VPA10454/008/001

Ingelvac PRRSFLEX EU lyophilisate and solvent for suspension for injection for pigs

Variation	Summary	Date
Vet - C10 a)	VNRA - Vet - C10 a) - a) Administrative information concerning the holder's representative - C10 a) Changes to the safety, efficacy and pharmacovigilance part of the dossier: Changes to the labelling or the package leaflet which shall not be connected with the SPC: — administrative information concerning the holder's representative	27/03/23
Vet - F.II.b.3 c)	VRA-S - Vet - F.II.b.3 c) - c) The product is a biological/immunological veterinary medicinal medicinal product and the change requires an assessment of comparability - F.II.b.3 c) Quality Changes - Finished Product -Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - The product is a biological/immunological veterinary medicinal medicinal product and the change requires an assessment of comparability	17/02/23
Vet - F.I.a.1 d)	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	16/12/22
C.I.1.a	IAin - C.I.1.a - a) The medicinal product is covered by the defined scope of the procedure - C.I.1.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a Union referral procedure - The medicinal product is covered by the defined scope of the procedure	28/02/22