Veterinary Medicines Directorate

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Post Authorisation Assessments

Poulvac Marek CVI

Vm 42058/4107

•	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.
•	27 October 2020	Change in the number of doses in a pack outside the range of the currently approved pack sizes of the finished product. Changes in the manufacturing process of the finished product. Change(s) in the manufacturing process of the active substance. Change(s) in the manufacturing process of the active substance. Update Part 2 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.
•	20 November 2018	Submission of a new Ph. Eur. TSE certificate of suitability from an already approved manufacturer. Deletion of Ph. Eur. TSE certificates of suitability.
•	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.
•	22 November 2013	Variation to monitor the active substance by testing the respecting method recommended by the European Pharmacopoeia Monograph 5.2.2.
•	19 September 2013	Grouped variation to transfer the Marketing Authorisation Holder and distributor. Change in the name of the manufacturer of the active substance, change in the

		name of the manufacturer of the finished product (including batch release), change in the name of the manufacturer of the finished product (all other), deletion of a manufacturing site for QC testing, labelling, and batch release. Addition of a site for batch release, not including testing.
•	03 October 2012	Variation to make minor changes to the product literature.
•	16 July 2012	Variation to replace test methods as recommended by the European Pharmacopoeia Monograph 5.2.2.
•	17 May 2012	Variation to change the dimensions of an aspect of the immediate packaging.
•	17 January 2012	Grouped variation to change the name of the site responsible for manufacture, QC testing, and batch release. Change of secondary packaging site.
•	20 December 2011	Change in specification parameters/limits of the finished product. Increase of product shelf life.
•	13 June 2011	Addition of a supplier of a starting material used in the manufacture process.
•	16 December 2010	Grouped variation to change the name of the manufacturer of the active substance, site for blending, filling and assembly, site for QC testing, site for labelling, and the site for batch release.
•	23 November 2010	Variation to change the name of a manufacturer.
•	13 October 2010	Variation to change the Marketing Authorisation Holder and distributor.
•	23 August 2010	Renewal.
•	22 December 2008	Addition of a final product testing site, final product labelling, and QP release site.
•	22 December 2008	Addition of a site to provide an additional location for antigen production.
•	06 August 2008	Addition of three additional active substance manufacturers.
•	29 July 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from PML to POM-VPS.
•	06 February 2007	Deletion of a manufacturing site.
•	09 June 2006	Variation to change the currently approved extraneous agents testing of the finished product.