

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 [F<sup>1</sup>Union] law may confer on it, in particular under Regulation (EEC) No 2377/90<sup>(1)</sup>, 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, [F<sup>1</sup>Union] nature of the authorisation requested and,

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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 [F<sup>1</sup>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;

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- 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**

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#### *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:

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- 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 [F<sup>1</sup>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 \(Text with EEA relevance\).](#)

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### 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;

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- 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 [F<sup>1</sup>Union] 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 [F<sup>1</sup>Union] 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.

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#### *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 [F<sup>1</sup>Union]. 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 [F<sup>1</sup>Union] 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 [F<sup>1</sup>Union] 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.

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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

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#### 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

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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.

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#### **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.



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- (1) Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a [<sup>F1</sup>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).

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**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).

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