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"

19-04-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of YELLOW FEVER VACCINE and the Risk of Tinnitus

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

Introduction

Yellow fever vaccine is indicated for active immunization for the prevention of yellow fever in persons 9 months of age and older. For most healthy individuals, a single dose of yellow fever vaccine provides long-lasting protection. [1] Tinnitus is commonly described as a ringing sound, but some people hear other types of sounds, such as roaring or buzzing. Tinnitus is common, with surveys estimating that 10 to 25% of adults have it. The causes of tinnitus are unclear, but most people who have it have some degree of hearing loss. [2] The aim of this review is to evaluate the risk of Tinnitus associated with the use of Yellow Fever Vaccine 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 Tinnitus and Yellow Fever Vaccine use. The search conducted on February 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 54 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, twenty-three cases were possibly linked to Yellow Fever Vaccine, while the remaining one case lacked sufficient information for a proper assessment.

Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Yellow Fever Vaccine. 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 Yellow Fever Vaccine and Tinnitus. 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 - YF-VAX- yellow fever virus strain 17d-204 live antigen injection, powder, lyophilized, for suspension DILUENT- sodium chloride injection (2024) Nih.gov. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=613aaac9-ec18-4b22-addb-599e1193e6f5.
2- National Institute on Deafness and Other Communication Disorders (2023) Tinnitus, NIDCD. Available at: https://www.nidcd.nih.gov/health/tinnitus.
3- Vigilyze.who-umc.org. 2025. [online] Available at: https://vigilyze.who-umc.org/.
4- Kimathi, D. et al. (2025) 'Low-Dose Yellow Fever Vaccine in Adults in Africa', New England Journal of Medicine, 392(8), pp. 788–797. Available at: https://doi.org/10.1056/nejmoa2407293.