Veterinary Medicines Directorate

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Post Authorisation Variations

Solvent for Cell Associated Poultry Vaccines

Vm 08327/4219

•	08 March 2023	Change in test procedure for the finished product.
•	03 February 2023	Addition of Bioluz Laboratory as an alternative manufacturer responsible for batch release of Solvent for cell associated poultry vaccines.
•	23 January 2023	Deletion of a batch control site for the finished product.
•	11 July 2022	Harmonise the solvent name used for the preparation of Cryomarex Rispens, Cryomarex HVT, Cryomarex Rispens+HVT. The diluent has also its own marketing authorisation under the trade-name of Dilumarex.
•	24 March 2022	Change to part of the (primary) packaging material not in contact with the finished product formulation.
•	22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	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.
•	10 April 2018	Tightening of specification limits of the finished product. Addition of a secondary packaging site of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Addition of a site where batch control/testing takes place. Replacement of a manufacturing site of the finished product.
•	24 May 2017	Deletion of the compatibility test.
•	24 March 2010	Renewal UK as CMS