8 September 2023
EMA/CVMP/379398/2023
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Poulvac Procerta HVT-IBD

Common name: Live recombinant turkey herpes virus, strain HVT-IBD, expressing the VP2 protein of infectious bursal disease virus

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 Poulvac Procerta HVT-IBD, concentrate and solvent for suspension for injection, intended for chicken and chicken embryonated eggs. The applicant for this veterinary medicinal product is Zoetis Belgium.

Poulvac Procerta HVT-IBD is an immunological veterinary medicinal product containing turkey herpes virus, strain FC-126, expressing infectious bursal disease virus VP2 protein, live (ATCvet code QI01AD15) as active substance which induces active immunity against infectious bursal disease (Gumboro disease) and Marek's disease in chickens.

The benefits of Poulvac Procerta HVT-IBD are its ability to provide active immunisation of one-day-old chickens and 18-19 day old embryonated chicken eggs to reduce mortality, clinical signs and lesions caused by Marek's disease (MD) virus and prevent mortality and clinical signs and reduce lesions caused by infectious bursal disease (IBD) virus. No symptoms have been observed after the administration of one dose or a 10-fold dose of the vaccine. Poulvac Procerta HVT-IBD is generally well tolerated at the recommended dose; no symptoms have been observed after the administration of a 10-fold dose of the vaccine.

The full indication is: For active immunisation of one-day-old chickens and 18-19 day-old embryonated chicken eggs to

- reduce mortality, clinical signs and lesions caused by Marek's disease virus and
- prevent mortality and clinical signs and reduce lesions caused by infectious bursal disease virus.

Onset of immunity: MD: 7 days post vaccination for *in ovo* and 9 days for subcutaneous use
IBD: 15 days post vaccination for *in ovo* and 12 days for subcutaneous use

[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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Duration of immunity:	MD: a single vaccination is sufficient to provide protection for the entire risk period IBD: 64 days of age

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 Poulvac Procerta HVT-IBD and therefore recommends the granting of the marketing authorisation.