Veterinary Medicines Directorate

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Post Authorisation Assessments

Rispoval IBR-Marker Inactivated

Vm 42058/5141

•	16 February 2023	Addition of Denmark, France, Germany and the Netherlands as a source of porcine pancreas used for the production of trypsin powder.
•	16 November 2022	Addition of Denmark, France, Germany and the Netherlands as a source of porcine pancreas used for the production of trypsin.
•	27 November 2019	Replacement of a test procedure for an excipient.
•	14 November 2019	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.
•	25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	10 July 2018	Changes to a test procedure for the finished product.
•	03 March 2016	Change in the release limits for the Thiomersal content of the product. Deletion of a release test that is no longer required.
•	27 July 2015	Update to section 4.2 of the SPC following new clinical data.
•	29 May 2015	Deletion of a test procedure.
•	30 April 2015	Change in the QPPV contact details.
•	17 July 2014	Change to the product's shelf-life, from 24 months to 36 months.
•	21 October 2013	Change in the name/address of the MAH in BE, FR and LU only.
•	09 October 2013	Change in the name of the active substance manufacturer. Change in the name of the finished product manufacturer and site of batch release. Change in the QPPV contact details.
•	31 July 2013	Change of MAH from Pfizer Ltd to Zoetis UK Limited. Change of distributor and editorial change to distributor address.
•	09 October 2012	Change to section 4.9 of the SPC and package leaflet.
•	01 August 2012	Change of contact details of the site and qualified person(s) responsible for pharmacovigilance.
•	03 June 2011	Approval of mock-ups for an authorised pack size.
•	25 May 2011	Change of name/address of the Spanish MAH
•	11 March 2011	Change of MAH address of the local office in Poland.
•	25 May 2010	Renewal.

•	14 August 2009	Removal of a safety test that is no longer required in line with Ph.Eur.
•	26 June 2008	Update to packaging to note the Irish legal category.
•	30 April 2008	Repeat Use.
•	27 December 2007	Extension of antigen shelf-life.
•	28 November 2007	Deletion of a manufacturer.
•	30 August 2006	Addition of a claim for foetal protection.
•	12 June 2006	Addition of a site of manufacture.
•	24 August 2005	Addition of a secondary manufacturing site (including blending, filling, finishing, and testing of the finished product).
•	30 June 2005	Change of distributor.
•	22 March 2005	Renewal.
•	16 September 2004	Cessation of printing the batch number of the aluminium caps.
•	16 September 2004	Addition of a secondary packaging site.
•	27 August 2004	Change of product name.
•	12 August 2004	Change of the name of the manufacturer of the finished product.
•	12 March 2004	Change to in-process controls.
•	23 February 2004	Change of MAH from Byer AG to Pfizer Ltd.
•	16 January 2004	Addition of a pack size.
•	04 July 2003	Change of a supplier of an intermediate used in the manufacturer of the active substance.
•	04 April 2002	Change to ingredient specification.
•	27 June 2000	Renewal.