Veterinary Medicines Directorate

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Post Authorisation Assessments

Nobivac DHP
Vm 01708/5117

•	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).