European Medicines Agency
Veterinary Medicines and Inspections

London, 11 December 2009
Doc. Ref.: EMA/CVMP/802298/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
POST-AUTHORISATION SUMMARY OF OPINION[*]
PORCILIS PCV

Vaccine against porcine circovirus

On 9 December 2009 the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[**] recommending to grant a variation to the terms of the marketing authorisation for the veterinary medicinal product Porcilis PCV. The Marketing Authorisation Holder for this veterinary medicinal product is Intervet International BV.

The change agreed by the CVMP concerns a change in the vaccination schedule for a single shot administration of one dose of 2 ml to pigs from an age of 3 weeks onwards in the case of low to medium levels of maternally derived antibodies against PCV2 and also to amend the indications for use to include reduction of mortality.

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

Based on the original and complementary data presented the Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the quality, safety and efficacy of Porcilis PCV for the addition of a single shot administration for pigs from an age of 3 weeks and an amendment of the indications to include reduction of mortality were considered to be in accordance with the requirements of Council Directive 2001/82/EC, as amended, and that the benefit-risk balance was favourable and that the application is approvable.

[*] Summaries of opinion are published without prejudice to the Commission Decision.
[**] 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.

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