Veterinary Medicines Directorate

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Post Authorisation Assessments

Program 80 mg Suspension for Injection for Cats

•	19 March 2018	Change in RMS from UK to ES.
•	24 November 2017	Minor change in the manufacturing process of the finished product.
•	26 October 2017	Minor changes to an approved test procedure of the finished product. Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Change to in-process tests or limits applied during the manufacture of the finished product. Replacement of a manufacturing site of the finished product.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	28 June 2016	Change in the name of the Marketing Authorisation Holder from Novartis Santé Animale to Elanco France in France only.
•	21 June 2016	Change in the name and address of the Marketing Authorisation Holder from Novartis Animal Health S.p.A to Elanco Italia S.p.A. in Italy only, and from Novartis Sanidad Animal, S.L. to Elanco Spain, S.L.U. in Spain only.
•	16 March 2016	Change in distributor details Change in legal entity
•	30 June 2015	Tightening of specification limits of the active substance. Addition of a new in-process test and limits for the active substance.
•	13 February 2015	Change in test procedure for the finished product in line with Ph. Eur.
•	27 March 2014	Change to the QPPV contact details and updates to the DDPS that do not affect the pharmacovigilance system.
•	16 January 2014	Change to the address of the MAH.
•	05 September 2013	Grouped variation to test procedures and specification parameters/limits for excipients.
•	04 July 2013	Variation to change the address of the Marketing Authorisation Holder.
•	05 April 2013	Variation to make minor changes to the existing pharmacovigilance system.
•	28 March 2013	Grouped variation to change the name and/or address of the Marketing Authorisation Holder.

•	18 August 2011	Variation to change the Active Ingredient Specifications.
•	26 August 2010	Grouped variation to change the name of a Manufacturer, to change the name of a EU QP for Pharmacovigilance, to change the contact details of a EU QP for Pharmacovigilance.
•	14 October 2008	Variation to change the name of the finished product manufacturer.
•	02 September 2008	Renewal.
•	19 March 2008	Variation to change the address of the Marketing Authorisation Holder.
•	19 January 2006	Minor change to the finished product manufacturer.
•	06 August 2004	Change of Active Ingredient Manufacturer.
•	27 November 2003	EUDE Renewal.
•	22 September 2003	QC Procedures.
•	21 November 2000	Shelf-life extension.
•	20 July 2000	EUDE Renewal.