EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 November 2014
EMA/CVMP/643808/2014
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/003878/FULL/0001

## Name of the substance: Virginiamycin (INN)

### Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, PHIBRO Animal Health Corporation submitted to the European Medicines Agency on 3 October 2013 an application for the establishment of maximum residue limits for virginiamycin in chicken.

On 13 February 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 4 August 2014.

### 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 virginiamycin in chicken tissues.

Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the maximum residue limits recommended in chicken tissues to tissues of other poultry species. Therefore the Committee recommends by consensus the establishment of maximum residue limits for virginiamycin in accordance with the following table:

| Pharmaco-logically active substance | Marker residue | Animal species | MRLs | Target tissues | Other provisions | Therapeutic classification |
|---|---|---|---|---|---|---|
| Virginiamycin | Virginiamycin factor S1 | Poultry | 10 µg/kg<br>30 µg/kg<br>10 µg/kg<br>60 µg/kg | Muscle<br>Skin and fat<br>Liver<br>Kidney | Not for use in animals from which eggs are produced for human consumption | 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 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, 6 November 2014

*Signature on file*

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

# Annex I

## European public MRL assessment report (EPMAR)