



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Teriparatide SUN

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
IB/0004	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	11/09/2024		SmPC, Labelling and PL	
IAIN/0005/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a	02/08/2024	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).



	manufacturing site for the FP - Secondary packaging site A.7 - Administrative change - Deletion of manufacturing sites				
N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/03/2024		PL	
IB/0002	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	30/01/2024	n/a		
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	03/09/2023		PL	