European Medicines Agency
Veterinary Medicines and Inspections

London, 15 October 2009
EMEA/608931/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

OPINION FOLLOWING AN ARTICLE 34[1] REFERRAL

Pulmotil 40 VET Premix, Pulmotil 100 VET Premix, Pulmotil 200 VET Premix and associated names

BACKGROUND INFORMATION

Pulmotil 40 VET Premix, Pulmotil 100 VET Premix, Pulmotil 200 VET Premix and associated names are premixes for medicated feeding stuff whose active ingredient is tilmicosin which is a chemically modified macrolide antibiotic with properties broadly similar to other macrolides. Marketing Authorisations for three different strengths (40g, 100g and 200g per kg) were granted in 19 Member States of the European Union via different authorisation procedures (mutual recognition procedures or national procedures).

Due to divergences (i.e. indications for use, amount to be administered and withdrawal period) amongst the nationally authorised Summary of Product Characteristics for Pulmotil 40 VET Premix, Pulmotil 100 VET Premix and Pulmotil 200 VET Premix, Belgium referred the matter to the EMEA on 3 July 2008, under Article 34 of Directive 2001/82/EC.

The referral procedure started on 16 July 2008. The Committee appointed Dr C. Rubio Montejano as rapporteur and Dr L. Jodkonis as co-rapporteur. Written explanations were provided by the Marketing Authorisation Holders on 15 January 2009 and supplementary information was submitted on 16 March 2009. Oral explanations were given by the Marketing Authorisation Holders 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 40 VET Premix, Pulmotil 100 VET Premix, Pulmotil 200 VET Premix and associated names is positive subject to the recommended changes of the Summary of the 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 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.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.europa.eu http://www.emea.europa.eu
© European Medicines Agency, 2009. Reproduction is authorised provided the source is acknowledged.