Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Nobivac DHP

Vm 06376/5034

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| September 2026 | Addition of an alternative sterility testing method for the finished product: automated growth detection systems.<br>Addition of an alternative sterility testing method for the active substance: automated growth detection systems. |
| 27 July 2026 | To add the use of recombinant trypsin in the manufacture of the Byco-C hydrolysed gelatin, to ensure uninterrupted supply. |
| 14 March 2026 | Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. |
| 18 December 2025 | To delete two sites for the manufacture of the active substance and solvent. |
| 12 March 2025 | Change in legal entity of the Marketing Authorisation Holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ United Kingdom to Intervet International B.V., Wim de Körverstraat 35 5831 AN Boxmeer, The Netherlands. |
| 19 January 2025 | Alignment of the product information with version 3 of the GB SPC/QRD template. |
| 26 February 2024 | The variation is to mention the use of animal derived trypsin in the manufacture of the Byco-C hydrolysed gelatin provided by Croda and to declare a change in the hydrolysis step of the gelatin (excipient) by replacing porcine trypsin by the use of either porcine or bovine trypsin. |
| 27 January 2023 | Change in the finished product. |
| 18 January 2023 | Change in the finished product. |
| 25 February 2022 | Change in the SPC, labelling or package leaflet due to new data. |
| 28 May 2021 | Change in the address of a manufacturer used in the manufacture of the active substance. |
| 14 August 2020 | Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited. |
| 27 April 2016 | Increase in the batch size for the finished product.<br>Increase in the maximum size of the bulk blend of the finished product. |
| 20 September 2013 | Variation to change the name of a Manufacturer of the finished product. |
| 22 December 2009 | Renewal. |
| 03 April 2009 | Addition of a production site for an antigen. |
| 09 February 2009 | Variation to waive a batch safety test. |
| 28 May 2008 | Variation to update a production process. |
| 30 January 2008 | Introduction of a new packaging material. |
| 15 August 2007 | Addition of manufacturing sites for antigens. |

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| 16 July 2007 | Variation to submit a new TSE European Pharmacopoeia Certificate of Suitability. |
| 04 April 2007 | Addition of a Manufacturer (blending, filling and freeze-drying). |
| 20 November 2006 | Variation to change onset of immunity. |
| 20 November 2006 | Variation to change excretion claim. |
| 03 July 2006 | Variation to harmonise the SPC. |
| 14 June 2006 | Addition of a Manufacturer (blending and filling). |