STATUTORY RULES OF NORTHERN IRELAND

2018 No. 173

DANGEROUS DRUGS

The Misuse of Drugs (Amendment No.2) Regulations (Northern Ireland) 2018

Made - - - -	*11th October 2018*
Coming into operation	*1st November 2018*

The Department of Health(**1**), makes the following Regulations in exercise of the powers conferred by sections 7, 10, 22 and 31 of the Misuse of Drugs Act 1971(**2**) as adapted by sections 7(9), 31(4) and 38 of that Act and now vested in it(**3**) and after consultation with the Advisory Council on the Misuse of Drugs in accordance with section 31(3) of that Act.

Citation, commencement, interpretation

1.—(1) These Regulations may be cited as the Misuse of Drugs (Amendment No.2) Regulations (Northern Ireland) 2018 and shall come into operation on 1st November 2018.

(2) The Interpretation Act (Northern Ireland) 1954(**4**) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

Amendment of the Misuse of Drugs Regulations (Northern Ireland) 2002

2. The Misuse of Drugs Regulations (Northern Ireland) 2002(**5**) are amended in accordance with regulations 3 to 7 below.

Amendment of regulation 2

3. In regulation 2(2) (interpretation)—

(a) at the appropriate places insert—

(**1**) Formerly the Department of Health, Social Services and Public Safety; see 2016 c.5 (N.I.), section 1(5)
(**2**) 1971 c.38 as amended by s.151 of, and Schedule 17 to, the Police Reform and Social Responsibility Act 2011 c.13
(**3**) S.R.&O.(N.I) 1973 No. 504, Article 5(a) and S.I. 1999/283 (N.1.1), Article 3(6)
(**4**) 1954 c.33 (N.I)
(**5**) S.R. 2002 No.1. Relevant amending Regulations are S.R. 2018 No.4, S.R. 2016 No.29, S.R. 2015 No. 227, S.R. 2015 No. 53, S.R. 2014 Nos .261, 158 and 21, S.R. 2013 No.78, S.R. 2012 No. 213, S.R. 2011 No.153, S.R .2010 Nos.247 and 148, S.R. 2009 No. 390, S.R. 2007 No.348 and S.R. 2005 No. 360

""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) that is derived from cannabis, cannabis resin or their constituents, and stereoisomers of dronabinol are to be construed accordingly;"; and

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

New regulation 16A

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

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

16A.—(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.

(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,

(**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.

(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

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

Amendment of Schedule 1

6. In Schedule 1 (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 apply to a cannabis based product for medicinal use in humans.".

Amendment of Schedule 2

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

(**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.

Sealed with the Official Seal of the Department of Health on 11th October 2018

Dr Mark Timoney
A senior officer of the Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Misuse of Drugs Regulations (Northern Ireland) 2002 (S.R. 2002 No.2) (the "2002 Regulations") to allow the wider use of cannabis based products for medicinal use in humans, essentially for medical purposes.

The Schedule to the 2002 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 2002 Regulations. Regulations 6 and 7(b) transfer these products from Schedule 1 to Schedule 2. 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)).

Additional controls, beyond those generally provided for in relation to drugs specified in Schedule 2 to the 2002 Regulations, are imposed for cannabis based products for medicinal use in humans. Regulation 4 inserts new regulation 16 A 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.