



## Post Authorisation Assessments

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### Sedastop 5 mg/ml Solution for Injection for Cats and Dogs Vm 19994/4014

•	22 November 2022	Change in the manufacturer of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier: -Introduction of a manufacturer of the active substance supported by an ASMF.
•	13 October 2022	Change in the manufacturer of a starting material- Introduction of a manufacturer of the active substance supported by an ASMF.
•	02 September 2019	Introduction of a new pharmacovigilance system.
•	16 May 2017	Change in the batch size (including batch size range) of the finished product.
•	27 August 2015	Renewal – UK as CMS.
•	07 October 2013	Change in distributor details.
•	27 April 2011	To submit mock-ups for approval prior to marketing (to be joint labelled with IE).
•	18 April 2011	To change the distributor.
•	30 March 2011	Grouped variation to replace the manufacturing site where the finished product is manufactured, packed and analysed.
•	23 February 2011	To change the address of the Marketing Authorisation Holder.