STATUTORY INSTRUMENTS

2018 No. 1055

DANGEROUS DRUGS, ENGLAND AND WALES
DANGEROUS DRUGS, SCOTLAND

The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018

Made - - - -	*9th October 2018*
Laid before Parliament	*11th October 2018*
Coming into force - -	*1st November 2018*

The Secretary of State, in exercise of the powers conferred by sections 7, 10, 22, 30 and 31 of the Misuse of Drugs Act 1971(**1**), makes the following Regulations.

In accordance with sections 7(7) and 31(3) of that Act the Secretary of State has consulted with the Advisory Council on the Misuse of Drugs.

Citation, commencement, interpretation and extent

1.—(1) These Regulations may be cited as the Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018, and come into force on 1st November 2018.

(2) In these Regulations—

"the 2001 Regulations" means the Misuse of Drugs Regulations 2001(**2**);

"the 2010 Regulations" means the Misuse of Drugs (Licence Fees) Regulations 2010(**3**); and

"the 2015 Order" means the Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015(**4**).

(3) These Regulations extend to England and Wales and Scotland.

(**1**) 1971 c. 38. Section 22 was amended by section 177(1) of, and paragraph 12 of Schedule 4, to the Customs and Excise Management Act 1979 (c. 2). Section 37 was amended by section 52 of the Criminal Law Act 1977 (c. 45). Other amendments have been made to sections 7, 10, 30, 31 and 37 not relevant to these Regulations. See the definition of "prescribed" in section 37(1).

(**2**) S.I. 2001/3998. Relevant amending instruments are S.I. 2003/1432, 2003/1653, 2003/2429, 2004/1031, 2004/1771, 2005/2712005/1653, 2005/2864, 2005/3372, 2006/986, 2006/1450, 2006/2178, 2007/2154, 2009/3136, 2010/1144, 2010/1799, 2011/448, 2011/2581, 2012/385, 2012/973, 2012/1311, 2012/1916, 2013/176, 2013/235, 2013/625, 2014/1275, 2014/1377, 2014/2081, 2014/3277, 2015/231, 2015/891, 2016/1125, 2017/631, 2017/1117 and 2018/682.

(**3**) S.I. 2010/2497; amended by S.I. 2011/2199.

(**4**) S.I. 2015/704. Relevant amending instruments are S.I. 2016/1124, 2017/632 and 2017/1118.

Amendment of the Misuse of Drugs Regulations 2001

2. The 2001 Regulations are amended in accordance with regulations 3 to 7.

Amendment of regulation 2 of the 2001 Regulations

3. In regulation 2(1) of the 2001 Regulations(**5**) (interpretation) at the appropriate places insert—

""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;";

""clinical trial" has the same meaning as in the Medicines for Human Use (Clinical Trials) Regulations 2004(**6**);";

""dronabinol" does not include any substance which—

(a) has the international non-proprietary name dronabinol (recommended by the World Health Organisation); and

(b) is derived from cannabis, cannabis resin or their constituents,

and stereoisomers of dronabinol are to be construed accordingly;; and"; and

""medicinal product" has the same meaning as in the Human Medicines Regulations 2012(**7**);".

New regulation 16A of the 2001 Regulations

4. After regulation 16 of the 2001 Regulations (provisions as to supply on prescription), insert—

"**16A Orders, supply and use of cannabis-based products for administration**

(1) Subject to paragraph (4), a person shall not order (whether by issuing a prescription or otherwise) a cannabis-based product for medicinal use in humans for administration, unless that product is—

(a) a special medicinal product that—

(i) is not also an investigational medicinal product, but

(ii) is for use in accordance with a prescription or direction of a specialist medical practitioner;

(b) an investigational medicinal product without a marketing authorisation that is for use in a clinical trial; or

(c) a medicinal product with a marketing authorisation.

(**5**) Regulation 2 has been amended by S.I. 2003/1653, 2003/2429, 2004/1771, 2005/271, 2005/2864, 2006/986, 2006/1450, 2006/2178, 2007/2154, 2011/2581, 2012/973, 2012/1916, 2013/235, 2015/891 and 2018/682.
(**6**) S.I. 2004/1031. See the definition of "clinical trial" in regulation 2.
(**7**) S.I. 2012/1916. See the definition of "medicinal product" in regulation 2.

