



Home Office

## Drug Licensing Factsheet- Cannabis, CBD and other cannabinoids

This factsheet represents the Home Office's view on the domestic control measures applicable to cannabis, cannabidiol (CBD) and controlled cannabinoids. It is intended as a resource for existing licensees and prospective licensees who may need to apply for a licence, having fully assessed any proposals they may wish to make in the context of this guidance and that provided by other regulators.

There are two separate licensing regimes relating to cannabis cultivation, according to whether the varieties are high or low THC (as differentiated in the Misuse of Drugs (Fees) Regulations 2010). This factsheet may also be read in conjunction with published guidance relating to low-THC Industrial Hemp cultivation and use of non-controlled hemp products from fibre and seed available at:

<https://www.gov.uk/guidance/controlled-drugs-licences-fees-and-returns#industrial-hemp>

**Important Note:** *This is intended as general guidance only; it is not legal advice. Anyone in doubt should seek their own independent legal advice to ensure they are compliant with any relevant legislation.*

### General legislative position and existing licensing arrangements

Cannabis is a Class B controlled drug under Part II, Schedule 2, of the Misuse of Drugs Act 1971 (MDA 1971). 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, 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.

"Cannabis-based products for medicinal use in humans" ("CBPM") - a defined category of cannabis, cannabis resin, cannabidiol and cannabidiol derivatives - are listed in Schedule 2 to the MDR 2001 and removed from designation under the 2015 Order. Home Office licensing requirements relating to these products are outlined below. The explanatory memorandum to the legislative changes can be found at:

<http://www.legislation.gov.uk/ukxi/2018/1055/memorandum/contents>

### So-called low-THC 'industrial hemp' licensing and use of non-controlled parts of the cannabis plant (seeds and fibre) in products.

The legislative controls identified above apply to cannabis plants cultivated for the production of drug material (e.g. hemp fibre or oil). Cultivation or possession of cannabis plants cannot lawfully be undertaken without the requisite Home Office Licence.

Home Office policy provides that licences may be issued for the cultivation of cannabis plants with a low tetrahydrocannabinol (THC) content for the production of hemp fibre for industrial purposes or the obtaining of seeds which are then pressed for their oil. For both of these uses, licences are granted to enable the use of non-controlled parts of the plant (i.e. seeds and fibre/ mature stalk only). This policy is only applicable where non-controlled parts of the plant are used.

There needs to be a defined commercial end use and the Home Office only issues licences for cultivation of plants from approved seed types with a THC content not exceeding 0.2%. The '0.2%' reference is used solely to identify varieties which may potentially be cultivated, within the scope of this policy, and to differentiate between the fee level is applicable under the Misuse of Drugs (Fees) Regulations 2010. The Hemp (Third Country Imports) Regulations 2002 also require, except in specified circumstances, that hemp from 'third countries' be imported under a licence and, in the case of hemp seeds other than for sowing, under an authorisation.

### **General licensing principles and interaction with other agencies:**

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 MDR 2001.

We also 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.

### **Impact of differing control status overseas and regulatory status:**

It is accepted that other countries may operate differing control regimes to the UK (which is outlined above). These alternative control regimes do not override UK domestic legislative requirements.

Furthermore, any 'opinion' of other regulatory bodies, e.g., the MHRA and 'medicinal status', is not determinative of the controls applicable to a substance under the MDA 1971 or MDR 2001.

## **Control status of cannabis-containing/ cannabinoid containing products in the UK:**

The applicable legislative controls within the UK are outlined above and apply to controlled parts of plants of the genus Cannabis, and to products containing controlled cannabinoids.

Therefore, if a product containing controlled cannabinoids (e.g., THC) or any other controlled substance(s) is imported from the EU, USA, or any other part of the world, then there is a requirement to obtain a Home Office controlled drug import licence to undertake this activity lawfully.

The presence of a controlled substance in a product will ultimately determine whether and on what basis the product could be made available to the public. For example, a product containing, schedule 1 substance(s) – e.g., controlled cannabinoids – could not practically be prescribed, administered, or supplied to the ‘public’ unless it is an exempt product or a CBPM.

### **Cannabidiol (CBD) and its control status:**

CBD as an isolated substance, *in its pure form*, would not be controlled under the MDA 1971 / MDR 2001.

If a CBD ‘product’ contained any controlled cannabinoids, unintentionally or otherwise (e.g. THC or THC-V), then it is highly likely that the product would be controlled. It is our understanding that it is very difficult to isolate pure CBD, and in our experience many products in fact do not fully disclose their contents or provide a full spectrum analysis at an appropriate level of sensitivity to accurately and consistently determine their true content or control status.

