Drug Licensing Factsheet:

Cannabis, CBD and other cannabinoids

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Introduction

1) This factsheet provides guidance on the domestic control measures, including licensing and exemptions applicable to cannabis, cannabidiol (CBD) and controlled cannabinoids under drugs legislation (namely, the Misuse of Drugs Act 1971 and associated secondary legislation).

2) **Important Note:** This is intended as general guidance only relating to controlled drugs; it is not legal advice. This factsheet does not provide guidance on regulatory or legal requirements applicable under other (non-drugs) regimes such as medicines or foods. Anyone in doubt should seek their own independent legal advice to ensure they are compliant with any and all relevant legislation.

General legislative position

3) Cannabis is a Class B controlled drug under Part 2 of Schedule 2 to the Misuse of Drugs Act 1971 (MDA 1971). Cannabis is defined in section 37(1) of the MDA 1971 and is, in essence, the plant or any part of the plant with limited exceptions (the exceptions are the mature stalk; fibre produced from the mature stalk; or the seed of any such plant). It is also listed in Schedule 1 to the Misuse of Drugs Regulations 2001 ("MDR 2001") and designated under the Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015 (2015 Order). As such, it is unlawful to possess, supply, offer to supply, produce, import or export this drug except under a Home Office licence. It is also an offence to cultivate any plant of the genus Cannabis except under a Home Office licence.

4) In addition to cannabis being controlled, a number of cannabinoids (i.e. the active chemical compounds found in the cannabis plant) are controlled as Class B drugs under Part 2 of Schedule 2 to the MDA 1971. Cannabinol is a Class B drug under Part 2 of Schedule 2 to the MDA 1971. Cannabinol derivatives are Class B drugs under Part 2 of Schedule 2 to the MDA 1971, including tetrahydrocannabinol (Δ9-THC or "THC"). Cannabinol and cannabinol derivatives are defined in Part 4 of Schedule 2 to the MDA 1971.

5) Cannabidiol ("CBD") is a cannabinoid present in the cannabis plant. Pure CBD, as an isolated substance, is not controlled under the MDA 1971. However, the legal status of CBD products varies depending on what the product is. Preparations or products containing controlled drugs are, themselves, controlled. The Home Office agrees with the assessment made by the Advisory Council on the Misuse of Drugs that, due to difficulties in isolating CBD from other cannabinoids, consumer CBD products also contain varying amounts of controlled cannabinoids, such as THC and delta-9-tetrahydrocannabinol-C3 (THC-V).

6) Any CBD products which contain controlled cannabinoids will be classified as Class B controlled drugs under paragraph 5 of Part 2 of Schedule 2 to the MDA

1971. However, if a product meets the "exempt product" definition in Regulation 2 of the MDR 2001, it will not be subject to the prohibitions on importation, exportation, production, supply and possession under the MDA 1971. This is explained further in paragraphs 26 to 36 of this document.

7) "Cannabis-based products for medicinal use in humans" ("CBPMs") are defined in Regulation 2 of the MDR 2001. They are any preparation or product which is, or contains, cannabis, cannabis resin, cannabinol and cannabinol derivatives (not being dronabinol or its stereoisomers), which is produced for medicinal use in humans and is a medicinal product, or a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product. Note that this definition excludes the cannabis-based medicines referred to in paragraph 8 below. CBPMs were placed in Schedule 2 to the MDR 2001 in 2018. CBPMs are Class B drugs, subject to additional controls in the MDR 2001 (see Regulation 16A), and Home Office licensing requirements relating to these products are outlined below[1]. A Circular was issued in 2018 explaining the changes to the MDR 2001, and can be found on legislation.gov.uk at the following link: Circular 018/2018: rescheduling of cannabis-based products for medicinal use in humans - GOV.UK (www.gov.uk).

8) In addition, some cannabis-based medicines have received marketing authorisation, granted in accordance with medicines legislation, and been separately scheduled in the MDR 2001 following ACMD advice. These are Sativex (captured by paragraph 5 of part 1 of Schedule 4 to the MDR 2001), and Epidyolex (captured by paragraph 10 of Schedule 5 to the MDR 2001).

Licensing principles and interaction with other agencies

9) The Home Office receives and considers licensing applications from companies and individuals in England, Wales and Scotland if they wish to produce, possess, supply, cultivate (in the case of cannabis plants) import or export controlled drugs. Each application is considered carefully on its merits taking account of the ability of the applicant to comply with regulatory standards in order to be issued with a licence under the Misuse of Drugs Act 1971 and MDR 2001.

10) The Home Office may take into account the applicant's ability to satisfy the requirements of other relevant regulatory bodies (such as the Medicines and Healthcare products Regulatory Agency (MHRA), Food Standards Agency (FSA) and Trading Standards) when deciding whether it would be appropriate to grant a licence, where they are relevant to the risk-based licensing assessment process we operate, but the views of these bodies are not determinative.

[1] Where a CBPM meets the exempt product definition, it will not be subject to the prohibitions on importation, exportation, production, supply and possession under the MDA 1971.

