EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2013
EMA/CVMP/651823/2013
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/003749/FULL/0001

Name of the substance: Lufenuron (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Novartis Animal Health Inc (Switzerland) submitted to the European Medicines Agency on 6 March 2013 an application for the establishment of maximum residue limits for lufenuron in Atlantic salmon and Rainbow trout.

On 18 July 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 13 September 2013.

Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by consensus the establishment of maximum residue limits for lufenuron in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Lufenuron (RS-isomers)	Lufenuron (RS-isomers)	Fin fish	1350 µg/kg	Muscle and skin in natural proportions	NO ENTRY	Antiparasitic agents / Agents (acting) against ectoparasites

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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 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, 12 December 2013

Signature on file

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

Annex I

European Public MRL assessment report (EPMAR)