Semglee

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) /	- Notification acc. Article 61(3) - Accepted	19/02/2026		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/0000326578	Update of the package leaflet with revised contact details of local representatives.				
Variation type IB / EMA/VR/0000321366	B.II.g.4 Changes to an approved change management protocol - B.II.g.4.b Minor changes to an approved change management protocol that do not change the strategy defined in the protocol - Accepted	26/01/2026			
Variation type IA / EMA/VR/0000323054	This was an application for a group of variations. B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an	16/01/2026			

	approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active				

	substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted				

	B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted				
Variation type IB / EMA/VR/0000295851	B.I.e.5 Implementation of changes foreseen in an approved change management protocol - B.I.e.5.c Implementation of a change for a biological/immunological medicinal product - Accepted	02/10/2025			
Variation type IB / EMA/VR/0000263665	This was an application for a group of variations. B.III.2 Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.z To reflect compliance with the Ph.Eur. and remove reference to the internal test method and test method number for active substances, excipients, active substance starting materials and immediate packaging materials - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to	06/05/2025			

	the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted				

	B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.z Other changes - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to				

	the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted				

	B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted				

Variation type IB / EMA/VR/0000262310	B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.f The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line) - Accepted	17/04/2025			
Variation type IA / EMA/VR/0000265595	This was an application for a group of variations. B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c	15/04/2025			

	Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.c.2 Change in the specification 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/0000254757	B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.c Addition of a new specification parameter to the specification	24/02/2025			

	with its corresponding test method - Accepted				
Variation type IA_IN / EMA/VR/0000244114	B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted	13/01/2025			
PSUR / EMA/PSUR/0000288220					Maintenance