VPA10826/005/001

Animedazon Spray, 2.45 % w/w cutaneous spray suspension for cattle, sheep and pigs

Variation	Summary	Date
Vet - B3 d)	VNRA - Vet - B3 d) - - Vet - B3 d) - Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) of — an active substance;— a starting material;— an intermediate or reagent used in the manufacturing process of the active substance	05/02/26
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	24/07/25
Vet - F.II.d.1 z)	VRA-R - Vet - F.II.d.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.d.1 z) Quality Changes - Finished Product -Control of finished product - 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 EMA/CMDv/7381/2021	02/09/24
Vet - C8	VNRA - Vet - C8 - Implementation of changes in the SPC not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C8 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Implementation of changes in the SPC not already covered elsewhere in the Annex to Regulation (EU) 2021/17	01/03/24
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	25/01/24
Vet - B44(Do not use)	VNRA - Vet - B44 - Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance, starting material, reagent or intermediate, excipient - B44 Changes to the quality part	15/02/23

	of the dossier: Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	