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"

28-10-2024

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

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

Introduction

Semaglutide is a type 2 diabetes medication that acts as a glucagon-like peptide-1 (GLP-1) receptor agonist.It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Also to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease. [1] Depression is a prevalent mental disorder characterized by persistent feelings of sadness, a diminished interest or pleasure in activities, and a prolonged duration of these symptoms. Approximately 3.8% of the population, including 5% of adults (4% among men and 6% among women), and 5.7% of adults over the age of 60, are estimated to experience depression. [2] The aim of this review is to evaluate the risk of Depression 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 causality between Depression and Semaglutide use. The search conducted on July 2024.

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 520 global case-reports while five local cases found. The authors used signal detection tool (Vigilyze) to retrieve all reported global cases. [3] Authors also applied WHO-UMC causality assessment criteria on 30 extracted ICSRs with top completeness score of 1.0. [4] Among them, 16 cases were probably and possibly linked to Semaglutide, and 8 cases assessed as not assessable due to lack of valuable information, while the remaining 6 case assessed as unlikely.

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 (0.6) for this drug/ADR combination which reflects slightly positive statistical association. [4]

Literature: The signal team searched the literature to find related publications linking this ADR to Semaglutide. The search showed two published case-reports of depression following the use of Semaglutide. [5]

Conclusion

The weighted cumulative evidence identified from assessed local and global cases, literature and disproportionality analysis are suggestive for causal association between Semaglutide and Depression. 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 - OZEMPIC- semaglutide injection, solution (no date) U.S. National Library of Medicine. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=adec4fd2-6858-4c99-91d4-531f5f2a2d79 [Accessed: 10/07/2024].

2- Depressive disorder (depression) (no date) World Health Organization. Available at: https://www.who.int/news-room/fact-sheets/detail/depression#:~:text=Depressive%20disorder%20(also%20known%20as,and%20feelings%20about%20everyday%20life. [Accessed: 11/07/2024].

3- Vigilyze.who-umc.org. 2024. [online] Available at: https://vigilyze.who-umc.org/ [Accessed: 12/07/2024].

4- 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 [Accessed: 12/07/2024].

5- Li, J.-R. et al. (2023) 'Case report: Semaglutide-Associated Depression: A report of two cases', Frontiers in Psychiatry, 14. doi:10.3389/fpsyt.2023.1238353.