VPA22033/029/001

Mectaject Plus Solution for Injection

Variation	Summary	Date
Vet - C1	VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	09/02/26
Vet - C6	VNRA - Vet - C6 - - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex	09/02/26
Vet - B9 a)	VNRA - Vet - B9 a) - a) Up to 10-fold increase compared to the originally approved batch size - B9 a) Changes to the quality part of the dossier: Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance — up to 10-fold increase compared to the originally approved batch size	07/01/25
Vet - F.I.a.1 a)	VRA-S - Vet - F.I.a.1 a) - a) Introduction of a manufacturer of the active substance supported by an ASMF - F.I.a.1 a) - 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 - Introduction of a manufacturer of the active substance supported by an ASMF	09/10/24