



Omvoht

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
IB/0003	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	22/12/2023		SmPC	
IB/0002	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a	30/08/2023	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).



	re-test period/storage period supported by real time data				
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	28/07/2023		PL	