DECISION OF THE EEA JOINT COMMITTEE

No 3/2004

of 6 February 2004

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 172/2003 of 5 December 2003 [1].

(2) Commission Regulation (EC) No 1084/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State [2] is to be incorporated into the Agreement.

(3) Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93 [3] is to be incorporated into the Agreement.

(4) Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use [4] is to be incorporated into the Agreement.

(5) Regulation (EC) No 1084/2003 repeals Commission Regulation (EC) No 541/95 [5], which is incorporated into the Agreement and which is consequently to be repealed under the Agreement.

(6) Regulation (EC) No 1085/2003 repeals Commission Regulation (EC) No 542/95 [6], which is incorporated into the Agreement and which is consequently to be repealed under the Agreement,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 text of points 15j (Commission Regulation (EC) No 541/95) and 15k (Commission Regulation (EC) No 542/95) are deleted.

2. The following is inserted in point 15q (Directive 2001/83/EC of the European Parliament and of the Council):

   ', as amended by:

   — 32003 L 0063: Commission Directive 2003/63/EC of 25 June 2003 (OJ L 159, 27.6.2003, p. 46).'

[1] OJ L 88, 25.3.2004, p. 45.
[2] OJ L 159, 27.6.2003, p. 1.
[3] OJ L 159, 27.6.2003, p. 24.
[4] OJ L 159, 27.6.2003, p. 46.
[5] OJ L 55, 11.3.1995, p. 7.
[6] OJ L 55, 11.3.1995, p. 15.

3. The following points are inserted after point 15q (Directive 2001/83/EC of the European Parliament and of the Council):

'15r. 32003 R 1084: Commission Regulation (EC) No 1084/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State (OJ L 159, 27.6.2003, p. 1).

15s. 32003 R 1085: Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93 (OJ L 159, 27.6.2003, p. 24).'

Article 2

The texts of Regulations (EC) No 1084/2003 and (EC) No 1085/2003 and Directive 2003/63/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 7 February 2004, provided that all the notifications pursuant to 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*.

Done at Brussels, 6 February 2004.

For the EEA Joint Committee

The President

P. WESTERLUND

(*) No constitutional requirements indicated.