



Mulpleo

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/10755 /201903	Periodic Safety Update EU Single assessment - lusutrombopag	03/10/2019	n/a		PRAC Recommendation - maintenance
N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/08/2019		PL	
IAIN/0001	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	11/07/2019		SmPC, Labelling and	

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).



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