VPA22693/007/001

Imec 10 mg/ml Solution for Injection

Variation	Summary	Date
Vet - C1	VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	13/11/26
Vet - C5	VNRA - Vet - C5 - - Vet - C5 - Change in the pharmacovigilance system master file (PSMF) location	13/11/26
Vet - G.I.18	VRA-S - Vet - G.I.18 - - Vet - G.I.18 - One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	11/09/26
Vet - B47 b)	VNRA - Vet - B47 b) - - Vet - B47 b) - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	26/06/25
Vet - B47 b)	VNRA - Vet - B47 b) - b) Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State - B47 b) Changes to the quality part of the dossier: Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: — change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	06/03/25
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	13/12/24
Vet - B3 e)	VNRA - Vet - B3 e) - e) Deletion of a test procedure - B3 e) Changes to the quality part of the dossier: Deletion of a test procedure — for the active substance or a starting material, reagent or intermediate of the active substance; —for the immediate packaging of the active substance; — for an excipient or the finished product; —for the immediate packaging of the finished product	22/02/24
Vet - B3 d)	VNRA - Vet - B3 d) - d) Deletion of a non-significant specification parameter (active substance, starting material, intermediate - B3 d) Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) of — an active substance; — a starting material; —an intermediate or reagent used in the manufacturing process of the active substance	22/02/24

Vet - F.II.e.5 b)	VRA-S - Vet - F.II.e.5 b) - b) Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products. - F.II.e.5 b) Quality Changes - Container closure system -Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products.	17/02/23
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 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	17/02/23