Veterinary Medicines Directorate

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Post Authorisation Assessments

Thyforon Flavoured 800 Microgram Tablets for Dogs

Vm 16849/4037

•	10 July 2024	Submission of mock ups.
•	10 July 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (NI)
•	18 June 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (GB)
•	19 October 2021	Minor changes to an approved test procedure of the finished product.
•	15 February 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	10 December 2020	Changes to SPC & product literature following a Periodic Safety Update Report (PSUR). Changes to adverse events section of SPC.
•	19 August 2020	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product for solid pharmaceutical forms. Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product. Addition of a manufacturing site of the finished product.
•	01 February 2019	Addition of a manufacturer responsible for batch release.
•	24 January 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	28 November 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	30 August 2018	Change in RMS from UK to NL.
•	17 July 2018	Repeat use MRP to add 7 CMS
•	26 January 2017	Renewal – UK as RMS
•	12 April 2016	Submission of 2 updated certificates of suitability.
•	31 October 2014	Change in a test procedure for the finished product.
•	20 August 2014	Approval of mock-ups. Change to the distributor. Introduction of joint labelling with Ireland.
•	10 April 2014	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product.
•	10 April 2014	Change to importer, batch release arrangements and quality control testing of the finished product.
•	10 April 2014	Change in the manufacturing process of the finished

		product.
•	18 April 2013	Change in specification limit of an excipient.
•	25 March 2013	Change of QPPV and contact details for the QPPV of an existing pharmacovigilance system.