EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 September 2019
EMA/CVMP/472052/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Gumbohatch

Common name: Avian infectious bursal disease vaccine (live)

On 12 September 2019, 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 Gumbohatch, lyophilisate and solvent for suspension for injection, intended for chickens and embryonated chicken eggs. The applicant for this veterinary medicinal product is LABORATORIOS HIPRA, S.A.

Gumbohatch is an immunological medicinal product containing infectious bursal disease virus, strain 1052, live (ATCvet code QI01AD09) as active substance.

The benefits of Gumbohatch are its efficacy in the treatment of 1 day old broiler chickens and embryonated broiler chicken eggs to reduce clinical signs and lesions of the bursa of Fabricius caused by very virulent avian infectious bursal disease virus infection. In laboratory studies, lymphocyte depletion was very common followed by a lymphocyte repopulation and regeneration of the bursa of Fabricius. This depletion does not cause immunosuppression in chickens.

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 Gumbohatch and therefore recommends the granting of the marketing authorisation.

[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.

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