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Post Authorisation Assessments

Thyforon Flavoured 800 Microgram Tablets for Dogs Vm 16849/4037

20 February 2025	Submission of an updated CEP from an already
20100100192020	approved manufacturer for an active substance. (GB).
15 January 2025	Submission of an updated Ph. Eur. CEP from an already
	approved manufacturer for a non-sterile active
	substance.
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
10 December 2020	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
19 August 2020	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.