



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

mRESVIA

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/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/03/2025		Labelling and PL	
IB/0002/G	This was an application for a group of variations. B.II.f.z - Stability of FP - Other variation	12/03/2025	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).



	B.I.d.z - Stability of AS - Other variation				
IB/0001	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	25/02/2025		SmPC and PL	