STATUTORY INSTRUMENTS.

S.I. No. 87 of 2015

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) REGULATIONS 2015

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I, LEO VARADKAR, 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 Article 1(20) of Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011[1], hereby make the following regulations:

1. (1) These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015.

(2) The collective citation "the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2015" includes these Regulations.

2. These Regulations shall come into operation on 24 June 2015.

3. In these Regulations—

"Regulations of 2005" means the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005 (S.I. No. 510 of 2005);

"Regulations of 2011" means the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 (S.I. No. 525 of 2011);

"Principal Regulations" means the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003).

4. Regulation 4(1) (as amended by Regulation 3 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2014 (S.I No. 504 of 2014)) of the Principal Regulations is amended—

(*a*) by substituting for the definition of "Act" the following definition:

> "'Act' means the Irish Medicines Board Act 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. 444 of 2001), Regulation 3 of the European Communities (Medical Devices) (Amendment) Regulations 2002 (S.I. 576 of 2002), the Irish Medicines

[1]OJ No. L 174, 1.7.2011, p. 74.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 17*th March*, 2015.

Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006), the European Communities (Amendment of the Irish Medicines Board Act 1995) Regulations 2007 (S.I. No. 542 of 2007) and the Health (Pricing and Supply of Medical Goods) Act 2013 (No. 14 of 2013);",

(*b*) by substituting for the definition of "board" the following definition:

"'Authority' means the Health Products Regulatory Authority";

(*c*) by inserting after the definition of "inhaler" the following definition:

'manufacturer's authorisation' means an authorisation granted and in force in pursuance of the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007);",

(*d*) in the definition of "marketing authorisation", by substituting "Authority" for "Board",

(*e*) by inserting after the definition of "parenteral administration" the following definition:

"'Pharmacy Act' means the Pharmacy Act 2007 (No. 20 of 2007), as amended by the European Communities (Recognition of Professional Qualifications Relating to the Profession of Pharmacist) (No. 2) Regulations 2008 (S.I. No. 489 of 2008), the Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010 (No. 24 of 2010), the European Union (Recognition of Professional Qualifications relating to the Profession of Pharmacist) Regulations 2012 (S.I. No. 235 of 2012), the Health (Pricing and Supply of Medical Goods) Act 2013 (No. 14 of 2013) and the European Union (Amendment of the Pharmacy Act 2007) Regulations 2015 (S.I. No. 86 of 2015);",

(*f*) in the definition of "sampling officer", by substituting "Authority" for "Board",

(*g*) by inserting after the definition of "sampling officer" the following definition:

"'Society' means the Pharmaceutical Society of Ireland;", and

(*h*) by substituting for the definition of "supply by way of wholesale dealing" the following definitions:

"'supply by wholesale' means the supply of a medicinal product to a person who obtains the product for one or more of the following purposes:

(*a*) supply in the course of a pharmaceutical business,

(*b*) administration in the course of a professional practice, or

(*c*) for or in connection with a service provided by a hospital;

'wholesaler's authorisation' means an authorisation granted and in force in pursuance of the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007).".

5. Regulation 10 (as amended by Regulation 3(*g*) of the Regulations of 2005) of the Principal Regulations is amended by substituting "supply by wholesale" for "by way of wholesale dealing" in both places where it occurs.

6. Regulation 16(3) of the Principal Regulations is amended by substituting "Authority" for "Board" in both places where it occurs.

7. Regulation 19 (as amended by Regulation 7 of the Regulations of 2011) of the Principal Regulations is amended by inserting after paragraph (4) the following paragraph:

"(5) The provisions of this Regulation shall also apply to the supply, by way of information society service, of medicinal products which by virtue of these Regulations may only be supplied on foot of a prescription."

