

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 25

1 When granting a marketing authorisation, the competent authority shall inform the holder of the summary of product characteristics that it has approved.

2 The competent authority shall take all necessary measures to ensure that information concerning the veterinary medicinal product, and in particular the labelling and package leaflet, is in conformity with the summary of product characteristics approved when the marketing authorisation was granted or subsequently.

3 The competent authority shall make the marketing authorisation publicly available without delay, together with the summary of product characteristics for each veterinary medicinal product that it has authorised.

4 The competent authority shall draw up an assessment report and comments on the file as regards the results of the pharmaceutical, safety and residue tests and the pre-clinical and clinical trials of the veterinary medicinal product concerned. The assessment report shall be updated whenever new information becomes available which is of importance for the evaluation of the quality, safety or efficacy of the veterinary medicinal product concerned.

The competent authority shall make the assessment report and its reasons for the opinion publicly available without delay, after deleting any information of a commercially confidential nature.]

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.](#)