Evenity

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/10824 /202401	Periodic Safety Update EU Single assessment - romosozumab	05/09/2024	n/a		PRAC Recommendation - maintenance
R/0025	Renewal of the marketing authorisation.	27/06/2024	22/08/2024	SmPC, Annex II and PL	

[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).

II/0024	B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS	16/05/2024	n/a		
II/0023	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	16/05/2024	n/a		
IB/0022	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	19/12/2023	n/a		
IA/0021	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	30/10/2023	n/a		
PSUSA/10824 /202301	Periodic Safety Update EU Single assessment - romosozumab	31/08/2023	n/a		PRAC Recommendation - maintenance
IB/0020	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	07/08/2023	22/08/2024	SmPC, Labelling and PL	
IB/0019	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	19/06/2023	n/a		
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/02/2023	22/08/2024	PL	

PSUSA/10824 /202207	Periodic Safety Update EU Single assessment - romosozumab	09/02/2023	n/a		PRAC Recommendation - maintenance
IB/0016/G	This was an application for a group of variations. B.II.z - Quality change - Finished product - Other variation B.I.z - Quality change - Active substance - Other variation	31/10/2022	n/a		
PSUSA/10824 /202201	Periodic Safety Update EU Single assessment - romosozumab	01/09/2022	n/a		PRAC Recommendation - maintenance
IB/0014	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	17/05/2022	n/a		
II/0010	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	07/04/2022	n/a		
PSUSA/10824 /202107	Periodic Safety Update EU Single assessment - romosozumab	10/02/2022	n/a		PRAC Recommendation - maintenance
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/10/2021	22/08/2024	Labelling and PL	

PSUSA/10824 /202101	Periodic Safety Update EU Single assessment - romosozumab	02/09/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10824 /202007	Periodic Safety Update EU Single assessment - romosozumab	11/02/2021	n/a		PRAC Recommendation - maintenance
IA/0008	B.II.d.2.e - Change in test procedure for the finished product - Update of the test procedure to comply with the updated general monograph in the Ph. Eur.	11/12/2020	n/a		
II/0005	B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	15/10/2020	n/a		
IB/0006	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	22/09/2020	n/a		
PSUSA/10824 /202001	Periodic Safety Update EU Single assessment - romosozumab	03/09/2020	n/a		PRAC Recommendation - maintenance
IB/0004	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	25/06/2020	n/a		
IB/0002	B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	13/03/2020	n/a		
IB/0001	B.IV.1.z - Change of a measuring or administration device - Other variation	03/02/2020	n/a		