VPA22020/020/001

Tylan Soluble Powder for Oral Solution

Variation	Summary	Date
Vet - B3 a)	VNRA - Vet - B3 a) - - Vet - B3 a) - Changes to the quality part of the dossier - Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for importation, manufacturer responsible for batch release, site where batch control takes place, or supplier of (1) a starting material for an active substance, (2) a reagent or (3) an excipient (when mentioned in the dossier)	05/06/26
Vet - G.I.18	VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	01/05/25
Vet - B3 e)	VNRA - Vet - B3 e) - e) Deletion of a test procedure - B3 e) Changes to the quality part of the dossier: Deletion of a test procedure — for the active substance or a starting material, reagent or intermediate of the active substance; —for the immediate packaging of the active substance; — for an excipient or the finished product; —for the immediate packaging of the finished product	23/07/24
Vet - B33 b)	VNRA - Vet - B33 b) - b) Update of the test procedure to reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number - B33 b) Changes to the quality part of the dossier: Change in test procedure for the finished product to comply with Ph. Eur.: — update of the test procedure to reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number	23/07/24
Vet - B4 b)	VNRA - Vet - B4 b) - b) Changes to quality control testing arrangements for the active substance: replacement or addition of a site where batch control or testing of the active substance takes place - B4 b) Changes to the quality part of the dossier: Changes to the production process or the storage of active substance where no Ph. Eur. CEP is part of the approved	14/05/24

	dossier of an active substance (including starting material, reagent or intermediate) - changes to quality control testing arrangements for the active substance: replacement or addition of a site where batch control or testing of the active substance takes place	
Vet - F.III.2 z)	VRA-R - Vet - F.III.2 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.III.2 z) Quality Changes - CEP/TSE/MONOGRAPHS - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	22/03/24
Vet - F.I.d. z)	VRA-R - Vet - F.I.d. z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.I.d. z) Quality Changes - Active Substance - Stability - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	22/03/24
Vet - F.III.1 a) z.	VRA-R - Vet - F.III.1 a) z. - a) European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.III.1 a) z. Quality Changes - CEP/TSE/MONOGRAPHS -Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: -For an active substance -For a starting material/reagent/intermediate used in the manufacturing process of the active substance -For an excipient European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	22/03/24
Vet - F.III.1 a) z.	VRA-R - Vet - F.III.1 a) z. - a) European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.III.1 a) z. Quality Changes - CEP/TSE/MONOGRAPHS -Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: -For an active substance -For a starting material/reagent/intermediate used in the manufacturing process of the active substance -For an excipient European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	22/03/24
Vet - A1 e)	VNRA - Vet - A1 e) - e) Change in the name or address or contact details of a manufacturer or importer of the finished product (including batch release or quality control testing sites) - A1 e) Administrative changes: Change in the name or address or contact details of a manufacturer or importer of the finished product (including batch release or quality control testing sites)	22/03/22