DECISION OF THE EEA JOINT COMMITTEE
No 72/2011

of 1 July 2011

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 25/2010 of 12 March 2010[1].

(2) Commission Regulation (EC) No 249/2009 of 23 March 2009 amending Council Regulation (EC) No 297/95 as regards the adjustment of the fees of the European Medicines Agency to the inflation rate[2] is to be incorporated into the Agreement.

(3) Directive 2009/35/EC of the European Parliament and of the Council of 23 April 2009 on the colouring matters which may be added to medicinal products (recast)[3] is to be incorporated into the Agreement.

(4) Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products[4] is to be incorporated into the Agreement.

(5) Commission Directive 2009/120/EC of 14 September 2009 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as regards advanced therapy medicinal products[5] is to be incorporated into the Agreement.

(6) Directive 2009/35/EC repeals Council Directive 78/25/EEC[6] which is incorporated in the Agreement and is therefore to be repealed under the Agreement,

---

1 OJ L 143, 10.6.2010, p. 18.
2 OJ L 79, 25.3.2009, p. 34.
3 OJ L 109, 30.4.2009, p. 10.
4 OJ L 168, 30.6.2009, p. 33.
5 OJ L 242, 15.9.2009, p. 3.
6 OJ L 11, 14.1.1978, p. 18.

HAS ADOPTED THIS DECISION:

Article 1

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

1. The text of point 4 (Council Directive 78/25/EEC) shall be replaced by the following:

   '**32009 L 0035**: Directive 2009/35/EC of the European Parliament and of the Council of 23 April 2009 on the colouring matters which may be added to medicinal products (OJ L 109, 30.4.2009, p. 10).'

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

   '- **32009 R 0249**: Commission Regulation (EC) No 249/2009 of 23 March 2009 (OJ L 79, 25.3.2009, p. 34).'

3. The following indent shall be added in point 15p (Directive 2001/82/EC of the European Parliament and of the Council):

   '- **32009 L 0053**: Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 (OJ L 168, 30.6.2009, p. 33).'

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

   '- **32009 L 0053**: Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 (OJ L 168, 30.6.2009, p. 33),

   - **32009 L 0120**: Commission Directive 2009/120/EC of 14 September 2009 (OJ L 242, 15.9.2009, p. 3).'

Article 2

The texts of Regulation (EC) No 249/2009 and Directives 2009/35/EC, 2009/53/EC and 2009/120/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 2 July 2011, provided that all the notifications under Article 103(1) of the Agreement have been made to the EEA Joint Committee[*].

[*] No constitutional requirements indicated.

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, 1 July 2011.

For the EEA Joint Committee
The President
Kurt Jäger

The Secretaries
to the EEA Joint Committee
Bergdís Ellertsdóttir Gianluca Grippa