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## **Post Authorisation Assessments**

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

## **Proteq West Nile Suspension for Injection for Horses**

Vm 04491/5046

• 17 November 2023	To add below statements in Product Information (PI), as agreed with EMA during the Veterinary Signal Assessment Report - addition of a sentence in section 4.6 of the SPC - 'injection site abscess' with a very rare frequency Proposed changes to meet GB national SPC/QRD template.
• 26 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
• 11 March 2022	Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics.  Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics.
• 26 March 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.