



SFDA SAFETY SIGNAL

“A signal is defined by the SFDA as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature”

29-4-2025

Saudi Food and Drug Authority (SFDA) – Safety Signal of Semaglutide and the Risk of Pancreatic carcinoma

*The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of **Pancreatic carcinoma** associated with the use of **Semaglutide**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Semaglutide, a glucagon-like peptide-1 (GLP-1) receptor agonist, is available as monotherapy in both subcutaneous and oral formulations, the latter representing the first approved oral GLP-1 receptor agonist. It is indicated as a second-line therapy to enhance glycemic control in patients with type 2 diabetes. Although semaglutide use might be linked to thyroid tumors, including cancer, clinical evidence supports its safety in adults and elderly patients with renal or hepatic impairment, with no requirement for dose adjustment. Cardiovascular outcome trials have further demonstrated its ability to reduce multiple cardiovascular risk factors in patients with established cardiovascular disease.^[1,2] Pancreatic cancer occurs when malignant cells develop in part of the pancreas. This may affect how the pancreas works, including the functioning of the exocrine or endocrine glands. Pancreatic cancer can occur in any part of the pancreas, but about 70% of pancreatic cancers are located in the head of the pancreas.^[3] The aim of this review is to evaluate the risk of Pancreatic carcinoma associated with the use of Semaglutide and to suggest regulatory recommendations if required.

Methodology

Signal Detection team at SFDA performed a signal review using National Pharmacovigilance Center (NPC) database, and World Health Organization (WHO) database, Vigibase, with literature screening to retrieve all related information to assess the causality between Pancreatic carcinoma and Semaglutide use. The search conducted on February 2025.

Results

Case Review: Signal detection team at SFDA have searched Saudi national database and WHO database to find individual case safety reports (ICSRs). The WHO database resulted in 174 global case-reports no case found. The authors used signal detection tool (Vigilyze) to retrieve global cases.^[4] Authors also applied WHO-UMC causality assessment criteria on the extracted ICSR with completeness score 0.8 and above (22 cases).^[5] Among them, 12 cases were possibly linked to Semaglutide, while 3 cases assessed as unlikely and the remaining 7 cases were unable to be assessed due to lack of important information.



Datamining: The disproportionality of the observed and the expected reporting rate for drug/adverse drug reaction pair is estimated using information component (IC), a tool developed by WHO-UMC to measure the reporting ratio. Positive IC reflects higher statistical association while negative values indicates less statistical association. The IC result is (2.0) for this drug/ADR combination which reflects positive statistical association. ^[4]

Conclusion

The weighted cumulative evidence identified from assessed cases and disproportionality analysis might be suggestive for causal association between Semaglutide and Pancreatic carcinoma. Health care professionals and health regulators must be aware of the potential risk in drug recipients.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to continue reporting adverse drug reactions (ADRs) resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority-Drug sector
4904 northern ring branch rd
Hittin District
Riyadh 13513 – 7148
Kingdom of Saudi Arabia
Toll free number: 19999
Email: NPC.Drug@sfda.gov.sa

References:

- 1- Mahapatra, M. K., Karuppasamy, M., & Sahoo, B. M. (2022). Semaglutide, a glucagon like peptide-1 receptor agonist with cardiovascular benefits for management of type 2 diabetes. *Reviews in endocrine & metabolic disorders*, 23(3), 521–539. <https://doi.org/10.1007/s11154-021-09699-1>
- 2- DailyMed U.S. National Library of Medicine (2025). Ozempic (semaglutide) injection, solution. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=adec4fd2-6858-4c99-91d4-531f5f2a2d79#>
- 3- Cancer Council Australia. (2023, February 14). *Pancreatic cancer: Causes, symptoms & treatments*. <https://www.cancer.org.au/cancer-information/types-of-cancer/pancreatic-cancer>
- 4- Vigilyze.who-umc.org. 2025. [online] Available at: <https://vigilyze.who-umc.org/> .
- 5- World Health Organization WHO (2013). WHO-UMC system for standardised case causality assessment. Available at <https://www.who.int/publications/m/item/WHO-causality-assessment> .