

## Post Authorisation Assessments

### Nobilis *E. coli* inac Emulsion for Injection for Chickens Vm 06376/3011

16 May 2026	The proposed variation is to add the use of animal-component-free recombinant trypsin in the manufacture of the hydrolysed gelatine Byco-C produced by Croda to ensure uninterrupted supply of this stabiliser component.
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.
17 April 2025	To add a manufacturer of raw material Ampicillin that is used for the antigen production.
10 December 2024	Change in legal entity of MA holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes MK7 7AJ, United Kingdom to Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands.
06 June 2024	Replacement of purified FT reference antigen used in antigenic mass ELISA for determination of the antigen content in FT antigen batches.
06 June 2024	Alignment of the product information text with version 1 of the GB and QRD template.
26 February 2024	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.
16 October 2020	Replacement of a site where batch control/testing takes place.
14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
18 June 2019	Changes in the manufacturing process of the active substance
20 April 2012	Change of manufacturer of the finished product
15 December 2010	Renewal
22 January 2010	Change of manufacturing process of the active substance
06 February 2008	Change of legal category from POM to POM-V
05 May 2006	Change of source of an excipient
10 June 2005	Change of distributor
17 March 2005	Renewal
10 January 2003	Change to specification of the active substance
13 July 2000	Change of address of the MAH
22 March 2000	Renewal
22 December 1999	Change to shelf life
29 January 1997	Change to composition of immediate packaging
14 January 1997	Change to test procedure performed on the finished product
11 November 1996	Change of product name from 'Nobivac <i>E. coli</i> (nl)' to 'Nobilis <i>E. coli</i> inac'
01 November 1996	Change to specification of the finished product

29 July 1996	Change of product name from 'Nobi-vac <i>E. coli</i> ' to 'Nobivac <i>E. coli</i> (nl)'
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