European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

OPINION FOLLOWING AN ARTICLE 34 REFERRAL

FOR METHOXASOL-T

BACKGROUND INFORMATION

On 8 September 2006, Germany presented to the EMEA a referral under Article 34 of Directive 2001/82/EC, as amended, concerning Methoxasol-T (including associated names), containing trimethoprim and sulfamethoxazole as active ingredient.

Methoxasol-T was authorised through a national procedure in The Netherlands in 1999, but a marketing authorisation was refused in Germany in 2001. Germany considered that the efficacy of Methoxasol-T as proposed by the applicant was not adequately justified, therefore resulting in a potential serious risk to the target animals.
An intended application for a marketing authorisation of a generic triggered Germany to submit the referral regarding the divergent decisions taken on Methoxasol-T.

The CVMP started the referral procedure during its meeting of 12-14 September 2006. The Marketing Authorisation Holder was requested:

1. To provide the relevant parts of the dossier of each Member State where an application has been submitted and to detail the differences between the dossiers.
2. To justify compliance of the dossier with respect to the requirements for obtaining a marketing authorisation (Annex I of Directive 2001/82/EC, as amended).
3. To consider in particular the issues mentioned in the referral notification as the grounds for refusing an authorisation in Germany.
4. To justify with field data, the use of the product and the adequacy of the recommended dose for each of the claimed indications in pigs and poultry. For poultry comment was required on the current use of the product, in particular on the dose used or prescribed under field conditions.
5. To propose and justify with data a suitable shelf life for the product, including an in-use shelf life where relevant.
6. To propose and justify a harmonised text of the Summary of Product Characteristics (SPC), including posology and method of administration as well as withdrawal periods for pigs and poultry.

The Marketing Authorisation Holder submitted written responses, defending the indications, recommended dose and shelf life, and proposing a harmonised SPC text. On the basis of the data provided, the CVMP agreed on the following harmonised indications for use:

- Pigs: treatment and prevention of respiratory infections caused by *Actinobacillus pleuropneumoniae* susceptible to trimethoprim and sulfamethoxazole where the disease has been diagnosed in the herd.

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- Broilers: treatment and prevention of respiratory infections caused by *Escherichia coli* susceptible to trimethoprim and sulfamethoxazole where the disease has been diagnosed in the flock.

The CVMP recommended in relation to the pharmacokinetic properties described that the inclusion of environmental effects should be deleted. The CVMP also recommended that the use of the product should be based on culture and sensitivity testing of micro-organisms from diseased cases on farm or from recent previous experience on the farm, as resistance against potentiated sulphonamides may vary.

Having considered the grounds for referral and the responses provided by the Marketing Authorisation Holder, CVMP concluded that the benefit/risk balance of the product is positive for use in both pigs and broilers subject to recommended changes to the Summary of Product Characteristics and product information, and that the concerns raised by Germany should not prevent the granting of a marketing authorisation.

The CVMP Opinion was adopted on 11 October 2007 and the subsequent Commission Decision on 11 January 2008.
