Veterinary Medicines Directorate

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Post Authorisation Assessments

HY-50 Vet 17 mg/ml Solution for Injection
Vm 10434/4078

•	12 May 2022	Addition of a site for microbiological testing for the finished product.
•	09 November 2020	Addition of a site where batch control/testing takes place.
•	07 May 2020	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	18 June 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	25 April 2018	Deletion of manufacturing site for the finished product.
•	07 December 2017	Addition of a site where batch control/testing takes place.
•	25 August 2016	Addition of a manufacturing site for secondary packaging.
•	19 April 2016	Updated labels and package leaflet approved.
•	02 March 2016	A change in the address of the Marketing Authorisation Holder from Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, ST7 1XW UK to Snaygill Industrial Estate, Keighley Road, Skipton North Yorkshire, BD23 2RW.
•	07 May 2015	Change to comply with an update of the Ph. Eur. Submission of an updated Ph. Eur. Certificate of Suitability.
•	23 April 2014	Change in control of the excipients.
•	09 April 2014	Changes to the manufacturing process of the active substance and changes to the specification parameters of the active. Addition of a supplier of the active.
•	23 December 2013	Change to an in-process test and limits applied during the manufacturing process.
•	01 October 2013	Variation to change the importer of the final dosage form (from outside the EU).
•	30 August 2013	Addition of a site for batch analysis.
•	22 April 2013	Change in the finished product test procedure.
•	05 February 2013	Variation to change the name of an excipient supplier.
•	05 February 2013	Change to a test method used in the manufacturing process.
•	19 December 2012	Grouped variation concerning the submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer, and the update of a related test method.
•	20 November 2012	Addition of a source of a packaging component.

•	25 April 2012	Variation to change the distributor.
•	14 March 2012	Variation to change the Marketing Authorisation Holder.
•	06 January 2012	Variation to change the manufacturer responsible for batch release.
•	07 January 2009	Addition of a new route of administration.
•	07 January 2009	EU Renewal.
•	03 March 2006	Change in the batch size of the finished product.
•	28 January 2005	Renewal.
•	11 June 2004	Change in the shelf life.
•	09 January 2004	Change in the address of the Marketing Authorisation Holder.
•	04 February 2003	New EUDE Marketing Authorisation (UK as CMS).