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

TITLE III

AUTHORISATION AND SUPERVISION OF VETERINARY MEDICINAL PRODUCTS

Chapter 1

Submission and examination of applications — Authorisations

Article 30

1 A Committee for Medicinal Products for Veterinary Use is hereby established. The Committee shall be part of the Agency.

2 Without prejudice to Article 56 and other tasks which **[**F1Union**]** law may confer on it, in particular under Regulation (EEC) No 2377/90(1), the Committee for Medicinal Products for Veterinary Use shall be responsible for drawing up the opinion of the Agency on any question concerning the admissibility of files submitted in accordance with the centralised procedure, the granting, variation, suspension or revocation of an authorisation to place a veterinary medicinal product on the market arising in accordance with the provisions of this Title, and pharmacovigilance.

3 At the request of the Executive Director of the Agency or the Commission representative, the Committee for Medicinal Products for Veterinary Use shall also draw up opinions on any scientific matters concerning the evaluation of veterinary medicinal products. The Committee shall take due account of any requests from Member States for an opinion. The Committee shall also formulate an opinion whenever there is disagreement in the assessment of a veterinary medicinal product through the mutual recognition procedure. The opinion of the Committee shall be made publicly accessible.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Article 31

1 Each application for the authorisation of a medicinal product for veterinary use shall specifically and exhaustively include the particulars and documents as referred to in Articles 12(3), 13, 13a, 13b and 14 of, and Annex I to, Directive 2001/82/EC. These particulars and documents shall take account of the unique, **[**F1Union**]** nature of the authorisation requested and,

otherwise than in exceptional cases relating to the application of the law on trade marks, shall include the use of a single name for the medicinal product.

The application shall be accompanied by the fee payable to the Agency for the examination of the application.

2 In the case of a veterinary medicinal product containing or consisting of genetically modified organisms within the meaning of Article 2 of Directive 2001/18/EC, the application shall also be accompanied by:

a a copy of the written consent of the competent authorities to the deliberate release into the environment of the genetically modified organisms for research and development purposes, as provided for in Part B of Directive 2001/18/EC or in Part B of Directive 90/220/EEC;

b the complete technical file supplying the information required under Annexes III and IV to Directive 2001/18/EC;

c the environmental risk assessment in accordance with the principles set out in Annex II to Directive 2001/18/EC; and

d the results of any investigations performed for the purposes of research or development.

Articles 13 to 24 of Directive 2001/18/EC shall not apply to veterinary medicinal products containing or consisting of genetically modified organisms.

3 The Agency shall ensure that the opinion of the Committee for Medicinal Products for Veterinary Use is given within 210 days after the receipt of a valid application.

In the case of a veterinary medicinal product containing or consisting of genetically modified organisms, the opinion of the said Committee must respect the environmental safety requirements laid down by Directive 2001/18/EC. During the process of evaluating applications for marketing authorisations for veterinary medicinal products containing or consisting of genetically modified organisms, necessary consultations shall be held by the rapporteur with the bodies set up by the **[**[F1]Union**]** or the Member States in accordance with Directive 2001/18/EC.

4 The Commission shall, in consultation with the Agency, Member States and interested parties, draw up a detailed guide regarding the form in which applications for authorisation are to be presented.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Article 32

1 In order to prepare its opinion, the Committee for Medicinal Products for Veterinary Use:

a shall verify that the particulars and documents submitted in accordance with Article 31 comply with the requirements of Directive 2001/82/EC and examine whether the conditions specified in this Regulation for granting a marketing authorisation are satisfied;

b may request that an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose test the veterinary medicinal product, its starting materials and, where appropriate, its intermediate products or other constituent materials in order to ensure that the control methods employed by the manufacturer and described in the application are satisfactory;

c may request a **[**F1Union reference laboratory, Official Medicines Control Laboratory or laboratory that a Member State has designated for that purpose to verify, using samples provided by the applicant, that the analytical detection method proposed by the applicant for the purposes of Article 12(3)(j), second indent, of Directive 2001/82/EC is satisfactory and is suitable for use to reveal the presence of residue levels, particularly those above the maximum residue level accepted by the Union**]** in accordance with the provisions of Regulation (EEC) No 2377/90;

d may request the applicant to supplement the particulars accompanying the application within a specific time-limit. Where the said Committee avails itself of this option, the time-limit laid down in Article 31(3), first subparagraph shall be suspended until such time as the supplementary information requested has been provided. Likewise, the time-limit shall be suspended for the time allowed to the applicant to prepare oral or written explanations.

