



## Post Authorisation Assessments

### Unistrain PRRS Lyophilisate and Solvent for Suspension for Injection for Pigs Vm 17533/4016

• 17 February 2022	Changes to the SPC/product labelling/package leaflet following an Article 35 referral. Change in the SPC, labelling or package leaflet due to new data.
• 15 July 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
• 01 February 2018	Change in the SPC, labelling or package leaflet due to new data.
• 14 September 2017	Renewal – UK as CMS.
• 22 December 2016	Update of section 4.7 of SPC to include safety warning for pregnant animals due to lack of safety data on use of vaccine beyond 60 days of pregnancy
• 04 February 2016	Change in the name of the local UK representative.
• 08 October 2015	Addition of a new target category (pigs from 4 weeks of age) and a new administration route in piglets. Change in the manufacturing process of the finished product and addition of alternative containers for the solvent. Addition of presentations of the solvent.
• 15 January 2015	Changes to the SPC and product literature to add a new claim of association between vaccines.
• 13 June 2014	Change in shelf life of the solvent as packaged for sale from 2 years to 5 years.