Veterinary Medicines Directorate

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Post Authorisation Assessments

AviPro Gumboro Vac Lyophilisate for Suspension for Chicken

Vm 00879/4192

•	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.
•	10 December 2020	Update of the quality dossier intended to implement the outcome of a Union referral procedure.
•	22 January 2020	Change to an approved stability protocol.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	18 January 2017	Minor changes to an approved test procedure of the finished product. Changes to a test procedure for the finished product.
•	21 November 2014	Update to the DDPS.
•	07 February 2014	Changes to an existing pharmacovigilance system as describe in the DDPS.
•	16 April 2013	Change in batch release arrangements and quality control of the finished product. Change in test procedure on the finished product.
•	16 May 2012	Change in name of MAH. Change in manufacturer of the finished product responsible for batch release and for quality control/testing. Change in manufacturer of the active substance.
•	09 June 2011	Changes to an existing pharmacovigilance system as described in the DDPS.
•	23 May 2011	Changes to the labelling/package leaflet which are unconnected to the SPC.
•	05 May 2011	Submission of an updated part 2 of the dossier. Introduction of an intermediate storage of finished product for up to 24 months.
•	17 December 2009	Renewal.
•	14 September 2009	Change of QPPV.
•	24 March 2009	Change in test procedure on the finished product.
•	14 December 2007	Change of filling volume.
•	28 November 2007	Change of test to bring in line with Ph. Eur. Monograph.
•	18 May 2007	Changes to the SPC to bring in line with new legislation.
•	01 February 2007	Change of product name from ‘Tad Gumboro Vac’ to ‘AviPro Gumboro Vac’.
•	07 December 2006	Change of batch size of active substance.
•	19 October 2006	Renewal.

•	10 November 2005	Changes in secondary packaging.
•	08 August 2002	QC procedures.