Veterinary Medicines Directorate

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Post Authorisation Assessments

Suvaxyn M Hyo Suspension for Injection for Pigs

Vm 42058/3025

•	02 February 2024	Update to the batch release protocol template to include references to the specific in process control test methods, as approved under Part 2d of the dossier.
•	23 November 2023	Harmonisation of the quality dossier.
•	10 January 2020	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.
•	08 July 2019	Deletion of a pack size of the finished product.
•	30 May 2019	Increase in the shelf-life of the finished product as packaged for sale, from 12 months to 27 months
•	07 November 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	09 March 2018	Change in RMS from UK to FR.
•	25 July 2017	Deletion of a non-significant specification parameter of the finished product.
•	11 January 2017	Change in the specification limits of a starting material/intermediate used in the manufacturing process of the active substance.
•	08 December 2016	Change of MAH address in France, Czech Republic and Slovakia.
•	12 February 2016	Change in the name of a manufacturer of the active substance. Change in the name of a manufacturer of the finished product.
•	05 May 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.
•	14 August 2014	Change to the specification parameters/limits of the finished product.
•	11 October 2013	Change in the address of the Marketing Authorisation Holder.
•	10 October 2013	Grouped variation to change the name of the active substance manufacturer, the manufacturer responsible for batch release, the manufacturer responsible for finished product (not including batch release) and also to change the QPPV contact details.

•	05 September 2013	Deletion of a manufacturer.
•	08 August 2013	Grouped variation to change the name and address of the Marketing Authorisation Holder.
•	13 June 2012	Variation to change the DDPS following the changes of Marketing Authorisation Holder.
•	15 September 2011	Addition of a site for labelling and batch release.
•	08 July 2011	Grouped variation to change the name of the manufacturer responsible for blending, filling and assembly, and manufacture of active substance. Variation to change the name of the site for in-process testing. Variation to change the name of the site for final product testing.
•	24 June 2010	Variation to change the Marketing Authorisation Holder and distributor.
•	30 March 2010	Renewal (UK as RMS).
•	07 December 2006	Change of site responsible for finished product release testing.
•	07 December 2006	Change in the reference vaccine for the product release.
•	21 July 2006	Increase in the maximum batch size of the active substance.
•	14 April 2005	Renewal.
•	22 September 2003	Change in the ingredient specification.
•	31 July 2002	Addition of a site for QC potency and sterility testing.
•	15 February 2002	Change to the assembler of dosage form.
•	23 April 2001	Change to control test.
•	20 June 2000	Completion of MRP.