Veterinary Medicines Directorate

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Post Authorisation Assessments

X-Spectra Flavoured Tablets for Medium and Small Dogs

Vm 15052/4055

•	22 June 2024	Addition of a manufacturer responsible for batch release.
•	18 June 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	21 December 2023	Deletion of an obsolete parameter in the specification parameters of the finished product. (NI)
•	21 December 2023	Minor changes to an approved test procedure, for a starting material used in the manufacturing process of the active substance. (NI)
•	20 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire HP10 0HH, United Kingdom.
•	23 December 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.
•	24 June 2020	Changes in the SPC, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning a Periodic Safety Update Report.
•	18 December 2019	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.
•	31 January 2019	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. 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. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	12 June 2018	Change of RMS from UK to FR

•	28 September 2017	Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product.
•	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.
•	10 March 2017	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	19 April 2016	Submission of an updated certificate of suitability.
•	22 December 2015	Updating of the DDPS system.
•	24 March 2015	Renewal – UK as RMS.
•	09 January 2014	Change in the batch size of the active substance, and change to manufacturing process of the active substance.
•	09 January 2014	Submission of a new or updated European Pharmacopoeia certificate of suitability.
•	31 December 2013	Submission of a new or updated European Pharmacopoeia certificate of suitability.
•	30 December 2013	Change in the manufacturing process of the finished product.
•	01 February 2013	Addition of a therapeutic indication.
•	06 January 2012	To change the address of the MAH.