

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

TITLE III

**MARKETING**

[<sup>F1</sup>CHAPTER 4

**Mutual recognition procedure and decentralised procedure]**

*[<sup>F1</sup>Article 31*

1 A coordination group shall be set up for the examination of any question relating to marketing authorisation of a veterinary medicinal product in two or more Member States in accordance with the procedures laid down in this Chapter. The Agency shall provide the secretariat of this coordination group.

2 The coordination group shall be composed of one representative per Member State appointed for a renewable period of three years. Members of the group may arrange to be accompanied by experts.

3 The coordination group shall draw up its own rules of procedure, which shall enter into force after a favourable opinion has been given by the Commission. These rules of procedure shall be made public.

*Article 32*

1 With a view to the granting of a marketing authorisation for a veterinary medicinal product in more than one Member State, the applicant shall submit an application based on an identical dossier in those Member States. The dossier shall contain all the administrative information and scientific and technical documentation described in Articles 12 to 14. The documents submitted shall include a list of Member States concerned by the application.

The applicant shall request one Member State to act as reference Member State and to prepare an assessment report in respect of the veterinary medicinal product in accordance with paragraphs 2 or 3.

Where appropriate, the assessment report shall contain an evaluation for the purposes of Article 13(5) or Article 13a(3).

2 If the veterinary medicinal product has already received a marketing authorisation at the time of application, the concerned Member States shall recognise the marketing authorisation granted by the reference Member State. To this end, the marketing authorisation holder shall request the reference Member State either to prepare an assessment report in respect of the veterinary medicinal product or, if necessary, to update any existing assessment report. The reference Member State shall prepare or update the assessment report within 90 days of receipt of a valid application. The assessment report together with the approved summary of product characteristics, labelling and package leaflet shall be forwarded to the concerned Member States and the applicant.

3 If the veterinary medicinal product has not received authorisation by the time of application, the applicant shall request the reference Member State to prepare a draft assessment

report and drafts of the summary of product characteristics, labelling and package leaflet. The reference Member State shall prepare these drafts within 120 days of the receipt of a valid application and shall send them to the concerned Member States and the applicant.

4 Within 90 days after receipt of the documents referred to in paragraphs 2 and 3, the Member States concerned shall approve the assessment report, the summary of product characteristics, the labelling and the package leaflet and inform the reference Member State accordingly. The reference Member State shall record the agreement of all parties, close the procedure and inform the applicant accordingly.

5 Each Member State in which an application following paragraph 1 has been submitted shall adopt a decision in conformity with the approved assessment report, summary of product characteristics, labelling and package leaflet within 30 days after acknowledgement of the agreement.

### *Article 33*

1 If a Member State cannot, within the period allowed in Article 32(4), agree with the assessment report, summary of product characteristics, labelling and package leaflet on grounds of a potential serious risk to human or animal health or to the environment, a detailed statement of the reasons shall be provided to the reference Member State, the other Member States concerned and the applicant. The points of disagreement shall be referred without delay to the coordination group.

If a Member State to which an application has been submitted invokes the reasons referred to in Article 71(1), it shall no longer be regarded as a Member State concerned by this Chapter.

2 The Commission shall adopt guidelines defining a potential serious risk for human or animal health or for the environment.

3 Within the coordination group, all Member States referred to in paragraph 1 shall use their best endeavours to reach agreement on the action to be taken. They shall provide the applicant with the opportunity to make his point of view known orally or in writing. If, within 60 days of the communication of the reasons for disagreement to the coordination group the Member States reach an agreement, the reference Member State shall record the agreement, close the procedure and inform the applicant accordingly. Article 32(5) shall apply.

4 If within the period of 60 days the Member States fail to reach an agreement, the Agency shall be immediately informed with a view to application of the procedure laid down in Articles 36, 37 and 38. The Agency shall be provided with a detailed description of the matters on which agreement could not be reached and the reasons for the disagreement. The applicant shall be provided with a copy of this information.

5 As soon as the applicant has been informed that the matter has been referred to the Agency, he shall forthwith forward to the Agency a copy of the information and documents referred to in the first subparagraph of Article 32(1).

6 In the case referred to in paragraph 4, the Member States that have approved the assessment report, summary of product characteristics, labelling and package leaflet of the reference Member State may, on request by the applicant, grant a marketing authorisation for the veterinary medicinal product without waiting for the outcome of the procedure laid down in Article 36. In that case, the authorisation granted shall be without prejudice to the outcome of that procedure.

