



Post Authorisation Assessments

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

RESPIPORC FLUp^{an} H1N1 Suspension for Injection for Pigs Vm 15052/5017

15 December 2025	To add a new manufacturing and in-process control testing site for the active substances including minor changes in the manufacturing process to adapt to the new manufacturing site settings.
11 January 2025	Addition of a method for thiomersal measurement. Addition of a new container. Addition of a new container. Addition of a new manufacturing and control testing site for the AS including minor changes in the manufacture of the AS based on the new manufacturing site. Change of minimum limit for thiomersal content during shelf-life. Addition of new sera including CEP. Addition of new sera including CEP. Addition of new sera including CEP. Addition of new sera including CEP. Addition of new sera including CEP. Addition of a new manufacturing and control testing site for the FP including changes in the vaccine formulation process and bulk batch size.
11 January 2025	Alignment of the SPC/QRD text with the newest EU version 9.0 QRD template and GB National SPC/QRD template.
June 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
20 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
17 May 2022	Renewal
22 February 2022	Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer.
15 February 2022	Change in the SPC, labelling or package leaflet due to new data.
08 July 2021	Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance.