Veterinary Medicines Directorate

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Post Authorisation Assessments

Animeloxan 5 mg/ml Solution for Injection for Dogs and Cats

Vm 24745/4014

•	13 October 2023	Amendments to relevant sections of the SPC following the endorsement by the European Commission of the CVMP Opinion on the Article 83 referral regarding VMPs containing N-methyl pyrrolidone (NMP) as an excipient.
•	16 July 2021	Submission of a new certificate of suitability for an active substance.
•	08 July 2019	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	24 April 2018	Deletion of a manufacturing site for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	06 December 2017	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years.
•	20 April 2017	Renewal – UK as RMS.
•	23 March 2017	Change in address of manufacturer of the finished product. Replacement of a manufacturer for secondary packaging.
•	22 June 2016	Addition of a site where batch control/testing takes place. Addition of a manufacturer responsible for batch release, not including batch control/testing. Addition of a secondary packaging site of the finished product. Replacement of a secondary packaging site of the finished product. Replacement of a manufacturing site for the manufacturing process of the finished product
•	30 March 2016	Deletion of a manufacturing site of the active substance. Submission of an updated Certificate of Suitability
•	10 July 2014	Submission of a new Ph. Eur. Certificate of Suitability for a new manufacturer of the active substance.
•	07 December 2012	To change the QPPV.