Veterinary Medicines Directorate

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Post Authorisation Assessments

NEMOVAC Lyophilisate for Oculonasal Suspension/use in Drinking Water

Vm 08327/5008

•	20 October 2024	This variation was aimed to change the name and address change of this subcontractor.
•	14 March 2024	Introduction of Local Representative information for UK(GB), UK(NI) and IE.
•	14 March 2024	Changes submitted in order to align certain sections of the GB QRD (outer carton and package leaflet) with the text agreed during the EU procedure.
•	10 November 2023	Update of SPC and QRD to GB national template v1.
•	01 November 2023	Update to the description of starting materials of biological origin.
•	26 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	10 February 2023	The variation is to introduce the use of recombinant trypsin as a substitute to porcine trypsin for the manufacture of the active substance.
•	12 December 2022	Additional site for secondary packaging for the finished product.
•	22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	10 November 2020	Change of a test procedure for the active substance.
•	27 October 2020	Change in the manufacturing process of the finished product.
•	22 July 2020	Change in the name of a manufacturer of the active substance.
•	18 June 2020	Change in the name of the manufacturer of the finished product.
•	27 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	16 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Limited, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG, United Kingdom to Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.
•	04 June 2018	Change of RMS from UK to FR.
•	12 April 2018	Change of a test procedure for the finished product.
•	31 October 2017	Replacement of a test procedure for the active substance.
•	30 August 2017	Change in the address of the marketing authorisation holder in BE, DK, FI, LU, NO, PT, ES & SE only.

•	26 August 2015	Change in the batch size of the finished product.
•	12 June 2014	Change of MAH address in Portugal only.
•	04 April 2014	Change of MAH address in Spain only.
•	13 July 2012	Deletion of an active substance manufacturer.
•	13 January 2011	Changes in the manufacturing process of the active substance.
•	22 April 2010	Renewal.
•	29 April 2009	Variation to implement the Ph. Eur. general chapter 2.6.25 "Avian live virus vaccines - tests for extraneous agents in batches of finished product"
•	19 May 2008	MRP – UK as RMS.
•	28 November 2007	To add an additional manufacturer of the active ingredient.
•	08 January 2007	To change the size of the container.
•	14 June 2006	Transfer of the freeze drying from Merials Lyon Gerland (LLG) site to the Merial's Lyon Porte des Alpes (LPA) site.
•	14 June 2006	The parameters for temperature and pressure have been slightly adapted.
•	12 January 2006	Renewal.
•	21 July 2004	Variation to update the SPC.
•	21 July 2004	Repeat use procedure.
•	19 January 2004	Change of batch release site.
•	28 November 2003	Change of address of the Marketing Authorisation Holder in France.
•	09 May 2003	Addition of suppliers for a starting material used in the manufacturing process of the active substance.
•	21 March 2002	Change to the ingredient specification.
•	14 July 2000	Change of address of a control site.