



SIBNAYAL

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
IAIN/0004	A.1 - Administrative change - Change in the name and/or address of the MAH	25/04/2022		SmPC, Labelling and PL	
II/0002/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of	10/02/2022	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 finished or intermediate product - Other variation B.II.b.3.b - Change in the manufacturing process of the finished or intermediate product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product				
IA/0001	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	15/06/2021	n/a		