DECISION OF THE EEA JOINT COMMITTEE

No 74/1999

of 28 May 1999

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

THE EEA JOINT COMMITTEE,

(1) Having regard to the Agreement on the European Economic Area, as adjusted by the Protocol Adjusting the Agreement on the European Economic Area, hereinafter referred to as 'the Agreement', and in particular Articles 98 to 101 thereof,

(2) Whereas Protocol 37 to the Agreement was amended by Decision of the EEA Joint Committee No 38/1999 of 30 March 1999[1];

(3) Whereas Annex II to the Agreement was amended by Decision of the EEA Joint Committee No 49/1999 of 30 April 1999[2];

(4) Whereas in the case of medicinal products for human use, the criteria of quality, safety and efficacy have been extensively harmonised by Council Directive 65/65/EEC[3], Council Directive 75/318/EEC[4] and Second Council Directive 75/319/EEC[5], as successively amended;

(5) Whereas in the case of veterinary medicinal products, similar results have been achieved by Council Directive 81/851/EEC[6] and by Council Directive 81/852/EEC[7], as amended;

(6) Whereas Council Directive 87/22/EEC[8] has established a mechanism for concertation, prior to any national decision relating to a high-technology medicinal product, with a view to arriving at uniform decisions;

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[1] OJ L …
[2] OJ L …
[3] OJ 22, 9.2.1965, p. 369/65.
[4] OJ L 147, 9.6.1975, p. 1.
[5] OJ L 147, 9.6.1975, p. 13.
[6] OJ L 317, 6.11.1981, p. 1.
[7] OJ L 317, 6.11.1981, p. 16.
[8] OJ L 15, 17.1.1987, p. 38.

(7) Whereas experience within the Community following the entry into force of Directive 87/22/EEC showed that it was necessary to establish a centralised Community procedure for technologically advanced medicinal products; whereas this procedure is available to persons placing on the market medicinal products containing new active substances intended for use in human beings or in food-producing animals;

(8) Whereas, therefore, the European Agency for the Evaluation of Medicinal Products, hereinafter referred to as 'the Agency' was established by Council Regulation (EEC) No 2309/93[9]; whereas it was necessary to ensure close cooperation between the Agency and scientists working in the Member States; whereas, therefore, exclusive responsibility for preparing opinions of the Agency on all matters relating to medicinal products for human use has been entrusted to the Committee for Proprietary Medicinal Products created by the Second Council Directive 75/319/EEC; whereas in respect of veterinary medicinal products this responsibility has been entrusted to the Committee for Veterinary Medicinal Products created by Directive 81/851/EEC;

(9) Whereas the Agency is also responsible for coordinating the activities of the Member States in the field of the monitoring of adverse reaction to medicinal products (pharmacovigilance); whereas it was also necessary to make provision for the supervision of medicinal products authorised by the Community; whereas, to this end, the Agency coordinates the verification of compliance with the principles of good manufacturing practice, good laboratory practice and good clinical practice;

(10) Whereas in the interest of public health it is necessary that decisions on the authorisation of such medicinal products should be based on the objective scientific criteria of the quality, safety and efficacy of the medicinal products concerned to the exclusion of economic and other considerations; whereas, however, Member States of the Community can exceptionally prohibit the use on their territory of medicinal products for human use which infringe objectively defined concepts of public order and public morality; whereas, moreover, a veterinary medicinal product may not be authorised by the Community if its use would contravene the legal measures laid down by the Community within the framework of the common agricultural policy;

[9] OJ L 214, 24.8.1993, p. 1.

