STATUTORY INSTRUMENTS.

S.I. No. 164 of 2013

MEDICINAL PRODUCTS (CONTROL OF WHOLESALE DISTRIBUTION) (AMENDMENT) REGULATIONS 2013

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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) 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], hereby make the following regulations:

1. (1) These Regulations may be cited as the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013.

(2) These Regulations shall be construed as one with the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 to 2010 and the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2012 (S.I. 274 of 2012), and may be cited together with those Regulations as the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 to 2013.

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) (Amendment) Regulations 2012 (S.I. No. 274 of 2012)) of the Principal Regulations is amended—

(*a*) by inserting after the definition of "authorisation holder" the following definitions:

> "'brokering of medicinal products' means all activities in relation to the sale or purchase of medicinal products, except for wholesale distribution and sale by wholesale, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person;
>
> 'brokers register' means the register maintained by the Board in pursuance of Regulation 14D;",

[1]OJ No. L 174, 1.7.2011, p. 74.
[2]OJ No. L 311, 28.11.2001, p. 67.

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

(*b*) by inserting after the definition of "Commission" the following definitions:

> "'Community marketing authorisation' means a marketing authorisation granted by the Commission under Regulation (EEC) No. 2309/93[3] or Regulation (EC) No. 726/2004;
>
> 'Community Regulation on medicinal products for paediatric use' means Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006[4], as amended by Regulation (EC) No. 1902/2006 of the European Parliament and of the Council of 20 December 2006[5];";

(*c*) by substituting for the definition of "2001 Directive" the following definition:

> "'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[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[10], Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009[11], Commission Directive 2009/120/EC of 14 September 2009[12], Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010[13] and Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011[1];",

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

> "'EudraGMDP database' means the Union database referred to in Article 111(6) of the 2001 Directive;",

[3]OJ No. L 214, 24.8.1993, p. 1.
[4]OJ No. L 378, 27.12.2006, p. 1.
[5]OJ No. L 378, 27.12.2006, p. 20.
[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 81, 20.3.2008, p. 51.
[11]OJ No. L 168, 30.6.2009, p. 33.
[12]OJ No. L 242, 15.9.2009, p. 3.
[13]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.

(*e*) by inserting after the definition of "exempt medicinal product" 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;",

(*f*) by inserting after the definition of "registered veterinary practitioner" the following definition:

"'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] and Regulation (EU) No. 1235/2010 of the European Parliament and of the Council of 15 December 2010[18];", and

(*g*) by inserting after the definition of "responsible person" the following definition:

"'safety features' means safety features affixed on the packaging of a medicinal product pursuant to Regulation 17 (inserted by Regulation 5 of the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2013 (S.I. 162 of 2013)) of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007);".

[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.

4. Regulation 9 of the Principal Regulations is amended by inserting after paragraph (5) the following paragraphs:

"(6) A wholesaler's authorisation granted under this Regulation shall state the premises within the State for which it is valid.

(7) The Board shall enter information in the EudraGMDP database in relation to every wholesaler's authorisation granted.".

5. Regulation 14A (inserted by the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2012 (S.I. No. 274 of 2012)) of the Principal Regulations is amended—

(*a*) in paragraph (1)—

(i) by substituting "Act, and Article 77(5) and Article 111" for "Act and Article 111", and

(ii) by inserting "repeated" after "by means of",

(*b*) in paragraph (2), by substituting "of good distribution practice" for "on good distribution practice",

(*c*) by substituting for paragraph (4) the following paragraphs:

"(4) If the outcome of an inspection referred to in paragraph (1) is that the inspected entity complies with the principles and guidelines of good distribution practice, the Board shall, when applicable, within 90 days of the inspection, issue to the inspected entity a certificate of good distribution practice.

(5) The Board shall enter the certificates of good distribution practice in the EudraGMDP database.

(6) If the outcome of an inspection referred to in paragraph (1) is that the inspected entity does not comply with—

(*a*) the legal requirements governing medicinal products, or

(*b*) the principles and guidelines of good distribution practice,

the Board shall enter the information in the EudraGMDP database.

(7) In this Regulation "the principles and guidelines of good distribution practice" means the guidelines[19] published by the Commission pursuant to Articles 84 and 85(*b*)(3) of the 2001 Directive.

