10 July 2015
EMA/CVMP/354791/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Vectormune ND

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

On 9 July 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 Vectormune ND, suspension and solvent for suspension for injection, intended for an active immunisation of 18 day-old chicken embryonated eggs or one-day-old chicks to reduce mortality and clinical signs caused by Newcastle disease virus and to reduce mortality, clinical signs and lesions caused by Marek's disease virus. The applicant for this veterinary medicinal product is CEVA-Phylaxia Veterinary Biologicals Co. Ltd.

Vectormune ND contains live recombinant turkey herpes virus (strain rHVT/ND) expressing the fusion (F) protein of Newcastle disease virus D-26 lentogenic strain and it is a medicinal product intended for the active immunisation against Newcastle disease (ND) and Marek's disease (MD) in chickens (ATCvet code QI01AD).

The benefits of Vectormune ND are its prophylactic immunisation to reduce mortality and clinical signs caused by Newcastle disease virus and to reduce mortality, clinical signs and lesions caused by Marek's disease virus in 18-day-old embryonated chicken eggs or one-day-old chicks. Onset of immunity against NDV infection is established at 3 weeks of age and duration of immunity is established for 9 weeks of age. Onset of immunity against MDV infection is established at 1 week of age and duration of immunity is lifelong.

Vectormune ND 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

[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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

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 Vectormune ND and therefore recommends the granting of the marketing authorisation.