

VPA10521/017/001

Tolfine 80 mg/ml solution for injection for cattle

Variation	Summary	Date
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	17/08/26
Vet - B3 d)	VNRA - Vet - B3 d) - - Vet - B3 d) - Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) of — an active substance;— a starting material;— an intermediate or reagent used in the manufacturing process of the active substance	15/07/26
Vet - F.I.a.1 a)	VRA-S - Vet - F.I.a.1 a) - - Vet - F.I.a.1 a) - 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	28/07/25
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 Regulation (EC) No 726/2004	24/06/25
Vet - A2	VNRA - Vet - A2 - Change in the (invented) name of the veterinary medicinal product - A2 Administrative changes: Change in the (invented) name of the veterinary medicinal product	27/03/25
Vet - G.I.19	VRA-R - Vet - G.I.19 - G.I.19 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet to implement the outcome of the MAH's signal management process according to Article 81(2) of Regulation (EU) 2019/6 - G.I.19 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet to implement the outcome of the MAH's signal management process according to Article 81(2) of Regulation (EU) 2019/6	28/08/24
Vet - B47 c)	VNRA - Vet - B47 c) - c) Change in specifications from a national	19/09/23

	pharmacopoeia of a Member State to the Ph. Eur. - B47 c) Changes to the quality part of the dossier: Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: — change in specifications from a national pharmacopoeia of a Member State to the Ph. Eur.	
Vet - A1 a)	VNRA - Vet - A1 a) - a) Change in the name or address or contact details of the marketing authorisation holder - A1 a) Administrative changes: Change in the name or address or contact details of the marketing authorisation holder	11/07/23
Vet - C1	VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	20/06/23
Vet - C6	VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17	20/06/23
Vet - A1 a)	VNRA - Vet - A1 a) - a) Change in the name or address or contact details of the marketing authorisation holder - A1 a) Administrative changes: Change in the name or address or contact details of the marketing authorisation holder	16/06/23