Pombiliti

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/0016	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	10/10/2024	n/a		
PSUSA/11047 /202403	Periodic Safety Update EU Single assessment - cipaglucosidase alfa	03/10/2024	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/0012	Update of section 4.8 of the SmPC in order to update the frequency of adverse drug reactions and to add swelling face to the list of adverse drug reactions (ADRs) with frequency Uncommon based on the updated integrated analysis of safety data for Pool 2 (All Studies ATB200-02/03/07). The Package Leaflet is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	12/09/2024		SmPC and PL	
IB/0014	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	11/07/2024	n/a		
II/0010	Update of sections 4.6 and 5.3 of the SmPC in order to provide information regarding pre-implantation loss based on the reassessment of non-clinical data. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.3 and to introduce editorial changes. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	27/06/2024		SmPC	For more information, please refer to the Summary of Product Characteristics.
IB/0011	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other	22/04/2024	n/a		

	changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				
PSUSA/11047 /202309	Periodic Safety Update EU Single assessment - cipaglucosidase alfa	11/04/2024	n/a		PRAC Recommendation - maintenance
IB/0009/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	27/02/2024	n/a		
IA/0008	A.7 - Administrative change - Deletion of manufacturing sites	03/01/2024	n/a		
IA/0007	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	12/12/2023	n/a		
IB/0005	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	12/12/2023	n/a		
IB/0004/G	This was an application for a group of variations. B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.d.2.z - Change in test procedure for the finished	11/12/2023	n/a		

	product - Other variation A.7 - Administrative change - Deletion of manufacturing sites				
IB/0003	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	17/11/2023	n/a		
IB/0002	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	17/07/2023	n/a		
IB/0001	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	22/06/2023	n/a		