European Medicines Agency
Veterinary Medicines and Inspections

London, 15 May 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION[*]
SUVAXYN PCV

On 13 May 2009, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[**] recommending to grant a marketing authorisation for the veterinary medicinal product Suvaxyn PCV, suspension for injection, intended for the active immunisation of pigs over the age of 3 weeks against Porcine Circovirus type 2 (PCV2) to reduce viral load in blood and lymphoid tissues, and the lesions in lymphoid tissues associated with PCV2 infection, as well as to reduce clinical signs - including loss of daily weight gain, and mortality associated with Post-Weaning Multisystemic Wasting Syndrome (PMWS).

The Applicant for this veterinary medicinal product is Fort Dodge Animal Health.

The active substance of Suvaxyn PCV is inactivated recombinant porcine circovirus (cPCV) 1-2.

The benefits of Suvaxyn PCV when administered as recommended to piglets from 3 weeks of age Are that it induces active immunisation against Porcine Circovirus Type 2 (PCV2) and is able to reduce viral load in blood and lymphoid tissues, and the lesions in lymphoid tissues associated with PCV2 infection, as well as to reduce clinical signs –including reduction of daily weight gain- and mortality associated with Post-Weaning Multisystemic Wasting Syndrome (PMWS). These indications have been justified in laboratory and/or field conditions. An onset and duration of immunity of respectively 3 weeks and 19 weeks post-vaccination have been demonstrated by challenge. This period covers the time during which most PCV2 infections are likely to occur under field European conditions. Efficacy of vaccination has been shown in the low to medium maternally-derived antibodies.

The most common side effects are a transient increase in body temperature (up to 1.7°C) during the first 24 hours after vaccination. This resolves spontaneously within 48 hours without treatment.
Local tissue reactions in the form of swelling at the injection site are very common and may last for up to 26 days. The area of local tissue reactions is in general below 5 cm in diameter, but in some cases a larger swelling may occur.
Vomiting occurs commonly during the first hour after vaccination, but no consequential negative effects are observed.

The approved indication is:

Active immunisation of pigs over the age of 3 weeks against Porcine Circovirus type 2 (PCV2) to reduce viral load in blood and lymphoid tissues, and the lesions in lymphoid tissues associated with PCV2 infection, as well as to reduce clinical signs - including loss of daily weight gain, and mortality associated with Post-Weaning Multisystemic Wasting Syndrome (PMWS).

Onset of immunity: from 3 weeks post-vaccination.
Duration of immunity: 19 weeks post-vaccination.

[*] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

[**] Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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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.

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