



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Parsabiv

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency's update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
Article 61(3) /	Outcome:	12/08/2026		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).



EMA/N/0000367752	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representatives and to delete 'United Kingdom (Northern Ireland)' from the list of local representatives in line with the QRD template v10.4.				
Variation type IA / EMA/VR/0000315323	Outcome: This was an application for a group of variations. B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.e Update of the test procedure to comply with the updated general monograph in the Ph. Eur. - Accepted	03/12/2025			
Variation type IB / EMA/VR/0000285768	Outcome: B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted	29/07/2025			
PSUR / EMA/PSUR/0000257856	EURD: PSUSA/00010533/202411 Active substance: etelcalcetide Outcome:	10/07/2025			Maintenance

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