6 November 2015
EMA/CVMP/705308/2015
Committee for Medicinal Products for Veterinary Use

Opinion of the Committee for Medicinal Products for Veterinary Use on the establishment of maximum residue limits

Procedure no: EU/ART27/11/192/IMB

Name of the substance: Rafoxanide (INN)

Basis for the opinion

Pursuant to Article 27(2) of Regulation (EC) No 470/2009 of 6 May 2009, Ireland (The Health Products Regulatory Authority) submitted to the European Medicines Agency on 19 August 2011 an application for the extrapolation of maximum residue limits for rafoxanide to bovine and ovine milk.

On 10 November 2011 the Committee for Medicinal Products for Veterinary Use adopted a list of questions to be addressed by the applicant. The response to the list of questions was submitted on 6 September 2013.

On 12 December 2013 the Committee for Medicinal Products for Veterinary Use adopted an opinion recommending the establishment of a provisional maximum residue limit for rafoxanide in bovine and ovine milk, and adopted a list of questions to be addressed by the applicant.

Commission Regulation (EU) No 681/2014 of 20 June 2014 established a provisional maximum residue limit for rafoxanide in bovine and ovine milk. The provisional maximum residue limit expires on 31 December 2015.

Ireland submitted, on 27 October 2015, a request for the extension of the time period applying to the provisional maximum residue limit in order to conclude the ongoing studies for the validation of the analytical method for monitoring of residues in milk.

Recommendation

The Committee, having considered the request from Ireland and the information provided on the ongoing studies for the validation of the analytical method in milk recommends by consensus and in accordance with Article 14(4) of Regulation (EC) 470/2009, the extension of the time period applying to the provisional maximum residue limit for rafoxanide in bovine and ovine milk and the amendment of the entry for rafoxanide in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010, in accordance with the following table:

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Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Rafoxanide	Rafoxanide	Bovine	30 µg/kg 30 µg/kg 10 µg/kg 40 µg/kg	Muscle Fat Liver Kidney	NO ENTRY	Antiparasitic agents/Agents against endoparasites
		Ovine	100 µg/kg 250 µg/kg 150 µg/kg 150 µg/kg	Muscle Fat Liver Kidney		
		Bovine, ovine	10 µg/kg	Milk	Provisional MRL expires on 31 December 2017	

The Icelandic and Norwegian CVMP members agree with the above-mentioned recommendation of the Committee.

The scientific conclusions of the Committee are presented in the European public MRL assessment report (EPMAR), provided in Annex I of this opinion.

The present opinion is forwarded to the European Commission and to the applicant together with its appendices.

London, 6 November 2015

Signature on file

Dr. D. Murphy
Vice-chair, on behalf of the CVMP

Annex I

European public MRL assessment report (EPMAR)