

VPA10996/277/001

Nobivac Respira Bb suspension for injection in pre-filled syringe for dogs

Variation	Summary	Date
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 - G.I.3 b)	VRA-R - Vet - G.I.3 b) - b) Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon - G.I.3 b) Safety, Efficacy, Pharmacovigilance changes - Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendations from the competent authority or the Agency concerning risk management measures in pharmacovigilance related to veterinary medicinal products - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon	09/01/23
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	09/01/23
B.II.d.2.d	IB - B.II.d.2.d - d) Other changes to a test procedure (including replacement or addition) - B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	09/05/22
B.II.a.3.b.3	II - B.II.a.3.b.3 - 3. Change that relates to a biological/immunological product - B.II.a.3.b.3 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a biological/immunological product	09/05/22