Veterinary Medicines Directorate

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Post Authorisation Assessments

Tylan Soluble Powder for Oral Solution

Vm 00879/4175

•	20 October 2023	Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State.
•	30 August 2023	Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State. Stability - other changes. Submission of an updated Ph.Eur certificate of suitability for the active substance. Submission of an updated Ph.Eur certificate of suitability for the active substance.
•	24 May 2023	Deletion of a site of batch release for the finished product.
•	08 April 2022	Change in the name of the manufacturer of the finished product.
•	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.
•	03 February 2020	Change in the name of the manufacturer of the finished product.
•	03 September 2019	Increase in batch size (including batch size range) of the finished product. Addition of a site where batch control/testing takes place. Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product. Addition of a secondary packaging site of the finished product.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	05 February 2019	Addition of a site where batch testing takes place. Addition of a site where batch testing takes place. Addition of a manufacturer responsible for batch release of the finished product.
•	10 December 2014	Submission of an updated Ph. Eur. Certificate of Suitability from an already approved manufacturer. Change to test procedures for the active substance. Change in the specification parameters of the finished product.
•	21 October 2014	Amendments to the SPC and product literature in line

		with Commission Decision regarding an Article 35 referral procedure.
•	11 September 2014	Amendments to the SPC and product literature in line with Commission Decision regarding an Article 35 referral procedure.
•	13 January 2014	Variation to change the supplier of a packaging component.
•	13 June 2012	Variation to change the specification parameters of a packaging component.
•	01 February 2012	Variation to introduce a single control on the weight of the bottle; resulting in a change in the tightening of a specification.
•	10 December 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	27 June 2008	Variation to decrease the chicken withdrawal period.
•	27 June 2008	Deletion of a contraindication.
•	04 January 2008	Variation to change the address of the Marketing Authorisation Holder.
•	02 January 2008	Renewal.
•	06 June 2006	Batch Control.
•	25 October 2005	Variation to change Part IV of the dossier.
•	26 September 2003	Renewal.
•	15 October 2002	Variation to change the name of a manufacturer.
•	12 January 2001	Change of shelf-life of the finished product.
•	09 February 1999	Renewal.
•	05 November 1998	Amendments to the indications and administration information on the SPC.
•	09 December 1997	Change of Marketing Authorisation Holder.
•	01 October 1996	Change of address of the ATC/PL Holder.