Veterinary Medicines Directorate

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Post Authorisation Assessments

Maximec Horse Oral Paste, 18.7 mg/g

Vm 50146/4020

•	April 2024	Deletion of a Ph. Eur. CEP for an active substance manufacturer. (NI) Deletion of a Ph. Eur. CEP for an active substance manufacturer. (NI)
•	08 March 2024	Deletion of a Ph. Eur. CEP for an active substance manufacturer. Deletion of a Ph. Eur. CEP for an active substance manufacturer. (GB)
•	08 March 2024	Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile. (GB)
•	08 March 2024	Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile. (NI)
•	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.
•	23 August 2019	Change in name (only) of quality control testing site. Change in the name and address of a manufacturer of the finished product, also responsible for batch release. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS
•	19 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.
•	15 March 2018	Change in RMS from UK to NL.
•	12 January 2016	Submission of an updated certificate of suitability.
•	20 December 2012	Variation to change the distributor.
•	18 October 2012	Submission of a new European Pharmacopoeia Certificate of Suitability for an active substance manufacturer.
•	29 March 2012	Grouped variation concerning the submission of two European Pharmacopoeia Certificates of Suitability.
•	11 November 2011	Variation to change the QRD test and as a result the mock-ups for the finished product in Belgium.
•	31 March 2011	Variation to update a TSE Ph. Eur. Certificate of Suitability for an excipient.
•	03 December 2010	Renewal (UK as RMS).
•	14 October 2009	Addition of a safety warning in the SPC and Product

		Literature.
•	21 April 2009	Change of address of the distributor.
•	08 October 2008	Submission of an updated European Pharmacopoeia Certificate of Suitability for the active substance.
•	23 February 2007	MRP (UK as RMS).