VPA10996/105/001

Cobactan LC, 75 mg, intramammary ointment for lactating cattle

Variation	Summary	Date
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	06/11/26
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	06/11/26
Vet - F.I.a.2 d)	VRA-R - Vet - F.I.a.2 d) - - Vet - F.I.a.2 d) - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File	06/11/26
Vet - F.II.e.2 z)	VRA-S - Vet - F.II.e.2 z) - - Vet - F.II.e.2 z) 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 this guidance	05/11/26
Vet - F.II.d.1 z)	VRA-S - Vet - F.II.d.1 z) - - Vet - F.II.d.1 z) - Change in the specification parameters and/or limits of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	05/11/26
Vet - F.II.d.2 b)	VRA-S - Vet - F.II.d.2 b) - - Vet - F.II.d.2 b) - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	05/11/26
Vet - F.II.b.1 d)	VRA-S - Vet - F.II.b.1 d) - - Vet - F.II.b.1 d) - 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 sterile veterianry medicinal products (including those that are aseptically manufactured) excluding biological/ immunological veterinary medicinal products	05/11/26
Vet - B22	VNRA - Vet - B22 - - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	05/11/26
Vet - B39	VNRA - Vet - B39 - - Vet - B39 - Change in any part of the primary packaging material not in contact with the finished product formulation (such as change of colour due to different plastic used for flip-off caps, colour code rings on ampoules or change of needle shield)	05/11/26
Vet - B12 a)	VNRA - Vet - B12 a) - - Vet - B12 a) - Minor changes:— to an approved test procedure — for active substance or a starting	11/03/26

	material, reagent or intermediate used in the manufacturing process of the active substance; — for the finished product;— for an excipient	
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.II.d.1 a)	VRA-S - Vet - F.II.d.1 a) - - Vet - F.II.d.1 a) - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	02/01/26
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	02/10/24
Vet - F.I.a.2 z)	VRA-R - Vet - F.I.a.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.a.2 z) Quality Changes - Active Substance - Manufacture - 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 EMA/CMDv/7381/2021	20/09/24
Vet - F.I.a.2 d)	VRA-R - Vet - F.I.a.2 d) - d) Minor change to the restricted part of an Active Substance Master File - F.I.a.2 d) Quality Changes - Active Substance - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File	20/09/24
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	19/03/24
Vet - B39	VNRA - Vet - B39 - Change in any part of the primary packaging material not in contact with the finished product formulation - B39 Changes to the quality part of the dossier:	01/03/24

	Change in any part of the primary packaging material not in contact with the finished product formulation (such as change of colour due to different plastic used for flip-off caps, colour code rings on ampoules or change of needle shield)	
B.I.b.1.z	IB - B.I.b.1.z - z Other variation - B.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 variation	20/06/22
B.I.b.1.c	IB - B.I.b.1.c - c) Addition of a new specification parameter to the specification with its corresponding test method - B.I.b.1.c - 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 - Addition of a new specification parameter to the specification with its corresponding test method	20/06/22
B.I.b.1.b	IB - B.I.b.1.b - b) Tightening of specification limits - B.I.b.1.b - 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 - Tightening of specification limits	20/06/22