ANNEX I

NAME, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCT, ANIMAL SPECIES, ROUTES OF ADMINISTRATION, AND MARKETING AUTHORISATION HOLDER

Applicant or Marketing Authorisation Holder	Product invented name	Pharmaceutical form	Strength	Animal species	Frequency and route of administration	Recommended dose
Eurovet animal Health B.V.	Solacyl 100% powder for oral solution	powder	100%	Calves and pigs	oral	Calves: 20 mg sodium salicylate per kg bodyweight twice daily, for 1 to 3 days. Administration: orally in drinking water or milk(replacer). Pigs: 35 mg sodium salicylate per kg bodyweight per day, for 3 to 5 days. Administration: orally in drinking water. Alternatively Solacyl can also be administered with the drinking water as pulse medication. Half of the calculated total daily amount of powder is mixed with 5-10 litres of clean water and stirred until evenly dispersed. This solution is then added, whilst stirring, into an amount of drinking water that will be consumed within approximately 3-4 hours and administered twice daily.

ANNEX II

SCIENTIFIC CONCLUSIONS

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1. Introduction and background

The Netherlands, reference member state in the decentralised procedure, notified the EMEA on 26 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. Pursuant to Article 33(4) of Council Directive 2001/82/EC, as amended, the matter was referred to the CVMP.

Ireland considers that, due to the absence of efficacy documentation it cannot be assumed that the product is efficacious and that this as such presents a potential serious risk to animal health.

CVMP noted that Solacyl 100% powder for oral solution is a generic of Natrium salicylaat (authorised in The Netherlands) and that the concerns raised by Ireland could only be addressed in the framework of this procedure, in case any differences between both products would justify different conclusions on the safety or efficacy.

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.

2. Discussion

The applicant was requested to provide the following information:

1. The application dossier and any data added to it up to Day 60 of the referral procedure in CMD(v) to be provided to all CVMP Members and the EMEA.

2. To indicate and to substantiate where necessary, any differences between Solacyl 100% powder and the reference product that could justify different conclusions on the efficacy for the two products.

In response to question 1, the applicant provided a copy of the original dossier as submitted in support of the application of a decentralised procedure, and the supplementary data submitted during the decentralised procedure in response to the phase I and phase II assessment and the referral procedure in CMD(v) thereafter.

In response to question 2, the applicant answered that Solacyl 100% powder for oral solution is identical to the reference product and that there is no reason to reach different conclusions on the efficacy of the two products.

3. Conclusions and Recommendations

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.

ANNEX III

SUMMARY OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE INSERT

The valid Summary of Product Characteristics, labelling and package leaflet are the versions agreed by the Reference Member State and Concerned Member States (except Ireland) at day 210 of the decentralised procedure.