

DECISION OF THE EEA JOINT COMMITTEE**No 23/2004****of 19 March 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 3/2004 of 6 February 2004 ⁽¹⁾.
- (2) Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use ⁽²⁾ is to be incorporated into the Agreement.
- (3) Directive 2003/94/EC repeals Commission Directive 91/356/EEC ⁽³⁾, which is incorporated into the Agreement and which is consequently to be repealed under the Agreement,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 following point shall be inserted after point 15s (Commission Regulation (EC) No 1085/2003):
'15t. **32003 L 0094**: Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22).'
2. The text of point 15 (Commission Directive 91/356/EEC) shall be deleted.

Article 2

The texts of Directive 2003/94/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 20 March 2004, provided that all the notifications pursuant to Article 103(1) of the Agreement have been made to the EEA Joint Committee (*).

⁽¹⁾ OJ L 116, 22.4.2004, p. 44.

⁽²⁾ OJ L 262, 14.10.2003, p. 22.

⁽³⁾ OJ L 193, 17.7.1991, p. 30.

(*) 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, 19 March 2004.

For the EEA Joint Committee

The President

P. WESTERLUND
