STATUTORY INSTRUMENTS.

S.I. No. 36 of 2019

MEDICINAL PRODUCTS (SAFETY FEATURES ON PACKAGING) REGULATIONS 2019

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I, SIMON HARRIS, 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 Commission Delegated Regulation (EU) 2016/161 of 2 October 2015[1], hereby make the following regulations:

Citation

1. (1) These Regulations may be cited as the Medicinal Products (Safety Features on Packaging) Regulations 2019.

(2) The Control of Placing on the Market Regulations, the Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) Regulations 2009 (S.I. No. 3 of 2009), the Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) (No. 2) Regulations 2009 (S.I. No. 553 of 2009), the Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) Regulations 2010 (No. 287 of 2010), the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2011 (S.I. No. 722 of 2011), the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2012 (S.I. No. 272 of 2012), the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2013 (S.I. No. 162 of 2013), the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2014 (S.I. No. 151 of 2014), the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2018 (S.I. No. 529 of 2018) and Regulation 6 may be cited together as "the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2019".

(3) The Control of Wholesale Distribution Regulations, the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (Amendment) Regulations 2009 (S.I. No. 2 of 2009), the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (Amendment) Regulations 2010 (S.I. No. 286 of 2010), the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2012 (S.I. No. 274 of 2012), the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013 (S.I. No. 164 of 2013) and Regulation 7 may be cited together as "the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 to 2019".

[1] OJ No. L 32, 9.2.2016, p. 1.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" 15*th of February*, 2019

(4) The Control of Manufacture Regulations, the Medicinal Products (Control of Manufacture) Regulations 2007 (Amendment) Regulations 2009 (S.I. No. 4 of 2009), the Medicinal Products (Control of Manufacture) Regulations 2007 (Amendment) Regulations 2010 (S.I. No. 288 of 2010), the Medicinal Products (Control of Manufacture) Regulations 2007 (Amendment) Regulations 2012 (S.I. No. 273 of 2012), the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2013 (S.I. No. 163 of 2013) and Regulation 8 may be cited together as "the Medicinal Products (Control of Manufacture) Regulations 2007 to 2019".

Commencement

2. These Regulations come into operation on 9 February 2019.

Interpretation

3. (1) In these Regulations—

"Authority" means the Health Products Regulatory Authority;

"Control of Manufacture Regulations" means the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007);

"Control of Placing on the Market Regulations" means the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007);

"Control of Wholesale Distribution Regulations" means the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007);

"Directive" means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001[2], as amended from time to time;

"EU Regulation" means Commission Delegated Regulation (EU) 2016/161 of 2 October 2015[1];

"health centre" means a health centre under the management or control of a hospital;

"healthcare institution" means a hospital, in patient or out patient clinic or health centre;

"in patient or out patient clinic" means an in patient or out patient, or day patient, clinic under the management or control of a hospital;

"packaging" means outer packaging or, in the case of a medicinal product with no outer packaging, the immediate packaging;

"Society" means the Pharmaceutical Society of Ireland;

[2] OJ No. L 311, 28.11.2001, p. 67.

"unique identifier" means the unique identifier required to be placed on the packaging of medicinal products under the EU Regulation;

"wholesaler" means the holder of a wholesaler's authorisation, as defined in Regulation 4(1) of the Control of Wholesale Distribution Regulations and, for the avoidance of doubt, does not include a pharmacist supplying medicinal products pursuant to Regulation 6(c) of those Regulations.

(2) A word or expression that is used in these Regulations and is also used in the EU Regulation or the Directive has, unless the context otherwise requires, the same meaning in these Regulations that it has in the EU Regulation or the Directive.

Competent authorities under EU Regulation

4. (1) The competent authority in the State for the purposes of Articles 18, 22(d), 24, 25(4)(b), 30, 35(1)(i)(ii), 36(i) and (m), 37(a), (d), and (e), 39, 43, 44 and 46 of the EU Regulation is the Authority.

(2) The competent authorities in the State for the purposes of Articles 31(2), 32(4), 35(1)(e), 36(j) and 37(f) and (g) of the EU Regulation are the Authority and the Society.

(3) The Authority and the Society may exchange and share information and data in carrying out their duties as competent authorities under the EU Regulation.

Obligation to verify and decommission before supply

5. (1) This Regulation applies to—

(*a*) medicinal products subject to prescription other than those listed in Annex I to the EU Regulation, and

(*b*) medicinal products which are not subject to prescription and are listed in Annex II to the EU Regulation.

