EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 June 2013
EMA/CVMP/317099/2013
Veterinary Medicines and Product Data Management

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

Procedure no: EU/12/203/MER

Name of the substance: Chloroform (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, MERIAL submitted to the European Medicines Agency on 01 October 2012 an application for the establishment of maximum residue limits for chloroform in all ruminants and porcine species.

On 7 February 2013 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 19 April 2013.

Recommendation

The Committee, having considered the application, recommends by consensus the removal of chloroform from Table 2 of the Annex to Regulation No. (EU) 37/2010 and its inclusion in Table 1 of that Regulation, in accordance with the following table:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions	Therapeutic classification
Chloroform	NOT APPLICABLE	All mammalian food producing species	No MRL required	NOT APPLICABLE	Only to be used as an excipient in vaccines and only at concentrations not exceeding 1% w/v and total doses not exceeding 20 mg per animal	NO ENTRY

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

London, 13 June 2013

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)