

**DECISION OF THE EEA JOINT COMMITTEE**  
**No 239/2018**

**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 Delegated Regulation (EU) 2018/1298 of 11 July 2018 amending Regulation (EU) No 658/2014 of the European Parliament and of the Council as regards the adjustment to the inflation rate of the amounts of the fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect 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 indent is added in point 16 (Regulation (EU) No 658/2014 of the European Parliament and of the Council) of Chapter XIII of Annex II to the EEA Agreement:

- ‘- **32018 R 1298**: Commission Delegated Regulation (EU) 2018/1298 of 11 July 2018 (OJ L 244, 28.9.2018, p. 1).’

*Article 2*

The text of Delegated Regulation (EU) 2018/1298 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*.

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<sup>1</sup> OJ L 244, 28.9.2018, p. 1.

\* No constitutional requirements indicated.

Done at Brussels, 5 December 2018.

*For the EEA Joint Committee  
The President*

*Oda Helen Sletnes*

*The Secretaries  
To the EEA Joint Committee*

*Hege M. Hoff    Mikołaj Karłowksi*

Provisional text