Veterinary Medicines Directorate

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Post Authorisation Assessments

Hyogen Emulsion for Injection for Pigs

Vm 15052/3013

•	28 April 2024	A new final product control test, testing the extractable volume of the finished product in addition to currently applied filling volume test performed during the filling process. To extend the shelf life of the vaccine from 15 months to 24 months. An additional new test measuring the paraffin oil content in the vaccine. A sandwich ELISA assay for antigen quantification using the same methodology, like the proposed in-vitro sandwich ELISA potency test. The proposed test is intended as in-process control test on the inactivated, concentrated antigen suspension. A new in-vitro method (sandwich ELISA assay) for control the potency of final product, replacing the current one, which is an in-vivo/iv-vitro test system measuring rabbit serology. Follow-up updates based on earlier variations. One-off alignment of the product information with version 9.0* of the QRD templates.
•	16 November 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF.
•	27 January 2023	Increase in the batch size of the finished product.
•	13 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
•	16 March 2022	Change in the SPC, labelling or package leaflet due to new data.
•	06 September 2021	Change in the fill volume of the finished product.
•	06 July 2021	Change in the manufacturer of a starting material used in the manufacturing process of the active substance.
•	23 June 2021	Replacement to a test procedure for the finished product.
•	10 June 2020	Replacement of a site where batch control/testing takes place.
•	27 March 2020	Renewal - UK as CMS.
•	21 November 2019	Changes in the SPC, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent

		authority under Articles 45 or 46 of Regulation 1901/2006.
•	21 November 2019	Increase in batch size of active substance or intermediate used in the manufacturing process of the active substance.
•	01 October 2019	Change to an approved stability protocol.
•	22 May 2019	Change in the fill volume of the finished product.
•	08 April 2019	Change in test procedure for an excipient.
•	31 January 2019	Change in the invented name of the veterinary medicinal product from Hyobloc (SE) and Mhyogen (DK) to Mhyogen vet in SE and DK.
•	19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	08 August 2017	Replacement to a test procedure for the finished product.
•	06 October 2016	Change in the specification limits of the finished product. Change in the manufacturing process of the active substance.
•	20 September 2016	Addition of an alternative site for the animal testing phase of the potency test.
•	06 January 2016	Submission of an updated DDPS.