EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 November 2016
EMA/CVMP/700160/2016
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Coliprotec F4/F18

Common name: Porcine post-weaning diarrhoea vaccine (live)

On 10 November 2016, 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 Coliprotec F4/F18, lyophilisate for oral suspension, intended for active immunisation of pigs against post-weaning *Escherichia coli* diarrhoea (PWD) and to reduce the faecal shedding of enterotoxigenic F4-positive and F18-positive *E. coli*. The applicant for this veterinary medicinal product is Prevtec Microbia GmbH. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Coliprotec F4/F18 is an immunological veterinary medicinal product containing a combination of two live non-pathogenic *E. coli* O8:K87 and non-pathogenic *E. coli* O141:K94 (ATCvet code QI09AE03) as active substance.

The benefits of Coliprotec F4/F18 are its prophylactic immunisation of pigs from 18 days of age against enterotoxigenic F4-positive and F18-positive *E. coli* in order to reduce the incidence of moderate to severe PWD in infected pigs and to reduce the faecal shedding of enterotoxigenic F4-positive and F18-positive *E. coli* from infected pigs. The onset of immunity is established at 7 days after vaccination. The duration of immunity is 21 days after vaccination. Coliprotec F4/F18 is generally well tolerated at the recommended dose. The adverse reaction (increase of rectal temperature) is only seen at overdoses.

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 Coliprotec F4/F18 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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