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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Suvaxyn PRRS MLV Lyophilisate and Solvent for Suspension for Injection for Pigs

Vm 42058/5075

•	28 July 2023	To include the nasal route as an additional administration route for the product.
•	28 July 2023	Modifications of indications in section 4.2 and section 5 of the SPC and in section 4 and section 15 of the leaflet, respectively, related to cross-protection against the virulent heterologous PRRSV -1 field strains (AUT15-33, BOR57 and Lena).
•	12 May 2023	Replacement of the media used for early stages of cell culture during antigen production.
•	17 April 2023	Addition of a secondary packaging site for the finished product. Addition of a secondary packaging site for the finished product.
•	27 February 2023	To include Lincoln site in the USA as an alternative site for preparation, testing and storage of new WCS for Suvaxyn PRRS MLV vaccine.
•	16 November 2022	Addition of Denmark, France, Germany and the Netherlands as a source of porcine pancreas used for the production of trypsin.
•	22 April 2022	Renewal