



STATUTORY INSTRUMENTS.

S.I. No. 504 of 2014



MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF
SUPPLY) (AMENDMENT) (NO. 2) REGULATIONS 2014

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 2) REGULATIONS 2014

I, LEO VARADKAR, Minister for Health, in exercise of the powers conferred on me by section 32 (as amended by section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006)) of the Irish Medicines Board Act 1995 (No. 29 of 1995) and for the purposes of giving further effect to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011¹ and giving effect to Commission Implementing Directive 2012/52/EU of 20 December 2012², hereby make the following Regulations:

1. (1) These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2014.

(2) The Principal Regulations, the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005 (S.I. No. 510 of 2005), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 (S.I. No. 201 of 2007), Part 4 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2008 (S.I. No. 512 of 2008), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2009 (S.I. No. 442 of 2009), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 (S.I. No. 525 of 2011), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2014 (S.I. No. 300 of 2014) and these Regulations may be cited together as the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2014 and shall be construed as one.

2. In these Regulations “Principal Regulations” means the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003).

3. Regulation 4(1) (as amended by Regulation 3 of the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011) of the Principal Regulations is amended—

(a) by inserting after the definition of “authorised person” the following definition:

“‘biological medicinal product’ means a product, the active substance of which is a biological substance as described in Part 1 of Annex 1 to the 2001 Directive;”,

¹OJ No. L 88, 4.4.2011, p. 45.

²OJ No. L 356, 22.12.2012, p. 68.

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 7th November, 2014.

- (b) by inserting after the definition of “clinical practice guidelines” the following definition:

“‘common name’ means the international non-proprietary name recommended by the World Health Organisation, or, if one does not exist, the usual common name;”,

- (c) by inserting after the definition of “controlled drug” the following definition:

“‘2001 Directive’ means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001², as amended by Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003³, Commission Directive 2003/63/EC of 25 June 2003⁴, Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004⁵, Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004⁶, Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006⁷, Regulation (EC) No. 1394/2007 of the European Parliament and of the Council of 13 November 2007⁸, Directive 2008/29/EC of the European Parliament and of the Council of 11 March 2008⁹, Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009¹⁰, Commission Directive 2009/120/EC of 14 September 2009¹¹, Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010¹², Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011¹³ and Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012¹⁴;”,

- (d) by inserting after the definition of “dosage unit” the following definitions:

“‘EEA Agreement’ means 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;

³OJ No. L 33, 8.2.2003, p. 30.

⁴OJ No. L 159, 27.6.2003, p. 46.

⁵OJ No. L 136, 30.4.2004, p. 85.

⁶OJ No. L 136, 30.4.2004, p. 34.

⁷OJ No. L 378, 27.12.2006, p. 1.

⁸OJ No. L. 324, 10.12.2007, p. 121. As affected by Corrigendum to Regulation (EC) No. 1394/2007, OJ No. L 87, 31.3.2009, p. 174.

⁹OJ No. L 81, 20.3.2008, p. 51.

¹⁰OJ No. L 168, 30.6.2009, p. 33.

¹¹OJ No. L 242, 15.9.2009, p. 3.

¹²OJ No. L 348, 31.12.2010, p. 74. As affected by Corrigendums to Directive 2010/84/EU, OJ No. L 21, 25.1.2011, p. 8 and OJ No. L 276, 21.10.2011, p. 63.

¹³OJ No. L 174, 1.7.2011, p. 74.

¹⁴OJ No. L 299, 27.10.2012, p. 1.

‘EEA state’ means a state, which is a contracting party to the EEA Agreement;

‘European Economic Area’ means the European Economic Area created by the EEA Agreement;”,

- (e) by inserting after the definition of “maximum strength” or “MS” the following definition:

“‘medicinal product subject to special medical prescription’ means a medicinal product which is subject to the prescription writing requirements specified in Article 13 of the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988);”

- (f) by substituting for the definition of “prescription” the following definition:

“‘prescription’ means a prescription issued by—

(a) a registered medical practitioner,

(b) a registered dentist,

(c) a registered nurse, or

(d) a practitioner of status equivalent to a registered medical practitioner or a registered dentist, practising in an EEA state other than the State, or a member of a regulated health profession within the meaning of Article 3(1)(a) of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005¹⁵ who is legally entitled to issue a prescription for the medicinal product concerned in the EEA state in which the prescription is issued, if the prescription has not been issued with a view to enabling the supply of a medicinal product by mail order;” and

- (g) by inserting after the definition of “sampling officer” the following definition:

“‘strength’ means the content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form;”.

