EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 September 2013
EMA/372468/2013
Veterinary Medicines and Product Data Management

EMEA/V/A/081

Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 35[1] referral for all injectable and pour-on veterinary medicinal products containing doramectin that are intended for use in mammalian food producing species

International non-proprietary name (inn): doramectin

Background information

Doramectin is an antiparasitic agent. It is a macrocyclic lactone closely related to ivermectin. Both compounds share a wide spectrum of antiparasitic activity and produce a similar paralysis in nematodes and parasitic arthropods.

On 22 March 2012, the Netherlands presented to the Agency a referral notification under Article 35 of Directive 2011/82/EC, regarding all injectable and pour-on veterinary medicinal products containing doramectin that are intended for use in mammalian food producing species. The CVMP was requested to give its opinion regarding the adequacy and consumer safety of the withdrawal periods for all injectable and pour-on veterinary medicinal products containing doramectin and whether there is a risk to the environment and the need for risk mitigation measures following use of the products concerned.

The referral started on 12 April 2012. The Committee appointed Mr G. J. Schefferlie as rapporteur and Dr B. Kolar as co-rapporteur. Written explanations were provided by the applicants and marketing authorisation holders on 17 September 2012, 3 January 2013 and 9 May 2013.

Based on the evaluation of the currently available data, the CVMP considered that overall benefit-risk profile for these products remains positive subject to changes of the product information related to harmonisation of the withdrawal periods, inclusion of warning sentences concerning the use in dairy animals and environmental risk mitigation measures. Therefore, the Committee adopted a positive opinion on 12 June 2013, recommending variations to the terms of the marketing authorisations for all injectable and pour-on veterinary medicinal products containing doramectin that are intended for use in mammalian food producing species.

[1] Article 35 of Directive 2001/82/EC, as amended

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II together with the amendments in the summaries of product characteristics, labelling and package leaflets in Annex III.

The final opinion was converted into a Decision by the European Commission on 6 September 2013.