Jaypirca

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Variation type IA_IN /	A. ADMINISTRATIVE CHANGES - A.1 Change	27/01/2026		SmPC,	

[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).

EMA/VR/0000315519	in the name and/or address of the marketing authorisation holder - Accepted			Labelling and PL	
PSUR / EMA/PSUR/0000268970	- - In view of available data on pirtobrutinib from clinical trials and spontaneous reports, including cases with a close temporal relationship, including positive de-challenges and re-challenges (of which one case had multiple positive rechallenges), the PRAC considers a causal relationship between pirtobrutinib and hepatic enzyme increased is at least a reasonable possibility. The PRAC concluded that the product information of products containing pirtobrutinib should be amended accordingly.	18/09/2025		SmPC	Variation.
Variation type IA / EMA/VR/0000278785	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted	08/09/2025	N/A		
Renewal - 1 year / EMA/R/0000264598	- Renewal - Accepted	24/07/2025	10/09/2025		
Variation type IB / EMA/VR/0000263297	B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active	23/04/2025	N/A		

	substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.z Other variation - Accepted				
Variation type IB / EMA/VR/0000248641	This was an application for a group of variations. B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Other changes - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Other changes - Accepted	07/03/2025	N/A		