



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”

08-10-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Dabigatran and the Risk of Sepsis

*The Saudi Food and Drug Authority (SFDA) recommends that all healthcare professionals be aware of the safety signal of **Sepsis** associated with the use of **Dabigatran**. The signal originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Dabigatran is used to decrease the risk of stroke and blood clots in patients with a serious heart rhythm problem called nonvalvular atrial fibrillation. Dabigatran is also used to treat and prevent blood clots (eg, deep vein thrombosis, pulmonary embolism) from occurring again in patients who already have received other medicines. It is also used to prevent deep vein thrombosis and pulmonary embolism after hip replacement surgery. It works by preventing harmful clots from forming in the blood vessels.^[1] Sepsis is a life-threatening condition that happens when the body's immune system has an extreme response to an infection, causing organ dysfunction. The body's reaction causes damage to its own tissues and organs and it can lead to shock, multiple organ failure and sometimes death, especially if not recognized early and treated promptly. Sepsis can affect anyone, but people who are older, very young, pregnant or have other health problems are at higher risk. Common signs of sepsis include fever, fast heart rate, rapid breathing, confusion and body pain. It can lead to septic shock, multiple organ failure and death.^[2] This review aims to evaluate this potential risk and to suggest regulatory recommendations if required.

Methodology

The Signal Detection Team at SFDA performed a signal review using the National Pharmacovigilance Center (NPC) database and the World Health Organization (WHO) database, Vigibase, along with a literature review to retrieve all relevant information and assess the potential link between sepsis and dabigatran use.

Results

Cases Review: The Signal Detection Team at SFDA searched the Saudi national database and the WHO database to identify individual case safety reports (ICSRs). The WHO database yielded 436 global case reports, while the NPC database yielded one local case with possible association which originally triggers this investigation. The authors used the signal detection tool (VigiLyze) to retrieve global cases.^[3] The author applied WHO Causality assessment tool on the extracted top 30 cases based on completeness score. Three cases were considered probably associated with dabigatran, 8 possibly to be associated, 4 was assessed as unlikely to be associated, and the remaining 15 cases were unassessable.

Datamining: The disproportionality between the observed and expected reporting rates for a drug/adverse drug reaction (ADR) pair is estimated using the Information Component (IC), a tool developed by WHO-UMC to measure the reporting ratio. A positive IC reflects a higher statistical association, while negative values indicate a lower statistical association. The IC result for this drug/ADR combination was 1.2, reflecting a positive statistical association.^[3]



Literature: The Signal Detection team reviewed regulatory sources and published literature to identify evidence linking dabigatran to the risk of sepsis. Two relevant articles were found supportive to this signal. ^[4,5]

Conclusion

The cumulative weight of evidence identified from local and global cases, literature, and disproportionality analysis suggests a potential causal association between dabigatran and sepsis. Healthcare professionals and health regulators should be aware of this potential risk in patients receiving dabigatran.

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@sfd.gov.sa

References

- 1- Mayo Clinic (2026). Dabigatran (oral route) - Side effects & dosage page. Available at: <https://www.mayoclinic.org/drugs-supplements/dabigatran-oral-route/description/drg-20074611>
- 2- World Health Organization. (2024, May 3). Sepsis. World Health Organization Available at: <https://www.who.int/news-room/fact-sheets/detail/sepsis>
- 3- Vigilyze.who-umc.org. 2026. Available at: <https://vigilyze.who-umc.org/>
- 4- Faris, M. K., Izzuddin, M. S., Norazrin, M. A., & Thiru, M. K. (2024). Dabigatran-induced Enterococcus Necrotizing Fasciitis in Medically Unfit Patient with Successful Conservative Treatment Outcome: A Case Report. Malaysian Orthopaedic Journal, 18(3), 80.
- 5- Rajarajen, A. P., Ashraf, R., Ahuja, N., & Bharati, J. (2021). Extensive skin necrosis in an elderly woman on dabigatran. BMJ Case Reports, 14(10), e245245.