EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 January 2015
EMA/CVMP/742823/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Coliprotec F4

Common name: *Escherichia coli*, type 08, strain K87 (live)

On 15 January 2015, 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, lyophilisate for oral suspension, intended for active immunisation of pigs against enterotoxigenic F4-positive *E.coli*. The applicant for this veterinary medicinal product is Prevtec Microbia GmbH, registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Coliprotec F4 contains live non-pathogenic culture of *E.coli* O8:K87 as active substance and is an immunological medicinal product (QI09AE03) intended for the active immunisation against enterotoxigenic F4-positive *E.coli* in pigs.

The benefits of Coliprotec F4 are its prophylactic immunization to reduce the incidence of moderate to severe post-weaning *E.coli* diarrhoea (PWD) in pigs and to reduce the colonisation of the ileum and faecal shedding of enterotoxigenic F4-positive *E.coli* from infected pigs. The most common side effects are a transient reduced weight gain during the first week after vaccination and shivering.

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 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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