Veterinary Medicines Directorate

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Post Authorisation Assessments

Poulvac Bursa Plus Lyophilisate for Suspension in Drinking Water

Vm 42058/4098

•	August 2023	Addition of test procedure for the finished product. (NI)
•	16 June 2023	Addition of test procedure for the finished product. (GB)
•	14 September 2022	Change in test procedures for the finished product.
•	14 November 2019	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.
•	25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	23 January 2018	Change in the RMS from UK to DE.
•	20 September 2017	Change of a test procedure for the finished product.
•	25 May 2016	Addition of an alternative test method.
•	09 February 2016	Change in the name of a manufacturer of the active substance. Change in the name of a manufacturer of the finished product.
•	05 May 2015	Change to the QPPV contact details.
•	22 November 2013	Change in the test procedure (used in the manufacturing process) for the active substance.
•	25 October 2013	Variation to transfer the Marketing Authorisation.
•	11 October 2013	Grouped variation to change the name of the manufacturer of the active substance, change the name of the manufacturer responsible for batch release, change the name of the manufacturer responsible for the finished product, and to change the QPPV contact details.
•	10 October 2013	Variation to change the name and address of the Marketing Authorisation Holder in Belgium.
•	05 September 2013	Variation to delete a manufacturer.
•	02 August 2013	Renewal.
•	16 July 2012	Variation to change the SPC testing specification.

•	13 June 2012	Variation to change the detailed description of the pharmacovigilance system (DDPS) following a change in Marketing Authorisation Holder.
•	04 August 2011	Change in the manufacture of the finished product.
•	07 July 2011	Grouped variation to change the name of the manufacture site for active substance, blending, filling, assembly, QC testing, labelling and batch release. Change in the name of the site for manufacture for active substance, blending, filling, assembly and in process testing. Variation to change the name of a QC testing site.
•	13 June 2011	Change in the supplier of a starting material.
•	19 May 2011	Variation to change the address of the Pfizer office in Poland.
•	26 January 2011	Variation to change the Marketing Authorisation Holder and Distributor.
•	04 March 2010	New MRP.
•	23 December 2008	Variation concerning Part II Clarification pre-MRP procedure.
•	29 August 2007	Variation concerning the addition of a site of testing and QP release site.
•	02 August 2007	Renewal.
•	24 January 2007	Variation to make changes to the batch safety test.
•	09 October 2006	Replace of a finished product manufacturer.
•	02 August 2006	Change in the shape and dimensions of the container.
•	22 June 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	09 June 2006	Change to comply with the European Pharmacopoeia for extraneous agents testing.
•	30 March 2006	Variation to change Part III of the dossier.
•	20 December 2005	Addition to Part III of the dossier.
•	09 June 2005	Line extension.
•	04 March 2005	Addition of a supplier of a starting material.
•	11 March 2004	Renewal.
•	23 May 2003	Line extension.
•	28 May 1999	Change to the ingredient specification.
•	28 May 1999	Change to the finished product specification.
•	23 April 1998	Variation to update licence particulars.