Veterinary Medicines Directorate

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Post Authorisation Assessments

X-Spectra Flavoured Tablets for Large Dogs

•	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 in 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.
•	25 March 2015	Renewal – UK as RMS.

•	11 July 2014	Change to the manufacturing process. Change to the specification of the finished product. (Large dogs product only).
•	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.
•	11 October 2013	Changes to an existing pharmacovigilance system as described in the DDPS.
•	01 February 2013	Addition of a therapeutic indication.
•	06 January 2012	To change the address of the MAH.