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 m ore 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"

14-12-2025

Saudi Food and Drug Authority (SFDA) – Safety Signal of Exenatide 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 **Exenatide**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Exenatide injection is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. [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. HCC is now the fifth most common cause of cancer worldwide. [2] The aim of this review is to evaluate the risk of HCC associated with the use of Exenatide 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 Exenatide use. The search conducted on November 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 41 global case-reports for the preferred terms (Hepatocellular Carcinoma and Hepatic cancer). while no local cases found. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] Authors also applied WHO-UMC causality assessment criteria on the extracted ICSRs. [4] Among them, nine cases were possibly linked to Exenatide, one case assessed as unlikely, while the remaining thirty-one cases lacked sufficient information for a proper assessment.

Literature: The signal team searched the literature to find related publications linking this ADR to The drug. The search showed a recent published study linking HCC to GLP-1 receptor agonists. [5]

Conclusion

The weighted cumulative evidence identified from assessed cases and literature are suggestive for causal association between Exenatide 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- DailyMed - EXENATIDE injection (2025) Nih.gov. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e6cb5c8f-e97f-4a6a-95a4-939fd2393949

2- Asafo-Agyei KO, Samant H. Hepatocellular Carcinoma. [Updated 2023 Jun 12]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK559177/

3- Vigilyze.who-umc.org. 2025. [online] Available at: https://vigilyze.who-umc.org/

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