Veterinary Medicines Directorate

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Post Authorisation Assessments

Pulmotil G100 Premix for Medicated Feedingstuff

Vm 00879/4169

•	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.
•	17 October 2014	Update to the current registration due to a change related to the product packaging.
•	16 July 2014	Minor change in the manufacturing process of the finished product.
•	31 December 2013	Change in the manufacturing process of the finished product.
•	23 October 2013	Variation to extend the shelf life of the finished product.
•	29 August 2013	Variation to change the immediate packaging of the finished product.
•	09 July 2013	Variation to update the in-process tests or limits applied during manufacture of the finished product.
•	13 December 2012	Variation to change the SPC, Labelling, and Package

		Leaflet following a procedure in accordance with an Article 35 referral.
•	01 September 2011	Variation to extend the shelf-life.
•	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, Product Literature, Leaflet in line with the Annex III European Commission decision.
•	11 December 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of legal category from MFS to POM-V.
•	12 March 2008	Minor change in the manufacturing process of the active substance.
•	04 January 2008	Variation to change the address of the Marketing Authorisation Holder.
•	14 September 2006	Variation to update a test procedure.
•	30 November 2005	Renewal.
•	01 July 2003	Addition of a pack type.
•	18 November 2002	Variation to change the name of the manufacturer and assembler of dosage form.
•	21 September 2001	Change to section 5.5 of the SPC.
•	04 May 2001	Renewal.
•	22 August 2000	Change to QC Procedures.
•	22 August 2000	Change in the packaging material of the non-sterile container.
•	22 August 2000	Variation to increase shelf-life/re-test period of the active substance.
•	22 August 2000	Change to QC Procedures.
•	07 September 1998	Change to the SPC. Change to the legal category and the dosage particulars.
•	08 December 1997	Change to the name of the Marketing Authorisation Holder.
•	29 October 1997	Change to the ingredient specification.
•	29 October 1997	Extension of shelf-life.