Veterinary Medicines Directorate

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Post Authorisation Assessments

Porcilis M Hyo ID Once Emulsion for Injection for Pigs

Vm 01708/3009

•	26 February 2024	To mention the use of animal derived trypsin in the manufacture of the Byco-C hydrolysed gelatin provided by Croda and to declare a change in the hydrolysis step of the gelatin (excipient) by replacing porcine trypsin by the use of either porcine or bovine trypsin.
•	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.
•	07 November 2023	To increase in maximum batch size of M. Hyopneumoniae antigen to 10000 litres. To remove the sterility test on the bacterial culture medium. To remove the second inactivation test from the finished product control tests. Addition of MSD AH Danube Biotech Gmbh, Krems, Austria as an additional antigen manufacturing site. Removal of the non-mandatory transfer to a 3rd vessel after inactivation. Some minor changes are to bring the dossier in line with the actual practice.
•	08 September 2023	To update the SPC/QRD as per the version 9.0 of the QRD templates (for NI) and as per the National SPC/QRD template v1 (for GB) in order to keep the joint labelling in UK(NI) and UK(GB).
•	22 February 2023	To introduce additional associated use combinations for products in the Porcilis range.
•	11 September 2020	Change in the name of a manufacturer used in the manufacture of the active substance.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	04 June 2020	Repeat Use application to add 1 new member state.
•	05 February 2019	Changes to the labelling and package leaflet.
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	12 April 2018	Change in the SPC, labelling or package leaflet due to new data.
•	23 November 2017	Renewal – UK as CMS.
•	22 December 2016	Change in the SPC, labelling or package leaflet due to new data.
•	22 December 2016	Deletion of an immediate packaging container. Change in shape or dimensions of the container or

		closure (immediate packaging). Change in shape or dimensions of the container or closure (immediate packaging) Change in type of container/addition of a new container for the finished product.
•	08 December 2016	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	09 October 2015	Addition of an alternative source for a substance used in the manufacturing process of the active substance.
•	01 December 2014	Update to the DDPS.