Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

M+PAC

Vm 01708/3030

•	12 March 2024	Addition of a secondary packaging site for the finished product.
•	14 November 2023	To include an additional sterilization method of PET bottles used as primary packaging for a range of the applicant's vaccines and solvents.
•	21 December 2022	Increase of the maximum batch size of M.hyopneumoniae antigen to 10,000 litres.
•	07 December 2021	Deletion of a non-significant in-process test applied during the manufacture of the active substance. Deletion of a non-significant in-process test applied during the manufacture of the active substance. Deletion of a non-significant in-process test applied during the manufacture of the active substance. Deletion of a non-significant in-process test applied during the manufacture of the active substance. Deletion of a non-significant in-process test applied during the manufacture of the active substance. Deletion of a non-significant in-process test applied during the manufacture of the active substance. Changes to a test procedure for the finished product. Change of a test procedure for the active substance. Change in the manufacturer of the active. Change in the manufacturing process of the active substance.
•	14 July 2021	Minor changes to an approved test procedure of the finished product.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	27 July 2020	Changes to a test procedure for the finished product.
•	22 December 2015	Approval of mock-ups for PET bottle presentations.
•	27 October 2015	Introduction of a change in the source (additional countries of origin) of a material used in the manufacturing process of the active substance.
•	28 July 2015	Change in test procedure for the finished product.
•	05 March 2015	Approval of updated mock-ups.
•	03 November 2014	To introduce PET vials as an addition immediate packaging of the finished product. Change in test procedure for the finished product.
•	20 December 2011	Change of MAH. Addition of a distributor.

		Changes to the Product Literature.
•	02 September 2011	Change in address of the MAH.
•	23 March 2011	Change of name of manufacturer for all manufacturing steps.
•	21 December 2010	Replacement of reference vaccine used in potency test.
•	12 September 2007	Renewal.
•	13 June 2007	Replacement of reference vaccine used in potency test.
•	24 October 2006	Change of address of the MAH.
•	21 July 2006	Change in formulation.
•	18 January 2006	Change to test procedure performed on he finished product.
•	21 September 2005	Repeat use procedure.
•	16 February 2005	Line extension (single injection).
•	30 June 2004	Change to parameters of batch potency test.
•	18 June 2004	QC Procedures.
•	04 November 2002	Change to shelf life.