



Post Authorisation Assessments

Forcyl Swine 160 mg/ml Solution for Injection for Pigs Vm 08007/4134

•	25 March 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	13 April 2022	Deletion of manufacturing site for an active substance. Changes to a test procedure for the active substance. Changes to a test procedure for the active substance. Change of a re-test period of the active substance.
•	11 September 2018	Change in the address of the marketing authorisation holder from Vétoquinol UK Limited, Vetoquinol House, Great Slade, Buckingham Industrial Park, Buckingham, MK18 1PA to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr Alderton, Towcester, Northamptonshire, NN12 7LS.
•	29 December 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	06 April 2017	Renewal – UK as CMS
•	10 November 2016	Addition of a new active substance manufacturing site. Change in the manufacturer of a starting material.
•	06 July 2016	Deletion of a manufacturing site for an active substance.
•	02 December 2015	Modification of an approved indication
•	20 March 2015	Minor change in the manufacturing process of the finished product. Additional manufacturer responsible for batch release. Additional manufacturer for secondary packaging. Additional manufacturer of the finished product.
•	05 June 2013	Changes to therapeutic indications – Addition of “In post-partum sows: - Treatment of metritis mastitis agalactia syndrome (form of postpartum dysgalactiae syndrome, PPDS) caused by bacterial strains of <i>E. coli</i> susceptible to marbofloxacin.” and additional warning: “Pain at the injection site has been commonly reported”