

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**

*[<sup>F1</sup>Article 23*

In order to examine the application submitted pursuant to Articles 12 to 13d, Member States' competent authorities:

- 1) shall check that the documentation submitted in support of the application complies with Articles 12 to 13d and ascertain whether the conditions for the issue of the marketing authorisation have been fulfilled;
- 2) may submit the medicinal product, its starting materials and if necessary intermediate products or other constituent materials for testing by an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose, in order to ensure that the testing methods employed by the manufacturer and described in the application documents, in accordance with point (i) of the first subparagraph of Article 12(3), are satisfactory;
- 3) may similarly check, in particular through consultation of a national or Community reference laboratory, that the analytical method used for detecting residues presented by the applicant for the purposes of Article 12(3)(j), second indent is satisfactory;
- 4) may, where appropriate, require the applicant to provide further information as regards the items listed in Articles 12, 13a, 13b, 13c and 13d. Where the competent authorities take this course of action, the time-limits specified in Article 21 shall be suspended until the further data required have been provided. Similarly, these time-limits shall be suspended for any period which the applicant may be given to provide oral or written explanations.]

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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.](#)