

VPA10996/152/001

**Bovilis Bovipast RSP suspension for injection for cattle**

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	30/08/24
Vet - F.V.b 1. c)	VRA-S - Vet - F.V.b 1. c) - c) 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 - F.V.b 1. c) Quality Changes - Changes to a marketing authorisation resulting from other regulatory procedures - 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	03/02/23
Vet - F.II.d.2 a)	VRA-S - Vet - F.II.d.2 a) - a) 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 - F.II.d.2 a) 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	03/02/23
Vet - F.II.d.2 a)	VRA-S - Vet - F.II.d.2 a) - a) 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 - F.II.d.2 a) Quality Changes - Finished Product -Control of finished product - Change in test procedure	03/02/23

	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	
Vet - F.II.d.2 a)	VRA-S - Vet - F.II.d.2 a) - a) 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 - F.II.d.2 a) 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	03/02/23
Vet - F.II.c.2 z)	VRA-R - Vet - F.II.c.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.c.2 z) Quality Changes - Finished Product -Control of excipients-Change in test procedure for an excipient - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	03/02/23
Vet - F.II.d.2 z)	VRA-R - Vet - F.II.d.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.d.2 z) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	03/02/23
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	03/02/23
Vet - F.I.b.1 z)	VRA-R - Vet - F.I.b.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.I.b.1 z) Quality Changes - Active Substance - Control of active substance -Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	03/02/23
Vet - F.I.b.2 z)	VRA-R - Vet - F.I.b.2 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.I.b.2 z) Quality Changes - Active Substance - Control of active substance - Change in test procedure for active substance or starting	03/02/23

	material/reagent/intermediate used in the manufacturing process of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	
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