Veterinary Medicines Directorate

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Post Authorisation Assessments

Nobilis E. coli inac Emulsion for Injection for Chickens

Vm 01708/5085

•	13 April 2024	To adapt the v2 Template of the GB SPC/QRD as part of a G.I.18 VRA application.
•	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.
•	28 December 2023	Replacement of reference material used during in-process testing.
•	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 *E. coli* (nl)’ to ‘Nobilis *E. coli* inac’
•	01 November 1996	Change to specification of the finished product
•	29 July 1996	Change of product name from ‘Nobi-vac *E. coli*’ to ‘Nobivac *E. coli* (nl)’