Veterinary Medicines Directorate

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Post Authorisation Assessments

Nobivac KC
Vm 01708/5092

•	03 April 2024	G.I.18 update of product information.
•	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.
•	09 August 2023	Extension of the storage period of antigen.
•	23 December 2021	Deletion of a pack size(s) of the finished product. 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.
•	15 April 2021	Change in the SPC, Labelling or Package Leaflet following a periodic safety update report (PSUR).
•	10 June 2020	Change of MAH from Intervet International BV, Represented by:, Intervet UK Ltd., Walton Manor, Walton, Milton Keynes, Bucks, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	02 April 2020	Change in the manufacturing process of the active substance.
•	17 April 2019	Changes in the SPC, Labelling or Package Leaflet intended to implement the outcome of a procedure concerning PSUR
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	07 March 2018	Change in RMS from UK to IT
•	13 June 2017	Changes in the manufacturing process of the finished product.
•	16 December 2016	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	16 December 2015	An addition of an alternative sterilisation method for stoppers.
•	16 December 2015	An introduction of a real-time PCR test.
•	01 October 2015	Minor amendments to SPC & package leaflet to implement outcome of PSUR.

•	29 April 2015	Approval of mock-ups.
•	13 March 2015	Removal of the administration device from the packaging.
•	04 December 2014	Update to the DDPS.
•	23 July 2013	Significant changes to the SPC/PL.
•	30 August 2012	Renewal.
•	17 June 2010	Changes to an existing pharmacovigilance system.
•	21 October 2009	Change of production site.
•	01 September 2009	Change of MAH name/address.
•	17 December 2008	Minor amendments to production process, addition of an alternative manufacturer,
•	03 April 2008	Repeat Use procedure.
•	03 April 2008	Renewal procedure.
•	30 January 2008	Simple text changes to SPC and product literature.
•	08 January 2008	To change product literature to comply with CMDV referral.
•	07 December 2007	New, updated TSE Ph. Eur CofS for excipient from an approved manufacturer.
•	14 December 2005	Other.
•	11 August 2005	Variation to comply with Ph. Eur. or MS national pharmacopoeia.
•	20 June 2005	Variation to change the distributor.
•	25 January 2005	Addition of a manufacturer responsible for blending, filling and freeze drying.
•	09 June 2004	Extension of the duration of immunity.
•	22 March 2002	Change to the ingredient specification according to TSE compliance.
•	27 December 2001	Addition of a distributor.
•	27 December 2001	Change of finished product formulation.
•	19 October 2000	MRP – UK as RMS.
•	30 June 2000	Change of name and address of the Marketing Authorisation Holder.
•	31 March 2000	Change to the therapeutic purpose.