Veterinary Medicines Directorate

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Post Authorisation Assessments

Cardisure Flavoured 2.5 mg Tablets for Dogs

Vm 16849/4027

•	23 March 2022	Minor change in the manufacturing process of the finished product.
•	17 August 2021	Increase in batch size (to 6.0 kg) of the active substance used in the manufacturing process of the active substance. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Change in the manufacture of the active substance. Extension of a re-test period of the active substance.
•	23 April 2020	Changes to the labelling and package leaflet.
•	31 December 2019	Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product. Addition of a manufacturing site of the finished product.
•	24 January 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	17 January 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
•	30 August 2018	Change in RMS from UK to NL.
•	11 October 2016	Change in product name in Norway only.
•	12 July 2016	Renewal – UK as RMS
•	24 June 2015	Change in name of supplier of a starting material. Tightening of specification limits of the active substance. Addition of a new specification parameter for the active substance.
•	17 June 2015	Changes to the labelling and package leaflet.
•	13 May 2014	Change of distributor and resulting change to mock-ups.
•	13 February 2014	Addition of a new manufacturing site responsible for the finished product, primary packaging, secondary packaging, batch control testing and batch release.
•	24 October 2013	Addition of a manufacturer for a starting material and changes in the manufacturing process of the active substance.
•	11 July 2013	Variation to correct the specification limits for protein of an excipient due to a typing error in original submission.

•	25 March 2013	Change of QPPV and contact details for the QPPV of an existing pharmacovigilance system.
•	20 December 2012	Minor change in the manufacturing process of the active substance.
•	18 October 2012	Minor change to an approved test procedure used in the manufacturing process of the active substance.
•	04 April 2012	Change in batch size of the active substance.
•	04 August 2011	Change to batch release arrangements and quality control testing of the finished product.