20 May 2020
EMA/CVMP/240531/2020
Committee for Medicinal Products for Veterinary Use

Opinion of the Committee for Medicinal Products for Veterinary Use on the granting of a marketing authorisation

EMEA/V/C/005058/0000

Veterinary medicinal product:	**International non-proprietary name/Common name:**	**Presentations:**
Prevexxion RN	Marek's disease vaccine (live recombinant)	See Annex A

Basis for opinion

Pursuant to Article 31 of Regulation (EC) No 726/2004, Boehringer Ingelheim Vetmedica GmbH (formerly MERIAL) submitted to the European Medicines Agency on 29 November 2018 an application for a marketing authorisation for the above-mentioned veterinary medicinal product.

The procedure started on 19 December 2018.

Opinion

1. The CVMP, having considered the application in accordance with Article 32 of Regulation (EC) No 726/2004, as set out in the appended assessment report, recommends by consensus the granting of a marketing authorisation for the above mentioned veterinary medicinal product for which the draft summary of product characteristics is set out in Annex I.

   The Icelandic and Norwegian CVMP members agree with the above-mentioned recommendation of the CVMP.

2. The manufacturers of the biological active substances and the manufacturers responsible for batch release, the conditions of the marketing authorisation, and the statement of the MRLs, are set out in Annex II.

3. The texts for labelling and package leaflet are set out in Annex III.

This opinion is forwarded to the European Commission, to Member States, to Iceland and Norway and to the applicant, together with its annexes and appendices.

Annex A

EMA Number	Invented name	Strength	Pharmaceutical form	Target species	Route of administration	Immediate packaging	Content	Package size	Withdrawal period
EU/2/20/254/001	Prevexxion RN	--1	Concentrate and solvent for suspension for injection	Chickens	Subcutaneous use	Ampoule (glass)	1000 doses per ampoule	5 ampoules	Zero days
EU/2/20/254/002	Prevexxion RN	--1	Concentrate and solvent for suspension for injection	Chickens	Subcutaneous use	Ampoule (glass)	2000 doses per ampoule	5 ampoules	Zero days
EU/2/20/254/003	Prevexxion RN	--1	Concentrate and solvent for suspension for injection	Chickens	Subcutaneous use	Ampoule (glass)	4000 doses per ampoule	4 ampoules	Zero days

--1 Cell-associated, live recombinant Marek's disease (MD) virus, serotype 1, strain RN1250: 2.9 to 3.9 log10 PFU*

*PFU: Plaque Forming Unit