Balversa

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
Article 61(3) /	Outcome:	19/06/2026		PL	

[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/N/0000356661	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representatives.				
Variation type IA_IN / EMA/VR/0000340655	Outcome: C.3 Change(s) in the summary of product characteristics, labelling or package leaflet intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Article 45 or 46 of Regulation (EC) No 1901/2006, or the outcome of a PRAC signal recommendation, or to adapt to a joint recommendation of EU competent authorities (e.g. a Core SmPC, or following the assessment of an Urgent Safety Restriction etc.) - C.3.a) Implementation of the agreed wording - Accepted	24/04/2026		SmPC and PL	
Variation type IA / EMA/VR/0000248998	Outcome: This was an application for a group of variations. B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.II.b.5 Change to in-process tests or limits	18/02/2025	23/02/2026	SmPC, Labelling and PL	

	applied during the manufacture of the finished product - B.II.b.5.z Minor change of an analytical procedure for an in-process control - Accepted B.II.e.1.b Change in type of container or addition of a new container - B.II.e.1.b.3 Deletion of an immediate packaging container that does not lead to the complete deletion of a strength or pharmaceutical form - Accepted				
PSUR / EMA/PSUR/0000282264	EURD: PSUSA/00011072/202504 Active substance: erdafitinib Outcome: Maintenance	30/10/2025			Maintenance