



Post Authorisation Assessments

Tuloxin 100 mg/ml Solution for Injection for Cattle, Pigs and Sheep Vm 01656/3074

23 April 2025	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.
06 July 2023	Unlimited renewal.
04 July 2023	Change in test procedure for the finished product to comply with Ph. Eur. (NI)
12 April 2023	Change in test procedure for the finished product to comply with Ph. Eur.
09 November 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 2 years to 3 years.