Veterinary Medicines Directorate

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Post Authorisation Assessments

Zermex 20 mg/ml LA Solution for Injection for Sheep

Vm 42058/4173

•	23 December 2022	Change in any part of the primary packaging material not in contact with the finished product formulation.
•	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
•	19 March 2019	Change in the dimensions of the container (immediate packaging) for a sterile medicinal product.
•	18 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 September 2016	Change(s) in the SPC, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning 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.
•	04 July 2014	Submission of an updated Ph. Eur. Certificate of Suitability.

•	30 October 2013	Changes to an existing pharmacovigilance system as described in the DDPS. Change to the name of the active substance manufacturer. Change to the name of the manufacturer for the finished product and for batch release.
•	23 October 2013	Change to the name of the MAH from Pfizer to Zoetis in AT, BE, FR and LU only.
•	30 July 2013	Transfer of MA from Pfizer Ltd to Zoetis (UK) Limited.
•	10 December 2012	Addition of a new therapeutic indication to the SPC and product literature.
•	13 June 2012	Introduction of a new pharmacovigilance system.
•	30 March 2012	To extend the shelf life of the finished product as packaged for sale from 2 years to 3 years.
•	04 November 2011	Change in the name and/or address of a manufacturer of the finished product, including quality control sites.
•	02 September 2011	Submission of a new or updated Ph. Eur. certificate of suitability.
•	26 May 2010	To change the MAH from “Fort Dodge Animal Health Ltd” to “Pfizer Limited”.