



STATUTORY INSTRUMENTS

S.I. No. 1 of 2009

EUROPEAN COMMUNITIES (CLINICAL TRIALS ON MEDICINAL
PRODUCTS FOR HUMAN USE) (AMENDMENT) REGULATIONS 2009

(Prn. A9/0040)

EUROPEAN COMMUNITIES (CLINICAL TRIALS ON MEDICINAL PRODUCTS FOR HUMAN USE) (AMENDMENT) REGULATIONS 2009

The Minister for Health and Children, in exercise of the powers conferred on her by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Article 4(1) of Regulation (EC) No. 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products⁽¹⁾ insofar as that Regulation impacts on Directive 2001/20/EC of 4 April 2001⁽²⁾, hereby make the following Regulations—

1. These Regulations may be cited as the European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment) Regulations 2009.

2. These Regulations shall be construed as one with the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 to 2007 and may be cited together with those Regulations as the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 to 2009.

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

4. Regulation 4(1) of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190 of 2004) is amended by inserting the following after the definition of “adult”:

“ ‘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⁽¹⁾,”

5. The European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (as amended) shall apply to tissue engineered products in the same manner as such Regulations apply to medicinal products for gene therapy and somatic cell therapy.

⁽¹⁾OJ No. L 324, 10.12.2007, p.121

⁽²⁾OJ No. L 121, 01.05.2001, p. 34



GIVEN under my 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 which provides that certain of the specific rules set out in Directive 2001/20/EC should apply to tissue engineered products.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ón
OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS,
TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,
nó tríd an bpost ó
FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA,
AONAD 20 PÁIRC MIONDÍOLA COIS LOCHA, CLÁR CHLAINNE MHUIRIS,
CONTAE MHAIGH EO,
(Teil: 01 - 6476834 nó 1890 213434; Fax: 094 - 9378964 nó 01 - 6476843)
nó trí aon díoltóir leabhar.

DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased directly from the
GOVERNMENT PUBLICATIONS SALE OFFICE
SUN ALLIANCE HOUSE, MOLESWORTH STREET, DUBLIN 2,
or by mail order from
GOVERNMENT PUBLICATIONS, POSTAL TRADE SECTION,
UNIT 20 LAKESIDE RETAIL PARK, CLAREMORRIS, CO. MAYO,
(Tel: 01 - 6476834 or 1890 213434; Fax: 094 - 9378964 or 01 - 6476843)
or through any bookseller.

€1.27

