



Post Authorisation Assessments

Prolusyn 50 micrograms/ml Solution for Injection for Cattle Vm 54400/4000

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.