Veterinary Medicines Directorate

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Post Authorisation Assessments

Prolusyn 50 micrograms/ml Solution for Injection for Cattle

Vm 54400/4000

09 March 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI)
08 March 2026	Change in the pharmacovigilance system master file (PSMF) location. GB & NI)
17 December 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI).
21 March 2025	Change in the address of the marketing authorisation holder. Replacement of the importer and manufacturer responsible for batch testing and sterility test. Replacement of a manufacturer responsible for batch release not including batch control or testing of a sterile or non-sterile finished product. (NI).
14 February 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI).
03 March 2022	Repeat use procedure to add four CMS
20 October 2021	Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
01 October 2021	Replacement of a manufacturer responsible for batch release of the finished product. Replacement addition of a site where batch control/testing takes place.