Zokinvy

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/0004	Update of sections 4.2, 4.4, 4.5 and 6.6 of the SmPC in order to include updated drug-drug interaction information based on the final results from Drug-Drug Interaction study EIG-LNF-021. This is a Phase I, open-label, single-centre, two period, single sequence study evaluating the effect of autoinhibition, and the effects of fluconazole, a non-specific strong CYP2C9 inhibitor and moderate	14/09/2023	19/10/2023	SmPC and PL	For more information, please refer to the Summary of Product Characteristics.

[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).

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	inhibitor of CYP2C9 and CYP3A, on the multiple-dose pharmacokinetics of lonafarnib. The Package Leaflet is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/11005 /202211	Periodic Safety Update EU Single assessment - lonafarnib	08/06/2023	n/a		PRAC Recommendation - maintenance
IB/0005/G	This was an application for a group of variations. B.II.z - Quality change - Finished product - Other variation 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)	21/04/2023	n/a		
IAIN/0003	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	23/03/2023	19/10/2023	Annex II and PL	
IB/0001	B.I.e.5.b - Implementation of changes foreseen in an approved change management protocol - Requires further supportive data	07/02/2023	n/a		