DECISION OF THE EEA JOINT COMMITTEE No 28/2022

of 4 February 2022

amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement [2022/1076]

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 Decision (EU) 2021/1240 of 13 July 2021 on the compliance of the EU portal and the EU database for clinical trials of medicinal products for human use with the requirements referred to in Article 82(2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council (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 18a (Commission Delegated Regulation (EU) 2017/1569) of Chapter XIII of Annex II to the EEA Agreement:

'18b. **32021 D 1240**: Commission Decision (EU) 2021/1240 of 13 July 2021 on the compliance of the EU portal and the EU database for clinical trials of medicinal products for human use with the requirements referred to in Article 82(2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council (OJ L 275, 31.7.2021, p. 1).'

Article 2

The text of Decision (EU) 2021/1240 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 5 February 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, 4 February 2022.

For the EEA Joint Committee
The President
Nicolas VON LINGEN

⁽¹⁾ OJ L 275, 31.7.2021, p. 1.

^(*) No constitutional requirements indicated.