EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 March 2017
EMA/CVMP/132641/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Ingelvac PCV FLEX

Common name: Porcine circovirus vaccine (inactivated)

On 16 March 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 Ingelvac PCV FLEX, suspension for injection, intended for active immunisation of pigs against porcine circovirus type 2 (PCV2). The applicant for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

Ingelvac PCV FLEX is a immunological veterinary medicinal product containing PCV2 ORF-2 protein minimum, Relative Potency (RP) 1.0 - 3.75 (ATCvet code QI09AA07) as active substance administered once via the intramuscular route to seronegative pigs from two weeks of age.

The benefits of Ingelvac PCV FLEX are its capability of reducing mortality, clinical signs and lesions in lymphoid tissues associated with PCV2 related diseases (PCVD) in seronegative animals in addition to a reduction of PCV2 nasal shedding, viral load in blood and lymphoid tissues, and duration of viraemia. The onset of protection is 2 weeks post vaccination and the duration of protection is at least 17 weeks. The most common side effect is a mild and transient hyperthermia on the day of vaccination. On very rare occasions anaphylactic reactions may occur that should be treated symptomatically.

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-risk balance for Ingelvac PCV FLEX 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 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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