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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject:	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 Annex XVII (Intellectual Property) to the EEA Agreement (Paediatric Regulation)

COUNCIL DECISION (EU) 2017/…

of …

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 Annex XVII (Intellectual Property)
to the EEA Agreement (Paediatric Regulation)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 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,

[1] OJ L 305, 30.11.1994, p. 6.

Whereas:

(1) The Agreement on the European Economic Area[1] ('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) and Annex XVII (Intellectual Property) to the EEA Agreement.

(3) Regulation (EC) No 1901/2006 of the European Parliament and of the Council[2] is to be incorporated into the EEA Agreement.

(4) Regulation (EC) No 1902/2006 of the European Parliament and of the Council[3] is to be incorporated into the EEA Agreement.

(5) Regulation (EC) No 469/2009 of the European Parliament and of the Council[4] is to be incorporated into the EEA Agreement.

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1 OJ L 1, 3.1.1994, p. 3.

2 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

3 Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20 December 2006 amending Regulation 1901/2006 on medicinal products for paediatric use (OJ L 378, 27.12.2006, p. 20).

4 Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 1).

(6) Commission Regulation (EU) No 488/2012[1] is to be incorporated into the EEA Agreement.

(7) Regulation (EC) No 469/2009 repeals Council Regulation (EEC) No 1768/92[2], which has been incorporated into the EEA Agreement and which is therefore to be repealed under the EEA Agreement.

(8) Commission Regulation (EC) No 658/2007[3] lays down rules concerning the application of financial penalties to the holders of marketing authorisations granted under Regulation (EC) No 726/2004. Once the Commission has granted a marketing authorisation, the EFTA States should simultaneously take corresponding decisions within 30 days from the grant. Due to the special circumstances, namely, that the Commission grants marketing authorisations, that the infringements affect the Union and its interests, and the complex and technical nature of the infringement procedures, the EFTA Surveillance Authority should cooperate closely with the Commission and await the Commission's assessment and proposal for action before taking a decision regarding the application of financial penalties to the holders of marketing authorisations established in an EFTA State.

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1 Commission Regulation (EU) No 488/2012 of 8 June 2012 amending Commission Regulation (EC) No 658/2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 150, 9.6.2012, p. 68).

2 OJ L 182, 2.7.1992, p. 1.

3 Commission Regulation (EC) No 658/2007 of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 155, 15.6.2007, p. 10).

(9) Annex II (Technical Regulations, Standards, Testing and Certification) and Annex XVII (Intellectual Property) to the EEA Agreement should therefore be amended accordingly.

(10) 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 to Annex II (Technical Regulations, Standards, Testing and Certification) and Annex XVII (Intellectual Property) 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 Brussels,

For the Council
The President

DRAFT

DECISION OF THE EEA JOINT COMMITTEE
No …/2017

of …

amending Annex II
(Technical Regulations, Standards, Testing and Certification)
and Annex XVII (Intellectual Property)
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 (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1] is to be incorporated into the EEA Agreement.

(2) Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20 December 2006 amending Regulation 1901/2006 on medicinal products for paediatric use[2] is to be incorporated into the EEA Agreement.

(3) Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (Codified version)[3] is to be incorporated into the EEA Agreement.

(4) Commission Regulation (EU) No 488/2012 of 8 June 2012 amending Commission Regulation (EC) No 658/2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council[4], as corrected by OJ L 338, 12.12.2012, p. 44, is to be incorporated into the EEA Agreement.

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1 OJ L 378, 27.12.2006, p. 1.
2 OJ L 378, 27.12.2006, p. 20.
3 OJ L 152, 16.6.2009, p. 1.
4 OJ L 150, 9.6.2012, p. 68.

(5) Regulation (EC) No 469/2009 repeals Council Regulation (EEC) No 1768/92[1], which has been incorporated into the EEA Agreement and which is therefore to be repealed under the EEA Agreement.

(6) Commission Regulation (EC) No 658/2007 lays down rules concerning the application of financial penalties to the holders of marketing authorisations granted under Regulation (EC) No 726/2004. Once the Commission has granted a marketing authorisation, the EFTA States should simultaneously take corresponding decisions within 30 days from the grant. Due to the special circumstances, notably that the Commission grants marketing authorisations, that the infringements affect the Union and its interests and the complex and technical nature of the infringement procedures, the EFTA Surveillance Authority should cooperate closely with the Commission and await the Commission's assessment and proposal for action before taking a decision regarding financial penalties to the holders of marketing authorisations established in an EFTA State.

(7) Annexes II and XVII to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

[1] OJ L 182, 2.7.1992, p. 1.

