European Medicines Agency
Veterinary Medicines and Inspections

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NOTE REGARDING CVMP GUIDELINES ON DATA REQUIREMENTS FOR VETERINARY MEDICINAL PRODUCTS INTENDED FOR MINOR USES OR MINOR SPECIES

For some time there has been considerable concern amongst all parties connected with animal health in the EU, especially the veterinary profession, about the decrease in the availability of authorised veterinary medicinal products. This problem is particularly acute in relation to availability of medicines for minor uses/minor species, where there are no authorised products for some uncommonly encountered disease conditions in major species or no authorised products at all for many indications in certain minor species. The EMEA at the behest of its Management Board began discussions and consultations on this increasing problem in 1998 and, since that time, the CVMP has worked on the matter and was active in initiatives to address the problem of lack of veterinary medicines.

It is generally accepted that the problem is, in large part due to the costs of research and development being a disincentive to industry to bring such new products to the market place when the return on investment is likely to be small and certainly less than that resulting for mainstream products for major species. One major cause of the lack of authorised veterinary medicinal products seems to be also the limited economic value of some farmed animals and the fact that the farmer has to bear the total cost of any treatment. Furthermore, the markets are much weaker and more fragmented than that of human health care.

The CVMP and its Efficacy Working Party (EWP) developed a document called Points to Consider Regarding Availability of Products for Minor Species and Minor Indications (EMEA/CVMP/610/01-Consultation), which was released for public consultation in February 2002. Having reviewed comments received from interested parties following the release of that document, the Committee developed its Position Paper regarding Availability of Products for Minor Uses and Minor Species (MUMS) (EMEA/CVMP/477/03). That document aims to define the problem in some depth and makes suggestions for possible solutions. The proposals are characterised as short, medium and long-term goals.

Much effort by the CVMP has focussed previously on extrapolation of existing maximum residue limits from major species to minor species and significant progress has been made in this area. It was however recognised that the issue requires a broader consideration. In particular it was proposed that the dossier requirements for minor uses in major species and minor species in general be reviewed with the view whether it would be feasible to adapt the data requirements (quality, safety and efficacy) for products for minor uses or minor species. This should be considered in the context of both extensions of products from major to minor species and new product development uniquely for minor species.

In the context of the discussion on the abovementioned Position Paper regarding availability (EMEA/CVMP/477/03-CONSULTATION), the CVMP requested its Working Parties to review dossier requirements for veterinary medicinal products intended for minor use and for minor species and to establish the appropriate standards of quality, safety and efficacy for these. The intention was to provide the industry with a degree of certainty for investing scarce and costly resources for the development of medicines for minor uses and minor species, while at the same time ensuring adequate safety, particularly for the consumer in relation to food producing animals. The scope of this review was widened following the consultation of the abovementioned CVMP Position Paper regarding

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availability and taking into consideration the comments received during the public consultation (see EMEA/CVMP/477/03-FINAL).

The CVMP with the support of its Efficacy and Safety Working Parties and the Joint CHMP/CVMP Quality Working Party has now completed this review regarding the data requirements for pharmaceutical veterinary medicinal products and has adopted three guidelines concerning data requirements for dossiers for veterinary medicinal products for minor species or minor uses taking into account, where appropriate, the comments received during the preceding public consultation:

- Guideline on the Quality data requirements for veterinary medicinal products intended for Minor Uses or Minor Species (EMEA/CVMP/QWP/128710/2004)

- Guideline on Safety and Residue data requirements for veterinary medicinal products intended for Minor Uses or Minor Species (EMEA/CVMP/SWP/66781/2005)

- Guideline on Efficacy and Target Animal Safety data requirements for veterinary medicinal products intended for Minor Uses or Minor Species (EMEA/CVMP/EWP/117899/2004)

In adopting these guidelines at their meeting in July 2006, the CVMP recognised that the revision of Annex I to Directive 2001/82/EC, as amended, had not yet been finalised. Should the revised text of Annex I necessitate any changes, the guidelines will be updated accordingly once the timetable for implementation of the revised Annex is established.

Please note also that the EMEA will be updating existing guidance documents relating to Minor Uses and/ or Minor Species. The intention is to create a comprehensive hierarchy of documents covering all aspects from procedures to determine whether or not CVMP considers that an application for the centralised procedure falls within the criteria for MUMS, through the data requirements that apply to compilation of the dossier, to the measures proposed to assist companies seeking to place such products on the market, including the provision of free scientific advice.

The review of data requirements for immunological veterinary medicinal products for minor species or minor uses has now also been completed by the CVMP and its Immunologicals Working Party and a draft guideline on data requirements for dossiers for immunological veterinary medicinal products for minor uses has been adopted for release for a 6-month period of public consultation.

- Draft Guideline on data requirements for immunological veterinary medicinal products intended for Minor Uses or Minor Species (EMEA/CVMP/IWP/123243/2006-CONSULTATION)