

**DECISION OF THE EEA JOINT COMMITTEE****No 15/2015****of 25 February 2015****amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement [2016/503]**

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 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council <sup>(1)</sup> 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 15zp (Commission Implementing Decision 2012/707/EU) of Chapter XIII of Annex II to the EEA Agreement:

- '15zq. **32012 R 0520**: Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council (OJ L 159, 20.6.2012, p. 5).'

*Article 2*The text of Implementing Regulation (EU) No 520/2012 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 26 February 2015, provided that all the notifications under Article 103(1) of the EEA Agreement have been made (\*).

<sup>(1)</sup> OJ L 159, 20.6.2012, p. 5.

(\*) Constitutional requirements indicated.

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*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, 25 February 2015.

*For the EEA Joint Committee*  
*The President*  
Gianluca GRIPPA

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