Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Nobivac DHPPi, Lyophilisate for Suspension for Injection for Dogs

Vm 01708/4359

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| • | 12 March 2024 | The registration dossiers of the concerned products are supplemented with (i) the information on the use of animal derived trypsin in the manufacture of the hydrolysed gelatin and with (ii) respective extraneous agents and TSE risk assessments. |
| • | 13 October 2022 | Update of the Product Information following the most recent PSUR assessment and editorial changes to comply with QRD template version 8.2. |
| • | 23 February 2022 | Minor changes to an approved test procedure of the finished product.<br>Minor change in the manufacturing process of an immediate release solid oral dosage form. |
| • | 19 January 2022 | Change in the SPC, labelling or package leaflet due to new data. |
| • | 23 April 2021 | Change in the address of a manufacturer used in the manufacture of the active substance. |
| • | 05 November 2020 | Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited |
| • | 30 January 2017 | Update of the product literature for Nobivac DHPPi (SPC section 4.8 and minor changes to sections 4.9 and 6.2 plus the product leaflet section 12) following the approval of the compatibility claim for mixing of Nobivac L4 with Nobivac DHPPi. |
| • | 11 August 2016 | Increase in batch size of active substance |
| • | 05 September 2013 | Change to the name of a manufacturer of the finished product. |
| • | 08 February 2013 | Addition of a manufacturer of the finished product, including batch release and addition of a site for QC testing. Addition of a test performed on the finished product. |
| • | 15 December 2011 | Change in batch size of the finished product. |
| • | 08 July 2010 | Renewal. |
| • | 18 March 2009 | Increase of batch size of the active substance and minor changes to the manufacturing process of the active substance. |
| • | 15 January 2009 | Change of batch safety test procedure. |
| • | 09 April 2008 | Minor change in the manufacture of the finished product. |
| • | 12 December 2007 | Change of packaging material. |
| • | 04 July 2007 | Addition of a manufacturer of the active substances. |

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| • | 01 June 2007 | Submission of an updated Ph. Eur. Certificate of Suitability for an excipient. |
| • | 14 September 2006 | Change of shelf life of active substances. |
| • | 17 May 2006 | Changes to bring the SPC and Product Literature in line with new legislation. |
| • | 20 October 2005 | Reviewed MA. |