Veterinary Medicines Directorate

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Post Authorisation Assessments

M+PAC

Vm 01708/5100

•	12 March 2024	Addition of a secondary packaging site for the finished product.
•	16 January 2024	Replacement of reference vaccine C112REF# with D077REF#. Addition of Intervet International B.V., Boxmeer, The Netherlands as finished product batch release site. Omission of IPC tests in manufacturing process of finished product. Addition of Intervet International B.V., Boxmeer, The Netherlands as antigen manufacturing site. Addition of MSD AH Danube Biotech GmbH, Krems, Austria as finished product QC testing site. Addition of MSD AH Danube Biotech GmbH, Krems, Austria as QC testing site for the IPC test on the M. hyo antigen. Addition of MSD AH Danube Biotech GmbH, Krems, Austria as blending and filling site for the finished product.
•	19 September 2023	Addition of alternative sterilisation method of the immediate packaging of the finished product.
•	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.