Veterinary Medicines Directorate

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Post Authorisation Assessments

Gallivac IBD

Vm 08327/4192

•	23 November 2023	Editorial changes to part 2E of the dossier.
•	24 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	14 December 2022	Additional secondary packaging site for the finished product.
•	15 February 2021	Deletion of manufacturing site for 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.
•	29 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	12 April 2018	Change of a test procedure for the finished product.
•	30 May 2012	Deletion of a manufacturing site of the active substances
•	04 March 2009	Harmonisation of the SPC
•	10 October 2008	Renewal
•	31 July 2008	Changes to comply with Ph. Eur.
•	24 October 2007	Change of manufacturer of the active substances
•	27 September 2006	Change of manufacturing site for secondary packaging
•	22 December 2004	Renewal
•	28 March 2003	Addition of 4 manufacturers of starting materials used in the manufacture of the active substances
•	25 July 2002	Addition of manufacturer of the dosage form
•	27 April 2001	QC Procedures
•	31 August 2000	Addition of a manufacturing site for the dosage form and quality control
•	16 April 1999	Change of formulation Update of licence particulars Additional presentation