

Home Office Circular 2018: Rescheduling of cannabis-based products for medicinal use in humans

Broad Subject: Drugs – Medicinal Cannabis

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From: Crime, Policing and Fire Group (CPFG) – Drugs and Alcohol Unit

Introduction

This circular draws attention to the contents of the Statutory Instrument (SI) – SI 2018/1055. The new provisions, *The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018*, (“the 2018 Regulations”) come into force today (1 November 2018). The SI together with the associated explanatory memorandum is available at: <http://www.legislation.gov.uk/ukxi/2018/1055/contents/made>.

Summary

We are amending the Misuse of Drugs Regulations 2001 (“the 2001 Regulations”) and Misuse of Drugs (Designation) Order 2015 to reschedule cannabis-based products for medicinal use in humans to Schedule 2 of the 2001 Regulations and to impose additional access and administration restrictions in relation to these products. This means that from today (1 November) there will be a legal route for cannabis-based products for medicinal use to be prescribed by doctors on the General Medical Council (GMC) specialist register in the strictly controlled circumstances required by the 2001 Regulations without the requirement for a Home Office licence.

The 2018 Regulations introduce a definition of ‘cannabis-based product for medicinal use in humans’. Only products meeting this definition will be rescheduled to Schedule 2 of the 2001 Regulations and de-designated from the 2015 Designation Order. Any other substance or product (which is or contains cannabis, cannabis resin, cannabinol or cannabinol derivatives) will remain a Schedule 1 drug. The definition does not impact on the offence of cultivation of the cannabis plant which would still require a Home Office licence or wider offences relating to recreational use of cannabis. Cannabis will remain controlled as a class B drug under the Misuse of Drugs Act 1971 (“the 1971 Act”) and the penalties for unauthorised supply, possession and cultivation of cannabis will remain unchanged.

The 2018 Regulations have also imposed special measures of control for the use, order and supply of these Schedule 2 products for the purposes of administration.

Specifically, such order and supply must be: for use in accordance with the prescription or direction of a specialist medical practitioner; an investigational medicinal product for use in a clinical trial in humans; or, a medicinal product with a marketing authorisation. The Regulations continue to prohibit smoking of cannabis and cannabis-based products for medicinal use.

Finally, the 2018 Regulations amend the Misuse of Drugs (Licence Fee) Regulations 2010 (“the 2010 Regulations”) to confirm that the Secretary of State may determine that no licence fee should be paid where he sees fit.

Background

Review of cannabis-based products for medicinal use

The 2001 Regulations provides access to controlled drugs for legitimate purposes. Drugs which are controlled under the 1971 Act are listed in one of five Schedules to the 2001 Regulations, based on an assessment of their medicinal or therapeutic usefulness, the need for legitimate access and their potential harms when misused. The Schedules into which a drug is placed primarily dictates the extent to which it is lawful to import, export, produce, possess, supply and administer. It imposes requirements around prescribing, record keeping, labelling, destruction, disposal and safe custody. Schedule 1 controlled drugs are subject to the greatest restrictions and Schedule 5 to the lowest. Controlled drugs which have no known legitimate medicinal uses are also ‘designated’ and placed in Schedule 1 to the 2001 Regulations which means they are subject to the strictest level of control.

There have been several cases recently that have proved the need to look more closely at the use of cannabis-based products for medicinal use in the UK. This is why in June 2018 the Home Secretary announced an urgent two-part review to look into the scheduling of cannabis under the 2001 Regulations. Part 1 of the review was conducted by Professor Dame Sally Davies, the Chief Medical Officer (CMO) for England and Chief Medical Advisor to the UK government, to explore the therapeutic benefits of cannabis-based products for medicinal use. The review for part one found conclusive evidence of the therapeutic benefit of cannabis-based products for certain medical conditions and reasonable evidence of therapeutic benefit in several other medical conditions. Professor Dame Sally Davies recommended ‘that the whole class of cannabis-based medicinal products be moved out of Schedule 1 of the Misuse of Drugs Regulations’.

Part 2 is being led by the Advisory Council on the Misuse of Drugs (ACMD) who published short term advice in July 2018 and will provide longer term advice in 2019. The purpose of part two of the review was to balance the potential risk of harm and diversion of cannabis and cannabis-based products and provide advice on whether these should be rescheduled under the 2001 Regulations and if so, into which

schedule they should be placed, as well as any other mitigating action to prevent risks of misuse and diversion. The ACMD recommended that “cannabis-derived medicinal products of the appropriate standard” be moved out of Schedule 1.

Synthetic cannabinoid receptor agonists (synthetic cannabinoids) were specifically excluded from this and reserved for further consideration. Synthetic cannabinoids are substances that mimic the effects of cannabis on the brain. However, as their name indicates, they are synthetic and chemically unrelated to the cannabis plant, covering thousands of different compounds. As part of the two-part review into the use of cannabis-based products for medicinal purposes the ACMD advice recommended that synthetic cannabinoids should remain in Schedule 1 to the 2001 Regulations pending their 12-month review which is due in July 2019.

