Veterinary Medicines Directorate

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Post Authorisation Assessments

AviPro Precise

•	27 May 2022	Tightening of specification limits of the finished product. Change in the fill weight / fill volume of the finished product.
•	17 August 2021	Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance Deletion of a specification parameter of the finished product.
•	16 December 2020	Change of MAH from Lohmann Animal Health GmbH, Heinz-Lohmann-Straße 4, D-27472 Cuxhaven, to Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	19 February 2020	Update of the quality dossier intended to implement the outcome of a Union referral procedure.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	17 May 2019	Changes to the labelling.
•	17 October 2017	Repeat Use application to add 1 new member state.
•	27 July 2017	Changes to the labelling and/or package leaflet.
•	18 January 2017	Minor changes to an approved test procedure of the finished product. Changes to a test procedure for the finished product.
•	07 February 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	16 April 2013	Change to batch release arrangements and quality control testing of the finished product. Change in test procedure on finished product.
•	27 April 2012	Change of name of MAH. Change of manufacturer of the active substance. Change in manufacturer responsible for batch release and quality control procedures.
•	04 April 2012	Submission of an updated part 2 of the dossier.
•	09 June 2011	Changes to an existing pharmacovigilance system as described in the DDPS.
•	14 September 2009	Change of QPPV.
•	14 December 2007	Change to fill volume.
•	28 November 2007	Change in test procedures to bring in line with Ph. Eur. Monograph.
•	21 May 2007	Renewal.
•	14 August 2005	Change to secondary packaging material – different colour code.