2 In those cases where the analytical method has not been subject to verification by one of the abovementioned laboratories under the procedures established by Regulation (EEC) No 2377/90, the verification shall be carried out within the framework of this Article.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Article 33

1 Upon receipt of a written request from the Committee for Medicinal Products for Veterinary Use, a Member State shall forward the information establishing that the manufacturer of a veterinary medicinal product or the importer from a third country is able to manufacture the veterinary medicinal product concerned and/or carry out the necessary control tests in accordance with the particulars and documents supplied pursuant to Article 31.

2 Where it considers it necessary in order to complete its examination of the application, the said Committee may require the applicant to undergo a specific inspection of the manufacturing site of the veterinary medicinal product concerned. Such inspections may be made unannounced.

The inspection, which shall be completed within the time-limit referred to in Article 31(3), first subparagraph, shall be undertaken by inspectors from the Member State who possess the appropriate qualifications; they may be accompanied by a rapporteur or expert appointed by the said Committee.

Article 34

1 The Agency shall forthwith inform the applicant if the opinion of the Committee for Medicinal Products for Veterinary Use is that:

a the application does not satisfy the criteria for authorisation set out in this Regulation;

b the summary of the product characteristics should be amended;

c the labelling or package leaflet of the product is not in compliance with Title V of Directive 2001/82/EC;

d the authorisation should be granted subject to the conditions provided for in Article 39(7).

2 Within 15 days after receipt of the opinion referred to in paragraph 1, the applicant may provide written notice to the Agency that he wishes to request a re-examination of the opinion. In that case the applicant shall forward to the Agency the detailed grounds for the request within 60 days after receipt of the opinion.

Within 60 days after receipt of the grounds for the request, the said Committee shall re-examine its opinion in accordance with the conditions laid down in Article 62(1), fourth subparagraph. The reasons for the conclusion reached shall be annexed to the final opinion.

3 Within 15 days after its adoption, the Agency shall forward the final opinion of the said Committee to the Commission, to Member States and to the applicant, together with a report describing the assessment of the veterinary medicinal product by the Committee and stating the reasons for its conclusions.

4 If an opinion is favourable to the granting of the relevant authorisation to place the relevant veterinary medicinal product on the market, the following documents shall be annexed to the opinion:

a a draft summary of the product characteristics, as referred to in Article 14 of Directive 2001/82/EC; where appropriate, this draft shall reflect differences in the veterinary conditions in the Member States;

b in the case of a veterinary medicinal product intended for administration to food-producing animals, a statement of the maximum residue level which may be accepted by the **[**[F1]Union**]** in accordance with Regulation (EEC) No 2377/90;

c details of any conditions or restrictions which should be imposed on the supply or use of the veterinary medicinal product concerned, including the conditions under which the veterinary medicinal product may be made available to users, in conformity with the criteria laid down in Directive 2001/82/EC;

d details of any recommended conditions or restrictions with regard to the safe and effective use of the medicinal product;

e the draft text of the labelling and package leaflet proposed by the applicant, presented in accordance with Title V of Directive 2001/82/EC;

f the assessment report.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Article 35

1 Within 15 days after receipt of the opinion referred to in Article 30(2), the Commission shall prepare a draft of the decision to be taken in respect of the application.

Where a draft decision envisages the granting of marketing authorisation, it shall include or make reference to the documents mentioned in Article 34(4)(a) to (e).

Where the draft decision is not in accordance with the opinion of the Agency, the Commission shall annex a detailed explanation of the reasons for the differences.

The draft decision shall be forwarded to Member States and the applicant.

2 The Commission shall take a final decision in accordance with, and within 15 days after the end of, the procedure referred to in Article 87(3).

