

VPA10436/002/001

Bimoxivet LA 150 mg/ml, Suspension for Injection for cattle, sheep and pigs

Variation	Summary	Date
Vet - F.III.1 a) 1.	VRA-R - Vet - F.III.1 a) 1. - - Vet - F.III.1 a) 1. - Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability - For an active substance, For a starting material/reagent/intermediate used in the manufacturing process of the active substance, For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where mwater is used in the last steps of the synthesis and the material is not claimed to be endotoxin free	07/10/25
Vet - F.I.d.1 c)	VRA-R - Vet - F.I.d.1 c) - - Vet - F.I.d.1 c) - 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 real time data	07/10/25
Vet - C6	VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17	05/12/24
Vet - A1 a)	VNRA - Vet - A1 a) - a) Change in the name or address or contact details of the marketing authorisation holder - A1 a) Administrative changes: Change in the name or address or contact details of the marketing authorisation holder	19/09/24
Vet - F.I.d.1 c)	VRA-R - 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 real time data	01/09/23
Vet - F.II.b.4 z)	VRA-R - Vet - F.II.b.4 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.4 z) Quality Changes - Finished Product -Manufacture - Change in the batch size (including batch size ranges) of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	09/03/23
Vet - F.II.e.1 b) 2.	VRA-S - Vet - F.II.e.1 b) 2. - b) Change in type of container or addition of a new container 2. Sterile medicinal products and	09/03/23

	biological/ immunological medicinal products - F.II.e.1 b) 2. Quality Changes - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Sterile medicinal products and biological/immunological medicinal products	
Vet - F.II.b.1 d)	VRA-R - Vet - F.II.b.1 d) - d) Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile veterinary medicinal products (including those that are aseptically manufactured) excluding biological/ immunological veterinary medicinal products - F.II.b.1 d) Quality Changes - Finished Product -Manufacture - 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 veterinary medicinal products (including those that are aseptically manufactured) excluding biological/ immunological veterinary medicinal products	09/03/23
Vet - F.II.b.2 b) z.	VRA-R - 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	09/03/23
Vet - F.II.b.2 a) z.	VRA-R - Vet - F.II.b.2 a) z. - a) Replacement or addition of a site where batch control/testing takes place 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 a) 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 site where batch control/testing takes place - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	09/03/23
Vet - F.II.b.3 a)	VRA-R - Vet - F.II.b.3 a) - a) Minor change in the manufacturing process - F.II.b.3 a) Quality Changes - Finished Product -Manufacture - 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	09/03/23
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)	09/03/23