Veterinary Medicines Directorate

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Post Authorisation Assessments

Poulvac NDW

Vm 42058/4110

•	12 May 2023	Update of the quality control monograph for stoppers.
•	19 August 2022	Replacement of the current biochemical identification method with an alternative identity test based on mass spectroscopy.
•	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.
•	06 November 2018	Change of a test procedure for the finished product.
•	20 September 2017	Change of a test procedure for the finished product.
•	21 November 2016	Change in test procedure for the finished product.
•	7 January 2016	Change in test procedure for the finished product
•	23 March 2015	Changes in supplier of packaging components.
•	31 July 2014	Change in test procedure for the finished product.
•	22 November 2013	Change in test procedure for active substance or starting material/intermediate.
•	06 November 2013	Change of MAH from Pfizer Lts to Zoetis UK Limited. Change in the name of a manufacturer of the active substance, change in name of the manufacturer of the finished product (including batch release), deletion of a manufacturing site for quality control testing, labelling and batch release.
•	16 July 2012	Change in testing specification for an egg supplier.
•	20 June 2012	Update to a testing method to comply with Ph.Eur. requirements.
•	22 February 2012	Increase in shelf-life and change to test limits for the end of shelf life.
•	01 February 2012	Clarification regarding the release testing, secondary labelling/packaging and batch release site.
•	08 August 2011	Change in the name of a site responsible for manufacture of the active substance, blending, filling, assembly, quality control testing, labelling and batch release.
•	13 April 2011	Change in the specification of a compliant to bring in line with Ph.Eur.
•	16 December 2010	Change in the name of the manufacture of the active substance and site for blending, filling, assembly, quality control testing, labelling and batch release.

•	24 June 2010	Change in the MAH and distributor.
•	23 March 2010	Increase in shelf life and change to limits for a shelf life test.
•	04 September 2009	Addition of a site of manufacture of finished product including blending, filling, quality control testing and release.
•	15 February 2007	Changes to the SPC and product literature to bring them into line with new legislation.
•	04 October 2006	Renewal
•	09 March 2006	Change to the vial stopper.
•	09 March 2001	Renewal
•	29 January 1998	Change of MAH.
•	22 May 1997	Change in formulation.
•	22 May 1997	Change in dosage form.
•	07 May 1997	Change of product name.
•	22 April 1997	Change in dosage form.