3 The Standing Committee for Veterinary Medicinal Products referred to in Article 87(1) shall adjust its rules of procedure so as to take account of the tasks assigned to it by this Regulation.

The adjustments shall provide that:

a the opinion of the said Standing Committee is to be given in writing;

b Member States shall have 22 days to forward their written observations on the draft decision to the Commission; however, if a decision has to be taken urgently, a shorter time-limit may be set by the Chairman according to the degree of urgency involved. This time-limit shall not, otherwise than in exceptional circumstances, be shorter than 5 days;

c Member States may request in writing that the draft decision referred to in paragraph 1 be discussed at a plenary meeting of the said Standing Committee, stating their reasons in detail.

4 Where, in the opinion of the Commission, the written observations of a Member State raise important new questions of a scientific or technical nature which have not been addressed in the opinion delivered by the Agency, the Chairman shall suspend the procedure and refer the application back to the Agency for further consideration.

5 The provisions necessary for the implementation of paragraph 4 shall be adopted by the Commission in accordance with the procedure referred to in Article 87(2).

6 The Agency shall disseminate the documents referred to in Article 34(4) (a) to (e).

Article 36

If an applicant withdraws an application for a marketing authorisation submitted to the Agency before an opinion has been given on the application, the applicant shall communicate its reasons for doing so to the Agency. The Agency shall make this information publicly accessible and shall publish the assessment report, if available, after deletion of all information of a commercially confidential nature.

Article 37

1 The marketing authorisation shall be refused if, after verification of the particulars and documents submitted in accordance with Article 31, it appears that:

a the applicant has not properly or sufficiently demonstrated the quality, safety or efficacy of the veterinary medicinal product;

b in the case of zootechnical veterinary medicinal products and performance enhancers, when the safety and welfare of the animals and/or consumer safety have not been sufficiently taken into account;

c the withdrawal period recommended by the applicant is not long enough to ensure that foodstuffs obtained from treated animals do not contain residues which might constitute a health hazard for the consumer or is insufficiently substantiated;

d the veterinary medicinal product is presented for a use prohibited under other **[**F1Union**]** provisions.

Authorisation shall likewise be refused if particulars or documents provided by the applicant in accordance with Article 31 are incorrect or if the labelling and package leaflets proposed by the applicant are not in accordance with Title V of Directive 2001/82/EC.

2 The refusal of a **[**F1Union marketing authorisation shall constitute a prohibition on the placing on the market of the veterinary medicinal product concerned throughout the Union**]**.

3 Information about all refusals and the reasons for them shall be made publicly accessible.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Article 38

1 Without prejudice to Article 71 of Directive 2001/82/EC, a marketing authorisation which has been granted in accordance with this Regulation shall be valid throughout the **[**F1Union**]**. It shall confer the same rights and obligations in each of the Member States as a marketing authorisation granted by that Member State in accordance with Article 5 of Directive 2001/82/EC.

Authorised veterinary medicinal products shall be entered in the **[**F1Union**]** Register of Medicinal Products and shall be given a number which shall appear on the packaging.

2 Notification of marketing authorisation shall be published in the *Official Journal of the European Union*, quoting in particular the date of authorisation and the number in the **[**F1Union**]** Register, any International Non-proprietary Name (INN) of the active substance of the medicinal product, its pharmaceutical form, and any Anatomical Therapeutic Chemical Veterinary Code (ATC Vet Code).

3 The Agency shall immediately publish the assessment report on the veterinary medicinal product drawn up by the Committee for Medicinal Products for Veterinary Use and the reasons for its opinion in favour of granting authorisation, after deletion of any information of a commercially confidential nature.

The European Public Assessment Report (EPAR) shall include a summary written in a manner that is understandable to the public. The summary shall contain in particular a section relating to the conditions of use of the medicinal product.

4 After a marketing authorisation has been granted, the holder of the authorisation shall inform the Agency of the dates of actual placing on the market of the veterinary medicinal product in Member States, taking into account the various presentations authorised.

The holder shall also notify the Agency if the product ceases to be placed on the market, either temporarily or permanently. Such notification shall, other than in exceptional circumstances, be made no less than 2 months before the interruption in the placing of the product on the market.

