

22 March 2019 EMA/CVMP/153784/2019 Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (post-authorisation)

Innovax-ND-IBD

Cell-associated live recombinant turkey herpesvirus expressing the fusion protein of ND virus and the VP2 protein of IBD virus

On 21 March 2019, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion², recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product Innovax-ND-IBD. The marketing authorisation holder for this veterinary medicinal product is Intervet International B.V.

Innovax-ND-IBD is currently authorised as suspension and solvent for suspension for injection for active immunisation of chicks against Newcastle disease, infectious bursal disease and Marek's disease viruses. The extension concerns the addition of a new route of administration (*in ovo*) for chicken embryonated eggs.

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.

