Veterinary Medicines Directorate

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Post Authorisation Assessments

PropoFlo Plus, 10 mg/ml, Emulsion for Injection for Dogs and Cats

Vm 42058/5136

•	03 March 2021	Tightening of specification limits of the finished product. Tightening of specification limits of the finished product. Tightening of specification limits of the finished product. Tightening of specification limits of the finished product. Tightening of specification limits of the finished product. Tightening of specification limits of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Deletion of a non-significant specification parameter of the finished product.
•	05 November 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	22 September 2020	Change to part of the (primary) packaging material not in contact with the finished product formulation.
•	12 November 2019	Change in the address of the marketing authorisation holder from Zoetis UK Limited 5th Floor, 6 St. Andrew Street London EC4A 3AE to Zoetis UK Limited 1st Floor, Birchwood Building Springfield Drive Leatherhead Surrey KT22 7LP.
•	09 May 2019	Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	23 April 2018	Change in RMS from UK to ES.
•	27 September 2017	Deletion of manufacturing site for a finished product manufacturer responsible for batch release
•	29 December 2016	Change in the address of the marketing authorisation holder in France, Czech Republic & Slovakia.
•	27 April 2016	Renewal – UK RMS
•	05 April 2016	Change to in-process tests or limits applied during the manufacture of the finished product
•	30 July 2015	Introduction of a new pharmacovigilance system.

•	27 July 2015	Change of MAH, from Abbott Laboratories Ltd to Zoetis UK Limited. Addition of a distributor.
•	12 June 2015	Increase to the shelf-life of the finished product from 2 years to 3 years.
•	15 October 2014	To remove and replace a site of active substance manufacture. Submission of a new Ph. Eur. Certificate of Suitability for the new manufacturer. Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer.
•	31 July 2014	Change in test procedure for an excipient. Changes to the DDPS.
•	20 March 2014	Repeat use procedure.
•	7 March 2013	Additional warnings added to section 4.6 of the SPC
•	23 August 2012	Additional site of manufacturer of secondary packaging and site of batch release.
•	16 August 2011	To change the contact details of QPPV.
•	18 April 2011	To change the pH limits of the product at release from 8.0-9.0 to 7.5-8.5.
•	18 April 2011	Change to rubber stoppers and increase in shelf life.
•	06 January 2011	Change in the specification of the finished product.