

VPA10387/007/001

Colombovac PMV

Variation	Summary	Date
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	17/02/23
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)	17/02/23
Vet - F.II.d.1 b)	VRA-S - Vet - F.II.d.1 b) - b) Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product - F.II.d.1 b) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product	17/02/23
Vet - F.II.c.1 a)	VRA-S - Vet - F.II.c.1 a) - a) Change outside the approved specifications limits range - F.II.c.1 a) Quality Changes - Finished Product -Control of excipients - Change in the specification parameters and/or limits of an excipient - Change outside the approved specifications limits range	17/02/23