EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 September 2014
EMA/CVMP/450050/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Porcilis PCV M Hyo

Common name: porcine circovirus type 2 ORF2 subunit antigen / *Mycoplasma hyopneumoniae* J strain ATCC 25934 inactivated

On 11 September 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 Porcilis PCV M Hyo emulsion for injection, intended for the active immunisation of pigs to reduce viremia, virus load in lungs and lymphoid tissues, virus shedding caused by porcine circovirus type 2 (PCV2) infection, and severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection. The applicant for this veterinary medicinal product is Intervet International B.V.

The active substance of Porcilis PCV M Hyo is porcine circovirus type 2 ORF2 subunit antigen / *Mycoplasma hyopneumoniae* J strain ATCC 25934 inactivated, a combination vaccine for the stimulation of active immunity against porcine circovirus type 2 and *Mycoplasma hyopneumoniae*.

The benefits of Porcilis PCV M Hyo are the reduction of viraemia and of the porcine circovirus load in lungs and lymphoid tissues, the shedding of PCV2, the reduction of the severity of lung lesions caused by *Mycoplasma hyopneumoniae* and the reduction of loss of daily weight gain during the finishing period in face of infections with *Mycoplasma hyopneumoniae* and/or PCV2. The most common side effect is a transient increase in body temperature. Porcilis PCV M Hyo is generally well tolerated at the recommended dose.

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 M Hyo and therefore recommends the granting of the marketing authorisation.

[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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