



## Post Authorisation Assessments

### Apralan G200 Premix for Medicated Feeding Stuff Vm 00879/4167

|   |                   |  |
|---|-------------------|--|
| • | 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<br>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<br>Change in invented name of product from 'Apramycin G100' to 'Apralan G200 Premix for Medicated Feeding Stuff'   |