Vaborem

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
R/0019	Renewal of the marketing authorisation.	25/05/2023	24/07/2023	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Vaborem in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.

[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).

PSUSA/10727 /202208	Periodic Safety Update EU Single assessment - meropenem / vaborbactam	16/03/2023	n/a		PRAC Recommendation - maintenance
IA/0018	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	09/12/2022	n/a		
IB/0016	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	24/11/2022	n/a		
II/0010/G	This was an application for a group of variations. A grouped application including 8 type II variations (C.I.4) and 1 type II variation (C.I.13): Update of sections 4.5 and 5.2 of the SmPC based on the results of a series of non-clinical drug-drug interaction studies undertaken with vaborbactam or meropenem. The Package Leaflet has been updated accordingly. In addition, the MAH has submitted non-clinical data on the phototoxicity potential of meropenem from a 3T3 neutral red uptake phototoxicity test. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to	19/05/2022	18/11/2022	SmPC and PL	The in vitro studies conducted to assess vaborbactam and meropenem CYP450 enzyme and transporter-mediated interaction potential indicated low potential for PK interactions between vaborbactam and meropenem and other drugs with regards to CYP inhibition and transporters but not for CYP induction. Relevant drug-drug interactions due to CYP3A4 induction by vaborbactam and meropenem cannot be excluded. Vaborbactam and meropenem were identified as OAT3 substrates in the in vitro assay, but no clinically relevant inhibition of OAT3 by vaborbactam and meropenem is expected. Vaborem may decrease the efficacy of hormonal contraceptive drugs containing oestrogen and/or progesterone. Women of childbearing potential should be advised to use alternative effective contraceptive methods during treatment with Vaborem and for a period of 28 days after discontinuation of treatment. For more information, please refer to the Summary of Product Characteristics.

	new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				Regarding the potential phototoxicity of meropenem, the in vitro phototoxicity study is indicative of lack of phototoxicity for this active substance.
PSUSA/10727 /202108	Periodic Safety Update EU Single assessment - meropenem / vaborbactam	07/04/2022	n/a		PRAC Recommendation - maintenance
IB/0014	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	18/11/2021	18/11/2022	SmPC	The Applicant has taken the opportunity to add minor editorial changes in the French, German, Dutch, Portuguese, Greek, Finnish, Swedish and Spanish product information and to adjust the numbering of the tables in module 3.2.P.8.1 and 3.2.P.8.3.
PSUSA/10727 /202102	Periodic Safety Update EU Single assessment - meropenem / vaborbactam	30/09/2021	n/a		PRAC Recommendation - maintenance

PSUSA/10727 /202008	Periodic Safety Update EU Single assessment - meropenem / vaborbactam	09/04/2021	n/a		PRAC Recommendation - maintenance
IB/0012	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	30/03/2021	n/a		
IB/0011	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	20/01/2021	n/a		
IB/0008	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	15/10/2020	19/10/2021	SmPC, Annex II and PL	
PSUSA/10727 /202002	Periodic Safety Update EU Single assessment - meropenem / vaborbactam	01/10/2020	n/a		PRAC Recommendation - maintenance
IB/0007/G	This was an application for a group of variations. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/09/2020	n/a		

PSUSA/10727 /201908	Periodic Safety Update EU Single assessment - meropenem / vaborbactam	12/03/2020	n/a		PRAC Recommendation - maintenance
IAIN/0004/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.7 - Administrative change - Deletion of manufacturing sites B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished	07/11/2019	27/03/2020	SmPC, Annex II and PL	

	product - Minor changes to an approved test procedure B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.2.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				
PSUSA/10727 /201902	Periodic Safety Update EU Single assessment - meropenem / vaborbactam	03/10/2019	n/a		PRAC Recommendation - maintenance
IAIN/0002	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	17/04/2019	27/03/2020	SmPC, Labelling and PL	
T/0001	Transfer of Marketing Authorisation	07/01/2019	20/02/2019	SmPC, Labelling and	

				PL	