Veterinary Medicines Directorate

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Post Authorisation Assessments

Hyogen Emulsion for Injection for Pigs

•	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.