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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

GUMBOHATCH Lyophilisate and Solvent for Suspension for Injection for Chickens

Vm 17533/5005

•	April 2024	To add a clarification step in the manufacturing process of the IBD specific IgYs solution, a biological excipient of the product. To remove the increase of temperature currently applied during the blending process. To extend the shelf life of the IBD-specific IgYs solution up to 12 months.
•	24 April 2024	Unlimited renewal.
•	28 September 2023	To add a new manufacturer for the HIPRAHATCH solvent.
•	04 May 2023	Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet to various sections. One-off alignment of the product information with version 9.0* of the QRD templates.
•	05 August 2022	Change the name of the solvent for the product GUMBOHATCH, from 'Solvent of GUMBOHATCH' to 'HIPRAHATCH solvent, for poultry vaccines'.
•	20 July 2022	Introduction of ready-to-use nystatin suspension from external suppliers as an alternative to in-house prepared suspension.
•	11 July 2022	Change in the manufacturing process of the finished product. Establishing of a new minimum protective dose due to new preclinical data. Addition of a new volume pack for the solvent. Addition of new presentations of virus lyophilisate. Change in test procedure for the finished product.
•	19 May 2022	Changes to a test procedure for the finished product.
•	26 January 2021	Deletion of a specification parameter of the finished product