Veterinary Medicines Directorate

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Post Authorisation Assessments

Tetroxy Vet 200 mg/ml Solution for Injection for Cattle, Sheep and Pigs

Vm 50146/4008

•	18 June 2024	Replacement of a manufacturer responsible for batch release. Replacement of a secondary packaging site.
•	13 July 2022	Submission of a new or updated Ph. Eur. certificate of suitability.
•	18 March 2021	Replacement of a secondary packaging site of the finished product.
•	03 March 2021	Renewal - UK as CMS.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	23 September 2019	Change in the name and address of a manufacturer of the finished product, also responsible for batch release. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	18 October 2018	Change of MAH, from Cross Vetpharm Group Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland.
•	07 March 2018	Change in the RMS from UK to IE
•	05 December 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	01 December 2016	Minor change in test procedure for the finished product.