



Post Authorisation Assessments

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

Respiporc Flu3 Suspension for Injection for Pigs Vm 15052/5016

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.
20 February 2025	G.I.18 Update to version 3 of the national template.
17 January 2025	<p>Addition of a new method for thiomersal measurement (ICP-MS in accordance with Ph. Eur. 2.2.58).</p> <p>Addition of a new container (50 ml LDPE bottles for 25 doses).</p> <p>Addition of a new container (100 ml LDPE bottles for 50 doses).</p> <p>Addition of a new manufacturing site (Ceva-Phylaxia) for the FP including changes in the vaccine formulation process and bulk batch size.</p> <p>Change of minimum limit for thiomersal content during shelf-life.</p> <p>Addition of a new control testing site (CevaPhylaxia) for the FP including test methods transfer.</p> <p>Addition of new sera including CEP (FBS from Cytiva, Hyclone – R1-CEP 2000-076).</p> <p>Addition of new sera including CEP (FBS from SAFC - R1- CEP 2005-087).</p> <p>Addition of new sera including CEP (BCS from Cytiva, Hyclone – R1-CEP 2000-080).</p> <p>Addition of new sera including CEP (BCS from Selborne – R1-CEP 2001-451).</p> <p>Addition of new sera including CEP (FBS from Biowest – R1-CEP 2007-074).</p> <p>Addition of a new manufacturing and control testing site (Ceva-Phylaxia)</p>
21 June 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
01 February 2023	Approval of mock ups.
19 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.
22 February 2022	Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer.
07 July 2021	Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance.