European Medicines Agency
Veterinary Medicines and Inspections

London, 14 November 2008
Doc. Ref.: EMEA/CVMP/573498/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*
PORCILIS PCV

On 12 November 2008, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product Porcilis PCV, intended for the immunisation of pigs against porcine circovirus type 2. The Applicant for this veterinary medicinal product is Intervet International BV.

The active substance of Porcilis PCV is porcine circovirus type 2 ORF2 subunit antigen, and it is an inactivated porcine circovirus vaccine (ATCvet code QI09AA07) to stimulate active immunity against porcine circovirus type 2.

The benefits of Porcilis PCV are to reduce the virus load in blood and lymphoid tissues and to reduce weight loss associated with PCV2 infection occurring during the fattening period in pigs. The most common side effects are transient local reactions at the injection site that may occur after vaccination mainly in the form of a hard, warm and sometimes painful swelling (diameter up to 10 cm). These reactions resolve spontaneously over a period of approximately 14-21 days without any major consequence on the general health status of the animals. Immediate systemic hypersensitivity-like reactions may occur after vaccination, resulting in minor neurological symptoms such as tremors and/or excitation, which normally resolve within minutes without requiring treatment. A transient increase in body temperature, normally not exceeding 1°C, may occur until 2 days after vaccination. Occasionally, an increase of rectal temperature up to 2.5 °C lasting less than 24 hours may occur. Some piglets may be depressed and show a reduced feed intake for up to 5 days. Vaccination may result in a transient impairment of growth rate in the immediate period after administration of the vaccine.

The approved indication is: “For the active immunisation of pigs to reduce the virus load in blood and lymphoid tissues and to reduce weight loss associated with PCV2 infection occurring during the fattening period”.

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 Porcilis PCV and therefore recommends the granting of the marketing authorisation.

* 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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