17 July 2020
EMA/CVMP/349868/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Mhyosphere PCV ID

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

On 16 July 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 Mhyosphere PCV ID, emulsion for injection, intended for pigs. The applicant for this veterinary medicinal product is Laboratorios Hipra, S.A.

Mhyosphere PCV ID is an immunological veterinary medicinal product containing recombinant *Mycoplasma hyopneumoniae*, strain 7304 (Nexhyon), expressing the capsid protein of porcine circovirus type 2a, inactivated (ATCvet code QI09AL08) as active substance, intended to protect against two swine pathogens at the same time.

The benefits of Mhyosphere PCV ID are its effectiveness to reduce lung lesions associated with porcine enzootic pneumonia caused by *Mycoplasma hyopneumoniae* and to reduce the incidence of these lesions and to reduce viraemia, virus load in lungs and lymphoid tissues and the duration of the viraemic period associated with diseases caused by Porcine circovirus type 2. The onset of immunity is 3 weeks after vaccination for *Mycoplasma hyopneumoniae* and 2 weeks after vaccination for Porcine circovirus type 2. The duration of immunity is 23 weeks after vaccination for *Mycoplasma hyopneumoniae* and 22 weeks after vaccination for Porcine circovirus type 2. In addition, a reduction in nasal and faecal shedding and the duration of nasal excretion of PCV2 was demonstrated in animals challenged at 4 weeks and at 22 weeks after vaccination.

Administration of Mhyosphere PCV ID in accordance with SPC recommendations is generally well tolerated. The most common side effects are mild transient local reactions consisting of non-painful skin inflammations, of less than 3 cm in diameter, which are very common. Moderate inflammation (between 3-5 cm) at day 1 post-vaccination is commonly observed, which generally decrease to less than 3 cm the next day. These local reactions can be observed during the first week after vaccination and last for 1 to 3 days. One or two weeks later, these local reactions can reappear lasting for 1 to 7

[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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days. Local reactions disappear completely within approximately 3 weeks after vaccination without treatment. A slight transient increase in body temperature (mean 0.3 ºC, in individual pigs less than 1.5 ºC) occurred commonly in field studies. This slight increase subsided spontaneously within 48 hours without treatment.

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 Mhyosphere PCV ID and therefore recommends the granting of the marketing authorisation.