Veterinary Medicines Directorate

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Post Authorisation Assessments

Reproval 50mg/ml Solution for Injection for Dogs and Cats

•	March 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	04 March 2021	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	24 December 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	02 September 2019	Replacement of a test procedure for the finished product.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	03 June 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	17 May 2019	Change in the manufacturer of a starting material used in the manufacturing process of the active substance
•	20 December 2018	Change in RMS from UK to ES.
•	26 November 2018	Change in specification parameter of the finished product.
•	02 August 2018	Minor change in the manufacturing process of the finished product.
•	28 November 2014	Update to the DDPS.
•	25 September 2014	Addition of text to the storage conditions in the SPC and corresponding QRD text.
•	19 September 2014	Change in distributor details.
•	02 November 2012	Change of the product name in France and Germany to Carprieve 50 mg/ml Solution for Dogs and Cats.
•	09 October 2012	Renewal procedure.