7 May 2015
EMA/CVMP/259372/2015
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/003915/FULL/0001

## Name of the substance: Sisapronil (INN)

### Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Zoetis Belgium SA submitted to the European Medicines Agency on 27 November 2013 an application for the establishment of maximum residue limits for sisapronil in bovine species.

On 10 April 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 7 August 2014.

On 15 January 2015 the Committee for Medicinal Products for Veterinary Use adopted an opinion recommending the establishment of maximum residue limits for sisapronil in bovine and caprine species.

On 27 January 2015 the applicant submitted a request to re-examine the CVMP opinion of January 2015. The grounds for re-examination were submitted on 9 March 2015.

The applicant provided oral explanations to the Committee on 9 April 2015.

### Recommendation

The Committee, having considered the application and the grounds for re-examination, recommends by consensus the establishment of maximum residue limits for sisapronil in bovine species. Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the maximum residue limits recommended in bovine species to caprine species. Therefore the Committee recommends by consensus the establishment of maximum residue limits for sisapronil in accordance with the following table:

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| Pharmaco-logically active substance | Marker residue | Animal species | MRLs | Target tissues | Other provisions | Therapeutic classification |
|---|---|---|---|---|---|---|
| Sisapronil | Sisapronil | Bovine, caprine | 100 µg/kg<br>2000 µg/kg<br>200 µg/kg<br>100 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney | Not for use in animals from which milk is produced for human consumption. | Antiparasitic agents / Agents 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 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, 7 May 2015

*Signature on file*

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

# Annex I

## European public MRL assessment report (EPMAR)