Rhokiinsa

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	15/01/2026	N/A		To update the RMP by removing the PASS study

[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/0000290523	following a worksharing procedure according to Article 20 of Commission Regulation (EC) 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.z Other RMP changes (e.g. agreed wording + template change) - Accepted C.I.11.z (Type IB) – To update the RMP by removing the PASS study from the RMP, as agreed during the MEA 001.6 (EMA/PAM/0000272898) procedure.				from the RMP, as agreed during the MEA 001.6 (EMA/PAM/0000272898) procedure.
Variation type II / EMA/VR/0000274637	This was an application for a group of variations. B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.z Change in supplier of sterilised primary container components, which are to be used in the aseptic manufacture of medicinal products - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.d Deletion of a non-significant specification parameter (e.g.	09/10/2025		SmPC	The SmPC section 6.5 has been updated as follows: "Rhokiinsa is supplied sterile in white low density polyethylene bottles (2.5 ml fill) and tips with white polypropylene caps and anti-tamper seals."

	deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) - Accepted B.II.e.1.b Change in type of container or addition of a new container - B.II.e.1.b.2 Sterile medicinal products and biological/ immunological medicinal products - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.z Other changes - Accepted				

Variation type IB / EMA/VR/0000278055	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.z Other variation - Accepted To update SmPC section 4.4 and 4.8 to include "Reticular epithelial corneal oedema" with the frequency not known as assessed as part of a PSUSA for products containing latanoprost / netarsudil. The package leaflet is updated accordingly. Furthermore, the MAH took this opportunity to remove the local representative for UK/NI in line with the current QRD template.	22/07/2025		SmPC and PL	To update SmPC section 4.4 and 4.8 to include "Reticular epithelial corneal oedema" with the frequency not known as assessed as part of a PSUSA for products containing latanoprost / netarsudil. The package leaflet is updated accordingly. Furthermore, the MAH took this opportunity to remove the local representative for UK/NI in line with the current QRD template.
Variation type IB / EMA/VR/0000246584	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of	13/03/2025	N/A		

	the approved dossier - B.I.a.1.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place - Accepted				