Tacforius

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
IB/0013/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO	10/01/2023		SmPC and PL	Update of sections 4.4 and 4.8 of the SmPC in order to add a warning on the adverse reaction Thrombotic microangiopathy (TMA) following assessment of the same changes adopted for the parent product (EMEA/H/C/2241/G). The package leaflet is updated accordingly. Update of sections 4.5 and 4.8 of the SmPC in

[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).

	new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				order to add the drug-drug interaction between tacrolimus and caspofungin following assessment of the same changes adopted for the parent product. The package leaflet is updated accordingly. Update of section 5.2 of the SmPC in order to add that tacrolimus is metabolized by the cytochrome P450-3A5 (CYP3A5) following assessment of the same changes adopted for the parent product. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes.
IA/0012	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	06/09/2022	n/a		
R/0010	Renewal of the marketing authorisation.	23/06/2022	05/08/2022	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Tacforius in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0011/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO	08/06/2022	05/08/2022	SmPC, Annex II, Labelling and PL	

	new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IA/0009	A.7 - Administrative change - Deletion of manufacturing sites	25/10/2021	n/a		
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/07/2021	05/08/2022	PL	
IA/0008	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	17/06/2021	n/a		
IB/0006	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	08/10/2020	n/a		

IAIN/0005	B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	18/09/2020	n/a		
IB/0004/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	16/04/2020	26/03/2021	SmPC and PL	
IB/0003/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the	02/10/2019	17/02/2020	SmPC, Annex II, Labelling and PL	

	assessment done under A 45/46 - Other variation				
IAIN/0002	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	28/02/2019	17/02/2020	SmPC	
IA/0001	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	06/02/2019	n/a		