

## 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

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

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*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 **Dulaglutide**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

#### Introduction

Dulaglutide is a long-acting glucagon-like peptide-1 receptor agonist that is administered once weekly and approved for treating adults with type 2 diabetes mellitus. It can be used as a monotherapy or in addition to oral hypoglycemic or insulin therapy. Although dulaglutide use might be linked to thyroid tumors, including cancer, evidence from studies including a recent study in Saudi Arabia showed its safe and effective therapy with favorable glycemic control and weight reduction in obese type 2 diabetes patients.<sup>[1,2]</sup> 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.<sup>[3]</sup> The aim of this review is to evaluate the risk of Pancreatic carcinoma associated with the use of Dulaglutide 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 Dulaglutide 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 190 global case-reports no case found. The authors used signal detection tool (Vigilyze) to retrieve global cases.<sup>[4]</sup> Authors also applied WHO-UMC causality assessment criteria on the extracted ICSR with completeness score 0.8 and above (12 cases).<sup>[5]</sup> Among them, 7 cases were possibly linked to Dulaglutide, while 2 cases assessed as unlikely and the remaining 3 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 (1.9) for this drug/ADR combination which reflects positive statistical association. <sup>[4]</sup>

### **Conclusion**

The weighted cumulative evidence identified from assessed cases and disproportionality analysis might be suggestive for causal association between Dulaglutide 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](mailto:NPC.Drug@sfda.gov.sa)

### **References:**

- 1- Albargawi, M. S., Alharbi, R. N., Alajlani, M. A., Abdulaal, I. A., & Aldakhil, L. O. (2024). Efficacy and Safety of Injectable Dulaglutide 1.5 mg Among Type 2 Diabetes Patients in Clinics at King Saud Medical City, Riyadh, Saudi Arabia. *Journal of Epidemiology and Global Health*, 14(3), 720-729.
- 2- DailyMed U.S. National Library of Medicine. (2024). TRULICITY (dulaglutide) injection, solution. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=463050bd-2b1c-40f5-b3c3-0a04bb433309>
- 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> .