VPA10996/215/001

Paracox-5, suspension for oral suspension for chickens

Variation	Summary	Date
Vet - F.I.a.1 g)	VRA-S - Vet - F.I.a.1 g) - - Vet- F.I.a.1 g)- Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place	19/11/26
Vet - F.I.b.2 b)	VRA-R - Vet - F.I.b.2 b) - - Vet - F.I.b.2 b) - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate	19/11/26
Vet - F.II.e.1 b) 2.	VRA-S - Vet - F.II.e.1 b) 2. - - Vet - F.II.e.1 b) 2. - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Sterile medicinal products and biological/ immunological medicinal products	19/11/26
Vet - A1 b)	VNRA - Vet - A1 b) - - Vet A1 b) Administrative changes - Change in the name or address or contact details of a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or a quality control testing site (where ecified in the dossier) where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier.	16/04/26
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	17/02/26
Vet - F.V.b 1. c)	VRA-S - Vet - F.V.b 1. c) - - Vet - F.V.b 1. c) - Harmonisation of the quality dossier Harmonisation of the quality dossier for the same purely national products and/or the same products approved in MR/DC procedures which are owned by the same MAH not participating in a former union interest referral procedure or SPC harmonisation procedure	07/10/25
Vet - F.I.a.1 d)	VRA-S - Vet - F.I.a.1 d) - - Vet - F.I.a.1 d) - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The change relates to a biological/immunological active substance	07/10/25

	or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product	
Vet - B3 a)	VNRA - Vet - B3 a) - a) Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier) - B3 a) Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier)	22/08/24
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	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 -	17/06/22

	Change outside the approved specifications limits range	