Rybelsus

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 IB / EMA/VR/0000294825	B.I.e.5 Implementation of changes foreseen in an approved change management protocol - B.I.e.5.c Implementation of a change for a biological/immunological	17/11/2025	N/A		

	medicinal product - Accepted				
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. 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.	23/10/2025		SmPC and PL	
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	25/09/2025		SmPC and PL	

	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 EMA/PAM/0000262468 of PSUR EMEA/H/C/PSUSA/00010671/202405 (1 June 2023 - 31 May 2024).				
Variation type II / EMA/VR/0000244874	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 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 A grouped application consisting of: C.I.4: Update of sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC in order to update clinical efficacy and safety information based on the final results from study EX9924-4473(SOUL); this is a phase 3b study	18/09/2025		SmPC and PL	

	comparing oral semaglutide versus placebo and added to standard of care in patients with type 2 diabetes at high risk of cardiovascular events; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial changes to the PI. C.I.4: Update of sections 4.2, and 5.1 of the SmPC in order to introduce chronic kidney disease outcomes based on final results from study NN9535-4321 (FLOW); this is a phase 3b study evaluating the effect of semaglutide versus placebo on the progression of renal impairment in subjects with type 2 diabetes and chronic kidney disease; the Package Leaflet is updated accordingly.				
Variation type IB / EMA/VR/0000282011	This was an application for a group of variations. B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - Accepted	29/08/2025	N/A		
Variation type IB / EMA/VR/0000269116	B.I.c.1 Change in immediate packaging of the active substance - B.I.c.1.a Qualitative	03/06/2025	N/A		

	and/or quantitative composition - Accepted				
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 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.	22/05/2025		SmPC and PL	
Variation type IB / EMA/VR/0000263278	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	02/05/2025	N/A		

Variation type IB / EMA/VR/0000256146	B.I.e.4 Changes to an approved change management protocol - B.I.e.4.b Minor changes to an approved change management protocol that do not change the strategy defined in the protocol - Accepted	21/03/2025	N/A		
Variation type IB / EMA/VR/0000246407	This was an application for a group of variations. 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.a The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer - Accepted B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.a Up to 10-fold increase compared to the originally approved batch size - Accepted	19/02/2025	N/A		

PSUR / EMA/PSUR/0000296561	- -				