VPA10996/216/001

Bovilis Rotavec Corona emulsion for injection for cattle

Variation	Summary	Date
Vet - B3 a)	VNRA - Vet - B3 a) - - Vet - 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 importation, manufacturer responsible for batch release, site where batch control takes place, or supplier of (1) a starting material for an active substance, (2) a reagent or (3) an excipient (when mentioned in the dossier)	14/04/26
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.I.a.2 b)	VRA-S - Vet - F.I.a.2 b) - b) The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol - F.I.a.2 b) Quality Changes - Active Substance - Manufacture - Changes in the manufacturing process of the active substance - The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol	20/05/25
Vet - B3 c)	VNRA - Vet - B3 c) - c) Deletion of a non-significant in-process test during the manufacture of the active substance - B3 c) Changes to the quality part of the dossier: Deletion of a non-significant in-process test during the manufacture of the active substance (e.g. deletion of an obsolete in-process test)	24/03/25
Vet - B3 c)	VNRA - Vet - B3 c) - c) Deletion of a non-significant in-process test during the manufacture of the active substance - B3 c) Changes to the quality part of the dossier: Deletion of a non-significant in-process test during the manufacture of the active substance (e.g. deletion of an obsolete in-process test)	24/03/25
Vet - I.II.1 a)	VRA-E - Vet - I.II.1 a) - a) Change of bioavailability - I.II.1 a) Changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species - Changes to strength, pharmaceutical form and route of administration - Change of bioavailability	08/10/24
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)	05/07/24

	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	
Vet - G.I.4	VRA-S - Vet - G.I.4 - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. - G.I.4 Safety, Efficacy, Pharmacovigilance changes - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.	05/07/24
Vet - F.II.b.2 a) 1.	VRA-S - Vet - F.II.b.2 a) 1. - a) Replacement or addition of a site where batch control/testing takes place 1. Replacement or addition of a site where batch control/testing takes place for a biological/immunological veterinary medicinal product and any of the test methods performed at the site is a biological/immunological method - F.II.b.2 a) 1. Quality Changes - Finished Product -Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place - Replacement or addition of a site where batch control/testing takes place for a biological/immunological veterinary medicinal product and any of the test methods performed	02/04/24
Vet - F.II.b.1 a)	VRA-S - Vet - F.II.b.1 a) - a) Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/immunological veterinary medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes - F.II.b.1 a) Quality Changes - Finished Product -Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/immunological veterinary medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes	28/09/23
Vet - F.II.b.4 d)	VRA-R - 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	28/09/23

	medicinal product is increased / decreased without process change (e.g. duplication of line)	
Vet - F.II.b.2 a) 1.	VRA-S - Vet - F.II.b.2 a) 1. - a) Replacement or addition of a site where batch control/testing takes place 1. Replacement or addition of a site where batch control/testing takes place for a biological/immunological veterinary medicinal product and any of the test methods performed at the site is a biological/immunological method - F.II.b.2 a) 1. Quality Changes - Finished Product -Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place - Replacement or addition of a site where batch control/testing takes place for a biological/immunological veterinary medicinal product and any of the test methods performed	28/09/23
Vet - F.II.b.2 b) z.	VRA-S - Vet - F.II.b.2 b) z. - b) Replacement or addition of a manufacturer responsible for importation and/or batch release z. Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.2 b) z. Quality Changes - Finished Product -Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	28/09/23
Vet - B21	VNRA - Vet - B21 - Replacement or addition of a secondary packaging site of a finished product - B21 Changes to the quality part of the dossier: Replacement or addition of a secondary packaging site of a finished product	07/09/23
B.I.a.1.j	II - B.I.a.1.j - j) 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 - B.I.a.1.j - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - 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	30/09/22
B.I.b.2.d	II - B.I.b.2.d - d) Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance - B.I.b.2.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting	30/09/22

	material/reagent/intermediate used in the manufacturing process of the active substance - Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance	
B.II.d.2.c	II - B.II.d.2.c - c) Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol - B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol	30/09/22
B.II.d.2.c	II - B.II.d.2.c - c) Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol - B.II.d.2.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol	30/09/22
C.I.4	II - C.I.4 - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - C.I.4 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data	30/09/22