Veterinary Medicines Directorate

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Post Authorisation Assessments

Porcilis Ery+Parvo+Lepto Suspension for Injection for Pigs

Vm 01708/3016

•	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.
•	05 October 2023	One-off alignment of the product information with version 9.0 of the QRD templates.
•	15 December 2022	The maximum batch size of E. rhusiopathiae antigen to be increased from the currently registered 2000 L to 3000 L. Correction of the blending order of the finished product Addition of MSD AH Danube Biotech GmbH, Krems, Austria as production site for E. rhusiopathiae antigen 1.Add the possibility for aseptic addition of polysorbate-80 to the main fermenter medium prior to use as alternative for addition during medium preparation. 2. Replace the indicative parameters for when the main fermenter culture should be terminated: from a change in oxygen level and/or in the use of NaOH for pH control to optical density. 3. Add the possibility to use purified water as alternative for water for injections to adjust the cell content of the antigen concentrate.
•	30 May 2022	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	22 September 2021	Deletion of a non-significant specification parameter of the finished product.
•	25 August 2021	Renewal – UK as CMS.
•	13 July 2021	Change in distributor details. From various addresses to Same as MAH, Alternative distributor in Northern Ireland, Intervet Ireland Limited, Magna Drive, Magna Business Park, Citywest Road, Dublin 24.
•	11 September 2020	Change in the name of a manufacturer used in the manufacture of the active substance.
•	10 June 2020	Change of MAH from Intervet International BV, Represented by:, Intervet UK Ltd., Walton Manor, Walton, Milton Keynes, Bucks, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	02 April 2020	Changes to the labelling and package leaflet.
•	20 September 2019	Changes in the composition (excipients) of the finished product. Changes in the manufacturing process of the active

		substance. Changes in the manufacturing process of the active substance.
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	28 June 2018	Change in the specification limits of the finished product
•	05 January 2017	Changes to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH.