EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Vibativ

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
PSUSA/2879/ 201703	Periodic Safety Update EU Single assessment - telavancin	28/09/2017	n/a		PRAC Recommendation - maintenance
IAIN/0031	A.1 - Administrative change - Change in the name and/or address of the MAH	08/09/2017		SmPC, Labelling and PL	
IB/0029	C.I.11.z - Introduction of, or change(s) to the obligations and conditions of a marketing	21/04/2017		Annex II	

[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).

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	authorisation, including the RMP - Other variation				
PSUSA/2879/201609	Periodic Safety Update EU Single assessment - telavancin	06/04/2017	n/a		PRAC Recommendation - maintenance
T/0027	Application for Transfer of Marketing Authorisation from Clinigen Healthcare Ltd to Theravance Biopharma Ireland Ltd. Transfer of Marketing Authorisation	06/10/2016	03/11/2016	SmPC, Labelling and PL	
PSUSA/2879/201603	Periodic Safety Update EU Single assessment - telavancin	29/09/2016	n/a		PRAC Recommendation - maintenance
R/0025	Renewal of the marketing authorisation.	01/04/2016	26/05/2016	SmPC, Annex II, Labelling and PL	
PSUSA/2879/201509	Periodic Safety Update EU Single assessment - telavancin	14/04/2016	n/a		PRAC Recommendation - maintenance
II/0023	Update of section 4.2 and 5.2 of the SmPC and Annex II of the Product Information in order to update the dose recommendation for obese patients and to remove the reference to PK obesity study following the assessment of ANX/001.1 post authorisation measure. The Package Leaflet is updated accordingly. Consequently an updated RMP ver.3 is provided. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance	28/01/2016	26/02/2016	SmPC, Annex II and PL	Body mass index (BMI) at baseline was found to influence telavancin pharmacokinetics in the population pharmacokinetic analysis in healthy (without infection) adult subjects. Exposure to telavancin increases with increase in BMI; for each 10-unit increase in BMI, it is estimated that plasma exposure will increase by up to 25%. Obese patients (defined as those with BMI >30 kg/m2) should receive telavancin at the reduced dose of 7.5 mg/kg once every 24 hours.

	data				
PSUSA/2879/201503	Periodic Safety Update EU Single assessment - telavancin	08/10/2015	n/a		PRAC Recommendation - maintenance
IAIN/0022	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	01/07/2015	n/a		
IA/0020	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	08/05/2015	n/a		
PSUSA/2879/201409	Periodic Safety Update EU Single assessment - telavancin	10/04/2015	n/a		PRAC Recommendation - maintenance
IAIN/0018	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	28/11/201	n/a		
IAIN/0017	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in th PSMF location	10/10/2014	n/a		
PSUV/0014	Periodic Safety Update	09/10/2014	n/a		PRAC Recommendation - maintenance
II/0015	Update of section 5.1 of the SmPC in order to implement the EUCAST approved breakpoint for Staphylococcus aureus (including methicillin resistant	25/09/2014	30/09/2015	SmPC and PL	In accordance with the EUCAST revised breakpoint and accepted abbreviation, the minimum inhibitory concentration (MIC) breakpoints for S. aureus (including

	strains). The MAH implemented some minor corrections in the Package Leaflet. In addition, the MAH took the opportunity to correct some typographical errors in the DE, ES, FR, IT, NL and PT translations of the Package Leaflet. The Annex A was corrected to include the correct pharmaceutical form “powder for concentrate for solution for infusion”. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				methicillin resistant strains) has been changed to 0.12 µg/ml.
IAIN/0016	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	12/08/2014	n/a		
PSUV/0013	Periodic Safety Update	10/04/2014	n/a		PRAC Recommendation - maintenance
II/0006/G	This was an application for a group of variations. - To replace Ben Venue Laboratories, Inc.as a site responsible for manufacture, primary packaging and stability of the finished product with a new site. - to replace a currently registered test method with a different Ph.Eur. test method for the finished product - to delete two manufacturing and batch release sites for the finished product - to delete two testing sites for the finished product - to add a packaging site for the finished product - to add a site responsible for batch release of the	22/05/2014	12/03/2014	Annex II and PL	

	finished product and - to add a testing site for the finished product vials. B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing				
PSUV/0012	Periodic Safety Update	06/03/2014	n/a		PRAC Recommendation - maintenance
II/0009	to change the batch size of the finished product for the 750 mg vials.	23/01/2014	n/a		

	B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes				
II/0008	to change the specification of the finished product. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	23/01/2014	n/a		
II/0007	to introduce changes to the manufacturing process of the finished product B.II.b.3.b - Change in the manufacturing process of the finished or intermediate product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product	23/01/2014	n/a		
T/0005	Transfer of Marketing Authorisation	24/07/2013	03/09/2013	SmPC and PL	New Marketing Authorisation Holder: Clinigen Healthcare Ltd Previous Marketing Authorisation Holder: Theravance UK Limited
T/0004	Transfer of Marketing Authorisation	21/12/2012	08/02/2013	SmPC, Labelling and PL	New Marketing Authorisation Holder: Theravance UK Limited Previous Marketing Authorisation Holder:

					Astellas Pharma Europe B.V.
II/0002	To update the SmPC section 4.4 (Special warnings and precautions for use) and 4.8 (Undesirable effects) with hypersensitivity reactions, including anaphylaxis. The Package Leaflet (PL) was proposed to be updated in accordance. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	19/04/2012	08/02/2013	SmPC and PL	The current approved SmPC of Vibativ already lists a number of manifestations of allergic type and infusion reactions that are highly likely to represent drug related reactions, including red man syndrome like reactions, including flushing of the upper body, urticaria, pruritus or rash. However, there is biologic plausibility for anaphylaxis and cross reactivity to vancomycin to occur after exposure to telavancin. Based on the cumulative review of the cases related to hypersensitivity reaction (inclusive anaphylaxis) and the literature review on anaphylaxis with other antibacterial agents, including glycopeptides, it is agreed to add “hypersensitivity reactions, including anaphylaxis” to the SmPC. The PL is updated accordingly. The benefit–risk balance of Vibativ mg powder for concentrate for solution for infusion remains unchanged.
IAIN/0003/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV C.I.9.d - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the safety database C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD	30/01/2012	n/a		

	C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system				