VPA22664/083/001

Closamectin Solution for Injection for Cattle and Sheep

Variation	Summary	Date
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuirng device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device	12/11/24
Vet - B33 a)	VNRA - Vet - B33 a) - a) Update of the test procedure to comply with the updated general monograph in the Ph. Eur. - B33 a) Changes to the quality part of the dossier: Change in test procedure for the finished product to comply with Ph. Eur.: — update of the test procedure to comply with the updated general monograph in the Ph. Eur.	12/11/24
Vet - B37	VNRA - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product - B37 Changes to the quality part of the dossier: Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	12/11/24
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: 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)	12/11/24
Vet - F.II.e.4 b)	VRA-R - Vet - F.II.e.4 b) - b) Sterile medicinal products - F.II.e.4 b) Quality Changes - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	27/06/24
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	27/06/24
Vet - F.II.a.3 b) 1.	VRA-S - Vet - F.II.a.3 b) 1. - b) Other excipients 1. Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the veterinary medicinal product - F.II.a.3 b) 1. Quality Changes - Finished Product - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Qualitative or quantitative changes in one or more excipients that may have a significant	27/06/24

	impact on the safety, quality or efficacy of the veterinary medicinal product	
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	25/07/23
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	20/03/23
Vet - G.I.11 b)	VRA-R - Vet - G.I.11 b) - b) Deletion not resulting from a safety issue - G.I.11 b) Safety, Efficacy, Pharmacovigilance changes - Deletion of a food producing or non-food producing target species - Deletion not resulting from a safety issue	06/12/22
Vet - B3 t)	VNRA - Vet - B3 t) - t) Deletion of a Ph. Eur. CEP - B3 t) Changes to the quality part of the dossier: Deletion of a Ph. Eur. CEP — for an active substance; — for a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for an excipient	04/08/22
B.I.z	II - B.I.z - z Other variation - B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Other variation	09/06/22