



CVMP POINTS TO CONSIDER REGARDING EFFICACY REQUIREMENTS FOR MINOR SPECIES AND MINOR INDICATIONS

FVE COMMENTS

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General

FVE welcomes and supports the EMEA and CVMP continuous efforts to address the issue of the availability of veterinary medicinal products and to find solutions to the absence of products approved for the animal species to be treated, a situation faced with increasing frequency in veterinary practice.

FVE supports the view that efficacy requirements need to be reviewed and minimised whenever possible to facilitate the development of products intended for minor species or minor indications.

FVE finds that the paper should be streamlined to discuss only efficacy requirements and that other aspects, such as defining minor species or minor indications, simplifying procedures, financial support and provisional authorisations should be dealt with in a separate paper, as they do not relate to efficacy requirements.

On the subject of the cascade, FVE wants to stress that the cascade was not intended for life threatening situations, but for situations *where there exists no authorised medicinal product for a condition*. The reality is that there are so many conditions for which no product is authorised that it is impossible to list them and that the cascade is used routinely by veterinary surgeons because they have no other option, apart from not treating the animals!

Regarding the definition of a minor species or minor indication, FVE agrees that it is important to have clear definitions but is concerned that some species (salmonidae, laying hens) are still considered as major food-producing species. The problem is that these definitions are based on the number of animals in the EU and not on the readiness or ability of the pharmaceutical industry to develop products for these species. This can be illustrated with the example of laying hens, which are classified as major species, when the number of MRLs established for eggs and of products licensed for laying hens is so low that in many cases laying hens have to be treated with products licensed for broilers only.

With 300 millions laying hens in the Community, it might be difficult to justify that laying hens are a minor species but measures are desperately needed to facilitate the marketing of products licensed for laying hens. These comments would apply to more or less the same extent to salmonidae.

President

F. Nind

Vice-Presidents

O. Bro-Jorgensen
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B. Zemljic

In addition, we take this opportunity to stress again that the CVMP policy to include, in some of its recommendations and in the absence of specific data, statements such as "*not for use in animals from which eggs are produced for human consumption*" or "*not for use in animals from which milk is produced for human consumption*" is causing great difficulties in veterinary practice.

FVE is indeed aware that in many Member States, many products licensed for broilers and containing substances, for which MRL were established with the above-mentioned statements, are then contra-indicated in laying hens. It becomes thus impossible for veterinary practitioners to use these products under the cascade.

Specific comments

Page 2 – Point 1.1 third paragraph

FVE believes that this paragraph needs to be clarified. The current CVMP position is that extrapolation to all food producing is possible when there are MRLs already established for 3 major species.

Page 3 – Point 1.1, First paragraph

Sheep milk was listed as a minor food-producing species on the previous page and now appears to be a major food-producing species. This needs to be clarified but FVE would regard dairy sheep as a minor food-producing species and would suggest referring to dairy sheep instead of milking sheep.

The list of food-producing animals also includes cats and dogs!

Page 4 – Point 1.2, Last sentence of first paragraph

For the purpose of defining efficacy requirements, dogs, cats and horses should be considered as major species, the other species of pet animals as minor species.

Page 4 – Point 1.2, Last sentence of second paragraph

FVE does not believe that this statement is entirely correct. There will always be local indications, for which local companies might be interested to develop products.

Page 4 – Point 1.2 Second paragraph

It would be better to state the amount of meat and milk consumed rather than the number of animals.

Page 4 – Point 1.2 Third paragraph

Two millions Euro seems to be a low threshold value. Can a pharmaceutical company get any return on invested money if the total European expected sales are as low as this? Should not the threshold be increased?

Page 5 – Point 2.1, Second paragraph

FVE would suggest amending “GLP/GCP requirements could be relaxed” into “GLP/GCP requirements should be relaxed”.

Page 5 – Point 2.2 – Provisional authorisations

The proposal to grant provisional authorizations for minor species and minor indications on the basis of a minimum data package is a good one. However, one year to collect additional efficacy data might be too short, especially for diseases with a low prevalence. In addition, it can take up to several months between the time of approval of a product and the time it reaches the practitioner's shelf. This should be borne in mind when deciding on the duration of a provisional authorization. FVE would therefore suggest that provisional authorizations granted for products for use in a minor species and/or minor indication should be granted for a period of two years at least.

After two years a comprehensive report, discussing in particular efficacy and pharmacovigilance aspects, should be provided to the competent authorities for reviewing the conditions of the provisional marketing authorization.

Annex I – table 1

The number of dairy sheep in Sweden is higher than 200. In the table for other sheep in Sweden the figure given includes also lambs. If the same system is used for dairy sheep the number should be at least ten times higher. Perhaps a 0 is missing?

Annex II – Decision tree

The decision tree should be clarified. What's about ecotoxicity requirements, which can significantly increase development costs?