Veterinary Medicines Directorate

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Post Authorisation Assessments

Gallimune 303 ND + IB + ART

Vm 08327/3020

•	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.
•	14 March 2024	To align the product information with QRD template v9.0.
•	14 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	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.
•	20 January 2023	Deletion of a manufacturing site of the active substance.
•	12 December 2022	Addition of a secondary packaging site.
•	09 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.
•	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.
•	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.
•	13 July 2009	Addition of a manufacturing site for an active substance
•	09 July 2009	Renewal
•	07 March 2007	Joint labelling between UK and IE
•	12 February 2007	Addition of a manufacturer of active substances