Veterinary Medicines Directorate

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Post Authorisation Assessments

Fenflor 300 mg/ml Solution for Injection for Pigs

Vm 01656/4027

•	21 March 2022	Change to the sterility test procedure for the finished product.
•	11 August 2021	Change in the name and address of a manufacturer of active substance used in the manufacture of the active substance. Changes to the quality control testing arrangements for the active substance – addition of a site where batch testing takes place.
•	12 April 2019	Tightening of specification limits of an active substance used in the manufacturing process. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance.
•	08 March 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	28 January 2019	Extension of a re-test period of the active substance.
•	23 October 2018	Update to the Local Representative details.
•	17 April 2018	Change in RMS from UK to DE.
•	05 April 2018	Change to the quality control testing arrangements for the active substance - addition of a site where batch control takes place. Change to the quality control testing arrangements for the active substance - addition of a site where batch control takes place.
•	08 July 2015	Approval of mock-ups.
•	26 March 2015	Removal of distributor.
•	15 March 2013	Change to increase the shelf life of the finished product from 2 years to 3 years.
•	03 February 2012	To add a new supplier for rubber stopper.
•	03 September 2010	New MA – Extension to add a new route of administration (subcutaneous route).
•	02 June 2010	To add a distributor.
•	29 September 2009	New MA (MRP).
•	14 August 2007	Change of Marketing Authorisation Holder.