Veterinary Medicines Directorate

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## **Post Authorisation Assessments**

For details of post authorisation assessments prior to 1<sup>st</sup> January 2021, please refer to the <u>EMA</u> website.

## Loxicom 5 mg/ml Solution for Injection for Dogs and Cats

Vm 02000/5006

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•	28 April 2023	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability.
•	10 March 2023	Editorial changes to part 2 of the dossier
•	28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, Co Down, BT35 6QQ, Northern Ireland.
•	29 April 2022	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.
•	14 April 2022	Deletion of a non-significant specification parameter of an excipient.
•	08 March 2022	Increase in the shelf-life of the finished product as packaged for sale, from 18 months to 3 years.
•	13 July 2021	Minor change in the manufacturing process of an immediate release solid oral dosage form. Minor change in the manufacturing process of an immediate release solid oral dosage form. Minor change in the manufacturing process of an immediate release solid oral dosage form. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product.