Litfulo

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
II/0007	Update of section 4.8 of the SmPC in order to update the safety information based on interim results from study B7981032 listed as a category 3 study in the RMP; this is a phase 3 open-label, multi-center, long-term study investigating the safety and efficacy of ritlecitinib in adult and adolescent participants with	13/02/2025		SmPC	

[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).

	alopecia areata. The RMP version 2 is acceptable. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/133/202406	Periodic Safety Update EU Single assessment - ritlecitinib	16/01/2025	n/a		PRAC Recommendation - maintenance
IB/0006	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)	11/10/2024		SmPC	
IA/0004	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	28/08/2024	n/a		
PSUSA/133/202312	Periodic Safety Update EU Single assessment - ritlecitinib	11/07/2024	n/a		PRAC Recommendation - maintenance
IAIN/0003	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	05/06/2024		SmPC, Annex II and PL	
IB/0001	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	27/03/2024		SmPC and Labelling	