



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Locametz

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
N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/03/2024		PL	
IA/0005	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	28/02/2024	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).



	the AS -replacement or addition of a site where batch control/testing takes place				
PSUSA/11030 /202303	Periodic Safety Update EU Single assessment - gozetotide	26/10/2023	n/a		PRAC Recommendation - maintenance
N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/09/2023		PL	
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/01/2023		PL	