STATUTORY INSTRUMENTS.

S.I. No. 414 of 2022

MEDICINAL PRODUCTS (CONTROL OF MANUFACTURE) (AMENDMENT) (NO. 2) REGULATIONS 2022

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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 Manufacture) (Amendment) (No. 2) Regulations 2022.

(2) The Principal Regulations, the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2009 (S.I. No. 4 of 2009), the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2010 (S.I. No. 288 of 2010), the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2012 (S.I. No. 273 of 2012), the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2013 (S.I. No. 163 of 2013), Regulation 8 of the Medicinal Products (Safety Features on Packaging) Regulations 2019 (S.I. No. 36 of 2019), the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2019 (S.I. No. 219 of 2019), the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2022 (S.I. No. 43 of 2022) and these Regulations may be cited together as "the Medicinal Products (Control of Manufacture) 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 Manufacture) Regulations 2007 (S.I. No. 539 of 2007).

4. Regulation 3(1) 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 on the Community code relating to medicinal products for human use[3] (as amended);",

(b) by substituting for the definition of "export" the following:
"'export' means exportation to a third country, other than Northern Ireland;", and

(c) by substituting for the definition of "import" the following:

[1] OJ No. L. 118, 20.4.2022, p.4.
[3] 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.

"'import' means importation from a third country, other than Northern Ireland;".

5. Regulation 4(a) of the Principal Regulations is amended by inserting "or in Northern Ireland" after "EEA".

6. Regulation 5 of the Principal Regulations is amended –

(a) by inserting after subparagraph 5(1)(f) the following:

"(g) until 31 December 2024, 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, which shall be allowed by the Board following receipt of a request from the holders of the marketing authorisations for the medicinal products, where 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 relevant Community provisions, by the Health Products Regulatory Authority 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.", and

(b) by inserting after subparagraph 5(3) the following:

"(4) 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 sub-paragraph 5(1)(g).".

7. Regulation 13 of the Principal Regulations is amended –

(a) in Regulation 13(3), by the substitution of "Without prejudice to Regulations 13(9) and 13(10), the functions of a qualified person shall be -" for "The functions of the qualified person shall be -",

(b) in Regulation 13(4):

(i) by the substitution of "Without prejudice to Regulations 13(9) and 13(10), the batches" for "The batches", and

(ii) by the insertion of "or Northern Ireland" after "in another EEA State",

(c) in Regulation 13(5), by the substitution of "Without prejudice to Regulations 13(9) and 13(10), in the case of medicinal products" for "In the case of medicinal products",

(d) by inserting after subparagraph (8) the following:
"(9) Until 31 December 2024, with regard to quality control testing carried out in parts of the United Kingdom other than Northern Ireland regarding medicinal products included in the list referred to in Article 127d of the 2001 Directive other than those authorised by the Commission, the Board may consider that there is a justifiable case within the meaning of point (b) of the first paragraph of Article 20 of the 2001 Directive, without carrying out a case-by-case assessment provided that –

(a) each batch of the medicinal products concerned is released by a qualified person on a site in the Union or in Northern Ireland or by a qualified person on a site in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 51 of the 2001 Directive,

(b) the establishment designated by the third party conducting the quality control testing is supervised by the competent authority of the United Kingdom, including by performing on-the-spot checks, and

(c) where the batch release is carried out by a qualified person who operates in parts of the United Kingdom other than Northern Ireland, the manufacturing authorisation holder declares that it does not have at its disposal a qualified person who resides and operates in the Union on 20 April 2022.", and

(e) by inserting after subparagraph (9) the following:
"(10) Until 31 December 2024, for batches of medicinal products which are exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently imported into the State, the controls upon importation referred to in the first and second subparagraphs of Article 51(1) of the 2001 Directive shall not be required, provided that those batches have undergone such controls in a Member State prior to being exported to parts of the United Kingdom other than Northern Ireland and that they are accompanied by the control reports referred to in the third subparagraph of Article 51(1) of the 2001 Directive."

8. The Principal Regulations are amended by inserting after Regulation 16 the following:

"17. (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 Regulations 5(1)(g), 13(9) and 13(10) of these Regulations.

(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 Regulations 5(1)(g), 13(9) and 13(10) of these Regulations 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. Manufacturers and importers 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)."

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.

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(4), 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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