ACMD

Advisory Council on the Misuse of Drugs

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Rt. Hon. Priti Patel MP
Home Secretary
2 Marsham Street
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27 November 2020

Dear Home Secretary,

RE: 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

In February 2019, the then-Home Secretary commissioned the Advisory Council on the Misuse of Drugs (ACMD) to conduct a longer-term review of cannabis-based products for medicinal use (CBPMs).

One of the three components of the commission asked the ACMD to provide further advice on:

i. whether the scheduling of products which currently fall under the definition of cannabis-based products for medicinal use is appropriate
ii. If not, can the ACMD advise on the appropriate rescheduling?
iii. whether any further legislative amendments regarding CBPMs are required under the 2001 Regulations.

Since 1 November 2018, products which met the three limbs of the following definition were considered CBPMs and therefore fell under Schedule 2 of the Misuse of Drugs Regulations 2001 (MDR):

"cannabis-based product for medicinal use in humans" means a preparation or other product, other than one to which paragraph 5 of part 1 of Schedule 4 applies, which:

(a) is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative (not being dronabinol or its stereoisomers);
(b) is produced for medicinal use in humans; and—
(c) is—
(i) a medicinal product, or
(ii) a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product;"

In the definition above, "medicinal product" has the same meaning as in the Human Medicines Regulations 2012.

Scheduling of CBPMs

There is a diverse range of products falling under the CBPM definition set out in the MDR, containing different cannabinoids in varying concentrations. The ACMD has considered that the harms associated with these products may therefore vary substantially.

Since the legislative change in November 2018, only Epidyolex has received marketing authorisation as a licensed medicine and has subsequently been rescheduled based on an assessment of the evidence of harms of that product. Based on its low risk of abuse potential, low risk of dependency and low risk of diversion, Epidyolex was moved to Schedule 5 of the MDR in June 2020 – following a recommendation by the ACMD.[1] Epidyolex is therefore no longer a CBPM as it is defined separately under the MDR.

No other products falling under the definition of a CBPM have received marketing authorisation in the UK or from the European Commission since the legislative change.

In order to permit the legitimate use of CBPMs in specific clinical circumstances, CBPMs should not fall under Schedule 1 of the MDR. Since the scheduling of CBPMs as Schedule 2 drugs, these products have been prescribed in small quantities.

However, due to the range of unlicensed products falling under the definition of a CBPM, which may not have been tested for safety, efficacy and quality to the same degree as licensed cannabis-based medicines, the ACMD does not yet have the evidence to support the rescheduling of this group of compounds as a whole to Schedules 3-5 of the MDR.

[1] https://www.gov.uk/government/publications/advice-on-epidyolex

It is important to make clear that the ACMD continues to consider that CBPMs are distinct from herbal cannabis not intended for medicinal use in humans, which remains a Schedule 1 drug.

Range of products captured by the definition of CBPMs

Epidyolex met the definition of a CBPM until it was rescheduled to Schedule 5 of the MDR on 24 June 2020. After this date, Epidyolex was defined elsewhere under the MDR and was specifically excluded from the legislative definition of a CBPM. Two further licensed cannabis-based medicines, Sativex and Nabilone, were already separately defined under the MDR.

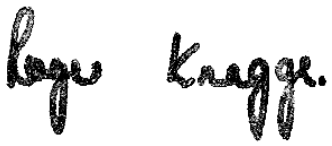
The ACMD is unaware of any other legitimate cannabis-based medicines which fall outside of the definition of CBPMs under the MDR. The ACMD is also not aware of any products which inappropriately fall under the MDR definition of CBPMs.

Recommendation

The ACMD therefore recommends to the Home Office that the scheduling of CBPMs under Schedule 2 of the MDR remains appropriate and that no further legislative amendments to the MDR regarding CBPMs are required at this point in time.

In the event that there is a marked increase in the number of CBPMs achieving marketing authorisation and being individually considered as candidates for rescheduling by the ACMD, the ACMD will again review the scheduling of CBPMs as a whole.

Yours sincerely,



Professor Owen Bowden-Jones — **Chair of ACMD**

Professor Roger Knaggs — **Chair of ACMD Technical Committee**

CC: Kit Malthouse MP (Minister of State for Crime and Policing)
Rt Hon. Matt Hancock MP (Secretary of State for Health and Social Care)