12 December 2014
EMA/CVMP/699011/2014
Committee for Medicinal Products for Veterinary Use

**Summary of opinion[1] (initial authorisation)**

# Suvaxyn CSF Marker

## Common name: Classical swine fever vaccine (recombinant live)

On 11 December 2014, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Suvaxyn CSF Marker, lyophilisate and solvent for suspension for injection, intended for active immunisation of pigs from 7 weeks of age onwards to prevent mortality and reduce infection and disease caused by classical swine fever virus (CSFV).

The applicant for this veterinary medicinal product is Zoetis Belgium SA.

The active substance of Suvaxyn CSF Marker is a live recombinant E2 gene deleted Bovine Viral Diarrhoea Virus containing Classical Swine Fever E2 (CP7_E2alf).

This vaccine has been developed to allow discrimination of vaccinated pigs from naturally infected pigs with classical swine fever virus (CSFV) in line with the DIVA principle (differentiation of infection from vaccination) using an appropriate serological test.

The benefit of Suvaxyn CSF Marker is the stimulation of active immunity against classical swine fever in pigs from 7 weeks of age onwards to prevent mortality and reduce infection and disease caused by classical swine fever virus. The onset of immunity is 14 days after completion of the basic vaccination scheme and the duration of immunity is at least 6 months.

Suvaxyn CSF Marker is generally well tolerated at the recommended dose, no adverse reactions were seen.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Suvaxyn CSF Marker and therefore recommends the granting of the marketing authorisation.