Against this background, the presumption has to be one of caution - that is, that a CBD containing product would be controlled under the MDA 1971 / MDR 2001 as a result of its other cannabinoid content.

In addition to any issues associated with controlled substance content, cannabis/ cannabis extract products may also need to satisfy other regulatory requirements if clinical/medicinal benefits are claimed. In this respect, companies may wish to contact the MHRA for their view on whether the cannabis/ cannabis extract products are additionally subject to their licensing regime and control.

### **THC-A and its control status:**

THC-A as an isolated substance, *in its pure form*, would not be controlled under the MDA 1971 / MDR 2001. However, it is understood that THC-A readily degrades both naturally, and with a catalyst or environmental change (e.g. ingestion) to THC which is a Schedule 1 controlled cannabinoid.

Against this background, the presumption is similarly one of caution, namely that THC-A will become a controlled substance by virtue of its degradation.

### **CBD and other cannabinoid ‘Products’**

For a CBD and other cannabinoid products to be lawfully available for human consumption it needs to either meet the Exempted Product Criteria in Regulation 2 of the MDR 2001 or the definition of a CBPM in Schedule 2 to the MDR 2001 for its possession to be lawful.

Where a product is neither a CBPM nor an ‘Exempted Product’, licences would not ordinarily be issued to enable the use of a ‘Schedule 1’ controlled drug product outside of bona-fide research or a recognised UK clinical trial.

### **Cannabis Based Products for Medicinal Use in Humans (CBPM)s – Regulation 2 and Schedule 2 MDR 2001**

With effect from 1 November 2018, CBPMs will be listed in Schedule 2 to the MDR 2001.

Regulation 2 of the MDR 2001 defines CBPMs as<sup>1</sup>:

*“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, cannabidiol or a cannabidiol 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;”*

A CBD preparation or product containing controlled cannabinoids (e.g. THC or CBD-V) which meets the three limbs of this definition may be a CBPM.

Specialist Doctors can prescribe CBPMs without requiring a Home Office licence to lawfully write a prescription. However, as with other controlled drugs in Schedule 2, companies wishing to possess, supply, produce, manufacture and/ or import/ export these products will require Home Office Controlled Drug licences to lawfully undertake these activities, unless a limited licensing ‘exemption’ applies - e.g. a pharmacist or person conducting a retail pharmacy business acting in their respective capacities (however see guidance here on wholesale dealing: <https://www.gov.uk/guidance/controlled-drugs-licences-fees-and-returns>). It should be noted that Regulation 16A of the MDR 2001 imposes additional controls for the order and supply of CBPMs for the purpose of administration.

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<sup>1</sup> <http://www.legislation.gov.uk/ukxi/2018/1055/contents/made>

Where a preparation or product containing cannabis, cannabis resin, cannabidiol or a cannabidiol derivative does not meet the definition of a CBPM, it will be a Schedule 1 drug under the MDR 2001 unless the exempt product definition applies.

### **The ‘exempted product’ definition - Regulation 2 of the MDR 2001<sup>2</sup>.**

Regulation 2 (Interpretation) of the MDR 2001 provides that some products may, in limited circumstances, be considered ‘exempt’ from control, notwithstanding their ‘controlled drug’ content.

The regulation sets out:

*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.*

To meet the criteria of an exempted product all three limbs of the definition must be met.

The Home Office view is that this definition may apply to drug preparations or products in any form- for example an Active Pharmaceutical Ingredient (API) or a medicinal product in Finished Dose Form (although it is highly likely that in a ‘bulk form’ the 1mg threshold would cease to be met).

It is the Home Office view that, to establish that the definition is met, testing e.g. a full spectrum analysis to the appropriate threshold by an independent and licensed UK company, and provision of comprehensive and independently verifiable information and research of an appropriately rigorous nature will be required. It is likely that the product will be subjected to regulation as a medicinal product (or to an equivalent UK regulatory standard) as a way of demonstrating that there is no intention of administering the controlled drug element of the product (referred to in (a)). The purpose and intended method of administration of a product may affect this. It is the Home Office view that the applicable unit of measure for the 1mg ‘threshold’ referred to in (c) is that of the ‘container’ (i.e. bottle or packet) and not the ‘typical dose’ (of any product).

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<sup>2</sup> <http://www.legislation.gov.uk/ukxi/2001/3998/regulation/2/made>