8 October 2015
EMA/CVMP/619915/2015
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/003669/EXPL/0002

Name of the substance: Gentamicin (INN)

Basis for the opinion

Pursuant to Article 27(2) of Regulation (EC) No 470/2009 of 6 May 2009, the European Commission submitted to the European Medicines Agency on 29 June 2015 a request for an opinion on extrapolation of the existing maximum residue limits for gentamicin to other species and tissues.

Recommendation

The Committee, having considered the request and the data available for the previous evaluation, recommends by consensus the extrapolation of maximum residue limits for gentamicin to all mammalian food producing species and to fin fish and the amendment of the entry for gentamicin 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
Gentamicin	Sum of gentamicin C1, gentamicin C1a, gentamicin C2 and gentamicin C2a	All mammalian food producing species and fin fish	50 µg/kg 50 µg/kg 200 µg/kg 750 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	For fin fish the muscle MRL relates to 'muscle and skin in natural proportions' For porcine species the fat MRL relates to 'skin and fat in natural proportions'	Anti-infectious agents / Antibiotics

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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 together with its appendices.

London, 8 October 2015

Signature on file

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

Annex I

European Public MRL assessment report (EPMAR)