



STATUTORY INSTRUMENTS.

**S.I. No. 217 of 2019**



MEDICINAL PRODUCTS (CONTROL OF WHOLESALE DISTRIBUTION)  
(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 2001<sup>1</sup>, hereby make the following regulations:

1. (1) These Regulations may be cited as the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2019.

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

2. In these Regulations—

“Principal Regulations” means the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007);

“Regulations of 2019” means the Medicinal Products (Safety Features on Packaging) Regulations 2019 (S.I. No. 36 of 2019).

3. Regulation 4(1) (as amended by Regulation 7(a) of the Regulations of 2019) of the Principal Regulations is amended by deleting the definition of “exempt sourced medicinal product”.

4. Schedule 2 (as amended by Regulation 7(b) of the Regulations of 2019) to the Principal Regulations is amended—

(a) in paragraph 2(1), by inserting “and paragraph 2A” after “subparagraph (2)”,

(b) by inserting after paragraph 2 the following paragraph:

“2A. The authorisation holder shall only order and obtain his or her supplies of medicinal products which are intended for onward supply through his or her wholesaler’s authorisation via an account or equivalent supply arrangement established with his or her supplier exclusively for the purpose of obtaining medicinal products for wholesale distribution.”,

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<sup>1</sup> OJ No. L 311, 28.11.2001, p. 67.

(c) by inserting after paragraph 4 the following paragraph:

“4A. In the case of paragraph 4(d), the authorisation holder shall only supply medicinal products via an account or equivalent supply arrangement established with the recipient exclusively for the purpose of supply to the public and no further wholesale distribution of the products shall take place.”, and

(d) in paragraph 17—

(i) in subparagraph (1)—

(I) by substituting “exempt medicinal product” for “exempt sourced medicinal products”, and

(II) by substituting “such product” for “such products”, and

(ii) in subparagraphs (2), (3), (4), (5), (6) and (8), by substituting “exempt medicinal product” for “exempt sourced medicinal product” in each place where it occurs.



GIVEN under the Official Seal of the Minister for Health

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 Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007).

The purpose of these Regulations is to update the obligations on holders of wholesaler's authorisations to allow for greater traceability and transparency in the wholesale distribution supply chain and make the necessary amendments associated with enabling the importation of exempt medicinal products from third countries by holders of wholesaler's authorisations.

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