



Post Authorisation Assessments

Pyratape P Horse Wormer 40% w/w Oral Paste Vm 50146/4013

14 January 2026	Submission of a Ph. Eur. CEP for an active substance
18 December 2025	Change to comply with an update of the relevant monograph of the Ph. Eur.
10 July 2025	Removal of statements regarding dosing intervals from product literature.
18 September 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.
29 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.
27 July 2020	Change in distributor details from Intervet UK Ltd, Walton Manor, Walton, Milton Keynes, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ.
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.
15 January 2018	Changes to the labelling and package leaflet.
03 December 2013	Variation to update the Certificate of Suitability for the Active Substance.
06 September 2012	Variation to amend the limits and test procedure for the finished product.
22 September 2011	Variation concerning the addition of a site of batch release.
22 September 2011	Variation to update the European Pharmacopoeia TSE Certificate of Suitability.
08 March 2011	Variation to change test procedure for the finished product.
15 February 2011	Variation to submit a new Certificate of Suitability for an excipient.

30 June 2010	Variation to submit an updated Certificate of Suitability for the Active Substance.
20 October 2009	Variation to harmonise the shelf-life specification and the in-process specification with the finished product specification.
07 July 2009	Variation to submit an updated Certificate of Suitability for the Active Substance.
07 April 2009	Variation to make a minor change to the finished product manufacturer.
19 October 2008	Submission of a new European Pharmacopoeia Certificate of Suitability for the Active Substance.
11 June 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from PML to POM-VPS.
11 November 2007	Variation to change part of the primary packaging material not in contact with the finished product formulation.
13 June 2007	Minor change to the manufacturing process for the Active Substance.
17 May 2006	Renewal.
14 January 2005	Addition of an Assembler of Dosage Form.
04 November 2004	Extension of horse withdrawal period.
08 September 2003	Renewal.
08 September 2003	Variation to amend the shelf life specification.
06 June 2003	Variation to change the Active Substance Manufacturer.
21 March 2003	Variation to change the Active Substance Specification.
12 April 2002	Variation to change the container shape.
09 November 2001	Variation to change the Dosage Form Manufacturer.
31 October 2001	Change of Distributor.
02 February 2001	Change of Distributor.