EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 May 2014
EMA/CVMP/158893/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

ERYSENG PARVO

Common name: Porcine parvovirus and *Erysipelothrix rhusiopathiae*

On 8 May 2014, 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 ERYSENG PARVO,a suspension for injection, intended for the active immunisation of female pigs for the protection of progeny against transplacental infection caused by *Porcine Parvovirus* and for the active immunisation of male and female pigs to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by *Erysipelothrix rhusiopathiae*, serotype 1 and serotype 2.

The applicant for this veterinary medicinal product is Laboratorios HIPRA, S.A.

The active substances of ERYSENG PARVO are the inactivated porcine parvovirus, strain NADL-2 and the inactivated *Erysipelothrix rhusiopathiae*, strain R32E11. ERYSENG PARVO is an inactivated viral and bacterial vaccine (QI09AL01) for pigs that stimulates active immunisation against porcine parvovirus and *swine erysipelas*.

The benefits of ERYSENG PARVO are the active immunisation of female pigs for the protection of progeny against transplacental infection caused by porcine parvovirus and the active immunisation of male and female pigs to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by *Erysipelothrix rhusiopathiae*, serotype 1 and serotype 2.

The most common side effects are mild to moderate inflammation at the injection site that typically resolves within four days but in some cases may persist for up to 12 days post-vaccination, and a transient increase in body temperature within the first 6 hours after vaccination, which spontaneously resolves within 24 hours.

The onset of immunity is against porcine parvovirus from the beginning of the gestation period and for *Erysipelothrix rhusiopathiae* the onset is three weeks after completion of the basic vaccination scheme.

Vaccination provides foetal protection against porcine parvovirus for the duration of gestation. Vaccination protects against swine erysipelas until the time of the recommended revaccination (approximately six months).

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 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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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 to risk balance for ERYSENG PARVO and therefore recommends the granting of the marketing authorisation.