10 October 2013
EMA/CVMP/604655/2013
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/12/199/PFZ

Name of the substance: Tulathromycin (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Pfizer Animal Health SA submitted to the European Medicines Agency on 2 February 2012 an application for the modification of the ADI and maximum residue limits for tulathromycin in bovine and porcine species. The company subsequently changed the name to Zoetis Belgium SA.

On 14 June 2012 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 11 January 2013.

Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by consensus the modification of the maximum residue limits for tulathromycin 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
Tulathro-mycin	(2R,3S,4R,5R,8R,10R, 11R,12S,13S,14R)-2-ethyl-3,4,10,13-tetrahydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-ß-D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one expressed as tulathromycin equivalents	Bovine	300 µg/kg 200 µg/kg 4500 µg/kg 3000 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption Provisional MRLs expire on 1 January 2015	Anti-infectious agents/ Antibiotics
		Porcine	800 µg/kg 300 µg/kg 4000 µg/kg 8000 µg/kg	Muscle Skin and fat in natural propor-tions Liver Kidney	Provisional MRLs expire on 1 January 2015	

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 preliminary analytical method for monitoring of residues is appended to this opinion.

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

London, 10 October 2013

Signature on file

Dr. A. Holm
Chair, on behalf of the CVMP

Annex I

European public MRL assessment report (EPMAR)