



Post Authorisation Assessments

Equip Rotavirus Emulsion for Injection for Horses

Vm 60021/3087

13 February 2026	To add a previously omitted site for Physical/Chemical testing of the finished product to the manufacturing flow chart.
13 October 2025	Submission of mock ups.
20 May 2025	Change of Marketing Authorisation Holder from Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP to Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown, Dublin 18, D18 T3Y1, Ireland.
10 March 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
26 February 2025	G.I.18 update of product information to version 3 of the national template.
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

	<p>manufacture of the finished product.</p> <p>Replacement * / addition * of a secondary packaging site of the finished product.</p> <p>Addition* / replacement* / Changes* to a test procedure for the finished product.</p> <p>Addition of a new specification parameter to the specification with its corresponding test method of the finished product.</p> <p>Change in type of container* / addition of a new container* for the finished product.</p> <p>Changes in the manufacturing process of the finished product.</p> <p>Replacement* or addition* of a manufacturer responsible for importation* / batch release* including batch control / testing.</p> <p>Replacement * / addition * of a manufacturing site of the finished product.</p>
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.