Veterinary Medicines Directorate

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Post Authorisation Assessments

Effitix 402 mg/3600 mg Spot-on Solution for Very Large Dogs

Vm 05653/5072

•	22 March 2024	Change in the packaging material of bulk product not in contact with the bulk product formulation.
•	14 December 2023	Minor changes to an approved test procedure for the finished product. (NI)
•	11 January 2023	Addition of presentation modification of over-blister
•	11 January 2023	Minor changes to an approved test procedure for the finished product.
•	28 April 2021	Repeat Use Application to add 3 new member states.
•	27 March 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	27 February 2020	Deletion of manufacturing site for an active substance.
•	14 August 2019	Minor change in the manufacturing process of the finished product. Change in the name of the manufacturer of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Increase in the shelf-life of the finished product as packaged for sale, from 2 to 3 years. Change in the specification limits of the finished product. Change in the specification limits of the finished product.
•	28 March 2019	Renewal – UK as CMS
•	12 October 2018	Change of specifications of a former non Pharmacopoeial active substance to comply with the Ph. Eur. monograph 2869.
•	10 September 2018	Change in RMS from UK to FR.
•	14 June 2017	Change in the name and address of a manufacturer used in the manufacture of the active substance. Addition of a manufacturer of the active substance.
•	16 March 2017	Minor change in the manufacturing process of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	28 January 2016	Change in test procedure of the finished product. Addition of a manufacturing site for the active substance.
•	10 December 2015	Change to the therapeutic indications
•	19 January 2015	Change to the finished product specification limits.
•	18 September 2014	Minor change in the composition of the finished product with respect to excipients.