Glyxambi

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Variation type IB /	C. Safety, efficacy, pharmacovigilance	28/03/2026		SmPC,	

[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).

EMA/VR/0000332881	changes - C.z Other variation - Accepted C.z (Type IB) – To implement updates throughout the Product Information to correct typographical errors and ensure alignment with the QRD template. In addition, the MAH has amended the details of the the local representative for NO in the Package Leaflet and removed the local representative for UK (NI), in line with the QRD template requirements. Furthermore, the MAH has introduced editorial updates throughout the annexes in all languages.			Labelling and PL	
Variation type IA / EMA/VR/0000282383	A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted	30/07/2025			
Article 61(3) / EMA/N/0000281785	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with the addition of contact details of local representatives.	30/06/2025		PL	
Variation type II / EMA/VR/0000248932	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC)	05/06/2025			

	No 1234/2008. C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* - Accepted Submission of an updated RMP version 15.0 for Trajenta and Jentadueto and updated RMP version 12.0 for Glyxambi in order to review the list of safety concerns in line with GVP Module V, Rev 2.				
Article 61(3) / EMA/N/0000263596	- Notification acc. Article 61(3) - Accepted Update of the list of local representatives in the package leaflet.	01/04/2025		PL	
Variation type IA_IN / EMA/VR/0000260241	C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.a Implementation of wording agreed by the	25/03/2025		SmPC	

	competent authority - Accepted				
Variation type IA / EMA/VR/0000249092	A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted	11/03/2025			