STATUTORY INSTRUMENTS

S.I. No. 3 of 2009

MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET) REGULATIONS 2007 (AMENDMENT) REGULATIONS 2009

(Prn. A9/0042)

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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 Placing on the Market) Regulations 2007 (Amendment) Regulations 2009.

2. These Regulations shall be construed as one with the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) and may be cited together with those Regulations as the Medicinal Products (Control of Placing on the Market) 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 Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).

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

(*a*) by inserting the following after 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[19];"

(*b*) by substituting the following for the definition of "2001 Directive":

" '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[20]as amended by—

[19]OJ No. L 324, 10.12.2007, p.121
[20]OJ No. L. 311, 28.11.2001, p.67.

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

(*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[21],

(*b*) Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use[22],

(*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[23],

(*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[24], and

(*e*) the advanced therapy regulation;";

(*c*) by substituting the following for the definition of "Regulation (EC) No. 726/2004":

" 'Regulation (EC) No. 726/2004' means Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[25], read in conjunction with the advanced therapy regulation;";

(*d*) in the definition of "relevant Community provisions", by substituting the following for paragraphs (*g*) and (*h*):

" (*g*) Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency,

(*h*) the Community Regulation on medicinal products for paediatric use, and

(*i*) the advanced therapy regulation;";

(*e*) by substituting the following for the definition of "summary of product characteristics":

[21]OJ No. L. 33, 08.02.2003, p.30.
[22]OJ No. L. 159, 27.06.2003, p.46.
[23]OJ No. L. 136, 30.04.2004, p.85.
[24]OJ No. L. 136, 30.04.2004, p.34.
[25]OJ No. L. 136, 30.04.2004, p.1.

" 'summary of product characteristics' means the information required to accompany any application for a marketing authorisation or certificate of traditional-use registration by virtue of article 11 of the 2001 Directive. In the case of advanced therapy medicinal products, such information is instead required to contain the information listed in Annex II of the advanced therapy regulation, in the order indicated in that Annex;".

6. Regulation 5(2) of the principal regulations is amended by substituting the following for paragraphs (*c*) and (*d*):

"(*c*) Regulation (EC) No. 141/2000, of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products;

(*d*) Articles 4, 39.2, 49.1 and 51 of the Community Regulation on medicinal products for paediatric use; and

(*e*) the advanced therapy regulation.".

7. Regulation 6 of the principal regulations is amended by substituting the following for paragraph (4):

"(4) Subject to subparagraph (5), Schedule 1 shall have effect, in respect of medicinal products other than advanced therapy medicinal products to which paragraph (5) is applicable, for the purpose of making certain exemptions from the provisions of this Regulation and for imposing certain obligations in connection with such exemptions.

(5) Schedule 1A shall have effect, in respect of advanced therapy medicinal products, for the purpose of making certain exemptions from the provisions of this Regulation and for imposing certain obligations in connection with such exemptions.".

8. Regulation 16 of the principal regulations is amended—

(*a*) by substituting the following for paragraph (1):

"(1) Without prejudice to the provisions of Regulation 16 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) and subject to paragraphs (4), (5) and (6), a person responsible for placing a medicinal product on the market, which is the subject of a Community marketing authorisation or of a marketing authorisation, certificate of registration or certificate of traditional-use registration, shall not sell, supply or procure the sale or supply of such product unless—

(*a*) the labelling and any package leaflet accompanying the product are in compliance with Title V of the 2001 Directive; and

(*b*) except where all the information required to be included in the said package leaflet is directly conveyed on the outer packaging or immediate packaging of the product, the packaging contains a package leaflet in compliance with Title V of the 2001 Directive.".

(*b*) by inserting the following after paragraph (3):

"(4) In the case of advanced therapy medicinal products and by way of derogation from Articles 54 and 55(1) of Directive 2001/83/EC, the particulars listed in Annex III to the advanced therapy regulation shall appear on the outer package of such products or, where there is no outer package, on the immediate packaging.

(5) In the case of advanced therapy medicinal products, in addition to the particulars mentioned in Article 55(2) and (3) of Directive 2001/83/EC, the following particulars shall appear on the immediate packaging for such products:

(*a*) the unique donation and product codes, as referred to in Article 8(2) of Directive 2004/23/EC[26];

(*b*) in the case of advanced therapy medicinal products for autologous use, the unique patient identifier and the statement 'For autologous use only'.

(6) In the case of advanced therapy medicinal products and by way of derogation from Article 59(1) of Directive 2001/83/EC, the package leaflet for such products shall be drawn up in accordance with the summary of product characteristics and shall include the information listed in Annex IV to the advanced therapy regulation, in the order indicated therein.".

9. The principal regulations are amended by the insertion of the following after Regulation 19

"PART 3A

TRACEABILITY OF ADVANCED THERAPY MEDICINAL PRODUCTS

19A. (1) The holder of a marketing authorisation for 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) The hospital, institution or private practice where the advanced therapy medicinal product is used shall establish and maintain a system for patient and

[26]OJ No. L.102, 07.04.2004, p.48.

product traceability. That system shall contain sufficient detail to allow linking of each product to the patient who received it and vice versa.

