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
R/0028	Renewal of the marketing authorisation.	30/01/2025	24/03/2025	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 Zeposia 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).

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PSUSA/10852 /202405	Periodic Safety Update EU Single assessment - ozanimod	30/01/2025	24/03/2025	SmPC, Annex II and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10852/202405.
II/0024/G	This was an application for a group of variations. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data A.6 - Administrative change - Change in ATC Code/ATC Vet Code	11/07/2024	24/03/2025	SmPC and PL	
IA/0026	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	19/06/2024	n/a		
II/0023	Update of sections 4.4 and 5.1 of the SmPC in order to update efficacy and safety information based on the final results from study RPC01-3001, listed as a category 3 study in the RMP. This is a multi-site, open label extension trial of RPC1063 in relapsing multiple sclerosis. The study's main objectives were to characterize the long-term safety and tolerability, and the long-term efficacy of ozanimod in patients with relapsing multiple sclerosis. The RMP was updated to version 7.1. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	16/05/2024	24/03/2025	SmPC	Section 4.4 of the SmPC subsection Prior and concomitant treatment with antineoplastic, non-corticosteroid immunosuppressive, or immune-modulating therapies has been updated to inform that Ozanimod can generally be started immediately after discontinuation of glatiramer. Section 4.4 of the SmPC subsection Return of MS disease activity after ozanimod discontinuation has been updated to inform that in the ozanimod long-term extension study, following permanent discontinuation of ozanimod, clinical relapses were reported in 3.3% of patients, none with severe exacerbation of disease or severe increase in disability. Section 5.1 of the SmPC subsection Long-term Data has been updated based on the final results on AAR and 6-month confirmed disability progression from study

					RPC01-3001. For more information, please refer to the Summary of Product Characteristics.
IA/0025/G	This was an application for a group of variations. B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or	24/04/2024	n/a		

	deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer				
PSUSA/10852 /202305	Periodic Safety Update EU Single assessment - ozanimod	25/01/2024	09/04/2024	Annex II and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10852/202305.
IB/0022/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.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	14/12/2023	n/a		
IB/0020	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	14/08/2023	n/a		
PSUSA/10852 /202211	Periodic Safety Update EU Single assessment - ozanimod	08/06/2023	n/a		PRAC Recommendation - maintenance

IB/0019	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	10/05/2023	n/a		
II/0016	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	23/02/2023	24/03/2023	SmPC, Annex II and PL	
IA/0018/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.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold	31/01/2023	n/a		
PSUSA/10852 /202205	Periodic Safety Update EU Single assessment - ozanimod	01/12/2022	n/a		PRAC Recommendation - maintenance
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 authorisation, including the RMP - Other variation	22/11/2022	n/a		
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	25/10/2022	n/a		

	intermediate used in the manufacture of the AS or manufacturer of a novel excipient				
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	24/11/2021	n/a		

	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				
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 interaction with BCRP inhibitors based on the study report from a drug interaction study with cyclosporine l(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).	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

	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 A.7 - Administrative change - Deletion of manufacturing sites	15/06/2021	n/a		
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	