Veterinary Medicines Directorate

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Post Authorisation Assessments

Zermex 100 mg/ml LA Solution for Injection for Cattle

Vm 42058/4172

•	12 April 2021	Change in batch size range of the finished product.
•	23 March 2021	Change in distributor details. From Downland Marketing Limited, 15 Victoria Place, Carlisle, Cumbria, CA1 1EW to Downland Marketing Limited, Main Mill, Warwick Mill Business Centre, Warwick Bridge, Carlisle, Cumbria, CA4 8RR.
•	22 October 2019	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	10 May 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	12 December 2018	Change to part of the (primary) packaging material not in contact with the finished product formulation. Change in shape or dimensions of the container or closure (immediate packaging).
•	13 November 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	30 January 2018	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	28 December 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	13 January 2017	Submission of a new or updated Eur. certificate of suitability.
•	01 August 2016	Variation to implement changes in the product information as requested by the RMS as a result of the review of PSUR.
•	08 July 2015	Submission of a new Ph. Eur. Certificate of Suitability.
•	05 June 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure
•	10 December 2014	Renewal.
•	4 July 2014	Submission of an updated Ph. Eur. Certificate of Suitability.
•	30 October 2013	Change in name of manufacturer of the finished product and batch release. Change in QPPV contact details.
•	23 October 2013	Change in name of the MAH in Austria, Belgium,

		France and Luxembourg only.
•	30 July 2013	Change of MAH.
•	4 November 2011	Change in the name of a manufacturer of the finished product.
•	2 September 2011	Submission of new Ph. Eur. Certificate of Suitability.
•	14 October 2010	Change in the specifications of the finished product. Change in the shelf-life of the finished product. Change in the specifications/parameters of the finished product.
•	26 May 2010	To change the MAH from “Fort Dodge Animal Health Ltd” to “Pfizer Limited”.