DECISION OF THE EEA JOINT COMMITTEE
No 62/2009

of 29 May 2009

amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area, as amended by the Protocol adjusting the Agreement on the European Economic Area, hereinafter referred to as 'the Agreement', and in particular Article 98 thereof,

Whereas:

(1) Annex II to the Agreement was amended by Decision of the EEA Joint Committee No 6/2009 of 5 February 2009 [1].

(2) Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products[2] is to be incorporated into the Agreement.

(3) Commission Regulation (EC) No 1277/2005 of 27 July 2005 laying down implementing rules for Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and for Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors[3] is to be incorporated into the Agreement.

(4) Council Regulation (EC) No 1905/2005 of 14 November 2005 amending Regulation (EC) No 297/95 on fees payable to the European Medicines Agency[4] is to be incorporated into the Agreement,

HAS DECIDED AS FOLLOWS:

Article 1

Chapter XIII of Annex II to the Agreement shall be amended as follows:

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1 OJ L 73, 19.3.2009, p. 39.
2 OJ L 91, 9.4.2005, p. 13.
3 OJ L 202, 3.8.2005, p. 7.
4 OJ L 304, 23.11.2005, p. 1.

1. The following indent shall be added in point 15h (Council Regulation (EC) No 297/95):

'- **32005 R 1905**: Council Regulation (EC) No 1905/2005 of 14 November 2005 (OJ L 304, 23.11.2005, p. 1).'

2. The following shall be inserted after point 15zd (Commission Regulation (EC) No 507/2006):

'15ze. **32005 R 1277**: Commission Regulation (EC) No 1277/2005 of 27 July 2005 laying down implementing rules for Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and for Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (OJ L 202, 3.8.2005, p. 7).

The provisions of the Regulation shall, for the purpose of this Agreement, be read with the following adaptation:

The Regulation shall only apply to the EEA EFTA States with regard to Regulation (EC) No 273/2004.

15zf. **32005 L 0028**: Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13).'

Article 2

The texts of Regulations (EC) Nos 1277/2005 and 1905/2005 and Directive 2005/28/EC in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 30 May 2009, provided that all the notifications under Article 103(1) of the Agreement have been made to the EEA Joint Committee[*].

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

[*] Constitutional requirements indicated.

Done at Brussels, 29 May 2009.

For the EEA Joint Committee
The President

Alan Seatter

The Secretaries
to the EEA Joint Committee

Bergdis Ellertsdóttir *Matthias Brinkmann*