



Post Authorisation Assessments

Tulaxa 100 mg/ml Solution for Injection for Cattle, Pigs and Sheep Vm 01656/3073

• 18 May 2024	One-off alignment of the product information with version 9.0 of the QRD templates.
• 03 May 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
• 04 July 2023	Change in test procedure for the finished product to comply with Ph. Eur. (NI)
• 16 June 2023	Unlimited renewal
• 14 April 2023	Change in test procedure for the finished product to comply with Ph. Eur.
• 20 October 2021	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
• 17 February 2021	Tightening of specification limits of an active substance used in the manufacturing process of the active substance.
• 19 August 2020	Minor changes to an approved test procedure of the finished product
• 24 September 2019	Increase in the shelf-life of the finished product as packaged for sale, from 24 months to 36 months.