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.