8 September 2023
EMA/CVMP/398578/2023
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Prevexxion RN+HVT

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

On 7 September 2023, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Prevexxion RN+HVT, concentrate and solvent for suspension for injection, intended for chickens. The applicant for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

Prevexxion RN+HVT is an immunological veterinary medicinal product containing live recombinant Marek's disease (MD) virus, serotype 1, strain RN1250 and live attenuated Marek's disease (MD) virus, serotype 3, strain HVT FC126 as active substance.

The benefit of Prevexxion RN+HVT is the stimulation of active immunity in one-day-old chicks to prevent mortality and reduce clinical signs and lesions caused by MD virus (including very virulent MD virus).

The onset of immunity is 5 days after vaccination and the duration of immunity covers the entire risk period.

Prevexxion RN+HVT is generally well tolerated at the recommended dose.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC) which will be published in the Union Product Database (UPD) 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 Prevexxion RN+HVT and therefore recommends the granting of the marketing authorisation.

[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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