Veterinary Medicines Directorate

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Post Authorisation Assessments

Poulvac TRT Vaccine, Lyophilisate for Suspension for Spray, Eye Drop or Nose Drop administration for Turkeys.

Vm 42058/3043

•	18 July 2023	Update of the quality control monograph for stoppers. (NI)
•	12 May 2023	Update of the quality control monograph for stoppers. (GB)
•	29 July 2021	Change in the number of units (pack size) in a pack within the range of the currently approved pack sizes of the finished product.
•	10 January 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.
•	21 May 2019	Change to increase the shelf-life for the vaccine after reconstitution is proposed to increase to 4 hours. Update to Part II dossier.
•	20 March 2019	Change in RMS from UK to FR.
•	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.
•	20 September 2017	Change of a test procedure for the finished product.
•	08 December 2016	Change of MAH address in France, Czech Republic and Slovakia.
•	21 November 2016	Change in test procedure for the finished product.
•	7 January 2016	Change in test procedure for the finished product
•	05 May 2015	Change in the QPPV contact details.
•	17 April 2015	Change in supplier of packaging components of devices.
•	31 July 2014	Change in test procedure for the finished product.
•	26 March 2014	Change in test procedure for the finished product.
•	25 October 2013	Change of MAH from Pfizer Ltd to Zoetis UK Limited.
•	25 October 2013	Change of distributor.
•	11 October 2013	Change of the name and/or address of the MAH.
•	13 June 2012	Change in the Detailed Description of the Pharmacovigilance System.
•	08 March 2012	Renewal.
•	02 March 2012	Change in the name of the sites responsible for batch release, blending, filling, assembly, quality control testing, secondary packaging and labelling.
•	02 March 2012	Change of address of the manufacturer of the active substance.

•	24 June 2010	Change of MAH and distributor.
•	26 August 2009	Addition of a quality control and batch release site.
•	26 August 2009	Addition of a manufacturer of the finished product.
•	17 December 2008	Addition of a manufacturer of a starting material.
•	13 February 2008	Change of product stabiliser.
•	03 August 2007	Update to the testing of the finished product.
•	19 October 2006	Renewal.
•	13 July 2006	Change of container.
•	13 March 2003	Change in the ingredient specification.