



## Post Authorisation Assessments

### Spasmiium Comp. 500 mg/ml + 4 mg/ml Solution for Injection Vm 57446/5008

17 March 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
27 November 2024	One-off alignment of the product information with version 9.0* of the QRD templates.
11 June 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