DECISION OF THE EEA JOINT COMMITTEE

No 41/2014

of 8 April 2014

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 ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

(1) Commission Implementing Regulation (EU) No 198/2013 of 7 March 2013 on the selection of a symbol for the purpose of identifying medicinal products for human use that are subject to additional monitoring [1] is to be incorporated into the EEA Agreement.

(2) Commission Regulation (EU) No 220/2013 of 13 March 2013 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 EEA Agreement.

(3) Commission Recommendation 2013/172/EU of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union [3] is to be incorporated into the EEA Agreement.

(4) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

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

(1) the following indent is added in point 15h (Council Regulation (EC) No 297/95):

'— **32013 R 0220**: Commission Regulation (EU) No 220/2013 of 13 March 2013 (OJ L 70, 14.3.2013, p. 1).';

(2) the following point is inserted after point 15zn (Directive 2010/53/EU of the European Parliament and of the Council):

'15zo. **32013 R 0198**: Commission Implementing Regulation (EU) No 198/2013 of 7 March 2013 on the selection of a symbol for the purpose of identifying medicinal products for human use that are subject to additional monitoring (OJ L 65, 8.3.2013, p. 17).'

Article 2

The following is inserted after point 9 (Commission Regulation (EU) No 207/2012) of Chapter XXX of Annex II to the EEA Agreement:

'*ACTS OF WHICH THE CONTRACTING PARTIES SHALL TAKE NOTE*

The Contracting Parties take note of the content of the following acts:

1. **32013 H 0172**: Commission Recommendation 2013/172/EU of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union (OJ L 99, 9.4.2013, p. 17).'

Article 3

The texts of Implementing Regulation (EU) No 198/2013 and Regulation (EU) No 220/2013 and Recommendation 2013/172/EU in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

[1] OJ L 65, 8.3.2013, p. 17.
[2] OJ L 70, 14.3.2013, p. 1.
[3] OJ L 99, 9.4.2013, p. 17.

Article 4

This Decision shall enter into force on 9 April 2014, provided that all the notifications under Article 103(1) of the EEA Agreement have been made (*).

Article 5

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, 8 April 2014.

For the EEA Joint Committee
The President
Gianluca GRIPPA

(*) No constitutional requirements indicated.