

## DECISION OF THE EEA JOINT COMMITTEE

No 161/2013

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 2013/51/EU of 23 January 2013 on the assessment of a third country's regulatory framework applicable to active substances of medicinal products for human use and of the respective control and enforcement activities pursuant to Article 111b of 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 15q (Directive 2001/83/EC of the European Parliament and of the Council) of Chapter XIII of Annex II to the EEA Agreement:

'15qa. **32013 D 0051**: Commission Implementing Decision 2013/51/EU of 23 January 2013 on the assessment of a third country's regulatory framework applicable

to active substances of medicinal products for human use and of the respective control and enforcement activities pursuant to Article 111b of Directive 2001/83/EC of the European Parliament and of the Council (OJ L 21, 24.1.2013, p. 36).'

*Article 2*

The text of Implementing Decision 2013/51/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

<sup>(1)</sup> OJ L 21, 24.1.2013, p. 36.

(\*) No constitutional requirements indicated.