



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Gencebok

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/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/01/2024		PL	
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/02/2022	26/09/2022	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).



IB/0007	B.II.f.1.b.z - Stability of FP - Extension of the shelf life of the finished product - Other variation	18/11/2021	26/09/2022	SmPC	
IAIN/0006/G	This was an application for a group of variations. B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	14/10/2021	26/09/2022	Annex II and PL	
IAIN/0005	A.1 - Administrative change - Change in the name and/or address of the MAH	11/08/2021	22/10/2021	SmPC, Labelling and PL	
IB/0004	B.II.f.1.b.z - Stability of FP - Extension of the shelf life of the finished product - Other variation	04/05/2021	22/10/2021	SmPC	The shelf life was extended t\from 2 years to 30 months.
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/02/2021	22/10/2021	PL	
IAIN/0003	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	07/01/2021	n/a		
IB/0001	B.II.f.1.b.z - Stability of FP - Extension of the shelf life of the finished product - Other variation	27/10/2020	22/10/2021	SmPC	