Veterinary Medicines Directorate

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Post Authorisation Assessments

Lambivac
Vm 01708/4509

•	01 November 2023	Change to comply with Ph. Eur.
•	14 April 2023	To add an in vitro potency ELISA for C. perfringens type C beta toxoid (FPC test). To add Intervet International B.V., Boxmeer, NL, as finished product Quality Control test site for the C. perfringens type C beta toxoid potency test.
•	12 December 2022	To add use of bovine liver extract in Clostridia growth media used for the production of Clostridial antigens as an alternative to porcine liver extract.
•	31 May 2022	Change of a test procedure for the active substance.
•	05 October 2021	Update of the test procedure to comply with the updated general Ph. Eur monograph. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Addition of a site where batch control/testing takes place.
•	17 March 2021	Change in the manufacturing process of the finished product.
•	01 October 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	11 September 2020	Change in the name of a manufacturer used in the manufacture of the active substance
•	02 June 2020	Change in the name of the MAH, from Intervet UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	01 April 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	30 March 2017	Change in name of a manufacturer of the active substance.
•	19 July 2013	Variation to change the manufacturing process of the Active Substance.
•	19 July 2013	Change in the in-process control tests for the Active Substance. Removal of the Target Animal Batch Safety Test from the finished product testing.

•	22 March 2012	Variation to change the manufacturer of the finished product.
•	19 July 2011	Variation to update the detailed description of the production process.
•	22 April 2010	Renewal.
•	08 July 2009	Addition of an alternative site for filling of the product, with a consequential change to the packaging details.
•	26 July 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	17 October 2005	Review of Marketing Authorisation.