Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Nobivac Ducat
Vm 06376/5013

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.
20 January 2026	To delete a site for manufacture of the active substance and the solvent.
14 November 2024	Change in legal entity of MA holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ to Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands.
07 June 2024	Alignment of the product information text with version 2 of the GB and 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.
23 March 2023	This variation proposes to change the product information (update SPC section 4.6), assessed by VMD and RMS. The period of assessment of the PSUR covers 1 Aug 2017 to 31 July 2020. The wording has already been agreed, and this variation implements those changes. Updated to the Annotated Updated National SPC QRD Template.
28 May 2021	Change in the address of a manufacturer used in the manufacture of the active substance.
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.
13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
26 June 2018	Increase in batch size of active substance or intermediate used in the manufacturing process of the active substance.
01 June 2018	Change in the specification limits of the finished product.
05 January 2017	Changes to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH.
28 April 2016	Change in test procedure for the finished product.

19 February 2015	Approval of mock-ups.
28 November 2014	Update to the DDPS.
16 October 2014	To introduce PET boxes as additional secondary packaging.
14 January 2011	Variation concerning the addition of a Manufacturer.
29 May 2010	Variation to make changes to an existing pharmacovigilance system.
19 August 2009	European Renewal.
30 January 2008	Introduction of a new packaging material.
16 January 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2001.
20 November 2006	Variation concerning the addition of a Manufacturer.
17 May 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
18 April 2006	Addition of Manufacturing sites.
05 August 2005	Variation to change a finished product test procedure.
18 October 2004	New EUDE.