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Post Authorisation Assessments

Buprenodale Multidose 0.3 mg/ml Solution for Injection for Dogs, Cats and Horses

•	02 October 2019	Replacement of a site where batch control/testing takes place.
•	31 May 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	16 January 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	16 October 2018	Renewal – UK as RMS.
•	10 October 2018	Change in RMS from UK to IE.
•	12 January 2018	Minor changes to an approved test procedure of the finished product.
•	22 May 2015	Changes to the product literature design.
•	08 April 2015	Change to the address of the MAH.