Copiktra

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
PSUSA/10939 /202109	Periodic Safety Update EU Single assessment - duvelisib	07/04/2022	n/a		PRAC Recommendation - maintenance
II/0002	Update of section 5.1 of the SmPC based on the final overall survival results from Study IPI-145-07, an interventinal Phase 3 Study of duvelisib (IPI-145) vs	27/01/2022		SmPC	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).

	ofatumumab in patients with relapsed or refractory Chronic Lymphocytic leukemia/Small Lymphocytic Lymphoma. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
T/0001	Transfer of Marketing Authorisation	16/07/2021	20/08/2021	SmPC, Labelling and PL	