16 June 2017
EMA/CVMP/327193/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Suvaxyn PRRS MLV

Common name: Porcine respiratory and reproductive syndrome (PRRS) virus vaccine (live)

On 15 June 2017, 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 PRRS MLV, lyophilisate and solvent for suspension for injection, intended for active immunisation of clinically healthy pigs against porcine respiratory and reproductive syndrome (PRRS) virus (genotype 1). The applicant for this veterinary medicinal product is Zoetis Belgium SA.

Suvaxyn PRRS MLV is an immunological veterinary medicinal product containing porcine respiratory and reproductive syndrome virus, live (ATCvet code QI09AD03) as active substance.

The benefit of Suvaxyn PRRS MLV is its efficacy for the active immunisation of clinically healthy pigs from one day of age in a PRRS virus contaminated environment to reduce viraemia and nasal shedding caused by infection with European strains of PRRS virus (genotype 1). Suvaxyn PRRS MLV was also demonstrated to significantly reduce lung lesions in fattening piglets. In addition, pre-pregnancy vaccination of clinically healthy sows and gilts was demonstrated to reduce the transplacental infection during the third trimester of pregnancy, and to reduce the associated negative impact on reproductive performance.

Suvaxyn PRRS MLV is well tolerated at the recommended dose. The most common side effects, transient increase in temperature and local reactions in the form of swellings, are common and resolve spontaneously within three days. Anaphylactic-type reactions (vomiting, tremors and/or mild depression) may uncommonly occur.

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 67 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-risk balance for Suvaxyn PRRS MLV and therefore recommends the granting of the marketing authorisation.