

**DECISION OF THE EEA JOINT COMMITTEE No 305/2022**  
**of 9 December 2022**  
**amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement**  
**[2023/1247]**

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 Implementing Regulation (EU) 2021/1281 of 2 August 2021 laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and on the format, content and summary of the pharmacovigilance system master file for veterinary medicinal products <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 22i (Regulation (EU) 2022/839 of the European Parliament and of the Council) of Chapter XIII of Annex II to the EEA Agreement:

‘22j. **32021 R 1281**: Commission Implementing Regulation (EU) 2021/1281 of 2 August 2021 laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and on the format, content and summary of the pharmacovigilance system master file for veterinary medicinal products (OJ L 279, 3.8.2021, p. 15).’

*Article 2*

The text of Implementing Regulation (EU) 2021/1281 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 10 December 2022, 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, 9 December 2022.

*For the EEA Joint Committee*  
*The President*  
Kristján Andri STEFÁNSSON

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<sup>(1)</sup> OJ L 279, 3.8.2021, p. 15.

\* No constitutional requirements indicated.