European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

OPINION FOLLOWING AN ARTICLE 40 REFERRAL

FOR SUVAXYN PARVO/E

BACKGROUND INFORMATION

France notified the EMEA on 11 July 2006 of a Referral under Article 40 of Council Directive 2001/82/EC, as amended, in relation to Suvaxyn Parvo/E.

Suvaxyn Parvo/E is indicated for the active immunisation of pigs (gilts and sows) to prevent reproductive disorders caused by porcine parvovirus and to reduce clinical signs caused by *Erysipelothrix rhusiopathiae* infections, serotype 2 and serotype 1.

The referral deals with the issue that in the opinion of France equivalence between the reference vaccine batch for the erysipelas batch potency test validated in the original dossier and the new reference vaccine batches was not shown for these 2 batches and that consequently the CVMP needed to consider whether to vary, withdraw or suspend the marketing authorisation.

The Committee for Medicinal Products for Veterinary Use (CVMP) started the referral procedure on 19 July 2006.

The CVMP concluded that, based on all available data, there was no concern regarding safety or efficacy for the product. However, it was important to ensure that the pass limits of the potency test do not drift from the original. In addition, a more robust test for potency should be applied to the product in the future.

The CVMP, therefore, recommended that the Marketing Authorisation should be varied to reduce the variability of the serological potency test in mice by appropriate measures such as the replacement of the use of a reference vaccine in the serological potency test in mice with the use of reference serum.

The CVMP Opinion was adopted on 17 January 2007 and the subsequent Commission Decision on 17 April 2007.

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7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.europa.eu http://www.emea.europa.eu