(3) Where an advanced therapy medicinal product contains human cells or tissues, the holder of the marketing authorisation, as well as the hospital, institution or private practice where the product is used, shall ensure that the traceability systems established in accordance with paragraphs 1 and 2 of this Regulation 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[27] as regards human blood cells.

(4) The holder of the marketing authorisation shall keep the data referred to in paragraph (1) for a minimum of 30 years after the expiry date of the product, or longer if required by the Commission as a term of the marketing authorisation.

(5) In case of bankruptcy or liquidation of the holder of the marketing authorisation, and in the event that the marketing authorisation is not transferred to another legal entity, the data referred to in paragraph (1) shall be transferred to the Agency.

(6) In the event that the marketing authorisation is suspended, revoked or withdrawn, the holder of the marketing authorisation shall remain subject to the obligations laid down in paragraphs (1), (3) and (4).

19B The provisions of Regulation 19A shall also apply to an advanced therapy medicinal product to which Regulation 6(5) applies and on the basis that—

(*a*) every reference in Regulation 19A to the holder of a marketing authorisation, or to a marketing authorisation, shall be construed as a reference to the holder of the relevant manufacturing authorisation, or, as the case may be, to the relevant manufacturing authorisation, and

(*b*) the reference in Regulation 19A(5) to the Agency shall be construed as a reference to the Board.".

10. Regulation 25 of the principal regulations is amended by inserting the following after paragraph (5):

"(6) The provisions of these regulations shall not apply—

(*a*) in the case of advanced therapy medicinal products, other than tissue engineered products, which were legally on the Community market in accordance with national or Community legislation on 30 December 2008, until 30 December 2011; and

[27]OJ No. L. 93, 8.02.2003, p.30.

(*b*) in the case of tissue engineered products that were legally on the Community market in accordance with national or Community legislation on 30 December 2008, until 30 December 2012.".

11. Paragraphs 3 and 5 of Schedule 1 to the principal regulations are amended by substituting the following for subparagraph (*b*) and for subparagraph (3)(*f*) respectively:

"no advertisement or representation relating to the medicinal product is issued with a view to it being seen by the general public in the State and that no advertisement relating to the product, other than one that states only the trade name, pack size, price and dose, is issued at the request or with the consent of, the person selling the product by retail or by way of wholesale dealing or the person who manufactures it, and that the sale or supply is in response to a bona fide unsolicited order.".

12. The principal regulations are amended by the insertion of the following after Schedule 1:

"SCHEDULE 1A

1. The provisions of paragraphs (1) and (2) of Regulation 6 shall not apply to the sale or supply of an advanced therapy medicinal product which is prepared, on a non-routine basis according to specific quality standards, to comply with an individual medical prescription for a custom-made product for an individual patient, and which is used in a hospital in the State under the exclusive responsibility of a medical practitioner, but such sale or supply shall be subject to the conditions specified in paragraph 2.

2. The conditions referred to in paragraph 1 are that—

(*a*) the advanced therapy medicinal product is supplied to a practitioner in accordance with paragraph 1;

(*b*) the manufacture of the advanced therapy medicinal product is carried out in the State by the holder of a manufacturer's authorisation which relates specifically to the manufacture of products to which paragraph (1) applies;

(*c*) the manufacture of the advanced therapy medicinal product is carried out under the supervision of such staff and such precautions are taken as are adequate to ensure that the product is of the character required by and meets the specifications and quality standards required by the individual medical prescription;

(*d*) a system is established ensuring that the individual advanced therapy medicinal 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;

(*e*) written records as to the manufacture in accordance with subparagraph (*c*) and those necessary for the purposes of subparagraph (*d*) are made and maintained and are available to the Board on request;

(*f*) the advanced therapy medicinal product is distributed by way of wholesale dealing by the holder of a wholesaler's authorisation or by the person who has manufactured the product, being the holder of a manufacturer's authorisation which relates specifically to the manufacture of the product concerned; and

(*g*) no advertisement or representation relating to the advanced therapy medicinal product is issued with a view to it being seen by the general public in the State and that no advertisement relating to the product, other than one that states only the trade name, pack size, price and dose, is issued at the request or with the consent of, the person selling the product by retail or by way of wholesale dealing or the person who manufactures it, and that the sale or supply is in response to a bona fide unsolicited order for a custom-made product for an individual patient.".

L.S.

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.

The Regulations also provide for controls in respect of advanced therapy medicinal products which are prepared on a non-routine basis according to specific quality standards, and used within the State in a hospital under the exclusive professional responsibility of a medical practitioner, to comply with an individual medical prescription for a custom-made product for an individual patient.

Provisions are also included in respect of the traceability of all advanced therapy medicinal products

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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