Veterinary Medicines Directorate

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Post Authorisation Assessments

Cyclix Porcine 87.5 Microgram/ml Solution for Injection

Vm 05653/5039

•	03 March 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	27 February 2020	Minor changes to an approved test procedure of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Deletion of a non-significant specification parameter of the finished product. Changes to a test procedure for the finished product. Minor change in the manufacturing process of the finished product. Qualitative changes to the excipients.
•	27 August 2015	Change in the manufacturing process of the finished product.
•	17 July 2015	Change in test procedure for the finished product. Change in the immediate packaging of the finished product.
•	15 February 2015	Deletion of a manufacturing site of the finished product.
•	20 December 2012	Introduction of 50 ml pack size.
•	06 September 2012	Change in test procedure for the active substance.
•	01 August 2012	To change the test procedure for the finished product.
•	30 August 2011	Repeat Use Comm
•	11 July 2011	Renewal Marketing Authorisation.
•	13 January 2011	To add an environmental risk assessment (updating the original dossier)
•	06 November 2009	To add a production site of the finished product.
•	08 August 2008	Replacement or addition of a manufacturing site.
•	08 August 2008	Change to batch release arrangements
•	07 August 2008	To change the MAH from Intervet UK Ltd to Virbac S.A., France, and to change the Distributor from Intervet UK Ltd to VIRBAC Limited, Suffolk
•	06 August 2008	To change the name of the manufacturer of the active substance from Avecia Limited to NPIL Pharmaceuticals (UK) Ltd.