Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Poulvac Hitchner B1

Vm 42058/4100

•	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.
•	27 July 2017	Changes to the labelling and/or package leaflet.
•	21 November 2016	Change in test procedure for the finished product.
•	07 January 2016	Change in test procedure for the finished product
•	17 November 2015	Change in batch size of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in control of the finished product. Unforeseen (agreed at CMDv)
•	23 October 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.
•	06 June 2014	Deletion of a manufacturing site.
•	26 March 2014	Change in test procedure for the finished product.
•	27 February 2014	Approval of mock-ups.
•	22 November 2013	Change in test procedure for active substance/starting material/intermediate used in the manufacturing process of the active substance.
•	30 May 2013	Grouped variation to change the name of the active substance manufacturer, change the name of the finished product manufacturer (responsible for batch release), change the name of the finished product manufacturer. Submission of mock-ups for a dosage presentation.
•	20 May 2013	Grouped variation concerning the addition of a site responsible for batch control/testing of the finished product. Deletion of a manufacturing site. Addition of an in-process test method. Update to extraneous agent testing to comply with the Ph. Eur. Monograph 2.6.25.
•	16 July 2012	Variation to replace test methods as recommended in the Ph. Eur. Monograph 5.2.2.
•	25 July 2011	Replacement of an alternative site for batch release.
•	25 July 2011	Variation to change the name and address of the

		secondary packaging site.
•	13 June 2011	Addition of a supplier of a starting material/reagent/intermediate used in in the manufacture of the active substance.
•	16 December 2010	Grouped variation to change the name of the manufacturer of active substance, site for blending, filling, assembly, site for QC testing, site for labelling, site for batch release. Change to imported for final dosage form from outside the EU, and the site for QC retesting if imported from outside the EU.
•	23 November 2010	Variation to change the name of an active substance manufacturer.
•	23 July 2010	Renewal.
•	02 June 2010	Variation to replace the currently approved antibiotic.
•	21 April 2010	Variation to change the Marketing Authorisation Holder and Distributor.
•	13 November 2008	Variation to update a test method.
•	25 June 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from PML to POM-VPS.