Article 1

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

1. The following text is inserted after the words ‘Committee on Orphan Medicinal Products (COMP)’ in the 13th paragraph of the introductory text:

   ‘, the Paediatric Committee’

2. The following indent is added in points 15q (Directive 2001/83/EC of the European Parliament and of the Council) and 15zb (Regulation (EC) No 726/2004 of the European Parliament and of the Council):

   ‘- **32006 R 1901**: Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 (OJ L 378, 27.12.2006, p. 1).’

3. The adaptation text of point 15zb (Regulation (EC) No 726/2004 of the European Parliament and of the Council) is replaced by the following:

   ‘The powers vested in the European Commission in relation to the infringement procedure foreseen in Article 84(3), including the power to impose financial penalties on the holders of marketing authorisations, shall, in the cases where the marketing authorisation holder is established in an EFTA State, be carried out by the EFTA Surveillance Authority in close cooperation with the Commission. Before the EFTA Surveillance Authority takes a decision regarding financial penalties, the Commission shall provide it with its assessment and a proposal on how to act.’

4. The text of point 15zj (Commission Regulation (EC) No 658/2007) is replaced by the following:

‘**32007 R 0658**: Commission Regulation (EC) No 658/2007 of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 155, 15.6.2007, p. 10), as amended by:

– **32012 R 0488**: Commission Regulation (EU) No 488/2012 of 8 June 2012 (OJ L 150, 9.6.2012, p. 68), as corrected by OJ L 338, 12.12.2012, p. 44.

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

The powers vested in the European Commission in relation to the infringement procedure, including the power to impose financial penalties on the holders of marketing authorisations, shall, in the cases where the marketing authorisation holder is established in an EFTA State, be carried out by the EFTA Surveillance Authority in close cooperation with the Commission. Before the EFTA Surveillance Authority takes a decision regarding financial penalties, the Commission shall provide it with its assessment and a proposal on how to act.’

5. The following point is inserted after point 15zo (Commission Implementing Regulation (EU) No 198/2013):

‘15zp. **32006 R 1901**: Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1), as amended by:

– **32006 R 1902**: Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20 December 2006 (OJ L 378, 27.12.2006, p. 20).

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

(a) The application of Article 36(3) shall not be made dependent on an authorisation of the medicinal product in Liechtenstein.

(b) The powers vested in the European Commission in relation to the infringement procedure foreseen in Article 49(3), including the power to impose financial penalties on the holders of marketing authorisations, shall, in the cases where the marketing authorisation holder is established in an EFTA State, be carried out by the EFTA Surveillance Authority in close cooperation with the Commission. Before the EFTA Surveillance Authority takes a decision regarding financial penalties, the Commission shall provide it with its assessment and a proposal on how to act.’.

Article 2

The text of point 6 (Council Regulation (EEC) No 1768/92) of Annex XVII to the EEA Agreement is replaced by the following:

‘**32009 R 0469**: Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (Codified version) (OJ L 152, 16.6.2009, p. 1).’

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

(a) The following paragraphs shall be added to Article 7:

‘6. Paragraph 5 shall not apply to the EFTA States.

7. Notwithstanding paragraph 4, for five years following the entry into force of Regulation (EC) No 1901/2006 in the EFTA State concerned, the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry of the certificate.’;

(b) The following paragraphs shall be added to Article 21:

‘3. An application for an extension of the duration of a certificate can only be granted in an EFTA State where the certificate expires less than 6 months prior to the entry into force of Regulation (EC) No 1901/2006 in the EFTA state concerned. In cases where the certificate expires prior to the entry into force of Regulation (EC) No 1901/2006 in the EFTA state concerned, the extension shall take effect only with respect to the time following after both such entry into force in the EFTA state concerned and the date of the publication of the application for the extension. However, paragraph 3 of Article 13 shall apply as to the calculation of the duration of the extension.

4. Notwithstanding paragraph 7 of Article 7, in cases where a certificate expires earlier than seven months after the entry into force of Regulation (EC) No 1901/2006 in the EFTA state concerned, the application for an extension of the duration of a certificate shall be lodged no later than one month after such entry into force in the EFTA state concerned. In these cases the extension takes effect only with respect to the time following the date of publication of the application for an extension. However, paragraph 3 of Article 13 shall apply as to the calculation of the duration of the extension.

5. An application for an extension of the duration of a certificate lodged in accordance with paragraphs 3 and 4 shall not prevent any third party who, between the expiry of the certificate and the publication of the application for an extension of the duration of the certificate, in good faith has commercially used the invention or made serious preparation for such use, to continue such use.’;

(c) In view of the patent union between Liechtenstein and Switzerland, Liechtenstein shall not deliver any supplementary protection certificates for medicinal products as laid down in this Regulation.

Article 3

The texts of Regulations (EC) No 1901/2006, (EC) No 1902/2006, (EC) No 469/2009 and Commission Regulation (EU) No 488/2012, as corrected by OJ L 338, 12.12.2012, p. 44, 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 4

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

* [Constitutional requirements indicated.]

Article 5

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