8. The Principal Regulations are amended by inserting after Regulation 19 (as amended by the Regulations of 2011) the following Regulations:

"Supply by information society services

19A. (1) Without prejudice to the provisions of the Pharmacy Act and the Regulations made under that Act, a person shall not supply a non-prescription medicinal product at a distance to the public in an EEA State by means of information society services, unless—

(*a*) he or she has been entered on the ISS supply list,

(*b*) he or she complies with these Regulations,

(*c*) the medicinal product is the subject of a marketing authorisation in the EEA State of destination, and

(*d*) the website offering the non-prescription medicinal products contains at least—

(i) the contact details of the Society,

(ii) a hyperlink to the website referred to in paragraph (13),

(iii) the common logo, established in accordance with Commission Implementing Regulation (EU) No. 699/2014 of 24 June 2014[2] and Article 85c(3) of the 2001 Directive, clearly displayed on every page of the website that relates to the offer for supply at a distance to the public of medicinal products and containing a hyperlink to the entry of the person in the ISS supply list,

(iv) a statement that a record of each transaction for the supply of medicinal products at a distance to the public by means of information society services will be retained for two years from the date of the transaction.

(2) The requirements of paragraph (1)(*d*) are without prejudice to the information requirements set out in Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000[3].

(3) The Society shall establish and maintain a list, in accordance with paragraph (4), to be known as the "ISS supply list" of persons who have made valid applications in accordance with paragraph (5), in respect of the relevant 12 month period, to supply non-prescription medicinal products at a distance to the public by means of information society services.

(4) The ISS supply list referred to in paragraph (3) shall be divided into two Parts and the Society shall enter—

(*a*) in Part A of the list—

(i) the name of each pharmacy owner who has made a valid application in accordance with paragraph (5) in respect of the relevant 12 month period to supply, at a distance, to the public by means of information society services, non-prescription medicinal products,

(ii) the address of the registered retail pharmacy business from which such supply shall occur,

(iii) the address of the website used for the purposes of such supply (in URL form, rather than hypertext), and

(iv) the business name or trading style, if different from the name referred to in subparagraph (i), used in connection with such supply, and

(*b*) in Part B of the list—

(i) the name of every other person who has made a valid application in accordance with paragraph (5) in respect of the relevant 12 month period to supply, at a distance to the public by means of information society services, non-prescription medicinal products available on general sale under Regulation 12(1)(*b*)(ii) of the

[2]OJ No. L 184, 25.6.2014, p. 5.
[3]OJ No. L 178, 17.7.2000, p. 1.

Medicinal Products (Control of Placing on the Market) Regulations 2007;

(ii) the address of the premises, which shall not be a dwelling, from which such supply shall occur,

(iii) the address of the website used for the purposes of such supply, and

(iv) the business name or trading style, if different to the name referred to in paragraph (i), used in connection with such supply.

(5) An application for entry on to the ISS supply list shall—

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

(*b*) be signed by or on behalf of the applicant, or in the case of a corporate body by a person authorised in that behalf by that corporate body,

(*c*) indicate the Part of the ISS supply list, in accordance with paragraph (4), in respect of which the application for listing is made,

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

(*e*) include at least the particulars listed in the Ninth Schedule, and

(*f*) be made for each 12 month period for which entry on to the list is sought.

(6) Subject to paragraph (7), and without prejudice to the provisions of the Pharmacy Act and the Regulations made under that Act, the Misuse of Drugs Acts 1977 to 2015 and the Orders and Regulations made under that Act and these Regulations, a person shall not supply a non-prescription medicinal product at a distance to the public by means of information society services unless the following conditions are complied with:

(*a*) each medicinal product, intended to be supplied at a distance to the public by means of information society services, is–

(i) sourced from a person who holds a manufacturer's authorisation or a wholesaler's authorisation in respect of the medicinal product, or an authorisation granted by the competent authority of another EEA State authorising the manufacture or wholesale distribution of such product,

(ii) stored at and supplied from the fixed premises identified in the application for entry on to the ISS supply list, which, in the case of a pharmacy owner listed in Part A of the ISS supply list, shall be a registered retail pharmacy business premises,

(iii) stored and supplied in accordance with the requirements of the marketing authorisation of the product, and

(iv) packaged such that its integrity is maintained while in transit to the customer;

(*b*) the following records are kept at the fixed premises identified in the application for entry on to the ISS supply list for a period of at least two years from the date of receipt or supply of the medicinal product, as the case may be:

