

Izba

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, please also refer to EPAR - Procedural steps taken and scientific information after authorisation (archive).

Application number	Scope	Opinion/ Notification 1 issued on	Product Information affected ³	Summary
Variation type IA_IN /	This was an application for a group of	22/01/2025	Annex II and	

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/VR/0000245405	variations.		PL		
	A.5 Change in the name and/or address of a				
	manufacturer/importer of the finished				
	product (including batch release or quality				
	control testing sites) - A.5.a The activities				
	for which the manufacturer/importer is				
	responsible include batch release - Accepted				
	A. ADMINISTRATIVE CHANGES - A.7				
	Deletion of manufacturing sites for an active				
	substance, intermediate or finished product,				
	packaging site, manufacturer responsible for				
	batch release, site where batch control takes				
	place, or supplier of a starting material,				
	reagent or excipient (when mentioned in the				
	dossier)* - Accepted				