



Tyruko

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/0008/G	This was an application for a group of variations. A.6 - Administrative change - Change in ATC Code/ATC Vet Code C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	20/01/2025		SmPC and Annex II	

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).



	<p>assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p>				
II/0004	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	05/12/2024	n/a		
IA/0006/G	<p>This was an application for a group of variations.</p> <p>A.z - Administrative change - Other variation</p> <p>B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits</p>	28/08/2024	n/a		
IB/0005	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	22/08/2024	n/a		
IB/0003	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	20/03/2024	n/a		
IB/0002	B.I.e.4.z - Changes to an approved change management protocol - Other variation	15/03/2024	n/a		

IAIN/0001

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

30/10/2023

27/09/2024

Annex II and PL