(i) every invoice or other similar record in respect of each quantity of a medicinal product obtained by him or her for the purposes of supply at a distance to the public by means of information society services, including–

(I) the date of the transaction,

(II) the name and quantity of the medicinal product obtained, and

(III) the name and address of the supplier,

(ii) subject to paragraph (17), a record of each transaction involving the supply of a medicinal product at a distance to the public by means of information society services, including–

(I) the order for supply of the medicinal product at a distance to the public by means of information society services,

(II) the date of the transaction,

(III) the name and quantity of the medicinal product supplied,

(IV) the name and address of the person to whom the medicinal product was supplied, and

(V) a record to show that the requirements of subparagraph (*c*) and, in the case of a person listed in Part A of the ISS supply list, paragraph (7) have been complied with; and

(*c*) in the course of each transaction for such supply, prior to supplying to the purchaser and having regard to any previous supply to that purchaser, the person making the supply checks that–

(i) the purchaser is over 18 years old,

(ii) the purchaser is aware that the medicinal product should be used in accordance with the recommendations for use contained on the packaging of the product, and

(iii) subject to the provisions of these Regulations, the total quantity of the product to be supplied in the transaction is a quantity that

is reasonably required by the purchaser for his or her personal treatment.

(7) A person listed in Part A of the ISS supply list shall not supply a non-prescription medicinal product at a distance to the public by means of information society services unless prior to the supply of the medicinal product a registered pharmacist–

(*a*) personally reviews each order for supply and personally supervises and authorises the supply of the product at a distance to the public by means of information society services, and

(*b*) fulfils the requirements of Regulation 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. 488 of 2008).

(8) Nothing in this Regulation shall be construed as permitting–

(*a*) the supply of a medicinal product at a distance to the public by means of information society services to a person in a State other than an EEA State,

(*b*) the supply of a medicinal product subject to prescription control in the State at a distance to the public by means of information society services to a person in the State,

(*c*) the supply at a distance to the public, except in accordance with these Regulations, of a non-prescription medicinal product,

(*d*) the supply at a distance to the public of a non-prescription medicinal product which is not the subject of a marketing authorisation in the EEA State of destination, or

(*e*) the supply at a distance to the public of a non-prescription medicinal product that requires refrigerated storage, unless it can be verified that the labelled storage requirements of such product shall be complied with whole in transit to the customer.

(9) A person shall not display the common logo established in accordance with Article 85c(3) of the 2001 Directive and Article 1 of Commission Implementing Regulation (EU) No. 699/2014 of 24 June 2014 unless his or her name is entered in the ISS supply list.

(10) A person listed on the ISS supply list shall keep the information submitted pursuant to paragraph (5) up to date, shall notify the Society without unnecessary delay, of any changes to that information and shall include with such notification any fee which may be payable in connection with same.

(11) A person who has made an application in accordance with paragraph (5) and a person listed on the ISS supply list shall comply with any requirement of the Society to—

(*a*) verify anything contained in the application,

(*b*) supply further information in relation to the application,

(*c*) make a statutory declaration supplying that information.

(12) The Society may without delay remove a person from the ISS supply list where—

(*a*) he or she does not make a valid application in accordance with paragraph (5) in respect of the relevant 12 month period for entry in the ISS supply list,

(*b*) he or she fails to comply with these Regulations or a requirement of entry on to the list,

(*c*) he or she requests the removal,

(*d*) he or she fails to respond to a written request from the Society seeking confirmation that he or she continues to be engaged in offering non-prescription medicinal products for supply at a distance to the public by means of information society services, or

(*e*) he or she has submitted information pursuant to paragraphs (5) or (11) that is false or materially inaccurate.

(13) The Society shall establish and maintain a website in accordance with Article 85c(4) of the 2001 Directive and shall publish the ISS supply list on the website.

(14) The Authority and the Society may carry out inspections of the premises of persons supplying non-prescription medicinal products by means of information society services under section 32 of the Act and section 67 of the Pharmacy Act 2007.

