Matever

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, please 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 /	C.I.2 Change(s) in the Summary of Product	16/05/2025		SmPC,	To update section 4.8 of the SmPC to include

[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/0000265766	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 C.I.2.a - To update section 4.8 of the SmPC to include additional information on the signs and symptoms of Drug Reactions with Eosinophilia and Systemic Symptoms (DRESS), based on a safety review and after the approval of the same change to the reference product, Keppra. The package leaflet is updated accordingly. Additionally, the MAH took the opportunity to implement editorial changes to the PI in line with the QRD template, remove the local representative for the UK (Northern Ireland), and correct typographical errors.			Labelling and PL	additional information on the signs and symptoms of Drug Reactions with Eosinophilia and Systemic Symptoms (DRESS), based on a safety review and after the approval of the same change to the reference product, Keppra. The package leaflet is updated accordingly.