VPA10387/097/001

Versican Plus Bb Oral lyophilisate and solvent for oral suspension for dogs

Variation	Summary	Date
Vet - F.I.a.1 c)	VRA-R - 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	07/11/23
Vet - G.I.3 a)	VRA-R - 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	17/10/23
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	17/10/23
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 pharmacovigilance data.	17/10/23