(2) Subject to paragraph (3), a wholesaler shall verify and decommission the unique identifier of a medicinal product before he or she supplies that product to any of the following persons or institutions:

(*a*) persons authorised to supply medicinal products to the public who do not operate within a healthcare institution or within a pharmacy;

(*b*) a veterinary practitioner, as defined in section 2(1) of the Veterinary Practice Act 2005 (No. 22 of 2005);

(*c*) retailers of veterinary medicinal products;

(*d*) registered dentist, as defined in section 2 of the Dentists Act 1985 (No. 9 of 1985);

(*e*) persons registered with the Optical Registration Board under the Health and Social Care Professionals Act 2005 (No. 27 of 2005);

(*f*) paramedics and emergency medical practitioners;

(*g*) the Defence Forces, An Garda Síochána and other governmental institutions maintaining stocks of medicinal products for the purposes of civil protection and disaster control;

(*h*) universities and other higher education establishments using medicinal products for the purposes of research and education, with the exception of healthcare institutions;

(*i*) prisons;

(*j*) schools;

(*k*) hospices;

(*l*) nursing homes.

(3) Paragraph (2) shall not apply where, before the wholesaler supplies the medicinal product, the person or institution to be supplied informs the wholesaler that such person or institution will verify and decommission the unique identifier before supplying the product to the public.

Amendment of Control of Placing on the Market Regulations

6. The Control of Placing on the Market Regulations are amended—

(*a*) in Regulation 3(1) (as amended by Regulation 3 of the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2018), by inserting after the definition of "Regulation (EC) No. 726/2004" the following definition:

"'Regulation (EU) 2016/161' means Commission Delegated Regulation (EU) 2016/161 of 2 October 2015;", and

(*b*) in Regulation 17 (inserted by Regulation 6 of the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2013)—

(i) in paragraph (1), by inserting ", in accordance with Regulation (EU) 2016/161," after "safety features",

(ii) in paragraph (2), by inserting ", in accordance with Regulation (EU) 2016/161," after "device", and

(iii) in paragraph (3), by substituting for subparagraphs (b) and (c) the following:

"(b) medicinal products subject to prescription which are listed in Annex I to Regulation (EU) 2016/161, and

(c) medicinal products which are not subject to prescription and are not listed in Annex II to the Regulation (EU) 2016/161.".

Amendment of Control of Wholesale Distribution Regulations

7. The Control of Wholesale Distribution Regulations are amended—

(*a*) in Regulation 4(1) (as amended by Regulation 3(g) of the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013)—

(i) by substituting for the definition of "safety features" the following:

"'safety features' means the unique identifier and anti-tampering device required to be affixed on the packaging of a medicinal product under Regulation (EU) 2016/161;", and

(ii) by inserting after the definition of "Regulation (EC) No. 726/2004" the following definition:

"'Regulation (EU) 2016/161' means Commission Delegated Regulation (EU) 2016/161 of 2 October 2015;", and

(*b*) in Schedule 2 (as amended by Regulation 8 of the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013), in paragraph 19(1), by substituting "Regulation (EU) 2016/161" for "the measures adopted by the Commission pursuant to Article 54a(2) of the 2001 Directive".

Amendment of Control of Manufacture Regulations

8. The Control of Manufacture Regulations are amended—

(*a*) in Regulation 3(1) (as amended by Regulation 3(a) of the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2013)—

(i) by substituting for the definition of "safety features" the following:

"'safety features' means the unique identifier and anti-tampering device required to be affixed on

the packaging of a medicinal product under Regulation (EU) 2016/161;", and

(ii) by inserting after the definition of "Regulation (EC) No. 726/2004" the following definition:

"'Regulation (EU) 2016/161' means Commission Delegated Regulation (EU) 2016/161 of 2 October 2015;", and

(*b*) in Regulation 14F(2)(a) (inserted by Regulation 7 of the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2013), by substituting "of Regulation (EU) 2016/161" for "adopted by the Commission pursuant to Article 54a(2) of the 2001 Directive".

L.S.

GIVEN under my Official Seal,
8 February 2019

SIMON HARRIS,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

The purpose of these Regulations is to designate the Health Products Regulatory Authority (and in some cases also the Pharmaceutical Society of Ireland) as the competent authority responsible for enforcing Commission Delegated Regulation (EU) 2016/161 of 2 October 2015. In addition, these Regulations provide for the verification and decommissioning of the unique identifier of a medicinal product by a wholesaler before supply in certain circumstances. Finally, these Regulations amend the Medicinal Products (Control of Manufacture) Regulations 2007, the Medicinal Products (Control of Placing on the Market) Regulations 2007 and the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 to take account of Commission Delegated Regulation (EU) 2016/161.

These Regulations may be cited as the Medicinal Products (Safety Features on Packaging) Regulations 2019 and come into operation on 9 February 2019.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
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