VPA10988/101/001

CANIXIN DHPPi lyophilisate and solvent for suspension for injection for dogs

Variation	Summary	Date
Vet - G.I.3 a)	VRA-S - Vet - G.I.3 a) - a) Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH - G.I.3 a) Safety, Efficacy, Pharmacovigilance changes - Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendations from the competent authority or the Agency concerning risk management measures in pharmacovigilance related to veterinary medicinal products - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH	18/10/23
Vet - F.I.a.1 c)	VRA-S - Vet - F.I.a.1 c) - c) New manufacturer of material for which an assessment is required of viral safety and/or TSE risk - F.I.a.1 c) - 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 - New manufacturer of material for which an assessment is required of viral safety and/or TSE risk	03/08/23
Vet - B11 b)	VNRA - Vet - B11 b) - b) Tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance - B11 b) Changes to the quality part of the dossier: Change in the specification parameters or limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance or of the immediate packaging of the active substance — tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance	24/10/22