Veterinary Medicines Directorate

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Post Authorisation Assessments

Cestem Flavoured Tablets for Large Dogs

Vm 15052/4039

•	27 June 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	22 June 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
•	22 June 2024	Addition of a manufacturer responsible for batch release.
•	15 December 2023	Deletion of an obsolete parameter in the specification parameters of the finished product. (NI)
•	14 December 2023	Minor changes to an approved test procedure for an excipient. (NI)
•	24 July 2023	Change in test procedure for the finished product.
•	10 May 2023	Minor changes to an approved test procedure for an excipient.
•	18 April 2023	Change in test procedure for the finished product.
•	29 March 2023	Deletion of a non-significant specification parameter of the finished product.
•	04 October 2022	Change of MAH address 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.
•	24 March 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Introduction of a re-test period of the active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	02 March 2022	Addition of a site where batch control/testing takes place.
•	20 May 2021	Changes to the labelling and/or package leaflet.
•	22 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.
•	20 August 2020	Changes in the SPC, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning a PSUR.
•	09 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.
•	06 February 2019	Change to comply with an update for 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 and already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from and already approved manufacturer. Addition of a new Ph. Eur certificate of suitability for an active substance from a new manufacturer.
•	13 June 2018	Change in RMS from UK to NL.
•	23 November 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.
•	19 September 2017	Change in the name and/or address of the MAH in Spain only.
•	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.
•	09 July 2015	Renewal – UK as RMS.
•	06 February 2015	Change to the MAH address in Slovakia and Czech Republic only.
•	11 July 2014	Change to the manufacturing process. Change to the specification of the finished product.
•	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 to manufacturing process for finished product and an intermediate used in the manufacture of the finished product.
•	11 October 2013	Changes to an existing pharmacovigilance system as described in the DDPS.
•	02 March 2012	Submission of a new or updated European Pharmacopoeia certificate of suitability.
•	02 March 2012	Submission of a new or updated European Pharmacopoeia certificate of suitability.
•	05 January 2012	To change the name and address of the MAH in Italy only.
•	25 October 2011	To change the address of the MA Holder.

•	15 September 2009	MRP procedure – UK as RMS.
•	17 August 2009	Submission of a new or updated European Pharmacopoeia certificate of suitability.
•	28 July 2009	New primary and secondary packaging site
•	13 July 2009	Packaging site for product added.