11 September 2015
EMA/CVMP/511548/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Suvaxyn Circo + MH RTU

Common name: Porcine circovirus and porcine enzootic pneumonia vaccine (inactivated).

On 10 September 2015, 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 Suvaxyn Circo + MH RTU, suspension for injection, intended for active immunisation of pigs against Porcine circovirus type 2 (PCV2) and *Mycoplasma hyopneumoniae*. The applicant for this veterinary medicinal product is Zoetis Belgium SA.

Suvaxyn Circo + MH RTU is an immunological medicinal product containing a combination of an inactivated recombinant chimeric porcine circovirus type 1 containing the porcine circovirus type 2 ORF2 protein and the inactivated *M. hyopneumoniae* strain P-5722-3 (ATCvet code QI09AL) as active substance.

The benefits of Suvaxyn Circo + MH RTU are its prophylactic immunisation of pigs from 3 weeks of age to reduce viral load in blood and lymphoid tissues, and faecal shedding caused by infection with PCV2 and to reduce lung lesions caused by infection with *M. hyopneumoniae*. Onset of immunity is established at 3 weeks after vaccination and duration of immunity is established for 23 weeks after vaccination for PCV2 and 16 weeks after vaccination for *M. hyopneumoniae*. The most common side effects are a transient increase in body temperature and local swelling at the injection site.

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 Suvaxyn Circo + MH RTU 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
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