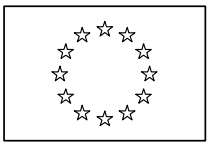

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 18.2.2009
SEC(2009) 160 final

Draft

DECISION OF THE EEA JOINT COMMITTEE

amending Annex II (Technical regulations, standards, testing and certification) and Protocol 37 to the EEA Agreement

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. In order to ensure the requisite legal security and homogeneity of the Internal Market, the EEA Joint Committee is to integrate all the relevant Community legislation into the EEA Agreement as soon as possible after its adoption.

2. The EEA Joint Committee should therefore adopt the attached draft Decision to amend Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement by adding new Community acquis concerning medicinal products. The decision concerns the following acts:

   Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

   Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

   Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

   Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

   Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises.

   Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council.

   Furthermore, Protocol 37 to the EEA Agreement should be extended to include the Coordination groups for Mutual Recognition and Decentralised procedures (human and veterinary) in accordance with Article 101 of the Agreement.

3. This draft Joint Committee Decision establishes the modalities for the participation of the EEA EFTA States in the European Medicines Agencies, as well as a number of relevant committees and co-ordination groups. In the Agency's management board and these other bodies, the EEA EFTA States will be fully associated, but without the right to vote. There are specific provisions concerning mutual recognition of market authorisations. Furthermore, the draft Decision includes adaptations taking into account the country specific situation of Liechtenstein.

4. Article 1(3) of Council Regulation (EC) No 2894/94 concerning the arrangements for implementing the EEA Agreement envisages that the Council establishes the Community position for decisions extending Community legislation with substantial changes.

5. The draft decision of the EEA Joint Committee is submitted for the approval of the Council, after which the Commission will put forward the position of the Community in the EEA Joint Committee at the earliest possible occasion.

Draft

DECISION OF THE EEA JOINT COMMITTEE
No

of

amending Annex II (Technical regulations, standards, testing and certification) and Protocol 37 to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area, as amended by the Protocol adjusting the Agreement on the European Economic Area, hereinafter referred to as 'the Agreement', and in particular Article 98 and 101 thereof,

Whereas:

(1) Annex II to the Agreement was amended by Decision of the EEA Joint Committee No ... of …[1].

(2) Protocol 37 to the Agreement was amended by Decision of the EEA Joint Committee No ... of …[2].

(3) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[3] is to be incorporated into the Agreement.

(4) Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use[4] is to be incorporated into the Agreement.

(5) Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products[5] is to be incorporated into the Agreement.

(6) Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive

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1 OJ L …
2 OJ L …
3 OJ L 136, 30.4.2004, p. 1.
4 OJ L 136, 30.4.2004, p. 34.
5 OJ L 136, 30.4.2004, p. 58.

2001/83/EC on the Community code relating to medicinal products for human use[6] is to be incorporated into the Agreement.

(7) Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises[7] is to be incorporated into the Agreement.

(8) Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council[8] is to be incorporated into the Agreement.

(9) Protocol 37 to the Agreement is to be extended to include the Coordination groups for Mutual Recognition and Decentralised procedures (human) and (veterinary) in accordance with Article 101 of the Agreement,

HAS DECIDED AS FOLLOWS:

Article 1

Annex II and Protocol 37 to the Agreement shall be amended as specified in the Annex to this Decision.

Article 2

The texts of Regulations (EC) Nos 726/2004, 2049/2005 and 507/2006 and Directives 2004/27/EC, 2004/28/EC and 2004/24/EC 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 3

This Decision shall enter into force on […] or on the day following the last notification to the EEA Joint Committee under Article 103(1) of the Agreement, whichever is the later[*]. For Liechtenstein, this Decision shall enter into force on the same day or on the day of entry into force of the Agreement between Liechtenstein and Austria laying down the technical details for Liechtenstein's recognition of Austrian marketing authorisations within the decentralized procedure (DCP) and the mutual recognition procedure (MRP), whichever is the later.

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6 OJ L 136, 30.4.2004, p. 85.
7 OJ L 329, 16.12.2005, p. 4.
8 OJ L 92, 30.3.2006, p. 6.
[*] [No constitutional requirements indicated.] [Constitutional requirements indicated.]

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

ANNEX

to Decision of the EEA Joint Committee No […]

Annex II and Protocol 37 to the Agreement shall be amended as follows:

1. The text of the introductory part of Chapter XIII of Annex II to the Agreement shall be replaced as of the fourth paragraph by the following:

'When decisions on approval of medicinal products are taken according to the Community procedures laid down in Regulation (EC) No 726/2004 of the European Parliament and of the Council, Directive 2001/83/EC of the European Parliament and of the Council, as amended by Directive 2004/27/EC of the European Parliament and of the Council, and Directive 2001/82/EC of the European Parliament and of the Council, as amended by Directive 2004/28/EC of the European Parliament and of the Council, the EFTA States will simultaneously and within 30 days of the Community Decision, take corresponding decisions on the basis of the relevant acts. The EEA Joint Committee shall be informed and shall periodically publish lists of such decisions in the EEA Supplement to the Official Journal.

The EFTA Surveillance Authority will monitor the application of the decisions taken by the EFTA States as provided for in Article 109 of the Agreement.

Where any of the relevant acts provide for Community procedures on the granting, suspension and withdrawal of a marketing authorisation as well as supervision, including pharmacovigilance, and inspections and sanctions, these and similar tasks shall be carried out by the competent authorities in the EFTA States, on the basis of the same obligations as those of the competent authorities of EC Member States.

Should any disagreement between the contracting parties arise as to the administration of these provisions, Part VII of the Agreement shall apply *mutatis mutandis*.

The EFTA States shall participate in the work of the European Medicines Agency, hereinafter referred to as 'the Agency', as set up by Regulation (EC) No 726/2004 of the European Parliament and of the Council.

