

## DECISION OF THE EEA JOINT COMMITTEE

No 263/2014

of 12 December 2014

**amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement [2015/2130]**

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 357/2014 of 3 February 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council as regards situations in which post-authorisation efficacy studies may be required <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 15qb (Commission Implementing Decision 2012/715/EU) of Chapter XIII of Annex II to the EEA Agreement:

'15qc. **32014 R 0357**: Commission Delegated Regulation (EU) No 357/2014 of 3 February 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council as regards situations in which post-authorisation efficacy studies may be required (OJ L 107, 10.4.2014, p. 1).'

*Article 2*

The text of Delegated Regulation (EU) No 357/2014 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 13 December 2014, 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, 12 December 2014.

*For the EEA Joint Committee**The President*

Kurt JÄGER

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<sup>(1)</sup> OJ L 107, 10.4.2014, p. 1.

(\*) No constitutional requirements indicated.