European Medicines Agency
Veterinary Medicines and Inspections

London, 15 October 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

OPINION FOLLOWING AN ARTICLE 34[1] REFERRAL

Pulmotil AC and associated names

BACKGROUND INFORMATION

Pulmotil AC and associated names is a concentrate for oral solution whose active ingredient is tilmicosin with a strength of 250 mg/ml. Tilmicosin is a chemically modified macrolide antibiotic with properties broadly similar to other macrolides. Marketing Authorisations were granted in 18 Member States of the European Union via different authorisation procedures (mutual recognition procedures or national procedures).

Due to divergences (i.e. target species, indications for use, withdrawal periods, shelf life and environmental properties) amongst the nationally authorised Summary of Product Characteristics for Pulmotil AC and associated names, Germany referred the matter to the EMEA on 30 July 2008, under Article 34 of Directive 2001/82/EC.

The referral procedure started on 16 September 2008. The Committee appointed Dr C. Rubio Montejano as rapporteur and Dr L. Jodkonis as co-rapporteur. Written explanations were provided by the Marketing Authorization Holder on 12 January 2009 and supplementary information was submitted on 16 March 2009. Oral explanations were given by the Marketing Authorisation Holder on 15 April 2009

Based on evaluation of currently available data and the rapporteur's assessment report, the CVMP considered that the benefit/risk profile of Pulmotil AC and associated names is positive subject to the recommended changes to the Summary of Product Characteristics and product information and therefore adopted an Opinion in May 2009 recommending amendments of the Marketing Authorisations. A revised Opinion, necessitated by purely administrative changes, was adopted by written procedure in July 2009.

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 and labelling in the Annex III

The final opinion was converted into a Decision by the European Commission on 15 October 2009.

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

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