



Council of the
European Union

128958/EU XXV. GP
Eingelangt am 16/01/17

Brussels, 16 January 2017
(OR. en)

5346/17
ADD 1

AELE 4
EEE 1
N 2
ISL 1
FL 1
MI 40
ECO 5
SAN 25

PROPOSAL

From: Secretary-General of the European Commission,
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 13 January 2017

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of
the European Union

No. Cion doc.: COM(2017) 13 final - ANNEX 1

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

Delegations will find attached document COM(2017) 13 final - ANNEX 1.

Encl.: COM(2017) 13 final - ANNEX 1



EUROPEAN
COMMISSION

Brussels, 13.1.2017
COM(2017) 13 final

ANNEX 1

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 Annex XVII (Intellectual Property) to the EEA Agreement

(Paediatric Regulation)

DECISION OF THE EEA JOINT COMMITTEE

No

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 726/2004¹ 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 use² 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 Council⁴, as corrected by OJ L 338, 12.12.2012, p. 44, is to be incorporated into the EEA Agreement.
- (5) Regulation (EC) No 469/2009 repeals Council Regulation (EEC) No 1768/92⁵ 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. Marketing authorisations are granted by the Commission and the EFTA States shall simultaneously and within 30 days take corresponding decisions. Due to the special circumstances, notably that the

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 OJ L 182, 2.7.1992, p. 1.

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 shall 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:

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 dependant 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*.

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
[...]

* [Constitutional requirements indicated.]