Veterinary Medicines Directorate

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Post Authorisation Assessments

ACP Injection 2 mg/ml Solution for Injection

•	25 September 2020	Change in the address of the MAH from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood, Business Park, Hook, RG27 9XA, United Kingdom.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	13 January 2016	Change of Marketing Authorisation Holder from Novartis Animal Health UK Ltd to Elanco Europe Ltd. Change in distributor details.
•	05 March 2015	Changes to section 4.10 of the SPC and corresponding sections of the product literature.
•	19 August 2014	Replacement of the site for EU market batch release.
•	09 May 2012	Grouped variation: Increase in batch size. Change in manufacturing site (manufacture, assembly, and batch control/testing). Change to batch release arrangements and quality control testing. Change of active substance manufacturer.
•	06 March 2009	Batch Control.
•	25 June 2008	Variation to bring the SPC and labels in line with the new legislation and to transfer the legal category from POM to POM-V.
•	17 June 2008	Addition of a manufacturer of the active substance.
•	01 February 2008	Change of address of the MA Holder and Distributor.
•	12 December 2006	Renewal.
•	29 November 2005	Changes to section 5.2 of the SPC: ‘Indications for Use’.
•	16 May 2003	Renewal.
•	09 May 2003	Assessment of Benzene in accordance with VICH guidelines.
•	16 August 2002	Change of name and address of MAH.
•	15 December 1997	QC Procedures.
•	11 September 1997	Renewal.
•	08 May 1997	Amendment of safety warnings.
•	14 June 1996	Change in distributor.