

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

[^{F1}CHAPTER 4

Mutual recognition procedure and decentralised procedure]

[^{F1}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.

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.

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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.]

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.](#)