RAYVOW

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/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/03/2024		PL	
II/0005	C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of	08/02/2024	n/a		The RMP version 1.1 has been updated to include a descriptive interim analysis in the study design of 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).

	change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				H8H-MC-B006
II/0004	Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with dabigatran and rosuvastatin based on the results from study LAIO, An Open-Label, 2-Part Study to Investigate the Effect of Lasmiditan on the Pharmacokinetics of Dabigatran and Rosuvastatin in Healthy Volunteers. The aim of study LAIO was to investigate the effect of lasmiditan on the pharmacokinetic profiles of dabigatran (a P-glycoprotein substrate) and rosuvastatin (breast cancer resistance protein substrate) in healthy volunteers. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	14/12/2023		SmPC and PL	Update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with dabigatran and rosuvastatin. SmPC new text For more information, please refer to the Summary of Product Characteristics.
PSUSA/11011 /202304	Periodic Safety Update EU Single assessment - lasmiditan	26/10/2023	n/a		PRAC Recommendation - maintenance
PSUSA/11011 /202210	Periodic Safety Update EU Single assessment - lasmiditan	12/05/2023	n/a		PRAC Recommendation - maintenance
IA/0001	B.II.d.2.a - Change in test procedure for the finished	13/12/2022	n/a		

	product - Minor changes to an approved test procedure				