

Post Authorisation Assessments

Maximec Horse Oral Paste, 18.7 mg/g Vm 50146/5008

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| 10 February 2026 | Replacement of a secondary packaging site. Replacement of a batch release site. |
| 10 February 2026 | Replacement of a manufacturing site for the manufacture of the finished product. Change in the manufacturing process of the finished product. |
| 12 December 2025 | Deletion of a non-significant specification parameter in the specification parameters or limits of an excipient. |
| 17 April 2025 | One-off alignment of the product information with version 9.0* of the QRD templates. |
| 23 September 2024 | Change in the manufacturing process of the finished product. |
| 03 May 2024 | Deletion of a Ph. Eur. CEP for an active substance manufacturer. 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 |

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| | 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). |