VPA10454/071/001

Omeproshield 370 mg/g oral paste for horses

Variation	Summary	Date
Vet - G.I.17 b)	VRA-R - Vet - G.I.17 b) - - Vet - G.I.17 b) - Changes in relation to MR/SR procedures - Adaptation of the Product Information for the original Concerned Member States after a SRP	27/08/26
Vet - B43	VNRA - Vet - B43 - - Vet - B43 - Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible	13/07/26
Vet - B3 e)	VNRA - Vet - B3 e) - - Vet - 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	13/07/26
Vet - B3 t)	VNRA - Vet - B3 t) - - Vet - B3 t) - Changes to the quality part of the dossier: Deletion of a Ph. Eur. CEP — for an active substance;— for a starting material, reagent or intermediate used in the manufacturing process of the active substance;— for an excipient	25/07/25
Vet - B38	VNRA - Vet - B38 - - Vet - B38 - Change in pack size (number of units e.g. tablets, ampoules, etc. in a pack) within the range of the currently approved pack size	24/06/25
Vet - B47 c)	VNRA - Vet - B47 c) - c) Change in specifications from a national pharmacopoeia of a Member State to the Ph. Eur. - B47 c) Changes to the quality part of the dossier: Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: — change in specifications from a national pharmacopoeia of a Member State to the Ph. Eur.	09/06/25
Vet - F.II.e.2 z)	VRA-R - Vet - F.II.e.2 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.e.2 z) Quality Changes - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	06/06/25
Vet - F.II.d.1 a)	VRA-S - Vet - F.II.d.1 a) - a) Change outside the approved specifications limits range - F.II.d.1 a) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	06/06/25
Vet - F.IV.1 b)	VRA-S - Vet - F.IV.1 b) - b) Addition or replacement of a device which is an integrated part of the primary packaging - F.IV.1 b) Quality Changes - Devices - Change of a measuring or administration device - Addition or replacement of a device which is an integrated part of the primary packaging	06/06/25

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	28/03/24
Vet - C6	VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17	07/07/23
Vet - C1	VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	07/07/23
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)	08/08/22
Vet - A1 a)	VNRA - Vet - A1 a) - a) Change in the name or address or contact details of the marketing authorisation holder - A1 a) Administratvie changes: Change in the name or address or contact details of the marketing authorisation holder	08/08/22