Veterinary Medicines Directorate

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Post Authorisation Assessments

Poulvac Marek CVI + HVT to be suspended in Poulvac Marek Diluent

Vm 42058/4108

10 April 2025	Alignment of the immediate label text in line with the EMEA/CMDv/352379/2009 with regards to the conclusions and recommendations of CMDv on Diluents and EMA/CVMP/50607/2015 on Q&A on mentioning solvents in the product information of veterinary medicinal products authorised via the CP (QRD template). -Adjustment of the diluent/solvent name to Poulvac Solvent. Introduction of polypropylene bags and stoppers due to a ban of the PVC plastic bags containing DEHP (REACH). Introduction of polypropylene bags and stoppers due to a ban of the PVC plastic bags containing DEHP (REACH) -Harmonization of the Quality dossier including lowering of the minimum pH during shelf-life, introduction of fill volume tests in all sections of the dossier including adjustment of the specifications to include a maximum fill volume and some other minor corrections to the manufacturing process and Ph. Eur. compliant raw material section.
11 October 2022	Addition of an alternative stopper for use with the diluent PVC bags.
27 July 2022	Addition of a new presentation (800 ml) for Poulvac Marek Diluent. Addition of a new presentation (4000 doses) for Poulvac Marek CVI vaccine.
22 April 2021	Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer.
30 March 2021	Increase in batch size from minimum 5740 ml to a maximum of 14,700 ml to minimum 5740 ml to a maximum of 17,075 ml of the finished product. Change in the specification parameters and/or limits of the finished product. Changes in the manufacturing process of the active substance.
02 September 2020	Changes in the manufacturing process of the finished product. Change in the manufacturing process of the active substance. Update of the quality dossier.
14 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.
18 December 2019	Changes to the labelling and/or package leaflet.
21 November 2018	Submission of new Ph. Eur. TSE certificates of suitability from new and already approved manufacturers.
06 November 2018	Change of a test procedure for the finished product.
21 April 2017	Changes to the labelling and package leaflet.
21 November 2016	Change in test procedure for the finished product.
7 January 2016	Change in test procedure for the finished product
18 November 2015	Change in name of manufacturer of the active substance. Change in name of manufacturer of the finished product.
20 October 2015	Change in name of manufacturer.
25 April 2014	Change to the immediate packaging.
17 February 2014	Change to the immediate packaging.
02 January 2014	Submission of a new EDQM certificate of suitability.
22 November 2013	Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance.
18 September 2013	Change of MAH from Pfizer Ltd to Zoetis UK Limited.
18 September 2013	Change of distributor, change of name of manufacturer of the active substance, change of name of finished product manufacturers (including batch release), deletion of a manufacturing site and change in batch release site.
18 July 2012	Variation regarding clarification batch release and batch control sites.
16 July 2012	Replacement of test methods.
17 May 2012	Change in dimensions of immediate packaging.
17 January 2012	Change in name of site of manufacturer of diluent, QC testing and batch release. Additional site of secondary packaging.
13 June 2011	Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance.
11 April 2011	Change in the name of the manufacturer of the active substance, site for blending, filling and assembly, site for QC testing, site for labelling, and site for batch release.
23 November 2010	Change in the name of an active substance manufacturer.
21 April 2010	Change in MAH and distributor.
27 November 2008	Renewal.
13 November 2008	Update of a test method in line with Ph.Eur.
06 August 2008	Addition of a supplier of a starting material.
04 April 2008	Addition of a supplier of a starting material.
04 October 2007	Addition of a final product testing site.
20 July 2007	Changes to the SPC and product literature to bring them into line with new legislation.
20 July 2007	Change in legal category from PML to POM-VPS.
06 February 2007	Deletion of a manufacturing site.

29 December 2006	Addition of a manufacturing site of the finished product.
09 June 2006	Change in testing of the fished product.
16 June 2005	Additional manufacturing site.
29 April 2005	Extension of the shelf life of the vaccine diluent supplied in bags.
22 December 2004	Renewal.
05 March 2004	Changes in test methods of the active substance.
20 January 2003	Change in shelf life of the finished product.
30 July 2002	Addition of 200ml, 400ml, and 500ml collapsible plastic bags for the diluent.