Veterinary Medicines Directorate

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Post Authorisation Assessments

Cefenil RTU 50 mg/ml Suspension for Injection for Pigs and Cattle

Vm 02000/4330

•	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.
•	31 July 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	12 July 2019	Replacement of a supplier of packaging components or devices. Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product. Replacement of a manufacturing site of the finished product. Changes in the composition (excipients) of the finished product.
•	08 November 2017	Renewal – UK as CMS.
•	13 July 2017	Addition of a manufacturer of the active substance.
•	12 December 2016	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Update of the test procedure to comply with the updated general Ph. Eur monograph. Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	17 May 2016	Variation to extend the shelf life of the finished product as packaged for sale in high density polyethylene vials from 1 to 2 years and maintain the 2 year shelf life in type I clear glass vials.
•	09 March 2016	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	29 August 2014	Changes to the DDPS.

•	13 November 2013	To change the shelf-life of the product as packaged for sale from 1 year to 2 years.