VPA10846/019/001

Suiseng Coli /C Suspension for injection for pigs

Variation	Summary	Date
Vet - F.I.a.3 z)	VRA-R - Vet - F.I.a.3 z) - - Vet - F.I.a.3 z) - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	06/07/26
Vet - F.I.a.2 b)	VRA-S - Vet - F.I.a.2 b) - - Vet - F.I.a.2 b) - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol	06/07/26
Vet - F.I.a.2 z)	VRA-R - Vet - F.I.a.2 z) - - Vet - F.I.a.2 z) - Changes in the manufacturing process of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	06/07/26
Vet - F.I.a.2 z)	VRA-R - Vet - F.I.a.2 z) - - Vet - F.I.a.2 z) - Changes in the manufacturing process of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	06/07/26
Vet - F.II.f.1 a) 5.	VRA-R - Vet - F.II.f.1 a) 5. - a) Extension of the shelf life of the finished product 5. Extension of the shelf-life of a biological/immunological medicinal product in accordance with an approved stability protocol. - F.II.f.1 a) 5. Quality Changes -Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - Extension of the shelf-life of a biological/immunological medicinal product in accordance with an approved stability protocol.	09/04/25
Vet - F.II.f.1 a) 5.	VRA-R - Vet - F.II.f.1 a) 5. - a) Extension of the shelf life of the finished product 5. Extension of the shelf-life of a biological/immunological medicinal product in accordance with an approved stability protocol. - F.II.f.1 a) 5. Quality Changes -Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - Extension of the shelf-life of a biological/immunological medicinal product in accordance with an approved stability protocol.	29/05/24
Vet - G.I.4	VRA-S - Vet - G.I.4 - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. - G.I.4 Safety, Efficacy, Pharmacovigilance changes - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or	26/10/23

	pharmacovigilance data.	
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	26/10/23
Vet - F.II.a.3 b) 2.	VRA-S - Vet - F.II.a.3 b) 2. - b) Other excipients 2. Change that relates to a biological/immunological product - F.II.a.3 b) 2. Quality Changes - Finished Product - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a biological/immunological product	26/10/23
Vet - I.I.1 c)	VRA-E - Vet - I.I.1 c) - c) Replacement of a biological active substance with one of a slightly different molecular structure where the efficacy/safety characteristics are not significantly different, with the exception of the changes mentioned in G.I.13 and G.I.14 - I.I.1 c) Changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species - Changes to the active substance(s) - Replacement of a biological active substance with one of a slightly different molecular structure where the efficacy/safety characteristics are not significantly different, with the exception of the changes mentioned in G.I.13 and G.I.14	26/10/23