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Post Authorisation Assessments

Thyforon Flavoured 600 Microgram Tablets for Dogs Vm 16849/4036

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•	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
•	19 December 2016	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.
	40.4. 11.00 1 1	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
_	10 April 2014	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
•	10 Αριίι 2014	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.
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