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Post Authorisation Assessments

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

ProteqFlu-Te Suspension for Injection for Horses

Vm 04491/5048

•	28 April 2024	Editorial changes to part 2B.1 of the dossier.
•	26 May 2023	Change to more restrictive storage conditions of the active substance.
•	05 May 2023	Change in name and address details of the active substance manufacturer.
•	28 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	28 April 2023	To update the SPC/QRD to the current version of the GB template.
•	20 May 2022	Composition changes to the immediate packaging of the active substance. Replacement of a site where batch/control testing including a biological / immunological / immunochemical method takes place.
•	21 January 2022	Changes to the labelling and/or package leaflet.
•	23 July 2021	Change in the manufacturer of a starting material used in the manufacturing process of the active substance. Replacement of a site where batch/control testing takes place.
•	26 March 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.