European Medicines Agency
Veterinary Medicines and Inspections

London, September 2008
EMEA/436209/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP) OPINION FOLLOWING AN ARTICLE 35 REFERRAL FOR SODIUM SALICYLATE

BACKGROUND INFORMATION

On 27 November 2007, Ireland presented to the EMEA a referral under Article 35 of Directive 2001/82/EC, as amended, concerning all oral soluble powders containing sodium salicylate which are indicated for calves and pigs.

Ireland considered that there was a potentially serious risk to animal health by providing for the authorisation of a potentially ineffective medicine for mass use by farmers, especially when there are several authorised NSAIDs available for individual animal use. Ireland believed that the use of such a medicine for mass medication could mask the clinical signs of a developing infectious disease which could spread to other animals and thereby pose both an animal health and public health risk.

The referral procedure started on 11 December 2007 and after adoption of a list of questions, the clock was stopped on 15 January 2008. Further to the submission of responses to questions, the clock was re-started on 14 March 2008.

The aim of the assessment was to establish whether marketing authorisations and applications included in the referral procedure should be granted, maintained, suspended, varied or revoked with view to the grounds for referral. As the procedure concerns a range of products, the assessment has been limited to specific parts of the authorisations in accordance with Article 35(2) of Directive 2001/82/EC, as amended.

The Marketing Authorisation Holders and Applicant submitted written responses and the clock was re-started on 14 March 2008. The clock was stopped again on 14 May 2008 and restarted on 6 June when responses to the outstanding issues where received. Oral explanations were provided on 15 July 2008 and the CVMP Opinion was adopted on 16 July 2008.

Having considered the grounds for referral and the responses provided by the Marketing Authorisation Holder and Applicant the CVMP concludes that:

- Therapeutic concentrations are established and maintained following oral use of sodium salicylate in calves and pigs. The dosage required for calves is however 40 mg/kg bodyweight.

- The efficacy of sodium salicylate as supportive treatment when given to calves and pigs was demonstrated in respiratory infections and the usefulness of this compound was clear for the treatment of inflammation in combination with concurrent antibiotic therapy.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

- The benefit/risk balance of the product was shown to be positive, however in young animals, the summary of Product Characteristics should state that the product is not to be used in neonates or very young calves of less than 2 weeks of age nor in piglets of less than 4 weeks of age.

The following indications have been justified:

Asprimax 850 mg/g

4.2 Indications for use, specifying the target species

Pigs: to promote recovery of respiration and to reduce coughing in respiratory tract infections with concurrent antibiotic therapy.

NA-Salicylaat, 100%, powder for solution for oral administration

4.2 Indications for use, specifying the target species

Calves: supportive treatment of pyrexia in acute respiratory disease, in combination with appropriate (e.g. anti-infective) therapy if necessary.

Pigs: For the treatment of inflammation in combination with concurrent antibiotic therapy.

NA-Salicylaat, 80% WSP

4.2 Indications for use, specifying the target species

Calves: supportive treatment of pyrexia in acute respiratory disease, in combination with appropriate (e.g. anti-infective) therapy if necessary.

Pigs: For the treatment of inflammation in combination with concurrent antibiotic therapy.

SOLACYL 100 %, powder for oral solution for calves and pigs

4.2 Indications for use, specifying the target species

Calves: supportive treatment of pyrexia in acute respiratory disease, in combination with appropriate (e.g. anti-infective) therapy if necessary.

Pigs: For the treatment of inflammation in combination with concurrent antibiotic therapy.

The CVMP Opinion was adopted on 16 July 2008 and the subsequent Commission Decision adopted on 26 September 2008.