Ozempic

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 /	This was an application for a variation	27/11/2025		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).

EMA/VR/0000292593	following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.z Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of veterinary medicinal products intended to implement the outcome of a procedure concerning PSUR: implementation of wording agreed by the competent authority - Accepted Update of section 4.8 of the SmPC in order to add Dysaesthesia to the list of adverse drug reactions (ADRs) for Ozempic and Rybelsus following PRAC request for cumulative review of "Altered skin sensation" for semaglutide PSUR (EMEA/H/C/PSUSA/00010671/202405); the Package Leaflet is updated accordingly.				
Variation type IA_IN / EMA/VR/0000309379	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	26/11/2025	N/A		

	site - Accepted				
Variation type IB / EMA/VR/0000285674	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.II.g.5 Implementation of changes foreseen in an approved change management protocol - B.II.g.5.c Implementation of a change for a biological/immunological medicinal product - 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	20/11/2025	N/A		
Variation type IB / EMA/VR/0000308238	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	17/11/2025	N/A		
Variation type II / EMA/VR/0000249026	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	23/10/2025		SmPC and PL	

	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 4.4 and 4.8 of the SmPC in order to add a new warning on gastroparesis following review of the data from clinical trials; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring editorial changes to the PI.				
Variation type IB / EMA/VR/0000287437	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. - - Accepted C.I.z - to update sections 4.4 and 4.8 of the SmPC and sections 2 and 4 of the Package Leaflet to include the warning for Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) in line with the outcome of the Pharmacovigilance Risk Assessment Committee (PRAC) Assessment Report for the Post-Authorisation Measure Procedures EMA/PAM/0000262449, EMA/ PAM/0000262475, and	25/09/2025		SmPC and PL	

	EMA/PAM/0000262468 of PSUR EMEA/H/C/PSUSA/00010671/202405 (1 June 2023 - 31 May 2024).				
Variation type IB / EMA/VR/0000279598	B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.z Other changes, including change from single batch size to a range of batch sizes - Accepted	28/08/2025	N/A		
Variation type IB / EMA/VR/0000275308	This was an application for a group of variations. B.II.g.5 Implementation of changes foreseen in an approved change management protocol - B.II.g.5.c Implementation of a change for a biological/immunological medicinal product - Accepted B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.f The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line) - Accepted	04/07/2025	N/A		
Variation type II / EMA/VR/0000244910	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	19/06/2025		SmPC	

	quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.1, and 5.1 of the SmPC in order to update the efficacy information based on final results from study NN9535-4533 (STRIDE); this is a 52-week, randomised, double-blind, placebo-controlled phase 3b trial evaluating effects of semaglutide on functional capacity in patients with type 2 diabetes and peripheral arterial disease. The study concerns clinical pharmacokinetics, efficacy and safety.				
Variation type IB / EMA/VR/0000266216	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	27/05/2025	N/A		
Variation type II / EMA/VR/0000249034	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	22/05/2025		SmPC and PL	

	Update of section 4.8 of the SmPC in order to add headache to the list of adverse drug reactions (ADRs) with frequency common following review of the clinical trial and post-marketing data; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to bring editorial changes to the PI.				
Variation type IA / EMA/VR/0000267870	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	20/05/2025	N/A		
Variation type IB / EMA/VR/0000263973	B.II.g.4 Changes to an approved change management protocol - B.II.g.4.b Minor changes to an approved change management protocol that do not change the strategy defined in the protocol - Accepted	29/04/2025	N/A		
Variation type IB / EMA/VR/0000262655	This was an application for a group of variations. B.II.g.5 Implementation of changes foreseen	25/04/2025	N/A		

	in an approved change management protocol - B.II.g.5.c Implementation of a change for a biological/immunological medicinal product - 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				
Variation type II / EMA/VR/0000256592	This was an application for a group of variations. B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.e Change outside the approved specifications limits range - Accepted B.IV.1 Change of a measuring or administration device - B.IV.1.c Addition or replacement of a device which is an integrated part of the primary packaging - Accepted B.II.e.5 Change in pack size of the finished product - B.II.e.5.c Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/ immunological	10/04/2025		SmPC, Labelling and PL	

	medicinal products - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.2 After first opening (supported by real time data) - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted				
Variation type IB / EMA/VR/0000244317	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 Other changes - Accepted	10/04/2025	N/A		
Variation type IB / EMA/VR/0000245602	B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted	13/02/2025		SmPC	

PSUR / EMA/PSUR/0000296561	- -				