EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 November 2020
EMA/CVMP/551905/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Enteroporc Coli

Common name: Neonatal piglet colibacillosis vaccine (recombinant, inactivated)

On 5 November 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, suspension for injection, intended for pigs. The applicant for this veterinary medicinal product is IDT Biologika GmbH.

Enteroporc Coli is an immunological medicinal product containing inactivated fimbrial adhesins of *Escherichia coli* as active substances (ATCvet code QI09AB02), and aluminium hydroxide as adjuvant.

The benefit of Enteroporc Coli 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. The onset of immunity is established within 12 hours after birth and the duration of immunity is 'first days of life'.

Enteroporc Coli 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.

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 and therefore recommends the granting of the marketing authorisation.

[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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