16 May 2012
EMA/CVMP/840899/2011 – Final – Rev.1
Committee for Medicinal Products for Veterinary Use

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

## Procedure no: EU/10/180/MER

## Name of the substance: Neomycin (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 1 September 2010 an application for the modification of maximum residue limits for neomycin in bovine species.

On 12 January 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 12 August 2011.

On 10 November 2011 the Committee adopted an opinion recommending the modification of maximum residue limits for neomycin in all food producing species.

On 23 November 2011, the applicant submitted a request for a re-examination of the CVMP opinion.

The grounds for re-examination were submitted on 9 January 2012.

The applicant provided oral explanations to the Committee on 7 February 2012.

On 8 March 2012 the Committee adopted an opinion recommending the modification of the maximum residue limits for neomycin in all food producing species.

On 23 April 2012 the European Commission requested a review of the opinion in order to improve the clarity of the document.

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## Recommendation

The Committee, having considered the detailed grounds for the re-examination request in accordance with Article 8(3) of Regulation (EC) No 470/2009 of 6 May 2009 and reviewed the request from the Commission recommends by consensus the modification of maximum residue limits for neomycin and the amendment of table 1 of the Annex to 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 |
|---|---|---|---|---|---|---|
| Neomycin (including framycetin) | Neomycin B | All food producing species | 500 µg/kg<br>500 µg/kg<br>5500 µg/kg<br>9000 µg/kg<br>1500 µg/kg<br>500 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney<br>Milk<br>Eggs | For fin fish the muscle MRL relates to 'muscle and skin in natural proportions'. MRLs for fat, liver and kidney do not apply to fin fish.<br>For porcine and poultry species the fat MRL relates to 'skin and fat in natural proportions'. | Anti-infectious agents/ Antibiotics |

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, 16 May 2012

*Signature on file*

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

# Annex I

# European public MRL assessment report (EPMAR)