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"

01-02-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Liraglutide and the Risk of Hepatocellular Carcinoma

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

Introduction

Liraglutide injection is used with diet and exercise to lower blood sugar in people with type 2 diabetes. It is also used to reduce the risk of life-threatening events, including heart attack and stroke, in adults with type 2 diabetes and established heart or blood vessel disease. This medicine is a glucagon-like peptide-1 (GLP-1) receptor agonist. [1] Hepatocellular carcinoma (HCC) is a primary tumor of the liver and constitutes more than 90% of the primary tumor of the liver. Hepatocellular carcinoma occurs in approximately 85% of patients diagnosed with cirrhosis. [2] The aim of this review is to evaluate the risk of Hepatocellular carcinoma associated with the use of Liraglutide 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 potential link between hepatocellular carcinoma and Liraglutide use. The search conducted on January 2026.

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 29 global case reports while no local cases found. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] The author applied WHO causality assessment tool on all cases. [3] Three cases showed a possible association with liraglutide, while twenty-six cases were unassessable.

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 (-0.7) for this drug/ADR combination which reflects negative statistical association. [3]

Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Liraglutide. The search identified one published study suggesting a possible association between the drug and this potential risk. [4]

Conclusion

The weighted cumulative evidence identified from assessed cases and literature are suggestive for causal association between Liraglutide and hepatocellular 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- Liraglutide (subcutaneous route) - Side effects & dosage - Mayo Clinic: https://www.mayoclinic.org/drugs-supplements/liraglutide-subcutaneous-route/description/drg-20073828
2- MayoCliniceDiseases- Hepatocellular carcinoma: https://www.mayoclinic.org/diseases-conditions/hepatocellular-carcinoma/cdc-20354552
3- Vigilyze.who-umc.org. 2026. [online] Available at: <https://vigilyze.who-umc.org/>
4- Titus, J., Katukuri, V., Boktor, M. et al. Association of GLP1-Receptor Agonists with Risk of Hepatocellular Carcinoma: A Retrospective Cohort Study. Drug Saf (2025).