Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021,
please refer to the EMA website.

Tulinovet 100 mg/mL Solution for Injection for Cattle, Pigs and Sheep
Vm 19968/5000

	14 March 2024	Change in test procedure for the finished product: - Other changes to a test procedure. Change in the shelf-life or storage conditions of the finished product: - Extension of the shelf life of the finished product as packaged for sale. Change in the batch size (including batch size ranges) of the finished product.
•	20 July 2023	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
•	18 July 2023	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. Change in the specification parameters or limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance or of the immediate packaging of the active substance:– tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance. 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, or of a measuring or administration device. Minor changes:– to an approved test procedure, for a starting material, reagent or intermediate used in the manufacturing process of the active substance, or for an excipient
•	26 May 2023	Change in the specification parameters or limits of an active substance.
•	13 January 2022	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	21 October 2021	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.