Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Gallimune 302 ND + IB + EDS Emulsion for Injection

Vm 61700/3008

02 December 2025	Change in legal entity of MA holder from Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom to Boehringer Ingelheim Vetmedica GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany.
25 March 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
22 November 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
11 April 2023	To replace the current PCR method for the chlamydia purity test of a starting material by another in-house PCR method.
03 March 2023	Addition of a secondary packaging site.
24 January 2023	Replacement of the currently subcontracted PCR method for the chlamydia purity test of duck embryo cells by an in-house PCR method.
14 December 2022	Additional secondary packaging site for the finished product.
06 September 2022	Changes in the manufacturing process of the active substance.
04 July 2022	Correction of mistakes and editorial change in the description of the manufacturing process of active substance.
22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
22 October 2021	Review and subsequent adjustment of a manufacturing process.
02 July 2021	Change in the specification parameters and/or limits of the immediate packaging of the finished product.
19 March 2021	Minor changes to an approved test procedure of the finished product
15 February 2021	Deletion of manufacturing site for the finished product.
14 January 2021	Deletion of manufacturing site for an active substance.
14 August 2020	Changes in the manufacturing process of the finished product.
22 July 2020	Change in the name of a manufacturer of the active substance.
18 June 2020	Change in the name of the manufacturer of the finished

	product.
27 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
16 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Limited, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG, United Kingdom to Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.
28 June 2018	Change in the name of a manufacturer used in the manufacture of the active substance. Change in the name of the manufacturer of the finished product.
05 June 2017	Changes to a test procedure (including replacement * or addition*) for a reagent used in the manufacturing process of the active substance.
07 November 2016	Addition of a manufacturing site of the finished product
21 March 2014	Change in the name and/or address of the marketing authorisation holder
13 January 2014	Change in the name and/or address of the marketing authorisation holder
05 July 2013	Update to Part II of the dossier
06 March 2013	Changes to comply with Ph. Eur.
06 July 2012	Deletion of a manufacturing site of an active substance
23 November 2010	Minor change of manufacturing process of an active substance
09 July 2009	Renewal
29 January 2009	Change to shelf life of the Egg Drop Syndrome active substance from 7 months to 12 months
17 January 2008	Change of manufacturer of the active substances
08 March 2007	Change of legal category from POM to POM-V
12 February 2007	Addition of a manufacturer of active substances