VPA10826/026/003

Enrotron 100 mg/ml Solution for injection for cattle, sheep, goats and pigs

Variation	Summary	Date
Vet - F.II.e.1 b) 2.	VRA-S - Vet - F.II.e.1 b) 2. - - Vet - F.II.e.1 b) 2. - 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	26/08/25
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	26/08/25
Vet - F.II.e.1 a) 2.	VRA-S - Vet - F.II.e.1 a) 2. - - Vet - F.II.e.1 a) 2. - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/ immunological medicinal products.	26/08/25
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	06/08/25
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	27/05/25
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 veterianry 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	10/02/25

	- 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	
Vet - B44(Do not use)	VNRA - Vet - B44 - Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance, starting material, reagent or intermediate, excipient - B44 Changes to the quality part of the dossier: Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	09/07/24
Vet - C10 a)	VNRA - Vet - C10 a) - a) Administrative information concerning the holder's representative - C10 a) Changes to the safety, efficacy and pharmacovigilance part of the dossier: Changes to the labelling or the package leaflet which shall not be connected with the SPC: — administrative information concerning the holder's representative	31/10/23
Vet - G.I.1 a)	VRA-R - Vet - G.I.1 a) - a) The medicinal product is not covered by the defined scope of the procedure but the change(s) implements the outcome of the procedure and no new additional data is required to be submitted by the MAH - G.I.1 a) Safety, Efficacy, Pharmacovigilance changes - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6 - The medicinal product is not covered by the defined scope of the procedure but the change(s) implements the outcome of the procedure and no new additional data is required to be submitted by the MAH	12/09/22