Veterinary Medicines Directorate

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Post Authorisation Assessments

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

Vm 36547/4002

05 March 2025	Replacement of a manufacturing site for the finished product.
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