11 August 2004
EMA/249804/2014
Veterinary Medicines and Inspections

EMEA/V/A/008

Committee for Medicinal Products for Veterinary use (CVMP)

Opinion following an Article 34[1] referral for Eprinex pour-on and its associated names

International non-proprietary name (INN): eprinomectin

Background information

Eprinex and its associated names are a pour-on solution for external use. Eprinex contains eprinomectin as an active substance at 5 mg per ml. Eprinomectin is a semi-synthetic compound of the avermectin family, intended for the treatment of internal and external parasites in cattle including lactating cows.

Due to divergent national decisions taken by Member States concerning the marketing authorisations of Eprinex and its associated names, on 20 June 2003 Germany referred the issue to the CVMP under Article 34 of Directive 2001/82/EC, in order to resolve discrepancies regarding the withdrawal period for cattle meat and offal across the European Union.

The referral procedure started on 23 July 2003. The Committee appointed H. Hoogland as rapporteur and M. Arboix as co-rapporteur.

Written explanations were provided by the marketing authorisation holder on 25 November 2003.

Based on the available data, the CVMP considered that for Eprinex and its associated names a withdrawal period of 15 days for cattle meat and offal should be recommended. Therefore, the CVMP adopted a positive opinion on 11 February 2004 for the above-mentioned product.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II.

The final opinion was converted into a Decision by the European Commission on 11 August 2004.

[1] Article 34 of Directive 2001/82/EC, as amended

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