EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 January 2018
EMA/CVMP/739766/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Vectormune ND

Newcastle disease and Marek's disease vaccine (live recombinant)

On 18 January 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Vectormune ND. The marketing authorisation holder for this veterinary medicinal product is CEVA-Phylaxia Veterinary Biologicals Co. Ltd.

Vectormune ND is currently authorised as a suspension and solvent for suspension for injection. The application is to add a new category of target species, i.e. layer chickens, to the indication. Additionally the current indication has been reworded to specify that the vaccine is effective against a "virulent" phenotype of Marek's disease. The SPC has been updated accordingly.

Detailed conditions for the use of this product are described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[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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