



Post Authorisation Assessments

Vanguard CPV

Vm 42058/5179

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| 14 January 2025 | Change in legal entity of MA holder for Northern Ireland only 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. |
| 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. |
| 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. |
| 19 October 2018 | Change in the specification parameters and/or limits of the finished product. |
| 09 November 2016 | Change in the composition (excipients) of the finished product. |
| 19 February 2014 | Transfer of MA from Pfizer Ltd to Zoetis UK Limited and change of distributor. Change of name of the active substance manufacturer and change of name of the finished product manufacturer responsible for batch release. |
| 16 December 2010 | Renewal. |
| 18 November 2010 | Removal of a test. |
| 07 July 2010 | Reduction of the immunity period of an active substance. |
| 17 February 2010 | Addition of suppliers of starting materials. |
| 15 July 2009 | Changes to the wording of Section 4.2 of the SPC. |
| 25 May 2006 | Changes to the SPC and product literature to bring them into line with new legislation. |