



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 May 2020  
EMA/CVMP/240890/2020  
Committee for Medicinal Products for Veterinary Use

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Prevexxion RN

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

On 20 May 2020, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion<sup>2</sup>, recommending the granting of a marketing authorisation for the veterinary medicinal product Prevexxion RN, concentrate and solvent for suspension for injection, intended for chickens. The applicant for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

Prevexxion RN is an immunological veterinary medicinal product containing live recombinant Marek's disease (MD) virus, serotype 1, strain RN1250 (ATCvet code QI01AD03) as active substance.

The benefit of Prevexxion RN is the stimulation of active immunity of one-day-old chicks in order to prevent mortality and clinical signs and reduce lesions caused by MD virus (including very virulent MD virus). The onset of immunity is 5 days after vaccination. The duration of immunity covers the entire risk period.

Prevexxion RN is generally well tolerated at the recommended dose, adverse reactions (limited and transient effect on growth) are only seen at overdoses.

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 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 and therefore recommends the granting of the marketing authorisation.

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<sup>1</sup> Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.

<sup>2</sup> 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.

