



Post Authorisation Assessments

Colombovac PMV

Vm 42058/4020

•	16 November 2023	Addition of test for pH determination. Change of end of shelf-life specification for thiomersal content. Deletion of extraneous agents test on the finished product, based on assessment conducted in accordance Ph. Eur. 5.2.5. Update/harmonisation of the Part 2 dossier within current manufacturing practice in all countries.
•	19 August 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	11 January 2017	Change in the manufacturing process of the active substance.
•	02 October 2014	Change in a minor test procedure for this finished product. Deletion of a test procedure for the finished product. Replacement of a manufacturing site for the active substance. Replacement of a batch release site for the finished product. Replacement of a manufacturing site for the finished product.
•	12 December 2014	Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product.
•	22 November 2013	Change in test procedure for the active substance.
•	16 July 2012	Change in test procedure performed on a starting material used in the manufacture of the active substance
•	19 December 2011	Changes to an existing pharmacovigilance system as described in the DDPS
•	02 September 2011	Addition of a site for secondary packaging and batch release
•	29 March 2011	Renewal
•	10 March 2011	Change of name of manufacturer of the active substance, blending, filling and assembly, quality control testing, labelling and batch release
•	16 June 2010	Change of MAH

•	15 December 2009	Change of method of manufacture of the active substance
•	27 June 2008	Harmonisation of SPC
•	28 May 2008	Change of legal category from NFA-VPS to POM-VPS
•	16 November 2006	Change of legal category from P to NFA-VPS Changes to the SPC and Product Literature to bring in line with new legislation