Veterinary Medicines Directorate

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Post Authorisation Assessments

Versiguard Rabies Suspension for Injection

Vm 42058/4194

•	07 December 2022	Replace in vivo potency test with in vitro antigen capture assay.
•	03 June 2021	Changes in the manufacturing process of the active substance.
•	23 April 2021	Deletion of a manufacturing site for a supplier of a starting material. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. Updating of the product information according to the latest QRD template.
•	07 August 2020	Renewal - UK as CMS.
•	01 November 2019	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	05 December 2017	Change to part of the (primary) packaging material not in contact with the finished product formulation.
•	24 February 2017	Deletion of a pack size(s) of the finished product. Change in the number of units (e.g. tablets*, ampoules*, etc.) in a pack outside the range of the currently approved pack sizes of the finished product.
•	05 January 2017	Update to Section 4.8 of the SPC.
•	21 July 2016	Change in the SPC, labelling or package leaflet due to new data.
•	05 April 2016	Addition of a new in-process test and limit applied during the manufacture of the active substance. Change(s) in the manufacturing process of the active substance. Change(s) in the manufacturing process of the active substance. Change(s) in the manufacturing process of the active substance.
•	30 March 2016	New manufacturer of material for which an assessment is required of viral safety and/or TSE risk. New/updated certificate from an already-approved/new manufacturer.
•	15 March 2016	Change in the invented name of the veterinary medicinal product.