



STATUTORY INSTRUMENTS.

S.I. No. 218 of 2019



MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET)
(AMENDMENT) 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 further effect to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001¹, hereby make the following regulations:

1. (1) These Regulations may be cited as the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2019.

(2) The collective citation “the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2019” includes these Regulations.

2. Paragraph 3 of Schedule 1 (as amended by Regulation 11 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) Regulations 2009 (S.I. No. 3 of 2009)) to the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) is amended—

- (a) in subparagraph (e)—
 - (i) by deleting “or imported into the State from a third country,”,
 - (ii) in clause (i), by deleting “or imported” and “or import”, and
 - (iii) in clause (ii), by deleting “or imported” and “and”, and

- (b) by substituting for subparagraph (f) the following subparagraphs:

“(f) if the medicinal product is imported into the State from a third country, the product is imported by—

- (i) the holder of a wholesaler’s authorisation, or
- (ii) the holder of a manufacturer’s authorisation where that manufacturer normally conducts a manufacturing activity relating specifically to the medicinal product to which paragraph 2 applies; and

¹ OJ No. L 311, 28.11.2001, p. 67.

- (g) the medicinal product is distributed by way of wholesale dealing by the holder of a wholesaler's authorisation or by the holder of a manufacturer's authorisation who has manufactured or imported the product.”.



GIVEN under my Official Seal,
15 May 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.)

These Regulations amend the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).

The purpose of these Regulations is to enable the holder of a wholesaler's authorisation to import an exempt medicinal product from a third country and to update the subsequent requirements to be met by the holder of that authorisation.

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