10 July 2014
EMA/CVMP/347869/2014
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: EMEA/V/MRL/003660/EXTN/0003

Name of the substance: Doxycycline (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Industria Italiana Integratori TREI spA submitted to the European Medicines Agency on 4 September 2013 an application for the extension of maximum residue limits for doxycycline to rabbits.

On 15 January 2014, 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 4 April 2014.

Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by consensus the establishment of maximum residue limits for doxycycline in rabbit tissues.

Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the maximum residue limits established in bovine, porcine and poultry species and now recommended in rabbits, to all food producing species. Therefore, the Committee recommends by consensus to modify the entry for doxycycline in table 1 of the Annex to Regulation (EU) No 37/2010 as follows:

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Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Doxycycline	Doxycycline	All food producing species	100 µg/kg 300 µg/kg 300 µg/kg 600 µg/kg	Muscle Fat Liver Kidney	For fin fish the muscle MRL relates to 'muscle and skin in natural proportions'. MRLs for fat, liver and kidney do not apply to fin fish. For porcine and poultry species the fat MRL relates to 'skin and fat in natural proportions'. Not for use in animals from which milk or eggs are produced for human consumption.	Anti-infectious agents/Antibiotics

The Icelandic CVMP member agrees 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 analytical method for monitoring of residues in rabbits tissues is appended to this opinion.

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

London, 10 July 2014

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)