Veterinary Medicines Directorate

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Post Authorisation Assessments

Omeproshield 370 mg/g Oral Paste for Horses

Vm 08327/3024

•	11 May 2024	Removal of the 'treatment' indication. Update to v.9.0 of the QRD template.
•	22 March 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
•	11 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	31 January 2023	Change in address of manufacturer of the finished product.
•	16 August 2022	Change in address of manufacturer of the finished product.
•	01 December 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	28 May 2020	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	19 March 2020	Renewal - UK as CMS.
•	05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	23 September 2019	Change of distributor from Newmarket Equine, Hospital, Cambridge Road, Newmarket, Suffolk, CB8 0FG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.
•	07 February 2019	Change in the name of the manufacturer of the finished product.
•	16 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Limited, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG, United Kingdom to Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.
•	26 June 2018	Change in RMS from UK to IE.
•	06 February 2018	Submission of a new Ph. Eur. Certificate of Suitability for an active substance from a new manufacturer.
•	09 August 2017	Deletion of manufacturing site for an active substance.

•	09 August 2017	Change in the specification limits of the finished product.
•	15 June 2017	Changes to a test procedure for the active substance.
•	06 April 2017	Change to part of the packaging material not in contact with the finished product formulation.
•	13 January 2017	Submission of an updated certificate of suitability.
•	28 September 2016	Approval of mock-ups. Change in distributor details. From Merial Animal Health Ltd. to Newmarket Equine Hospital.
•	08 December 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure