Veterinary Medicines Directorate

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Post Authorisation Assessments

Equip Rotavirus Emulsion for Injection for Horses

Vm 42058/4063

•	27 June 2023	Addition of source places of a starting material used in the manufacturing process of the active substance.
•	10 November 2021	Replacement to a test procedure for the finished product.
•	05 June 2020	Increase in the shelf-life of the finished product, from 12 months to 18 months.
•	01 June 2020	Repeat Use application to add 1 new member state.
•	12 December 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.
•	10 January 2019	Change in RMS from UK to IE.
•	28 December 2018	Minor change in the manufacturing process of the finished product. Reduction of the shelf life of the finished product as packaged for sale from 2 years to 1 year. Change in the manufacturer of a starting material / reagent/intermediate used in the manufacturing process of the active substance and change in the manufacturer of the active substance.
•	25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	01 June 2018	Changes to a test procedure for the finished product.
•	01 December 2017	Addition of a new specification parameter to the specification with its corresponding test method of an excipient. Deletion of a non-significant specification parameter of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Replacement * / addition * of a secondary packaging site of the finished product. Addition* / replacement* / Changes* to a test procedure for the finished product. Addition of a new specification parameter to the specification with its corresponding test method of

		the finished product. Change in type of container* / addition of a new container* for the finished product. Changes in the manufacturing process of the finished product. Replacement* or addition* of a manufacturer responsible for imporation* / batch release* including batch control / testing. Replacement * / addition * of a manufacturing site of the finished product.
•	18 October 2016	Renewal - UK as RMS
•	05 May 2015	Change in the QPPV contact details.
•	30 June 2014	Deletion of an obsolete, non-significant specification parameter.
•	11 October 2013	Change to the QPPV contact details.
•	10 October 2013	Change of MAH from Pfizer to Zoetis in Belgium and Luxembourg only.
•	12 July 2013	Increase in shelf life of Veterinary Medicinal Product as packaged for sale from 12 Months to 2 years (24 months).
•	20 June 2013	Transfer of MA and change of distributor from Pfizer Ltd to Zoetis UK Ltd.
•	01 March 2013	Repeat Use procedure.
•	12 October 2012	To update the SPC and product literature.
•	13 April 2012	Change in invented name of the veterinary medicinal product.
•	13 April 2012	Replacement of a test procedure for an adjuvant.
•	28 July 2011	To introduce a new Pharmacovigilance system.
•	11 February 2011	Grouped variation to change the name of the manufacturing site.
•	28 July 2010	Change in test procedure of the finished product.
•	16 June 2010	Change of MAH holder and distributor from Fort Dodge Animal Health Ltd to Pfizer Ltd.