



Post Authorisation Assessments

Nobivac DHP Vm 06376/3036

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.
16 February 2026	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 9.0* of the 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. 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.
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).