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Veterinary Medicines

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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 33(4)[1] referral for Norbonex 5 mg/ml Pour-On Solution for Beef and Dairy Cattle

International non-proprietary name (INN): eprinomectin

Background information

Norbonex 5 mg/ml Pour-On Solution for Beef and Dairy Cattle contains eprinomectin as an active substance and is intended for use in cattle as a topical application for the treatment and control of infections from gastrointestinal roundworms (adults and fourth stage larvae), lungworms (adults and fourth stage larvae), warbles (parasitic stages), mange mites, lice and horn flies.

The applicant, Norbrook Laboratories Ltd, submitted an application for a decentralised procedure for Norbonex 5 mg/ml Pour-On Solution for Beef and Dairy Cattle. This is a 'hybrid' application according to Article 13(3) of Directive 2001/82/EC, as amended, referring to the reference product Eprinex Pour-On Solution for Beef and Dairy Cattle. The United Kingdom is the reference Member State and Germany and the Netherlands are concerned Member States.

The decentralised procedure started on 21 February 2012. Potential serious risks were identified during the decentralised procedure by Germany regarding the environmental safety of the product.

On day 210, these issues remained unsolved and therefore a referral under Article 33(1) of Directive 2001/82/EC to the Coordination group for Mutual recognition and Decentralised procedures (veterinary) (CMD(v)) was started on 18 February 2013. Day 60 of the CMD(v) procedure was on 18 April 2013, and since the Member States concerned failed to reach an agreement regarding the product the procedure was referred to the CVMP.

On 26 April 2013, the reference Member State, the United Kingdom, notified the Agency that the CMD(v) had failed to reach an agreement regarding the product and referred the matter to the CVMP pursuant to Article 33(4) of Directive 2001/82/EC.

[1] Article 33(4) of Directive 2001/82/EC, as amended

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The referral procedure started on 15 May 2013. The Committee appointed C. Ibrahim as rapporteur and H. Jukes as co-rapporteur. Written explanations were provided by the applicant on 19 November 2013.

Based on the evaluation of the currently available data, the CVMP considered that the benefit-risk profile of Norbonex 5 mg/ml Pour-On Solution for Beef and Dairy Cattle is positive. Therefore, the Committee adopted by consensus a positive opinion on 15 January 2014 recommending the granting of the marketing authorisations for Norbonex 5 mg/ml Pour-On Solution for Beef and Dairy Cattle with amendment to the summary of product characteristics and package leaflet of the reference Member State.

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 and package leaflet in Annex III.

The opinion was converted into a Decision by the European Commission on 21 March 2014.