Vaborem

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Variation type II /	C.I HUMAN AND VETERINARY MEDICINAL	12/02/2026		SmPC and PL	SmPC new text

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

EMA/VR/0000315162	PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.4 and 4.8 of the SmPC in order to warn for the risk of rhabdomyolysis, which has been observed with meropenem monotherapy. The package leaflet is updated accordingly.				Rhabdomyolysis has been reported with the use of meropenem, a component of meropenem/vaborbactam. If signs or symptoms of rhabdomyolysis such as muscle pain, tenderness or weakness, dark urine, or elevated creatine phosphokinase are observed, discontinue meropenem/vaborbactam should be discontinued and initiate appropriate therapy initiated. Rhabdomyolysis was also added to the table of adverse reactions under Musculoskeletal and connective tissue disorders SOC, with frequency 'Unknown' and with a footnote stating that Rhabdomyolysis has been observed post-marketing with meropenem, a component of Vaborem. For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000321369	This was an application for a group of variations. B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.a The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer - Accepted	03/02/2026			

	B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.c Deletion of a non-significant in-process test - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer				

	(including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted				

	B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted B.I.b.1 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 - B.I.b.1.d Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted				
Variation type IB / EMA/VR/0000288346	C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet	16/10/2025		SmPC and PL	To update Section 4.4 and 4.8 of the SmpC and Section 2 and 4 of the PL to implement the wording

	of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.z Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon - Accepted C.I.3.z (Type IB) – To update Section 4.4 and 4.8 of the SmpC and Section 2 and 4 of the PL to implement the wording agreed by the PRAC following the outcome of the PSUR procedure PSUSA/00001989/202408 on products containing meropenem, with adaptations to accommodate the monosubstance proposed wording to the combination product PI. In addition, the MAH took the opportunity to implement editorial changes, including: (1) Removal of the local representative for the UK (NI), in line with the QRD template, (2) Updating Section 5.1 of the SmPC with the link to EUCAST breakpoint and MIC data, (3) Correction of typographic errors in the DE and FR PI, and (4) Updating the wording from Clostridium difficile to Clostridioides difficile in Sections 4.4 and 4.8 of the SmPC, and from carbapenemases to β-lactamases in Section 4.4 of the SmPC				agreed by the PRAC following the outcome of the PSUR procedure PSUSA/00001989/202408 on products containing meropenem, with adaptations to accommodate the monosubstance proposed wording to the combination product PI.
