Veterinary Medicines Directorate

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Post Authorisation Assessments

Rispoval 4

Vm 42058/5171

27 March 2026	To add an already authorised site for biological 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.
06 November 2025	G.I.18 Update to version 3 of the national template.
15 November 2024	Change of Legal Entity for UK(NI) from Zoetis UK Limited to Zoetis Belgium S.A.
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.
03 September 2020	Deletion of a specification parameter of the finished product.
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 November 2017	Tightening of specification limits of the finished product. Change in the fill weight/fill volume of the finished product.
20 October 2016	Deletion of a test procedure for the finished product.
22 December 2015	Harmonization in the vial size of the 5 dose presentation
08 August 2012	Extension of shelf-life of antigen bulks.
09 May 2012	Extension of shelf-life of the finished product.
07 December 2011	Removal of a test from the FPS.
09 November 2011	Change in the manufacturing process of the finished product.
09 November 2011	Change in the manufacturing process of the active substance.
29 December 2009	Addition of suppliers of materials.
27 February 2008	Changes to the SPC and product literature to bring them into line with new legislation.
04 October 2006	Renewal
27 June 2005	Additional distributors.
10 December 2004	Change in specifications of a starting material.
16 April 2004	Increase in shelf-life of the finished product.
05 March 2004	Change in specification of active substance.