VPA10425/007/001

Vigophos 100 mg / ml + 0.05 mg / ml solution for injection for cattle

Variation	Summary	Date
Vet - A1 a)	VNRA - Vet - A1 a) - - A1 a) Administrative changes - Change in the name or address of - the marketing authorisation holder	14/10/25
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	30/07/25
Vet - I.III.1	VRA-E - Vet - I.III.1 - a) Change or addition of target species - I.III.1 a) Changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species - Other changes specific to veterinary medicinal products to be administered to food-producing animals - Change or addition of target species	28/03/25
Vet - G.I.10	VRA-E - Vet - G.I.10 - Variations concerning a change to or addition of a non-food producing target species. - G.I.10 Safety, Efficacy, Pharmacovigilance changes - Variations concerning a change to or addition of a non-food producing target species.	28/03/25
Vet - G.I.2 b)	VRA-S - Vet - G.I.2 b) - b) Harmonisation of the generic/hybrid product according to article 71(1) after SPC harmonisation of the reference product - G.I.2 b) Safety, Efficacy, Pharmacovigilance changes - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid medicinal product following assessment of the same change for the reference product - Harmonisation of the generic/hybrid product according to article 71(1) after SPC harmonisation of the reference product	28/03/25
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	28/03/25

	Regulation (EC) No 726/2004	
Vet - F.I.f.1	VRA-S - Vet - F.I.f.1 - 1. Substantial changes in the updated version of the ASMF or the active substance part of the dossier - F.I.f.1 Quality Changes - Active Substance - Other changes to the active substance - Substantial changes in the updated version of the ASMF or the active substance part of the dossier	12/06/24
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	05/03/24
Vet - B21	VNRA - Vet - B21 - Replacement or addition of a secondary packaging site of a finished product - B21 Changes to the quality part of the dossier: Replacement or addition of a secondary packaging site of a finished product	11/10/22
Vet - B44(Do not use)	VNRA - Vet - B44 - Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance, starting material, reagent or intermediate, excipient - B44 Changes to the quality part of the dossier: Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	11/08/22