STATUTORY INSTRUMENTS.

S.I. No. 162 of 2013

MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET) (AMENDMENT) REGULATIONS 2013

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MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET) (AMENDMENT) REGULATIONS 2013

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 2011/62/EU of the European Parliament and of the Council of 8 June 2011[1], and for the purpose of giving further effect to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001[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. (1) These Regulations may be cited as the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2013.

(2) These Regulations shall be construed as one with the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2010, the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2011 (S.I. 722 of 2011) and the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2012 (S.I. 272 of 2012) and may be cited together with those Regulations as the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2013.

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 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 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[2], as amended by Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003[4], Commission Directive 2003/63/EC of 25 June 2003[5], Directive 2004/24/EC of the European Parliament and of the Council of 31 March

[1]OJ No. L 174, 1.7.2011, p. 74.
[2]OJ No. L 311, 28.11.2001, p. 67.
[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.
[4]OJ No. L 33, 8.2.2003, p. 30.
[5]OJ No. L 159, 27.6.2003, p. 46.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 28*th May*, 2013.

2004[6], Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004[7], 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[8], Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009[9], Commission Directive 2009/120/EC of 14 September 2009[10], Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010[3] and Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011[1];",

(*b*) by inserting after the definition of "European Economic Area" the following definition:

"'falsified medicinal product' means any medicinal product with a false representation of—

(*a*) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients,

(*b*) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder, or

(*c*) its history, including the records and documents relating to the distribution channels used,

but does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights;", and

(*c*) by inserting after the definition of "relevant Community provision" the following definition:

"'relevant date' means—

(*a*) in the case of a medicinal product placed on the market in the State, the date 3 years after the date of publication of the delegated acts adopted by the Commission pursuant to Article 54a(2) of the 2001 Directive, or

(*b*) in the case of a medicinal product placed on the market in an EEA State which, on 21 July 2011, had in place a system of safety features, the date 6 years after the date of publication of the delegated acts adopted by the Commission pursuant to Article 54a(2) of the 2001 Directive;".

[6]OJ No. L 136, 30.4.2004, p. 85.
[7]OJ No. L 136, 30.4.2004, p. 34.
[8]OJ No. L 81, 20.3.2008, p. 51.
[9]OJ No. L168, 30.6.2009, p. 33.
[10]OJ No. L 242, 15.9.2009, p. 3.

4. Regulation 10 (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 paragraph (9) the following paragraphs:

"(9) Save in the case of an application made to the Board in accordance with Article 28 or Article 35 of the 2001 Directive, and subject to paragraph (9A), the provisions of Schedule 2 shall have effect where the Board—

(*a*) proposes to grant a marketing authorisation, certificate of registration or certificate of traditional-use registration subject to the carrying out of certain obligations by the holder of the authorisation or of the certificate as the case may be,

(*b*) proposes to grant a marketing authorisation, certificate of registration or certificate of traditional-use registration that is materially different from the application,

(*c*) proposes to vary a marketing authorisation, certificate of registration or certificate of traditional-use registration in a way that is materially different from the application, or

(*d*) proposes to refuse to grant or vary a marketing authorisation, certificate of registration or certificate of traditional-use registration.

(9A) Where the Board proposes to grant or vary a marketing authorisation, certificate of registration or certificate of traditional-use registration, otherwise than in accordance with the application, the provisions of Schedule 2 shall not automatically apply but may be invoked by the applicant, and the Board shall inform the applicant of the opportunity to invoke same ",

(*b*) in paragraph (10)(*a*) by deleting ", in accordance with the application, but",

(*c*) in paragraph (10)(*b*) by inserting "or varies" after "grants", and

(*d*) in paragraph (10)(*c*) by inserting "or vary" after "refuses to grant".

5. Regulation 14 (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 paragraph (9) the following:

"(9) The provisions of Schedule 2 shall have effect where the Board—

(*a*) proposes to suspend, revoke or refuse to renew a marketing authorisation, certificate of registration or certificate of traditional-use registration, in accordance with this Regulation,

(*b*) proposes to vary a marketing authorisation, certificate of registration or certificate of traditional-use registration, in the absence of an application by the holder of the authorisation or certificate, as the case may be, or

(*c*) proposes to make a marketing authorisation, certificate of registration or certificate of traditional-use registration, conditional on the carrying out of certain obligations by the holder of the authorisation or certificate, as the case may be.", and

(*b*) by substituting for paragraph (10) the following:

"(10) Where the Board—

(*a*) suspends, revokes or refuses to renew a marketing authorisation, certificate of registration or certificate of traditional-use registration, in accordance with this Regulation,

(*b*) varies a marketing authorisation, certificate of registration or certificate of traditional-use registration in the absence of an application by the holder of the authorisation or certificate, as the case may be, or

(*c*) proposes to make a marketing authorisation, certificate of registration or certificate of traditional-use registration, conditional on the carrying out of certain obligations by the holder of the authorisation or certificate, as the case may be,

the Board shall give the applicant or the holder of the authorisation or certificate a notice in writing stating in detail the reasons on which its decision is based.".