Upon request by the Agency, particularly in the context of pharmacovigilance, the marketing authorisation holder shall provide the Agency with all data relating to the volume of sales of the medicinal product at **[**F1Union**]** level, broken down by Member State, and any data in the holder's possession relating to the volume of prescriptions.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Article 39

1 Without prejudice to paragraphs 4 and 5, a marketing authorisation shall be valid for five years.

2 The marketing authorisation may be renewed after five years on the basis of a re-evaluation by the Agency of the risk-benefit balance.

To this end, the marketing authorisation holder shall submit a consolidated list of all documents submitted in respect of quality, safety and efficacy, including all variations introduced since the marketing authorisation was granted, at least six months before the marketing authorisation ceases to be valid in accordance with paragraph 1. The Agency may require the applicant to submit the listed documents at any time.

3 Once renewed, the marketing authorisation shall be valid for an unlimited period, unless the Commission decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal in accordance with paragraph 2.

4 Any authorisation which is not followed by the actual placing of the medicinal product for veterinary use on the **[**F1Union**]** market within three years after authorisation shall cease to be valid.

5 When an authorised medicinal product previously placed on the market is no longer actually present on the market for three consecutive years, the authorisation shall cease to be valid.

6 In exceptional circumstances and on public and/or animal health grounds the Commission may grant exemptions from the provisions of paragraphs 4 and 5. Such exemptions must be duly justified.

7 In exceptional circumstances and following consultation with the applicant, authorisation may be granted subject to a requirement for the applicant to introduce specific procedures, in particular concerning product safety, notification to the relevant authorities of

any incident relating to its use, and action to be taken. This authorisation may be granted only for objective, verifiable reasons. Continuation of the authorisation shall be linked to the annual reassessment of these conditions.

8 When an application is submitted for a marketing authorisation in respect of veterinary medicinal products of major interest, particularly from the point of view of animal health and from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure. The request shall be duly substantiated.

If the Committee for Medicinal Products for Veterinary Use accepts the request, the time-limit laid down in Article 31(3), first subparagraph, shall be reduced to 150 days.

9 When adopting its opinion, the said Committee shall include a proposal concerning the conditions for the prescription or use of the veterinary medicinal products.

10 Veterinary medicinal products which have been authorised in accordance with the provisions of this Regulation shall benefit from the provisions on protection in Articles 13 and 13a of Directive 2001/82/EC.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Article 40

The granting of authorisation shall not affect the civil or criminal liability of the manufacturer or the holder of the marketing authorisation pursuant to the applicable national law in Member States.

Chapter 2

Supervision and sanctions

Article 41

1 After an authorisation has been granted in accordance with this Regulation, the holder of the marketing authorisation shall, in respect of the methods of manufacture and control provided for in Article 12(3)(d) and (i) of Directive 2001/82/EC, take account of technical and scientific progress and make any variations that may be required to enable the medicinal products to be manufactured and checked by means of generally accepted scientific methods. He shall apply for approval of these variations in accordance with this Regulation.

2 The competent authority of a Member State or the Agency may require the holder of the marketing authorisation to provide substances in sufficient quantities for the performance of tests to detect the presence of residues of the veterinary medicinal products concerned in foodstuffs of animal origin.

3 At the request of the competent authority of a Member State or the Agency, the holder of the marketing authorisation shall provide technical expertise to facilitate the implementation

of the analytical method for detecting residues of veterinary medicinal products by the **[**[F1]Union**]** reference laboratory or, where appropriate, national reference laboratories designated in accordance with Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products[(2)].

4 The holder of the marketing authorisation shall forthwith supply to the Agency, the Commission and the Member States any new information which might entail the variation of the particulars or documents referred to in Articles 12(3), 13, 13a, 13b and 14 of Directive 2001/82/EC, in Annex I thereto, or in Article 34(4) of this Regulation.

He shall forthwith inform the Agency, the Commission and the Member States of any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is marketed and of any other new information which might influence the evaluation of the benefits and risks of the veterinary medicinal product concerned.

In order that the risk-benefit balance may be continuously assessed, the Agency may at any time ask the holder of the marketing authorisation to forward data justifying that the risk-benefit balance remains favourable.

