Veterinary Medicines Directorate

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Post Authorisation Assessments

Boflox 100 mg/ml Solution for Injection for Cattle and Pigs

Vm 36547/4002

•	26 April 2024	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance. (NI)
•	26 April 2024	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance. (GB+NI)
•	11 August 2023	Update to Ph. Eur. CEP.
•	15 March 2023	Addition of a secondary packaging site of a finished product.
•	20 February 2023	Addition of a secondary packaging site of a finished product.
•	18 August 2021	Introduction of a re-test period of the active substance.
•	29 January 2021	Addition of a manufacturer responsible for batch release of the finished product. Addition of a secondary packaging site of the finished product.
•	17 August 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	15 June 2018	Renewal – UK as CMS.
•	02 June 2016	Addition of a site for quality control testing. Change to batch size range.
•	17 December 2015	Variation to add a new manufacturer of the active substance
•	11 February 2014	Change in manufacturer of the finished product. Change to part of the packaging not in contact with the finished product formulation.
•	10 October 2013	Variation to seek approval of mock-ups.
•	08 August 2013	Addition of a secondary packaging site for the finished product Addition of a manufacturer responsible for batch release, excluding batch control/testing