VPA10996/274/001

AquaVac PD3 emulsion for injection for Atlantic salmon

Variation	Summary	Date
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	27/03/25
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.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	20/12/22
Vet - F.I.d.1 c)	VRA-S - 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	20/12/22

	real time data	
Vet - F.I.c.1 a)	VRA-S - Vet - F.I.c.1 a) - a) Qualitative and/or quantitative composition for sterile and non-frozen biological/immunological active substances - F.I.c.1 a) Quality Changes - Active Substance - Container closure system - Change in immediate packaging of the active substance - Qualitative and/or quantitative composition for sterile and non-frozen biological/immunological active substances	20/12/22
Vet - F.I.a.3 b)	VRA-S - Vet - F.I.a.3 b) - b) The scale for a biological/immunological active substance is increased/decreased without process change (e.g. duplication of line) - F.I.a.3 b) Quality Changes - Active Substance - Manufacture -Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - The scale for a biological/immunological active substance is increased/decreased without process change (e.g. duplication of line)	20/12/22
Vet - F.I.a.1 d)	VRA-S - Vet - F.I.a.1 d) - d) The change relates to a biological/immunological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product - F.I.a.1 d) - 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 - The change relates to a biological/immunological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product	20/12/22