7 May 2015
EMA/CVMP/245930/2015
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/003923/FULL/0001

Name of the substance: Purified semi-solid extract from *Humulus lupulus L.* containing approximately 48% of beta acids (as potassium salts)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Vita (Europe) Limited submitted to the European Medicines Agency on 6 January 2014 an application for the establishment of maximum residue limits for purified semi-solid extract from *Humulus lupulus L.* containing approximately 48% of beta acids (as potassium salts) in honey.

On 5 June 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 4 December 2014.

Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by the majority of 30 out of 31 votes the establishment of maximum residue limits for purified semi-solid extract from *Humulus lupulus L.* containing approximately 48% of beta acids (as potassium salts) in accordance with the following table:

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Send a question via our website www.ema.europa.eu/contact

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Purified semi-solid extract of *Humulus lupulus L.* containing approximately 48% of beta acids (as potassium salts)	NOT APPLICABLE	Bees	No MRL required	Honey	NO ENTRY	Antiparasitic agents / Agents acting against 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 divergent position is presented in Annex II of this opinion.

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

London, 7 May 2015

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)

Annex II

Divergent position