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#### *Article 34*

1 If two or more applications submitted in accordance with Articles 12 to 14 have been made for marketing authorisation for a particular veterinary medicinal product and Member States have adopted divergent decisions concerning the authorisation of that veterinary medicinal product, or suspension or revocation of authorisation, a Member State, or the Commission, or the marketing-authorisation holder may refer the matter to the Committee for Medicinal Products for Veterinary Use, hereinafter referred to as 'the Committee', for the application of the procedure laid down in Articles 36, 37 and 38.

2 With a view to promoting the harmonisation of veterinary medicinal products authorised in the Community, and to strengthening the efficiency of the provisions of Articles 10 and 11, Member States shall send to the coordination group, no later than 30 April 2005, a list of veterinary medicinal products for which a harmonised summary of product characteristics should be prepared.

The coordination group shall agree on a list of medicinal products, on the basis of proposals sent by Member States, and shall forward the list to the Commission.

The medicinal products on the list shall be subject to the provisions in paragraph 1 in accordance with a timetable established in cooperation with the Agency.

The Commission, acting in collaboration with the Agency, and taking into consideration the views of the interested parties, shall agree the final list and timetable.

#### *Article 35*

1 Member States or the Commission or the applicant or marketing authorisation holder shall, in specific cases where the interests of the Community are involved, refer the matter to the Committee for the application of the procedure laid down in Articles 36, 37 and 38 before a decision is reached on a request for a marketing authorisation or on the suspension or withdrawal of an authorisation, or on any other variations to the terms of a marketing authorisation which appear necessary, so as to take account in particular of the information collected in accordance with Title VII.

The Member State concerned or the Commission shall clearly identify the question which is referred to the Committee for consideration and shall inform the applicant or the marketing authorisation holder.

The Member State and the applicant or the marketing authorisation holder shall forward to the Committee all available information relating to the matter in question.

2 Where the referral to the Committee concerns a range of medicinal products or a therapeutic class, the Agency may limit the procedure to specific parts of the authorisation.

In that case, Article 39 shall apply to those medicinal products only if they are covered by the marketing authorisation procedure referred to in this Chapter.

#### *Article 36*

1 When reference is made to the procedure laid down in this Article, the Committee shall consider the matter concerned and shall issue a reasoned opinion within 60 days of the date on which the matter was referred to it.

However, in cases submitted to the Committee in accordance with Articles 34 and 35, this period may be extended by the Committee for a further period of up to 90 days, taking into account the views of the marketing authorisation holders concerned.

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In an emergency, and on a proposal from its Chairman, the Committee may agree to a shorter deadline.

2 In order to consider the matter, the Committee shall appoint one of its members to act as rapporteur. The Committee may also appoint independent experts to advise it on specific questions. When appointing such experts, the Committee shall define their tasks and specify the time limit for the completion of these tasks.

3 Before issuing its opinion, the Committee shall provide the applicant or the marketing authorisation holder with an opportunity to present written or oral explanations within a time limit that it will specify.

The opinion of the Committee shall include the draft summary of product characteristics and the drafts of the labelling and package leaflet.

If it considers appropriate, the Committee may invite any other person to provide information relating to the matter before it.

The Committee may suspend the time limit referred to in paragraph 1 to allow the applicant or the marketing authorisation holder to prepare the explanations.

4 The Agency shall forthwith inform the applicant or the marketing authorisation holder when the opinion of the Committee is that:

- the application does not satisfy the criteria for authorisation, or
- the summary of product characteristics proposed by the applicant or the marketing authorisation holder in accordance with Article 14 should be amended, or
- the authorisation should be granted subject to conditions, with regard to conditions considered essential for the safe and effective use of the veterinary medicinal product including pharmacovigilance, or
- a marketing authorisation should be suspended, varied or revoked.

Within 15 days after receipt of the opinion, the applicant or the marketing authorisation holder may notify the Agency in writing of his intention to request a re-examination of the opinion. In that case, he shall forward to the Agency the detailed grounds for the request within 60 days after receipt of the opinion.

Within 60 days following receipt of the grounds for the request, the Committee shall re-examine its opinion in accordance with the fourth subparagraph of Article 62(1) of Regulation (EC) No 726/2004. The reasons for the conclusion reached shall be annexed to the assessment report referred to in paragraph 5 of this Article.

5 Within 15 days after its adoption, the Agency shall forward the final opinion of the Committee to Member States, the Commission and the applicant or the marketing authorisation holder, together with a report describing the assessment of the veterinary medicinal product and the reasons for its conclusions.

