16 May 2025
EMA/155368/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Innovax-ND-IBD-ILT

Common name: Avian infectious laryngotracheitis, infectious bursal disease, Marek's disease and Newcastle disease vaccine (live recombinant)

On 15 May 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Innovax-ND-IBD-ILT, concentrate and solvent for suspension for injection, intended for chicken and chicken embryonated eggs. The applicant for this veterinary medicinal product is Intervet International B.V.

Innovax-ND-IBD-ILT is an immunological medicinal product containing turkey herpesvirus strain HVT/ND/IBD/ILT (cell-associated), expressing the fusion protein gene of Newcastle disease virus, the VP2 protein of infectious bursal disease virus and the glycoproteins gD and gI of infectious laryngotracheitis virus, live (ATCvet code QI01AD20) as active substance.

The benefits of Innovax-ND-IBD-ILT are its efficacy in active immunisation of one-day-old chicks or 18-19-day-old embryonated chicken eggs against Newcastle disease, Marek's disease virus, avian infectious laryngotracheitis virus and infectious bursal disease virus.

The product is generally well tolerated in the target animal. No adverse reactions were observed after a tenfold overdose of Innovax-ND-ILT-IBD by the subcutaneous or *in ovo* route.

The full indication is:

For active immunisation of one-day-old chicks or 18-19 day-old embryonated chicken eggs:

- to reduce mortality and clinical signs caused by Newcastle disease (ND) virus,
- to reduce mortality, clinical signs and lesions caused by avian infectious laryngotracheitis (ILT) virus, Marek's disease (MD) virus and infectious bursal disease (IBD) virus.

[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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Onset of immunity:	ND: 4 weeks of age,
	IBD: 3 weeks of age,
	ILT: 4 weeks of age,
	MD: 5 days of age.
Duration of immunity:	ND: 62 weeks,
	IBD: 100 weeks,
	ILT: 100 weeks,
	MD: entire risk period.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC) which will be published in the Union Product Database (UPD) 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-risk balance for Innovax-ND-IBD-ILT and therefore recommends the granting of the marketing authorisation.