EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 March 2023
EMA/CVMP/116044/2023
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (initial authorisation)

Newflend ND H9

Common name: Newcastle disease and avian influenza vaccine (live, recombinant)

On 22 March 2023, 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 Newflend ND H9, concentrate and solvent for suspension for injection, intended for chicken and chicken embryonated eggs. The applicant for this veterinary medicinal product is Ceva-Phylaxia Co. Ltd.

Newflend ND H9 is an immunological veterinary medicinal product containing live recombinant turkey herpes virus, strain rHVT/ND expressing Newcastle disease virus and the haemagglutinin of low pathogenic avian influenza virus, subtype H9, as active substance.

The benefits of Newflend ND H9 are the active immunisation of one-day-old chicks or 18-day-old chicken embryonated eggs to reduce clinical signs, lesions and virus shedding caused by Newcastle disease virus (NDV) and to reduce mortality in the most susceptible period, clinical signs, lesions, and virus shedding caused by H9 subtype of low pathogenic avian influenza virus (LPAIV-H9).

Newflend ND H9 is generally well tolerated at the recommended dose, adverse reactions have not been observed even at overdoses.

Onset of immunity:

- NDV: 3 weeks (reduction of virus shedding has been demonstrated from 4 weeks of age)
- LPAIV H9: 4 weeks

Duration of immunity:

- NDV: until 9 weeks after vaccination
- LPAIV H9: until 9 weeks after vaccination

[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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Detailed conditions for the use of this product are 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 Newflend ND H9 and therefore recommends the granting of the marketing authorisation.