Baiama

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 IB /	This was an application for a variation	12/06/2025		SmPC and 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/VR/0000266291	following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted Type IB (C.I.2.a) - to update section 4.8 of the SmPC and the corresponding section 4 of the Package Leaflet, in order to add `scleritis' to the list of adverse drug reactions (ADRs) with frequency of `0.2 cases per 1 million injections' based on pharmacovigilance data, following the assessment of the same change for the reference product Eylea. Additional minor changes: Furthermore, the MAH took the opportunity to add the list of local representatives to section 6 of the package leaflets as part of this regulatory procedure. In addition, few corrections in the English PI have been introduced and, accordingly, in the translations as applicable: · A few spelling mistakes and formatting errors (dashes, spaces and period) have been corrected. · Within the approved				

	polysorbate note, the until style has been adjusted from `ml' to `mL' to align with the rest of the PI. · A minor error of wrongly displaying a `%' has been corrected to be in line with the reference product. · The date of first authorisation has been added for Baiama (for Ahzantive this had been added already in the PI for MAH transfer EMA/T/0000257507 as approved by EC on 23 April 2025). In the translations, additional minor changes have been implemented: · In line with QRD Appendix IV (EMA/286379/2019 Rev.14), the terms/abbreviations used for 'batch number' and 'expiry date' have been adjusted for the carton and vial labels, as appropriate, to offer flexibility for multilingual packaging combinations. · In line with QRD decisions on stylistic matters in product information (EMA/25090/2002 rev.23), formatting errors (spaces, periods, colons, commas instead of dots for decimals) and grey-shading as appropriate have been corrected.				