Veterinary Medicines Directorate

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Post Authorisation Assessments

PMSG Intervet 5000IU Powder and Solvent for Solution for Injection

Vm 06376/4096

•	22 November 2024	Change in legal entity of MA holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to Intervet International B.V., Wim de Körverstraat, 35, 5831 AN Boxmeer, The Netherlands.
•	17 March 2023	Change in immediate packaging of the finished product.
•	27 June 2022	Change in the manufacturer of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier.
•	28 April 2021	Change in name of the MAH from Intervet UK Ltd, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	12 June 2019	Change in the name of the manufacturer of the finished product.
•	22 July 2015	Amendments to the details of the suppliers of raw materials in the ASMF.
•	28 October 2014	Change to the name of the active substance manufacturer.
•	09 January 2014	Change of manufacturing site, change of site for control testing and addition of a manufacturer for secondary packaging and batch release. Change to the immediate packaging, changes to the manufacturing process and update to the product literature.
•	17 January 2013	Change of storage conditions from ‘Store below 25˚C’ to ‘Store in a refrigerator (+2˚C - +8˚C)
•	06 July 2011	Change in manufacture of the active substance
•	03 February 2010	Change to in-process limits applied to the finished product
•	04 August 2009	Submission of an updated Active Substance Master File (ASMF)
•	03 July 2008	Addition of a manufacturer of the active substance
•	27 February 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	21 March 2007	Change of manufacturing site for an ingredient used in the manufacture of the finished product
•	12 June 2006	Renewal
•	01 June 2006	Changes to Part II of the Dossier
•	03 November 2005	Change of distributor

•	03 July 2001	Change of distributor
•	20 June 2000	Update of licence particulars
•	02 September 1999	Renewal
•	04 May 1995	Changes to dosage particulars