DECISION OF THE EEA JOINT COMMITTEE
No 173/2025

of 11 July 2025

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 Implementing Regulation (EU) 2024/1381 of 23 May 2024 laying down, pursuant to Regulation (EU) 2021/2282 on health technology assessment, procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of joint clinical assessments of medicinal products for human use at Union level, as well as templates for those joint clinical assessments[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

Annex II to the EEA Agreement is amended as follows:

1. The following point is inserted after point 23 (Regulation (EU) 2021/2282 of the European Parliament and of the Council) of Chapter XIII:

'23a. **32024 R 1381**: Commission Implementing Regulation (EU) 2024/1381 of 23 May 2024 laying down, pursuant to Regulation (EU) 2021/2282 on health technology assessment, procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of joint clinical assessments of medicinal products for human use at Union level, as well as templates for those joint clinical assessments (OJ L, 2024/1381, 24.5.2024).'

2. The following point is inserted after point 17 (Regulation (EU) 2021/2282 of the European Parliament and of the Council) of Chapter XXX:

'17a. **32024 R 1381**: Commission Implementing Regulation (EU) 2024/1381 of 23 May 2024 laying down, pursuant to Regulation (EU) 2021/2282 on health technology assessment, procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of joint clinical assessments of medicinal products for human use at Union level, as well as templates for those joint clinical assessments (OJ L, 2024/1381, 24.5.2024).'

[1] OJ L, 2024/1381, 24.5.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/1381/oj

Article 2

The text of Implementing Regulation (EU) 2024/1381 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 12 July 2025, 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, 11 July 2025.

For the EEA Joint Committee
The President

Kristján Andri Stefánsson

The Secretaries
To the EEA Joint Committee

Knut Hermansen *Matúš Minárik*

* No constitutional requirements indicated.