Veterinary Medicines Directorate

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Post Authorisation Assessments

Progressis Emulsion for Injection for Pigs (Sows and Gilts)

Vm 15052/5054

•	15 August 2023	Deletion of a manufacturing site for an active substance.
•	24 January 2023	Change in product name from Progressis Vet Emulsion for Injection for Pigs to Progressis Emulsion for Injection for Pigs in DK only.
•	12 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.
•	21 July 2021	Change in the name of a manufacturer used in the manufacture of the active substance. Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	15 July 2021	Changes to the labelling and/or package leaflet.
•	23 March 2021	Change to part of the (primary) packaging material not in contact with the finished product formulation. Removal of the details of sterilisation for the aluminium cap in the quality documentation.
•	12 June 2020	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Change in the manufacturer of a starting material used in the manufacturing process of the active. Change in the manufacturer of the active. Addition of a site where batch control/testing takes place. Addition of a manufacturing site of the finished product.
•	19 March 2019	Change in the manufacturing process of the finished product
•	03 September 2018	Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of the active substance.
•	16 July 2018	Introduction of a new pharmacovigilance system.
•	13 June 2017	Change of MAH address from Merial Animal Health Limited to Ceva Animal Health Ltd. Change in distributor details from Merial Animal Health Limited to Ceva Animal Health Ltd.
•	28 March 2017	Addition of a manufacturer responsible for batch release of the finished product. Addition of secondary packaging site of the finished product

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•	17 January 2017	Changes to a test procedure (including replacement) for a reagent used in the manufacturing process of the active substance.
•	17 January 2017	Minor change in the manufacturing process of the active substance.
•	29 June 2016	Addition of site as alternative manufacturing site for the active ingredient.
•	11 September 2015	Changes in the manufacturing process of the active substance.
•	09 July 2015	Submission of two new TSE certificates for a starting material.
•	17 June 2014	Change of the MA holder address in Portugal only.
•	31 March 2014	Change of the MA holder address in Spain only.
•	23 January 2014	Change to the MA holder address in Belgium only.
•	14 July 2010	Renewal, UK as CMS.
•	09 January 2008	Change to comply with the Ph. Eur. or MS National Pharmocopoeia.
•	26 April 2006	Variation to update labels to allow dual labelling with IE.
•	22 February 2005	Renewal.
•	22 January 2004	Change in the address of the manufacturer responsible for batch release in the EEA.
•	05 December 2003	Change in the name of the Marketing Authorisation Holder in France.
•	10 June 2003	Addition of suppliers of an active substance.
•	26 March 2002	Variation concerning a change to the specification of a starting material.
•	03 November 2000	New MRP.