Finlee

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
PSUR / EMA/PSUR/0000296502		29/01/2026	25/03/2026	SmPC and PL	Variation

[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).

	In view of available data on events of radiation recall and sensitisation from clinical trials, the literature, spontaneous reports including in some cases a close temporal relationship, localisation of the event within the irradiated field and in view of a plausible mechanism of action, the PRAC considers a causal relationship between dabrafenib and potentiation of radiation toxicity at least a reasonable possibility. The PRAC concluded that the product information of products containing dabrafenib should be amended accordingly.				
Variation type IA / EMA/VR/0000323418	A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted	21/01/2026	25/03/2026	Annex II and PL	
Variation type IB / EMA/VR/0000308721	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.a Minor change in the manufacturing process - Accepted B.II.b.2 Change to importer, batch release	26/11/2025			

	arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.e Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products - Accepted				
Variation type IA_IN / EMA/VR/0000308071	C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.z Implementation of wording agreed by the competent authority + QRD update - Accepted	03/11/2025	25/03/2026	SmPC and PL	To update Section 4.8 of the SmPC and Section 4 of the PL to implement the signal recommendations on 'Tattoo associated skin reaction (EPITT no 20160)' adopted at the 4 September 2025 PRAC.