Tacforius

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	03/12/2024		SmPC, Annex	

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[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/0000236795 | 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 4.6 of the SmPC has been updated to reflect the results of the study that tacrolimus crosses the placenta and the risk of hyperkalaemia in newborns. The package leaflet is updated accordingly. In addition, the MAH has taken this opportunity to make minor corrections in line with the current QRD version and to amend the details of the local representative for EL and CY. | | | II and PL | |