9 October 2020
EMA/CVMP/495892/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

CircoMax Myco

Common name: Porcine circovirus vaccine (inactivated, recombinant) and *Mycoplasma hyopneumoniae* vaccine (inactivated)

On 7 October 2020, 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 CircoMax Myco, emulsion for injection, intended for pigs for fattening. The applicant for this veterinary medicinal product is Zoetis Belgium SA.

CircoMax Myco is an immunological medicinal product containing recombinant chimeric porcine circovirus 1 containing the porcine circovirus 2a open reading frame 2 protein, inactivated, recombinant chimeric porcine circovirus 1 containing the porcine circovirus 2b open reading frame 2 protein, inactivated and *Mycoplasma hyopneumoniae* antigen, inactivated (ATCvet code QI09AL08), as active substances. CircoMax Myco is a trivalent inactivated vaccine intended for active immunisation of pigs over the age of three days to reduce virus load in blood and lymphoid tissues, virus shedding, and lesions in lymphoid tissues associated with porcine circovirus type 2 infection and lung lesions associated with *Mycoplasma hyopneumoniae* infection.

The benefits of CircoMax Myco are its capacity to induce active immunisation of pigs against PCV2 subtypes 2a and 2b and reduce viral load in blood and lymphoid tissues and faecal shedding caused by infection with PCV2; and to induce active immunisation against *Mycoplasma hyopneumoniae* and reduce lung lesions. Cross-protection against PCV 2d was demonstrated in three US studies. The product was shown to have an onset of immunity at 3 weeks after vaccination with duration of immunity of 23 weeks after vaccination against PCV2 and *Mycoplasma hyopneumoniae*. The efficacy of the vaccine was adequately confirmed in the presence of maternally derived antibodies.

CircoMax Myco has a safety profile with mainly local reactions and transient temperature increases as potential adverse reactions. A transient increase in body temperature, not exceeding 2.1°C, is very common after vaccination and resolves spontaneously within 24 hours without treatment. In a laboratory study, a post-mortem examination of the injection site, performed 2 weeks after the

[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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administration of a repeated single dose of the vaccine, very commonly revealed a mild lymphocytic-granulomatous inflammatory response, as evidenced by the absence of tissue necrosis and absence of fibrosis. Local tissue reactions in the form of swelling at the injection site, below 2 cm in diameter, are common and may last for up to 10 days. Erythema may be uncommonly observed during the first 24 hours after vaccination. Hypersensitivity reactions, vomiting, incoordination, lethargy, and laboured breathing were uncommonly observed in field studies. The animals mostly recover within 24 hours.

The vaccine is safe in minimum age piglets when administered by the recommended route and regimens.

The full indication is: Active immunisation of pigs against porcine circovirus type 2 to reduce viral load in blood and lymphoid tissues, fecal shedding and the lesions in lymphoid tissues associated with PCV2 infection. Protection was demonstrated against porcine circovirus types 2a, 2b and 2d.

Active immunisation of pigs against *Mycoplasma hyopneumoniae* to reduce the lung lesions associated with *Mycoplasma hyopneumoniae* infection.

Onset of immunity (both vaccination schedules): 3 weeks after (the last) vaccination.

Duration of immunity (both vaccination schedules): 23 weeks after (the last) vaccination.

In addition, vaccination has been shown to reduce body weight gain losses under field conditions.

Detailed conditions for the use of this product are 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 CircoMax Myco and therefore recommends the granting of the marketing authorisation.