

**DECISION OF THE EEA JOINT COMMITTEE**  
**No 238/2018**

**of 5 December 2018**

**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 Regulation (EU) 2018/781 of 29 May 2018 amending Regulation (EC) No 847/2000 as regards the definition of the concept ‘similar medicinal product’<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 is added in point 15n (Commission Regulation (EC) No 847/2000) of Chapter XIII of Annex II to the EEA Agreement:

‘, as amended by:

- **32018 R 0781**: Commission Regulation (EU) 2018/781 of 29 May 2018 (OJ L 132, 30.5.2018, p. 1).’

*Article 2*

The text of Commission Regulation (EU) 2018/781 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 6 December 2018, 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, 5 December 2018.

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<sup>1</sup> OJ L 132, 30.5.2018, p. 1.

\* No constitutional requirements indicated.

*For the EEA Joint Committee  
The President*

*Oda Helen Sletnes*

*The Secretaries  
To the EEA Joint Committee*

*Hege M. Hoff    Mikołaj Karłowski*

Provisional text