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
R/0018	Renewal of the marketing authorisation.	09/11/2023	05/01/2024		Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Mulpleo in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.

[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).

PSUSA/10755 /202209	Periodic Safety Update EU Single assessment - lusutrombopag	14/04/2023	n/a		PRAC Recommendation - maintenance
IAIN/0017/G	This was an application for a group of variations. B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.1 - Administrative change - Change in the name and/or address of the MAH	07/03/2023	05/01/2024	SmPC, Annex II, Labelling and PL	
IG/1553	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	06/12/2022	n/a		
PSUSA/10755 /202109	Periodic Safety Update EU Single assessment - lusutrombopag	05/05/2022	n/a		PRAC Recommendation - maintenance
N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/12/2021	05/01/2024	PL	
PSUSA/10755 /202103	Periodic Safety Update EU Single assessment - lusutrombopag	28/10/2021	n/a		PRAC Recommendation - maintenance
IA/0011	A.7 - Administrative change - Deletion of manufacturing sites	08/06/2021	31/01/2022	Annex II and PL	
PSUSA/10755	Periodic Safety Update EU Single assessment -	06/05/2021	n/a		PRAC Recommendation - maintenance

/202009	lusutrombopag				
IG/1359	A.7 - Administrative change - Deletion of manufacturing sites	10/03/2021	n/a		
IA/0009	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	02/02/2021	n/a		
IB/0008	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)	06/01/2021	31/01/2022	SmPC	
PSUSA/10755 /202003	Periodic Safety Update EU Single assessment - lusutrombopag	29/10/2020	n/a		PRAC Recommendation - maintenance
PSUSA/10755 /201909	Periodic Safety Update EU Single assessment - lusutrombopag	17/04/2020	n/a		PRAC Recommendation - maintenance
IAIN/0005/G	This was an application for a group of variations. 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 B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	24/03/2020	13/07/2020	Annex II and PL	

	site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing				
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	13/07/2020	PL	
IAIN/0001	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	11/07/2019	13/07/2020	SmPC, Labelling and PL	