Veterinary Medicines Directorate

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Post Authorisation Assessments

Autoworm First Grazer 8750 mg Pulsatile-Release Intraruminal Device

Vm 42058/4009

•	13 January 2021	Addition of a site where batch control/testing takes place. Addition of a manufacturer responsible for batch release of the finished product.
•	21 August 2020	Change in the address of the MAH, 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.
•	24 June 2020	Change in the specification parameters for the finished product.
•	25 September 2019	Deletion of manufacturing site for a finished product.
•	08 January 2014	Change in distributor details Transfer of MAH
•	19 December 2011	Changes to an existing pharmacovigilance system as described in the DDPS
•	08 June 2011	Addition of a manufacturing site of the finished product
•	11 May 2011	Addition of a primary packaging site
•	02 March 2011	Change of batch size of the finished product Changes to batch release arrangements Change in test procedure on the finished product Addition of a secondary packaging site
•	02 June 2010	Submission of an updated Ph. Eur. Certificate of Suitability Corrections/minor text layout changes to SPC and/or product literature
•	14 April 2009	Change of MAH
•	10 December 2008	Change of legal category from PML to POM-VPS Changes to SPC and Product Literature to bring in line with new legislation
•	07 March 2008	Renewal
•	28 June 2005	Renewal
•	10 December 2001	Change to ingredient specification Change in QC procedures Change in formulation
•	31 January 2001	Addition of a manufacturer of the active substance
•	21 February 2000	Addition of a 24 bolus presentation
•	13 December 1999	Change of route of administration
•	27 November 1998	Changes to ingredient specification Change in formulation Change to safety warnings