

DECISION OF THE EEA JOINT COMMITTEE

No 162/2013

of 8 October 2013

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 Decision 2012/715/EU of 22 November 2012 establishing a list of third countries with a regulatory framework applicable to active substances for medicinal products for human use and the respective control and enforcement activities ensuring a level of protection of public health equivalent to that in the Union, in accordance with Directive 2001/83/EC of the European Parliament and of the Council ⁽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 15qa (Commission Implementing Decision 2013/51/EU) of Chapter XIII of Annex II to the EEA Agreement:

- '15qb. **32012 D 0715**: Commission Implementing Decision 2012/715/EU of 22 November 2012 establishing a list of third countries with a regulatory framework

applicable to active substances for medicinal products for human use and the respective control and enforcement activities ensuring a level of protection of public health equivalent to that in the Union, in accordance with Directive 2001/83/EC of the European Parliament and of the Council (OJ L 325, 23.11.2012, p. 15).'

Article 2

The texts of Implementing Decision 2012/715/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.

Article 3

This Decision shall enter into force on 9 October 2013, 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, 8 October 2013.

For the EEA Joint Committee

The President

Thórir IBSEN

⁽¹⁾ OJ L 325, 23.11.2012, p. 15.

^(*) No constitutional requirements indicated.