Veterinary Medicines Directorate

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Post Authorisation Assessments

Enrox Flavour 150 mg Tablets for Dogs

Vm 01656/4009

16 May 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI)
21 April 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
16 September 2025	Change of Distributor from: Unidrug Distribution Group Limited, Amber Park 1, 2, 3 and 5 Berristow Lane, South Normanton, Alfreton, Derbyshire, DE55 2FH; Centaur Services Limited, Centaur House, Torbay Road, Castle Cary, Somerset, BA7 7EU; Movianto UK Limited, 1A Progress Park, Elstow, Bedford, Bedfordshire, MK42 9XE; National Veterinary Services Limited, Unit 4, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW; Potter Logistics Limited, Charleywood Road, Knowsley Industrial Park, Liverpool, L33 7SG; Henry Schein UK Holdings Limited, Medcare North, Centurion Close, Gillingham Business Park, Gillingham, Kent, ME8 0SB To: KRKA UK Ltd, Thames House, Waterside Drive, Langley, SL3 6EZ, United Kingdom.
25 June 2025	Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State to reflect compliance with the Ph. Eur. by removing reference to the internal test method and test method number. Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
11 June 2025	Deletion of a site where batch control takes place. (NI).
11 June 2025	Deletion of a site where batch control takes place. (GB).
27 January 2025	Alignment of the product information with version 9.0* of the QRD templates.
09 January 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex (NI)
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.