(2) Subject to paragraph (4), a person shall not supply a cannabis-based product for medicinal use in humans by way of or for the purpose of the administration of that product, unless the supply—

(a) is pursuant to an order that complies with paragraph (1); and

(b) is—

(i) in the case of a product that is a special medicinal product but is not also an investigational medicinal product, for use in accordance with a prescription or direction of a specialist medical practitioner,

(ii) in the case of a product that is an investigational medicinal product without a marketing authorisation, for use in a clinical trial, or

(iii) of a medicinal product with a marketing authorisation.

(3) A person shall not self-administer a cannabis-based product for medicinal use in humans by the smoking of the product (other than for research purposes in accordance with regulation 13);

(4) Nothing in this regulation shall have effect in relation to the order or supply of a cannabis-based product for medicinal use in humans for administration to animals for research purposes.

(5) In this regulation, "investigational medicinal product", "marketing authorisation", and "special medicinal product" have the same meanings as in the Human Medicines Regulations 2012(**8**).

(6) In this regulation, "specialist medical practitioner" means a doctor included in the register of specialist medical practitioners kept under section 34D of the Medical Act 1983(**9**) (the Specialist Register).".

Amendment of regulation 18 of the 2001 Regulations

5. In regulation 18 of the 2001 Regulations (marking of bottles and other containers), in paragraph (3), omit the definition of "clinical trial".

Amendment of Schedule 1 to the 2001 Regulations

6. In Schedule 1 to the 2001 Regulations (controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 19, 20, 23, 26 and 27), after paragraph 5 insert—

"**6.** But paragraphs 1 to 5 do not include a cannabis-based product for medicinal use in humans.".

Amendment of Schedule 2 to the 2001 Regulations

7. In Schedule 2 to the 2001 Regulations (controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 19, 20, 21, 23, 26 and 27)—

(a) in the heading, after "16," insert "16A,";

(b) in paragraph 1, at the appropriate place insert "Cannabis-based product for medicinal use in humans"; and

(c) after paragraph 5 insert—

"**5A.** But paragraphs 2 to 5 only apply in respect of a cannabis-based product for medicinal use in humans if the cannabis-based product that would, as a consequence of

(**8**) S.I. 2012/1916. See the definition of those terms in regulation 8.
(**9**) 1983 c. 54; section 34D was inserted by S.I. 2010/234.

paragraphs 2 to 5, be specified in this Schedule but for the operation of this paragraph, is produced for medicinal use in humans.".

Amendment of the Misuse of Drugs (Licence Fees) Regulations 2010

8.—(1) The 2010 Regulations are amended as follows.

(2) After regulation 2(5) (prescribed fee), insert—

"(6) No fee is payable in respect of a licence where the Secretary of State determines that the fee should be waived.".

Amendment of the Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015

9.—(1) Schedule 1 to the 2015 Order (which specifies the controlled drugs to which section 7(4) of the Misuse of Drugs Act 1971 applies) is amended as follows.

(2) In paragraph 1(a) of Part 1(**10**)—

(a) after "Cannabinol" insert "(not being the product specified in paragraph 10(1) or (2))";

(b) after "Cannabinol derivatives not being dronabinol or its stereoisomers" insert "(and not being the product specified in paragraph 10(1) or (2))";

(c) for "Cannabis (not being the substance specified in paragraph 4 of Part 2 of this Schedule)", substitute "Cannabis (not being the substance specified in paragraph 9 or product specified in paragraph 10(1) or (2))"; and

(d) after "Cannabis resin" insert "(not being the product specified in paragraph 10(1) or (2))".

(3) In Part 2 (which specifies controlled drugs excepted from Part 1), after paragraph 9 insert—

"**10.**—(1) A cannabis-based product for medicinal use in humans.

