DECISION OF THE EEA JOINT COMMITTEE

No 128/2009

of 4 December 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 62/2009 of 29 May 2009 ([1]).

(2) Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 ([2]), as corrected by OJ L 87, 31.3.2009, p. 174, is to be incorporated into the Agreement.

(3) Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products ([3]) is to be incorporated into the Agreement.

(4) Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription ([4]) is to be incorporated into the Agreement.

(5) Regulation (EC) No 1234/2008 repeals Commission Regulations (EC) No 1084/2003 ([5]) and (EC) No 1085/2003 ([6]) which are incorporated into the Agreement and are therefore to be repealed under the Agreement,

HAS DECIDED AS FOLLOWS:

Article 1

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

1. the following indent shall be added in point 15q (Directive 2001/83/EC of the European Parliament and of the Council):

'— **32007 R 1394**: Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 (OJ L 324, 10.12.2007, p. 121), as corrected by OJ L 87, 31.3.2009, p. 174.';

2. the following shall be added in point 15zb (Regulation (EC) No 726/2004 of the European Parliament and of the Council):

', as amended by:

— **32007 R 1394**: Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 (OJ L 324, 10.12.2007, p. 121), as corrected by OJ L 87, 31.3.2009, p. 174.';

([1]) OJ L 232, 3.9.2009, p. 18.
([2]) OJ L 324, 10.12.2007, p. 121.
([3]) OJ L 334, 12.12.2008, p. 7.
([4]) OJ L 349, 12.12.2006, p. 15.
([5]) OJ L 159, 27.6.2003, p. 1.
([6]) OJ L 159, 27.6.2003, p. 24.

3. the text of points 15r (Commission Regulation (EC) No 1084/2003) and 15s (Commission Regulation (EC) No 1085/2003) shall be deleted;

4. the following points shall be inserted after point 15zf (Commission Directive 2005/28/EC):

'15zg. **32006 L 0130**: Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription (OJ L 349, 12.12.2006, p. 15).

15zh. **32007 R 1394**: Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121), as corrected by OJ L 87, 31.3.2009, p. 174.

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

The EFTA States shall be fully associated with the work of the Committee for Advanced Therapy, but without the right to vote.

15zi. **32008 R 1234**: Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7).'

Article 2

The texts of Regulations (EC) No 1394/2007, as corrected by OJ L 87, 31.3.2009, p. 174, and (EC) No 1234/2008, and Directive 2006/130/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 5 December 2009, provided that all the notifications under Article 103(1) of the Agreement have been made to the EEA Joint Committee (*), or on the date of entry into force of Decision of the EEA Joint Committee No 61/2009 of 29 May 2009, whichever is the later.

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*.

Done at Brussels, 4 December 2009.

For the EEA Joint Committee
The President
Oda Helen SLETNES

(*) No constitutional requirements indicated.