Veterinary Medicines Directorate

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Post Authorisation Assessments

PLT Tablets

•	15 April 2020	Minor changes to an approved test procedure for the immediate packaging of the finished product.
•	03 October 2019	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product for solid pharmaceutical forms. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product for solid pharmaceutical forms Changes in the manufacturing process of the finished product.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	22 August 2017	Changes to the labelling and/or package leaflet.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	30 September 2016	Change in the name and address of the Marketing Authorisation Holder. Change of distributor details.
•	27 January 2016	Change in the specification limits of the finished product
•	21 August 2013	Addition of a manufacturer of the finished product, for secondary assembly, and batch release Change of batch size
•	11 June 2013	Submission of updated Ph. Eur. Certificates of Suitability for the active substance
•	15 February 2013	Change in supplier of a packaging component
•	17 August 2011	Change to shelf life from 24 months to 18 months
•	28 January 2009	Deletion of 2 manufacturers of the active substance
•	24 October 2008	Addition of a manufacturing site for batch release and Quality Control testing
•	21 May 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	18 March 2008	Addition of a manufacturer for assembly of the dosage form
•	21 August 2007	Change of address of the MAH
•	24 May 2007	Renewal
•	27 February 2007	Change to re-test interval for the active substance
•	17 October 2006	Addition of a manufacturing site of the active substance
•	17 July 2003	Renewal
•	13 September 2002	Change of MAH
•	26 November 1997	Renewal
•	15 February 1997	Change of batch size

		Change to QC procedures
•	26 February 1997	Addition of manufacturer of the active substance and dosage form
•	28 April 1995	Addition of manufacturers of the dosage form