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"

26-04-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Morphine Sulfate and the Risk of Shortness of Breath

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

Introduction

A drug used to treat moderate to severe pain. It is made from a natural substance found in the seed pods of the opium poppy plant. Morphine sulfate works by binding to opioid receptors, such as the mu opioid receptor, in the central nervous system and other tissues. This blocks pain signals and changes how the body responds to pain. It is a type of opiate and a type of analgesic (pain reliever). [1] Dyspnea, or shortness of breath (SOB), is the feeling that you can't get enough air into your lungs. It might feel like your chest is tight, you're gasping for air or you're working harder to breathe. Heart and lung conditions are common causes of dyspnea. [2] The aim of this review is to evaluate the risk of SOB associated with the use of Morphine sulfate 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 SOB and Morphine sulfate use. The search conducted on March 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 1321 global case reports while one local cases found which triggers this 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 1.0 (top 30 cases). [3] Among them, 20 cases were probably linked to Morphine sulfate, 8 cases resulted in possible association, 2 cases resulted in unlikely association.

Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Morphine. 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 alongside with literature are suggestive for causal association between Morphine sulfate and SOB. 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- National Cancer Institute. (n.d.). Morphine sulfate. National Cancer Institute. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/morphine-sulfate
2- Cleveland Clinic. (2022, November 11). Dyspnea (shortness of breath). Cleveland Clinic. https://my.clevelandclinic.org/health/symptoms/16942-dyspnea
3- Vigilyze.who-umc.org. 2026. [online] Available at: <https://vigilyze.who-umc.org/> (Accessed: 8 September 2025).
4- Algera, M. H., Kamp, J., van der Schrier, R., van Velzen, M., Niesters, M., Aarts, L., Dahan, A., & Olofsen, E. (2019). Opioid-induced respiratory depression in humans: A review of pharmacokinetic–pharmacodynamic modelling of reversal. British Journal of Anaesthesia, 122(6), e168–e179. https://doi.org/10.1016/j.bja.2019.02.029
5- Palkovic, B., et al. (2020). Opioid-induced respiratory depression: Pathophysiology and prevention. Frontiers in Physiology, 11, 596862. https://doi.org/10.3389/fphys.2020.596862