8 May 2015
EMA/235978/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Innovax-ILT

Common name: Avian infectious laryngotracheitis and Marek's disease vaccine (live)

On 7 May 2015, 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-ILT, suspension and solvent for suspension for injection, intended for active immunisation of chickens to reduce mortality, clinical signs and lesions of avian infectious laryngotracheitis (ILT) and Marek's disease (MD). The applicant for this veterinary medicinal product is Intervet International B.V.

Innovax-ILT contains as active substance a live recombinant turkey herpesvirus (strain HVT/ILT-138) expressing the glycoproteins gD and gI of infectious laryngotracheitis virus and it is a medicinal product (ATCvet code QI01AD) intended for active immunization against avian infectious laryngotracheitis virus (ILTV) and Marek's disease virus (MDV) in chickens.

The benefit of Innovax-ILT is its prophylactic immunisation to reduce mortality, clinical signs and lesions due to infection with ILTV and MDV. Onset of immunity is established at 4 weeks after vaccination against ILTV infection and at 9 days after vaccination against MDV infection. Duration of immunity against ILTV infection is established for 60 weeks after vaccination and against MDV is lifelong.

Innovax-ILT is generally well tolerated at the recommended dose and no adverse reactions were 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-ILT and therefore recommends the granting of the marketing authorisation.

[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.