STATUTORY INSTRUMENTS.

S.I. No. 273 of 2012

MEDICINAL PRODUCTS (CONTROL OF MANUFACTURE) (AMENDMENT) REGULATIONS 2012

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

2. In these Regulations “Principal Regulations” means the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007).

3. Regulation 3(1) (as amended by the Medicinal Products (Control of Manufacture) Regulations 2007 (Amendment) Regulations 2010 (S.I. No. 288 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:


(d) by inserting after the definition of “EEA State” the following definition:

“‘EudraGMP database’ means the Community database referred to in Article 111(6) of the 2001 Directive;”

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 manufacturing practice are complied with.

(2) The Board shall share information with the Agency on inspections which have been carried out, and inspections which are planned and shall cooperate with the Agency in coordinating inspections in third countries.

⁷OJ No. L 159, 27.6.2003, p. 46.
⁹OJ No. L 136, 30.4.2004, p. 34.
(3) After every inspection referred to in paragraph (1), the Board shall report on whether the inspected entity complies with the principles and guidelines of good manufacturing practice.

(4) 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.

(5) The Board shall enter the certificates of good manufacturing practice in the EudraGMP database.

(6) If the outcome of an inspection referred to in paragraph (1) is that the inspected entity does not comply with the principles and guidelines of good manufacturing practice, the Board shall enter the information in the EudraGMP database.

(7) In this Regulation, “the principles and guidelines of good manufacturing practice” means the principles and guidelines adopted by the Commission pursuant to Article 47 of the 2001 Directive, including those laid down in the GMP Directive.”

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


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