(2) A product which is—

(a) specified in Part 1 as a consequence of the application of paragraphs 2 to 5 to a preparation or other product (not being the substance specified in paragraph 9) which is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative (not being dronabinol or its stereoisomers); and

(b) produced for medicinal use in humans.

(3) In this paragraph—

"cannabis-based product for medicinal use in humans" means a preparation or other product (not being the substance specified in paragraph 9), 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; and

"medicinal product" has the same meaning as in the Human Medicines Regulations 2012(**11**).

(**10**) Paragraph 1 has been amended by S.I. 2017/632.
(**11**) S.I. 2012/1916. See the definition of "medicinal product" in regulation 2.

(4) In this Schedule, "dronabinol" does not include any substance which—

(a) has the international non-proprietary name dronabinol (recommended by the World Health Organisation); and

(b) is derived from cannabis, cannabis resin or their constituents,

and stereoisomers of dronabinol are to be construed accordingly.".

Nick Hurd
Minister of State
Home Office

9th October 2018

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Misuse of Drugs Regulations 2001 (S.I. 2001/3998) (the "2001 Regulations") and the Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015 (S.I. 2015/704) ("the 2015 Order") to allow the wider use of cannabis-based products for medicinal use in humans, essentially for medical purposes. They also amend the Misuse of Drugs (Licence Fees) Regulations 2010 (S.I. 2010/2497) (the "2010 Regulations") to provide for waiver of licence fees under those Regulations.

Section 7(3) of the Misuse of Drugs Act 1971 (c. 38) (the 1971 Act) requires regulations to be made to allow the use for certain purposes, including medical use, of the drugs which are subject to control under that Act. Section 7(4)(b) of the 1971 Act provides, however, that designated controlled drugs will be exempt from this easement and so cannot lawfully be prescribed, administered, produced, compounded or supplied except under licence or other authority issued by the Secretary of State. The designations in question are in the 2015 Order and include cannabis, cannabis resin, cannabinol and cannabinol derivatives not being dronabinol or its stereoisomers. Regulation 9 varies the 2015 Order to exclude cannabis-based products for medicinal use in humans, and some related products, from the relevant designations.

The 2001 Regulations are correspondingly amended to permit legitimate access. The Schedule to the 2001 Regulations in which a controlled drug is placed affects the extent to which the drug can be lawfully imported, exported, produced, supplied or possessed. Regulation 3 inserts the definition of a cannabis-based product for medicinal use in humans into the 2001 Regulations. Regulations 6 and 7(b) transfer these products from Schedule 1 to Schedule 2 to permit, subject to controls, those activities that are effectively prohibited by designation under the 2015 Order. The rescheduling also applies (as a consequence of existing provisions of Schedule 2) to related products such as stereoisomeric forms, salts and esters of cannabis-based products for medicinal use in humans where these related products are also produced for medicinal use in humans (by regulation 7(c)). A synthetic version of a constituent of cannabis, dronabinol, was already listed in Schedule 2, and a new definition is inserted to ensure its position is unchanged (regulation 3(c) and 9(4)).

Additional controls, beyond those generally provided for in relation to drugs specified in Schedule 2 to the 2001 Regulations, are imposed for cannabis-based products for medicinal use in humans. Regulation 4 inserts new regulation 16A to specify requirements for the order and supply of these products for the purpose of administration (whether to humans or animals) and their use. The order (by prescription, direction or otherwise) must be for: a special medicinal product (an existing category of medicines without marketing authorisations) 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. Supply, by administration or for the purpose of administration, must be pursuant to such an order. Additionally, a person is restricted from self-administration of a cannabis-based product for medicinal use in humans by way of smoking other than for research purposes. An exception is, however, created for order and supply of such products for administration to animals for research purposes.

Regulation 8 amends the 2010 Regulations, which prescribe the fee payable where a licence is issued to engage in various activities in relation to controlled drugs, to provide that no fee is payable where the Secretary of State determines that the fee should be waived.

A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available and is published with the Explanatory Memorandum alongside the

instrument on www.legislation.gov.uk. Copies may be obtained from the Home Office at 2 Marsham Street, London, SW1P 4DF.