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Post Authorisation Assessments

Floron 40 mg/g Premix for Medicated Feeding Stuff for Swine Vm 01656/4011

•	27 July 2021	Changes to the quality control testing arrangements for
		the active substance – addition of a site where batch
		control / testing takes place.
		Change in the name and address of a manufacturer
		used in the manufacture of the active substance.
•	19 November 2020	Update to ASMF.
•	21 June 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	15 January 2019	Minor change in the manufacturing process of the finished product.
•	18 December 2018	Extension of a re-test period of the active substance.
•	06 July 2018	Change in the RMS from UK to CZ.
•	02 July 2018	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	14 March 2018	Changes to the quality control testing arrangements for
		the active substance – addition of a site where batch
		control / testing takes place. Changes to the quality control testing arrangements for
		the active substance – addition of a site where batch
		control / testing takes place.
•	26 October 2017	Change in contact details for local representative.
•	06 July 2015	Renewal – UK as RMS.
•	29 May 2015	Addition of a local representative.
•	16 March 2015	Change of distributor.
•	24 October 2014	To change the date of submission of the PSUR.
•	11 September 2014	To extend the shelf life of the finished product, from 2 years to 4 years.