

VPA22664/146/001

Tulieve 100 mg/ml solution for injection for cattle, pigs and sheep

Variation	Summary	Date
Vet - B3 m)	VNRA - Vet - B3 m) - m) Deletion of a non-significant specification parameter (excipient) - B3 m) Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) in the specification parameters or limits of an excipient	18/07/24
Vet - B3 m)	VNRA - Vet - B3 m) - m) Deletion of a non-significant specification parameter (excipient) - B3 m) Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) in the specification parameters or limits of an excipient	18/07/24
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	25/07/23
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuring device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device	01/06/23
C.I.2.a	IB - C.I.2.a - a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH - C.I.2.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data is required to be submitted by the MAH	10/03/22