Veterinary Medicines Directorate

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# Post Authorisation Assessments

## NEMOVAC Lyophilisate for Oculonasal Suspension/use in Drinking Water

Vm 08327/5008

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| 29 October 2026 | Deletion of a manufacturer responsible for a starting material. |
| 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 |

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| | 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. |