SOTYKTU

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/11046 /202409	Periodic Safety Update EU Single assessment - deucravacitinib	10/04/2025	n/a		PRAC Recommendation - maintenance
IB/0012/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a	17/10/2024	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).

	starting material/reagent/intermediate for AS - Other variation B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size				
PSUSA/11046 /202403	Periodic Safety Update EU Single assessment - deucravacitinib	03/10/2024	n/a		PRAC Recommendation - maintenance
IB/0011	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	03/07/2024	25/04/2025	SmPC	
IA/0010	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	21/06/2024	n/a		
IA/0009/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material	28/05/2024	n/a		

IA/0007	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	16/05/2024	25/04/2025	SmPC	
IA/0006	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	29/04/2024	n/a		
PSUSA/11046 /202309	Periodic Safety Update EU Single assessment - deucravacitinib	11/04/2024	n/a		PRAC Recommendation - maintenance
IA/0005/G	This was an application for a group of variations. B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits A.7 - Administrative change - Deletion of manufacturing sites	01/02/2024	n/a		
IB/0004	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	25/01/2024	n/a		
N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/12/2023	25/04/2025	PL	
IB/0001	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	10/10/2023	n/a		