

## DECISION OF THE EEA JOINT COMMITTEE

No 75/2000

of 2 October 2000

**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 adjusted 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 No 57/2000 of the EEA Joint Committee of 28 June 2000<sup>(1)</sup>.
- (2) Commission Regulation (EC) No 1069/98 of 26 May 1998 amending Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93<sup>(2)</sup> is to be incorporated into the Agreement.
- (3) Commission Regulation (EC) No 1146/98 of 2 June 1998 amending Regulation (EC) No 541/95 concerning the examination of variations in the terms of a marketing authorisation granted by a competent authority of a Member State<sup>(3)</sup> is to be incorporated into the Agreement.
- (4) Council Regulation (EC) No 2743/98 of 14 December 1998 amending Regulation (EC) No 297/95 on fees payable to the European Agency for the Evaluation of Medicinal Products<sup>(4)</sup> is to be incorporated into the Agreement.
- (5) Commission Directive 1999/82/EC of 8 September 1999 amending the Annex to Council Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products<sup>(5)</sup> is to be incorporated into the Agreement.
- (6) Commission Directive 1999/83/EC of 8 September 1999 amending the Annex to Council Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products<sup>(6)</sup> is to be incorporated into the Agreement.

HAS DECIDED AS FOLLOWS:

*Article 1*

The following indents shall be added in point 2 (Council Directive 75/318/EEC) in Chapter XIII of Annex II to the Agreement:

- **399 L 0082:** Commission Directive 1999/82/EC of 8 September 1999 (OJ L 243, 15.9.1999, p. 7),
- **399 L 0083:** Commission Directive 1999/83/EC of 8 September 1999 (OJ L 243, 15.9.1999, p. 9).'

<sup>(1)</sup> OJ L 237, 21.9.2000, p. 73.

<sup>(2)</sup> OJ L 153, 27.5.1998, p. 11.

<sup>(3)</sup> OJ L 159, 3.6.1998, p. 31.

<sup>(4)</sup> OJ L 345, 19.12.1998, p. 3.

<sup>(5)</sup> OJ L 243, 15.9.1999, p. 7.

<sup>(6)</sup> OJ L 243, 15.9.1999, p. 9.

*Article 2*

The following shall be added in point 15h (Council Regulation (EC) No 297/95) in Chapter XIII of Annex II to the Agreement:

‘, as amended by:

- **398 R 2743**: Council Regulation (EC) No 2743/98 of 14 December 1998 (OJ L 345, 19.12.1998, p. 3).’

*Article 3*

The following shall be added in point 15j (Commission Regulation (EC) No 541/95) in Chapter XIII of Annex II to the Agreement:

‘, as amended by:

- **398 R 1146**: Commission Regulation (EC) No 1146/98 of 2 June 1998 (OJ L 159, 3.6.1998, p. 31).’

*Article 4*

The following shall be added in point 15k (Commission Regulation (EC) No 542/95) in Chapter XIII of Annex II to the Agreement:

‘, as amended by:

- **398 R 1069**: Commission Regulation (EC) No 1069/98 of 26 May 1998 (OJ L 153, 27.5.1998, p. 11).’

*Article 5*

The texts of Regulations (EC) No 1069/98 and (EC) No 1146/98, Regulation (EC) No 2743/98 and Directives 1999/82/EC and 1999/83/EC in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Communities*, shall be authentic.

*Article 6*

This Decision shall enter into force on 3 October 2000, provided that all the notifications under Article 103(1) of the Agreement have been made to the EEA Joint Committee(\*).

*Article 7*

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

Done at Brussels, 2 October 2000.

*For the EEA Joint Committee*

*The President*

G. S. GUNNARSSON

---

(\*) No constitutional requirements indicated.