

DECISION OF THE EEA JOINT COMMITTEE**No 213/2015****of 25 September 2015****amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement [2017/520]**

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) Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC ⁽¹⁾ is to be incorporated into the EEA Agreement.
- (2) Regulation (EU) No 536/2014 repeals Directive 2001/20/EC of the European Parliament and of the Council ⁽²⁾, which is incorporated into the EEA Agreement, and which is consequently to be repealed under the EEA Agreement with effect from 6 months after the publication of the notice referred to in Article 82(3) of Regulation (EU) No 536/2014, but in any event no earlier than 28 May 2016.
- (3) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Chapter XIII of Annex II to the EEA Agreement shall be amended as follows:

- (1) the following point is inserted after point 17 (Commission Directive (EU) 2015/566):

'18. **32014 R 0536**: Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).';

- (2) the text of point 15o (Directive 2001/20/EC of the European Parliament and of the Council) shall be deleted with effect from 6 months after the publication of the notice referred to in Article 82(3) of Regulation (EU) No 536/2014, but in any event no earlier than 28 May 2016.

Article 2

The text of Regulation (EU) No 536/2014 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 26 September 2015, provided that all the notifications under Article 103(1) of the EEA Agreement have been made (*).

⁽¹⁾ OJ L 158, 27.5.2014, p. 1.

⁽²⁾ OJ L 121, 1.5.2001, p. 34.

(*) Constitutional requirements indicated.

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 September 2015.

For the EEA Joint Committee
The President
Ingrid SCHULERUD