(8) The Board may carry out inspections at the premises of brokers of medicinal products.".

[19]OJ No. C 68, 08.03.2013, p. 1.

6. The Principal Regulations are amended by inserting after Regulation 14A (inserted by the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2012 (S.I. No. 274 of 2012)) the following Regulations:

"Falsified medicinal products

14B. A person shall not distribute, broker or sell by wholesale a medicinal product if he or she knows, or there are sufficient grounds to suspect, that it is a falsified medicinal product.

Obligations of brokers

14C. (1) A person shall not broker a medicinal product in or from the State unless—

(*a*) the product is covered by—

(i) in the case of a product to be placed on the market of an EEA State, a marketing authorisation or a certificate of registration, or

(ii) in the case of a product to be supplied to a state other than an EEA State, any authorisation which may be required by that state,

(*b*) he or she is registered on the brokers register,

(*c*) he or she has an emergency plan which ensures effective implementation of any recall from the market ordered by the Board or carried out in cooperation with the holder of the manufacturer's authorisation, marketing authorisation, certificate of registration or certificate of traditional-use registration for the medicinal product concerned,

(*d*) he or she keep records, available for inspection by the Board for a period of five years, either in the form of purchase or sales invoices or on computer, or in any other form, giving for the transaction brokered at least the following information:

(i) the date,

(ii) the name of the medicinal product,

(iii) the quantity brokered,

(iv) the name and address of the supplier, broker or consignee, as appropriate, and

(v) in the case of products required to bear safety features, the batch number of the medicinal product,

(*e*) he or she complies with the principles and guidelines of good distribution practice published by the Commission pursuant to Article 84 of the 2001 Directive, and

(*f*) he or she maintains a quality system setting out responsibilities, processes and risk management measures in relation to his or her activities.

(2) A person brokering medicinal products shall immediately inform the Board and, where applicable, the holder of the relevant marketing authorisation, certificate of registration, certificate of traditional-use registration, or, in the case of a product intended for a state other than an EEA State, the holder of the relevant authorisation in that state, if he or she is offered or brokers a medicinal product and he or she knows, or subsequently becomes aware after having brokered the product, or there are sufficient grounds to suspect, that the product is a falsified medicinal product.

(3) The Board may carry out inspections of the premises of persons brokering medicinal products in or from the State to ensure compliance with this Regulation.

Brokers register

14D. (1) The Board shall maintain a publicly accessible register, to be known as the brokers register, listing the name, corporate name, permanent addresses and contact details of persons brokering medicinal products in or from the State.

(2) An application for entry on to the brokers register shall—

(*a*) be made in writing to the Board,

(*b*) be signed by or on behalf of the applicant, whether in ink or by means of electronic signature, and

(*c*) be accompanied by any fee which may be payable in connection with that application.

(3) A person listed on the brokers register shall notify the Board, without unnecessary delay, of any changes to his or her name, corporate name, permanent address or contact details.

(4) If a person on the brokers register does not comply with these Regulations, the Board may remove that person from the brokers register and, in such cases, shall notify the said person of his or her removal.".

7. Regulation 15 of the Principal Regulations is amended by inserting after paragraph (3) the following paragraph:

"(4) Notwithstanding Regulation 14C(1)(*b*), a person who commenced brokering in or from the State before 2 January 2013 may continue such activity, without being on the brokers register, until the 14 June 2013.".

8. Schedule 2 (as amended by the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (Amendment) Regulations 2009 (S.I. No. 2 of 2009)) to the Principal Regulations is amended—

(*a*) by substituting for paragraph 2 the following:

"2. (1) Subject to subparagraph (2), the authorisation holder shall obtain his or her supplies of medicinal products only from persons—

(*a*) who are themselves the holders of a manufacturer's authorisation or a wholesaler's authorisation in respect of such products, or

(*b*) who are the holders of an authorisation granted by the competent authority of another EEA State authorising the manufacture or the wholesale distribution of such products.

(2) Where a medicinal product is directly received from a state other than an EEA State but not imported into the State—

(*a*) subparagraph (1) shall not apply, and

(*b*) the authorisation holder shall ensure that the medicinal product is obtained only from persons who are authorised or entitled to supply medicinal products in accordance with the applicable legal and administrative provisions of the state concerned",

(*b*) in paragraph 4—

(i) in subparagraph (*d*), by deleting "or",

(ii) in subparagraph (*e*), by substituting "as a hospital, or" for "as a hospital.", and

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

"(*f*) who are authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in a state other than an EEA State in accordance with the applicable legal and administrative provisions of the state concerned."

