ACMD

Advisory Council on the Misuse of Drugs

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Kit Malthouse MP
Minister of State for Crime Reduction and Policing
2 Marsham Street
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17 December 2021

Dear Minister,

RE: Consumer CBD (cannabidiol) products: review of exempt product definition

The Advisory Council on the Misuse of Drugs (ACMD) was commissioned on the 11 January 2021 to review the exempt product definition within the Misuse of Drugs Regulations 2001 (MDR) in the context of consumer CBD products. The commission requested advice from the ACMD 'to give effect to the intent surrounding its introduction, being to only exempt products used for scientific or diagnostic purposes which contain an extremely small amount and proportion of controlled drugs, but unambiguously excludes consumer products and any products intended for human consumption, other than in scientific research'.

Intention for the introduction of the exempt product definition

The exempt product definition was added to the MDR in 1999 (SI 1999/1404) to address issues which had arisen following the adoption during the 1990s of large-scale in-employment testing of urine samples for evidence of drug use, including in-employment testing by the UK military. The diagnostic test kits used to screen samples include, for quality control purposes, extremely low amounts of controlled drugs, reflecting the levels to be found in urine, but, in the absence of a *de minimis* exemption in the Regulations, the kits were required to comply with the full licensing regimen including import controls (there being no UK manufacturer). Such kits containing "an extremely small amount and proportion of controlled drugs" were

assessed at the time by the ACMD to be of very low risk and an exempt product clause was developed to exclude them from control.

The current definition of an “exempt product” is a preparation or other product consisting of one or more component parts, any of which contains a controlled drug, where:

(a) the preparation or other product is not designed for administration of the controlled drug to a human being or animal; [the first limb]

(b) the controlled drug in any component part is packaged in such a form, or in combination with other active or inert substances in such a manner, that it cannot be recovered by readily applicable means or in a yield which constitutes a risk to health; [the second limb] and

(c) no one component part of the product or preparation contains more than one milligram of the controlled drug or one microgram in the case of lysergide or any other N-alkyl derivative of lysergamide [the third limb].

The originally proposed exempt product definition had four limbs – the three in the current exemption clause, plus a fourth requiring that the materials were intended “for scientific or diagnostic purposes”. At the time the Home Office considered it was not appropriate to include end-use requirements within the Regulations, however, the intent of the exemption was clarified in the Explanatory Note attached to the Statutory Instrument.

Several issues with the current definition have been identified by the ACMD. These include:

1. The first limb is being interpreted still to be met if the controlled drug is present as an impurity, rather than a major intended component, within a preparation or product intended for administration to a human being.

   This ambiguity has allowed the exempt product definition to be used for clinical trials using cannabinoids when the investigative medicinal product to be consumed is not a controlled drug and consumer CBD products. The later use is the issue raised by the commission.

2. Within the first limb the term administration is not defined.

3. The third limb is ambiguous as to whether it means per packet or individual preparation.

4. A number of controlled substances with potencies similar to or greater than lysergide have appeared but the third limb has not been updated to reflect this.

5. The third limb only controls the amount of controlled drug rather than concentration.

6. The definition was designed for diagnostic purposes and so could be better designed for scientific use. For example, to permit its application for other scientific purposes, such as the supply of small quantities of controlled drugs to act as reference materials to support forensic and toxicological analysis.

The advice in this letter is designed to specifically cover the issue raised in the current commission. Further advice on the exempt product definition (in the context of barriers to research) will be provided by the ACMD in due course.

International approaches

There are international comparisons to be made. The closest is the exempt product definition in Guernsey which is the same as the UK but with the addition of the following fourth limb:

> *"The preparation or other product is used, or intended to be used, only as analytical reference material by an authorised analyst."*

Other countries have utilised other approaches to facilitate the use of controlled materials for scientific or analytical purposes. For example, both Belgium and Switzerland exclude from control solutions containing up to 1 mg/ml of controlled substances and Germany exclude from the controls of their New Psychoactive Substances Act (NpSG) "uses of a NPS recognised to be in line with the state of the art in science and technology for commercial, industrial or scientific purposes". The United States permits exemptions for specific chemical preparations if they are agreed not to present significant potential for abuse and are intended for laboratory, industrial, educational, or special research purposes and not for administration to a human being.

Such approaches reduce the administrative burden on licensing authorities, reference material suppliers, research institutes and forensic drug and toxicology laboratories.

Short term options

The two short-term options considered by the ACMD were:

1. Addition of a fourth limb to specify end use,

2. Clarify that the first limb relates to the intended use of the preparation or product containing the controlled drug as a whole, whether or not the controlled drug is present as an unintended impurity except for research purposes.

Both options would prevent the use of the exemption clause for consumer CBD products. The complexity with the first option would be the interpretation of 'scientific or diagnostic use' which might need to be specified. However, there is now precedent to specify the end use within the 2018 MDR amendment for Cannabis Based Products for Medicinal use (CBPM) definition, which includes an end-use requirement (for medicinal use).

The second option would require a definition for 'research' purposes. A possible solution would be to adapt the definition written within the Psychoactive Substances Act 2016 which was designed to cover clinical trials using Novel Psychoactive Substances. This option will clarify that the exempt product definition covers those not intending the product containing the controlled drug to be consumed, whilst permitting use in clinical trials only.

Recommendation

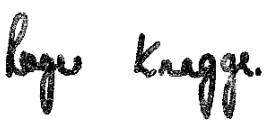
The ACMD recommends changing the first limb of exempt product definition to refer to the 'preparation or other product containing the controlled drug' rather than the 'controlled drug' except for 'research' purposes as defined in Schedule two of the Psychoactive Substances Act 2016. An example of such a wording could be:

(a) the preparation or product containing the controlled drug is not intended for administration to a human being or animal other than for the purpose of approved scientific research, as defined in Schedule 2 of the Psychoactive Substances Act 2016.

Lead organisation: Home Office

Measure of impact: This will have been implemented by a change to the Misuse of Drugs Regulations 2001.

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)