



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 June 2025
EMADOC-1700519818-2191067
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion¹ (post-authorisation)

Poulvac E. coli

Vaccine common name: Avian colibacillosis vaccine (live)

On 12 June 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a negative opinion², recommending the refusal of a variation 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.

The scope of the variation was to add new information to the SPC/PI to reflect that administration of the vaccine was shown to reduce the use of antibiotics used to treat colibacillosis in the vaccinated chicken flocks.

The grounds for the negative opinion relate to the following points:

- The statement that Poulvac E. coli reduces the use of antibiotics used to treat colibacillosis in the corresponding flocks was not considered to be information that qualifies for inclusion in the product information compatible with the provisions of Regulation (EU) 2019/6.

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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