STATUTORY INSTRUMENTS.

S.I. No. 323 of 2014

MISUSE OF DRUGS (AMENDMENT) REGULATIONS 2014

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I, ALEX WHITE, Minister of State at the Department of Health, in exercise of the powers conferred on me by sections 4, 5 (as amended by section 4 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006)), 18 and 38 of the Misuse of Drugs Act 1977 (No. 12 of 1977), and the Health (Delegation of Ministerial Functions) Order 2012 (S.I. No. 553 of 2012) hereby make the following Regulations:

Collective citation

1. (1) These Regulations may be cited as the Misuse of Drugs (Amendment) Regulations 2014.

(2) The Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988), the Misuse of Drugs (Amendment) Regulations 1993 (S.I. No. 342 of 1993), the Misuse of Drugs (Amendment No. 1) Regulations 1999 (S.I. No. 273 of 1999), the Misuse of Drugs (Amendment) Regulations 2006 (S.I. No. 53 of 2006), the Misuse of Drugs (Amendment) Regulations 2007 (S.I. No. 200 of 2007), the Misuse of Drugs (Amendment) Regulations 2009 (S.I. No. 63 of 2009), the Misuse of Drugs (Amendment) (No. 2) Regulations 2009 (S.I. No. 122 of 2009), the Misuse of Drugs Regulations 2010 (S.I. No. 200 of 2010), the Misuse of Drugs (Amendment) (No. 2) Regulations 2010 (S.I. No. 607 of 2010), the Misuse of Drugs (Amendment) Regulations 2011 (S.I. No. 552 of 2011) and these Regulations may be cited together as the Misuse of Drugs Regulations 1988 to 2014 and shall be construed together as one.

Interpretation

2. In these Regulations"Principal Regulations" means the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988).

Amendment of Article 3 of the Principal Regulations

3. Article 3 (as amended by Regulation 3 of the Misuse of Drugs (Amendment) (No. 2) Regulations 2010) of the Principal Regulations is amended by inserting after the definition of "installation manager" the following definition:

> "'marketing authorisation' means an authorisation or licence which is for the time being in force and which has been granted by–
>
> (*a*) the Health Products Regulatory Authority in accordance with–
>
> (i) the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007), including a product authorisation or a parallel import licence, or

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 15*th July*, 2014.

(ii) Article 126a of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001[1],

(*b*) the European Commission under Council Regulation (EEC) No. 2309/93 of 22 July 1993[2] or Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004[3],

(*c*) the competent authority of a state which is a contracting party to the Agreement on the European Economic Area signed in Oporto on 2 May 1992, as adjusted by the Protocol to that Agreement done at Brussels on 17 March 1993[4], in accordance with Article 6 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, or

(*d*) the competent authority in the Swiss Confederation for the granting of authorisations or licences for the marketing of medicinal products;".

Amendment of Article 13 of the Principal Regulations

4. Article 13 (as amended by Regulation 4 of the Misuse of Drugs (Amendment) (No. 2) Regulations 2010) of the Principal Regulations is amended by inserting the following after sub-article (3):

"(4) In the case of a prescription for a controlled drug specified in the Schedule to the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations 1998 (S.I. No 225 of 1998), the requirements specified in sub-article (1)(*f*) and (*g*) shall not be required to be in the practitioner's own handwriting.".

Amendment of Schedule 1 to the Principal Regulations

5. Paragraph 1(*a*) of Schedule 1 (as amended by Regulation 3 of the Misuse of Drugs (Amendment) Regulations 2011) to the Principal Regulations is amended by substituting for "Cannabis and cannabis resin." the following:

"Cannabis (not being a preparation specified in paragraph 10 of Schedule 2).

Cannabis resin.".

Amendment of Schedule 2 to the Principal Regulations

6. Schedule 2 (as amended by Regulation 4 of the Misuse of Drugs (Amendment) Regulations 2011) to the Principal Regulations is amended by inserting after paragraph 9 the following paragraphs:

"10. An extract of cannabis which–

(*a*) is a medicinal product for human use which has been granted a marketing authorisation and which is presented as a liquid formulation

[1]OJ No. L. 311, 28.11.2001, p. 67.
[2]OJ No. L.214, 24.8.1993, p. 1.
[3]OJ No. L. 136, 30.4.2004, p. 1.
[4]OJ No. L. 1, 3.01.1994, p. 572.

for administration to a person through a meter dose pump as amucosal mouth spray, and

(*b*) has a concentration of not more than 30 milligrams of cannabidiol per millilitre, and not more than 30 milligrams of delta-9-tetrahydrocannabinol per millilitre, where the ratio of cannabidiol to delta-9-tetrahydrocannabinol is between 0.7 to 1.3.

11. Any stereoisomeric form of a substance specified in paragraph 10.

12. Any preparation or other product containing any proportion of a substance or product specified in any of paragraphs 10 or 11, not being a preparation specified in Schedule 5.".

GIVEN under my Hand,
11 July 2014.

ALEX WHITE,
Minister of State at the Department of Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

The purpose of these Regulations is to amend the Misuse of Drugs Regulations 1988. The Regulations of 1988 apply controls to the groups of drugs specified in Schedules 1 to 5 of the Regulations (being drugs to which the Misuse of Drugs Acts 1977 and 1984 apply), the effect of which is to impose restrictions on the production, supply, importation and exportation of the drugs in question, which vary according to the extent to which these drugs are used for medical or scientific purposes and having regard to the likelihood of their being abused.

These Regulations amend the Misuse of Drugs Regulations 1988—

(*a*) to insert into Schedule 2 authorised medicinal products containing a liquid extract of cannabis having a specified composition and presentation, in order to permit such products to be prescribed, supplied and possessed for the treatment of patients, and

(*b*) to remove the handwriting requirements in relation to certain details on prescriptions for controlled drugs specified in the Schedule to the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations 1998 (S.I. No. 225 of 1998).

These Regulations may be cited as the Misuse of Drugs (Amendment) Regulations 2014.

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