Veterinary Medicines Directorate

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Post Authorisation Assessments

Zobuxa 50 mg Tablets for Cats and Dogs

•	24 April 2018	Change in RMS from UK to DE.
•	16 April 2018	Change to in-process test applied during the manufacture of the finished product.
•	12 October 2017	Update to the SPC, labelling or package leaflet to implement the outcome of a PSUR
•	12 May 2017	Deletion of manufacturing site for a site where batch control takes place Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	12 January 2017	Change in the name of a manufacturer of the finished product.
•	21 December 2016	Renewal - UK as RMS.
•	21 June 2016	Change in the name and address of the Marketing Authorisation Holder from Novartis Animal Health S.p.A to Elanco Italia S.p.A. in Italy only, and from Novartis Sanidad Animal, S.L. to Elanco Spain, S.L.U. in Spain only.
•	13 January 2016	Change of Marketing Authorisation Holder from Novartis Animal Health UK Ltd to Elanco Europe Ltd. Change in distributor details.
•	27 March 2014	Change to the QPPV contact details and updates to the DDPS that do not affect the pharmacovigilance system.
•	16 January 2014	Change to the address of the MAH.
•	04 July 2013	Change to the address of the MAH.
•	28 March 2013	Change to the address of the MAH.
•	03 August 2012	Change to DDPS.
•	07 June 2012	Submission of an updated certificate of suitability.
•	30 March 2012	To change the flavouring component in the finished product.
•	01 March 2012	To change the shelf life as packaged for sale from 2 years to 3 years.