(11) Whereas Council Directive 93/39/EEC of 14 June 1993 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products[10] provides that in the event of disagreement between Member States of the Community about the quality, safety or efficacy of a medicinal product which is subject to the decentralised Community authorisation procedure, the matter should be resolved by a binding Community Decision following a scientific evaluation of the issues involved; whereas similar provisions have been laid down in respect of veterinary medicinal products by Council Directive 93/40/EEC of 14 June 1993 amending Directives 81/851/EEC and 81/852/EEC[11];

(12) Whereas it is paramount to ensure uniform protection of human and animal health and to protect consumers of medicinal products within the European Economic Area;

(13) Whereas it is necessary to secure the proper functioning of the Agreement by adoption of uniform regulatory decisions primarily based on objective scientific criteria concerning the placing on the market and use of medicinal products;

(14) Whereas, therefore, the relevant Community legislation and principles on a centralised procedure for technologically advanced medicinal products and medicinal products containing new active substances which are intended for use in human beings or in food-producing animals, as well as the legislation on a decentralised procedure providing that in the event of disagreement between the Contracting Parties about the quality, safety and efficacy of a medicinal product the matter shall be resolved by a binding decision following a scientific evaluation of the issues involved, shall be incorporated into the Agreement by amendment of Annex II thereto;

(15) Whereas, as it is called for by the good functioning of the Agreement, representatives from the competent authorities of the EFTA States concerned shall be associated with the work of the Committee for Proprietary Medicinal Products created by the Second Council Directive 75/319/EEC and the Committee for Veterinary Medicinal Products created by Directive 81/851/EEC;

[10] OJ L 214, 24.8.1993, p. 22.
[11] OJ L 214, 24.8.1993, p. 31.

(16) Whereas it is therefore necessary to amend Protocol 37 which lists committees to the work of which experts from EFTA States shall be associated when it is called for by the good functioning of the Agreement;

(17) Whereas it is necessary to amend Annex II to the Agreement in connection with the amendment of Protocol 37 in order to specify the detailed arrangements of association,

HAS DECIDED AS FOLLOWS:

Article 1

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

Article 2

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

Article 3

The texts of Council Directives 93/39/EEC, 93/40/EEC and 93/41/EEC, Council Regulations (EEC) No 2309/93 and (EC) No 297/95 and Commission Regulations (EC) No 540/95, (EC) No 541/95, (EC) No 542/95 and (EC) No 2141/96 in the Icelandic and Norwegian languages, which are annexed to the respective language versions of this Decision, are authentic.

Article 4

Dates concerning the entry into force or implementation of the acts mentioned in Annex II to this Decision shall for the purposes of the Agreement, be read as follows:

– where the date of entry into force or implementation of the act precedes the date of entry into force of this Decision, the date of entry into force of this Decision shall apply;

– where the date of entry into force or implementation of the act is after the date of entry into force of this Decision, the date of entry into force or implementation of the act shall apply.

Article 5

This Decision shall enter into force on 29 May 1999 provided that all the notifications under Article 103(1) of the Agreement have been made to the EEA Joint Committee.

Article 6

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Communities*.

Done at Brussels, 28 May 1999.

For the EEA Joint Committee
The President

F. Barbaso

The Secretaries
to the EEA Joint Committee

G. Vik *E. Gerner*

ANNEX I

to Decision of the EEA Joint Committee No 74/1999

Protocol 37 (containing the list provided for in Article 101) to the Agreement shall be amended as specified below.

The following shall be added in Protocol 37 to the Agreement:

‘10. Committee for Proprietary Medicinal Products (Second Council Directive 75/319/EEC);

11. Committee for Veterinary Medicinal Products (Council Directive 81/851/EEC)’.

ANNEX II

to Decision of the EEA Joint Committee No 74/1999

Annex II (Technical regulations, standards, testing and certification), Chapter XIII (Medicinal products) to the Agreement shall be amended as specified below.

1. In the text of Chapter XIII of Annex II to the Agreement the following shall be inserted after the third paragraph:

   'When decisions on approval of medicinal products are taken according to the Community procedures laid down in Council Regulation (EEC) No 2309/93, Second Council Directive 75/319/EEC, as amended by Council Directive 93/39/EEC, and Council Directive 81/852/EEC, as amended by Council Directive 93/40/EEC, the EFTA States will simultaneously 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 Community 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, Contracting Parties to this Agreement, shall participate in the work of the European Agency for the Evaluation of Medicinal Products (EMEA), hereinafter referred to as 'the Agency', as set up by Council Regulation (EEC) No 2309/93[1]. Liechtenstein may participate in, and contribute financially to, the work of the Agency once its medicinal control authority disposes of the necessary technical means.

