Mounjaro

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
II/0038	Update of sections 4.1, 4.8 and 5.1 of the SmPC based on final results from the Phase 3 trial I8F-MC-GPID (SUMMIT). SUMMIT was a randomized, multicenter, international, placebo-controlled, double-blind, parallel-arm study in participants with HFpEF and obesity. The study was designed to	29/01/2026		SmPC and PL	Please refer to Scientific Discussion 'Mounjaro-H-C-005620-II-0038'

[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).

	evaluate the effect of tirzepatide compared with placebo on both clinical and symptomatic or functional outcomes. The Package Leaflet is updated accordingly. Version 4.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
N/0041	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/02/2025	22/01/2026	Labelling and PL	
PSUSA/11019 /202405	Periodic Safety Update EU Single assessment - tirzepatide	12/12/2024	14/02/2025	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/11019/202405.
IB/0037/G	This was an application for a group of variations. B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.e.5.b - Implementation of changes foreseen in an approved change management protocol - Requires further supportive data	16/01/2025	n/a		

IB/0040/G	This was an application for a group of variations. B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.e.5.b - Implementation of changes foreseen in an approved change management protocol - Requires further supportive data	09/01/2025	n/a		
IB/0039/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	09/01/2025	n/a		

II/0027	Update of sections 4.1, 4.8 and 5.1 of the SmPC based on final results from studies I8F-MC-GPI1 and I8F-MC-GPI2. These are multicentre, randomized, parallel-arm, double-blind, placebo-controlled studies investigating the effects of tirzepatide compared with placebo in adult participants with moderate-to-severe OSA and obesity. The Package Leaflet is updated accordingly. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	12/12/2024	14/02/2025	SmPC and PL	Please refer to Scientific Discussion 'Mounjaro-H-C-005620-II-0027'
IB/0036/G	This was an application for a group of variations. B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - 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 B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	22/11/2024	n/a		
IAIN/0035	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	02/10/2024	14/02/2025	SmPC and PL	

IAIN/0034/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	02/10/2024	14/02/2025	Annex II and PL	
IB/0031/G	This was an application for a group of variations. B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.g.5.b - Implementation of changes foreseen in an approved change management protocol - Requires further supporting data B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	19/09/2024	n/a		
IAIN/0033	B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data	30/08/2024	n/a		
PSUSA/11019 /202311	Periodic Safety Update EU Single assessment - tirzepatide	27/06/2024	22/08/2024	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

					PSUSA/11019/202311.
IA/0032	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	21/08/2024	n/a		
IA/0030	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	21/08/2024	n/a		
IB/0028/G	This was an application for a group of variations. B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch	14/08/2024	n/a		

	control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
II/0022	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	25/07/2024	n/a		
II/0021/G	This was an application for a group of variations. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	25/07/2024	14/02/2025	SmPC and PL	
IAIN/0026/G	This was an application for a group of variations. B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	19/07/2024	n/a		

IB/0025/G	This was an application for a group of variations. B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	04/07/2024	14/02/2025	Annex II and PL	
IAIN/0024/G	This was an application for a group of variations. B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data	21/06/2024	n/a		
IAIN/0023/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	11/06/2024	22/08/2024	Annex II and PL	

	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing				
X/0015	Extension application to add 6 new strengths of 2.5 mg/dose (4.17 mg/ml), 5 mg/dose (8.33 mg/ml), 7.5 mg/dose (12.5 mg/ml), 10 mg/dose (16.67 mg/ml), 12.5 mg/dose (20.83 mg/ml) and 15 mg/dose (25 mg/ml) for Mounjaro solution for injection in pre-filled pen (KwikPen), multidose. Annex I_2.(c) Change or addition of a new strength/potency	22/02/2024	19/04/2024	SmPC, Annex II, Labelling and PL	
IB/0020	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	05/03/2024	n/a		
IAIN/0019/G	This was an application for a group of variations. B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process	29/02/2024	n/a		

