



EMA/319241/2020

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 /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 | 24/03/2020 | | Annex II and PL | |

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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| <p>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</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site</p> <p>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site</p> <p>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</p> <p>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</p> | | | | |
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| | 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 | | 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 PL | |