Veterinary Medicines Directorate

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Post Authorisation Assessments

Apralan G200 Premix for Medicated Feeding Stuff

•	24 September 2020	Change of MAH from Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to Elanco Europe Ltd. Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	23 July 2019	Addition of a site where batch control/testing takes place.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	14 January 2019	Addition of a manufacturer responsible for batch release not including batch control/testing.
•	14 June 2018	Change in test procedure for an excipient.
•	24 October 2017	Minor change in the manufacturing process of the active substance.
•	11 April 2016	Deletion of a non-significant specification parameter of an excipient
•	29 August 2013	Changes in the manufacturing process of the active substance Change to comply with Ph. Eur. or the national Pharmacopoeia of a member state
•	21 August 2013	Change to composition of outer packaging
•	15 June 2010	Minor change to the manufacturing process of the active substance
•	11 December 2008	Changes to the SPC and Product Literature to bring in line with new legislation
•	04 January 2008	Change to the address of the MAH
•	16 October 2007	Renewal
•	25 April 2007	Change in legal category from MFS to POM-V
•	01 July 2003	Change in composition of immediate packaging and storage conditions
•	30 April 2003	Renewal
•	27 September 2002	Change of manufacturer and assembler of dosage form
•	24 November 1998	Change in formulation Change in invented name of product from ‘Apramycin G100’ to ‘Apralan G200 Premix for Medicated Feeding Stuff’