Veterinary Medicines Directorate

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Post Authorisation Assessments

Therios 300 mg Palatable Tablets for Dogs

Vm 15052/5072

•	04 May 2024	Change in test procedure for the finished product to comply with Ph. Eur.
•	04 May 2024	Change in the specification parameters and/or limits of the finished product.
•	07 October 2022	Change in the MAH address, from Ceva Animal Health Ltd, Unit 3, Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Ceva Animal Health Ltd, Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
•	22 February 2022	Deletion of a non-significant specification parameter of an excipient.
•	05 March 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	23 May 2019	Replacement of a site where batch control/testing takes place
•	28 January 2019	Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product.
•	15 August 2018	Deletion of packaging site. Replacement of a manufacturer responsible for batch release of the finished product.
•	28 March 2018	Change in the product name in DK only.
•	19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	19 September 2017	Change in the name and/or address of the MAH in Spain only.
•	25 April 2017	Deletion of a non-significant specification parameter of an excipient
•	08 September 2016	Change in the name of a manufacturer of the finished product, also responsible for batch release. Change in the name of a manufacturer of the finished product, also responsible for batch release. Change in the name of the manufacturer of the finished

		product.
•	06 September 2016	Change in the name an address of the MAH in Italy only.
•	25 August 2016	Approval of mock-ups for change of design/layout.
•	29 June 2016	Introduction of a new pharmacovigilance system which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.
•	14 June 2016	Change of MAH, from Sogeval to Ceva Animal Health Ltd and Change of Distributor to Ceva Animal Health Ltd.
•	05 November 2014	Renewal.
•	04 September 2013	Submission of an updated Ph. Eur. Certificate of Suitability. Submission of a new Ph. Eur. Certificate of Suitability. Change in specification parameters of an active substance.
•	30 September 2010	To change the manufacturing process of the finished product.
•	22 July 2010	Grouped variation to change the manufacture of the finished product, primary packaging and secondary packaging site.