11) The Home Office does not assess claims that a product does not contain controlled drugs or that a product containing controlled drugs is nevertheless exempt from licensing control. Anyone handling materials that may contain controlled drugs, including manufacturers, importers and retailers, should take their own legal advice, and undertake any appropriate testing to ensure that the activities they are undertaking are lawful in the UK.

12) The applicable legislative controls within the UK are summarised in this guidance, and apply to controlled parts of plants of the genus Cannabis, and to products containing controlled cannabinoids. Other countries operate differing control regimes to the UK. These alternative control regimes do not override UK legislative requirements.

13) If a product containing controlled cannabinoids (e.g. THC) or any other controlled substances is imported from the EU, USA, or any other part of the world, then there is a requirement to obtain a Home Office import licence to undertake this activity lawfully (unless the exempt product definition applies – see below). UK testing laboratories holding Home Office domestic licences can apply for an import licence to enable the analysis of products produced outside the UK.

Cultivation of the cannabis plant

14) It is unlawful to cultivate or possess cannabis plants (as defined in section 37(1) of the MDA 1971) without the requisite Home Office licence. There are two separate licensing regimes relating to cannabis cultivation. This factsheet should be read together with guidance relating to hemp cultivation and use of non-controlled hemp products from fibre and seed[2].

Cannabis Based Products for Medicinal Use in Humans (CBPMs) – Regulation 2 and Schedule 2 MDR 2001

15) CBPMs are listed in Schedule 2 to the MDR 2001. Regulation 2 of the MDR 2001 defines CBPMs:

““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 or paragraph 10 of Schedule 5 applies[3], 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—

[2] The Home Office guidance document “Industrial hemp licensing: factsheet” is available at the following link: Industrial hemp licensing: factsheet - GOV.UK (www.gov.uk)
[3] See paragraph 8 above.

(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"

16) A CBD preparation or product containing controlled cannabinoids (e.g. THC) which meets this definition will be a CBPM.

17) Specialist medical practitioners can prescribe CBPMs without requiring a Home Office licence. However, as with other controlled drugs in Schedule 2, companies wishing to possess, supply, produce, manufacture, import or export these products, if they are not exempt products, will require Home Office licences to lawfully undertake these activities, unless a limited licensing 'exemption' under the MDR 2001 applies - e.g. a pharmacist or person conducting a retail pharmacy business acting in their respective capacities (however see guidance on wholesale dealing, which is available at the following link: Controlled drugs: domestic licences - GOV.UK (www.gov.uk)). Regulation 16A of the MDR 2001 imposes additional controls on the order and supply of CBPMs for the purpose of administration (even if they are exempt products).

18) Where a preparation or product containing cannabis, cannabis resin, cannabinol or a cannabinol derivative does not meet the definition of a CBPM, and has not been separately scheduled, it will be a Schedule 1 drug under the MDR 2001. It will therefore be subject to the restrictions for Schedule 1 drugs (but will not be subject to the prohibitions on importation, exportation, production, supply and possession under the MDA 1971 if the exempt product definition applies).

Acid precursors and their control status

19) The acid precursors[4] to THC include 2-carboxyl ∆9-THC (also referred to as ∆9-THCA-A) and 4-carboxyl ∆9-THC (also referred to as ∆9-THCA-B), and will be jointly referred to here as "THC-A". As an isolated substance, in its pure form, THC-A would not be controlled under the MDA 1971. However, it is understood that THC-A readily degrades both naturally, and with a catalyst or environmental change (e.g. heat) to THC which is a Class B, Schedule 1 controlled cannabinoid.

Cannabidiol (CBD) and CBD products

20) CBD as an isolated substance, in its pure form, is not controlled under the MDA 1971.

21) However, cannabis is a Class B drug under Part 2 of Schedule 2 to the MDA 1971; and a number of cannabinoids (i.e. the active chemical compounds found in the cannabis plant) are controlled as Class B drugs, including cannabinol and cannabinol derivatives, such as THC and THC-V.

[4] "Acid precursors" in this context should not be confused with drug precursor chemicals, which are subject to a separate licensing regime. Further information about drug precursor chemicals is available at the following link: Precursor chemical licensing - GOV.UK (www.gov.uk)

22) The Home Office view is that it is nearly impossible to extract and isolate CBD from the cannabis plant or to create CBD synthetically without traces of other controlled cannabinoids, such as THC and THC-V. It is therefore highly likely that CBD products will contain controlled Class B cannabinoids, such as THC and THC-V.

23) CBD products that meet the definition of a CBPM will be Class B controlled drugs and subject to Regulation 16A and the relevant restrictions for Schedule 2 drugs[5]. CBD products that meet the definition of a cannabis-based medicine that has been separately scheduled will be Class B drugs in the appropriate schedule (such as Epidyolex, which is a Schedule 5 drug). Otherwise, CBD products that contain controlled cannabinoids will be Class B, Schedule 1 controlled drugs under the MDA 1971 and the MDR 2001 and therefore subject to the restrictions for Schedule 1 drugs[6].

