8 January 2010
EMA/214243/2009
Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 33(4)[1] referral for Pharmasin 100% W/W Water Soluble Granules and associated names

Background information

Tylosin is a macrolide antibiotic. It exerts its antimicrobial effect by inhibiting protein synthesis of susceptible micro-organisms.

The applicant, Huvepharma NV, submitted an application for a decentralised procedure for Pharmasin 100% W/W Water Soluble Granules and associated names indicated for oral use in pigs, chickens (broilers, pullets), turkeys and calves. The application was submitted in the framework of Article 32 of Directive 2001/82/EC, as amended, where the reference member state was the Netherlands and the concerned member states (CMSs) were Austria, Belgium, Bulgaria, Czech Republic, Germany, Denmark, Spain, Hungary, Ireland, Italy, Poland, Portugal, Romania and United Kingdom.
The Decentralised Procedure NL/V/0127/001/DC started on 23 March 2007.

On 29 April 2008 the Netherlands referred the matter to the European Medicines Agency (the Agency) under Article 33 (4) of Directive 2001/82/EC, due to concerns, raised by Germany, that tylosin may present a potential serious risk to the environment (risk to algae and to terrestrial plants).

The referral procedure started on 14 May 2008. The rapporteur and co-rapporteur appointed were: Dr Cristina Muñoz Madero (Spain) and Dr Boris Kolar (Slovenia), respectively. Written explanations were provided by the applicant on 18 August 2008.

On 16 September 2008 the CVMP agreed a list of outstanding issues and the written explanations were provided by the applicant on 12 November 2008.

During its 9-11 December 2008 meeting, the CVMP in light of the overall data submitted and the scientific discussion within the Committee, considered by consensus that the application did not satisfy the criteria for authorisation in respect of environmental risk. Therefore the CVMP recommended the refusal of the granting of the marketing authorisations for Pharmasin 100% W/W Water Soluble Granules and associated names. Furthermore, the CVMP recommended the revocation of the marketing authorisations for the above-mentioned product already granted in Austria, Ireland, the Netherlands and the United Kingdom.

[1] Article 33(4) of Directive 2001/82/EC, as amended.

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On 24 December 2008, Huvepharma NV, notified the Agency of his intention to request the re-examination of the CVMP opinion. The detailed grounds for the request were submitted to the Agency on 5 February 2009. The rapporteur and co-rapporteur appointed for the re-examination were: Dr Ruth Kearsley as the rapporteur and Dr Michael Holzhauser-Alberti as the co-rapporteur respectively.

The re-examination procedure started on 6 February 2009 and oral explanations were given by Huvepharma NV on 10 March 2009.

During its 10-12 March 2009 meeting, the Committee, having considered the grounds for appeal and the oral explanations provided by Huvepharma NV, concluded by consensus that its opinion of 10 December 2008 should not be revised and that the marketing authorisations for Pharmasin 100% W/W Water Soluble Granules and associated names should be refused by the member states. Furthermore, the CVMP recommended that the existing marketing authorisations for the above-mentioned product should be revoked.

In line with the restrictions in legislation with respect to data on environmental risk, the Committee limited its considerations to the data presented by Huvepharma NV in the dossier for Pharmasin 100% W/W Water Soluble Granules and associated names. No consideration was given nor conclusion drawn regarding the applicability of the conclusions to other licensed products containing the same active ingredients.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II.

The final opinion was converted into a Decision by the European Commission on 8 January 2010.