6 November 2014
EMA/CVMP/380629/2014-Rev.1
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/003044/EXTN/0005

Name of the substance: Tylvalosin (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Eco Animal Health Ltd submitted to the European Medicines Agency on 30 October 2013 an application for the extension of maximum residue limits for tylvalosin to eggs.

On 13 March 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 9 May 2014.

On 10 July 2014 the Committee for Medicinal Products for Veterinary use adopted an opinion recommending the establishment of a maximum residue limit for tylvalosin in chicken eggs and the extrapolation of this MRL to poultry eggs.

On 1 October 2014 the European Commission requested the Committee to review its opinion of 10 July 2014 and to make efforts to retain a sufficient portion of the ADI for future use, if possible.

Recommendation

The Committee, having considered the application and having considered the request from the Commission, recommends by consensus the establishment of a maximum residue limit for tylvalosin in chicken eggs.

Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the maximum residue limit recommended in chicken eggs to eggs of other poultry species, and therefore recommends by consensus the amendment of the entry for tylvalosin in poultry in table 1 of the Annex to 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
Tylvalosin	Sum of tylvalosin and 3-O-acetyltylosin	Poultry	50 µg/kg 50 µg/kg	Skin and fat Liver	NO ENTRY	Anti-infectious agents / Antibiotics
	Tylvalosin	Poultry	200 µg/kg	Eggs		

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

London, 6 November 2014

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)