EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Ivozall

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
IB/0006	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	06/03/2023		SmPC and PL	To update section 4.6 of the SmPC to align to reference product to include the recommendations on the duration of contraception following the end of treatment with a genotoxic drug' and available data. Package leaflet has been updated accordingly. Furthermore, the MAH included changes for the local representative for Lithuania.

[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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N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	03/11/2021	02/12/2021	PL	
PSUSA/805/202012	Periodic Safety Update EU Single assessment - clofarabine	08/07/2021	n/a		PRAC Recommendation - maintenance
IAIN/0002/G	This was an application for a group of variations. 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 B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	11/12/2020	02/12/2021	Annex II and PL	
IA/0003/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	10/12/2020	n/a		
PSUSA/805/2	Periodic Safety Update EU Single assessment -	23/07/2020	17/09/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending

01912	clofarabine				the variation to terms of the Marketing Authorisation(s)' for PSUSA/805/201912.