Veterinary Medicines Directorate

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Post Authorisation Assessments

Gallimune 407 ND + IB + EDS + ART

Vm 08327/4217

•	31 October 2023	Update to the description of starting materials of biological origin.
•	17 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	11 April 2023	To replace the current PCR method for the chlamydia purity test of a starting material by another in-house PCR method.
•	08 March 2023	Addition of a secondary packaging site.
•	10 February 2023	The variation is to introduce the use of recombinant trypsin as a substitute to porcine trypsin for the manufacture of the active substance.
•	03 February 2023	Deletion of a manufacturer of the active substance.
•	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	Addition of a secondary packaging site for the finished product.
•	12 December 2022	Deletion of a manufacturer of the active substance.
•	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.
•	10 November 2020	Change of a test procedure for the active substance.
•	14 October 2020	Change in the name of a manufacturer of active substance used in the manufacture of the 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.
•	23 July 2018	Replacement of a test procedure for the finished product.
•	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.
•	31 October 2017	Replacement of a test procedure for the active substance.
•	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 for an active substance
•	23 November 2010	Change to manufacturing process of an active substance
•	13 July 2009	Addition of a manufacturing site for the active substance
•	09 July 2009	Renewal
•	26 January 2009	Change of 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