5 If the holder of the marketing authorisation for the veterinary medicinal product proposes to make any variation of the particulars and documents referred to in paragraph 4, he shall submit the relevant application to the Agency.

[[F2]6 The Commission shall, after consulting the Agency, adopt appropriate provisions for the examination of variations to marketing authorisations in the form of a regulation. Those measures, designed to amend non-essential elements of this regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 87(2a).**]**

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

F2 Substituted by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Two.

Article 42

The applicant or the holder of a marketing authorisation shall be responsible for the accuracy of the documents and of the data submitted.

Article 43

1 In the case of veterinary medicinal products manufactured within the **[**[F1]Union**]**, the supervisory authorities shall be the competent authorities of the Member State or Member States which granted the manufacturing authorisation provided for in Article 44(1) of Directive 2001/82/EC in respect of the manufacture of the medicinal product concerned.

2 In the case of veterinary medicinal products imported from third countries, the supervisory authorities shall be the competent authorities of the Member State or Member States that granted the authorisation provided for in Article 44(3) of Directive 2001/82/EC to the importer, unless appropriate agreements have been made between the **[**F1Union and the exporting country to ensure that those controls are carried out in the exporting country and that the manufacturer applies standards of good manufacturing practice at least equivalent to those laid down by the Union**]**.

A Member State may request assistance from another Member State or the Agency.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Article 44

1 The supervisory authorities shall be responsible for verifying on behalf of the **[**F1Union that the holder of the marketing authorisation for the veterinary medicinal product or the manufacturer or importer established within the Union**]** satisfies the requirements laid down in Titles IV, VII and VIII of Directive 2001/82/EC.

2 Where, in accordance with Article 90 of Directive 2001/82/EC, the Commission is informed of serious differences of opinion between Member States as to whether the holder of the marketing authorisation for the veterinary medicinal product or a manufacturer or importer established within the **[**F1Union**]** satisfies the requirements referred to in paragraph 1, the Commission may, after consultation with the Member States concerned, request an inspector from the supervisory authority to undertake a new inspection of the holder of the marketing authorisation, the manufacturer or the importer; the inspector in question shall be accompanied by two inspectors from Member States which are not party to the dispute and/or by two experts nominated by the Committee for Medicinal Products for Veterinary Use.

3 Subject to any agreements which may have been concluded between the **[**F1Union**]** and third countries in accordance with Article 43(2), the Commission may, upon receipt of a reasoned request from a Member State or from the said Committee, or on its own initiative, require a manufacturer established in a third country to submit to an inspection.

The inspection shall be undertaken by inspectors from the Member State who possess the appropriate qualifications; they may be accompanied by a rapporteur or expert appointed by the said Committee. The report of the inspectors shall be made available to the Commission, the Member States and the said Committee.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Article 45

1 Where the supervisory authorities or the competent authorities of any other Member State are of the opinion that the manufacturer or importer established within the **[**[F1]Union**]** is no longer fulfilling the obligations laid down in Title VII of Directive 2001/82/EC, they shall forthwith inform the Committee for Medicinal Products for Veterinary Use and the Commission, stating their reasons in detail and indicating the course of action proposed.

The same shall apply where a Member State or the Commission considers that one of the measures envisaged in Title VIII of Directive 2001/82/EC should be applied in respect of the veterinary medicinal product concerned or where the said Committee has delivered an opinion to that effect in accordance with Article 30 of this Regulation.

2 The Commission shall request the opinion of the Agency within a time-limit which it shall determine in the light of the urgency of the matter, in order to examine the reasons advanced. Whenever practicable, the holder of the marketing authorisation for the medicinal product shall be invited to provide oral or written explanations.

3 Following an opinion by the Agency, the Commission shall adopt the necessary provisional measures, which shall be applied immediately.

A final decision shall be adopted within six months, in accordance with the procedure referred to in Article 87(3).

4 Where urgent action is essential to protect human or animal health or the environment, a Member State may, on its own initiative or at the Commission's request, suspend the use on its territory of a veterinary medicinal product which has been authorised in accordance with this Regulation.

