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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the <u>EMA</u> website.

Nobivac Myxo-RHD PLUS Lyophilisate and Solvent for Suspension for Injection for Rabbits

Vm 01708/5050

	14 May 2024	One-off alignment of the SPC/QRD as per the GB national template v2.
•	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.
•	24 January 2023	To replace the tissue culture medium used during finished product formulation (blending) with a basal medium.
•	12 October 2022	Change(s) in the SPC, labelling or package leaflet to section 4.6 and 6 adverse reactions.
•	06 December 2021	Changes to the labelling and/or package leaflet.