26 March 2010
EMA/115640/2010
Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 33(4)[1] referral for CEVAZURIL 50 mg/ml oral suspension for piglets

Background information

Toltrazuril is a triazinon derivative administered orally to piglets for the prevention of clinical signs of coccidiosis in neonatal piglets on farms with a confirmed history of coccidiosis caused by *Isospora suis*.

The Applicant, Ceva Santé Animale, submitted an application for a decentralised procedure for CEVAZURIL 50 mg/ml oral suspension for piglets. The application was submitted in the framework of Article 32 of Directive 2001/82/EC, where the Reference Member State was France and the Concerned Member States were Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Spain and United Kingdom. The Decentralised Procedure FR/V/195/01/DC started on 29 February 2008.

On 6 May 2009 France, referred the matter to the Agency under Article 33(4) of Directive 2001/82/EC, due to concerns, raised by Germany, Spain, Portugal, Poland and the United Kingdom, that the marketing authorisation of CEVAZURIL 50 mg/ml oral suspension for piglets may present a potential serious risk to the environment.

The referral procedure started on 12 May 2009. The Rapporteur and Co-Rapporteur appointed were: Dr A. Holm and Dr B. Kolar, respectively. Written explanations were provided by the Applicant on 18 August 2009. Oral explanations were given on 8 December 2009.

Based on the evaluation of the rapporteur's assessment of the currently available data, on 9 December 2009 the CVMP considered that the objections raised during the decentralised procedure should not prevent the granting of a Marketing Authorisation for CEVAZURIL 50 mg/ml oral suspension for piglets.

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 26 March 2010.

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

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