Balversa

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/11072 /202410	Periodic Safety Update EU Single assessment - erdafitinib	08/05/2025	n/a		PRAC Recommendation - maintenance
II/0001	Update of section 4.8 of the SmPC in order to add cataract as a new ADR with frequency common based on a review of new information observed in clinical	28/11/2024	23/02/2026	SmPC and PL	Update of section 4.8 of the SmPC in order to add cataract as a new ADR with frequency common. For more information, please refer to the Summary of

[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).

	studies and in the post marketing setting. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of the most common ADRs in the SmPC section 4.8 and to make editorial corrections in the SmPC and Package Leaflet. The requested variation proposed amendments to the Summary of Product Characteristics and Package Leaflet. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				Product Characteristics.