(*c*) by inserting after paragraph 5 the following paragraph:

"5A. The authorisation holder shall maintain a quality system setting out responsibilities, processes and risk management measures in relation to his or her activities.",

(*d*) in paragraph 8(1)—

(i) by substituting "received, dispatched or brokered" for "received or dispatched",

(ii) by substituting "receipt, supply or brokering" for "receipt or supply",

(iii) by substituting "received, supplied or brokered" for "received or supplied",

(iv) by substituting "supplier, consignee or broker" for "supplier or consignee", and

(v) by inserting after "as appropriate" the following:

"— in the case of products required to bear safety features, the batch number of the medicinal product received, supplied or brokered.",

(*e*) in paragraph 10—

(i) by substituting "paragraph 4(*d*), (*e*) and (*f*)" for "paragraph 4(*d*) and (*e*)", and

(ii) by inserting after "the name and address of the consignor" the following:

"— in the case of products required to bear safety features, the batch number of the medicinal product.",

(*f*) by substituting for paragraph 12 the following paragraph:

"12. Where an authorisation holder proposes to import from another EEA State a medicinal product in respect of which he is not the holder of the relevant marketing authorisation or is not acting on behalf of such person, he or she shall notify the holder of the authorisation and—

(*a*) in the case of a marketing authorisation other than a Community marketing authorisation, notify the Board and pay the appropriate fee to the Board in respect of the notification, or

(*b*) in the case of a Community marketing authorisation, notify the Agency and pay the appropriate fee to the Agency, in accordance with Article 76(3) of the 2001 Directive.",

(*g*) by substituting for paragraph 13 the following paragraph:

"13. The authorisation holder shall comply with the principles and guidelines of good distribution practice for medicinal products published by the Commission pursuant to Article 84 of the 2001 Directive.", and

(*h*) by inserting after paragraph 18 the following paragraphs:

"19. (1) Subject to subparagraph (2), the authorisation holder shall verify that the medicinal products received are not falsified by checking

any safety features on the outer packaging, in accordance with the measures adopted by the Commission pursuant to Article 54a(2) of the 2001 Directive.

(2) Subparagraph (1) shall not apply where a medicinal product is directly received from a third country but not imported into the State.

20. The authorisation holder shall immediately inform the Board and, where applicable, the holder of the relevant marketing authorisation, certificate of registration certificate of traditional-use registration, or in the case of a product intended for a state other than an EEA State the holder of the relevant authorisation in that state if he or she receives, is offered or sells by wholesale a medicinal product and he or she knows, or subsequently becomes aware after having sold by wholesale the product, or there are sufficient grounds to suspect, that the product is a falsified medicinal product.

21. Where a medicinal product is obtained from another wholesale distributor, the authorisation holder shall verify that the supplying wholesale distributor—

(*a*) complies with the principles and guidelines of good distribution practice published by the Commission pursuant to Article 84 of the 2001 Directive, and

(*b*) holds a wholesaler's authorisation, or an equivalent authorisation granted in another EEA State.

22. Where a medicinal product is obtained from a manufacturer or importer, the authorisation holder shall verify that the supplying manufacturer or importer holds an appropriate marketing authorisation, certificate of registration, certificate of traditional-use registration or in the case of a product obtained from a state other than an EEA State, the relevant authorisation issued in that state.

23. Where a medicinal product is obtained through brokering, the authorisation holder shall verify that the broker involved fulfils the requirements set out in these Regulations and the 2001 Directive.".

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 Wholesale Distribution) Regulations 2007 (S.I. No. 538 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.

These Regulations may be cited as the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013.

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nó trí aon díoltóir leabhar.

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DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
52 ST. STEPHEN'S GREEN, DUBLIN 2.
(Tel: 01 - 6476834 or 1890 213434; Fax: 01 - 6476843)
or through any bookseller.

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ISBN 978-1-4468-1283-9

€3.05

9 781446 812839

Wt. (B29884). 285. 5/13. Clondalkin. Gr 30-15.