Veterinary Medicines Directorate

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Post Authorisation Assessments

Rapidexon 2 mg/ml Solution for Injection

•	24 January 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	30 August 2018	Change in RMS from UK to NL.
•	02 August 2018	Change in the specification limits of the finished product
•	19 June 2018	Deletion of manufacturing site for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	26 January 2017	To obtain Joint-Labelling of Mock-ups with Ireland.
•	05 August 2016	Change in distributor details.
•	27 February 2014	To change the distributor.
•	02 January 2014	Change of withdrawal period from 7 days for cattle and 11 days for horses to 8 days for both species for meat and offal.
•	19 April 2013	Change of QPPV contact details for QPPV for an already existing pharmacovigilance system.
•	19 August 2011	Submission of an updated certificate of suitability for the active substance.
•	14 July 2011	Renewal – UK as RMS.
•	09 December 2009	Change of distributor.
•	19 September 2008	New MA (MRP).
•	02 May 2007	SPC/label changes.
•	13 December 2006	Change in the name of the medicinal product.
•	11 October 2006	Change of distributor.