Veterinary Medicines Directorate

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Post Authorisation Assessments

Tildren 500 mg Lyophilisate for Solution for Infusion for Horses

Vm 44684/3000

•	22 June 2024	One-off alignment of the product information with version 9.0 of the EU QRD templates.
•	28 February 2023	Replacement or addition of a site where batch control/testing takes place.
•	31 October 2022	Replacement or addition of a site where batch control/testing takes place.
•	21 March 2022	Change in the address of the marketing authorisation holder from AUDEVARD, 42-46 rue Médéric, 92110 Clichy, France to AUDEVARD, 37-39 rue de Neuilly, 92110 Clichy, France. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	16 April 2021	Renewal – UK as CMS.
•	23 March 2021	Deletion of manufacturing site for an active substance.
•	18 June 2019	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	08 April 2019	Change in RMS from UK to AT.
•	28 March 2017	Introduction of a new pharmacovigilance system
•	21 December 2016	Change in Distributor details. From Ceva Animal Health Ltd to AUDEVARD.
•	18 October 2016	Change of Marketing Authorisation holder from Ceva Animal Health Ltd to AUDEVARD.