Grasustek

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/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/03/2023		PL	
IB/0008/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other	24/02/2023	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).

	variation B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test				
IB/0010/G	This was an application for a group of variations. B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	10/02/2023	n/a		
IA/0007	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	22/11/2022	n/a		
PSUSA/2326/202201	Periodic Safety Update EU Single assessment - pegfilgrastim	29/09/2022	n/a		PRAC Recommendation - maintenance
N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/08/2022		PL	
IB/0004/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 B.I.a.2.a - Changes in the manufacturing process of	02/12/2021	n/a		

	the AS - Minor change in the manufacturing process of the AS B.I.z - Quality change - Active substance - Other variation				
IB/0003/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	25/06/2021	08/07/2022	SmPC, Labelling and PL	
IB/0002	B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation	18/05/2020	n/a		
IB/0001	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	05/03/2020	26/03/2021	SmPC, Annex II, Labelling and PL	