

DECISION OF THE EEA JOINT COMMITTEE
No 237/2021

of 24 September 2021

**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) 2017/556 of 24 March 2017 on the detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council¹ is to be incorporated into the EEA Agreement.
- (2) Implementing Regulation (EU) 2017/556 repeals Commission Directive 2005/28/EC², which is incorporated into the EEA Agreement and which is consequently to be repealed under the EEA Agreement with effect from the date referred to in the second paragraph of Article 17 of Implementing Regulation (EU) 2017/556.
- (3) Commission Directive (EU) 2017/1572³, incorporated into the EEA Agreement by Joint Committee Decision No 48/2018⁴, repeals Commission Directive 2003/94/EC⁵, which is incorporated into the EEA Agreement and which is consequently to be repealed under the EEA Agreement with effect from the date referred to in the first paragraph of Article 15 of Directive (EU) 2017/1572.
- (4) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Chapter XIII of Annex II to the EEA Agreement shall be amended as follows:

1. The following is inserted after point 20 (Regulation (EU) 2020/1043 of the European Parliament and of the Council) of Chapter XIII of Annex II to the EEA Agreement:
 21. **32017 R 0556**: Commission Implementing Regulation (EU) 2017/556 of 24 March 2017 on the detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council (OJ L 80, 25.3.2017, p. 7).’

¹ OJ L 80, 25.3.2017, p. 7.

² OJ L 91, 9.4.2005, p. 13.

³ OJ L 238, 16.9.2017, p. 44.

⁴ OJ L 26, 30.1.2020, p. 26.

⁵ OJ L 262, 14.10.2003, p. 22.

2. The text of point 15t (Commission Directive 2003/94/EC) shall be deleted with effect from the date referred to in the first paragraph of Article 15 of Directive (EU) 2017/1572.
3. The text of point 15zf (Commission Directive 2005/28/EC) shall be deleted with effect from the date referred to in the second paragraph of Article 17 of Implementing Regulation (EU) 2017/556.

Article 2

The text of Implementing Regulation (EU) 2017/556 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 25 September 2021, 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, 24 September 2021.

*For the EEA Joint Committee
The President*

Rolf Einar Fife

*The Secretaries
To the EEA Joint Committee*

Hege M. Hoff

Mikołaj Karłowski

* No constitutional requirements indicated.