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Post Authorisation Assessments

Rispoval 2 / BRSV + Pi3 Lyophilisate and Solvent for Suspension for Injection for Cattle

Vm 60021/3051

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.
15 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.
01 October 2024	Identical updates to section 3.2 & 3.9 of the SPC and section 4 & 8 of the package leaflet. 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 February 2022	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.