

VPA10996/169/001

**Nobivac Lepto 2 Suspension for Injection for Dogs**

<b>Variation</b>	<b>Summary</b>	<b>Date</b>
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