Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Rispoval 3 BRSV Pi3 BVD Lyophilisate and Suspension for Suspension for Injection for Cattle

Vm 60021/3044

11 March 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
14 January 2025	Change of MAH 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.
22 June 2024	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.
03 September 2020	Deletion of a specification parameter of the finished product.
19 August 2020	Change of a test procedure for the finished product.
10 January 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.
07 November 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
13 December 2017	Change in the fill volume of the finished product.
01 November 2016	Deletion of a test procedure for the finished product.
27 October 2015	Change to comply with Ph.Eur. Changes in pack size of the finished product. Changes to SPC following change in pack size and PSUR data.
05 June 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure
30 October 2013	Change in the name of the manufacturer of the active substance, change in the name of the manufacturer of the finished product responsible for batch release, change in the QPPV contact details.
22 October 2013	Change of MAH in BE, FR and LU only.
31 July 2013	Change of MAH from Pfizer Ltd to Zoetis UK Limited.
13 July 2012	Change of contact details for the QPPV.
26 July 2011	Change of MAH name/address in Spain only.

29 March 2011	Change to the manufacturing process of the active substance and change to the manufacturing process of the finished product.
11 March 2011	Change of MAH address in Poland only.
25 March 2010	Renewal
22 July 2009	Additional suppliers of materials.
26 June 2008	Change of legal category from POM to POM-V.
13 June 2007	Removal of a test.
27 February 2007	Extension of shelf-life to 36 months.
30 June 2005	Addition of a distributor.