EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 February 2021
EMA/CVMP/74964/2021
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Ultifend ND IBD

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

On 17 February 2021, 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 Ultifend ND IBD, concentrate and solvent for suspension for injection, intended for chickens and chicken embryonated eggs. The applicant for this veterinary medicinal product is Ceva-Phylaxia Veterinary Biologicals Co. Ltd.

Ultifend ND IBD is an immunological veterinary medicinal product containing cell-associated live recombinant turkey herpesvirus (rHVT-ND-IBD) expressing the fusion protein of Newcastle disease virus and the VP2 protein of infectious bursal disease virus, as active substance.

The benefit of Ultifend ND IBD is the stimulation of active immunity in one-day-old chicks or 18-day-old chicken embryonated eggs in order to reduce mortality, clinical signs and lesions caused by Newcastle disease virus (NDV) and to reduce virus shedding; to reduce mortality, clinical signs and bursa lesions caused by very virulent infectious bursal disease virus (IBDV); and to reduce mortality, clinical signs and lesions caused by classical Marek's disease virus (MDV).

Ultifend ND IBD is generally well tolerated at the recommended dose. No adverse reactions were observed after the administration of the recommended dose or a 10-fold overdose.

Detailed conditions for the use of this product are 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 Ultifend 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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