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Veterinary Medicines Division

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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 34[1] referral for Micotil 300 Injectie and its associated names

International non-proprietary name (INN): tilmicosin

Background information

Micotil 300 Injectie is a solution for injection containing tilmicosin with a strength of 300 mg per ml. Tilmicosin is a macrolide antibiotic synthesized from tylosin which has an antibacterial spectrum similar to tylosin with enhanced activity against *Pasteurella multocida* and *Mannheimia haemolytica*. Micotil 300 Injectie and its associated names are veterinary medicinal products authorised for use in the target species cattle, sheep and rabbits for treatment of various infections caused by microorganisms susceptible to tilmicosin.

Due to divergent national decisions taken by Member States concerning the authorisations of Micotil 300 Injectie and its associated names, on 24 April 2012 the Netherlands referred the issue to the CVMP under Article 34(1) of Directive 2001/82/EC, in order to resolve discrepancies in the product information across the European Union.

The referral procedure started on 15 May 2012. The Committee appointed Mr G. Johan Schefferlie as rapporteur and Dr Michael Holzhauser-Alberti as co-rapporteur.

Written explanations were provided by the marketing authorisation holders on 18 September 2012, 11 February 2013 and 26 May 2013. Oral explanations were given on 11 June 2013.

Based on the currently available data, the CVMP considered that the benefit-risk profile of Micotil 300 Injectie and its associated names remains positive, subject to variation of the marketing authorisations in accordance with the recommended product information. The Committee adopted a positive opinion by consensus on 18 July 2013.

[1] Article 34 of Directive 2001/82/EC, as amended

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The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the amended Summary of Product Characteristics, labelling and package leaflet in Annex III.

The final opinion was converted into a Decision by the European Commission on 18 October 2013.