16 June 2017
EMA/CVMP/290079/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Innovax-ND-IBD

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

On 15 June 2017, 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-IBD, suspension and solvent for suspension for injection, intended for active immunisation of one-day-old chicks:

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

The applicant for this veterinary medicinal product is Intervet International B.V.

Innovax-ND-IBD is an immunological medicinal product containing cell-associated live recombinant turkey herpesvirus expressing the fusion protein of ND virus and the VP2 protein of IBD virus (ATCvet code QI01AD) as active substance.

The benefits of Innovax-ND-IBD are its efficacy in vaccination of chickens against ND, IBD and MD.

Innovax-ND-IBD is well tolerated at the recommended dose, adverse reactions are not seen at overdoses.

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-IBD 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.

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