



## Post Authorisation Assessments

### Tylan Soluble Powder for Oral Solution Vm 52127/5122

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| 05 March 2026     | Submission of a Ph. Eur. CEP for an active substance.<br>Change in the name of a manufacturer or importer of the finished product.  |
| 01 September 2025 | Change of distributor details from Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom to Elanco UK AH Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.<br>Change in legal entity of MA holder from Elanco Europe Ltd, Form 2, Bartley Way Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom to Elanco GmbH, Heinz-Lohmann Strasse 4, Groden, 27472 Cuxhaven, Germany. |
| 18 July 2025      | One-off alignment of the product information with Version 3 of the GB QRD template.   |
| 07 April 2025     | Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.   |
| 02 April 2025     | Change(s) in the name or address or contact details of a qualified person for pharmacovigilance.  |
| 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.<br>Stability - other changes.<br>Submission of an updated Ph.Eur certificate of suitability for the active substance.<br>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.<br>Addition of a site where batch control/testing takes place.<br>Addition of a secondary packaging site of the finished product.<br>Addition of a primary packaging site of the finished product.   |

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|                   | 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.<br>Change to test procedures for the active substance.<br>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.   |