Veterinary Medicines Directorate

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Post Authorisation Assessments

Fenflor 300 mg/ml Solution for Injection for Cattle

Vm 01656/5116

11 December 2024	Implementation of wording from CMDv for VMPs containing florfenicol. One-off alignment of the product information with version 9.0.
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.
17 April 2018	Change in RMS from UK to DE.
13 April 2018	Changes to the quality control testing arrangements for the active substance – addition of a site where batch control / testing takes place. Changes to the quality control testing arrangements for the active substance – addition of a site where batch control / testing takes place.
26 October 2017	Change in contact details for local representative.
17 September 2015	Renewal – UK as RMS.
28 July 2015	Changes to labelling and packaging not connected with the SPC.
26 March 2015	Removal of a 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.