

NOTICE TO APPLICANTS

VOLUME 6 C

**GUIDELINE ON THE PACKAGING
INFORMATION OF VETERINARY
MEDICINAL PRODUCTS
AUTHORISED BY THE UNION**

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Legal framework

Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹ (hereinafter "the Regulation") lays down a centralised Union procedure for the authorisation of medicinal products for human and veterinary use. This means that there is a single application, a single evaluation and a single authorisation allowing direct access to the EU market of a medicinal product bearing a single set of information.

The Regulation provides that an application for the authorisation of a medicinal product for veterinary use should specifically and completely include the particulars and documents as referred in particular in Article 12(3)(1) of Directive 2001/82/EC, which provides that:

“The application for marketing authorisation shall include all the administrative information and scientific documentation necessary for demonstrating the quality, safety and efficacy of the veterinary medicinal product in question. The file shall be submitted in accordance with Annex I and shall contain, in particular, the following information: [...]summary in accordance with Article 14 of the product characteristics, a mock-up of the immediate packaging and the outer packaging of the veterinary medicinal product, together with the package leaflet, in accordance with Articles 58 to 61”.

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for veterinary use² (hereinafter "Directive 2001/82/EC") contains in Title V 'Labelling and Package Insert' provisions on the text of the label and package leaflet of medicinal products placed on the EU market.

¹ OJ L 136, 30.04.2004, p. 1

² OJ L 311, 28.11.2001, p. 1

Purpose

The purpose of this guideline is to describe how the above mentioned provisions of Directive 2001/82/EC apply in the case of a marketing authorisation granted by the Union.

This guideline shall assist applicants and marketing authorisation holders when drawing up the labelling and package leaflet and preparing the mock-up³ and specimens of the sales presentation.

³ A mock-up is a copy of the flat artwork design in full colour, presented so that, following cutting and folding where necessary, it provides a replica of both the outer and immediate packaging so that the three dimensional presentation of the labelling text is clear. This mock-up is generally referred to as a paper copy and not necessarily in the material of the sales presentation. A specimen is a sample of the actual printed out outer and immediate packaging materials and package leaflet (i.e. the sales presentation).

Section A - Label

1. Legal Status on the label

In addition to appearing in Annex II of the Commission Decision, the legal status shall appear in the label text, which is included in Annex IIIA of the Commission Decision. However, the expression of the legal status in the label text in the Commission Decision is limited, at present, to one of the main classifications following the criteria of Article 67 of Directive 2001/82/EC ("veterinary medicinal product subject to prescription") which is common to all EEA countries. Where sub-categories exist in some EEA countries they shall not be stated in Annex IIIA but shall be included in the *blue box* area covered in point 4.

2. The label text

The Union authorisation for a veterinary medicinal product includes the label text, which content is identical for all packs of the same size of that medicinal product throughout the Union, without prejudice to exceptions covered in point 4 as indicated below. Applicants should refer to the [EMA webpage for veterinary mock-ups](#)⁴ for further specific guidance in this respect.

3. Language

The content of all language versions must be identical (apart from text appearing in the blue box area covered in point 4). If more than one language is used, then all of the text must be translated into each language.

In accordance with Article 58(4) of Directive 2001/82/EC, the labelling must be presented at least in the language or languages of the Member State(s) where the product is placed on the market⁵. The EU language(s) used on the label must be the same as the language(s) used in the package leaflet.

4. Additional labelling information required by some EEA countries (the so-called *blue box*)

Additional information on the labelling which may be required nationally must go into the so-called *blue box* providing it is not contradictory to Union legislation (article 63 of Directive 2001/82/EC) or to the Commission Decision.

Therefore, EEA countries may require the use of certain forms of labelling making it possible to indicate, in particular:

- Member State-specific sub-category of the legal status or national requirements concerning conditions of supply;
- specific information on product identification.

For national *blue box* requirements and additional information on labelling/package leaflet, applicants should refer to the guidance published on the CMDv's website:

[CMDv-GUI-027094, EMA/CMDv/391895/2012](#)

⁴ <https://www.ema.europa.eu/en/veterinary-regulatory/marketing-authorisation/product-information/qa-mock-ups>

⁵ Article 61(1) of Directive 2001/82/EC states that, "Competent authorities may exempt labels and package leaflets for specific veterinary medicinal products from the obligation for certain particulars to appear and for the leaflet to be in the official language or languages of the Member State in which the product is placed on the market, when the product is intended to be administered only by a veterinarian."

