

VPA10996/146/001

Heptavac P Plus

Variation	Summary	Date
Vet - F.II.b.1 a)	VRA-S - Vet - F.II.b.1 a) - - Vet - F.II.b.1 a) - 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	12/08/26
Vet - F.II.b.4 d)	VRA-R - Vet - F.II.b.4 d) - - Vet - F.II.b.4 d) - 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)	12/08/26
Vet - F.II.b.3 a)	VRA-R - Vet - F.II.b.3 a) - - Vet - F.II.b.3 a) - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process	12/08/26
Vet - F.II.b.1 z)	VRA-R - Vet - F.II.b.1 z) - - Vet - F.II.b.1 z) - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	12/08/26
Vet - F.II.b.5 z)	VRA-R - Vet - F.II.b.5 z) - - Vet - F.II.b.5 z) - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	12/08/26
Vet - F.II.d.2 z)	VRA-R - Vet - F.II.d.2 z) - - Vet - F.II.d.2 z) - Change in test procedure for the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	12/08/26
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.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 or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product	05/09/25
Vet - F.I.a.1 d)	VRA-S - Vet - F.I.a.1 d) - - Vet - F.I.a.1 d) - Change in the	05/09/25

	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	
Vet - F.I.a.2 z)	VRA-R - Vet - F.I.a.2 z) - - Vet - F.I.a.2 z) - Changes in the manufacturing process of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	05/09/25
Vet - F.I.a.2 z)	VRA-R - Vet - F.I.a.2 z) - - Vet - F.I.a.2 z) - Changes in the manufacturing process of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	05/09/25
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	05/09/25
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	05/09/25
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	05/09/25
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	05/09/25
Vet - F.I.a.4 z)	VRA-R - Vet - F.I.a.4 z) - - Vet - F.I.a.4 z) Change to in-process tests or limits applied during the manufacture of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	05/09/25
Vet - F.I.a.4 z)	VRA-R - Vet - F.I.a.4 z) - - Vet - F.I.a.4 z) Change to in-process tests or limits applied during the manufacture of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	05/09/25
Vet - F.II.e.4 z)	VRA-R - Vet - F.II.e.4 z) - - Vet - F.II.e.4 z) - Change in shape or dimensions of the container or closure (immediate	05/09/25

	packaging) - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	
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)	29/01/25
Vet - F.I.b.2 z)	VRA-S - 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 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	20/11/24
Vet - F.II.d.2 z)	VRA-S - 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	20/11/24
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	24/09/24
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	20/09/24

	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 - B47 b)	VNRA - Vet - B47 b) - b) Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State - B47 b) Changes to the quality part of the dossier: Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: — change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	20/10/23
Vet - F.II.d.2 b)	VRA-S - Vet - F.II.d.2 b) - b) Other changes to a test procedure (including replacement or addition) - F.II.d.2 b) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	01/08/23
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	17/04/23
Vet - F.II.d.2 b)	VRA-S - Vet - F.II.d.2 b) - b) Other changes to a test procedure (including replacement or addition) - F.II.d.2 b) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	17/04/23
Vet - F.II.d.2 b)	VRA-R - Vet - F.II.d.2 b) - b) Other changes to a test procedure (including replacement or addition) - F.II.d.2 b) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	17/04/23
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	29/03/23

	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	
Vet - F.I.b.2 a)	VRA-S - Vet - F.I.b.2 a) - a) Substantial change to or replacement of a biological/immunological/immunochemical test - F.I.b.2 a) Quality Changes - Active Substance - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Substantial change to or replacement of a biological/immunological/immunochemical test	29/03/23
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 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	17/06/22
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 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	17/06/22
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 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	17/06/22
B.II.d.2.d	IB - B.II.d.2.d - d) Other changes to a test procedure	10/06/22

	(including replacement or addition) - B.II.d.2.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	
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	26/05/22
B.I.a.2.c	II - B.I.a.2.c - c) 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 - B.I.a.2.c - 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	16/02/22
B.I.a.2.c	II - B.I.a.2.c - c) 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 - B.I.a.2.c - 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	16/02/22
B.I.a.2.c	II - B.I.a.2.c - c) 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	16/02/22

	significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol - B.I.a.2.c - 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	
B.I.a.2.c	II - B.I.a.2.c - c) 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 - B.I.a.2.c - 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	16/02/22
B.I.a.2.c	II - B.I.a.2.c - c) 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 - B.I.a.2.c - 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	16/02/22
B.I.a.2.c	II - B.I.a.2.c - c) 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 - B.I.a.2.c - 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	16/02/22

	significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol	
B.I.b.2.e	IB - B.I.b.2.e - e) Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - 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	16/02/22