Veterinary Medicines Directorate

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Post Authorisation Assessments

Spasmium Comp. 500 mg/ml + 4 mg/ml Solution for Injection

Vm 57446/3007

•	27 November 2024	One-off alignment of the product information with version 9.0* of the QRD templates.
•	06 July 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
•	18 May 2024	Change in name of manufacturer of the finished product.
•	03 November 2023	Change in distributor details from Chanelle Animal Health Ltd, 7 Rodney Street, Liverpool, L1 9HZ to Chanelle Vet UK Ltd, 483 Green Lanes, London, N13 4BS.
•	09 June 2023	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
•	23 January 2023	Change in MAH from Richter Pharma AG, Feldgasse 19, 4600 Wels, Austria to VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria.
•	06 January 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	20 August 2020	Renewal – UK as CMS.
•	10 April 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	26 June 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	09 August 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	15 March 2017	Increase in the shelf life of the finished product as packaged for sale from 30 months to 3 years
•	27 April 2016	Change in the specification limits of the finished product