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

Suramox 15 % LA and its associated name **Stabox 15 % LA**

International Non-Proprietary Name (INN): Amoxicillin

BACKGROUND INFORMATION

Suramox 15% LA is an injectable suspension containing amoxicillin, which is a beta-lactam antibiotic, belonging to the group of penicillins. The product is used in the treatment of respiratory infections caused by *Pasteurella multocida* and *Mannheimia haemolytica* in cattle and for the treatment of respiratory infections due to *Pasteurella multocida* in pigs. In both species the product is administered intramuscularly at a dose rate of 15 mg amoxicillin/kg bw (equivalent to 1 ml of Suramox 15% LA / 10 kg bw) twice at 48 hours interval.

A Marketing Authorisation for Suramox 15% LA was previously granted to Virbac S.A. in France on 6 July 2004 based on an abridged application having Duphamox LA as reference medicinal product, with a withdrawal period of 58 days in cattle for meat and offal and 35 days in pigs for meat and offal. The withdrawal period for milk was 2.5 days.

A mutual recognition procedure was started on 28 April 2005. The Reference Member State was France and the Concerned Member States were Belgium, the Czech Republic, Germany, Italy, Spain, and the United Kingdom. The product was accepted by the Czech Republic, Italy and Spain. Concerns were raised by Belgium, Germany and the United Kingdom regarding the inadequacy of the withdrawal periods and the applications were withdrawn from these countries. Belgium referred the reason for disagreement to the EMEA on 28 July 2005.

The scope of the referral was to agree whether the proposed withdrawal periods of 58 days for cattle and 35 days for pigs were adequately established.

The arbitration procedure started on 8 September 2005 with the adoption of list of questions. The rapporteur was Dr. J. Schefferlie and the co-rapporteur was Prof. R. Kroker. The Marketing Authorisation Holder (MAH) provided written explanations on 16 January 2006.

At the request of the MAH the evaluation procedure was suspended on 15 March 2006 in order to allow for the MAH to prepare for the provision of oral explanations. The oral explanations were presented on 17 May 2006 by the MAH to the Committee.

During its May 2006 meeting, the CVMP, in light of the overall data submitted and the scientific discussion within the Committee, adopted by consensus an opinion recommending the suspension of the

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

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marketing authorisations for Suramox 15% LA and the associated invented name Stabox 15% LA, for cattle and pigs. The reasons being the following:

- it was not possible to establish a withdrawal period for cattle and pigs based on the data available;
- the currently established withdrawal periods for cattle and pigs are inadequate to ensure that residues do not exceed the MRLs;
- the currently authorised withdrawal periods are inadequate to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer.

On 1 June 2006, the representative of the MAH notified the EMEA on his intention to request the reexamination of the CVMP opinion in accordance with Article 36(4)[2]. During their June 2006 meeting, the CVMP appointed Dr. R. Breathnach as rapporteur for the assessment of the grounds for the request for re-examination of the opinion. The detailed grounds for the request were submitted to the EMEA on 18 July 2006 and the evaluation procedure for the re-examination started on 19 July 2006.

On 13 September 2006 the CVMP, considered the detailed grounds the re-examination of the opinion and confirmed its previous opinion concluding that the marketing authorisations for Suramox 15% LA should be suspended. The reasons for the suspension were the same as those identified in the May 2006 CVMP meeting.

On 25 October 2006 the European Commission forwarded a draft decision to the Standing Committee on Veterinary Medicinal Products for adoption by written procedure. During the written procedure a request was received from the France for new studies made available by the Marketing Authorisation Holder to be scientifically assessed.

On 14 November 2006 the European Commission suspended the written procedure and on 16 November 2006, requested the CVMP, to consider the new residue studies in the assessment of the referral and to revise as appropriate the opinion of 13 September 2006.

The Marketing Authorisation Holder submitted the new residue studies to the CVMP on 9 January 2007 and provided oral explanations to the Committee on 13 March 2007 including presentation of a new residue study in pigs and a new calculation and proposal for the withdrawal period for pigs.

During its March 2007 meeting, the CVMP, considered the new residue studies submitted with regard to Suramox 15% LA and concluded that the new data did not allow establishment of withdrawal periods for edible tissues in cattle and pigs. Therefore the Committee adopted by consensus a revised opinion confirming its previous recommendation for the suspension of the marketing authorizations for Suramox 15% LA and the associated invented name, Stabox 15% LA. The reasons being the following:

- in cattle, residue concentration at the injection site were still above the MRL at the last slaughter time point;
- in pigs, residue concentrations at the injection site were still above the MRL at the last slaughter time point.

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 13 June 2007.

[2] Article 36(4) of Directive 2001/82/EC, as amended