

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]

Article 38

[^{F1} 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,
- [^{F1}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).

[^{F13} 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.]

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.](#)