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

CVMP/1129/01

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS (CVMP)

SUMMARY INFORMATION ON A REFERRAL OPINION FOLLOWING AN ARBITRATION PURSUANT TO ARTICLE 18 OF COUNCIL DIRECTIVE 81/851/EEC AS AMENDED, FOR

AVINEW

BACKGROUND INFORMATION

Avinew is a freeze-dried live vaccine intended for use in chickens from the age of 1 day for the active immunisation against Newcastle disease to reduce mortality and clinical signs associated with the disease. The product is administered by ocular route (eye drop application) or oculo-nasal route (coarse spray application) for the primary vaccination and by oral route (drinking water application) for the booster vaccination. The withdrawal period when first authorised in France was zero days.

In December 2000 and January 2001, the Marketing Authorisation Holder, Merial, submitted applications for mutual recognition of Avinew with France as Reference Member State. The Mutual Recognition Procedure started on 1 February 2001 with Austria, Belgium, Germany, Finland, Greece, Ireland, Luxembourg, the Netherlands, Portugal and Spain as Concerned Member States.

During the procedure, the Netherlands raised concerns regarding a potential risk to public health concerning section 5.10 (Withdrawal period) of the SPC which could not be resolved and referred the reasons for disagreement to the EMEA on 2 May 2001, with a request to initiate an arbitration procedure in order to clarify the matter.

The arbitration procedure started on 16 May 2001.

The CVMP, having considered the points of disagreement, the written comments provided by the Marketing Authorisation Holder and the joint Rapporteur-Co-Rapporteur's assessment report, was of the opinion, by consensus, that the objections raised by the Netherlands should not prevent the granting of a marketing authorisation.

The CVMP therefore adopted a positive opinion on 12 September 2001 recommending the granting of the Marketing Authorisation for Avinew with the SPC as authorised in the Reference Member State, France.

An overall summary of the scientific evaluation is provided, together with the SPC.

On the basis of the opinion adopted by the CVMP, the European Commission issued a Decision on 4 February 2002.

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SCIENTIFIC CONCLUSIONS

The basis for arbitration procedure was the withdrawal period of zero days. Concern was expressed by the Netherlands, that a withdrawal time of zero days would not be acceptable. Considering the product to be a live vaccine with a zoonotic agent and the fact that live Newcastle Disease virus was found in the cloaca and trachea of vaccinated birds up to 8 days after vaccination, a withdrawal period of 7 days was considered acceptable by the Netherlands.

The CVMP considered the written responses provided by the Applicant, the joint Rapporteur-Co-Rapporteur's assessment report on the response of the Applicant and the comments from CVMP members.

Taking into account

- the lower pathogenicity of vaccinal strains of Newcastle Disease virus in comparison to wild-type virus strains,
- the removal of the main sources of virus (i.e. intestines and upper respiratory tract) in the processing plant,
- the likelihood of significant Newcastle disease virus inactivation by proper cooking procedures,
- the absence of confirmed cases of Newcastle Disease in humans following oral ingestion of meat from vaccinated birds,
- that ocular contamination with a significant viral load following handling of meat from a vaccinated bird is unlikely,
- that vaccinated birds are unlikely to be sent for immediate slaughter,

the CVMP agreed that a zero-day withdrawal period was sufficient to protect the consumer from any zoonotic hazard posed by the strain of Newcastle disease virus present in the product Avinew, when used in accordance with the SPC.

Therefore, the CVMP has recommended the granting of the Marketing Authorisations for which the Summary of Product Characteristics is set out in the Annex to this summary.