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Clarification regarding name of veterinary medicinal product

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CMDv reflections on what constitutes the name of a veterinary medicinal product

According to article 1 item 22 of Directive 2001/82/EC, as amended, the name of a veterinary medicinal product can be either:

- a) an invented name not liable to confusion with the common name,
- b) a common name accompanied by a trademark or the name of the marketing authorisation holder or
- c) a scientific name accompanied by a trademark or the name of the marketing authorisation holder.

The common name, according to article 1 item 23 of Directive 2001/82/EC, as amended, is the “international non-proprietary name recommended by the World Health Organisation, or, if one does not exist, the usual common name.”

The name as such is usually not sufficient to identify the product. For identification purpose the strength (when relevant), pharmaceutical form and possibly the target species would be required. Such a combination is sometimes referred to as “full information name”.

In the summary of product characteristics, labelling text and package leaflet the name of the product shall be stated, followed by qualifiers according to Directive 2001/82/EC, as amended:

Article 14:

The summary of the product characteristics shall contain, in the order indicated below, the following information:

- 1) name of the veterinary medicinal product followed by the strength and the pharmaceutical form;

Article 58:

Packaging shall bear the following information ...

- (a) The name of the medicinal product, followed by its strength and pharmaceutical form. The common name shall appear if the medicinal product contains only one active substance and its name is an invented name;

Article 61:

Leaflets shall contain at least the following information, in the order indicated, ...

- (b) name of the veterinary medicinal product followed by its strength and pharmaceutical form.

When drafting the SPC, labelling and PL, the guidance in the [annotated QRD/CMDv product information template](#) should be respected, i.e. the name followed by specific information.