



## Post Authorisation Assessments

### Lutalyse 12.5 mg/ml Solution for Injection for Cattle Vm 42058/4189

•	15 September 2023	Addition of a test for microbial purity on the active substance specification.
•	15 September 2023	Submission of a new Ph. Eur. certificate of suitability for an addition of a new active substance manufacturer.
•	24 January 2023	Change to the analytical method used for the quantitative analysis for the benzyl alcohol excipient.
•	15 November 2021	Minor changes to an approved test procedure of the finished product.
•	07 April 2021	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	09 December 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	06 November 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	17 September 2020	Renewal – National.
•	23 October 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	22 August 2017	Change in the manufacturing process of the finished