17 February 2023
EMA/CVMP/45112/2023
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Innovax-ILT-IBD

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

On 15 February 2023, 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-ILT-IBD, concentrate and solvent for suspension for injection, intended for chickens and chicken embryonated eggs. The applicant for this veterinary medicinal product is Intervet International B.V.

Innovax -ILT-IBD is an immunological medicinal product containing turkey herpes virus, expressing infectious bursal disease virus and avian infectious laryngotracheitis virus, strain HVT/IBD/ILT, live (ATCvet code QI01AD18) as active substance.

The benefits of Innovax-ILT-IBD are its efficacy in active immunisation of day-old chicks or 18-19-day-old embryonated chicken eggs against 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-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, clinical signs and lesions caused by avian infectious laryngotracheitis (ILT) virus and Marek's disease (MD) virus.
- to prevent mortality and to reduce clinical signs and lesions caused by infectious bursal disease (IBD) virus.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 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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Onset of immunity:

IBD: 3 weeks of age,
ILT: 4 weeks of age,
MD: 5 days of age.

Duration of immunity:

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-ILT-IBD and therefore recommends the granting of the marketing authorisation.