8 October 2021
EMA/CVMP/522701/2021
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Suiseng Diff/A

Common name: *Clostridioides difficile* and *Clostridium perfringens* vaccine, inactivated

On 7 October 2021, 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 Suiseng Diff/A, suspension for injection, intended for pigs. The applicant for this veterinary medicinal product is Laboratorios Hipra, S.A.

Suiseng Diff/A is an immunological medicinal product (ATCvet code QI09AB12) containing *Clostridioides difficile* toxoid A/*Clostridioides difficile* toxoid B/*Clostridium perfringens*, type A, alpha toxoid as active substances and it is indicated for the passive immunisation of neonatal piglets by means of the active immunisation of breeding sows and gilts to prevent mortality and reduce clinical signs and macroscopic lesions caused by *C. difficile*, toxins A and B and to reduce clinical signs and macroscopic lesions caused by *C. perfringens* type A, α-toxin.

Suiseng Diff/A is generally well tolerated at the recommended dose. The most common side effects are transient mild inflammation at the injection site and slight transient increase in body temperature.

The full indication is:

'For the passive immunisation of neonatal piglets by means of the active immunisation of breeding sows and gilts:

- to prevent mortality and reduce clinical signs and macroscopic lesions caused by *C. difficile,* toxins A and B.
- to reduce clinical signs and macroscopic lesions caused by *C. perfringens* type A, α-toxin.

The reduction of the occurrence of neonatal diarrhoea has been demonstrated under field conditions.

Onset of immunity:
Protection was demonstrated in suckling piglets on the first day of life in challenge studies.

[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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Duration of immunity: Neutralising protective antibodies transferred via colostrum to the piglets were present up to 28 days after birth in the majority of piglets.

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 Suiseng Diff/A and therefore recommends the granting of the marketing authorisation .