2026/952

21.5.2026

DECISION OF THE EEA JOINT COMMITTEE No 22/2026

of 6 February 2026

amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement [2026/952]

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) Regulation (EU) 2023/1182 of the European Parliament and of the Council of 14 June 2023 on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC ([1]) is to be incorporated into the EEA Agreement.

(2) Directive (EU) 2022/642 of the European Parliament and of the Council of 12 April 2022 amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta ([2]) is to be incorporated into the EEA Agreement.

(3) 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 is amended as follows:

1. Point 15q (Directive 2001/83/EC of the European Parliament and of the Council) is amended as follows:

   (i) the following indents are added:

   '— **32022 L 0642**: Directive (EU) 2022/642 of the European Parliament and of the Council of 12 April 2022 (OJ L 118, 20.4.2022, p. 4),

   — **32023 R 1182**: Regulation (EU) 2023/1182 of the European Parliament and of the Council of 14 June 2023 (OJ L 157, 20.6.2023, p. 1).';

   (ii) adaptations (b) to (d) shall be renumbered as adaptations (c) to (e);

   (iii) the following adaptation is inserted after adaptation (a):

   '(b) Article 5a, Article 8(2a), Article 8(2b), second subparagraph of Article 20 and Article 126c shall not apply to the EFTA States.'.

2. The following is inserted after point 23b (Commission Implementing Regulation (EU) 2025/117):

   '24. **32023 R 1182**: Regulation (EU) 2023/1182 of the European Parliament and of the Council of 14 June 2023 on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC (OJ L 157, 20.6.2023, p. 1).

   The Regulation shall, for the purposes of this Agreement, be read with the following adaptation:

   Article 1(3), Articles 3–6 and Articles 8–12 shall not apply to the EFTA States.'

([1]) OJ L 157, 20.6.2023, p. 1.
([2]) OJ L 118, 20.4.2022, p. 4.

Article 2

The texts of Regulation (EU) 2023/1182 and Directive (EU) 2022/642 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 7 February 2026, 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, 6 February 2026.

For the EEA Joint Committee
The President
Nicolas VON LINGEN

(*) No constitutional requirements indicated.