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Committee for Medicinal Products for Veterinary Use

Questions and answers on mentioning solvents in the product information of veterinary medicinal products authorised via the centralised procedure

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Aim and scope

This general guidance, in the form of a question and answer document, is intended to clarify how the product information (Summary of Product Characteristics (SPC), labelling and package leaflet) should be prepared for products which require solvents for their administration.

The scope of this Questions & Answers (Q & A) document is products in the centralised procedure only; it is applicable to immunologicals and pharmaceuticals, although it is acknowledged that there may be, on occasion, specific cases which might not fall into the general scenarios presented here.

Solvents which are considered “simple” (e.g. saline) and “complex” (e.g. containing adjuvants) are considered within the scope of this document. Where a solvent contains one or more antigens, it is considered as a constituent part of the veterinary medicinal product and not a solvent and is therefore not within the scope of this document.

Guidance for solvents either packaged together with the product or packaged separately is provided.

Where possible the CMDv recommendations[1] for simple solvents have been taken into account.

N.B. For the purposes of this document, the term veterinary medicinal product (VMP) means either a pharmaceutical or an immunological veterinary medicinal product.

[1] CMDv recommendations EMEA-CMDv-352379-2009_ed._01.pdf

1. Annex I to Directive 2001/82/EC refers to "diluents", why is the term "solvents" being used here?

The preferred term is "solvent". The European Directorate for the Quality of Medicines and Healthcare (EDQM) standard terms definition for solvent is as follows:

"Liquid preparation consisting of an excipient that contains no active substances itself but is intended to be used in the preparation of a pharmaceutical product, e.g. for diluting/dissolving/dispersing the item(s) containing the active substance(s). The term is intended to cover all such excipients, with the particular specifications (e.g. sterility requirements) depending on the final product and its intended use".

The word solvent is used to describe any solvent or diluent, even if the final preparation is not a solution. The use of the term "diluent" is discouraged, even though it is acknowledged that the term diluent is used in Annex I of Directive 2001/82/EC.

2. The solvent has a registered trade name – can I mention it in the product information for the veterinary medicinal product?

It is possible to mention the registered trade name of the solvent in the product information.

3. My product is authorised for use with more than one solvent – how should this be mentioned in the product information?

It is possible to refer to more than one solvent in the product information if data has been provided in the marketing authorisation dossier for the veterinary medicinal product to support the use of more than one solvent. A list of suitable solvents for which no data on the use of the VMP with a solvent has been submitted cannot be included in the product information.

If the solvents have registered trade names, the names should be mentioned under the appropriate sections of the SPC, labelling of the solvent and package leaflet. N.B. Solvent trade names must be the same in all language versions of the product information. The SPC should make reference to the solvent under:

- 2 (if applicable) and 6.1: composition
- 4.9: administration
- 6.3: shelf life of the solvent(s)
- 6.4: storage conditions (in case different from vaccine fraction)
- 6.5: presentations (material, packaging, supply)

and corresponding sections of the package leaflet.

4. The solvent for my product is packaged <u>with</u> the product – how should this be mentioned in the product information?

The solvent even if packed together with the product may have a registered trade name different from the name of the VMP.

a) When the solvent has not got a different registered trade name, the solvent labelling should be as follows:

Section 1: **NAME OF THE VETERINARY MEDICINAL PRODUCT**

"Solvent for [PRODUCT NAME]" or "[PRODUCT NAME] solvent"

b) When the solvent has got a different registered trade name, the name of the solvent may be followed by a short description of the solvent as follows:

Section 1: **NAME OF THE VETERINARY MEDICINAL PRODUCT**

"[Solvent trade name]" "short description of the solvent".

Examples:

"[Solvent trade name], for cell associated poultry vaccines"

"[Solvent trade name], oculo/nasal solvent for chicken "

"[Solvent trade name], sterile solvent for dilution of [product name] suspension"

The name of the solvent should be included in the sections of the SPC and package leaflet indicated in question 3 above.

5. The solvent for my product is not packaged with the product – how should the solvent be mentioned?

When the solvent is not packed together with the product, the solvent name on the **solvent label** should be as follows:

a) If the invented name of the product is part of the solvent name:

Section 1: **NAME OF THE VETERINARY MEDICINAL PRODUCT**

"Solvent for [PRODUCT NAME]" or "[PRODUCT NAME] solvent"

b) If the solvent has got a registered trade name which differs from the invented name of the product, the name of the solvent may be followed by a short description of the solvent as follows (in line with CMDv recommendations):

Section 1: **NAME OF THE VETERINARY MEDICINAL PRODUCT**

"[Solvent trade name]" "short description of the solvent".

See question 4 b for examples.

The name of the solvent should be included in the sections of the SPC and package leaflet indicated in question 3 above.

c) If the name of the solvent is not reflecting the product name but only a general name (e.g. "sterile solvent"), the name of the solvent may be followed by a short description.

Example:

Section 1: **NAME OF THE VETERINARY MEDICINAL PRODUCT**

"Solvent oculo/nasal for chicken"

"Sterile solvent for cell-associated poultry vaccines"

6. Should the marketing authorisation number(s) of the veterinary medicinal product(s) appear on the packaging of the solvent?

The marketing authorisation number(s) of the veterinary medicinal product(s) should not normally appear on the solvent's packaging.

7. Do the different scenarios addressed above affect the name of the veterinary medicinal product in the product information?

In any of the different cases addressed above, the name of the veterinary medicinal product should still be formed as indicated in the QRD template:

[Invented name] followed by the strength (if applicable) and the pharmaceutical form and, if necessary, the target species.