



## Post Authorisation Assessments

### Zylexis for Horses

Vm 42058/5208

17 December 2025	To add an already authorised site for Physical/Chemical testing of the active substance to the manufacturing flow chart. To add an already authorised site for Physical/Chemical testing of the finished product to the manufacturing flow chart.
19 May 2025	Change of Marketing Authorisation Holder from Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP to Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown, Dublin 18, D18 T3Y1, Ireland (NI-only).
14 June 2024	a. The addition of acceptable countries of origin as source for the porcine pancreas used to make the porcine trypsin powder. b. The removal of the countries of origin for the lactose used in the production process of porcine trypsin. c. To make some editorial changes in the TSE risk assessment.
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.