4. Regulation 7 of the Principal Regulations (as amended by Regulation 8 of the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2008) is amended—

- (a) in paragraph (1)—

¹⁵OJ No. L 255, 30.9.2005, p. 22.

- (i) by substituting “Subject to paragraph (1A), for the purposes” for “For the purposes”, and
 - (ii) by substituting “a prescription issued for dispensing within the State” for “a prescription”,
- (b) by inserting after paragraph (1) the following paragraph:

“(1A) For the purposes of these Regulations and subject to paragraph (11), a prescription issued by a practitioner of status equivalent to a registered medical practitioner or a registered dentist, practising in an EEA state other than the State, or a member of a regulated health profession within the meaning of Article 3(1)(a) of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005¹⁵ who is legally entitled to issue a prescription for the medicinal product concerned in the EEA state in which the prescription is issued, and which is presented by a patient for dispensing in the State shall—

- (a) be in ink or other permanent and unalterable electronic form and be signed and dated by the person issuing the prescription with his or her usual signature, either in handwriting or by electronic signature;
- (b) clearly indicate the full name, including the full first name, of the person issuing the prescription and specify his or her professional qualification;
- (c) specify the work address, including the name of the relevant EEA state, of the person issuing the prescription;
- (d) specify the email address, and telephone or fax number (with the appropriate international prefix) of the person issuing the prescription;
- (e) specify the full name, including the full first name, and date of birth of the person for whose treatment the prescription is issued; and
- (f) specify the following details, where applicable, of the product to be supplied on foot of the prescription:
 - (i) the common name of the medicinal product;
 - (ii) the brand name of the medicinal product if—
 - (I) the medicinal product prescribed is a biological medicinal product, or
 - (II) the person issuing the prescription has deemed it medically necessary to include the brand name on

the prescription and has stated on the prescription the reasons justifying the use of the brand name;

- (iii) the pharmaceutical form;
- (iv) the quantity;
- (v) the strength of the medicinal product; and
- (vi) the dosage regime.”, and

(c) by inserting after paragraph (10) the following paragraph:

“(11) A prescription to which paragraph (1A) applies shall not be used to authorise the supply of any product which is a medicinal product subject to special medical prescription.”.

5. The Principal Regulations are amended by inserting after Regulation 7 the following Regulation:

“Requirements for prescriptions to be dispensed in EEA State other than the State

7A. (1) For the purpose of these Regulations and subject to paragraph (2), a prescription issued by a registered medical practitioner, a registered dentist or a registered nurse for dispensing in an EEA state other than the State shall—

- (a) be in ink and be signed by the person issuing the prescription with his usual signature and be dated by him or her;
- (b) clearly indicate the full name, including the full first name, of the person issuing the prescription and state—
 - (i) whether he or she is a registered medical practitioner, a registered dentist or a registered nurse, and
 - (ii) in the case of a registered nurse, the registration number assigned to the nurse in the register of nurses;
- (c) specify the work address in the State of the person issuing the prescription;
- (d) specify the email address, and telephone or fax number (with the appropriate international prefix) of the person issuing the prescription;
- (e) specify the full name, including the full first name, address and date of birth of the person for whose treatment the prescription is issued; and
- (f) specify the following details, where applicable, of the product to be supplied on foot of the prescription:

- (i) the common name of the medicinal product;
- (ii) the brand name of the medicinal product only if—
 - (I) the medicinal product prescribed is a biological medicinal product, or
 - (II) the person issuing the prescription has deemed it medically necessary to include the brand name on the prescription and has stated on the prescription the reasons justifying the use of the brand name;
- (iii) the pharmaceutical form;
- (iv) the quantity;
- (v) the strength of the medicinal product; and
- (vi) the dosage regime.

(2) A prescription issued by a registered medical practitioner, a registered dentist or a registered nurse for dispensing in an EEA state other than the State shall not be issued for, or used to authorise the supply of, any product which is a medicinal product subject to special medical prescription.”.



GIVEN under my Official Seal,
5 November 2014.

LEO VARADKAR,
Minister for Health.

EXPLANATORY NOTE

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

These Regulations amend the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003).

The Regulations give effect to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare and Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State.

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