ACMD

Advisory Council on the Misuse of Drugs

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Kit Malthouse MP
Minister of State for Crime, Policing and the Fire Service
2 Marsham Street
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29th January 2020

Dear Minister,

RE: Epidyolex

The Advisory Council on the Misuse of Drugs (ACMD) are grateful to the Medicines and Healthcare products Regulatory Agency (MHRA) for providing a written dossier and oral presentation on the cannabis-based product for medicinal use (CBPM), "Epidyolex". Further to these representations, the ACMD are able to provide advice regarding the appropriate Schedule for this medicine under the Misuse of Drugs Regulations 2001.

Epidyolex was approved for marketing by the European Commission on 19th September 2019 for the adjunctive therapy of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome, in conjunction with clobazam, for patients from 2 years of age and older.

The ACMD Technical Committee considered the issue of the scheduling for Epidyolex and have recommended that it would be most appropriate for Epidyolex to be placed in Schedule 5 under the Misuse of Drugs Regulations 2001.

The ACMD has concluded that Epidyolex, where Δ^9-tetrahydrocannabinol (Δ^9-THC) is present only as an impurity and is specified within the product's approved marketing authorisation to be limited to <0.10% w/w, has a low risk of abuse potential, low risk of dependency and low risk of diversion.

The ACMD's advice has been based solely on the Δ^9-THC content of Epidyolex, rather than its cannabidiol (CBD) content - given CBD is not a controlled drug. It is the limited quantity of Δ^9-THC in Epidyolex which guided the ACMD scheduling recommendation.

The ACMD note that Epidyolex is distinct from other commercially available CBD-containing supplements that have not sought marketing authorisation as a medicine.

Given the ongoing discussions at an international level following recommendations of the World Health Organisation's Expert Committee on Drug Dependence (ECDD) regarding the scheduling of CBD under the 1961 Convention on Narcotic Drugs (CND), the ACMD note that the scheduling of Epidyolex may need to be reviewed again in the future.

The ACMD is aware that it will not be appropriate to refer to "Epidyolex", which is a proprietary name, in any amendment to the Misuse of Drugs Regulations 2001 - and that a suitable description of the relevant component(s*)* of "Epidyolex" must instead be scheduled.

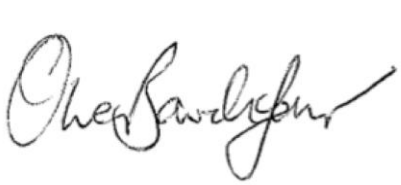
The Home Office have presented to the ACMD a proposed definition for Epidyolex for insertion into the Misuse of Drugs Regulations 2001. The ACMD gave detailed consideration to the options and has concluded that the most appropriate definition is:

"A liquid formulation —

> ***(a) containing cannabidiol obtained by extraction and purification from Cannabis;***
>
> ***(b) Where the concentration of—***
>
> ***(i) delta-9-tetrahydrocannabinol is not more than 0.1 milligram per millilitre; and***
>
> ***(ii) cannabidiol is 95 - 105 milligrams per millilitre; and***
>
> ***(c) which is presented in a bottle, as an oral solution for oral administration; and***
>
> ***(d) which was approved for marketing by the European Commission on 19th September 2019."***

It is important to make clear that the ACMD continues to consider that Epidyolex and other CBPMs are distinct from herbal cannabis which remains a Schedule 1 drug.

Yours sincerely,



Prof Owen Bowden-Jones
Chair of the ACMD

Prof Roger Knaggs
Chair of the ACMD's Technical Committee

CC: Rt Hon. Priti Patel MP (Home Secretary)
Rt Hon. Matt Hancock MP (Secretary of State for Health and Social Care)