Veterinary Medicines Directorate

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Post Authorisation Assessments

Flovuxin 300/16.5 mg/ml Solution for Injection for Cattle

Vm 01656/5033

•	16 October 2023	Approval of mock ups.
•	11 August 2023	Changes in the Summary of Product Characteristics (SPC), labelling and package leaflet intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6.
•	19 May 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	17 March 2023	Change(s) in the SPC, labelling or package leaflet to section adverse events.
•	08 December 2022	Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendations from the competent authority, including addition of a local representative for adverse event reporting. Alignment of the product information with version 9.0* of the QRD templates.