

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

CHAPTER 3

Procedure for marketing authorization

[^{F1}Article 28

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

2 The authorisation may be renewed after five years on the basis of a re-evaluation 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 competent authority 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 competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal in accordance with paragraph 2.

4 Any authorisation that is not followed within three years of its granting by the actual placing on the market of the authorised veterinary medicinal product in the authorising Member State shall cease to be valid.

5 When an authorised veterinary medicinal product previously placed on the market in the authorising Member State is no longer actually present on the market in that Member State for a period of three consecutive years, the authorisation granted for that veterinary medicinal product shall cease to be valid.

6 The competent authority may, in exceptional circumstances, and on human or animal health grounds, grant exemptions from paragraphs 4 and 5. Such exemptions shall be duly justified.]

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.](#)