Orbactiv

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
T/0022	Transfer of Marketing Authorisation	06/12/2018	11/01/2019	SmPC, Labelling and PL	
PSUSA/10368 /201803	Periodic Safety Update EU Single assessment - oritavancin	04/10/2018	n/a		PRAC Recommendation - maintenance
T/0020	Transfer of Marketing Authorisation	12/07/2018	13/08/2018	SmPC, Labelling and	

[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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				PL	
PSUSA/10368 /201709	Periodic Safety Update EU Single assessment - oritavancin	26/04/2018	25/06/2018	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10368/201709.
IAIN/0018	C.I.11.a - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of wording agreed by the competent authority	11/04/2018	n/a		
PSUSA/10368 /201703	Periodic Safety Update EU Single assessment - oritavancin	28/09/2017	n/a		PRAC Recommendation - maintenance
PSUSA/10368 /201609	Periodic Safety Update EU Single assessment - oritavancin	06/04/2017	n/a		PRAC Recommendation - maintenance
IA/0014	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	12/12/2016	n/a		
PSUSA/10368 /201603	Periodic Safety Update EU Single assessment - oritavancin	29/09/2016	n/a		PRAC Recommendation - maintenance
II/0012/G	This was an application for a group of variations. Group of variations consisting of: 1. Update of sections 4.4 and 4.5 of the SmPC in order to delete the warning related to the interaction with warfarin and include the results of the interaction study (MDCO-ORI-14-02) , respectively. The Package	15/09/2016	12/12/2016	SmPC and PL	Update of sections 4.4 and 4.5 of the SmPC in order to delete the warning related to the interaction with warfarin and include the results of the new interaction study (MDCO-ORI-14-02). This study was to assess the drug-drug interaction effect of a single 1200mg dose of oritavancin on the pharmacokinetics of S-warfarin following a single dose was conducted in 36 healthy subjects. S-warfarin

	Leaflet and RMP (version 2.2) are updated in accordance. 2. Update of the RMP (version 2.2) to delete the category 3 study MDCO-ORI-14-03 C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				pharmacokinetics were evaluated following a single dose of warfarin 25mg given alone, or administered at the start, 24, or 72 hours after a single 1200mg dose of oritavancin. The results showed no effect of oritavancin on S-warfarin exposure (AUC) and maximum concentration (Cmax).
PSUSA/10368 /201509	Periodic Safety Update EU Single assessment - oritavancin	14/04/2016	n/a		PRAC Recommendation - maintenance
IB/0010	B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products	30/03/2016	n/a		
II/0008	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	17/03/2016	n/a		
IB/0009	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	05/02/2016	n/a		

IB/0007	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	22/12/2015	n/a		
II/0003	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	17/12/2015	12/12/2016	SmPC and PL	
IB/0005/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	30/10/2015	n/a		
IA/0004/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	14/10/2015	n/a		

	B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits				
II/0002	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	17/09/2015	n/a		
IB/0001	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	22/05/2015	n/a		