Zeposia

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
IA/0015	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	22/11/2022	n/a		
IB/0013	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing	22/11/2022	n/a		

[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).

	authorisation, including the RMP - Other variation				
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	25/10/2022	n/a		
IB/0011/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	09/08/2022	n/a		
PSUSA/10852 /202111	Periodic Safety Update EU Single assessment - ozanimod	10/06/2022	n/a		PRAC Recommendation - maintenance
IAIN/0009	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	10/12/2021	18/11/2022	Annex II and PL	

PSUSA/10852 /202105	Periodic Safety Update EU Single assessment - ozanimod	02/12/2021	n/a		PRAC Recommendation - maintenance
IA/0008/G	This was an application for a group of variations. 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 B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	24/11/2021	n/a		
II/0002/G	This was an application for a group of variations. C.I.6.a (Extension of indication) Extension of indication to include the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent for Zeposia; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC and Annex IID are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement editorial changes throughout the product information. Version 2.1 of the RMP has been approved. C.I.4 Update of sections 4.4 and 4.5 of the SmPC in order to update the current SmPC description about PK	14/10/2021	18/11/2021	SmPC, Annex II and PL	Please refer to Scientific Discussion on Zeposia EMEA/H/C/004835/II/0002/G

	interaction with BCRP inhibitors based on the study report from a drug interaction study with cyclosporine I(RPC-1063-CP-001). The group of variations leads to amendments to the Summary of Product Characteristics, Annex II and Package Leaflet and to the Risk Management Plan (RMP). C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
II/0005	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	02/09/2021	18/11/2021	SmPC, Annex II and PL	
IB/0006	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	20/07/2021	n/a		
IA/0004/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	15/06/2021	n/a		

	A.7 - Administrative change - Deletion of manufacturing sites				
PSUSA/10852 /202011	Periodic Safety Update EU Single assessment - ozanimod	10/06/2021	n/a		PRAC Recommendation - maintenance
T/0001	Transfer of Marketing Authorisation	09/09/2020	09/10/2020	SmPC, Labelling and PL	