
TITLE III
MARKETING

CHAPTER 3
Procedure for marketing authorization

Article 26

[F1] 1. The marketing authorisation may require the holder to indicate on the immediate packaging and/or the outer wrapping and the package leaflet, where the latter is required, other particulars essential for safety or health protection, including any special precautions relating to use and any other warnings resulting from the clinical and pharmacological trials prescribed in Article 12(3)(j) and in Articles 13 to 13d or from experience gained during the use of the veterinary medicinal product once it has been marketed.]

[F2] 2. ..................................................

[F3] 3. In exceptional circumstances, and following consultation with the applicant, the authorisation may be granted subject to a requirement for the applicant to introduce specific procedures, in particular concerning the safety of the veterinary medicinal product, notification to the competent authorities of any incident relating to its use, and action to be taken. Such authorisations may be granted only for objective, verifiable reasons. Continuation of the authorisation shall be linked to the annual reassessment of these conditions.]

Textual Amendments
