Alymsys

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	06/02/2026		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/0000326153	Update of the package leaflet with revised contact details of local representative.				
Renewal - 5 year / EMA/R/0000276471		13/11/2025	19/01/2026	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Alymsys in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUR / EMA/PSUR/0000274402	In view of available data on hyaline occlusive glomerular microangiopathy reported in the literature, including in some cases a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between bevacizumab and hyaline occlusive glomerular microangiopathy is at least a reasonable possibility. The PRAC concluded that the product information of products containing bevacizumab should be amended accordingly.	16/10/2025	18/12/2025	SmPC	Variation
Variation type II / EMA/VR/0000272167	B.I.e) Design Space and post-approval change management protocols - B.I.e.2 Introduction of a post approval change management protocol related to the active substance - Accepted	09/10/2025			

Variation type IB / EMA/VR/0000276462	This was an application for a group of variations. B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.d Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.I.d.1 Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - B.I.d.1.c Change to an approved stability protocol - Accepted 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	03/07/2025			

Variation type IB / EMA/VR/0000269765	This was an application for a group of variations. B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.z Other changes - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.d Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted	26/05/2025			
Variation type IB / EMA/VR/0000269362	This was an application for a group of variations. 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.a Minor change in the manufacturing process - Accepted B.I.b) Control of active substance - B.I.b.z If information on the level of testing performed by the FP manufacturer on receipt of the AS batches is already present in the approved registration dossier, the applicant is advised	22/05/2025			

	to apply for a Type IB (B.I.b.z) variation to remove this information from the dossier. - Accepted				
Variation type IA / EMA/VR/0000264674	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 approved test procedure - Accepted	08/04/2025			
Variation type IB / EMA/VR/0000247279	B.II. FINISHED PRODUCT - B.II.z To update Module 3.2.A.1 for a biotech medicinal product - Accepted	25/02/2025			

Variation type IB / EMA/VR/0000244798	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	12/02/2025			