2024/1844

5.7.2024

COUNCIL DECISION (EU) 2024/1844

of 25 June 2024

on the position to be adopted, on behalf of the European Union, within the EEA Joint Committee concerning the amendment of Annex II (Technical regulations, standards, testing and certification) and Protocol 37 containing the list provided for in Article 101 to the EEA Agreement (Reinforced role for EMA in crisis preparedness and management for medicinal products and medical devices)

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (c) in conjunction with Article 218(9) thereof,

Having regard to Council Regulation (EC) No 2894/94 of 28 November 1994 concerning arrangements for implementing the Agreement on the European Economic Area [1], and in particular Article 1(3) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The Agreement on the European Economic Area [2] ('the EEA Agreement') entered into force on 1 January 1994.

(2) Pursuant to Article 98 of the EEA Agreement, the EEA Joint Committee may decide to amend, inter alia, Annex II (Technical Regulations, standards, testing and certification) ('Annex II') and Protocol 37 containing the list provided for in Article 101 ('Protocol 37') to the EEA Agreement.

(3) Regulation (EU) 2022/123 of the European Parliament and of the Council [3] should be incorporated into the EEA Agreement.

(4) Annex II and Protocol 37 to the EEA Agreement should therefore be amended accordingly.

(5) The position of the Union within the EEA Joint Committee should therefore be based on the attached draft Decision,

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted, on behalf of the Union, within the EEA Joint Committee on the proposed amendment of Annex II (Technical Regulations, standards, testing and certification) and Protocol 37 containing the list provided for in Article 101 to the EEA Agreement, shall be based on the draft Decision of the EEA Joint Committee attached to this Decision.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Luxembourg, 25 June 2024.

For the Council

The President

H. LAHBIB

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[1] OJ L 305, 30.11.1994, p. 6.
[2] OJ L 1, 3.1.1994, p. 3.
[3] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).

DRAFT

DECISION OF THE EEA JOINT COMMITTEE NO …

of …

amending Annex II (Technical regulations, standards, testing and certification) and Protocol 37 containing the list provided for in Article 101 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) Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices ([1]), as corrected by OJ L 71, 9.3.2023, p. 37, is to be incorporated into the EEA Agreement.

(2) Annex II and Protocol 37 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 two paragraphs are inserted after the eighteenth paragraph of the introductory part:

'The EFTA States shall be fully associated with the work of the Executive Steering Group on Shortages and Safety of Medicinal Products as set up by Article 3 of Regulation (EU) 2022/123 of the European Parliament and of the Council and shall have the same rights and obligations within it as the EU Member States, except for the right to vote.

The EFTA States shall be fully associated with the work of the Emergency Task Force as set up by Article 15 of Regulation (EU) 2022/123 of the European Parliament and of the Council and shall have the same rights and obligations within it as the EU Member States, except for the right to vote.'.

2. The text of point 15ze is replaced by the following:

'**32022 R 0123**: Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1), as corrected by OJ L 71, 9.3.2023, p. 37.

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

In Article 34(2), the words "or Article 53 of the EEA Agreement" shall be inserted after the words "Article 101 TFEU".'.

Article 2

The following point is inserted after point 15 (Commission Implementing Regulation (EU) 2020/1207) of Chapter XXX of Annex II to the EEA Agreement:

'16. **32022 R 0123**: Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1), as corrected by OJ L 71, 9.3.2023, p. 37.

Modalities for the association of the EFTA States in accordance with Article 101 of this Agreement:

The EFTA States shall be fully associated with the work of the Executive Steering Group on Shortages of Medical Devices and shall have the same rights and obligations within it as the EU Member States, except for the right to vote.

([1]) OJ L 20, 31.1.2022, p. 1.

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

In Article 34(2), the words "or Article 53 of the EEA Agreement" shall be inserted after the words "Article 101 TFEU".'.

Article 3

The text of point 30 of Protocol 37 to the EEA Agreement is replaced by the following:

'Executive Steering Group on Shortages and Safety of Medicinal Products, Emergency Task Force and Executive Steering Group on Shortages of Medical Devices (Regulation (EU) 2022/123 of the European Parliament and of the Council).'.

Article 4

The text of Regulation (EU) 2022/123, as corrected by OJ L 71, 9.3.2023, p. 37, 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 5

This Decision shall enter into force on …, provided that all the notifications under Article 103(1) of the EEA Agreement have been made (*).

Article 6

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, …

For the EEA Joint Committee

The President

The Secretaries

To the EEA Joint Committee

(*) [No constitutional requirements indicated.] [Constitutional requirements indicated.]