Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

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Diluents - Conclusions and recommendations of CMDv -

Introduction

In 2007 the CMDv discussed issues related to:

1) Validation phase of a procedure: one or more procedures to follow and dossier requirements;
2) End of the procedure: SPC and labelling of the diluents.

With regard to the first item, Annex I to Directive 2001/82/EC is replaced by Annex I to the Commission Directive 2009/9/EC of 10 February. The amended Annex I states that diluents may be packed together with the vaccine vials or separately. Information on diluents needed for making the final vaccine preparation should be included in the dossier. Further, an immunological veterinary medicinal product is regarded as one product even when more than one diluent is required, so that different preparations of the final product can be prepared, which may be for administration by different routes or methods of administration.

In fact no sub-procedures are required anymore in order to handle a procedure for a product with one or more diluents or an optional diluent.

It should be reiterated that the diluents under discussion were only “simple” diluents e.g. saline, buffered saline, water etc and not those containing adjuvants or antigens.

Labelling – conclusions and recommendations –

The diluent is part of the authorisation of the veterinary medicinal product and the dossier contains all necessary information with regard to the use of the diluent(s) as part of the product (quality of the diluent and efficacy and safety used in combination with the active substance containing fraction).

The diluent in the SPC
Being part of the authorisation the diluent is mentioned in the SPC as part of the product or as optional diluent.

The SPC should make reference to the diluent under:
2 (if applicable) and 6.1: composition;
4.9: administration
6.3: shelf life of the diluent(s)

6.4: storage conditions (in case different from vaccine fraction)
6.5: presentations (material, packaging, supply)

Labelling
If the dossier contains the information stated above and adequate reference is made in the SPC to the diluent in section 2, 4.9, 6.1, 6.3, 6.4 and 6.5, and further the package leaflet does refer clearly to the diluent, a general label would be preferred for the diluent. The particulars to appear on the immediate packaging (label) were discussed and a general template agreed on by the majority of CMDv.

The use of a trade name for the diluent is not supported by most of the Member States, but would be possible together with a brief description (properties diluent for example). The group could agree on a more describing way of naming, without numbers and names of specific marketing authorisations, see Annex II.

Finally it should be mentioned that the traceability will be under the responsibility of the applicant.

Annex I

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING (LABEL) OF THE DILUENT
(normal sized bottles)

1. NAME OF THE DILUENT

"Trade" name (together with a brief description)

or

a more describing way of naming (Solvent/diluent…. for type of vaccines it can be used with or properties of the diluent).

2. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

For example: 200/400/600/800/1000/1200 ml.

3. ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

4. STORAGE CONDITIONS

For example: Store below 25°C.

5. BATCH NUMBER

Lot (number)

6. EXPIRY DATE

EXP {month/year}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Company logo or name of company