(15) In any proceedings for an offence under the Act—

(*a*) a document signed by the registrar of the Society stating—

(i) what is or is not listed in the ISS supply list, or

(ii) what was or was not listed in the ISS supply list and when,

is, in the absence of evidence to the contrary, proof of the matters stated,

(*b*) a printed document—

(i) appearing to be a copy of any part of or an extract from the ISS supply list, and

(ii) bearing a signed statement by the registrar that it is such a copy or extract,

is, in the absence of evidence to the contrary, proof of the content of so much of the list that is copied or extracted, and

(*c*) a signature appearing to be that of the registrar of the Society on any document referred to in subparagraph (*a*) or (*b*) is, in the absence of evidence to the contrary, to be taken as being the registrar's.

(16) In this Regulation and in the Ninth Schedule—

'fixed premises' does not include a vehicle, trailer, caravan, or other thing which may be transported on, in, or attached to a vehicle, or, a tent, awning, or hut, shed, or an unroofed or temporary structure or stall or a yard, field roadway, or casual trading area;

'information society services' has the meaning assigned to it by Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998[4];

'ISS supply list' means the list established and maintained by the Society pursuant to paragraph (3);

'marketing authorisation' includes a Community marketing authorisation and a marketing authorisation issued by the competent authority of an EEA State, in accordance with the 2001 Directive;

'non-prescription medicinal product' means a medicinal product which by virtue of these Regulations may be supplied to the public otherwise than in accordance with a prescription;

'relevant 12 month period' means the period of 12 months beginning on the date of entry on the ISS supply list, which date shall be the first day of the relevant month.

(17) Where records are kept in electronic form under paragraph (6)(*b*)(ii), they shall be kept in a permanent and unalterable form from the date on which the record was created."

9. Regulation 20(1) (as amended by Regulation 3(i) of the Regulations of 2005) of the Principal Regulations is amended—

(*a*) in subparagraph (*a*)(ii) by substituting "Authority" for "Irish Medicines Board", and

(*b*) in subparagraph (*b*) by substituting "supply by wholesale" for "the supply of a medicinal product by way of wholesale dealing".

10. The Principal Regulations are amended by inserting after the Eighth Schedule (inserted by the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011) the following schedule:

[4]OJ No. L 204, 21.7.1998, p. 37.

"NINTH SCHEDULE

Regulation 19A(5)

Particulars to be included in application for entry on to ISS supply list

1. The name of the person to be listed, and in the case of a registered retail pharmacy business, the name as it appears in the Register of Retail Pharmacy Businesses established under section 13(1) of the Pharmacy Act.

2. In the case of an application under Regulation 19A(4)(*b*), the name of the natural person who is responsible for ensuring compliance with these regulations.

3. The business name or trading style to be used by the person to be listed in connection with the supply of non-prescription medicinal products at a distance to the public by means of information society services, where that name is different to the name required to be provided by paragraph 1.

4. In the case of a corporate body controlled under the Companies Act 1963–

(*a*) the registered name of the body,

(*b*) the address of the registered office of the body, and

(*c*) the Companies Office Registration Number of the body.

5. The permanent address of the fixed premises at which the medicinal products are to be stored and from which they are to be supplied.

6. Where the premises is at a registered retail pharmacy business, the registration number of the retail pharmacy business concerned in the Register of Retail Pharmacy Businesses established under section 13(1) of the Pharmacy Act, or, where the premises is not such a business, a description and floor plan of the fixed premises.

7. The starting date of the activity of offering medicinal products for sale at a distance to the public by means of information society services.

8. The address of the website used for that activity and all relevant information necessary to identify that website.

9. The classification sub-category or sub-categories in accordance with Regulation 12(1)(*b*) of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) of the non-prescription medicinal products offered for sale at a distance to the public by means of information society services.

10. A statement that the supply of medicinal products to the public at a distance by means of information society services will be conducted in compliance with these Regulations.

L.S.

GIVEN under my Official Seal,
12 March 2015.

LEO VARADKAR,
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 (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003).

These Regulations give effect to Article 1(20) of Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 which amended Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 by inserting new Articles 85c and 85d.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015.

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