STATUTORY INSTRUMENTS.

S.I. No. 416 of 2022

MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET) (AMENDMENT) 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 Placing on the Market) (Amendment) Regulations 2022.

(2) The Principal 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), Regulation 6 of Medicinal Products (Safety Features On Packaging) Regulations 2019 (S.I. No. 36 of 2019), the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2019 (S.I. No. 218 of 2019) and these Regulations may be cited together as "the Medicinal Products (Control of Placing on the Market) 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 Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).

4. Regulation 3(1) of the Principal Regulations is amended by substituting for the definition of "2001 Directive" the following:

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

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

"'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[5] (as amended);".

5. Regulation 9 of the Principal Regulations is amended by substituting for subparagraph 6 the following:

"(6) (a) The applicant for the grant of a marketing authorisation shall –

be established in an EEA State, or

until 31 December 2024, be established in parts of the United Kingdom other than Northern Ireland, where the marketing authorisation is sought pursuant to the mutual recognition or the decentralised procedure laid down in Chapter 4 of the 2001 Directive,

and shall be responsible for the accuracy of any documents and data submitted in support of any such application,

(b) The applicant for the renewal of a marketing authorisation shall –

(i) be established in an EEA State, or
(ii) until 31 December 2024, be established in parts of the United Kingdom other than Northern Ireland,

and shall be responsible for the accuracy of any documents and data submitted in support of any such application,

(c) until 31 December 2024, the Board may extend marketing authorisations already granted prior to 20 April 2022 to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland,

(d) marketing authorisations granted or extended by the Board in accordance with subparagraphs (a)(ii), b(ii) or (c) shall cease to be valid at the latest on 31 December 2026, unless the marketing authorisation has been transferred to a holder established in an EEA State prior to that date,

(e) The applicant for the grant or renewal of a certificate of registration and a certificate of traditional-use registration shall be established in an EEA State and shall be responsible for the accuracy of any documents and data submitted in support of any such application."

6. Regulation 15 of the Principal Regulations is amended by substituting for subparagraph 5 the following:

"(5) (a) The holder of a marketing authorisation granted or renewed shall –

(i) be established in an EEA State, or
(ii) until 31 December 2024, be established in parts of the United Kingdom other than Northern Ireland,

and shall be responsible for the accuracy of any documents and data submitted in connection with such authorisation,

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

(b) until 31 December 2024, the Board may extend marketing authorisations already granted prior to 20 April 2022 to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland,

(c) marketing authorisations granted or extended by the Board in accordance with subparagraphs (a)(ii) or (b) shall cease to be valid at the latest on 31 December 2026, unless the marketing authorisation has been transferred to a holder established in an EEA State prior to that date,

(d) The holder of a certificate of registration or certificate of traditional-use registration, granted or renewed shall be established in an EEA State and shall be responsible for the accuracy of any documents and data submitted in connection with such authorisation or certificate."

7. The Principal Regulations are amended by inserting after Part 9 the following Part:

"PART 10

DEROGATIONS

41. (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 9(6) and 15(5) 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 9(6) and 15(5) 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."

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(2) 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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