Doptelet

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
IA/0013	A.7 - Administrative change - Deletion of manufacturing sites	20/06/2022		Annex II and PL	
IB/0012/G	This was an application for a group of variations. B.II.b.1.e - Replacement or addition of a	05/01/2022	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).

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	manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products 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 B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.b - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process				
PSUSA/10779 /202105	Periodic Safety Update EU Single assessment - avatrombopag	02/12/2021	n/a		PRAC Recommendation - maintenance
IB/0010	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	22/07/2021	n/a		

PSUSA/10779 /202011	Periodic Safety Update EU Single assessment - avatrombopag	10/06/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10779 /202005	Periodic Safety Update EU Single assessment - avatrombopag	28/01/2021	31/03/2021	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10779/202005.
II/0004/G	This was an application for a group of variations. Extension of indication to include the treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments; consequently, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2 of the SmPC are updated. Additionally, the SmPC section 5.3 is updated with data from juvenile toxicity studies. Furthermore, an additional pack size of 30 tablets has been introduced with subsequent updates of sections 6.5 and 8 of the SmPC. The Package Leaflet and Labelling are updated in accordance. Version 2.7 of the RMP has also been updated. Furthermore, the PI is brought in line with the latest QRD template version 10.1. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	10/12/2020	18/01/2021	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion 'Doptelet-H-C-4722-II-0004-G'.

T/0007	Transfer of Marketing Authorisation	07/09/2020	09/10/2020	SmPC, Labelling and PL	
IAIN/0005/G	This was an application for a group of variations. 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.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	06/08/2020	09/10/2020	Annex II and PL	
PSUSA/10779 /201911	Periodic Safety Update EU Single assessment - avatrombopag	11/06/2020	n/a		PRAC Recommendation - maintenance
IB/0001	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)	04/12/2019	09/10/2020	SmPC	