The information specific to a Member State should be placed on the label in a boxed area⁶, to appear on one side of the pack. Each boxed area (the so-called *blue box*), should only be presented in the official language or languages of the Member State concerned and should state the name of that Member State. The location of the *blue box* on the package should be the same for all language versions. When one pack is intended for marketing in several EEA countries, it is preferable to have only one *blue box* on the pack. This box will contain different information in each Member State.

Applicants should refer to the [EMA's pre-submission guidance \(Q&As\)](#) regarding information on where local representatives can be mentioned on the packaging, as well as information on what logos can be included⁷.

4.1 Legal status

As far as the legal status is concerned, it should be noted that the main category, "medicinal product subject to veterinary prescription" shall already be included in the labelling. Hence, the boxed area may only contain the specific sub-category and/or a symbol expressing this main category. See also, Section B hereafter. Symbols used in some EEA countries to designate the legal status on the label shall appear in the *blue box*.

4.2 Optional information

The labelling may include symbols or pictograms (designed to clarify certain information mentioned already in the label) and other information compatible with the Summary of Product Characteristics which is useful to the veterinarian and the end user to the exclusion of any element of promotional nature. Applicants should refer to the [EMA/QRD webpage for further specific guidance on the use of approved pictograms on the packaging of veterinary medicinal products](#)⁸.

Additional use of label information in Braille is possible, even if it is not mentioned in Directive 2001/82/EC.

5. Marketing authorisation number

This is the marketing authorisation number consisting of "EU" followed by a nine-digit number (e.g. "EU/2/97/003/000"). It must not be accompanied by any suffix or prefix.

This number must appear on the package. Any other (national) identification number or reference, if any, can only appear (once) in the *blue box*.

⁶ A blue outline is recommended to avoid confusion with other colours used in labelling.

⁷ <https://www.ema.europa.eu/en/veterinary-regulatory/marketing-authorisation/pre-submission-guidance-qa-introduction/qa-21-39>

⁸ <https://www.ema.europa.eu/en/veterinary-regulatory/marketing-authorisation/product-information/product-information-reference-documents-guidelines>

Section B - Package Leaflet

1. The text of the package leaflet

The text of the package leaflet forms part of the Union authorisation and must therefore be approved by the EMA on behalf of the Commission. Thus, the Union authorisation of a veterinary medicinal product includes the text of the package leaflet, which is the same for all packs of that veterinary medicinal product throughout the Union.

The package leaflet must be written in clearly and easily understood terms for the users and clearly legible.

2. Language

The package leaflet must be presented at least in the language(s) of the Member State(s) where the product is placed on the market (article 61 of Directive 2001/82/EC). The EU language(s) used in the package leaflet must be the same as the language(s) used on the label⁵. The content of all language versions must be identical. The same principle applies to a multi-lingual pack leaflet.

3. Additional package leaflet text

The approved package leaflet may include other particulars essential for safety or health protection at the discretion of the CVMP. According to article 26(1) of Directive 2001/82/EC it may include any precautions relating to the use and any other warnings resulting from the clinical and pharmacological trials or from experience gained during the use of the veterinary medicinal product once it has been marketed. Any element of a promotional nature must be excluded.

4. Local representative

Applicants should refer to the EMA's pre-submission guidance (Q&As) regarding information on local representatives within the package leaflet. Further practical guidance on inclusion of local representatives is provided within the corresponding section of the [annotated QRD template](#)⁹.

⁹ <https://www.ema.europa.eu/en/veterinary-regulatory/marketing-authorisation/product-information/product-information-templates>

Section C - Presentation of the medicinal product

1. Pack design (logo, colour, etc.)

As provided in Article 12(3)(k) of Directive 2001/82/EC an application for a marketing authorisation to be granted by the Union must include one or more specimens or mock-ups of the outer packaging and of the immediate packaging of the medicinal product, together with the draft package leaflet.

Applicants should refer to the [EMA webpage for veterinary mock-ups](#)¹⁰ for further specific guidance in this respect.

All proposed changes to any aspect of the presentation should be submitted to the EMA, who will inform the Commission.

¹⁰ <https://www.ema.europa.eu/en/veterinary-regulatory/marketing-authorisation/product-information/qa-mock-ups>