The financial provisions of Title IV, Chapter 2, of Regulation (EC) No 726/2004 of the European Parliament and of the Council shall apply to the participation of the EFTA States in the work of the Agency.

The EFTA States shall therefore participate in the Community contribution referred to in Article 67(3) of Regulation (EC) No 726/2004 of the European Parliament and of the Council.

For this purpose the procedures laid down in Article 82(1)(a) and Protocol 32 of the Agreement shall apply *mutatis mutandis* with regard to the financial contribution of the EFTA States to the above mentioned Community contribution.

The EFTA States may send observers to meetings of the Agency's Management Board.

The EFTA States shall be fully associated with the work of the Committee for Medicinal Products for Human Use (CHMP), the Committee for Medicinal Products for Veterinary Use (CVMP), the Committee on Orphan Medicinal Products (COMP) and the Committee on Herbal Medicinal Products (HMPC). The detailed arrangements of participation for the representatives of EFTA States shall be in accordance with the provisions of Title IV, chapter 1, of European Parliament and Council Regulation (EC) No 726/2004. Such representatives will, however, not participate in the voting and their positions shall be recorded separately. The position of Chairman shall be reserved for a member nominated by an EC Member State.

The EFTA States shall be fully associated with the work of the Coordination Group as set up by Article 27 of Directive 2001/83/EC of the European Parliament and of the Council, as amended by Directive 2004/27/EC of the European Parliament and of the Council, and Article 31 of Directive 2001/82/EC of the European Parliament and of the Council, as amended by Directive 2004/28/EC of the European Parliament and of the Council. The representatives of the EFTA States will, however, not participate in the voting and their positions shall be recorded separately. The position of Chairman shall be reserved for a member nominated by an EC Member State.

An EFTA State may request the Agency to initiate an arbitration procedure according to Title III, Chapter 4 of Directive 2001/83/EC of the European Parliament and of the Council, as amended by Directive 2004/27/EC of the European Parliament and of the Council, and according to Title III, Chapter 4 of Directive 2001/82/EC of the European Parliament and of the Council, as amended by Directive 2004/28/EC of the European Parliament and of the Council. Such a request shall, in the first place, be addressed to the Commission which shall, where it considers that the request is of common interest, forward it to the Agency for further processing.

The EFTA States shall fully participate in the Telematic Exchange of Information on Medicinal Products (IMP) programme.

Iceland and Norway shall provide their national competent authorities and the marketing authorisation holders with the linguistic version of the marketing authorisations required to access their own market.

A marketing authorisation granted for a medicinal product following an opinion adopted by the competent EMEA scientific Committee in accordance with Article 9 or Article 34 of Regulation (EC) No 726/2004 of the European Parliament and of the Council shall not be subject to any fees other than those referred to in Article 67(3) and Article 70 of Regulation (EC) No 726/2004 of the European Parliament and of the Council.

The Agency having legal personality shall enjoy in all the states of the Contracting Parties the most extensive legal capacity accorded to legal persons under their laws.

The EFTA States shall apply to the Agency the Protocol of Privileges and Immunities of the European Communities.

Regulation (EC) No 1049/2001 of the European Parliament and the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents shall, for the application of Regulation (EC) No 726/2004, apply to any documents of the Agency regarding the EFTA States as well.

By way of derogation from Article 12(2)(a) of the Conditions of employment of other servants of the European Communities, nationals of the EFTA States enjoying their full rights as citizens may be engaged under contract by the Executive Director of the Agency.'

2. The text of point 15g (Council Regulation (EEC) No 2309/93) of Chapter XIII of Annex II to the Agreement shall be deleted.

3. The following shall be added in point 15p (Directive 2001/82/EC of the European Parliament and of the Council) of Chapter XIII of Annex II to the Agreement:

', as amended by:

- **32004 L 0028**: Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 (OJ L 136, 30.4.2004, p. 58).'

4. The following indents shall be added in point 15q (Directive 2001/83/EC) of Chapter XIII of Annex II to the Agreement:

'- **32004 L 0027**: Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ L 136, 30.4.2004, p. 34),

- **32004 L 0024**: Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 (OJ L 136, 30.4.2004, p. 85).'

5. The following shall be added in points 15p (Directive 2001/82/EC of the European Parliament and of the Council) and 15q (Directive 2001/83/EC of the European Parliament and of the Council) of Chapter XIII of Annex II to the Agreement, after the transitional arrangements:

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

Liechtenstein shall not be obliged to participate in the decentralized procedure (DCP) and in the mutual recognition procedure (MRP) and shall, therefore, not be obliged to issue the corresponding marketing authorisations. Instead, Austrian marketing authorisations within the DCP and the MRP will be valid for Liechtenstein upon request of a marketing authorisation applicant.'

6. The following points shall be inserted after point 15za (Commission Regulation (EC) No 1950/2006) of Chapter XIII of Annex II to the Agreement:

'15zb.**32004 R 0726**: Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

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

The right to impose financial penalties on the holders of marketing authorisations in accordance with Article 84(3) shall in the cases where the marketing authorisation holder is established in an EFTA State be carried out by that EFTA State based on a proposal of the European Commission.

15zc. **32005 R 2049**: Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises (OJ L 329, 16.12.2005, p. 4).

15zd. **32006 R 0507**: Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 92, 30.3.2006, p. 6.)'

7. The following points shall be inserted in Protocol 37 to the Agreement (containing the list provided for in Article 101):

'27. Coordination Group for Mutual Recognition and Decentralised procedure (human) (Directive 2001/83/EC of the European Parliament and the Council).

28. Coordination Group for Mutual Recognition and Decentralised procedure (veterinary) (Directive 2001/82/EC of the European Parliament and the Council).'