The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines and Inspections

EMEA/CVMP/1136/03-FINAL

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

GENERAL CRITERIA FOR GRANTING FREE SCIENTIFIC ADVICE IN RESPECT OF SUPPORTING THE RESEARCH AND DEVELOPMENT OF VETERINARY MEDICINAL PRODUCTS DESTINED FOR MINOR USE IN MAJOR SPECIES AND MINOR SPECIES

ADOPTION BY CVMP FOR RELEASE FOR CONSULTATION	12 February 2004
START OF CONSULTATION	13 February 2004
END OF CONSULTATION	13 March 2004
FINAL ADOPTION	12 May 2004
ENTRY INTO EFFECT	14 May 2004

Public

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.eu.int http://www.emea.eu.int

General criteria for granting free scientific advice in respect of supporting the research and development of veterinary medicinal products destined for minor use in major species and minor species

A. Background

The ongoing concerns about the shortage of veterinary medicinal products for rare indications - minor uses - or diseases affecting minor species in the EU have received much attention in the last few years. The European Medicines Evaluation Agency (EMEA) and its Committee for Veterinary Medicinal Products (CVMP) has undertaken a number of initiatives in recent years to address the problem and, at its meeting in June 2003, adopted a draft position paper regarding availability of medicines for Minor Uses and Minor Species (MUMS) (EMEA/CVMP/477/03-CONSULTATION) for consultation, setting out its strategic approach to identify further solutions to be implemented.

The position paper sets out a number of short, medium and long-term proposals, which explore the possibility of adapting the data requirements necessary for the authorisation of such products, whilst at the same time ensuring compliance with EU legislation based on the criteria of satisfactory quality, safety and efficacy and also guaranteeing public health.

Council Regulation EC No 297/95 on fees payable to the Agency as amended by Regulation (EC) No 2743/98 and Regulation (EC) No 494/2003 does provide for the possibility of a total or partial exemption of fees for medicinal products for treating rare diseases or diseases affecting minor species. The provision relates to all types of fees including fees for scientific advice, although in the past this provision has only been applied in respect of applications for the centralised procedure or for the establishment of maximum residue limits.

One of the major short-term proposals of the CVMP in its draft position paper was that there could be a significant incentive to industry in providing free scientific advice to any company considering the development of medicinal products for rare indications - minor uses - or diseases affecting minor species.

At its October 2003 meeting, the Management Board of the EMEA considered a proposal from CVMP to agree to a 12-month pilot project where scientific advice may be granted free for potential marketing authorisations and MRL applications in respect of Minor Uses and Minor Species, according to criteria to be agreed and adopted by the CVMP and notified to the Board. This paper sets out those criteria as agreed by the CVMP following public consultation on a draft version and having considered the comments received.

B. Proposal

The intention of the EMEA and its Committee for Veterinary Medicinal Products throughout its efforts to develop a policy on Minor Uses and Minor Species, has been to support the principle of Duty of Care by veterinarians in achieving an adequate level of animal health and welfare in the EU, whilst guaranteeing consumer safety. Such a principle requires the provision of adequate authorised veterinary medicinal products for the veterinarian to avoid animal suffering, where the need for such medicines can be adequately substantiated medically.

In its position paper the CVMP's recommendation, supported by the EMEA Management Board, is to grant free scientific advice to potential applicants intending to research and develop medicinal products that are demonstrated to meet the criteria outlined below. Furthermore the Committee proposal foresees the provision of funds to support such free advice to be made available from the European Community subsidy that makes up part of the Agency's funding. It was therefore intended

that the spirit of the CVMP proposal would exclude support of medicinal products that might be developed as an adjunct to conventional therapy, and/or where the real need for such a product by veterinarians is not established. In summary, such products (and their active substances) are to be considered eligible for free scientific advice within the terms of the proposed CVMP policy for minor uses and minor species products when they are critically important for the health of the species concerned.

C. General criteria for products which can be subject to free scientific advice by CVMP when their use is intended for Minor Uses in Major Species or for use in Minor Species

The definition of minor species shall be that detailed in the aforementioned CVMP position paper. The criteria for free scientific advice for development of products (and their active substances) for use for minor uses in major species or use in a minor species shall be as follows:

i) <u>New product for minor use in major species</u>

- The product is indicated for a specific disease or indication considered on a case-by-case basis as judged by the Committee (geographical considerations may also be considered)
- No other product is authorised in the Community for this indication, or existing products have proven to be ineffective, and where such proof is provided as documented evidence, or where the availability of a nationally approved product in one member state re-submitted through the mutual recognition procedure would facilitate the problem in other member states.
- Treatment of the diseases indicated is critically important for animal health, or for human health where in the latter case an over-reliance on the off-label use is inappropriate and might compromise consumer safety.

ii) <u>New Product for Minor Species</u>

- The product is for a specific indication (not necessarily a rare disease or circumstance).
- The product is not already authorised for a similar indication in a major species, or is already authorised in a major species but where significant additional studies to extend the use to the minor species concerned would be required.
- No other product is authorised in the Community for this indication in this minor species. or existing products have proven to be ineffective, and where such proof is provided as documented evidence, or where the availability of a nationally approved product in one member state re-submitted through the mutual recognition procedure would facilitate the problem in other member states.
- Treatment of the disease is critically important for the health of the minor species concerned**.**

Speciality medicinal products for companion animal medicine are excluded from the provision of free scientific advice subject to considerations arising out of concerns for public health.

Procedure

All applications shall be submitted to the CVMP in accordance with the Standard Operating Procedure (SOP) for Scientific Advice (EMEA/CVMP/458/02-Rev.2) and the decision on whether the application meets the above criteria shall be entirely that of the CVMP. The procedure for processing the application and granting of the advice shall be in accordance with the said SOP and without prejudice to any future opinion the CVMP may arrive at, in respect of a subsequent application for the same product in the same species.

The granting of free scientific advice by CVMP shall be agreed for one application only for one active substance for one indication in one species but follow up questions/requests for clarification in respect of this same application can be accommodated in the procedure. Subsequent or follow-up applications for scientific advice in respect of the same active substance for different indications in the same

species or in other species will not be granted free and shall be levied a fee accordingly. Follow-up scientific advice is defined as a request to reconsider advice already given in the light of new information available to the company or in case of changes to or amendments to the development programme for which scientific advice was given.

The provision of scientific advice shall begin for a 12-month period beginning 1 June 2004.