



STATUTORY INSTRUMENTS.

S.I. No. 219 of 2019



MEDICINAL PRODUCTS (CONTROL OF MANUFACTURE)
(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 Manufacture) (Amendment) Regulations 2019.

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

2. The Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007) are amended—

(a) in Regulation 5(1), by inserting after subparagraph (e) the following subparagraph:

“(f) the importation of a medicinal product for supply under Article 5(1) of the 2001 Directive or Article 83 of Regulation (EC) No. 726/2004.”,

(b) in Regulation 13(5), by deleting “, in the form of a Mutual Recognition Agreement,”, and

(c) in paragraph 2 of Schedule 2—

(i) in subparagraph (b), by deleting “and”,

(ii) in subparagraph (c), by inserting “and” after “2001 Directive;”, and

(iii) by inserting after subparagraph (c) the following subparagraph:

“(d) in the distribution within the State of medicinal products which—

¹ OJ No. L 311, 28.11.2001, p. 67.

- (i) are exempt medicinal products, and
- (ii) have not been manufactured within the State,

comply with the requirements set out in paragraph 17 of Schedule 2 to the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007), as amended.”.



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 Manufacture) Regulations 2007 (S.I. No. 539 of 2007).

The purpose of these Regulations is to update Regulation 5 to enable the holder of a wholesaler's authorisation to import an exempt medicinal product from a third country and to update Regulation 13 to remove the requirement for a Mutual Recognition Agreement as an appropriate arrangement made by the European Union and a third country.

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