When it does so on its own initiative, the Member State shall inform the Commission and the Agency of the reasons for its action at the latest on the next working day following the suspension. The Agency shall inform the other Member States without delay. The Commission shall immediately initiate the procedure provided for in paragraphs 2 and 3.

5 In this case, the Member State shall ensure that health-care professionals are rapidly informed of its action and the reasons for the action. Networks set up by professional associations may be used to this effect. Member States shall inform the Commission and the Agency of actions taken for this purpose.

6 The suspensive measures referred to in paragraph 4 may be maintained until such time as a definitive decision has been reached in accordance with the procedure referred to in Article 87(3).

7 The Agency shall, upon request, inform any person concerned of the final decision and make the decision publicly accessible, immediately after it has been taken.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Chapter 3

Pharmacovigilance

Article 46

For the purpose of this Chapter, Article 77(2) of Directive 2001/82/EEC shall apply.

Article 47

The Agency, acting in close cooperation with the national pharmacovigilance systems established in accordance with Article 73 of Directive 2001/82/EC, shall receive all relevant information about suspected adverse reactions to veterinary medicinal products which have been authorised by the **[**F1Union**]** in accordance with this Regulation. Where appropriate the Committee for Medicinal Products for Veterinary Use shall, in accordance with Article 30 of this Regulation, draw up opinions on the measures necessary. These opinions shall be made publicly accessible.

These measures may include amendments to the marketing authorisation granted in accordance with Article 35. They shall be adopted in accordance with the procedure referred to in Article 87(3).

The holder of the marketing authorisation and the competent authorities of the Member States shall ensure all relevant information about suspected adverse reactions to the veterinary medicinal products authorised under this Regulation is brought to the attention of the Agency in accordance with the provisions of this Regulation. Animal owners and breeders shall be encouraged to communicate any adverse reaction to health-care professionals or to the competent national authorities responsible for pharmacovigilance.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Article 48

The holder of the marketing authorisation for a veterinary medicinal product granted in accordance with the provisions of this Regulation shall have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance.

That qualified person shall reside in the **[**F1Union**]** and shall be responsible for the following:

(a) establishing and managing a system which ensures that information about all suspected adverse reactions which are reported to the personnel of the company and to

medical representatives is collected, evaluated and collated so that it may be accessed at a single point within the **[**[F1]Union**]**;

(b) preparing the reports referred to in Article 49(3) for the competent authorities of the Member States and the Agency in accordance with the requirements of this Regulation;

(c) ensuring that any request from the competent authorities for the provision of additional information necessary for the evaluation of the risks and benefits of a veterinary medicinal product is answered fully and promptly, including the provision of information about the volume of sales or prescriptions for the veterinary medicinal product concerned;

(d) providing the competent authorities with any other information relevant to the evaluation of the risks and benefits of a veterinary medicinal product, particularly information concerning post-authorisation safety studies, including information regarding the validity of the withdrawal period or lack of expected efficacy or potential environmental problems.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Article 49

1 The holder of the marketing authorisation for a veterinary medicinal product shall ensure that all suspected serious adverse reactions, and adverse human reactions to a veterinary medicinal product authorised in accordance with the provisions of this Regulation occurring within the **[**[F1]Union**]** which a health-care professional brings to his attention are recorded and reported promptly to the Member States in the territory of which the incident occurred no later than 15 days following receipt of the information.

The holder of the marketing authorisation shall record any other suspected serious adverse reactions and human adverse reactions occurring within the **[**[F1]Union**]**, in accordance with the guidelines referred to in Article 51, of which he may reasonably be expected to be aware, and promptly notify Member States in the territory of which the incident occurred and the Agency, and no later than 15 days following receipt of the information.

2 **[**[F2]The holder of the marketing authorisation for a veterinary medicinal product shall ensure that all suspected serious unexpected adverse reactions, and adverse human reactions, and any suspected transmission via a medicinal product of any infectious agent occurring in the territory of a third country are reported promptly to the Member States and the Agency, and no later than 15 days following receipt of the information. The Commission shall adopt provisions for the reporting of suspected unexpected adverse reactions which are not serious, whether occurring in the **[**[F1]Union**]** or in a third country. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 87(2a).**]**

Save in exceptional circumstances, these reactions shall be transmitted electronically in the form of a report and in accordance with the guide referred to in Article 51.

