Veterinary Medicines Directorate

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Post Authorisation Assessments

Pulmotil G200 Premix for Medicated Feedingstuff

Vm 00879/4170

•	25 March 2022	Change in the name of a manufacturer of the finished product.
•	02 November 2021	Change in batch size of the active substance. Minor change in the manufacturing process of the active substance.
•	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 September 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release. Change in the name of the manufacturer of the finished product.
•	19 May 2020	Change in batch size range of the active substance. Change in immediate packaging of the liquid active substance.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	09 May 2019	Minor change in the manufacturing process of the finished product. Addition of new tests and limits applied during the manufacture of the finished product.
•	13 February 2019	Addition of a site where batch control takes place. Addition of a manufacturer responsible for batch release of the finished product. Deletion of manufacturing site for an active substance.
•	12 November 2014	Change to the name of the active substance manufacturer.
•	14 August 2014	Addition of a primary packaging site.
•	24 June 2014	Addition of a secondary packaging site.
•	23 October 2013	Extension of the shelf life of the finished product.
•	29 August 2013	Change in the immediate packaging of the finished product.
•	13 December 2012	Variation to change the SPC, Labelling, and Packaging Leaflet following a procedure in accordance with Article 35.
•	01 September 2011	Extension of the shelf life of the finished product.
•	21 June 2011	Addition of an active substance manufacturer.
•	12 January 2011	Variation to change the assay method for the starting material.

•	03 March 2010	Submission of a revised SPC and Product Labelling/Leaflet in line with the text published by Annex III of the Commission Decision.
•	11 December 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from MFS to POM-V.
•	12 March 2008	Minor change in the manufacturing process of the active substance.
•	04 January 2008	Change of the address of the Marketing Authorisation Holder.
•	21 September 2006	Change in the finished product specification.
•	14 September 2006	Variation to change the test procedure.
•	30 November 2005	Renewal.
•	21 September 2001	Change to section 5.5 of the SPC.
•	02 May 2001	Renewal.
•	22 August 2000	Change to QC Procedures.
•	22 August 2000	Extension of the shelf life and re-test period of the active substance.
•	22 August 2000	Change to QC Procedures.
•	07 September 1998	Grouped variation concerning changes to the SPC, change of legal category and change to dosage particulars.
•	08 December 1997	Change in the name of the Marketing Authorisation Holder.
•	29 October 1997	Change to the active ingredient specification.