Roteas

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 /	This was an application for a variation	24/07/2025		SmPC and PL	To update section 5.2 of the SmPC to correct 3

[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/0000272457	following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted To update section 5.2 of the SmPC to correct 3 numbers in the sub-section `Paediatric population'. In addition, the Applicant took the opportunity to update the annexes to the latest QRD version and to make minor corrections throughout the annexes. The MAH also update the list of local representatives in the Package Leaflet for Lixiana for Czechia.				numbers in the sub-section `Paediatric population'. In addition, the Applicant took the opportunity to update the annexes to the latest QRD version and to make minor corrections throughout the annexes. The MAH also update the list of local representatives in the Package Leaflet for Lixiana for Czechia.
Variation type IA / EMA/VR/0000275040	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	12/06/2025	N/A		
Variation type IB / EMA/VR/0000265363	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.d.1.a Re-test period/storage period -	12/06/2025	N/A		

	B.I.d.1.a.4 Extension or introduction of a re-test period/storage period supported by real time data - Accepted				
Variation type IA / EMA/VR/0000248718	B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted B.II.e.1.a Qualitative and quantitative composition - B.II.e.1.a.1. Solid pharmaceutical forms - Accepted B.II.e.4 Change in shape or dimensions of the container or closure (immediate packaging) - B.II.e.4.a Non-sterile medicinal products - Accepted B.II.e.4 Change in shape or dimensions of the container or closure (immediate packaging) - B.II.e.4.a Non-sterile medicinal products - Accepted	12/02/2025	N/A		