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Post Authorisation Assessments

Alonate-P 400 mg/g Oral Paste for Horses and Ponies Vm 50146/4015

•	28 July 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	22 November 2022	Minor changes to an approved test procedure for active substance.
•	13 April 2021	Deletion of packaging site.
•	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.
•	02 June 2020	Renewal – National.
•	17 February 2020	Change in distributor details. From Farm and Stable Supplies LLP, Bridgelands, Ingrams Green, Midhurst, GU29 OLJ to GBA International LLP, Prospect House, Neston, CH64 3RU.
•	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.