Nexviadyme

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
N/0018	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/08/2024		PL	
IA/0017	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	28/05/2024	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).

	intermediate used in the manufacture of the AS or manufacturer of a novel excipient				
II/0015	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	04/04/2024		SmPC and PL	
PSUSA/11002 /202308	Periodic Safety Update EU Single assessment - avalglucosidase alfa	07/03/2024	n/a		PRAC Recommendation - maintenance
II/0008	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	30/11/2023	21/03/2024	SmPC and PL	
II/0012	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	16/11/2023	n/a		
IB/0011	B.I.a.3.e - Change in batch size (including batch size ranges) of AS or intermediate - The scale for a biological/immunological AS is increased/decreased without process change (e.g. duplication of line)	31/08/2023	n/a		
PSUSA/11002 /202302	Periodic Safety Update EU Single assessment - avalglucosidase alfa	31/08/2023	n/a		PRAC Recommendation - maintenance
IA/0013	B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier	01/08/2023	n/a		
IA/0010/G	This was an application for a group of variations.	24/05/2023	21/03/2024	Annex II	

	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) 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				
IAIN/0007	A.1 - Administrative change - Change in the name and/or address of the MAH	05/04/2023	21/03/2024	SmPC, Labelling and PL	
PSUSA/11002 /202208	Periodic Safety Update EU Single assessment - avalglucosidase alfa	16/03/2023	n/a		PRAC Recommendation - maintenance
IB/0006	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	21/12/2022	n/a		
IB/0005/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure 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	22/11/2022	n/a		

	material/intermediate				
II/0003/G	This was an application for a group of variations. B.II.d.1.f - Change in the specification parameters and/or limits of the finished product - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.I.b.1.e - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a specification parameter which may have a significant effect on the overall quality of the AS and/or the FP	06/10/2022	n/a		
II/0002	B.I.a.3.c - Change in batch size (including batch size ranges) of AS or intermediate - The change requires assessment of the comparability of a biological/immunological AS	22/09/2022	n/a		
II/0001	B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	22/09/2022	n/a		