Grasustek

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Article 61(3) /	Outcome:	12/06/2026		PL	

[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).

EMA/N/0000355372	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representatives.				
Article 61(3) / EMA/N/0000338145	Outcome: - Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representatives. Additionally, the MAH took the opportunity to introduce minor editorial amendments.	24/03/2026		PL	
Article 61(3) / EMA/N/0000307856	Outcome: - Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representatives. Additionally, the MAH took the opportunity to make minor editorial and grammatical changes in the French and Slovak translation.	04/11/2025		PL	
Variation type IB / EMA/VR/0000272956	Outcome: This was an application for a group of variations. B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted B.I.c.2 Change in the specification	17/06/2025			

	parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted				
Variation type IA / EMA/VR/0000244623	Outcome: B.III.2 Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.b Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State - Accepted	14/01/2025			
PSUR / EMA/PSUR/0000274399	EURD: PSUSA/00002326/202501 Active substance: pegfilgrastim Outcome: Maintenance	02/10/2025			