16 February 2018
EMA/CVMP/59625/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Porcilis PCV ID

Common name: Porcine circovirus vaccine (inactivated)

On 15 February 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Porcilis PCV ID. The marketing authorisation holder for this veterinary medicinal product is Intervet International B.V.

Porcilis PCV ID is currently authorised as emulsion for injection for pigs for the active immunisation of fattening pigs to reduce viraemia, virus load in lungs and lymphoid tissues and virus shedding caused by PCV2 infection and to reduce loss of daily weight gain and mortality associated with PCV2 infection.

The variation concerns the change to the SPC/leaflet wording on associated non-mixed use of Porcilis PCV ID and Porcilis M Hyo ID ONCE (also known as Porcilis M Hyo ID ONCE and Porcilis M Hyo ID ONCE vakcina A.U.V.). The product is indicated for the reduction of pulmonary lesions and decrease in daily weight gain during the finishing period due to infection caused by Mycoplasma hyopneumoniae. The registered associated non-mixed use of these vaccines means that the vaccines can be administered on the same day, at different sites. With this variation the text of the product information of both vaccines will be changed from "*at different sites*" to *"separated by at least 3 cm*" as a multi-nozzle injection device has been developed which allows simultaneous intradermal vaccination with injection spaced 3cm apart.

The product information was simultaneously aligned with the latest QRD template.

Detailed conditions for the use of this product are described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the to the marketing authorisation has been granted by the European Commission.

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