6. The Principal Regulations are amended by inserting after Regulation 16 (as amended by the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2012 (S.I. No. 272 of 2012)) the following:

"Safety features

17. (1) Subject to paragraph (3), from the relevant date, a person shall not place a medicinal product on the market unless the product bears safety features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to—

(*a*) verify the authenticity of the medicinal product, and

(*b*) identify individual packs,

(2) From the relevant date, a person shall not place a medicinal product on the market unless the product bears a device allowing verification of whether the outer packaging has been tampered with.

(3) Paragraphs (1) and (2) shall not apply to:

(*a*) radiopharmaceuticals,

(*b*) medicinal products subject to prescription which have been listed by the Commission, in accordance with the procedure set down in Article 54a(2) of the 2001 Directive, as not requiring safety features, and

(*c*) medicinal products not subject to prescription which have not been listed by the Commission, in accordance with the procedure set down in Article 54a(2) of the 2001 Directive, as requiring safety features."

7. Regulation 38 (inserted 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*) in paragraph (4), by substituting "paragraph (2)" for "paragraph (1)",

(*b*) in paragraph (5), by substituting "paragraph (4)" for "paragraph (3)", and

(*c*) in paragraph (6), by substituting "paragraph (2)" for "paragraph (1)".

8. The Principal Regulations are amended by inserting after Part 7 (inserted by the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2012 (S.I. No. 272 of 2012)) the following Parts:

"PART 8

FALSIFIED MEDICINES

Prohibitions in relation to falsified medicinal products

39. A person shall not—

(*a*) place a medicinal product on the market,

(*b*) place a medicinal product into circulation,

(*c*) introduce a medicinal product into the State, or

(*d*) sell or supply, or offer for sale or supply a medicinal product, including from a distance by means of information society services,

if he or she knows, or there are sufficient grounds to suspect, that it is a falsified medicinal product.

"PART 9

SYSTEM TO PREVENT MEDICINAL PRODUCTS, SUSPECTED OF PRESENTING A DANGER TO HEALTH, REACHING PATIENTS

System to be operated by the Board

40. (1) The Board shall, in accordance with this Regulation, operate a system, which aims to prevent medicinal products that are suspected of presenting a danger to health from reaching patients.

(2) The system referred to in paragraph (1) shall provide for—

(*a*) the receipt and handling of notifications of suspected falsified medicinal products and suspected quality defects of medicinal products,

(*b*) the recall from the market of medicinal products by holders of Community marketing authorisations, marketing authorisations, certificates of registration or certificates of traditional-use registration,

(*c*) the withdrawal from the market of medicinal products from all relevant actors in the supply chain both during and outside normal working hours,

(*d*) the recall from the market, where necessary with the assistance of health professionals, of medicinal products from patients who have received such products.

(3) If the Board identifies a medicinal product which is suspected of presenting a serious risk to public health, it shall, where necessary and without delay, rapidly transmit a notification to all EEA States and to all actors in the supply chain who are located in the State and who may hold stocks of the relevant medicinal product.

(4) In the event of such a medicinal product referred to in paragraph (3) being deemed to have reached patients, the Board shall, where necessary, issue urgent public announcements within 24 hours in order to recall that medicinal product from the patients.

(5) The announcements referred to in paragraph (4) shall contain sufficient information on the suspected quality defect or falsification of the medicinal product and the risks involved.".

9. 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 the heading, by substituting "AN AUTHORISATION OR CERTIFICATE THAT IS MATERIALLY DIFFERENT FROM THE

APPLICATION" for "OTHERWISE THAN IN ACCORDANCE WITH THE APPLICATION", and

(*b*) by substituting for paragraph 2(*c*) the following:

"(*c*) to grant an authorisation or certificate, or a variation to an authorisation or certificate, that is materially different from the application,".

L.S.

GIVEN under my Official Seal,
22 May 2013.

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 2011/62/EU of the European Parliament and of the Council of 8 June 2011, and give further effect to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 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 Placing on the Market) (Amendment) Regulations 2013.

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