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Veterinary Medicines and Information Technology

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Committee for Medicinal Products for Veterinary Use (CVMP)

Opinion following an Article 18¹ referral 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 marketing authorisation holder, Merial, submitted an application via mutual recognition for Avinew, on the basis of the marketing authorisation granted by France. The reference Member State is France. The concerned Member States are Austria, Belgium, Germany, Finland, Greece, Ireland, Luxembourg, the Netherlands, Portugal and Spain.

The mutual recognition procedure started on 1 February 2001. Potential serious risk to human health was identified during the mutual recognition procedure by the Netherlands regarding the withdrawal period of zero days.

On 2 May 2001, in view of the unsolved issues, the Netherlands submitted a referral notification under Article 18 of Council Directive 81/851/EEC to the CVMP.

The referral procedure started on 16 May 2001. The Committee appointed R. Breathnach as rapporteur and O. Papadopoulos as co-rapporteur. Written explanations were provided by the marketing authorisation holder on 13 July 2001.

Based on the evaluation of the available data, the CVMP considered that the objections raised by the Netherlands during the mutual recognition procedure should not prevent the granting of a marketing authorisation for Avinew. Therefore, the Committee adopted a positive opinion on 12 September 2001, recommending the granting of the marketing authorisation the above-mentioned product.

The scientific conclusions are provided in Annex I. The list of product names concerned is given in Annex II, together with the Summaries of Product Characteristics in Annex III.

The opinion was converted into a Decision by the European Commission on 4 February 2002.

¹ Article 18 of Council Directive 81/851/EEC, as amended