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Post Authorisation Assessments

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

Nobilis IB 4-91 Lyophilisate for Oculonasal Suspension/use in Drinking Water for Chickens
Vm 01708/5043

•	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 January 2024	Add onset of immunity and duration of immunity to the relevant sections of the product information text. Updating the Product Information in line with the version 9.0 of the QRD templates and updating GB template v1.0
•	13 January 2023	To add a claim for associated non-mixed use of Nobilis IB 4-91 with Innovax-ND-ILT in the product information text of Nobilis IB 4-91. This change affects section 4.8 of the SPC and section 12 of the Package leaflet.
•	06 May 2022	Approval of Mock-ups.
•	26 February 2021	Grouped variation: Addition of a manufacturing site of the finished product, change in the specification limits of the finished product, change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product, changes to a test procedure for the finished product, changes to a test procedure for the finished product, change in the number of units in a pack outside the range of the currently approved pack sizes of the finished product, addition of a secondary packaging site of the finished product, change in the number of units in a pack within the range of the currently approved pack sizes of the finished product, change in the number of units in a pack within the range of the currently approved pack sizes of the finished product and change in any part of the (primary) packaging material not in contact with the finished product formulation - Other variation.