Veterinary Medicines Directorate

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Post Authorisation Assessments

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Vm 01708/4627

•	28 May 2021	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance.
•	28 May 2021	Change in the address of a manufacturer used in the manufacture of the active substance.
•	17 November 2020	Change of MAH from: Intervet International BV, Represented by: Intervet UK Limited., Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to: MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	03 December 2015	Approval of revised mock-ups
•	11 November 2013	Changes in the manufacturing process of the Active Substance.
•	29 March 2012	Change in the name of an Active Substance Manufacturer.
•	29 March 2012	Change in the name of a finished product Manufacturer.
•	04 June 2010	Introduction of an in-process control method.
•	04 June 2010	Addition of a step in the manufacturing process.
•	04 June 2010	Addition of a step in the manufacturing process.
•	04 June 2010	Variation to the manufacturing process.
•	16 February 2010	Variation to introduce minor change in the production process.
•	16 February 2010	Variation to manufacturing process.
•	28 January 2010	Submission of an updated Pharmacopoeia Certificate of Suitability.
•	21 August 2009	Renewal.
•	06 February 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of legal category from POM to POM-V.
•	17 September 2007	Addition of an alternative site for final product QC testing.
•	10 June 2005	Change of Distributor.
•	10 August 2004	Renewal.
•	30 January 2003	Amendment to manufacture process.
•	05 December 2002	Amendment to manufacture process.
•	05 December 2002	Amendment to manufacture process.
•	26 March 2002	Change to ingredient specification.
•	31 August 2001	Addition of a Distributor.
•	21 March 2001	Addition of an Active Substance Manufacturer.
•	27 April 2000	New Marketing Authorisation.