

Kerendia

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
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/09/2024		PL	
IB/0008/G	<p>This was an application for a group of variations.</p> <p>B.II.b.3.a - Change in the manufacturing process of</p>	31/07/2024	n/a		

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>the finished or intermediate product - Minor change in the manufacturing process</p> <p>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</p> <p>B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products</p>				
IB/0007	B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	07/05/2024	n/a		
PSUSA/10978 /202307	Periodic Safety Update EU Single assessment - finerenone	08/02/2024	n/a		PRAC Recommendation - maintenance
IB/0006/G	<p>This was an application for a group of variations.</p> <p>B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p> <p>B.I.c.1.z - Change in immediate packaging of the AS</p>	24/11/2023	n/a		

	<ul style="list-style-type: none"> - Other variation <p>B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer</p>				
PSUSA/10978 /202301	Periodic Safety Update EU Single assessment - finerenone	31/08/2023	n/a		PRAC Recommendation - maintenance
IB/0003/G	<p>This was an application for a group of variations.</p> <p>B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p>	29/03/2023	n/a		
PSUSA/10978 /202207	Periodic Safety Update EU Single assessment - finerenone	09/02/2023	n/a		PRAC Recommendation - maintenance
II/0001/G	<p>This was an application for a group of variations.</p> <p>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority</p>	15/12/2022	06/02/2023	SmPC and PL	Please refer to Scientific Discussion Kerendia-H-C-5200-II-0001/G

<p>C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data</p>				
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