Veterinary Medicines Directorate

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Post Authorisation Assessments

Zylexis for Horses Vm 42058/4174

•	25 March 2024	Change in the source of a starting material used in the manufacturing process of the active substance.
•	08 April 2021	Updates to SPC and package leaflet as a result of a periodic safety update report. Update of product information in accordance with latest QRD text.
•	01 May 2020	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.
•	09 April 2020	Replacement of a test procedure for the finished product.
•	23 October 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	10 June 2015	Update to the DDPS.
•	13 May 2014	Transfer of MA from Pfizer Ltd to Zoetis UK Limited and change of distributor. Change of name of the active substance manufacturer and finished product manufacturer, and also change to the QPPV contact details.
•	18 February 2013	To replace the stabiliser used in the formulation.