

VPA10387/060/001

**Rispoval 3 BRSV Pi3 BVD Lyophilisate and suspension for suspension for injection for cattle**

| Variation            | Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Date     |
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| Vet - F.II.b.2 a) 1. | VRA-R - Vet - F.II.b.2 a) 1. - - Vet - F.II.b.2 a) 1. - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place - Replacement or addition of a site where batch control/testing takes place for a biological/immunological veterinary medicinal product and any of the test methods performed at the site is a biological/immunological method                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 20/02/26 |
| Vet - F.II.b.2 a) z. | VRA-R - Vet - F.II.b.2 a) z. - - Vet - F.II.b.2 a) z. - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place - Other changes under this code level, e.g.variations outlined in section 6 and 7 of this guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 20/02/26 |
| Vet - C1             | VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 10/01/25 |
| Vet - C6             | VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 10/01/25 |
| Vet - G.I.18         | VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 | 17/06/24 |

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| Vet - F.I.a.1 d) | <p>VRA-S - Vet - F.I.a.1 d) - d) The change relates to a biological/immunological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product - F.I.a.1 d) - Quality Changes - Active Substance - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The change relates to a biological/immunological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product</p> | 29/01/24 |
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