DECISION OF THE EEA JOINT COMMITTEE

No 88/2015

of 30 April 2015

amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement [2016/1271]

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 Delegated Regulation (EU) No 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use [1] is to be incorporated into the EEA Agreement.

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

HAS ADOPTED THIS DECISION:

Article 1

The following point is inserted after point 15qc (Commission Delegated Regulation (EU) No 357/2014) of Chapter XIII of Annex II to the EEA Agreement:

'15qd. **32014 R 1252**: Commission Delegated Regulation (EU) No 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use (OJ L 337, 25.11.2014, p. 1).'

Article 2

The text of Delegated Regulation (EU) No 1252/2014 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 1 May 2015, provided that all the notifications under Article 103(1) of the EEA Agreement have been made (*).

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, 30 April 2015.

For the EEA Joint Committee

The President

Gianluca GRIPPA

[1] OJ L 337, 25.11.2014, p. 1.

(*) No constitutional requirements indicated.