3 The holder of the marketing authorisation for a veterinary medicinal product shall maintain detailed records of all suspected adverse reactions occurring within or outside the **[**F1Union**]** which are reported to him.

Unless other requirements have been laid down as a condition for the granting of the marketing authorisation by the **[**F1Union, these records shall be submitted, in the form of a periodic safety update report, to the Agency and Member States immediately upon request or at least every six months after authorisation until the placing on the market. Periodic safety update reports shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the Union**]** market and once a year for the following two years. Thereafter, the reports shall be submitted at three-yearly intervals, or immediately upon request.

These reports shall be accompanied by a scientific evaluation, particularly of the risk-benefit balance of the medicinal product.

[F24 The Commission may lay down provisions to amend paragraph 3 in view of experience gained with its operation. Those measures, designed to amend non-essential elements of this regulation, shall be adopted in accordance with the procedure referred to in Article 87(2a).**]**

5 The holder of a marketing authorisation may not communicate information relating to pharmacovigilance concerns to the general public in relation to its authorised medicinal product without giving prior or simultaneous notification to the Agency.

In any case, the marketing authorisation holder shall ensure that such information is presented objectively and is not misleading.

Member States shall take the necessary measures to ensure that a marketing authorisation holder who fails to discharge these obligations is subject to effective, proportionate and dissuasive penalties.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

F2 Substituted by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Two.

Article 50

Each Member State shall ensure that all suspected serious adverse reactions, and adverse human reactions, occurring within its territory to a veterinary medicinal product authorised in accordance with the provisions of this Regulation which are brought to its attention are recorded and reported promptly to the Agency and the holder of the marketing authorisation for the veterinary medicinal product, and no later than 15 days following receipt of the information.

The Agency shall forward the information to the national pharmacovigilance systems set up in accordance with Article 73 of Directive 2001/82/EC.

Article 51

The Commission, in consultation with the Agency, Member States and interested parties, shall draw up a guide on the collection, verification and presentation of adverse-reaction reports. This guide shall contain, in particular, for the benefit of health-care professionals, recommendations concerning the communication of information on adverse reactions.

In accordance with this guide, holders of marketing authorisations shall use the medical terminology accepted at international level for the transmission of adverse-reaction reports.

The Agency, in consultation with the Member States and the Commission, shall set up a data-processing network for the rapid transmission of data between the competent **[**[F1]Union**]** authorities in the event of an alert relating to faulty manufacture, serious adverse reactions and other pharmacovigilance data regarding veterinary medicinal products authorised in accordance with Article 5 of Directive 2001/82/EC.

For a period of five years following the initial placing on the market in the Union, the Agency may request that the marketing authorisation holder arrange for specific pharmacovigilance data to be collected from targeted groups of animals. The Agency shall state the reasons for the request. The marketing authorisation holder shall collate and assess the data collected and submit it to the Agency for evaluation.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Article 52

The Agency shall cooperate with international organisations concerned with veterinary pharmacovigilance.

Article 53

The Agency and the Member States' competent authorities shall cooperate to continuously develop pharmacovigilance systems capable of achieving high standards of public health protection for all medicinal products, regardless of routes of authorisation, including the use of collaborative approaches, to maximise use of resources available within the **[**[F1]Union**]**.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

[F2 Article 54

The Commission may adopt any amendment which may be necessary to update the provisions of this Chapter in order to take account of scientific and technical progress. Those measures, designed to amend non-essential elements of this regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 87(2a).]

Textual Amendments

F2 Substituted by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Two.

(1) Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a **[**[F1]Union**]** procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ L 224, 18.8.1990, p. 1). Regulation as last amended by Commission Regulation (EC) No 1029/2003 (OJ L 149, 17.6.2003, p. 15).

(2) OJ L 125, 23.5.1996, p. 10. Directive as amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Status:
Point in time view as at 28/01/2019.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 726/2004 of the European Parliament and of the Council, TITLE III.