

**DECISION OF THE EEA JOINT COMMITTEE**  
**No 116/2019**

**of 8 May 2019**

**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 Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use<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 15qe (Commission Directive (EU) 2017/1572) of Chapter XIII of Annex II to the EEA Agreement:

‘15qf. **32016 R 0161**: Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).’

*Article 2*

The text of Delegated Regulation (EU) 2016/161 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 1 June 2019, provided that all the notifications under Article 103(1) of the EEA Agreement have been made\*.

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<sup>1</sup> OJ L 32, 9.2.2016, p. 1.

\* [No 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, 8 May 2019.

*For the EEA Joint Committee  
The President*

*Claude Maerten*

*The Secretaries  
to the EEA Joint Committee*

*Hege M. Hoff* *Mikołaj Karłowski*

Provisional