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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
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Subject:	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.

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2017/0005 (NLE)

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

The draft Decision of the EEA Joint Committee (annexed to the proposed Council Decision) aims to amend Annex II (Technical regulations, standards, testing and certification) and Annex XVII (Intellectual Property) to the EEA Agreement in order to incorporate the Paediatric Regulation[1] and the SPC Regulation[2] into the Agreement on the European Economic Area (EEA Agreement).

The EEA EFTA States (Iceland, Liechtenstein and Norway) are requesting adaptations which go above the level of mere technical adjustments. Therefore, in conformity with Article 1(3) of Council Regulation (EC) No 2894/94[3], the EU position on this EEA Joint Committee Decision shall be established by the Council.

• Consistency with existing policy provisions in the policy area

The annexed draft Joint Committee Decision extends the already existing EU policy to the EEA EFTA States.

• Consistency with other Union policies

The extension of the EU acquis in the EEA EFTA States, through their incorporation into the EEA Agreement is conducted in conformity with the objectives and principles of this Agreement aiming at establishing a dynamic and homogeneous European Economic Area, based on common rules and equal conditions of competition.

These efforts cover all policies in the area of the free movement of goods, persons, services and capital, as well as flanking and horizontal policies specified in the EEA Agreement.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The legislation to be incorporated into the EEA Agreement is based on Article 114 of the Treaty on the Functioning of the European Union.

Article 1(3) of Council Regulation (EC) No 2894/94 concerning arrangements for implementing the EEA Agreement provides that the Council establishes the position to be adopted on the Union's behalf on such Decisions, on a proposal from the Commission.

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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.

2 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 OJ L 305, 30.11.1994, p. 6–8

The Commission in cooperation with the EEAS submits the draft Decision of the EEA Joint Committee for adoption by the Council as the Union's position. The Commission would hope to be able to present it in the EEA Joint Committee at the earliest possible opportunity.

- **Subsidiarity (for non-exclusive competence)**

The proposal complies with the subsidiarity principle for the following reason.

The objective of this proposal, namely to ensure the homogeneity of the Internal Market cannot be sufficiently achieved by the Member States and can therefore, by reason of the effects, be better achieved at Union level.

- **Proportionality**

In accordance with the principle of proportionality, the proposal does not go beyond what is necessary in order to achieve its objective – to ensure the homogeneity of the Internal Market.

- **Choice of the instrument**

In conformity with Article 98 of the EEA Agreement, the chosen instrument is the EEA Joint Committee Decision. The EEA Joint Committee shall ensure the effective implementation and operation of the EEA Agreement. To this end, it shall take decisions in the cases provided for in the EEA Agreement.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Collection and use of expertise**

In the framework of the preparation of the legislation in question the Commission has widely consulted all interested parties.

- **Impact assessment**

In the framework of the preparation of the legislation in question the Commission has carried out a detailed impact assessment, analysing a wide range of various policy options.

The attached EEA Joint Committee Decision merely aims to extend the current system to the EEA EFTA States.

4. BUDGETARY IMPLICATIONS

Incorporation of this legislation into the EEA Agreement has no budgetary implications.

5. OTHER ELEMENTS

- **Justification of the main requested adaptations and proposed solution**

Adaptations to the Paediatric Regulation

(1) Article 36(3)

Article 36(3) of the Paediatrics Regulation reads as follows:

"Where the procedures laid down in Directive 2001/83/EC have been used, the six-month extension of the period referred to in paragraph 1 shall be granted only if the product is authorised in all Member States."

Under the terms of this Article, the extension of a supplementary protection certificate under the Paediatric Regulation is subject to the condition that the underlying medicinal product has been authorised in all Member States. However, in accordance with point 15q of Chapter XIII of Annex II of the EEA agreement Liechtenstein is not obliged to participate in the common procedures laid down in Directive 2001/83/EC. The proposal for the adaptation text takes this into account.

Proposed adaptation text:

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

(2) Article 49(3) (as amended by Regulation (EC) No 1902/2006)

In view of the two-pillar structure characterising the EEA Agreement, an adaptation text is suggested foreseeing that in the cases where the marketing authorisation holder of a centrally authorised product is established in an EFTA State, the EFTA Surveillance Authority will impose the financial penalties. However, due to the special circumstances, notably that the Commission grants marketing authorisations for centrally authorised products, 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.

Adaptations to the SPC Regulation:

Articles 7 and 21 of Regulation (EC) No 469/2009

Justification:

The proposal for an adaptation text concerns the fact that the extension of the supplementary protection certificates ('SPC') established by Regulation (EC) No 1901/2006 and codified by Regulation (EC) No 469/2009 enters into force in the EEA EFTA States at a later stage than in the EU Member States and that the six months period shall constitute a direct extension of the SPC.

