Veterinary Medicines Directorate

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Post Authorisation Assessments

Enrox Flavour 150 mg Tablets for Dogs

Vm 01656/4009

•	13 September 2022	Minor change in the manufacturing process.
•	24 March 2022	Deletion of manufacturing site for a finished product.
•	20 August 2021	Minor changes to an approved test procedure of the finished product.
•	22 April 2021	Addition of a manufacturer responsible for batch release of the finished product. Addition of a manufacturing site of the finished product.
•	19 February 2021	Deletion of manufacturing site for an active substance.
•	02 November 2020	Addition/Changes to a test procedure for the finished product.
•	28 April 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	11 June 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	27 March 2019	Addition of a site where batch testing takes place. Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product.
•	29 January 2017	Change in RMS from UK to IE.
•	26 October 2017	Change in contact details for local representative.
•	04 September 2015	Changes to the labelling or package leaflet which are not connected with the SPC. Change in distributor details.
•	24 May 2015	Submission of a new certificate of suitability. Submission of an updated certificate of suitability.
•	18 June 2014	To add a new active substance manufacturer and update the finished product specifications.
•	22 May 2014	Renewal procedure – UK as RMS.
•	04 June 2013	Submission of a new Ph. Eur. Certificate of Suitability for an already approved manufacturer of an active substance. Change of specification of a former non Pharmacopoeial active to comply with Ph. Eur.
•	16 January 2013	Changes to the labelling and package leaflet not connected to the SPC.
•	16 November 2012	Change in the manufacturing process of the finished product.
•	07 June 2012	Changes to the labelling and package leaflet not connected to the SPC.
•	10 December 2009	To change shelf life of the finished product from 2 years

		to 3 years.
•	17 November 2009	To add a batch release site (not including batch control).
•	20 August 2009	To change pack size of the finished product.