VPA22664/025/001

Levacide Injection 75 mg/ml

Variation	Summary	Date
Vet - F.II.b.1 z)	VRA-R - Vet - F.II.b.1 z) - - Vet - F.II.b.1 z) - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	06/03/26
Vet - F.II.b.4 z)	VRA-R - Vet - F.II.b.4 z) - - Vet - F.II.b.4 z) - Change in the batch size (including batch size ranges) of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	06/03/26
Vet - F.II.a.3 z)	VRA-R - Vet - F.II.a.3 z) - - Vet - F.II.a.3 z) - Changes in the composition (excipients) of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	06/03/26
Vet - F.II.b.5 z)	VRA-R - Vet - F.II.b.5 z) - - Vet - F.II.b.5 z) - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	06/03/26
Vet - F.II.e.1 b) 2.	VRA-S - Vet - F.II.e.1 b) 2. - - Vet - F.II.e.1 b) 2. - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Sterile medicinal products and biological/ immunological medicinal products	06/03/26
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	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	20/07/23

Vet - A1 c)	VNRA - Vet - A1 c) - c) Change in the name or address or contact details of an active substance master file (ASMF) holder - A1 c) Administratvie changes: Change in the name or address or contact details of an active substance master file (ASMF) holder	30/06/22
Vet - B47 a)	VNRA - Vet - B47 a) - a) Change of specification(s) of a former non EU Pharmacopoeial active substance, excipient or active substance starting material to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - B47 a) Changes to the quality part of the dossier: Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: — change of specification(s) of a former non EU Pharmacopoeial active substance, excipient or active substance starting material to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State	30/06/22