STATUTORY INSTRUMENTS.

S.I. No. 287 of 2010

MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET) REGULATIONS 2007 (AMENDMENT) REGULATIONS 2010

(Prn. A10/0866)

S.I. No. 287 of 2010

MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET) REGULATIONS 2007 (AMENDMENT) REGULATIONS 2010

The Minister for Health and Children, in exercise of the powers conferred on her by section 32 of the Irish Medicines Board Act 1995 (No. 29 of 1995), as amended by section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006) and adapted by the Health (Alteration of Name of Department and Title of Minister) Order 1997 (S.I. No. 308 of 1997), and for the purpose of giving effect to the amendment made by Commission Directive 2009/120/EC of 14 September 2009[1] to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001[2], hereby makes the following regulations:

Citation

1. These Regulations may be cited as the Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) Regulations 2010.

Collective citation and construction

2. The Medicinal Products (Control of Placing on the Market) Regulations 2007 and 2009 and these Regulations may be cited together as the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2010, and shall be construed together as one.

Commencement

3. These Regulations come into force on 11th June 2010.

Interpretation

4. (1) In these Regulations—

'principal regulations' mean the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007);

'2009 Regulations' means the Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) Regulations 2009 (S.I. No. 3 of 2009).

Amendment of Principal Regulations

5. The following definition is substituted for the definition of "2001 Directive" in Regulation 3(1) (as amended by Regulation 5(*b*) of the 2009 Regulations) of the principal regulations:

> " '2001 Directive' means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2], as amended by—

[1] OJ No. L.242, 15.09.2009, p.3
[2] OJ No. L.311, 28.11.2001, p.67

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 18*th June*, 2010.

(*a*) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components[3],

(*b*) Commission Directive 2003/63/EC of 25 June 2003 on the Community code relating to medicinal products for human use[4],

(*c*) Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 relating to traditional herbal medicinal products for human use[5],

(*d*) Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 on the Community code relating to medicinal products for human use[6],

(*e*) Regulation (EC) No. 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products[7], and

(*f*) Commission Directive 2009/120/EC of 14 September 2009 relating to advanced therapy medicinal products for human use[1];".

L.S.

GIVEN under my Official Seal,
11 June 2010.

MARY HARNEY,
Minister for Health and Children

[3] OJ No. L.33, 08.02.2003, p.30
[4] OJ No. L.159, 27.06.2003, p.46
[5] OJ No. L.136, 30.04.2004, p.85
[6] OJ No. L.136, 30.04.2004, p.34
[7] OJ No. L.324, 10.12.2007, p.121

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations give effect to Directive 2009/120/EC, which replaced Part IV (dealing with advanced therapy medicinal products) of Annex 1 of Directive 2001/83/EC, in so far as Part IV relates to control of the placing on the market of those products.

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