



STATUTORY INSTRUMENTS

**S.I. No. 4 of 2009**



MEDICINAL PRODUCTS (CONTROL OF MANUFACTURE)  
REGULATIONS 2007 (AMENDMENT) REGULATIONS 2009

**(Prn. A9/0043)**

MEDICINAL PRODUCTS (CONTROL OF MANUFACTURE)  
REGULATIONS 2007 (AMENDMENT) REGULATIONS 2009

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 as 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 full effect to Directive 2001/83/EC (as amended by Article 28 of Regulation (EC) No. 1394/2007), hereby make the following regulations—

*Citation*

1. These Regulations may be cited as the Medicinal Products (Control of Manufacture) Regulations 2007 (Amendment) Regulations 2009.

2. These Regulations shall be construed as one with the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007) and may be cited together with those Regulations as the Medicinal Products (Control of Manufacture) Regulations 2007 and 2009.

*Commencement*

3. These Regulations shall come into force on 14 January 2009.

*Interpretation*

4. (1) In these Regulations:

‘principal regulations’ mean the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007).

*Amendment of Regulations*

5. Regulation 3(1) of the principal regulations is amended—

(a) by inserting the following before the definition of “Act”:

“ ‘advanced therapy medicinal product’ means a product as defined in Article 2 of the advanced therapy regulation;

‘advanced therapy regulation’ means Regulation (EC) No. 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products<sup>16</sup>,”

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

<sup>16</sup>OJ No. L 324, 10.12.2007, p.121

*Notice of the making of this Statutory Instrument was published in  
“Iris Oifigiúil” of 16th January, 2009.*

“ ‘2001 Directive’ means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use<sup>17</sup> as amended by—

- (a) Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components<sup>18</sup>,
- (b) Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use<sup>19</sup>,
- (c) Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use<sup>20</sup>,
- (d) Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use<sup>21</sup>, and
- (e) the advanced therapy regulation;”;

6. Schedule 2 to the principal regulations is amended by the insertion of the following after paragraph 31:

“32. (1) The authorisation holder, in the case of an advanced therapy medicinal product, shall establish and maintain a system ensuring that the individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the hospital, institution or private practice where the product is used.

(2) Where an authorisation holder manufactures an advanced therapy medicinal product that contains human cells or tissues, he or she shall ensure that the traceability systems established in accordance with paragraph 1 are complementary to, and compatible with, the requirements laid down in Articles 8 and 14 of Directive 2004/23/EC as regards human cells and tissues other than blood cells, and Articles 14 and 24 of Directive 2002/98/EC<sup>22</sup> as regards human blood cells.

(3) The authorisation holder shall keep the data referred to in subparagraph (1) for a minimum of 30 years after the expiry date of the product.

<sup>17</sup>OJ No. L 311, 28.11.2001, p.67.

<sup>18</sup>OJ No. L 33, 08.02.2003, p.30.

<sup>19</sup>OJ No. L 159, 27.06.2003, p.46.

<sup>20</sup>OJ No. L 136, 30.04.2004, p.85.

<sup>21</sup>OJ No. L 136, 30.4.2004, p.34.

<sup>22</sup>OJ No. L 93, 8.2.2003, p.30.

(4) In case of bankruptcy or liquidation of the authorisation holder who has manufactured an advanced therapy medicinal product, and in the event that the manufacturing authorisation is not transferred to another legal entity, the data referred to in paragraph (1) shall be transferred to the Board.

(5) In the event that the manufacturing authorisation is suspended, revoked or withdrawn, the holder of the manufacturing authorisation shall remain subject to the obligations laid down in paragraphs (1), (2) and (3).

(6) Subparagraphs (3) to (5) shall not apply to an authorisation holder where the holder of a marketing authorisation for the relevant advanced therapy medicinal product is, by virtue of such marketing authorisation, responsible for the retention of such data.

33. In paragraphs 2(c), 19, 20 and 23(1)(b) and (c), every reference to a medicinal product shall be a reference to a medicinal product that is intended to be placed on the market in the State or in another EEA State.”.

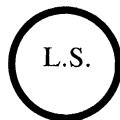
7. Schedule 3 to the principal regulations is amended—

(a) by the substitution of the following for paragraph 25(4):

“(4) The authorisation holder shall not issue any advertisement, other than one that states only the trade name, pack size, price and dose, relating to an exempt medicinal product or make any representations in respect of such product.”;

(b) by the insertion of the following after paragraph 25:

“26. In paragraphs 2(g), 3, 12(1)(b) and (c) and 14, every reference to a medicinal product shall be a reference to a medicinal product that is intended to be placed on the market in the State or in another EEA State.”.



GIVEN under the Official Seal,  
13 January 2009

MARY HARNEY.  
Minister for Health and Children.

## EXPLANATORY NOTE.

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

The main purpose of these Regulations is to facilitate the operation of Regulation (EC) No. 1394/2007 relating to advanced therapy medicinal products and to ensure that the requirements relating to the supply of medicinal products that are intended to be placed on the market in the State, or on the market in another EEA State, are applicable only to such products as intended by Directive 2001/83/EC (as amended).

The Judgment of the European Court of Justice in Case C-143/06 concerning the prohibition of the advertising of unauthorised medicinal products has also been taken into account in the making of these Regulations.

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