Darzalex

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 II /	C.I HUMAN AND VETERINARY MEDICINAL	26/03/2026		SmPC,	

[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/0000312940	PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 4.2 of the SmPC in order to introduce, upon physician's discretion, the possibility of self-administration of Darzalex SC by patients or their caregivers, based on results from four human factor studies. The Package Leaflet is updated accordingly. In addition, the Labelling section is updated to include information in Braille.			Labelling and PL	
Variation type II / EMA/VR/0000320811	B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted	19/03/2026			
Variation type II / EMA/VR/0000313969	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted	05/02/2026		SmPC and PL	Patients should be closely monitored for signs and symptoms of infection, and prophylactic antimicrobials according to treatment guidelines should be considered prior to and during treatment with daratumumab. For more information, please refer to the Summary of Product Characteristics.

	Update of section 4.4 of the SmPC in order to add a warning on 'Infections'. The Package Leaflet is updated accordingly.				
Variation type II / EMA/VR/0000282640	This was an application for a group of variations. B.II.c.2 Change in test procedure for an excipient - B.II.c.2.a Minor changes to an approved test procedure - Accepted B.II.c.2 Change in test procedure for an excipient - B.II.c.2.d Other changes to a test procedure (including replacement or addition) - Accepted B.II.c.4 Change in synthesis or recovery of a nonpharmacopoeial excipient (when described in the dossier) or a novel excipient - B.II.c.4.c The excipient is a biological/immunological substance - 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.II.e.1 Change in immediate packaging of the finished product - B.II.e.1.z Other changes - Accepted B.II.b.1 Replacement or addition of a	27/11/2025		Annex II and PL	The Annex II has been updated as follows: Section A MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURE RESPONSIBLE FOR BATCH RELEASE is being updated to include: Janssen Pharmaceutica NV Turnhoutseweg 30 2340 Beerse Belgium Under the 'Name and address of the manufacturer responsible for batch release' The Package Leaflet have been updated accordingly.

	manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted				

	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.c Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes - Accepted				
Variation type II / EMA/VR/0000284866	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.2 and 6.6 of the SmPC for the subcutaneous formulation in order to improve guidance for minimizing the risk for stopper coring. In addition, the MAH took the opportunity to introduce editorial and administrative changes to the PI, including to the Annex II, Labelling and the Package Leaflet. The list of local representatives in the Package Leaflet has also been updated.	18/09/2025		SmPC, Annex II, Labelling and PL	Updated guidance on the method of administration of DARZALEX's subcutaneous formulation to reduce the incidence of stopper coring. For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000278107	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC)	04/09/2025			

	No 1234/2008. 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.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place - Accepted				
Variation type IA_IN / EMA/VR/0000290174	This was an application for a group of variations. 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 B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted	04/08/2025		Annex II and PL	
Variation type II / EMA/VR/0000249270	This was an application for a group of variations.	26/06/2025			

	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 Minor change in the manufacturing process of a sterile finished product after the primary packaging step - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted 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.c Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes - Accepted				
Variation type II / EMA/VR/0000263940	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	12/06/2025	18/07/2025	Annex II and PL	The Annex II has been updated as follows: Addition of Samsung Biologics Co, Ltd., Plant 3, 300, Songdo bio-daero, Yeonsu-gu, Incheon, Republic of Korea as additional manufacturer of the biological active substance. The package leaflet has been updated as follows: Editorial correction to the local representatives for Iceland.
Variation type II / EMA/VR/0000254725	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted	08/05/2025	18/07/2025	SmPC, Annex II, Labelling and PL	Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study AMY3001 listed as PAES in the Annex II; this is a randomized phase 3 study to evaluate the efficacy and safety of daratumumab in combination with cyclophosphamide, bortezomib and dexamethasone (CyBorD) compared with CyBorD in

	Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study AMY3001 listed as PAES in the Annex II; this is a randomized phase 3 study to evaluate the efficacy and safety of daratumumab in combination with cyclophosphamide, bortezomib and dexamethasone (CyBorD) compared with CyBorD in newly diagnosed systemic AL amyloidosis.				newly diagnosed systemic AL amyloidosis.
PSUR / EMA/PSUR/0000257879					