Veterinary Medicines Directorate

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Post Authorisation Assessments

Pyratape P Horse Wormer 40% w/w Oral Paste

Vm 50146/4013

•	26 July 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	29 November 2022	Minor changes to an approved test procedure for active substance.
•	18 March 2021	Replacement of a secondary packaging site of the finished product.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	27 July 2020	Change in distributor details from Intervet UK Ltd, Walton Manor, Walton, Milton Keynes, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ.
•	05 August 2019	Change in the name used in the manufacture of the active substance. Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	25 October 2018	Change of MAH, from Cross Vetpharm Group Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	11 September 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	09 May 2018	Deletion of manufacturing site for an active substance.
•	15 January 2018	Changes to the labelling and package leaflet.
•	03 December 2013	Variation to update the Certificate of Suitability for the Active Substance.
•	06 September 2012	Variation to amend the limits and test procedure for the finished product.
•	22 September 2011	Variation concerning the addition of a site of batch release.
•	22 September 2011	Variation to update the European Pharmacopoeia TSE Certificate of Suitability.
•	08 March 2011	Variation to change test procedure for the finished product.
•	15 February 2011	Variation to submit a new Certificate of Suitability for an excipient.

•	30 June 2010	Variation to submit an updated Certificate of Suitability for the Active Substance.
•	20 October 2009	Variation to harmonise the shelf-life specification and the in-process specification with the finished product specification.
•	07 July 2009	Variation to submit an updated Certificate of Suitability for the Active Substance.
•	07 April 2009	Variation to make a minor change to the finished product manufacturer.
•	19 October 2008	Submission of a new European Pharmacopoeia Certificate of Suitability for the Active Substance.
•	11 June 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from PML to POM-VPS.
•	11 November 2007	Variation to change part of the primary packaging material not in contact with the finished product formulation.
•	13 June 2007	Minor change to the manufacturing process for the Active Substance.
•	17 May 2006	Renewal.
•	14 January 2005	Addition of an Assembler of Dosage Form.
•	04 November 2004	Extension of horse withdrawal period.
•	08 September 2003	Renewal.
•	08 September 2003	Variation to amend the shelf life specification.
•	06 June 2003	Variation to change the Active Substance Manufacturer.
•	21 March 2003	Variation to change the Active Substance Specification.
•	12 April 2002	Variation to change the container shape.
•	09 November 2001	Variation to change the Dosage Form Manufacturer.
•	31 October 2001	Change of Distributor.
•	02 February 2001	Change of Distributor.