



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 July 2011
EMA/CVMP/447493/2011
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/10/181/DOP

Name of the substance: Phenoxymethylpenicillin (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Dopharma Research B.V. submitted to the European Medicines Agency on 28 September 2010 an application for the establishment of maximum residue limits for phenoxymethylpenicillin in poultry eggs.

On 9 February 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 15 April 2011.

Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by consensus the establishment of a maximum residue limit for phenoxymethylpenicillin in eggs and the modification of the current entry for phenoxymethylpenicillin in table 1 of the Annex to Commission Regulation (EU) No 37/2010 of 22 December 2009, in accordance with the following table:



Pharmaco- logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Phenoxymethyl- penicillin	Phenoxymethyl- penicillin	Porcine	25 µg/kg 25 µg/kg 25 µg/kg	Muscle Liver Kidney	NO ENTRY	Anti-infectious agents/Antibiotics
		Poultry	25 µg/kg 25 µg/kg 25 µg/kg 25 µg/kg 25 µg/kg	Muscle Skin and fat Liver Kidney Eggs		

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 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, 14 July 2011

Signature on file

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

Annex I

European public MRL assessment report ([EPMAR](#))