24) A Home Office licence is required to lawfully import, export, supply, produce or possess a CBD preparation or product (including, if they are to be manufactured, the materials used to make it) under Regulation 5 of the MDR 2001, unless it meets the "exempt product" definition. Licences would not ordinarily be issued to enable the use of Schedule 1 controlled drugs unless the licence holder can provide evidence of a product with a lawful route to market. Exceptions may include, for example, use in bona-fide research or a recognised UK clinical trial.

25) Where an end product benefits from the exempt product definition or is a CBPM or a cannabis-based medicine, a Home Office licence will be required to cultivate cannabis or import, export, supply or possess controlled drugs (which are not themselves exempt products) in the process of producing such products. This could include, for example, the cultivation of the cannabis plant or possession of controlled parts of the cannabis plant in order to produce exempt products.

The exempt product definition - Regulation 2 of the MDR 2001

26) A preparation or product, including a CBD product, which meets the definition of an "exempt product" under Regulation 2 of the MDR 2001 ("the EPD") will not be subject to the prohibitions on importation, exportation, production, supply and possession under the MDA 1971. As such, a Home Office licence will not be required for those activities. (Note, however, as set out in paragraphs 24-25, the material used to manufacture it may require licensing).

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[5] As outlined above, any product which meets the "exempt product definition" will not be subject to the prohibitions on importation, exportation, production, supply and possession under the MDA 1971.

[6] Subject to the exceptions for "exempt products".

27) The EPD is set out in Regulation 2 as follows:

"*An "exempt product" means 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;
(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; 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."

28) To meet the criteria of an exempt product, all three limbs of the definition must be met.

29) The Home Office view is that this definition may apply to preparations or products in any form. It will be a matter of fact, determined on a case-by-case basis, whether the preparation or product meets the EPD.

Limb (a) - "not designed for administration of the controlled drug to a human being or animal"

30) It is the Home Office view that a variety of factors may determine whether the product is "not designed for administration of the controlled drug to a human being or animal". Relevant factors include –

a) The purpose the preparation or product is designed to achieve.
b) Whether there is an explanation for the presence of the controlled drug in the preparation or product, other than it being designed for administration of the controlled drug to a human being or animal.
c) If the controlled drug is present by design, the intended use of the preparation or product which does not involve administration to a human or animal.
d) If the controlled drug is not present by design, how it came to be present, and how difficult would it have been to produce the preparation or product for the intended purpose without (or with a smaller amount of) the controlled drug being present.

31) Relevant evidence could include, but is not limited to the product's:
a) stated purpose;
b) advertising, marketing, packaging, presentation, and labelling;
c) administration technique;
d) supply chain, such as the intended customers; and
e) manufacturing technique; such as evidence that the controlled drug is present as an impurity in, or byproduct of, some other substance that is

present by design, and that reasonable steps have been taken to remove or minimise its presence.

***Limb (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*.**

32) It is the Home Office view that, to establish that Limb (c) is met, testing of the products, such as a full spectrum analysis with the appropriate degree of sensitivity by a suitably accredited laboratory, is required. The laboratory must be accredited to ISO/IEC 17025 by a relevant accrediting body for the analytical methods used to assure appropriate method validation, quality management and independent assessment of the methods. For UK laboratories, the relevant accrediting body is UKAS. The appropriate degree of sensitivity will be the degree of sensitivity that is capable of demonstrating compliance with Limb (c) in the context of the size of the product, which should be explicit in the analysis.

33) It is the Home Office view that the applicable unit of measure (i.e. the component part of the product or preparation) for the 1mg 'threshold' referred to in Limb (c) is that of the container (such as a bottle of oil) and not (for example) the supposed typical dose (of any product).

34) To comply with Limb (c), the level of each controlled drug in the product must not exceed the 1mg threshold. Given the available capacity in the testing sector, the Home Office considers that producers should be able to demonstrate compliant levels of Δ9-THC, Δ8-THC, and CBN. The levels of the other controlled cannabinoids must not exceed the threshold.

The exempt product definition and Home Office controlled drug licensing

35) The Home Office Drugs and Firearms Licensing Unit (DFLU) is not an enforcement agency and does not have a prosecutorial function. DFLU will not assess or provide advice on whether a product meets the EPD unless the question is relevant to a domestic licensing application. Those intending to import, export, possess, supply, offer to supply or produce CBD products may wish to seek legal advice on the application of the exempt product definition to their products and any activities that they wish to undertake. They may wish to ensure that the product has been subject to testing as described in paragraphs 32-34 above, and to be in a position to provide evidence of this testing to enforcement bodies, such as Border Force and the Police.

36) Those producing cannabis-derived products to which the exempt product definition applies will require a domestic licence if their process involves

cultivation of the cannabis plant (including hemp), handling the controlled parts of the plant in their separated form, and any production or handling of bulk product to which the exempt product definition does not apply. They will be required to demonstrate that their end product meets the definition, in accordance with the guidance at paragraphs 32-34 above.