STATUTORY INSTRUMENTS.

S.I. No. 274 of 2012

MEDICINAL PRODUCTS (CONTROL OF WHOLESALE DISTRIBUTION) (AMENDMENT) REGULATIONS 2012
MEDICINAL PRODUCTS (CONTROL OF WHOLESALE DISTRIBUTION) (AMENDMENT) REGULATIONS 2012


1. These Regulations may be cited as the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2012.

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

3. Regulation 4(1) (as amended by the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (Amendment) Regulations 2010 (S.I. No. 286 of 2010)) of the Principal Regulations is amended—

(a) by substituting for the definition of “Act” the following:


(b) by inserting after the definition of “advanced therapy regulation” the following definition:


Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 27th July, 2012.

(c) by substituting for the definition of “2001 Directive” the following:


4. The Principal Regulations are amended by inserting after Regulation 14 the following Regulation:

“Inspections

14A. (1) Pursuant to ss. 32A to 32F of the Act and Article 111 of the 2001 Directive, the Board shall, by means of inspections, including unannounced inspections if necessary, ensure that the principles and guidelines of good distribution practice are complied with.

(2) After every inspection referred to in paragraph (1), the Board shall report on whether the inspected entity complies with the principles and guidelines on good distribution practice.

(3) The Board shall communicate the content of the report referred to in paragraph (3) to the inspected entity and shall, prior to adopting the report, give that person the opportunity to submit comments on the report.

(4) In this Regulation, “the principles and guidelines on good distribution practice” means the principles and guidelines published by the Commission pursuant to Article 84 of the 2001 Directive.”

7OJ No. L 159, 27.6.2003, p. 46.
9OJ No. L 136, 30.4.2004, p. 34.
L.S. GIVEN under my Official Seal,
25 July 2012.

JAMES REILLY,
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).


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