Veterinary Medicines Directorate

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Post Authorisation Assessments

Nobivac Parvo-C Lyophilisate for Suspension for Injection for Dogs

Vm 01708/4361

•	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.
•	05 January 2023	To replace the tissue culture medium used during finished product formulation (blending) with a basal medium.
•	18 November 2022	Change(s) in the SPC, labelling or package leaflet to section 4.6 and 6. Changes to the SPC and / or product literature to sections 4.3, 4.4, 4.5; 4.8; 4.9 and 4.10.
•	20 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.
•	27 July 2017	Update of the pharmaceutical form on the SPC to align with the EDQM Standard Term and to update the full product name in line with QRD requirements.
•	05 September 2013	Change of name of a manufacturer if the finished product
•	15 December 2011	Change in batch size of the finished product
•	08 July 2010	Renewal
•	18 March 2009	Addition of a manufacturing site for part of the manufacturing process of the finished product
•	19 January 2009	Change to batch safety test on the finished product
•	07 December 2007	Introduction of new packaging material
•	01 June 2007	Submission of an updated Ph. Eur. Certificate of Suitability for an excipient
•	14 September 2006	Change of shelf life of the active substance from 24 to 36 months
•	26 July 2006	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	24 October 2005	Review
•	13 June 2005	Renewal
•	10 June 2005	Change of distributor
•	09 December 2003	Change of re-vaccination interval from every 2 years to

		every 3 years
•	04 April 2003	Submission of a TSE Certificate
•	17 February 2003	Change of batch size of the finished product
•	13 August 2002	Change of re-vaccination interval from every 1 year to every 2 years
•	04 February 2002	Change of manufacturing site of the active substance
•	08 November 2001	Addition of a distributor in Northern Ireland
•	22 October 2001	Change of formulation
•	30 November 2000	Change of manufacturing site of the dosage form
•	25 July 2000	Renewal Change of MAH address
•	21 September 1999	Change of dosage particulars
•	25 February 1998	Change of specification for the finished product
•	26 March 1997	Change of product name from ‘Nobivac Parvo c’ to ‘Nobivac Parvo-C’
•	19 September 1996	Additional presentation
•	20 November 1995	Change of product name from ‘Nobi-vac Parvo-c’ to ‘Nobivac Parvo c’
•	07 August 1995	Renewal Change of manufacturer of the active substance