

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 1

Marketing authorization

f¹ Article 13b

In the case of veterinary medicinal products containing active substances used in the composition of authorised veterinary medicinal products but not hitherto used in combination for therapeutic purposes, the results of safety and residue tests, if necessary, and new pre-clinical tests or new clinical trials relating to that combination shall be provided in accordance with point (j) of the first subparagraph of Article 12(3), but it shall not be necessary to provide scientific references relating to each individual active substance.]

Textual Amendments

- F1** Inserted 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.](#)