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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	11 June 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2024) 242 final - Annex
Subject:	ANNEX to the Proposal for a COUNCIL DECISION on the position to be adopted, on behalf of the European Union, within the EEA Joint Committee concerning an amendment to 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)

Delegations will find attached document COM(2024) 242 final - Annex.

Encl.: COM(2024) 242 final - Annex

EUROPEAN
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Brussels, 11.6.2024
COM(2024) 242 final

ANNEX

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to the

Proposal for a

COUNCIL DECISION

on the position to be adopted, on behalf of the European Union, within the EEA Joint Committee concerning an amendment to 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)

ANNEX

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.'

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

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.

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 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, […].

For the EEA Joint Committee

The President

[…]

The Secretaries
To the EEA Joint Committee
[…]

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