STATUTORY INSTRUMENTS.

S.I. No. 273 of 2012

MEDICINAL PRODUCTS (CONTROL OF MANUFACTURE) (AMENDMENT) REGULATIONS 2012

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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 2008[1], Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009[2] and Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010[3], hereby make the following regulations:

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

2. In these Regulations "Principal Regulations" means the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007).

3. Regulation 3(1) (as amended by the Medicinal Products (Control of Manufacture) Regulations 2007 (Amendment) Regulations 2010 (S.I. No. 288 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:

[1]OJ No. L 81, 20.3.2008, p. 51.
[2]OJ No. L 168, 30.6.2009, p. 33.
[3]OJ 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 27*th 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 2004[4];",

(*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 2001[5], as amended by Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003[6], Commission Directive 2003/63/EC of 25 June 2003[7], Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004[8], Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004[9], 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 2008[1], Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009[2], Commission Directive 2009/120/EC of 14 September 2009[10] and Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010[3];", and

(*d*) by inserting after the definition of "EEA State" the following definition:

"'EudraGMP database' means the Community database referred to in Article 111(6) of the 2001 Directive;".

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 manufacturing practice are complied with.

(2) The Board shall share information with the Agency on inspections which have been carried out, and inspections which are planned and shall cooperate with the Agency in coordinating inspections in third countries.

[4]OJ No. L 136, 30.4.2004, p. 1.
[5]OJ No. L 311, 28.11.2001, p. 67.
[6]OJ No. L 33, 8.2.2003, p. 30.
[7]OJ No. L 159, 27.6.2003, p. 46.
[8]OJ No. L 136, 30.4.2004, p. 85.
[9]OJ No. L 136, 30.4.2004, p. 34.
[10]OJ No. L 242, 15.9.2009, p. 3.

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

(4) 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.

(5) The Board shall enter the certificates of good manufacturing practice in the EudraGMP database.

(6) If the outcome of an inspection referred to in paragraph (1) is that the inspected entity does not comply with the principles and guidelines of good manufacturing practice, the Board shall enter the information in the EudraGMP database.

(7) In this Regulation, "the principles and guidelines of good manufacturing practice" means the principles and guidelines adopted by the Commission pursuant to Article 47 of the 2001 Directive, including those laid down in the GMP Directive."

L.S.

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 Manufacture) Regulations 2007 (S.I. No. 539 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 Manufacture) (Amendment) Regulations 2012.

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DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased directly from the
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€2.54

ISBN 978-1-4064-9811-0

9 781406 498110

Wt. (B29334). 285. 7/12. Clondalkin Pharma & Healthcare (Glasnevin) Ltd. Gr 30-15.