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"

26-02-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Semaglutide and the Risk of Sleep disorder

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

Introduction

Semaglutide 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] Sleep disorders encompass several clinical problems encountered in outpatient settings. Sleep disorders have a broad differential diagnosis; therefore, standardized definitions and classifications are essential. There are many different types of sleep disorders. [2] The aim of this review is to evaluate the risk of Sleep disorder 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 potential link between Sleep disorder and Semaglutide 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). A total of 144 global case reports were retrieved from the WHO database, while 15 local case reports were identified from the NPC database, which collectively triggered the initiation of this signal investigation. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] The author applied WHO Causality assessment tool on the extracted cases with completeness score (> 0.8). [3] Among them, four cases were probably linked to Semaglutide, eleven cases resulted in possible association, five cases resulted in unlikely association, while the remaining seven cases resulted in Unassessable association.

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) 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 Semaglutide. The search identified two published studies suggesting a possible association between the drug and this potential risk. [4], [5]

Conclusion

The weighted cumulative evidence identified from assessed local and global cases, in addition to the published literature are suggestive for causal association between Semaglutide and Sleep disorder. 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

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2- Karna B, Sankari A, Tatikonda G. Sleep Disorder. [Updated 2023 Jun 11]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls
Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK560720/
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5- Kornelius, E., Huang, J. Y., Lo, S. C., Huang, C. N., & Yang, Y. S. (2024). The risk of depression, anxiety, and suicidal behavior in patients with obesity on glucagon like peptide-1 receptor agonist therapy. Scientific Reports, 14(1), 24433.