



Post Authorisation Assessments

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

Porcilis PCV M Hyo Emulsion for Injection for Pigs

Vm 01708/5056

• 19 September 2023	Omission of in-process control tests on SF21CB cells used in the manufacturing process of the antigen. Addition of MSD AH Danube Biotech GmbH, Krems, Austria as finished product quality control testing site. Addition of MSD AH Danube Biotech GmbH, Krems, Austria as QC testing site for two IPC tests for the M. hyopneumoniae antigen. Addition of MSD AH Danube Biotech GmbH, Krems, Austria as QC testing site for two IPC tests for the M. hyopneumoniae 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.
• 14 September 2023	To update the SPC/QRD as per the National SPC/QRD template v1 (for GB).
• 24 January 2023	Change in test procedure for the finished product.
• 21 December 2022	Increase of the maximum batch size of M. hyopneumoniae antigen to 10,000 litres.
• 15 November 2022	Approval of blue box update on outer box.
• 03 November 2022	Changes in the manufacturing process of the active substance.
• 19 October 2022	Increase of maximum batch size of M. hyopneumoniae antigen to 10,000 litres.