Veterinary Medicines Directorate

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Post Authorisation Assessments

Tylan G20 Premix for Medicated Feedingstuff

•	23 December 2020	Change in immediate packaging of the liquid active substance. Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.
•	22 December 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.
•	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.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	31 January 2019	Addition of a manufacturer responsible for batch release of the finished product. Addition of a site where batch control/testing takes place. Deletion of manufacturing site for an active substance.
•	21 May 2018	Changes to a test procedure for an excipient.
•	05 December 2017	Minor change in the manufacturing process of the active substance.
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•	05 December 2017	Deletion of a non-significant in-process test applied during the manufacture of the active substance. Minor change in the manufacturing process of the active substance.
•	11 January 2017	Change to a test procedure for an excipient.
•	30 March 2016	Deletion of a non-significant specification parameter.
•	01 May 2015	Minor change in the manufacturing process of the active substance.
•	12 November 2014	Change to the name of the active substance manufacturer.

•	11 September 2014	Amendments to the SPC and product literature in line with Commission Decision regarding an Article 35 referral procedure.
•	24 June 2014	Deletion of a non-significant specification parameter.
•	28 November 2013	Variation to update the current products with a number of minor changes to the manufacturing process of the active substance.
•	28 November 2013	Variation to update the specification parameters used in the manufacturing process of the active substance.
•	22 August 2013	Grouped variation to change the test method used for a finished product excipient, to replace the specification parameters of an excipient, and to remove a packaging presentation.
•	30 May 2013	Introduction of a test procedure used in the manufacture of the active substance.
•	28 May 2012	Variation to change the name of an active substance manufacturer.
•	21 December 2011	Reduction of a specification level used in the manufacturing process of the active substance.
•	21 January 2009	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	12 March 2008	Variation to remove the animal sourced TSE risk materials from the current starting materials used in the manufacturing process of the active substance.
•	14 February 2008	Change in the specification of an excipient.
•	04 January 2008	Variation to change the address of the Marketing Authorisation Holder.
•	19 December 2007	Change in the specification of an excipient.
•	30 October 2007	Renewal.
•	02 May 2007	Change in the test procedure for the finished product.
•	04 April 2007	Variation to decrease the finished product shelf life.
•	25 September 2003	Renewal.
•	01 July 2003	Change in the pack details.
•	15 November 2002	Change of manufacturing sites.
•	06 September 2001	Harmonisation of the SPC between the UK and IE.
•	15 January 1999	Renewal.
•	16 January 1998	Change in the dose and dosage form.
•	09 December 1997	Change of address of the manufacturer of the active substance, dosage form, and assembler of dosage form.
•	29 January 1997	Change to the therapeutic purpose.
•	12 November 1996	Addition of a manufacturer/assembler of dosage form.
•	01 October 1996	Change of address of the ATC/PL Holder.
•	02 April 1996	Variation concerning the addition of a formulation (ATC Only).
•	12 September 1995	Change to the ingredient/finished product specification.