

DATA CAPTURE SECTION

NATIONAL PHARMACOVIGILANCE CENTER





## **Data Report: National Pharmacovigilance Centre**

- Source: Spontaneous Vigilance System, National Pharmacovigilance Centre
- **Scope:** Adverse event following immunization reports. These are medical occurrences noted after the use of a vaccine but do not necessarily imply a direct causal link to the vaccine.
- Parameters:
  - o Routine and Covid vaccine reports (Drug reports excluded)
  - o Data extract from 1 July to 30 September, 2024

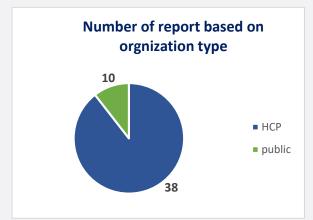
### **Understanding Pharmacovigilance**

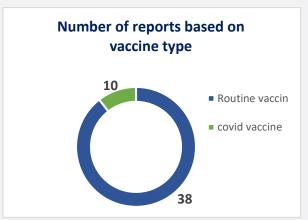
The National Pharmacovigilance Centre plays a crucial role in post-market vaccine safety monitoring. By collecting and analyzing adverse event reports following immunization, it helps identify serious issues and facilitates interventions to protect public health.

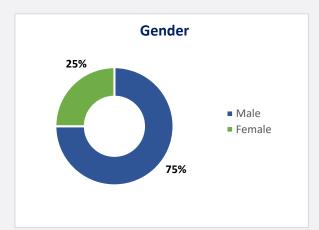
### **Important Notes**

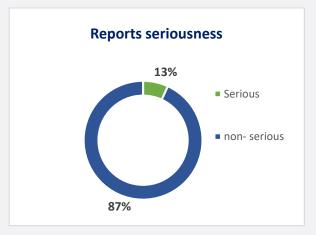
Important to understand that reports of adverse events following immunization do not automatically prove that the vaccine caused the event. Careful assessment is necessary to establish any potential relationship.

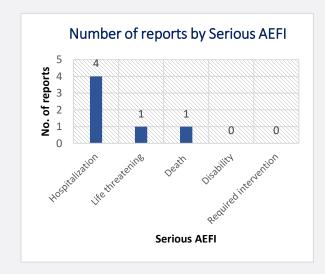


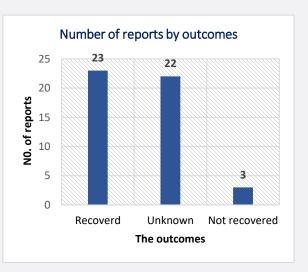




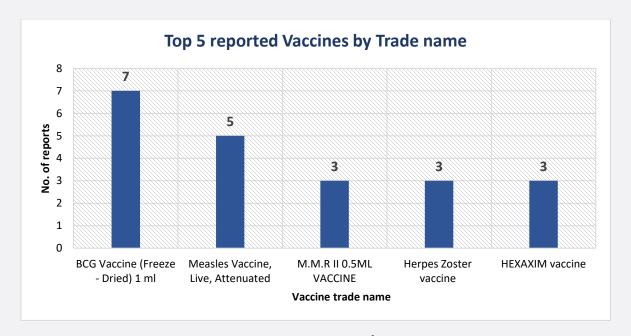




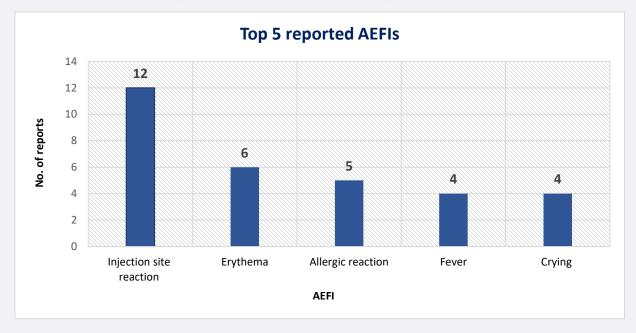








The top 5 Vaccines by (trade name<sup>1</sup>) reported in Q3 2024.

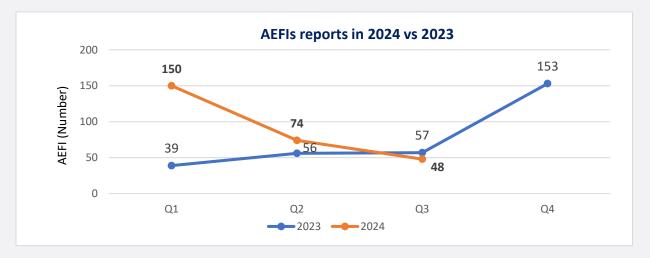


The top 5 AEFIs reported in Q3 2024.

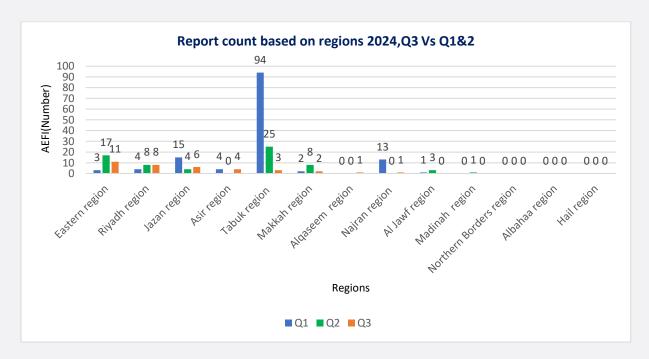
4

<sup>&</sup>lt;sup>1</sup> Trade names as reported





AEFIs reports in 2024 vs 2023



Reports count based on regions for year 2024, quarter 1&2&3



#### Recommendation:

After reviewing the reports and statistics for 2023 and the first two quarters of 2024, and based on our action plan following the visit to the silent regions conducted in Q3, we recommend monitoring the areas we visited, which include Najran, Tabuk, Al Baha, Hail, Al Jouf, and Madinah. It is essential to maintain ongoing communication with these regions to identify any barriers to improving reporting.

On one hand, we suggest arranging a visit to the **Northern Borders region**, as it is a silent area during the first, second, and third quarters. The purpose of these visits is to share best practices, address remaining challenges, and celebrate successes.

However, we have observed a significant decline in reporting rates in certain regions. Notably, **Tabuk**, which previously had the highest reporting rate, has decreased to a total of three reports in Q3. Additionally, **the Eastern region** has experienced a slight decline in reporting.

This drop may be attributed to the new skeletal framework in the Ministry of Health, which aims to separate the private sector from the governmental sector. Therefore, we need to arrange a meeting with all coordinators from both the private and governmental sectors in these two areas to discuss the reasons behind these declines. Our goal will be to work collaboratively on solutions to address these issues and improve reporting rates

# Action plan for the quarters in 2024:

- Improving the reporting rate for vaccines during the year 2024.
- **in-person visits to all regions:** Conducting visits to all regions to increase awareness about reporting and explain the reporting mechanism through vigilance system.
- **Reviewing the barriers:** Identifying and assessing the problems and challenges that prevent effective reporting through the vigilance system.
- Follow-up reporting: After the physical visits, will implementing a system for continuous monitoring
  and follow-up of reporting efforts during the 2nd, 3rd, and 4th quarters of 2024.
- Virtual meetings: Convening meetings for each region after the quarter to review the extent of improvement in reporting rates.