Veterinary Medicines Directorate

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Post Authorisation Assessments

Poulvac Bursine 2 Lyophilisate for Suspension for Spray Vaccination or for use in Drinking Water for Chickens

Vm 42058/3030

•	06 July 2024	Alignment of the SPC/QRD text with the newest EU version 9.0 QRD template and GB National SPC/QRD.
•	13 June 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
•	15 August 2023	Addition of test procedure for the finished product. (NI)
•	16 June 2023	Addition of test procedure for the finished product. (GB)
•	28 July 2022	To replace the current pharmatone-based stabiliser with the SPA stabiliser.
•	08 March 2022	Update of the quality dossier.
•	10 September 2020	Renewal – UK as CMS.
•	12 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.
•	26 January 2018	Change in the RMS from UK to HU.
•	20 September 2017	Change of a test procedure for the finished product.
•	25 August 2017	Introduction of updated mock ups.
•	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.
•	22 November 2013	Change in test procedure for active substance/starting material/reagent/intermediate used in the manufacturing process of the active substance.
•	16 July 2012	Variation to replace test methods recommended in the Ph. Eur. Monograph 5.2.2.

•	22 November 2011	Deletion of an in process during used during the manufacturing process.
•	02 September 2011	Addition of an alternative site for batch release.
•	02 September 2011	Addition of a site of labelling.
•	02 September 2011	Addition of an alternative site for QC testing, importer of final dosage form (from outside EU), site for QC retesting if imported from outside the EU.
•	13 June 2011	Addition of a supplier of a starting material.
•	18 January 2011	Grouped variation to change the name of the manufacturer of the active substance, site for blending, filliang and assembly, site for QC testing, stie for labelling, site for batch release, importer of the final dosage form outside EU, and the site of QC testing from outside the EU.
•	23 November 2010	Variation to change the name of the active substance manufacturer.
•	16 June 2010	Variation to change the Marketing Authorisation Holder and Distributor.
•	15 October 2008	Renewal.
•	27 August 2008	Alignment of the SPC and Product Literature between IE and UK.
•	15 July 2008	Addition of a testing site and site of QP release.
•	09 June 2006	Variation to change the currently approved extraneous agents testing.
•	16 July 2004	Renewal.
•	14 June 2002	Variation to make minor changes to the labels, carton, and datasheet for the product.
•	19 April 2002	Additional pack type (finished product).
•	08 March 2002	Variation to change the dosage form assembly site.
•	17 March 2000	Renewal.
•	12 March 1998	Change of Assembler.
•	12 March 1998	Production transfer.
•	03 February 1998	Change to name of Marketing Authorisation Holder.
•	19 September 1996	Change to a QC procedure.
•	19 September 1996	Change in the name of the medicinal product.