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Veterinary Medicines and Product Data Management

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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 13¹ referral for Cydectin TriclaMox (5 mg/ml and 200 mg/ml) pour-on solution for cattle

International non-proprietary names (INN): moxidectin and triclabendazole

Background information

Cydectin TriclaMox (5 mg/ml and 200 mg/ml) pour-on solution for cattle is a veterinary medicinal product containing 5 mg moxidectin per ml and 200 mg triclabendazole per ml. The product is administered topically on the back of the animal and is indicated for the treatment of mixed nematode and fluke infections in cattle.

The marketing authorisation holder, Pfizer Animal Health, submitted an application for a type II variation, according to Article 16 of Commission Regulation (EC) 1234/2008, to add a new indication against lice species (*Linognathus vituli*, *Bovicola bovis* and *Solenopotes capillatus*) for Cydectin TriclaMox 5 mg/ml and 200 mg/ml pour-on solution for cattle. The reference Member State was France and 12 concerned Member States were involved: Austria, Belgium, Denmark, Germany, Greece, Ireland, Italy, Luxembourg, Portugal, Slovenia, Spain and United Kingdom.

The type II variation procedure (FR/V/0201/002/II/006) started on 16 May 2012. During the variation procedure a potential serious risk to animal health was identified by Belgium and in particular that the efficacy against the lice species had been insufficiently substantiated.

On Day 90, major issues raised by the CMS, Belgium, remained unsolved. The procedure was thus referred to the Co-ordination Group for Mutual Recognition and Decentralised Procedures-Veterinary (CMD(v)) under Article 13(1) of Commission Regulation (EC) No 1234/2008 on 11 December 2012 by the RMS (France). The CMD(v) 60-day referral procedure was initiated on 14 January 2013. Day 60 of the CMD(v) procedure was on 14 March 2013, and since there was no agreement the procedure was referred to the CVMP.

¹ Article 13 of Commission Regulation (EC) No. 1234/2008



On 3 April 2013, France referred the matter to the CVMP under Article 13(2) of Commission Regulation (EC) No 1234/2008. The CVMP was requested to give its opinion on whether or not the data for the type II variation application support the new indication against lice infestations.

The referral procedure started on 10 April 2013. The Committee appointed Dr B. Urbain as rapporteur and Dr M. Holzhauser-Alberti as co-rapporteur. Written explanations were provided by the marketing authorisation holder on 20 May 2013.

Based on the evaluation of the available data, the CVMP adopted, on 16 July 2013, an opinion recommending the granting of the variation to the marketing authorisations for Cydectin TriclaMox (5 mg/ml and 200 mg/ml) pour-on solution for cattle. The CVMP concluded that a satisfactory efficacy towards *Linognathus vituli*, *Bovicola bovis* and *Solenopotes capillatus* can be expected in the field.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II together with the amendments of the relevant sections of the Summary of Product Characteristics, labelling and package leaflet in Annex III.

The final opinion was converted into a Decision by the European Commission on 25 September 2013.