12 September 2013
EMA/CVMP/497546/2013
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/ART11/10/184/EC

Name of the substance: Ivermectin (INN)

Basis for the opinion

Pursuant to Article 11 of Regulation (EC) No 470/2009 of 6 May 2009, the European Commission submitted to the European Medicines Agency on 15 December 2010 a request to issue a new opinion on the substance ivermectin including the possibility to establish a MRL for the tissue muscle.

On 9 June 2011 the Committee for Medicinal Products for Veterinary Use adopted an opinion recommending the establishment of maximum residue limits for ivermectin in tissues including muscle for all mammalian food producing species. The recommendation included in addition a residue level not to be exceeded at the injection site.

On 25 October 2011 the European Commission requested the Committee to reconsider its opinion of 9 June 2011 and to amend the part of the opinion referring to residue levels at the injection site in the "Other provisions" of Table I of the Annex to Commission Regulation (EU) 37/2010.

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Recommendation

The Committee, having considered the Commission's request recommends, by consensus, the amendment of the entry for ivermectin in table 1 of the Annex to Commission 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
Ivermectin	22,23-Dihydro-avermectin B 1a	All mammalian food producing species	30 µg/kg 100 µg/kg 100 µg/kg 30 µg/kg	Muscle Fat Liver Kidney	For porcine species the fat MRL relates to 'skin and fat in natural proportions'. Not for use in animals from which milk is produced for human consumption.	Antiparasitic agents/Agents acting against endo- and ectoparasites

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 together with its appendices.

London, 12 September 2013

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)