



STATUTORY INSTRUMENTS.

S.I. No. 274 of 2012



MEDICINAL PRODUCTS (CONTROL OF WHOLESALE
DISTRIBUTION) (AMENDMENT) REGULATIONS 2012

MEDICINAL PRODUCTS (CONTROL OF WHOLESALE DISTRIBUTION) (AMENDMENT) REGULATIONS 2012

I, JAMES REILLY, 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), for the purpose of giving further effect to Directive 2008/29/EC of the European Parliament and of the Council of 11 March 2008¹, Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009² and Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010³, hereby make the following regulations:

1. These Regulations may be cited as the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2012.

2. In these Regulations “Principal Regulations” means the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007).

3. Regulation 4(1) (as amended by the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (Amendment) Regulations 2010 (S.I. No. 286 of 2010)) of the Principal Regulations is amended—

(a) by substituting for the definition of “Act” the following:

“‘Act’ means the Irish Medicines Board Act 1995 (No. 29 of 1995), as amended by s. 197 of the Finance Act 1999 (No. 2 of 1999), Regulation 3 of the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001), Regulation 2 of the European Communities (Medical Devices) (Amendment) Regulations 2001 (S.I. No. 444 of 2001), Regulation 3 of the European Communities (Medical Devices) (Amendment) Regulations 2002 (S.I. No. 576 of 2002), the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006) and the European Communities (Amendment of the Irish Medicines Board Act 1995) Regulations 2007 (S.I. No. 542 of 2007);”

(b) by inserting after the definition of “advanced therapy regulation” the following definition:

¹OJ No. L 81, 20.3.2008, p. 51.

²OJ No. L 168, 30.6.2009, p. 33.

³OJ No. L 348, 31.12.2010, p. 74. As affected by Corrigendum to Directive 2010/84/EU, OJ No. L 21, 25.1.2011, p. 8.

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 27th July, 2012.

“‘Agency’ means the European Medicines Agency established by Article 55 of Regulation (EC) No. 726/2004/EC of the European Parliament and of the Council of 31 March 2004⁴,” and

(c) by substituting for the definition of “2001 Directive” the following:

“‘2001 Directive’ means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001⁵, as amended by Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003⁶, Commission Directive 2003/63/EC of 25 June 2003⁷, Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004⁸, Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004⁹, the Community Regulation on medicinal products for paediatric use, the advanced therapy regulation, Directive 2008/29/EC of the European Parliament and of the Council of 11 March 2008¹, Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009², Commission Directive 2009/120/EC of 14 September 2009¹⁰ and Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010³.”

4. The Principal Regulations are amended by inserting after Regulation 14 the following Regulation:

“Inspections

14A. (1) Pursuant to ss. 32A to 32F of the Act and Article 111 of the 2001 Directive, the Board shall, by means of inspections, including unannounced inspections if necessary, ensure that the principles and guidelines of good distribution practice are complied with.

(2) After every inspection referred to in paragraph (1), the Board shall report on whether the inspected entity complies with the principles and guidelines on good distribution practice.

(3) The Board shall communicate the content of the report referred to in paragraph (3) to the inspected entity and shall, prior to adopting the report, give that person the opportunity to submit comments on the report.

(4) In this Regulation, “the principles and guidelines on good distribution practice” means the principles and guidelines published by the Commission pursuant to Article 84 of the 2001 Directive.”

⁴OJ No. L 136, 30.4.2004, p. 1.

⁵OJ No. L 311, 28.11.2001, p. 67.

⁶OJ No. L 33, 8.2.2003, p. 30.

⁷OJ No. L 159, 27.6.2003, p. 46.

⁸OJ No. L 136, 30.4.2004, p. 85.

⁹OJ No. L 136, 30.4.2004, p. 34.

¹⁰OJ No. L 242, 15.9.2009, p. 3.



GIVEN under my Official Seal,
25 July 2012.

JAMES REILLY,
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 (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007).

These Regulations give further effect to Directive 2008/29/EC of the European Parliament and of the Council of 11 March 2008, Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 and Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010.

These Regulations may be cited as the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2012.

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