

VPA10996/215/001

**Paracox-5, suspension for oral suspension for chickens**

<b>Variation</b>	<b>Summary</b>	<b>Date</b>
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	12/02/24
Vet - F.II.e.2 z)	VRA-S - Vet - F.II.e.2 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.e.2 z) Quality Changes - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	24/10/23
Vet - F.II.b.4 d)	VRA-S - Vet - F.II.b.4 d) - d) The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line) - F.II.b.4 d) Quality Changes - Finished Product -Manufacture - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line)	02/10/23
Vet - F.II.d.1 a)	VRA-S - Vet - F.II.d.1 a) - a) Change outside the approved specifications limits range - F.II.d.1 a) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	17/06/22