HYFTOR

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/25/202405	Periodic Safety Update EU Single assessment - sirolimus (indicated for treatment of angiofibroma associated with tuberous sclerosis complex)	28/11/2024	n/a		PRAC Recommendation - maintenance
IA/0007	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	14/11/2024	n/a		

[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).

IB/0005	B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)	14/06/2024	n/a		
PSUSA/25/202311	Periodic Safety Update EU Single assessment - sirolimus (indicated for treatment of angiofibroma associated with tuberous sclerosis complex)	13/06/2024	n/a		PRAC Recommendation - maintenance
IA/0003	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	11/12/2023	04/12/2024	SmPC	
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/09/2023	04/12/2024	PL	
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/06/2023	04/12/2024	PL	