medicinal products*

The ACMD agrees with the Chief Medical Officer for England (CMO) that there is now evidence of medicinal benefit for some *Cannabis*-derived products in certain medical conditions for some patients.1–7

The ACMD advises that clinicians in the UK should have the option to prescribe *Cannabis*-derived medicinal products that meet the requirements for medicinal standards to patients with certain medical conditions. It is therefore appropriate for

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these medications to not be subjected to the requirements of Schedule 1 of the Misuse of Drugs Regulations 2001, as amended (MDR).

**Conclusion 1:** *Cannabis-derived medicinal products [Cannabis (excluding Sativex), Cannabis resin, cannabinol and cannabinol derivatives (not being Dronabinol or its stereoisomers)] of the appropriate medicinal standard should not be subjected to Schedule 1 requirements.*

2. **Defining Cannabis-derived medicinal products**

The CMO’s report states that “using other forms, such as grown or street Cannabis, as a medicine for therapeutic benefit is potentially dangerous”.\(^8\) The ACMD agrees that raw Cannabis (including Cannabis-based preparations) of unknown composition should not be given the status of medication.

Prescribers, patients, regulators and policy-makers must have confidence in the effectiveness, composition and consistency of Cannabis-derived medicinal products to ensure patient safety. Cannabis-derived medicinal products should meet defined safety and quality assurance standards to ensure that they do not put patients at risk of harm. Risks to patients may arise from impurities and adulterants, and variability in the composition of active constituents.

One of the complexities of this area is the lack of clarity of what Cannabis-derived medicinal products are. The ACMD has identified this as a problem that needs addressing with clear definitions. The Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency (MHRA) should agree on appropriate definitions and medicinal standards following appropriate consultation. The ACMD requests the development of appropriate definitions to be completed in a timely manner, so that it does not introduce unnecessary delays to the ACMD’s ‘longer term’ review, or prevents doctors prescribing Cannabis-derived medicinal products to patients where there is an identified need and likelihood of benefit.

**Recommendation 1:** The DHSC and MHRA to promptly develop a clear definition of a Cannabis-derived medicinal product.

In this short term review, the ACMD acknowledged that evidence of the benefits and harms associated with using Cannabis-derived medicinal products is still emerging. In light of this, the ACMD initially recommends the most stringent controls for prescription of Cannabis-derived medicinal products. The longer term review will consider the appropriate scheduling in more detail.

**Recommendation 2:** Once the definition of a Cannabis-derived medicinal product has been developed, the ACMD advises that only products meeting this definition be moved into Schedule 2 of the MDR pending our further advice.

There are currently a number of internationally available products which may meet these medicinal standards.

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3. Mitigating harms associated with inappropriate prescribing and diversion

The ACMD identified potential risks relating to inappropriate prescribing and diversion of Cannabis-derived medicinal products. These risks need to be carefully considered and appropriate ‘checks and balances’ applied to avoid harms to patients and others.

**Recommendation 3:** In addition to the provisions of Schedule 2 of the MDR, the ACMD recommends that the DHSC, MHRA and Home Office should develop additional frameworks and clinical guidance for ‘checks and balances’ to maintain safe prescribing of Cannabis-derived medicinal products.

The ACMD looks forward to working with the DHSC, MHRA and Home Office on these proposals as part of the longer term review and anticipates that wider consultation will be required.

4. Future research of Cannabis-derived products

Understanding of the potential therapeutic uses of Cannabis-derived products is still developing.\(^9\) Carefully conducted clinical trials are needed to establish the effectiveness of these products and to understand the short and long term safety of using them.

**Conclusion 2:** Clinical trials to establish the effectiveness and safety of Cannabis-derived medicinal products are urgently required.

The research community has expressed concern that Schedule 1 acts as a ‘barrier to research’. This is important to understand and is an issue with implications not just for Cannabis, but also for other Schedule 1 drugs where a potential therapeutic benefit has been proposed.

**Conclusion 3:** The ACMD considers that it is important that Cannabis is not seen in isolation but as an example of a wider issue of potential ‘barriers to research’ associated with other drugs in Schedule 1.

We await the Government’s full response to the ACMD’s interim advice on legitimate use of controlled drugs: research and healthcare (December 2017) and we are firmly committed to further work in this area.\(^{10}\)

5. Synthetic cannabinoids

Synthetic cannabinoids are available in illicit street products such as ‘Spice’ and ‘Mamba’. There is clear evidence of significant harms and a number of deaths

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caused by the use of synthetic cannabinoids in certain groups, including vulnerable populations (e.g. street homeless and prison populations).\textsuperscript{11,12,13,14}

While the ACMD accepts that further research into this complex group of diverse substances is important, given the associated potency and harms, the ACMD needs further time to consider and consult on the unintended consequences of potential rescheduling.

**Recommendation 4: At present, synthetic cannabinoids should remain in Schedule 1 of the MDR pending the ‘longer term’ review by the ACMD.**

6. **Compounds unintentionally captured by generic definitions of synthetic cannabinoids**

Current generic definitions intended to control synthetic cannabinoids have unintentionally captured a large number of compounds. Some of these compounds may have potential therapeutic benefits. The ACMD strongly supports further research to gain a better understanding of these compounds and to support the development of new medicines.

The ACMD’s ongoing work on legitimate use of controlled drugs: research and healthcare will address this issue.

Yours sincerely,

\[Signature\]

Dr Owen Bowden-Jones

Chair of the ACMD


\textsuperscript{12} Tait RJ, Caldicott D, Mountain D, Hill SL, Lenton S. (2016) A systematic review of adverse events arising from the use of synthetic cannabinoids and their associated treatment, Clinical Toxicology, 54:1, 1-13,
