



Post Authorisation Assessments

Risposal 4 Vm 42058/4125

•	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.