Veterinary Medicines Directorate

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Post Authorisation Assessments

Porcilis PRRS Lyophilisate and Solvent for Suspension for Injection for Pigs

Vm 01708/3006

•	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.
•	06 September 2023	Alignment of the product information.
•	22 February 2023	To introduce additional associated use combinations for products in the Porcilis range.
•	31 October 2022	To update the finished product Mycoplasma testing by culture method to include testing by PCR method according to Ph. Eur. 2.6.7.
•	29 December 2021	Changes to the SPC/product labelling/package leaflet following an Article XX referral.
•	28 May 2021	Change in the address of a manufacturer used in the manufacture of the active substance.
•	17 November 2020	Change of MAH from: Intervet International BV, Represented by: Intervet UK Limited., Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to: MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	21 July 2020	Change in the SPC, labelling or package leaflet due to new data.
•	11 June 2019	Change in the SPC, labelling or package leaflet due to new data.
•	15 March 2019	Changes to the labelling and package leaflet.
•	18 October 2018	Changes to the labelling and package leaflet. Change in immediate packaging of the finished product.
•	24 July 2018	RMS change from UK to FR
•	12 December 2013	Extension of finished product shelf-life.
•	07 March 2013	Variation to change the pack dimensions and minor corrections to the text layout of the Product Literature.
•	30 March 2012	Change to the name of the finished product Manufacturer.
•	30 March 2012	Variation to change the name of the Active Substance Manufacturer.
•	16 December 2011	Variation to submit a new European Pharmacopeia Certificate of Suitability.
•	16 December 2011	Addition of an Active Substance Manufacturer.
•	16 December 2011	Variation to implement an improvement of the manufacturing process of the Active Substance. Changes to composition of the finished product.
•	20 July 2011	Renewal.

•	09 September 2010	Variation to include a compatibility statement in the respective SPC.
•	01 September 2009	Change of Marketing Authorisation Holder address.
•	29 January 2008	Variation to update the detailed description of the production process.
•	11 January 2007	Variation to extend the shelf-life of the finished product.
•	11 January 2007	Variation to change the container.
•	06 October 2006	Variation concerning a change in the regime of the vaccination.
•	24 January 2006	Renewal.
•	21 July 2005	Change in the sterility test method according to the European Pharmacopoeia.
•	29 April 2005	Change of Distributor in Northern Ireland.
•	24 November 2004	Inclusion of a new category of the target species via alteration to the contraindication section of the SPC.
•	22 January 2004	Variation to amend the product literature.
•	28 February 2003	Variation to amend the SPC.
•	13 March 2002	Change to the ingredient specification.
•	27 February 2002	Addition of a production site.
•	31 August 2001	Addition of a Distributor in Northern Ireland.
•	21 September 2000	Mutual Recognition Marketing Authorisation – UK RMS.