European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

OPINION FOLLOWING AN ARTICLE 35[1] REFERRAL FOR

ALL AUTHORISED VETERINARY MEDICINAL PRODUCTS CONTAINING

TOLTRAZURIL INTENDED FOR USE IN POULTRY SPECIES

International Non-Proprietary Name (INN): Toltrazuril

BACKGROUND INFORMATION

Toltrazuril is a triazinetrione derivative administered orally in the drinking water for the treatment of coccidiosis in chickens and turkeys. The recommended dose and duration of treatment for chickens and turkeys is 7 mg/kg bodyweight per day for two consecutive days. In practice this means that in intensive systems all the birds in one house will be treated even if not all exhibit signs of disease.

Marketing Authorisations for veterinary medicinal products containing toltrazuril and intended for use in poultry species were previously granted to Bayer HealthCare and/or Ceva Santé Animale in Austria, Belgium, Bulgaria, Cyprus, Czech republic, France, Germany, Greece, Hungary, Ireland, Italy, Poland, Portugal, Romania, Slovakia, Slovenia, the Netherlands and the United Kingdom following national marketing authorisation procedures.

On 31 August 2007 a Community referral under Article 35 of Directive 2001/82/EC, as amended, was initiated by Germany for the nationally authorised product Baycox 2.5 % (solution for poultry). On 10 October 2007 the European Commission decided that the scope of the referral should include all authorised veterinary medicinal products containing toltrazuril (i.e. reference product and generics thereof) and intended for use in poultry species.

Germany referred the issue to CVMP due to concerns that toltrazuril may present a potential serious risk to the environment on the following grounds:

- An extended risk assessment on the basis of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guidelines fully and clearly demonstrated that veterinary medicinal products containing toltrazuril and intended for use in poultry species must be expected to have impact on the environment.

The arbitration procedure started on 11 October 2007 with the adoption of a list of questions to be put to the Marketing Authorisation Holders. The Rapporteur and Co-Rapporteur appointed were Mrs R. Kearsley and Mr G. J. Schefferlie respectively. The date set for submission of written responses by the Marketing Authorisation Holders was 14 January 2008.

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

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During its 11-13 December 2007 meeting, the CVMP agreed on a two month extension to the date for submission of responses to the list of questions following a request from Bayer HealthCare.

Written explanations were provided by the Marketing Authorisation Holders on 18 March 2008. The Marketing Authorisation Holders presented oral explanations to the CVMP on 18 June 2008.

During its July 2008 meeting, the CVMP, in light of the overall data submitted and the scientific discussion within the Committee, adopted by consensus an opinion concluding that the assessment of the risk presented by toltrazuril and its major metabolite, toltrazuril sulfone, to terrestrial plants and to groundwater demonstrated that use of products containing toltrazuril is acceptable. The CVMP concluded that the marketing authorisations can be maintained without special warnings in point 5.3 (Environmental properties) of the SPC provided that the product is used under the conditions agreed, i.e. a dose of 7 mg/kg bw on two consecutive days for the treatment of coccidiosis in chickens and turkeys. However, it was noted that the indications, species and posology in SPCs of some of the authorised products were different and these therefore needed to be amended to bring them in line with the indications and dosing regimens used in the environmental risk assessment.

Therefore the Committee recommended maintaining the Marketing Authorisations for all veterinary medicinal products containing toltrazuril intended for use in chickens and turkeys. The Committee further recommended that relevant Marketing Authorisations should be varied in order to harmonise the indications and dosing regimens to bring these in line with those used in the environmental risk assessment. This procedure will involve removing the following recommendations and indications for which no data were provided:

- repeat treatment can be administered after 5 days if infection is severe;
- prevention and control of coccidiosis;
- use in pigeons.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the amendments to the relevant sections of the Summary of Product Characteristics in Annex III.

The final opinion was converted into a Decision by the European Commission on 26 September 2008.