Veterinary Medicines Directorate

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Post Authorisation Assessments

Rispoval IBR-Marker Live

Vm 42058/3015

•	07 November 2023	To add the intranasal vaccination route to cattle of 3 months of age and above. One-off alignment of the product information with version 9.0 of the QRD templates.
•	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.
•	06 December 2021	Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer.
•	03 September 2020	Deletion of a specification parameter of the finished product.
•	19 August 2020	Change of a test procedure for the finished product.
•	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.
•	27 July 2015	Updates to SPC following Repeat Use procedure Updates to SPC due to new clinical data.
•	29 May 2015	Deletion of a test procedure.
•	30 April 2015	Change in the QPPV contact details.
•	23 October 2013	Repeat Use - Comment
•	21 October 2013	To change the name of the MAH in LU and BE only.

•	31 July 2013	Variation to transfer the MA and distributor from Pfizer Ltd to Zoetis UK Ltd. Also an editorial change to the distributor address.
•	01 August 2012	Changes to an established pharmacovigilance reporting system.
•	24 January 2012	Updating of SPC with regard to indications.
•	25 May 2011	Change in the name of the Spanish MAH.
•	15 March 2011	Extend the registered shelf-life of the freeze-dried fraction to up to 36 months at +2°C to +8°C and to allow a previous storage period at -20C or below for up to 15 months.
•	11 March 2011	Change of MAH address in Poland.
•	27 October 2010	Addition of new pack size.
•	26 May 2010	Renewal procedure.
•	14 August 2009	Removal of a safety test.
•	30 July 2008	Repeat Use procedure.
•	26 June 2008	Simple text changes to product literature/SPC.
•	05 March 2008	Deletion of a manufacturing site.
•	12 November 2007	Revision to 'method of administration'.
•	30 August 2006	Contraindications added.
•	07 August 2006	Add the alternative of a single vaccination either intramuscularly for seronegative calves from two weeks of age. Introduce a single vaccination intramuscularly for calves from three months of age with a six month duration of immunity.
•	08 June 2006	Addition of a manufacturing site.
•	30 June 2005	Change of distributor.
•	09 February 2005	Addition of a manufacturing site.
•	30 November 2004	Change to storage temperature
•	12 November 2004	Addition of a manufacturer. Quality of glass vials. Change of rubber stopper formulation
•	15 October 2004	Change in container shape. Change to test Method for Finished Product.
•	16 September 2004	Addition of secondary packaging site. Cessation of printing batch number on aluminium caps.
•	27 August 2004	Change of product name.
•	12 August 2004	Change the Name of the Manufacturer of the active substance. Change the Name of the Manufacturer of the Finished Product.
•	23 February 2004	Change MA Holder from Bayer Ag to Pfizer Ltd
•	04 July 2003	Change in supplier of an intermediate compound used in the manufacture of the active substance.
•	16 June 2002	Addition of a pack size.
•	26 March 2002	Ingredient Specification. TSE Compliance Format 2.
•	11 December 2000	Mutual recognition renewal.
•	30 November 2000	Change in manufacturing process of active substance. Change in Manufacturer of medicinal product. Change in test procedure of active substance.

		Change in test procedure of medicinal product. Sterile Containers.