Roclanda

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
II/0031/G	This was an application for a group of variations. B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new	15/05/2025	14/08/2025	SmPC	The SmPC section 6.5 has been updated as follows: "Roclanda is supplied in clear low density polyethylene bottles (2.5 ml fill in a 4 ml container), low density polyethylene tips with white polypropylene screw caps and anti-tamper seals."

[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).

	container - Sterile medicinal products and biological/immunological medicinal products B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
PSUSA/10905 /202406	Periodic Safety Update EU Single assessment - latanoprost / netarsudil	30/01/2025	28/03/2025	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10905/202406.
IB/0029/G	This was an application for a group of variations. B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	17/12/2024	n/a		

IA/0030	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	18/11/2024	n/a		
IA/0028	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	20/09/2024	n/a		
IB/0026/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	02/09/2024	n/a		
IAIN/0025	C.I.3.a - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Implementation of wording agreed by the competent authority	21/05/2024	03/02/2025	SmPC and PL	
IB/0023/G	This was an application for a group of variations. B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation B.II.d.2.z - Change in test procedure for the finished	09/02/2024	03/02/2025	Annex II and PL	

	product - Other variation B.II.b.z - Change in manufacture of the Finished Product - Other variation A.7 - Administrative change - Deletion of manufacturing sites				
IB/0024	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	16/01/2024	n/a		
PSUSA/10905 /202306	Periodic Safety Update EU Single assessment - latanoprost / netarsudil	11/01/2024	n/a		PRAC Recommendation - maintenance
N/0022	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/12/2023	03/02/2025	Labelling	
PSUSA/10905 /202212	Periodic Safety Update EU Single assessment - latanoprost / netarsudil	06/07/2023	n/a		PRAC Recommendation - maintenance
IB/0018	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	05/07/2023	n/a		
IB/0019	B.II.d.1.h - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product	14/06/2023	n/a		
II/0011	B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS -	01/06/2023	n/a		

	Introduction of a manufacturer of the AS supported by an ASMF				
IG/1627	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	29/05/2023	n/a		
IB/0017	B.II.z - Quality change - Finished product - Other variation	23/05/2023	n/a		
IB/0015	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	28/03/2023	n/a		
IB/0013	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	20/01/2023	n/a		
PSUSA/10905 /202206	Periodic Safety Update EU Single assessment - latanoprost / netarsudil	12/01/2023	n/a		PRAC Recommendation - maintenance
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/12/2022	24/03/2023	Labelling	
IAIN/0010	B.III.2.a.1 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS	17/11/2022	n/a		

IB/0008/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	15/09/2022	n/a		
PSUSA/10905 /202112	Periodic Safety Update EU Single assessment - latanoprost / netarsudil	07/07/2022	n/a		PRAC Recommendation - maintenance
IB/0007/G	This was an application for a group of variations. B.II.e.6.b - Change in any part of the (primary)	27/06/2022	n/a		

	packaging material not in contact with the finished product formulation - Change that does not affect the product information B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products B.II.e.2.d - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition or replacement of a specification parameter as a result of a safety or quality issue				
II/0002	C.I.4, Update of sections 4.8 and 5.1 of the SmPC in order to update efficacy and safety information based on final results from study PG324-CS303; this is a prospective, double-masked, randomised, multicentre, active-controlled, parallel-group, 6-month study assessing the safety and ocular hypotensive efficacy of Roclanda compared to bimatoprost + timolol in subjects with elevated intraocular pressure that was insufficiently controlled and/or deemed to be in need of combination IOP-lowering therapy. The Package Leaflet is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to	02/06/2022	24/03/2023	SmPC and PL	For more information, please refer to the Summary of Product Characteristics.

	new quality, preclinical, clinical or pharmacovigilance data				
IB/0006/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	29/03/2022	24/03/2023	SmPC, Labelling and PL	
IAIN/0004/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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	02/03/2022	24/03/2023	Annex II and PL	
T/0003	Transfer of Marketing Authorisation	11/01/2022	04/02/2022	SmPC, Labelling and PL	
PSUSA/10905 /202106	Periodic Safety Update EU Single assessment - latanoprost / netarsudil	13/01/2022	n/a		PRAC Recommendation - maintenance