17 July 2020
EMA/CVMP/350609/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Innovax-ND-ILT

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

On 16 July 2020 the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Innovax-ND-ILT concentrate and solvent for suspension for injection, intended for one-day-old chicks and embryonated chicken eggs. The applicant for this veterinary medicinal product is Intervet International B.V.

Innovax-ND-ILT is an immunological medicinal product containing cell-associated live recombinant turkey herpesvirus (strain HVT) expressing the fusion (F) protein of Newcastle disease (ND) virus and the glycoproteins gD and gI of avian infectious laryngotracheitis virus (ILT) (ATCvet code QI01AD17) as active substance.

The benefit of Innovax-ND-ILT is the stimulation of active immunity of one-day-old chicks or 18-19 day -old embryonated chicken eggs in order to reduce mortality and clinical signs caused by ND virus and to reduce mortality, clinical signs and lesions caused by ILT virus and Marek's disease (MD) virus. The onset of immunity is 5 weeks of age for ND, 4 weeks of age for ILT and 9 days post vaccination for MD. The duration of immunity is: 62 weeks for ND and ILTs and covers the entire risk period for MD.

Innovax-ND-ILT is well tolerated at the recommended dose, adverse reactions have not been observed.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) 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-ILT and therefore recommends the granting of the

[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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marketing authorisation.