Veterinary Medicines Directorate

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Post Authorisation Assessments

PG 600, Powder and Solvent for Solution for Injection

Vm 01708/4312

•	17 March 2023	Change in immediate packaging of the finished product.
•	11 October 2022	Substantial changes to an ASMF.
•	27 June 2022	Change in the manufacturer of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier.
•	23 June 2021	Deletion of a non-significant specification parameter of the finished product.
•	30 December 2020	Change in the name of the MAH from Intervet UK Limited to MSD Animal Health UK Limited.
•	20 November 2020	Change in the name of a manufacturer used in the manufacture of the active substance. Extension of the retest period for the intermediates used in the manufacture of the active substance.
•	23 September 2020	Tightening of specification limits of the finished product. Tightening of specification limits of the finished product. Change in the specification limits of the finished product. Change in the specification limits of the finished product. Change in the specification limits of the finished product.
•	12 June 2019	Change in the name of the manufacturer of the finished product.
•	18 September 2018	Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	20 September 2016	Change in the manufacturer of the active.
•	14 June 2016	Addition of a secondary packaging site of the finished product. Change in the manufacturing process of the finished

		product. Change in the manufacturing process of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Changes in the manufacturing process of the finished product. Changes in the manufacturing process of the finished product. Changes in the manufacturing process of the finished product. Addition of a manufacturer responsible for imporation / batch release including batch control / testing. Addition of a site where batch control/testing takes place. Addition of a manufacturing site of the finished product.
•	22 July 2015	Amendments to the details of the suppliers of raw materials in the ASMF.
•	19 March 2015	Change in the re-test period of the active substance. Change in control of the active substance. Change in the supplier of the starting material and thus a change to the information for the manufacturing process of the active substance.
•	27 October 2014	Change in the name of the manufacturer of the active substances.
•	18 April 2013	Variation to change the storage conditions of the finished product.
•	22 September 2011	Change in test procedure for the finished product.
•	24 August 2011	Variation to register the API Quality Dossier.
•	06 July 2011	Variation to replace the open and closed parts of the ASMF with an API Quality Dossier.
•	17 November 2010	Variation to change the specifications of an Active Substance.
•	23 June 2010	Variation to update the Drug Master File.
•	08 April 2010	Change to in-process control limits applied to filling volumes.
•	22 January 2009	Renewal.
•	07 August 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	25 June 2008	Addition of an Active Substance Manufacturer.
•	20 September 2007	Variation to update part of Dossier.
•	07 August 2007	Change in the name/address of an Active Substance Manufacturer.
•	21 March 2007	Addition of a Manufacturer.
•	22 September 2005	Variation to change the address of a Distributor.
•	22 July 2005	Renewal.
•	27 July 2001	Addition of a Distributor.
•	21 June 2000	Change in the address of a Marketing Authorisation Holder.
•	29 December 1999	Renewal.