8 February 2013
EMA/CVMP/15924/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

ECOPORC SHIGA

Vaccine for the active immunisation of piglets to reduce the mortality and clinical signs of oedema disease

On 7 February 2013 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 ECOPORC SHIGA, suspension for injection, intended for active immunisation of piglets from the age of four days, to reduce the mortality and clinical signs of oedema disease caused by Stx2e toxin produced by *E. coli* (STEC). The applicant for this veterinary medicinal product is IDT Biologika GmbH.

The active substance of ECOPORC SHIGA is genetically detoxified Shiga toxin (Stx2e antigen), an inactivated bacterial vaccine, ATC code QI09AB02, which induces active immunity against Shiga toxin 2e produced by *E. coli* the causative agent of oedema disease in pigs.

The benefit of ECOPORC SHIGA is the induction of active immunisation to reduce the mortality and clinical signs of oedema disease in pigs.

The most common side effects that may occur are small local reactions like mild swelling at the injection site and a transient increase in the body temperature.

The approved indication is: Active immunisation of piglets from the age of four days, to reduce the mortality and clinical signs of oedema disease caused by Stx2e Stx2e toxin produced by *E. coli* (STEC)

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.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[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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The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for ECOPORC SHIGA and therefore recommends the granting of the marketing authorisation.