Mounjaro

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 IA_IN /	This was an application for a group of	25/11/2025	N/A		

[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/0000313865	variations. B.I.e.5 Implementation of changes foreseen in an approved change management protocol - B.I.e.5.a The implementation of the change requires no further supportive data - Accepted B.I.e.5 Implementation of changes foreseen in an approved change management protocol - B.I.e.5.a The implementation of the change requires no further supportive data - Accepted B.I.e.5 Implementation of changes foreseen in an approved change management protocol - B.I.e.5.a The implementation of the change requires no further supportive data - Accepted B.I.e.5 Implementation of changes foreseen in an approved change management protocol - B.I.e.5.a The implementation of the change requires no further supportive data - Accepted B.I.e.5 Implementation of changes foreseen in an approved change management protocol - B.I.e.5.a The implementation of the change requires no further supportive data - Accepted				

Variation type IB / EMA/VR/0000310232	B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.a Up to 10-fold compared to the originally approved batch size - Accepted	20/11/2025			
Variation type II / EMA/VR/0000267397	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	13/11/2025	N/A		
Variation type II / EMA/VR/0000269552	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 section 5.1 of the SmPC in order to update efficacy information based on final results from study I8F-MC-GPHJ (SURMOUNT-5); this is a Phase 3, randomised, open-label, active comparator-controlled study that investigated the effects of treatment with tirzepatide 15 mg or MTD (10 mg or 15 mg) compared with semaglutide 2.4 mg or MTD (1.7 mg or 2.4 mg), in adult participants who had obesity or overweight with weight-related comorbidities.	23/10/2025		SmPC	The SmPC was updated to include information from trial I8F-MC-GPHJ (SURMOUNT-5). In this 72-week trial, which included 751 adult patients with obesity (BMI ≥ 30 kg/m2) or overweight (BMI ≥ 27 kg/m2 to < 30 kg/m2) with at least 1 weight-related comorbid condition, treatment with tirzepatide (15 mg or 10 mg once weekly) resulted in a superior and clinically meaningful reduction in body weight compared to semaglutide (2.4 mg or 1.7 mg once weekly). Tirzepatide also achieved superiority compared with semaglutide for the key secondary endpoints, i.e. proportion of patients achieving ≥10 %, ≥15 %, ≥20 %, and ≥25 % body weight reduction at week 72 as well as reduction of waist circumference at week 72. For more information, please refer to the Summary of Product Characteristics.

Variation type IB / EMA/VR/0000278526	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - 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.z Other changes - Accepted	27/08/2025	N/A		
Variation type IB / EMA/VR/0000289603	This was an application for a group of variations.	26/08/2025	N/A		

	B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.b Replacement or addition of a supplier - Accepted B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.b Replacement or addition of a supplier - Accepted				
Variation type IB / EMA/VR/0000281959	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.f Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted	31/07/2025	N/A		
Variation type II / EMA/VR/0000271741	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics,	24/07/2025		SmPC	For more information, please refer to the Summary of Product Characteristics.

	Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 5.1 of the SmPC in order to include 3-year efficacy data based on final results from study I8F-MC-GPHK (SURMOUNT-1); this is a phase 3, efficacy and safety of tirzepatide once weekly in participants without Type 2 diabetes who have obesity or are overweight with weight-related comorbidities: a randomized, double-blind, placebo-controlled trial.				
Variation type IB / EMA/VR/0000274140	This was an application for a group of variations. B.II.e.6 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - B.II.e.6.b Change that does not affect the product information - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Other changes - Accepted	25/06/2025		PL	

Variation type IB / EMA/VR/0000265586	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.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation - Accepted	19/06/2025	N/A		
Variation type IB / EMA/VR/0000272556	B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.a Up to 10-fold compared to the originally approved batch size - Accepted	17/06/2025	N/A		
Variation type IA_IN / EMA/VR/0000275737	B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.2 Including batch control/testing - Accepted	04/06/2025	N/A		
Variation type IB / EMA/VR/0000264453	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	06/05/2025	N/A		

	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.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.a Up to 10-fold compared to the originally approved batch size - Accepted				
Variation type IA_IN / EMA/VR/0000262378	This was an application for a group of variations. 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.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	14/04/2025		Annex II and PL	
Variation type IA_IN / EMA/VR/0000261866	B.I.e.5 Implementation of changes foreseen in an approved change management protocol - B.I.e.5.a The implementation of the change requires no further supportive data - Accepted	25/03/2025	N/A		

PSUR / EMA/PSUR/0000288292	- - To be added				Maintenance
PSUR / EMA/PSUR/0000248506	- -				Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing tirzepatide remains unchanged and therefore recommends the maintenance of the marketing authorisation(s).