Veterinary Medicines Directorate

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Post Authorisation Assessments

Gallimune Se + St, Water-in Oil Emulsion for Injection

Vm 08327/5044

08 March 2026	To update the manufacturing flowchart and the dossier to reflect the correct order of steps of manufacturing of the finished product.
01 April 2025	G.I.18 Update to version 3 of the national template.
November 2024	[Lowering of the current minimal irradiation dose (at least 25 kGy), used for sterilisation of the bottles before filling, to at least 17.5 kGy (by ebeam), while maintaining compliance to Ph. Eur. 5.1.1 requirement to keep a sterility assurance level (SAL) equal or less than 10^-6] Changes in the sterilisation process of the immediate packaging.
17 July 2024	Changes in the sterilisation process of the immediate packaging.
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. (NI)
17 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
14 January 2021	Deletion of manufacturing site for an active substance.
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.
21 June 2018	Change in the name and/or address of the marketing authorisation holder in BE, DK, ES, IT, NL, PT and LU only. Change in the name and address of a manufacturer of the finished product, also responsible for batch release. Change in the name and address of a manufacturer of an active substance.
07 June 2018	Change in RMS from UK to DE
30 August 2017	Change in the address of the marketing authorisation holder in BE, DK, FI, LU, NO, PT, ES & SE only.
23 November 2016	Replacement of a site where batch control/testing takes place.

31 July 2014	Deletion of a specification parameter of the finished product.
12 June 2014	Change of MAH address in Portugal only.
04 April 2014	Change of MAH address in Spain only.
16 January 2014	Change of MAH address in Belgium only.
02 March 2012	Renewal – UK as RMS
23 February 2011	To change the specifications for *Salmonella* Enteritidis component.
23 February 2011	To change the name of the site for control testing using animals.
23 February 2011	To change the sites for control Serological test for *Salmonella* Enteritidis and *Salmonella* Typhimurium components