Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Suvaxyn MH-One Emulsion for Injection for Pigs

Vm 42058/3023

•	18 May 2024	The scope of this G.I.18 VRA is to update the current SPC/PI text to align to QRD template v9.0, as required per regulation 2019/6. The Applicant also takes this opportunity to introduce minor editorial changes to the SPC/PI.
•	22 September 2021	Replacement to a test procedure for the finished product.
•	25 October 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.
•	16 April 2019	Addition of a supplier of packaging components.
•	25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	04 July 2018	Repeat Use application to add 3 new member states
•	15 February 2017	Minor change to an approved test procedure for the intermediate used in the manufacturing process of the active substance. 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 active substance. Addition of a new in-process test and limit applied during the manufacture of the active substance. Deletion of a non-significant in-process test applied during the manufacture of the finished product Changes to a test procedure for the active substance. Changes to a test procedure for the active substance. Change to a test procedure for the finished product. Change in the manufacturing process of the finished product. Change in the manufacturing process of the finished product. Update of specification parameters. Minor change in the manufacturing process of the active substance. Submission of a revised Part 2 dossier.
•	02 February 2016	Change in name of a manufacturer of the active substance.
•	12 June 2015	To extend the shelf-life of the finished product to 24 months.
•	30 April 2015	Change in the QPPV contact details.

•	10 April 2015	Update to the product dossier. Change of site for testing starting materials of biological origin. Change in test procedure for testing starting materials of biological origin.
•	22 January 2015	Transfer of test location for a test procedure.
•	16 January 2015	Removal of a test procedure for the finished product.
•	16 October 2014	To increase the shelf-life of the 50-dose and 125-dose presentations in HDPE bottles, from 12 months to 15 months. Change in the specification parameters/limits of the finished product.
•	30 May 2014	Change to two test procedures.
•	09 October 2013	Change of MAH in Austria, Belgium, France, Luxembourg only.
•	09 October 2013	Change in the name of manufacturer of the active substance. Changes in the name of manufacturer of the finished product. Change of QPPV contact details.
•	28 August 2013	Renewal.
•	07 January 2013	To tighten the specification limits. To reduce the minimum age for vaccine from 21 days to 7 days.
•	27 December 2012	Variation to reduce the onset of immunity of the vaccine, from 4 weeks to 2 weeks after the primary vaccination scheme.
•	15 August 2011	To change the name of the manufacturer for blending, filling, assembly, batch release, final product testing and labelling.
•	15 August 2011	To change the name and/or address of a manufacturer of the finished product, including quality control sites.
•	15 August 2011	To change the name and/or address of a manufacturer of the finished product, including quality control sites.
•	11 March 2011	To change the MAH address of the local office in Poland.
•	16 June 2010	To change the MAH and distributor from Fort Dodge Animal Health Ltd to Pfizer Limited.