[1] OJ L 214, 24.8.1993, p. 1.

The financial provisions of Title IV, Chapter 2, of Council Regulation (EEC) No 2309/93 shall apply to the participation of the EFTA States concerned in the work of the Agency.

The EFTA States concerned shall therefore, as from the entry into force of this Decision participate in the Community contribution referred to in Article 57(1) of Council Regulation (EEC) No 2309/93.

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 concerned to the abovementioned Community contribution.

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

The EFTA States concerned shall be fully associated with the work of the Committee for Proprietary Medicinal Products (CPMP) and the Committee for Proprietary Veterinary Products (CVMP). The detailed arrangements of participation for the representatives of EFTA States shall be in accordance with the provisions of Title IV, Chapter 1, of Council Regulation (EEC) No 2309/93. 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 a Member State of the Community. The internal rules of procedure of these committees shall be amended in order to give full effect to the EFTA States' participation.

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

The EFTA States concerned 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 31 of Council Regulation (EEC) No 2309/93 shall not be subject to any fees other than those referred to in Article 57(1) and Article 58 of Council Regulation (EEC) No 2309/93.

The EFTA States concerned shall, within a time limit to be set by the EEA Joint Committee, inform the Agency of the national competent authorities responsible for work of the type undertaken by the Agency and nominate appropriate persons to represent those authorities in the scientific committees referred to above.

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 concerned shall apply to the Agency the Protocol of Privileges and Immunities of the European Communities.

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 following indent shall be added in point 1 (Council Directive 65/65/EEC):

'– **393 L 0039**: Council Directive 93/39/EEC of 14 June 1993 (OJ L 214, 24.8.1993, p. 22).'

3. The following indent shall be added in point 2 (Council Directive 75/318/EEC):

'– **393 L 0039**: Council Directive 93/39/EEC of 14 June 1993 (OJ L 214, 24.8.1993, p. 22).'

4. The following indent shall be added in point 3 (Second Council Directive 75/319/EEC):

'– **393 L 0039**: Council Directive 93/39/EEC of 14 June 1993 (OJ L 214, 24.8.1993, p. 22).'

5. The following indent shall be added in point 5 (Council Directive 81/851/EEC):

'– **393 L 0040**: Council Directive 93/40/EEC of 14 June 1993 (OJ L 214, 24.8.1993, p. 31).'

6. The following indent shall be added in point 6 (Council Directive 81/852/EEC):

‘– **393 L 0040**: Council Directive 93/40/EEC of 14 June 1993 (OJ L 214, 24.8.1993, p. 31).’

7. The text of point 8 (Council Directive 87/22/EEC) shall be replaced by:

‘– **393 L 0041**: Council Directive 93/41/EEC of 14 June 1993 repealing Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology (OJ L 214, 24.8.1993, p. 40).’

8. The following new points shall be inserted after point 15 f (Council Directive 92/109/EEC):

‘15 g. **393 R 2309**: Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the evaluation of Medicinal Products (OJ L 214, 24.8.1993, p. 1).

15 h. **395 R 0297**: Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ L 35, 15.2.1995, p. 1).

15 i. **395 R 0540**: Commission Regulation (EC) No 540/95 of 10 March 1995 laying down the arrangements for reporting suspected unexpected adverse reactions which are not serious, whether arising in the Community or in a third country, to medicinal products for human or veterinary use authorised in accordance with the provisions of Council Regulation (EEC) No 2309/93 (OJ L 55, 11.3.1995, p. 5).

15 j. **395 R 0541**: Commission Regulation (EC) No 541/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation granted by a competent authority of a Member State (OJ L 55, 11.3.1995, p. 7).

15 k. **395 R 0542**: Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93 (OJ L 55, 11.3.1995, p. 15).

15 l. **396 R 2141**: Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of marketing authorisation for a medicinal product falling within the scope of Council Regulation (EEC) No 2309/93 (OJ L 286, 8.11.1996, p. 6).'