EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2006
EMA/250814/2014
Veterinary Medicines and Inspections

EMEA/V/A/010

Committee for Medicinal Products for Veterinary Use (CVMP)

Opinion following an Article 35[1] referral for Micotil 300 and its associated names

International non-proprietary name (INN): tilmicosin

Background information

Micotil 300 and its associated names are 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 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.

On 19 May 2004, France presented to the Agency a referral notification under Article 35 of Directive 2011/82/EC, regarding Micotil 300 and its associated names. The CVMP was requested to give its opinion as to whether the wording with regard to the user safety, including a restriction of use to veterinary surgeons and the volume to deliver per syringe, should be harmonised within the European Union.

The referral started on 16 June 2004. The Committee appointed M. Arboix as rapporteur and J. O'Brien as co-rapporteur. Written explanations were provided by the marketing authorisation holders on 30 September 2004. Oral explanations were given on 8 December 2004.

Based on the evaluation of the available data, the CVMP considered that overall the benefit-risk profile for these products remains positive, subject to the recommended changes of the product information related to harmonisation of the user safety warnings and harmonisation of the conditions of use to 'For use by veterinary surgeons only'. Therefore, the CVMP adopted by a majority an opinion on 8 December 2004, recommending variations to the terms of the marketing authorisations for the above-mentioned products.

[1] Article 35 of Directive 2001/82/EC, as amended

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On 11 April 2005, Spain and United Kingdom requested a meeting of the Standing Committee on Veterinary Medicinal Products to discuss the draft Commission Decision, in particular the proposed restriction for use by veterinary surgeons only. During the meeting held on 10 May 2005, important questions on the justification and the practical implementation of the proposed restriction for use by veterinary surgeons only were raised.

On 7 July 2005, the marketing authorisation holders informed the European Commission and the Member States having authorised the product, of the availability of results of new safety studies that could impact on the safe use of their product in particular for the treatment of persons having been accidentally self-injected. The Netherlands requested that those new safety data would be preferably assessed before the European Commission would propose a revised draft Commission Decision.
On 14 July 2005, the European Commission requested the CVMP to assess the new safety data and to review its previous opinion.

Written explanations were provided by the marketing authorisation holders on 6 September 2005 and 19 October 2005.

Based on the evaluation of the additional data, the CVMP recommended revised changes to the product information regarding the user safety warnings and confirmed the condition of use by veterinary surgeons only. Therefore, the CVMP adopted by a majority an opinion on 9 November 2005, recommending variations to the terms of the marketing authorisations for the above-mentioned products.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II together with the amendments in the summaries of product characteristics, labelling and package leaflets in Annex III. The conditions of the marketing authorisation are provided in Annex IV.

The final opinion was converted into a Decision by the European Commission on 23 June 2006.