



Brussels, 20 November 2024  
(OR. en)

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**Interinstitutional File:  
2024/0298(NLE)**

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**15947/24  
ADD 1**

**AELE 102  
N 99  
FL 52  
ISL 60  
MI 953  
SAN 663  
RELEX 1483**

**COVER NOTE**

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From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 20 November 2024

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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No. Cion doc.: COM(2024) 540 FV2

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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), Annex X (Services in general) and Protocol 37 (containing the list provided for in Article 101) to the EEA Agreement (Health Technology Assessment)

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Delegations will find attached document COM(2024) 540 FV2.

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Encl.: COM(2024) 540 FV2



Brussels, 20.11.2024  
COM(2024) 540 final

ANNEX

**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), Annex X (Services in general) and Protocol 37 (containing the list provided for in Article 101) to the EEA Agreement**

**(Health Technology Assessment)**

## ANNEX

### DRAFT DECISION OF THE EEA JOINT COMMITTEE

No [...]

of [...]

#### **amending Annex II (Technical regulations, standards, testing and certification), Annex X (Services in general) 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) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU<sup>1</sup> is to be incorporated into the EEA Agreement.
- (2) Annexes II and X and Protocol 37 to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

#### *Article 1*

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

1. The following is inserted after the seventeenth paragraph of the introductory part of Chapter XIII:

‘The EFTA States shall be fully associated with the work of the Member State Coordination Group on Health Technology Assessment, including its subgroups, as set up by Article 3 of Regulation (EU) 2021/2282 of the European Parliament and of the Council and shall have the same rights and obligations within it as the EU Member States. By way of derogation from the previous sentence, the members designated by the EFTA States shall not be entitled to participate in votes, however where voting takes place, positions of the members designated by the EFTA States shall be recorded separately upon their request.

Where consensus cannot be reached, pursuant to Article 12(2) of Regulation (EU) 2021/2282, divergent scientific opinions by the EFTA States, including the scientific grounds on which those opinions are based, shall be incorporated in the reports.’
2. The following is inserted after point 22g (Commission Delegated Regulation (EU) 2021/1760) of Chapter XIII:

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<sup>1</sup> OJ L 458, 22.12.2021, p. 1.

‘23. **32021 R 2282**: Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, p. 1).

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

Paragraph 4(a) of Protocol 1 to this Agreement shall not apply to Article 3.’

3. The following is inserted in the introductory part of Chapter XXX:

‘The EFTA States shall be fully associated with the work of the Member State Coordination Group on Health Technology Assessment, including its subgroups, as set up by Article 3 of Regulation (EU) 2021/2282 of the European Parliament and of the Council and shall have the same rights and obligations within it as the EU Member States. By way of derogation from the previous sentence, the members designated by the EFTA States shall not be entitled to participate in votes, however where voting takes place, the positions of the members designated by the EFTA States shall be recorded separately upon their request.

Where a consensus cannot be reached, pursuant to Article 12(2) of Regulation (EU) 2021/2282, divergent scientific opinions by the EFTA States, including the scientific grounds on which those opinions are based, shall be incorporated in the reports.’

4. The following point is inserted after point 15 (Commission Implementing Regulation (EU) 2020/1207) of Chapter XXX:

‘16. **32021 R 2282**: Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, p. 1).

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

Paragraph 4(a) of Protocol 1 to this Agreement shall not apply to Article 3.’

#### *Article 2*

The following is added in point 2 (Directive 2011/24/EU of the European Parliament and of the Council) of Annex X to the EEA Agreement:

‘, as amended by:

- **32021 R 2282**: Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 (OJ L 458, 22.12.2021, p. 1).’

#### *Article 3*

The following point is inserted in Protocol 37 to the EEA Agreement:

‘47. Member State Coordination Group on Health Technology Assessment (Regulation (EU) 2021/2282 of the European Parliament and of the Council).’

#### *Article 4*

The text of Regulation (EU) 2021/2282 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*

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