EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 September 2012
EMA/CVMP/594122/2012
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/10/182/BEE

Name of the substance: double stranded ribonucleic acid homologous to viral ribonucleic acid coding for part of the coat protein and part of the intergenic region of the Israel Acute Paralysis Virus

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Beeologics Holdings Ltd submitted to the European Medicines Agency on 29 October 2010 an application for the establishment of maximum residue limits for double stranded ribonucleic acid homologous to viral ribonucleic acid coding for part of the coat protein and part of the intergenic region of the Israel Acute Paralysis Virus in bees.

On 9 March 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 14 January 2012.

On 13 April 2012 the Committee adopted an opinion recommending the inclusion of double stranded ribonucleic acid homologous to viral ribonucleic acid coding for part of the coat protein and part of the intergenic region of the Israel Acute Paralysis Virus in table 1 of the Annex to Commission Regulation (EU) No. 37/2010, with a “No MRL required” status.

On 9 July 2012 the European Commission requested the Committee to consider whether existing guidance relating to human medicines would be relevant for the evaluation. The Commission also requested the Committee to provide additional justification for the proposed provision “For oral treatment of bees during periods when no collection of commercial honey is done”.

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Recommendation

The Committee, having considered the application, evaluated the response to the list of questions and considered the request from the European Commission, recommends by consensus the inclusion of double stranded ribonucleic acid homologous to viral ribonucelic acid coding for part of the coat protein and part of the intergenic region of the Israel Acute Paralysis Virus in table 1 of the Annex to Commission Regulation (EU) No. 37/2010, as follows:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Double stranded ribonucleic acid homologous to viral ribonucleic acid coding for part of the coat protein and part of the intergenic region of the Israel Acute Paralysis Virus	NOT APPLICABLE	Bees	No MRL required	Honey	NO ENTRY	NO ENTRY

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 appendices.

London, 13 September 2012

Signature on file

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

Annex I

European Public MRL Assessment Report (EPMAR)