

VPA10996/169/001

Nobivac Lepto 2 Suspension for Injection for Dogs

Variation	Summary	Date
Vet - F.I.a.2 z)	VRA-R - Vet - F.I.a.2 z) - - Vet - F.I.a.2 z) - Changes in the manufacturing process of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	01/04/26
Vet - F.II.d.2 b)	VRA-R - Vet - F.II.d.2 b) - - Vet - F.II.d.2 b) - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	01/04/26
Vet - F.II.a.3 b) 2.	VRA-S - Vet - F.II.a.3 b) 2. - - Vet - F.II.a.3 b) 2. - Changes in the composition (excipients) of the finished product - Changes in the composition (excipients) of the finished product - Changes in components of the flavouring or colouring system - Other excipients - Change that relates to a biological/immunological product	01/04/26
Vet - F.II.d.1 z)	VRA-R - Vet - F.II.d.1 z) - - Vet - F.II.d.1 z) - Change in the specification parameters and/or limits of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	01/04/26
Vet - C6	VNRA - Vet - C6 - - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex	17/02/26
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)	17/12/25
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	30/10/24

Vet - G.I.4	VRA-S - Vet - G.I.4 - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. - G.I.4 Safety, Efficacy, Pharmacovigilance changes - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.	30/10/24
B.III.1.b.5	II - B.III.1.b.5 - 5. New/updated certificate from an already approved/ new manufacturer using materials of human or animal origin for which an assessment of the risk with respect to potential contamination with adventitious agents is required - B.III.1.b.5 - 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 TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - New/updated certificate from an already approved/ new manufacturer using materials of human or animal origin for which an assessment of the risk with respect to potential contamination with adventitious agents is required	23/05/22