VPA10387/012/001

CYDECTIN 0.5% w/v Pour-On for cattle

Variation	Summary	Date
Vet - F.IV.1 a) 1.	VRA-R - Vet - F.IV.1 a) 1. - - Vet - F.IV.1 a) 1. - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device without CE marking	13/10/26
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	13/10/26
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)	13/10/26
Vet - F.II.c.1 z)	VRA-R - Vet - F.II.c.1 z) - - Vet - F.II.c.1 z) - Change in the specification parameters and/or limits of an excipient - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	13/10/26
Vet - F.II.a.3 z)	VRA-R - Vet - F.II.a.3 z) - - Vet - F.II.a.3 z) - Changes in the composition (excipients) of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	13/10/26
Vet - B37	VNRA - Vet - B37 - - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	10/12/25
Vet - B37	VNRA - Vet - B37 - - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	10/12/25
Vet - B37	VNRA - Vet - B37 - - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	10/12/25
Vet - B37	VNRA - Vet - B37 - - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	10/12/25
Vet - C1	VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	15/01/25
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	15/01/25

Vet - F.I.d.1 c)	VRA-R - Vet - F.I.d.1 c) - c) Extension or introduction of a re-test period/storage period supported by real time data - F.I.d.1 c) Quality Changes - Active Substance - Stability -Change in the re-test period/storage period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Extension or introduction of a re-test period/storage period supported by real time data	16/12/24
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	16/02/24
Vet - C4	VNRA - Vet - C4 - Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendation from the competent authority or the Agency concerning risk management measures in pharmacovigilance related to veterinary medicinal products - C4 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendation from the competent authority or the Agency concerning risk management measures in pharmacovigilance related to veterinary medicinal products	15/09/22