EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 December 2011
EMA/CVMP/845730/2011
Veterinary Medicine and Product Data Management

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

Procedure no: EU/11/189/INT

Name of the substance: Fenbendazole (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Intervet International BV submitted to the European Medicines Agency on 29 June 2011 an application for the extension of maximum residue limits for fenbendazole to chicken.

Recommendation

The Committee, having considered the application, recommends by consensus the modification of maximum residue limits for fenbendazole and the amendment of table 1 of the Annex to Regulation (EU) No 37/2010 in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Fenbendazole	Sum of extractable residues which may be oxidised to oxfendazole sulfone	All food producing species except fish	50 µg/kg 50 µg/kg 500 µg/kg 50 µg/kg 10 µg/kg 1300 µg/kg	Muscle Fat Liver Kidney Milk Eggs	For porcine and poultry species the fat MRL relates to 'skin and fat in natural proportions'	Antiparasitic agents/Agents against endoparasites

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

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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, 8 December 2011

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)