16 April 2012
EMA/CVMP/135528/2012
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Porcilis ColiClos

Vaccine for the passive immunization of piglets against *E. Coli* and *C. perfringens*

On 13 April 2012, 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 Porcilis ColiClos, a suspension for injection inactivated bacterial subunit vaccine. The applicant for this veterinary medicinal product is Intervet International BV.

The active substances of Porcilis ColiClos are the LT toxoid and the fimbrial antigens F4ab, F4ac, F5 and F6 from the various types of *E. coli* as well as the toxoid of *C. perfringens* type C. This is an immunological veterinary medicinal product, ATC code, QI09AB08 indicated for the passive immunisation of progeny by active immunisation of sows and gilts The benefits of Porcilis ColiClos are to reduce mortality and clinical signs in piglets during the first days of life, caused by those *E. coli* strains which express the adhesins F4ab (k88ab), F4ac (88ac), F5 (99) or F6 (987P) and by *C. perfringens* type C, respectively.

The most common side effects are an increase in the body temperatures of sows and gilts. Reduce activity and lack appetite on the day of vaccination commonly occurs and/or a sometimes painful hard swelling up to 10 cm diameter for up to 25 days may be observed at the site of the injection

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 to risk balance for Porcilis ColiClos 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 within 90 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union