25 May 2020
EMA/CVMP/240518/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Prevexxion RN+HVT+IBD

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

On 20 May 2020, 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 Prevexxion RN+HVT+IBD, 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+IBD is an immunological veterinary medicinal product containing live recombinant turkey herpesvirus, strain vHVT013-69 and live recombinant Marek's disease (MD) virus, serotype 1, strain RN1250, live (ATCvet code QI01AD) as active substances.

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

For MD, the onset of immunity is 5 days after vaccination and the duration of immunity covers the entire risk period. For infectious bursal disease, the onset of immunity is 14 days after vaccination and the duration of immunity is 10 weeks after vaccination.

Prevexxion RN+HVT+IBD 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

[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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

benefit-risk balance for Prevexxion RN+HVT+IBD and therefore recommends the granting of the marketing authorisation.