

Post Authorisation Assessments

Embotape Oral Paste 40% w/w Vm 50146/4014

20 January 2026	Submission of an updated Ph. Eur. CEP for an active substance.
18 December 2025	Change to comply with an update of the relevant monograph of the Ph. Eur.
11 July 2025	Removal of statements regarding dosing intervals from product literature.
17 October 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
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.