19 February 2016
EMA/CVMP/45330/2016
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Poulvac E. coli

Common name: Escherichia coli aroA gene deleted, type O78, strain EC34195 (live)

On 18 February 2016, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product Poulvac E. coli. The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium SA.

Poulvac E. coli is currently authorised as lyophilisate for suspension for spray vaccination or for use in drinking water for chickens.

The extension is to add a new food producing target animal species (turkeys), and is intended for active immunisation of turkeys in order to reduce mortality and lesions (pericarditis, perihepatitis, airsacculitis) associated with *Escherichia coli* serotype O78.

Poulvac E. coli is to be administered to turkeys as one dose of vaccine from 1 day of age followed by a second dose 3 weeks later by coarse spray administration. An onset of immunity 3 weeks after the second vaccination has been demonstrated.

Detailed conditions for the use of this product are described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the extension to 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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