Veterinary Medicines Directorate

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Post Authorisation Assessments

Embotape Oral Paste 40% w/w

Vm 50146/4014

•	26 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.
•	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.
•	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.
•	06 September 2012	Change of shelf life specification of the finished product.
•	22 September 2011	Submission of an updated Ph. Eur. Certificate of Suitability for an excipient from an already approved manufacturer. Addition of a site of batch release.
•	08 March 2011	Change of test method performed on the finished product.
•	15 February 2011	Submission of a new Ph. Eur. Certificate of Suitability for an excipient.
•	30 June 2010	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from a previously approved manufacturer.
•	20 October 2009	Change of specification of the finished product
•	07 July 2009	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from a previously

		approved manufacturer.
•	02 June 2009	Renewal.
•	07 April 2009	Minor change in the manufacture of the finished product.
•	19 October 2008	Change of manufacturer of the active substance.
•	11 June 2008	Change of legal category from PML to POM-VPS. Changes to the SPC and Product Literature to bring in line with new legislation.
•	11 November 2007	Change of packaging component.
•	13 June 2007	Minor change in the manufacturing process of the active substance.
•	14 January 2005	Addition of a site of assembly.