In the event of an opinion in favour of granting or maintaining a marketing authorisation, the following documents shall be annexed to the opinion:

- a a draft summary of the product characteristics, as referred to in Article 14; where necessary this will reflect the differences in the veterinary conditions in Member States;
- b any conditions affecting the authorisation within the meaning of paragraph 4;
- c details of any recommended conditions or restrictions with regard to the safe and effective use of the veterinary medicinal product; and
- d drafts of the labelling and package leaflet.

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### Article 37

Within 15 days after receipt of the opinion, the Commission shall prepare a draft of the decision to be taken in respect of the application, taking into account Community law.

In the event of a draft decision that envisages the granting of a marketing authorisation, the documents referred to in the second subparagraph of Article 36(5) shall be annexed.

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

The draft decision shall be forwarded to Member States and the applicant or marketing authorisation holder.]

### Article 38

[<sup>F1</sup> The Commission shall take a final decision in accordance with, and within 15 days after the end of, the procedure referred to in Article 89(3).]

2 The rules of procedure of the Standing Committee set up by Article 89(1) shall be adjusted to take account of the tasks incumbent upon it in accordance with this Chapter.

These adjustments shall involve the following:

- except in cases referred to in the third paragraph of Article 37, the opinion of the Standing Committee shall be obtained in writing,
- [<sup>F1</sup>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,
- Member States shall have the option of submitting a written request that the draft decision be discussed in a plenary meeting of the Standing Committee.]

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 of the Agency, the Chairman shall suspend the procedure and refer the application back to the Agency for further consideration.

The provisions necessary for the implementation of this paragraph shall be adopted by the Commission in accordance with the procedure referred to in Article 89(2).

[<sup>F13</sup> A decision as referred to in paragraph 1 shall be addressed to all Member States and communicated to the marketing authorisation holder or the applicant for information. The concerned Member States and the reference Member State shall either grant or withdraw marketing authorisation, or vary the terms of a marketing authorisation as necessary to comply with the decision within 30 days of its notification and shall refer to it. They shall inform the Commission and the Agency accordingly.]

### Article 39

1 Any application by the marketing authorization holder to vary a marketing authorization which has been granted in accordance with the provisions of this Chapter shall be submitted to all the Member States which have previously authorized the veterinary medicinal product concerned.

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<sup>F2</sup> . . . . .]

[<sup>F3</sup>The Commission shall adopt those arrangements in the form of an implementing regulation. That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).]

2 In case of arbitration submitted to the Commission, the procedure laid down in Articles 36, 37 and 38 shall apply by analogy to variations made to marketing authorizations.

#### Textual Amendments

- F2** Deleted by [Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products \(Text with EEA relevance\)](#).
- F3** Substituted by [Regulation \(EC\) No 596/2009 of the European Parliament and of the Council of 18 June 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 Four](#).

#### Article 40

1 Where a Member State considers that the variation of the terms of a marketing authorization which has been granted in accordance with the provisions of this Chapter or its suspension or withdrawal is necessary for the protection of human or animal health or the environment, the Member State concerned shall forthwith refer the matter to the Agency for the application of the procedures laid down in Articles 36, 37 and 38.

2 Without prejudice to the provisions of Article 35, in exceptional cases, where urgent action is essential to protect human or animal health or the environment, until a definitive decision is adopted, a Member State may suspend the marketing and the use of the veterinary medicinal product concerned on its territory. It shall inform the Commission and the other Member States no later than the following working day of the reasons for its action.

#### Article 41

Articles 39 and 40 shall apply by analogy to veterinary medicinal products authorized by Member States following an opinion of the Committee given in accordance with Article 4 of Directive 87/22/EEC before 1 January 1995.

#### Article 42

1 The Agency shall publish an annual report on the operation of the procedures laid down in this Chapter and shall forward it to the European Parliament and the Council for information.

[<sup>F12</sup> At least every ten years the Commission shall publish a report on experience gained on the basis of the procedures provided for in this chapter and shall propose any amendments necessary to improve the procedures. The Commission shall submit this report to the European Parliament and the Council.]

#### [<sup>F1</sup>Article 43

Articles 33(4), (5) and (6) and 34 to 38 shall not apply to the homeopathic veterinary medicinal products referred to in Article 17.

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Articles 32 to 38 shall not apply to the homeopathic veterinary medicinal products referred to in Article 19(2).]

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**Textual Amendments**

- F1** Substituted by [Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.](#)