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Committee for Medicinal Products for Veterinary Use (CVMP)

Opinion following an Article 33[1] referral for Bovimectin Injection and its associated names

International non-proprietary name (INN): ivermectin

Background information

Bovimectin Injection and its associated names are solutions for injection and contain ivermectin as active substance. They are intended for use in cattle as a subcutaneous injection for the treatment and prevention of infestations by gastro-intestinal roundworms, lungworms, eyeworms, warbles, mange mites and sucking lice.

The marketing authorisation holder, Cross Vetpharm Group Ltd, submitted an application via mutual recognition for Bovimectin Injection, on the basis of the marketing authorisation granted by Ireland. This is a generic application referring to the reference product Panomec. The reference Member State is Ireland and Belgium is concerned Member State.

The mutual recognition procedure started on 23 November 2001. Potential serious risks were identified during the mutual recognition procedure by Belgium regarding the demonstrated bioequivalence with the reference product.

On 21 February 2002, in view of the remaining unsolved issues Belgium submitted a referral notification under Article 33 of Directive 2001/82/EC to the CVMP.

The referral procedure started on 12 March 2002. The Committee appointed C. Friis as rapporteur and M. Arboix as co-rapporteur. Written explanations were provided by the marketing authorisation holder on 11 April 2002.

Based on the evaluation of the available data, the CVMP considered that the objections raised by Belgium during the mutual recognition procedure should not prevent the granting of a marketing authorisation for Bovimectin Injection and its associated names. Therefore, the Committee adopted by

[1] Article 33 of Directive 2001/82/EC, as amended

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majority a positive opinion on 12 June 2002 recommending the granting of the marketing authorisation the above-mentioned product.

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

The opinion was converted into a Decision by the European Commission on 12 September 2002.