STATUTORY INSTRUMENTS.

**S.I. No. 415 of 2022**

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# MEDICINAL PRODUCTS (CONTROL OF WHOLESALE DISTRIBUTION) (AMENDMENT) REGULATIONS 2022

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# MEDICINAL PRODUCTS (CONTROL OF WHOLESALE DISTRIBUTION) (AMENDMENT) REGULATIONS 2022

The Minister for Health, in exercise of the powers conferred on him 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 further effect to Directive (EU) 2022/642[1] of the European Parliament and of the Council of 12 April 2022, hereby makes the following regulations:

1. (1) These Regulations may be cited as the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2022.

(2) The Principal 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), Regulation 7 of the Medicinal Products (Safety Features On Packaging) Regulations 2019 (S.I. No. 36 of 2019), the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2019 (S.I. No. 217 of 2019), the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2021 (S.I. No. 1 of 2021) and these Regulations may be cited together as "the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2007 to 2022".

2. These Regulations shall be deemed to have come into operation on 1 January 2022.

3. In these Regulations "Principal Regulations" means the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007).

4. Regulation 4(1) of the Principal Regulations is amended 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 on the Community code relating to medicinal products for human use[1] (as amended);".

[1] OJ No. L. 118, 20.4.2022, p.4.
[1] OJ No. L. 311, 28.11.2001, p.67.

*Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of* 23*rd August,* 2022.

5. The Principal Regulations are amended by inserting after Regulation 15 the following:

"16. (1) By 20 May 2022, the Board shall establish, notify to the Commission and publish on its website a list of medicinal products to which it has applied or intends to apply the derogations as set out in paragraph 24 of Schedule 2.

(2) The Board shall ensure that the list referred to in paragraph (1) is updated at least on a six-monthly basis.

(3) Any marketing authorisation holder who intends to avail of the derogations set out in paragraph 24 of Schedule 2 shall notify the Board and ensure that the relevant medicinal product is included on the list referred to in paragraph (1) before the relevant medicinal product is placed on the market in the State. Wholesalers of medicinal products shall not apply those derogations with respect to any medicinal product until the relevant medicinal product is included on the list referred to in paragraph (1)."

6. Schedule 2 of the Principal Regulations is hereby amended by inserting after subparagraph 23 the following:

"24. (1) Notwithstanding anything to the contrary in these Regulations –

(a) until 31 December 2024, the Board shall allow the import of medicinal products from parts of the United Kingdom other than Northern Ireland by holders of a wholesaler's authorisation that are not in possession of a relevant manufacturing authorisation following submission of a request by the holders of the marketing authorisation for the medicinal products provided that all of the following conditions are fulfilled –

(i) the medicinal products have undergone quality control testing either in the Union, as provided for in Article 51(3) of the 2001 Directive, or in parts of the United Kingdom other than Northern Ireland in compliance with Article 20, first paragraph, point (b) of the 2001 Directive,

(ii) the medicinal products have been subject to batch release by a qualified person in the Union in accordance with Article 51(1) of the 2001 Directive, or in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 51(1) of the 2001 Directive,

(iii) the marketing authorisation for the medicinal product concerned has been granted in accordance with Union law, by the Board or by the Commission,

(iv) the medicinal products are only made available to patients or end-consumers in the State, and

(v) the medicinal products bear the safety features referred to in Article 54, point (o) of the 2001 Directive.

(2) Notwithstanding anything to the contrary in these Regulations, until 31 December 2024, Article 80, first subparagraph, point (b) of the 2001 Directive shall not apply to imports that fulfil the conditions laid down in paragraph (1).”

L.S.

GIVEN under the Official Seal of the Minister for Health,
18 August, 2022.

MUIRIS O'CONNOR,
A person authorised under section 15 of the Ministers and Secretaries Act 1924 to authenticate the seal of the Minister for Health.

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EXPLANATORY NOTE

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

The main purpose of these Regulations is to implement Articles 2(5) and 2(11) of Directive (EU) 2022/642 of the European Parliament and of the Council of 12 April 2022, which amend Directive 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use.

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