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 [2022/2014]

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 ([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 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 *.

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

([1]) OJ L 32, 9.2.2016, p. 1.
(*) No constitutional requirements indicated.