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

Introduction

Dulaglutide injection is used to treat type 2 diabetes mellitus. Dulaglutide is used together with diet and exercise to help control blood sugar. This medicine also lowers the risk of death, heart attack, or stroke in patients with diabetes and heart or blood vessel problems. [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 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 potential link between sleep disorder and Dulaglutide use. The search conducted on January 2026.

Results

Cases 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 104 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 the extracted cases with completeness score (> 0.8). [3] Among them, one case was probably linked to Dulaglutide, two cases resulted in possible association, while four 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 (-1.4) 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 Dulaglutide. The search identified one published study suggesting a possible association between the drug and this potential risk. Furthermore, The ADR is listed in Canadian drug monograph. [4],[5].

Conclusion

The weighted cumulative evidence identified from assessed cases and literature are suggestive for causal association between Dulaglutide 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/
3- Vigilyze.who-umc.org. 2026. [online] Available at: <https://vigilyze.who-umc.org/>
4- Yao, Yao and Chen, Lin and Chen, Xiaohong and Tian, Xiaojiang and Zhou, Wei, Real-World Data in Pharmacovigilance Database Provides a New Perspective for Understanding the Psychiatric Adverse Events Associated with Glucagon-Like Peptide-1 Receptor Agonists (Glp-1 RAs) Exposure. Available at SSRN: https://ssrn.com/abstract=4901779 or http://dx.doi.org/10.2139/ssrn.4901779
5- Trulicity ® , dulaglutide Product Monograph (no date). Available at: https://pdf.hres.ca/dpd_pm/00076182.PDF