



## Post Authorisation Assessments

### Nobilis Gumboro D78 Lyophilisate for Oculonasal Suspension/Use in Drinking Water for Chickens Vm 06376/4121

01 March 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
22 December 2025	One-off alignment of the product information with version 3 of the GB SPC and QRD templates.
18 June 2025	To replace the primary packaging component materials containing Bisphenol A (BPA) with BPA-free material.
25 March 2025	Change in test procedure for the finished product. Change in the storage conditions of the finished product. Change in storage conditions of the active substance. Change to in-process tests applied during the manufacture of the active substance. Changes in the manufacturing process of the active substance. Changes in the manufacturing process of the active substance.
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.
27 October 2021	Addition of new tests and limits applied during the manufacture of the finished product. Addition to a test procedure for the finished product. Addition to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Change in type of container for the finished product. Changes in the manufacturing process of the finished product.
25 June 2021	Change in the name and address of the manufacturer of the finished product.
12 February 2021	Change in the name of the MAH from Intervet UK Limited to MSD Animal Health UK Limited.
15 August 2018	Change in immediate packaging of the finished product. Changes in the manufacturing process of the finished product.
02 July 2015	Updates to the SPC and product literature.
28 March 2012	Change of manufacturer of the active substance
22 March 2012	Change of manufacturer of the finished product
20 November 2009	Change of name of manufacturer of excipients
31 July 2008	Renewal
17 June 2008	Addition of manufacturing site for testing

13 June 2007	Addition of 1,000, 2,000, 2,500, 3,000, 5,000 & 10,000 dose presentations
20 December 2006	Changes to the SPC and Product Literature to bring in line with new legislation Change to legal category from POM to POM-V
26 May 2005	Change of distributor
17 March 2005	Change of diluent container
18 February 2005	Change of finished product specification
04 June 2004	Renewal
24 July 2003	Addition of a manufacturing site for secondary packaging
04 September 2001	Addition of a distributor
13 July 2000	Change of address of the MAH
09 May 2000	Addition of a manufacturer of the active substance
06 July 1999	Renewal
28 January 1999	Renewal
09 January 1998	Change of legal category from PML to POM
15 July 1997	Update to licence particulars
17 June 1997	Change of product name from 'Gumboro Vaccine Nobilis D78' to 'Nobilis Gumboro D78 Live'
14 June 1996	Change to formulation
02 August 1994	Addition of a manufacturing and assembly site of the dosage form