OZAWADE

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/0012	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	16/10/2025		SmPC	Update of section 5.2 of the SmPC based on the final PopPK model (PH20043). For more information, please refer to the Summary of Product Characteristics.
PSUSA/10490 /202409	Periodic Safety Update EU Single assessment - pitolisant	08/05/2025	n/a		PRAC Recommendation - maintenance

[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).

II/0011/G	This was an application for a group of variations. B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.5.e - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	05/12/2024	n/a		
II/0010	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	17/10/2024	18/11/2024	SmPC and PL	Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to introduce a new posology regimen, change posology recommendations for patients with renal and hepatic impairment and to update the list of adverse drug reactions

					(ADRs) as well as efficacy information, based on the final results from study P15-13 (HAROSA III). For more information, please refer to the Summary of Product Characteristics.
II/0007	Submission of the final report from study P21-03. This is an open label, single centre, drug-drug interaction study to evaluate the effect of a combination of itraconazole and paroxetine treatment on the pitolisant pharmacokinetics at steady-state in eighteen healthy male Caucasian subjects. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	25/07/2024	18/11/2024	SmPC	Update of the SmPC section 4.5 to include information on the effect of CYP3A4 inhibition in CYP2D6 poor metabolisers. For more information, please refer to the Summary of Product Characteristics.
PSUSA/10490 /202309	Periodic Safety Update EU Single assessment - pitolisant	16/05/2024	n/a		PRAC Recommendation - maintenance
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/11/2023	18/11/2024	PL	
IG/1680	B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation	20/10/2023	n/a		
PSUSA/10490 /202209	Periodic Safety Update EU Single assessment - pitolisant	14/04/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10490	Periodic Safety Update EU Single assessment -	05/05/2022	n/a		PRAC Recommendation - maintenance

/202109	pitolisant				
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/05/2022	16/12/2022	PL	
IB/0003	B.I.d.z - Stability of AS - Other variation	28/04/2022	n/a		
IB/0001	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	06/01/2022	16/12/2022	SmPC, Labelling and PL	