Veterinary Medicines Directorate

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Post Authorisation Assessments

Sedaxylan 20 mg/ml Solution for Injection for Dogs, Cats, Horses and Cattle

Vm 16849/4001

•	13 May 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	24 January 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	22 February 2017	Variation to obtain joint-labelling with Ireland.
•	12 February 2015	Delete the distributor and adapt livery accordingly.
•	05 February 2015	Minor change in the manufacturing process of the finished product.
•	25 September 2014	Update to section 4.10 of the SPC and the related product information.
•	06 March 2013	Change of QPPV and contact details for QPPV.
•	05 December 2011	Deletion of manufacturing site.
•	20 December 2010	Submission of a new or updated Ph. Eur. Certificate of suitability.
•	09 December 2009	Change in Distributor of the product.
•	13 December 2007	Renewal.
•	11 September 2006	Variation to update the Monograph from the 4th to the 5th edition.
•	04 March 2005	Minor change in the manufacturing process of the finished product.
•	26 May 2004	Deletion of a contra-indication.
•	06 February 2004	Variation to change the sterilisation process.
•	21 November 2003	Addition of a distributor.
•	04 July 2003	New EUDE MRP (UK as CMS).