The same situation occurred when Regulation (EEC) No 1768/1992 was incorporated into the EEA Agreement, see point 6c of Annex XVII to the EEA Agreement. The proposal for an adaptation text is based on the same scheme as the current adaptation text to Article 19 of Regulation (EEC) No 1768/1992.

(1) New paragraphs 6 and 7 added to Article 7 of Regulation (EC) No 469/2009

According to Article 7(5) of Regulation (EC) No 469/2009, the application for an extension of the duration of the SPC shall, for a period of five years following the entry into force of Regulation (EC) No 1901/2006, be lodged not later than six months before the expiry of the SPC. In an EEA EFTA context there is a need for an adaptation on this point in such a way that the five years period shall be counted from the date where the regulation entered into force for the concerned EFTA state, see our proposal for Paragraphs 6 and 7 of Article 7 in Regulation (EC) No 469/2009.

(2) New paragraph 3 added to Article 21 of Regulation (EC) No 469/2009

There was also a need for an adaptation for situations where a SPC expires less than six months prior to the entry into force of Regulation (EC) No 469/2009 in an EEA EFTA state. Where a SPC expires earlier than six months prior to the entry into force of the regulation in an EFTA state, the extension will not have effect in the concerned EEA EFTA State, see our proposal for a new paragraph 3 to be added to Article 21 of Regulation (EC) No 469/2009. The reason for this is that the extension period shall follow as a direct prolongation to the SPC period. Where an SPC expires less than six months prior to the entry into force of Regulation (EC) No 1901/2006 and Regulation (EC) No 469/2009 in an EEA EFTA state, the possible extension should have effect for the period that remains of the six months extension period (counted from the expiry of the SPC) at the time where the Regulations enters into force in a concerned EEA EFTA state provided that the application for extension is published at this time.

(3) New paragraph 4 added to Article 21 of Regulation (EC) No 469/2009

For the situations where the SPC expires earlier than seven months after the entry into force of the Regulations in the EEA EFTA state concerned, we propose that the application for an extension of the duration of an SPC shall be lodged no later than one month after the entry into force of the Regulations in the EEA EFTA state concerned (see our proposal for a new paragraph 4 to be added to Article 21 of Regulation (EC) No 469/2009). According to our proposal the extension will take effect only with respect to the time following the date of publication of the application for an extension. Where the SPC expires after the entry into force of the Regulations in the EEA EFTA state concerned it will be possible to obtain the extension as a direct prolongation of the SPC. Where the SPC expires prior to the time of entry into force of the Regulations it will be possible to obtain that the remainder of the extension period take effect from the date the Regulations enter into force, provided that the application has already been lodged and the mention of it has been published. The extension will only have effect for the period that remains of the six months extension period (counted from the expiry of the SPC) at the time where the regulations enter into force in a concerned EFTA state and the application for extension is published.

(4) New paragraph 5 added to Article 21 of Regulation (EC) No 469/2009

According to our proposal for transitional arrangements a situation can occur where the protection first expires and then takes effect at a later stage, i.e. when the Regulations enter into force. For these situations we outline a provision on continued prior use below. A similar adaptation text was introduced as paragraph 5 to Article 19 of Regulation (EEC) No 1768/92 when this act was made part of the EEA Agreement.

Other adaptations proposed:

The *Paediatric Committee* should be inserted into the introductory text of Chapter XIII of Annex II to the EEA Agreement.

In view of the patent union between Liechtenstein and Switzerland, Liechtenstein does not deliver any supplementary protection certificates. In line with the practice of the EU since 2004 in the Treaty of Accession of new Member States the following text has been included as adaptation (d) to Regulation (EC) No 469/2009:

"(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."

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(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[4] concerning arrangements for implementing the Agreement on the European Economic Area, 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 ('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[5] is to be incorporated into the EEA Agreement.

(4) Regulation (EC) No 1902/2006 of the European Parliament and of the Council[6] is to be incorporated into the EEA Agreement.

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4 OJ L 305, 30.11.1994, p. 6–8.

5 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).

6 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).

(5) Regulation (EC) No 469/2009 of the European Parliament and of the Council[7] is to be incorporated into the EEA Agreement.

(6) Commission Regulation (EU) No 488/2012 of 8 June 2012[8], is to be incorporated into the EEA Agreement.

(7) Regulation (EC) No 469/2009 repeals Council Regulation (EEC) No 1768/92[9] 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[10] 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 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.

(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.

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7 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).

8 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).

9 OJ L 182, 2.7.1992, p. 1.

10 Commission Regulation (EC) No 658/2007of 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. 10–19).

Article 2

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

Done at Brussels,

For the Council
The President