DECISION OF THE EEA JOINT COMMITTEE No 371/2021

of 10 December 2021

amending Annex II (Technical regulations, standards, testing and certification) and Protocol 37 (containing the list provided for in Article 101) to the EEA Agreement [2024/711]

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 (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use ([1]) is to be incorporated into the EEA Agreement.

(2) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC ([2]) is to be incorporated into the EEA Agreement.

(3) Regulation (EU) 2019/6 repeals, with effect from 28 January 2022, Directive 2001/82/EC of the European Parliament and of the Council ([3]) which is incorporated into the EEA Agreement and which is consequently to be repealed under the EEA Agreement with effect from 28 January 2022.

(4) This Decision concerns legislation containing provisions regarding veterinary matters. Provisions regarding veterinary matters shall not apply to Liechtenstein as long as the application of the Agreement between the European Community and the Swiss Confederation on trade in agricultural products is extended to Liechtenstein.

(5) Annex II and Protocol 37 to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 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:

'For the purposes of this Chapter and notwithstanding the provisions of Protocol 1 to this Agreement, the terms Member States and competent authorities shall be understood to include, in addition to their meaning in the relevant EU acts, the EFTA States and their competent authorities, respectively.

When decisions on the authorisation of medicinal products are taken according to the Union 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 and Regulation (EU) 2019/6 of the European Parliament and of the Council, the EFTA States shall simultaneously and within 30 days of the Union 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 of the European Union*.

([1]) OJ L 4, 7.1.2019, p. 24.
([2]) OJ L 4, 7.1.2019, p. 43.
([3]) OJ L 311, 28.11.2001, p. 1.

The EFTA Surveillance Authority shall 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 Union 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 EU 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 Union 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 Union 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 on Orphan Medicinal Products (COMP), the Paediatric Committee, the Pharmacovigilance Risk Assessment Committee (PRAC) and the Committee on Herbal Medicinal Products (HMPC). The provisions of Title IV, Chapter 1, of Regulation (EC) No 726/2004 of the European Parliament and of the Council shall apply to members of the Committees appointed by the EFTA States. Members of the Committees appointed by the EFTA States shall have the same rights and obligations as the members appointed by the EU Member States, except for the right to vote. The positions of the members of the EFTA States shall be recorded separately. The position of Chairman shall be reserved for a member nominated by an EU Member State.

The EFTA States shall be fully associated with the work of the Committee for Veterinary Medicinal Products (CVMP). The provisions of Article 140 of Regulation (EU) 2019/6 of the European Parliament and of the Council shall apply to the members of the Committee appointed by the EFTA States. Members of the Committee appointed by the EFTA States shall have the same rights and obligations as the members appointed by the EU Member States, except for the right to vote. The positions of the members of the EFTA States shall be recorded separately. The position of Chairman shall be reserved for a member nominated by an EU Member State.

The EFTA States shall be fully associated with the work of the coordination groups as set up by Article 27 of Directive 2001/83/EC of the European Parliament and of the Council and Article 142 of Regulation (EU) 2019/6 of the European Parliament and of the Council. The members of the EFTA States shall not participate in the voting, however, their positions shall be recorded separately. The position of Chairman shall be reserved for a member nominated by an EU Member State. An objection raised by the competent authority of an EFTA State in accordance with Articles 49(5), 52(6), 53(8) or 66(8) of Regulation (EU) 2019/6 of the European Parliament and of the Council shall initiate the review procedure referred to in Article 54 of that Regulation.

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. 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 participate fully 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 centralised marketing authorisation granted for a medicinal product shall not be subject to any fees other than those referred to in Article 67(3) 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 grant privileges and immunities to the Agency equivalent to those contained in the Protocol on the Privileges and Immunities of the European Union.

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 of the European Parliament and of the Council, 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.'

Article 2

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

1. The text of point 15p (Directive 2001/82/EC of the European Parliament and of the Council) shall be deleted with effect from 28 January 2022.

2. The following indent is added in points 15q (Directive 2001/83/EC of the European Parliament and of the Council) and 15zr (Regulation (EC) No 1901/2006 of the European Parliament and of the Council):

   '— **32019 R 0005**: Regulation (EU) 2019/5 of the European Parliament and of the Council (OJ L 4, 7.1.2019, p. 24).'

3. Point 15zb (Regulation (EC) No 726/2004) shall be amended as follows:

   (i) the following indent is added:

   '— **32019 R 0005**: Regulation (EU) 2019/5 of the European Parliament and of the Council (OJ L 4, 7.1.2019, p. 24).'

   (ii) the text of the adaptation is replaced by the following:

   'The powers vested in the European Commission in relation to the infringement procedure foreseen in Article 84a, 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 following is inserted after point 21 (Commission Implementing Regulation (EU) 2017/556):

   '22. **32019 R 0006**: Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

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

(a) The following provisions of the Regulation regarding veterinary matters shall not apply to Liechtenstein:

— Article 57

— Articles 103 to 115, included.

(b) Liechtenstein shall not be obliged to participate in the decentralised 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 shall be valid for Liechtenstein upon request of a marketing authorisation applicant.

(c) In Article 136, the powers vested in the European Commission 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 3

The text of point 27 of Protocol 37 to the Agreement is replaced by the following:

'Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products (Regulation (EU) 2019/6 of the European Parliament and of the Council).'

Article 4

The texts of Regulations (EU) 2019/5 and (EU) 2019/6 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 5

This Decision shall enter into force on 11 December 2021, provided that all the notifications under Article 103(1) of the EEA Agreement have been made *.

Article 6

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, 10 December 2021.

For the EEA Joint Committee
The President
Rolf Einar FIFE

* Constitutional requirements indicated.