16 April 2012
EMA/CVMP/184381/2012
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Poulvac E. coli

Vaccine to reduce mortality and lesions associated with Escherichia coli serotype 078

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 Poulvac E. coli, lyophilisate for suspension for spray administration, intended for chickens (broilers, future layers/breeders).

The applicant for this veterinary medicinal product is Pfizer Limited.

The active substance of Poulvac E. coli is live aroA gene deleted *Escherichia coli*, type O78, strain EC34195.

Poulvac E. coli is intended for the active immunisation of broiler chickens and future layer/breeders in order to reduce mortality and lesions (pericarditis, perihepatitis, airsacculitis) associated with *Escherichia coli* serotype O78.

Onset of immunity: 2 weeks after vaccination for the reduction of lesions. The onset of immunity has not been established for the mortality claim.

Duration of immunity: 8 weeks after vaccination has been demonstrated for the reduction of lesions and 12 weeks after vaccination for the reduction of mortality.

A cross protection study showed reduction of incidence and severity of airsacculitis caused by E. coli serotypes O1, O2 and O18. For these serotypes no onset of immunity or duration of immunity was established.

[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.

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The benefits of Poulvac E. coli are its significant reduction of incidence of lesions typical of colibacillosis (pericarditis, perihepatitis, airsacculitis) and a significant reduction of mortality due to E. coli O78 infections.

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 Poulvac E. coli and therefore recommends the granting of the marketing authorisation.