Veterinary Medicines Directorate

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Post Authorisation Assessments

Nobivac Lepto 2

Vm 01708/4360

•	13 April 2022	Submission of a new Ph. Eur. certificate of suitability for a starting material (used in manufacturing process of active) from a new manufacturer.
•	21 July 2021	Change in the specification limits of the finished product. Change(s) in the SPC, Labelling or Package Leaflet Due to a Periodic safety Update Report.
•	31 March 2021	Deletion of a pack size(s) of the finished product. Change in the composition (excipients) of the finished product.
•	05 November 2020	Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited.
•	16 April 2019	Change in the batch size of the active substance used in the manufacturing process of the active substance. Change in the fill volume of the finished product. Changes in the manufacturing process of the active substance.
•	23 December 2015	Change in the specification limits of the finished product
•	15 April 2015	Approval of mock-ups for additional secondary packaging.
•	10 February 2015	Introduction of additional secondary packaging.
•	17 April 2013	Change to an in-process test applied during the manufacture of the Active Substance. Change in test procedure for the finished product.
•	03 January 2013	Variation to change the manufacturing process of the Active Substance.
•	15 June 2011	Submission of an updated Certificate of Suitability.
•	29 December 2009	Corrections to SPC/Product Literature.
•	27 April 2009	Submission of an updated TSE European Pharmacopoeia Certificate of Suitability from an already approved manufacturer.
•	10 September 2008	Variation to update test methods for the finished product.
•	12 December 2007	Corrections to the SPC/Product Literature.
•	26 January 2007	Renewal.
•	15 August 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	05 April 2006	Variation concerning the addition of a pack type and preservative.
•	20 June 2005	Change of distributor.
•	26 May 2005	Addition of a batch size for the Active Substance.

•	26 November 2004	Variation concerning minor corrections to the SPC/Product Literature.
•	22 July 2004	Addition of a Distributor of the finished product.
•	31 October 2003	Change to product Safety Warnings.
•	24 October 2003	Renewal.
•	19 September 2003	Addition of a second manufacturer of the Active Substance.
•	12 September 2003	Variation to correct SPC without safety implications.
•	31 May 2002	Review of Marketing Authorisation.