

VPA22664/038/001

Bovaclox DC Xtra

Variation	Summary	Date
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	26/02/24
Vet - F.III.1 a) z.	VRA-R - Vet - F.III.1 a) z. - a) European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.III.1 a) z. 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 Certificate of Suitability to the relevant Ph. Eur. Monograph - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	21/08/23
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