

DECISION OF THE EEA JOINT COMMITTEE**No 48/2018****of 23 March 2018****amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement
[2020/65]**

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 Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use ⁽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 is inserted after point 15qd (Commission Delegated Regulation (EU) No 1252/2014) of Chapter XIII of Annex II to the EEA Agreement:

- '15qe. **32017 L 1572**: Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use (OJ L 238, 16.9.2017, p. 44).

The provisions of the Directive shall, for the purposes of this Agreement, be read with the following adaptation:

The inspections in Liechtenstein shall be performed by the Swiss inspectorate on behalf of Liechtenstein on the basis of the agreement between Swissmedic and Amt für Gesundheit (Verwaltungsvereinbarung betreffend Inspektionen).'

*Article 2*The text of Directive (EU) 2017/1572 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 24 March 2018, provided that all the notifications under Article 103(1) of the EEA Agreement have been made (*).

⁽¹⁾ OJ L 238, 16.9.2017, p. 44.

(*) 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, 23 March 2018.

For the EEA Joint Committee

The President

Claude MAERTEN
