

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 V

**LABELLING AND PACKAGE INSERT**

*Article 64*

1 Without prejudice to paragraph 2, homeopathic veterinary medicinal products shall be labelled in accordance with the provisions of this title and identified by the inclusion on their labels, in clearly legible form, of the words ‘homeopathic medicinal product for veterinary use’.

[<sup>F12</sup> In addition to the clear mention of the words ‘homeopathic veterinary medicinal product without approved therapeutic indications’, the labelling and, where appropriate, package leaflet for the homeopathic veterinary medicinal products referred to in Article 17(1) shall bear the following information and no other information:]

- [<sup>F1</sup>the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the pharmacopoeia used in accordance with point (8) of Article 1. If the homeopathic veterinary medicinal product is composed of more than one stock, the labelling may mention an invented name in addition to the scientific names of the stocks,]
- name and address of the marketing authorization holder and, where appropriate, of the manufacturer,
- method of administration and, if necessary, route,
- expiry date, in clear terms (month, year),
- pharmaceutical form,
- contents of the sales presentation,
- special storage precautions, if any,
- target species,
- a special warning if necessary for the medicinal product,
- manufacturer's batch number,
- registration number.

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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.](#)