Wegovy

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
PSUSA/10671 /202305	Periodic Safety Update EU Single assessment - semaglutide	25/01/2024	21/03/2024	SmPC, Annex II and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10671/202305.
II/0018	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance	25/01/2024	21/03/2024	SmPC and 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).

	data				
IB/0015/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.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	11/10/2023	21/03/2024	Annex II and PL	
WS/2494/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size 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.z - Quality change - Active substance - Other variation	31/08/2023	n/a		

IB/0012	B.II.g.4.b - Changes to an approved change management protocol - Minor changes that do not change the strategy defined in the protocol	04/05/2023	n/a		
II/0009	Extension of indication to include treatment of adolescents for weight management based on the final results from study NN9536-4451; this trial was conducted to assess the efficacy and safety of semaglutide in paediatric patients of age 12 to <18 years with obesity. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.1 of the RMP was agreed during the procedure. Furthermore, the PI is brought in line with the latest QRD template version 10.2. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	30/03/2023	28/04/2023	SmPC and PL	Please refer to Scientific Discussion 'Wegovy-H-C-005422-II-0009'
PSUSA/10671 /202205	Periodic Safety Update EU Single assessment - semaglutide	26/01/2023	31/03/2023	SmPC and PL	Please refer to semaglutide PSUSA/10671/202205 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IA/0011	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	10/01/2023	n/a		
IB/0010	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	10/01/2023	n/a		

II/0003/G	This was an application for a group of variations. Update of section 5.1 of the SmPC in order to update the description of the pharmacodynamic effects and clinical efficacy and safety based on final results from interventional studies: Trial 4378 (STEP 5) which compared the two-year effect of semaglutide 2.4 mg once weekly versus placebo; Trial 4576 (STEP 8) which compared semaglutide s.c. 2.4 mg once weekly to liraglutide s.c. 3.0 mg once daily and Trial 4373 extension (STEP 1ext) which explored the change in body weight, cardiovascular risk factors and glucose metabolism in subjects who completed 68 weeks of treatment (semaglutide 2.4 mg or placebo) followed by a 52-week off-treatment period. 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 C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	21/07/2022	31/03/2023	SmPC	In STEP 5 trial, treatment with semaglutide for 104 weeks resulted in a significantly higher reduction in body weight compared to placebo. In STEP 8 trial, treatment with semaglutide once weekly for 68 weeks resulted in significantly higher reduction in body weight compared to daily liraglutide. In STEP 1ext trial, in the 52-week off-treatment period from week 68 to week 120, mean body weight increased lower in semaglutide than in the placebo treatment group. For more information, please refer to the Summary of Product Characteristics.
IB/0007	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	12/07/2022	n/a		

PSUSA/10671 /202111	Periodic Safety Update EU Single assessment - semaglutide	07/07/2022	n/a		PRAC Recommendation - maintenance
II/0001/G	This was an application for a group of variations. B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.g.2 - Introduction of a post approval change management protocol related to the finished product B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data) B.IV.1.c - Change of a measuring or administration	23/06/2022	31/03/2023	SmPC, Labelling and PL	

	device - Addition or replacement of a device which is an integrated part of the primary packaging 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.a.3.b.3 - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a biological/immunological product B.II.g.2 - Introduction of a post approval change management protocol related to the finished product B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range 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.b.3.b - Change in the manufacturing process of the finished or intermediate product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product				
IB/0006/G	This was an application for a group of variations.	30/05/2022	n/a		

	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				
IA/0005	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	20/04/2022	n/a		
IA/0004	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	14/03/2022	n/a		