European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP) OPINION FOLLOWING AN ARTICLE 33 (4) REFERRAL AS AMENDED FOR SOLACYL

BACKGROUND INFORMATION

Solacyl 100 % powder for oral solution for calves and pigs is indicated in calves for supportive treatment for reduction of pyrexia in acute respiratory disease, in combination with appropriate (e.g. anti-infective) therapy if necessary and in pigs for the supportive treatment for relief of pain in musculoskeletal disorders in combination with appropriate (e.g. anti-infective) therapy if necessary.

In August 2006 a Decentralised Procedure started with The Netherlands as Reference Member State and thirteen Concerned Member States.

Ireland considered that, due to the absence of efficacy documentation it could not be assumed that the product is efficacious and that this as such presents a potential serious risk to animal health. The Netherlands notified the EMEA in November 2007 that the Co-ordination Group for Mutual Recognition and Decentralised Procedures - Veterinary (CMD(v)) failed to reach an agreement for Solacyl 100% powder for oral solution and the matter was referred to the CVMP.

Solacyl 100% powder for oral solution is a generic of Natrium salicylaat (authorised in The Netherlands).

CVMP started the referral procedure on 11 December 2007 and agreed on a 37 day time frame. A List of Questions was adopted by CVMP and sent to the applicant on 12 December 2007. The applicant submitted written responses to the List of Questions on 10 January 2008 and the clock was re-started.

On the basis of the grounds for referral, CVMP considered any differences between Solacyl 100% powder and the reference product that could justify different conclusions on the efficacy for the two products.

The aim of the assessment is to establish whether marketing authorisations of veterinary medicinal products included in the referral procedure should be maintained, suspended, varied or revoked with view to the grounds for referral.

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Solacyl 100% powder for oral solution proved to be essentially similar to the reference product, Natrium salicylaat 100%. Consequently, the same conclusions on efficacy and safety apply to both products. The objections raised by Ireland should not prevent the granting of a marketing authorisation for Solacyl 100% powder for oral solution for calves and pigs.

It is recommended that Solacyl 100% powder for oral solution for calves and pigs should follow the outcome of the Community Referral according to Article 35(2) for sodium salicylate-containing oral soluble powders.

The CVMP Opinion was adopted on 13 February 2008 and the subsequent Commission Decision adopted on 17 April 2008.