SYLVANT

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
Variation type IB /	Outcome:	28/07/2026		SmPC, Annex	

[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/VR/0000357527	C.1 Change(s) in the summary of product characteristics, labelling or package leaflet intended to implement the outcome of a Union referral procedure - C.1.z Other variation - Accepted C.I.z (Type IB) – To update sections 2 and 4.4 of the SmPC and section 2 of the PL with information on the excipient polysorbate 80, based on the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'. In addition, the address of the batch release site (Patheon) is corrected in the product information in line with SPOR OMS. Furthermore, the MAH took the opportunity to: • Correct the address of the batch release site (Patheon) in Annex II and the PL in line with SPOR OMS. • Remove the description of the post-authorisation measure from Annex II, as previously approved (EMA/H/C/003708/II/0038). The description was inadvertently reintroduced during a previous procedure. • Correct typographical errors throughout the product information (EN, CS, IT, PT, SV).			II and PL	
Variation type IB / EMA/VR/0000342252	Outcome: This was an application for a group of variations.	27/05/2026			

	Q.II.g.5 Implementation of changes foreseen in a post-approval change management protocol (PACMP) - Q.II.g.5.c) Implementation of change foreseen in a PACMP via Type IB notification - Accepted Q.II.d.1 Change in the specification attribute and/or acceptance criteria of the finished product - Q.II.d.1.c) Addition of a new specification attribute with its corresponding analytical procedure and acceptance criteria - Accepted				
Variation type IB / EMA/VR/0000324825	Outcome: This was an application for a group of variations. Q.II.b.2 Change to batch release arrangements and batch control testing of the finished product - Q.II.b.2.b) Addition or replacement of a batch control/testing site applying a biological/immunological/immunochemical analytical procedure for a biological finished product - Accepted Q.II.b.2 Change to batch release arrangements and batch control testing of the finished product - Q.II.b.2.a) Addition or replacement of a batch control/testing site applying physicochemical and/or microbiological analytical procedures for the finished product - Accepted	24/03/2026			

	Q.II.b.2 Change to batch release arrangements and batch control testing of the finished product - Q.II.b.2.a) Addition or replacement of a batch control/testing site applying physicochemical and/or microbiological analytical procedures for the finished product - Accepted				
Variation type IA / EMA/VR/0000337997	Outcome: This was an application for a group of variations. Q.II.b.2.c) Addition or replacement of a site responsible for batch release (QP certification) - Q.II.b.2.c.1 Not including batch control/testing - Accepted Q.II.b.1 Change in the manufacturing site for part or all of the manufacturing process of the finished product (except for batch release and batch control testing sites) - Q.II.b.1.a) Addition or replacement of a site responsible for secondary packaging - Accepted	24/03/2026		Annex II and PL	
Variation type II / EMA/VR/0000279783	Outcome: B.II.g) Design Space and post approval change management protocol - B.II.g.2 Introduction of a post approval change management protocol related to the finished product - Accepted	04/12/2025			

Variation type II / EMA/VR/0000269593	Outcome: This was an application for a group of variations. B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.j Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place - 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.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits	24/07/2025		Annex II	

	applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.j Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.e The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product - Accepted				

Variation type IB / EMA/VR/0000279534	Outcome: B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Other changes - Accepted	15/07/2025			
PSUR / EMA/PSUR/0000288233	EURD: PSUSA/00010254/202504 Active substance: siltuximab Outcome: Maintenance	27/11/2025			Maintenance.