The Government accepted advice from the Chief Medical Officer and ACMD and committed to amending legislation by the autumn.

Definition of cannabis-based products for medicinal use in humans

The government has defined “a cannabis-based product for medicinal use in humans” as:

“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;”;

If the three limbs are met, then the preparation or product is considered as a ‘cannabis-based products for medicinal use in humans’ and a Schedule 2 drug under the 2001 Regulations.

Only products meeting this definition are being rescheduled. Products not meeting this definition will remain in Schedule 1 and will be kept under strict controls and only available for use under a Home Office licence.

Existing Schedule 2 requirements under the 2001 Regulations will apply. Cannabis-based products for medicinal use in humans remain subject to the strict requirements of Schedule 2 to the 2001 Regulations, along with other harmful substances, such as morphine, ketamine and fentanyl.

- Safety Custody
- Prescription requirements
- Marking bottles
- Mandatory requisition forms
- Record keeping
- Destruction

Additionally, cannabis-based products for medicinal use in humans for administration are subject to specific access restrictions (new Regulation 16A of the 2001 Regulations) over and above the requirements applicable to other Schedule 2 drugs.

Access Routes

There are three access routes available for the order and supply of these products for administration (to humans or animals):

- a special medicinal product that is for use in accordance with a prescription or direction of a specialist medical practitioner;
- an investigational medicinal product without a marketing authorisation that is for use in a clinical trial; or
- a medicinal product with a marketing authorisation

These access restrictions do not apply to orders or supplies which are not for the purposes of administration (which will be treated as other Schedule 2 drugs).

In the UK, all cannabis-based products for medicinal use apart from Sativex (listed in Schedule 4) are currently **unlicensed medicines** (special medicinal products). Due to the limited evidence base and their unlicensed nature, the government has chosen to restrict prescribing of such products to only those clinicians listed on the specialist register of the General Medical Council. This restriction has been set out in regulations.

Smoking of cannabis and cannabis-based products for medicinal use in humans continues to be prohibited.

Annex A

FOR MORE INFORMATION CONTACT:

Contact	Telephone	Email
General Enquiries		cannabisqueries@homeoffice.gov.uk

Annex B

Glossary

The 2018 Regulations	The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018
The 2010 Regulations	The Misuse of Drugs (Licence Fee) Regulations 2010
The 2001 Regulations	The Misuse of Drugs Regulations 2001
The 1971 Act	The Misuse of Drugs Act 1971
CMO	Chief Medical Officer
CMA	Chief Medical Advisor
ACMD	Advisory Council on the Misuse of Drugs
GMC	General Medical Council

Annex C

Guidance

To support specialist clinicians' prescribing decisions, the National Institute for Health and Care Excellence (NICE) has been asked by the Department of Health and Social Care to produce a clinical guideline on the prescribing of cannabis-based products for medicinal use in humans. This guidance is expected in 2019.

For more information and further guidance please go to:

Misuse of Drugs Act 1971: <http://www.legislation.gov.uk/ukpga/1971/38/contents>

Misuse of Drugs Regulations 2001 '2001 Regulations':
<http://www.legislation.gov.uk/uksi/2001/3998/contents/made>

Misuse of Drugs (Designation) Order 2015 – '2015 Designation Order':
<http://www.legislation.gov.uk/uksi/2015/704/contents/made>

Misuse of Drugs (Licence Fees) Regulations 2010 - '2010 Regulations':
<http://www.legislation.gov.uk/uksi/2010/2497/contents/made>

NHS England Guidance to clinicians:

<https://www.england.nhs.uk/publication/cannabis-based-products-for-medicinal-use-guidance-to-clinicians/>

NHS England Guidance to patients: <https://www.nhs.uk/conditions/medical-cannabis/>

Royal College of Physicians Guidance:

<https://www.rcplondon.ac.uk/projects/outputs/recommendations-cannabis-based-products-medicinal-use>

British Paediatric Neurology Association Guidance:

<https://www.bpna.org.uk/?page=c Demp>

Medicines & Healthcare products Regulatory Agency: specials guidance and additional cannabis guidance:

<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

Home Office Guidance on controlled drugs: licenses, fees and returns:

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

Home Office Drug Licensing Factsheet- Cannabis, CBD and other cannabinoids:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/674713/Factsheet- Cannabis CBD and Cannabinoids- January 2018.pdf

Chief Medical Officer's (CMO) Report:

<https://www.gov.uk/government/publications/cannabis-scheduling-review-part-1>

Advisory Council on the Misuse of Drugs (ACMD) Report:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/727333/ACMD_advice_on_scheduling_of_cannabis_derived_medicinal_products.pdf

CPS guidance about drug offences is available at: www.cps.gov.uk

NPCC guidance (unpublished) is available for police enforcement officers