	of the AS				
IAIN/0017/G	This was an application for a group of variations. B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	10/01/2024	19/04/2024	Annex II and PL	
II/0007	Extension of indication to include chronic weight management, including weight loss and weight maintenance, for MOUNJARO, as an adjunct to a reduced-calorie diet and increased physical activity in adults with an initial body mass index (BMI) of ≥ 30 kg/m2 (obesity), or ≥ 27 kg/m2 to < 30 kg/m2 (overweight) in the presence of at least one weight-related comorbid condition, based on a global, pivotal phase 3 study I8F-MC-GPHK (SURMOUNT-1) and five supportive phase 3 studies (SURPASS-1 to -5) in participants with T2DM and BMI ≥ 27 kg/m2. SURMOUNT-1 is a phase 3, randomized, double-blind, placebo-controlled trial to investigate the efficacy and safety of tirzepatide once weekly in participants without type 2 diabetes who have obesity or are overweight with weight related comorbidities. As a consequence, sections 4.1, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the	09/11/2023	11/12/2023	SmPC and PL	Please refer to Scientific Discussion 'EMEA-H-C-005620-II-0007'

	RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
PSUSA/11019 /202305	Periodic Safety Update EU Single assessment - tirzepatide	30/11/2023	n/a		PRAC Recommendation - maintenance
II/0010	Update of section 4.8 of the SmPC in order to add 'anaphylactic reaction' and 'angioedema' to the list of adverse drug reactions (ADRs) with frequency rare, based on reviews of post-marketing safety data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	09/11/2023	11/12/2023	SmPC and PL	Not applicable
IAIN/0016/G	This was an application for a group of variations. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within	25/10/2023	11/12/2023	SmPC, Labelling and PL	

	the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within				

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IAIN/0014	B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	25/10/2023	11/12/2023	SmPC, Labelling and PL	
IB/0012	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	05/10/2023	n/a		

II/0006/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.c - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer uses a substantially different route of synthesis or manufacturing conditions B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.e.2 - Introduction of a post approval change management protocol related to the AS B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.d.1.a.2 - Stability of AS - Change in the re-test period/storage period - Extension of the retest period based on extrapolation of stability data not in accordance with ICH/VICH guidelines B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	31/08/2023	n/a		
II/0004/G	This was an application for a group of variations. Please refer to the Recommendations section B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch	31/08/2023	11/12/2023	SmPC, Labelling and PL	The SmPC, Annexes IIIA, IIIB and A has been updated to reflect the registration of new presentations: - EU/1/22/1685/019: 2.5 mg; 0.5 ml (5 mg/ml); vial (glass); 1 vial - EU/1/22/1685/020: 5 mg; 0.5 ml (10 mg/ml); vial (glass); 1 vial - EU/1/22/1685/021: 7.5 mg; 0.5 ml (15 mg/ml); vial

	control/testing takes place B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - 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 B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished				(glass); 1 vial - EU/1/22/1685/022: 10 mg; 0.5 ml (20 mg/ml); vial (glass); 1 vial - EU/1/22/1685/023: 12.5 mg; 0.5 ml (25 mg/ml); vial (glass); 1 vial - EU/1/22/1685/024: 15 mg; 0.5 ml (30 mg/ml); vial (glass); 1 vial

	product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes				
PSUSA/11019 /202211	Periodic Safety Update EU Single assessment - tirzepatide	22/06/2023	23/08/2023	SmPC and PL	Please refer to Mounjaro PSUSA-11019-202211 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IB/0009/G	This was an application for a group of variations. B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - 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 B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.b.2.a - Change to importer, batch release	30/06/2023	n/a		

	arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
II/0008	Please refer to the Recommendations section B.I.e.2 - Introduction of a post approval change management protocol related to the AS	29/06/2023	n/a		Not applicable
IB/0005/G	This was an application for a group of variations. B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site A.6 - Administrative change - Change in ATC Code/ATC Vet Code	22/03/2023	23/08/2023	SmPC, Annex II and PL	
IB/0001/G	This was an application for a group of variations. B.II.e.z - Change in container closure system of the Finished Product - Other variation B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	03/03/2023	n/a		

N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/02/2023	23/08/2023	PL	