



## Post Authorisation Assessments

For details of post authorisation assessments prior to 1<sup>st</sup> January 2021,  
please refer to the [EMA](#) website.

### GUMBOHATCH Lyophilisate and Solvent for Suspension for Injection for Chickens Vm 17533/5005

• 18 May 2024	With this variation, the applicant proposes to include future layer chickens as a sub-category of target species.
• 18 May 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