Veterinary Medicines Directorate

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Post Authorisation Assessments

Poulvac MD Vac Lyophilisate and Diluent for Suspension for Injection

Vm 42058/4109

•	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.
•	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.
•	07 October 2019	Update of the quality dossier intended to implement the outcome of a Union referral procedure.
•	06 November 2018	Change of a test procedure for the finished product.
•	21 November 2016	Change in test procedure for the finished product.
•	8 September 2016	Changes to the labelling, or the package leaflet, which are not connected with the SPC.
•	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.
•	22 November 2013	Change in the test procedure for the active substance o starting material/reagent/intermediate used in the manufacturing process of the active substance.
•	19 September 2013	Change of MAH from Pfizer Litd to Zoetis UK Limited and change of name of manufacture of the active substance, changes of names of manufacturers of the finished product, deletion of a site responsible for quality control testing, labelling and batch release.
•	08 March 2013	Addition of a site responsible for batch control/testing of the finished product, to add in-process test methods, to remove an in-process test and to remove a site for an in-process test.
•	16 July 2012	Change testing specification for one of the suppliers.
•	04 July 2012	Replacement of a test with a Ph.Eur version and replacement of the site responsible for the test.
•	17 May 2012	Change of dimensions of the stopper of the 250ml and

		500ml vials.
•	10 January 2012	Change the name of the site responsible for manufacture of the diluent. Replacement of the site for labelling and addition of a site responsible for secondary packaging and batch release.
•	13 June 2011	Addition of an egg supplier.
•	04 February 2011	Change in the name/address of the manufacturer of the finished product.
•	23 November 2010	Change in the name of a manufacturing site.
•	12 August 2010	Renewal.
•	26 May 2010	Change of MAH and distributor.
•	03 December 2008	Change in a finished product release test method.
•	03 April 2008	Addition of a new supplier of a starting material.
•	19 December 2007	Changes to the SPC and product literature to bring them into line with new legislation.
•	19 December 2007	Change in legal category from PML to POM-VPS.
•	06 February 2007	Deletion of a manufacturing site of the finished product.