9 October 2020
EMA/CVMP/489228/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Enteroporc Coli AC

Common name: Neonatal piglet colibacillosis (recombinant, inactivated) and *Clostridium perfringens* 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 Enteroporc Coli AC, lyophilisate and suspension for suspension for injection, intended for pigs. The applicant for this veterinary medicinal product is IDT Biologika GmbH.

Enteroporc Coli AC is an immunological medicinal product containing inactivated fimbrial adhesins of *Escherichia coli* and toxoids of *Clostridium perfringens* type A and type C as active substances (ATCvet code QI09AB08), and aluminium hydroxide as adjuvant.

The benefit of Enteroporc Coli AC is the stimulation of active immunity in pregnant gilts and sows resulting in the passive immunisation of progeny and reduction of clinical signs (severe diarrhoea) and mortality caused by *Escherichia coli* strains expressing the fimbrial adhesins F4ab, F4ac, F5 and F6; clinical signs (diarrhoea during the first days of life) associated with *Clostridium perfringens* type A expressing alpha and beta2 toxins; and clinical signs and mortality associated with haemorrhagic and necrotising enteritis caused by *Clostridium perfringens* type C expressing beta1 toxin.

The product was shown to have an onset of immunity within 12 hours after birth against *E. coli* and at first day of life against *Clostridium perfringens* type A and type C. The duration of immunity was established as first days of life against *E. coli,* 14 days against *Clostridium perfringens* type A and 21 days against *Clostridium perfringens* type C.

Enteroporc Coli AC is well tolerated at the recommended dose. The most common side effects are a transient increase in body temperature after vaccination occurring in the day of vaccination which resolves spontaneously within 24 hours and transient local reactions at the injection site (swelling and redness) which resolve without treatment within seven days. A slightly depressed behaviour can also be observed on the day of vaccination.

[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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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 Enteroporc Coli AC and therefore recommends the granting of the marketing authorisation.