Veterinary Medicines Directorate

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Post Authorisation Assessments

Pimocard 1.25 mg Flavoured Tablets for Dogs

Vm 16849/4042

•	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.
•	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.
•	17 July 2018	Repeat use MRP to add 4 new CMS
•	05 October 2017	Renewal – UK as RMS
•	05 August 2016	Change in distributor details.
•	22 January 2015	Change in the name of a supplier of a starting material of the active substance. Change to the specification limits. Addition of a new specification parameter with its corresponding test method.
•	04 December 2014	To increase the batch size of the active substance. To change the test procedure of the active substance. Change to the manufacturing process. Addition of an alternative supplier/manufacturer for the starting material of the active substance. Addition of a supplier for the starting material of the active substance.
•	04 December 2014	To add a manufacturing site responsible for all activities to produce Pimocard, including primary and secondary packaging, batch control testing and batch release. Minor change in the manufacturing process.

		Change to the limits of an excipient.
•	12 July 2013	Change in QPPV and QPPV contact details.