STATUTORY INSTRUMENTS.

S.I. No. 151 of 2014

MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET) (AMENDMENT) REGULATIONS 2014

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MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET) (AMENDMENT) REGULATIONS 2014

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) and for the purpose of giving effect to Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012[1] and giving full effect to Regulation (EU) No. 1027/2012 of the European Parliament and of the Council of 25 October 2012[2] and Commission Implementing Regulation (EU) No. 198/2013 of 7 March 2013[3], hereby make the following regulations:

1. (1) These Regulations may be cited as the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2014.

(2) These Regulations shall be construed as one with the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2013 and may be cited together with those Regulations as the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2014.

2. In these Regulations "Principal Regulations" means the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).

3. Regulation 3(1) (as amended by Regulation 3 of the Medicinal Products (Control of Placing on the Market) Regulations (Amendment) Regulations 2013 (S.I. No. 162 of 2013)) of the Principal Regulations is amended—

(*a*) 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[4], as amended by Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003[5], Commission Directive 2003/63/EC of 25 June 2003[6], Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004[7], Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004[8], the Community Regulation on medicinal products for paediatric use, the advanced therapy

[1]OJ No. L 299, 27.10.2012, p. 1.
[2]OJ No. L 316, 14.11.2012, p. 38.
[3]OJ No. L 65, 8.3.2013, p. 17.
[4]OJ No. L 311, 28.11.2001, p. 67.
[5]OJ No. L 33, 8.2.2003, p. 30.
[6]OJ No. L 159, 27.6.2003, p. 46.
[7]OJ No. L 136, 30.4.2004, p. 85.
[8]OJ No. L 136, 30.4.2004, p. 34.

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regulation, Directive 2008/29/EC of the European Parliament and of the Council of 11 March 2008[9], Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009[10], Commission Directive 2009/120/EC of 14 September 2009[11], Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010[12], Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011[13] and Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012[1];",

(*b*) by substituting for the definition of "Regulation (EC) No. 726/2004" the following:

"Regulation (EC) No. 726/2004' means Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004[14], as amended by Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006[15], the advanced therapy regulation, Regulation (EC) No. 219/2009 of the European Parliament and of the Council of 11 March 2009[16], Regulation (EC) No. 470/2009 of the European Parliament and of the Council of 6 May 2009[17], Regulation (EU) No. 1235/2010 of the European Parliament and of the Council of 15 December 2010[18] and Regulation (EU) No. 1027/2012 of the European Parliament and of the Council of 25 October 2012[2];", and

(*c*) in the definition of "relevant Community provisions"—

(i) in subparagraph (i), by deleting "and",

(ii) in subparagraph (*j*), by substituting "2010, and" for "2010;", and

(iii) by inserting after subparagraph (*j*) the following subparagraph:

"(*k*) Commission Implementing Regulation (EU) No. 198/2013 of 7 March 2013[3];".

4. The Principal Regulations are amended by inserting after Regulation 13 the following Regulation:

"Urgent Action

13A. (1) Without prejudice to Article 31(1) of the 2001 Directive, the Board may, where urgent action is necessary to protect public health at any stage of the procedure initiated under Article 31 of the 2001 Directive, suspend a marketing

[9]OJ No. L 81, 20.3.2008, p. 51.
[10]OJ No. L 168, 30.6.2009, p. 33.
[11]OJ No. L 242, 15.9.2009, p. 3.
[12]OJ 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.
[13]OJ No. L 174, 1.7.2011, p. 74.
[14]OJ No. L 136, 30.4.2004, p. 1.
[15]OJ No. L 378, 27.12.2006, p. 1.
[16]OJ No. L 87, 31.3.2009, p. 109.
[17]OJ No. L 152, 16.6.2009, p. 11.
[18]OJ No. L 348, 31.12.2010, p. 1. As affected by Corrigendum to Regulation (EU) 1235/2010, OJ No. L 201, 27.7.2012, p. 138.

authorisation and prohibit the use of the medicinal product concerned until a definitive decision is adopted under that procedure.

(2) Without prejudice to Article 107i(1) and (1a), 107j and 107k of the 2001 Directive, where, on the basis of concerns resulting from the evaluation of data from pharmacovigilance data, it considers that urgent action is necessary to protect public health, the board may suspend a marketing authorisation and prohibit the use of the medicinal product concerned until a definitive decision is adopted under the procedure laid down in Articles 107j and 107k of the 2001 Directive.

(3) Where the Board takes urgent action under paragraph (1) or (2), it shall inform the Commission, the Agency and other EEA States no later than the following working day of the reasons for its action."

5. Regulation 15(6) (as amended by the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2012 (S.I. No. 272 of 2012)) of the Principal Regulations is amended—

(*a*) by substituting for subparagraph (*h*) the following:

"(*h*) if the medicinal product ceases to be placed on the market, either temporarily or permanently, notify the Board, no less than two months before the interruption in the placing on the market of the product or, in exceptional circumstances, less than two months before such interruption, and include in such notification the reasons for such action in accordance with Article 123(2) of the 2001 Directive",

(*b*) in subparagraph (*m*), by deleting "and",

(*c*) in subparagraph (*n*), by substituting "said request;" for "said request.", and

(*d*) by inserting after subparagraph (*n*) the following subparagraphs:

"(*o*) notify the Board of any action taken by the holder to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation, certificate of registration or certificate of traditional-use registration, or not to apply for the renewal of such authorisation or certificate, together with the reasons for such action and a declaration as to whether such action is based on any of the grounds set out in Article 116 and Article 117(1) of the 2001 Directive;

(*p*) notify the Board, in the manner described in subparagraph (*o*), of any action equivalent to that referred to in that subparagraph taken by the holder in a state outside the EEA, where such action is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive; and

(*q*) notify the Agency, where the action referred to in subparagraph (*o*) or (*p*) is taken on the basis of any of the grounds referred to in Article 116 or 117(1) of the 2001 Directive".

6. Schedule 2 (as amended by the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2012 (S.I. No. 272 of 2012)) to the Principal Regulations is amended—

(*a*) in paragraph 1, by substituting "Subject to paragraphs 6, 7 and 8" for "Subject to paragraph 6", and

(*b*) by inserting after paragraph 7 the following paragraph:

"8. Paragraph 2 shall not apply in the case of urgent action taken by the Board under Regulation 13A."

L.S.

GIVEN under my Official Seal,
26 March 2014.

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 Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).

These Regulations give effect to Directive 2012/26/EU of the European Parliament and of the Council of the 25 October 2012, which amended, as regards pharmacovigilance, Directive 2001/83/EC. The Regulations also give full effect to Regulation (EU) No. 1027/2012 of the European Parliament and of the Council of 25 October 2012 and Commission Implementing Regulation (EU) No. 198/2013.

These Regulations may be cited as the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2014.

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