DECISION OF THE EEA JOINT COMMITTEE

No 69/2001

of 19 June 2001

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 No 2/2001 of the Joint Committee of the EEA of 31 January 2001 ([1]).

(2) Commission Directive 2000/38/EC of 5 June 2000 amending Chapter Va (Pharmacovigilance) of Council Directive 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products ([2]) is to be incorporated into the Agreement.

(3) Commission Regulation (EC) No 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for designation of a medical product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and 'clinical superiority' ([3]) is to be incorporated into the Agreement,

HAS DECIDED AS FOLLOWS:

Article 1

The following indent shall be added in point 3 (Second Council Directive 75/319/EEC) in Chapter XIII of Annex II to the Agreement:

'— **32000 L 0038**: Commission Directive 2000/38/EC of 5 June 2000 (OJ L 139, 10.6.2000, p. 28).'

Article 2

The following point shall be inserted after point 15m (Regulation (EC) No 141/2000 of the European Parliament and of the Council) in Chapter XIII of Annex II to the Agreement:

'15n. **32000 R 0847**: Commission Regulation (EC) No 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for designation of a medical product as an orphan medicinal product and definitions of the concepts "similar medicinal product" and "clinical superiority" (OJ L 103, 28.4.2000, p. 5).'

Article 3

The texts of Directive 2000/38/EC and Regulation (EC) No 847/2000 in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Communities* shall be authentic.

([1]) OJ L 66, 8.3.2001, p. 44.
([2]) OJ L 139, 10.6.2000, p. 28.
([3]) OJ L 103, 28.4.2000, p. 5.

Article 4

This Decision shall enter into force on 20 June 2001, provided that all the notifications under Article 103(1) of the Agreement have been made to the EEA Joint Committee (*).

Article 5

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, 19 June 2001.

For the EEA Joint Committee
The President
P. WESTERLUND

(*) No constitutional requirements indicated