



Kingdom of Saudi Arabia  
Saudi Food & Drug Authority



## Descriptive Report of Adverse Event Following Immunization (AEFIS)

Saudi Arabia 2024

DATA CAPTURE SECTION  
NATIONAL PHARMACOVIGILANCE CENTER



## General notes:

### Data Report: National Pharmacovigilance Centre

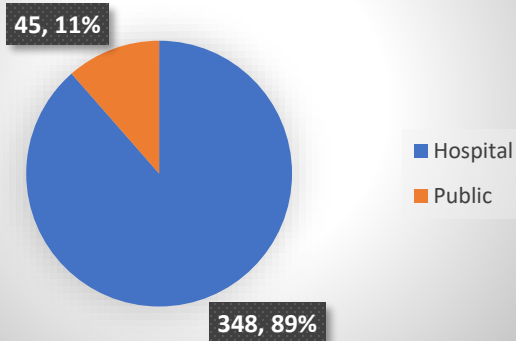
- **Source:** Spontaneous Vigilance System, National Pharmacovigilance Centre
- **Scope:** Adverse event following immunization reports. These are medical occurrences noted after the use of a vaccine but do not necessarily imply a direct causal link to the vaccine.
- **Parameters:**
  - Routine and COVID-19 vaccine reports (Drug reports excluded)
  - Data extract from **January 1<sup>st</sup> to December 31<sup>st</sup>, 2024.**

### Understanding Pharmacovigilance

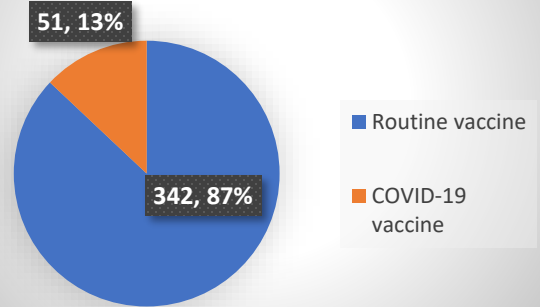
The National Pharmacovigilance Centre plays a crucial role in post-market drug safety monitoring. By collecting and analyzing adverse drug event reports, it helps identify potential safety signals and facilitates interventions to protect public health.

**Important Note:** 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.

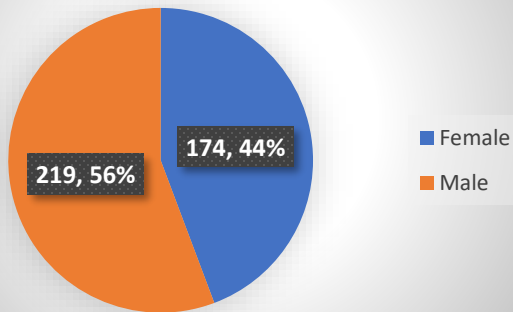
### Number of report based on organization type



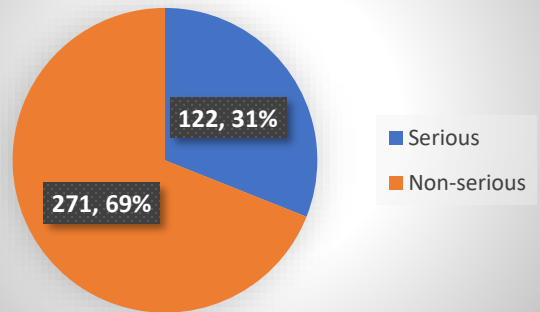
### Number of reports based on vaccine type



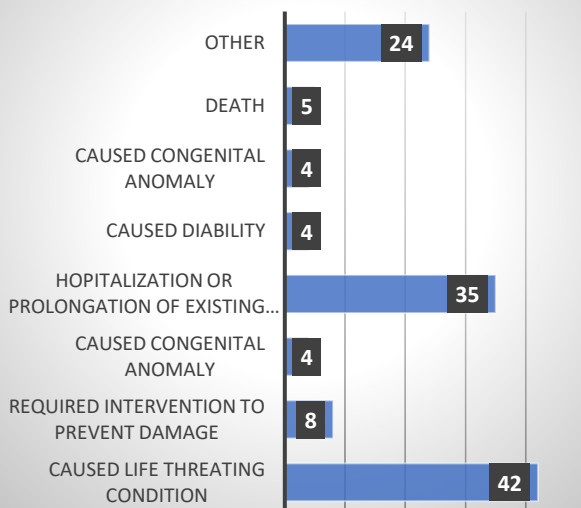
### Gender



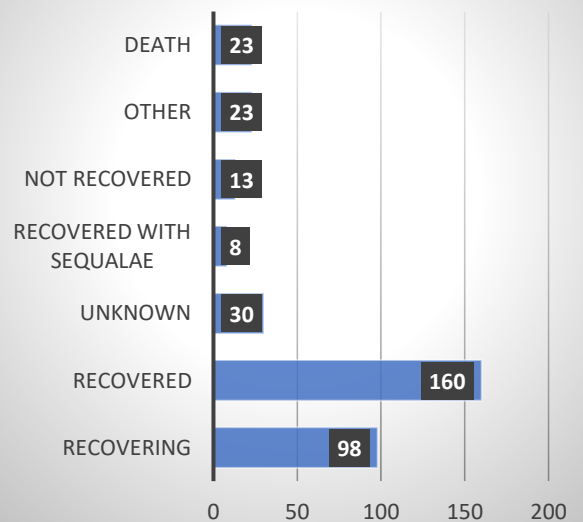
### Reports seriousness



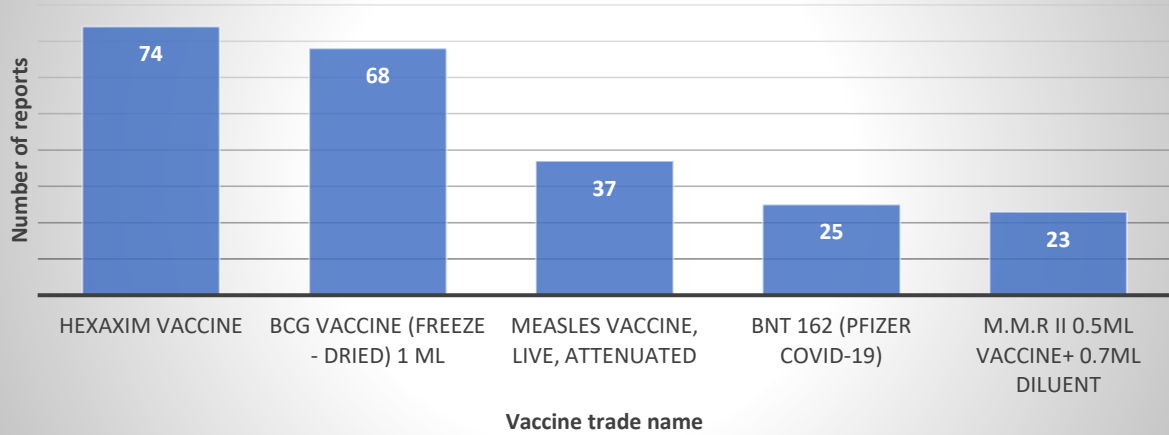
### Number of reports by Serious AEFI



### Number of reports by outcomes

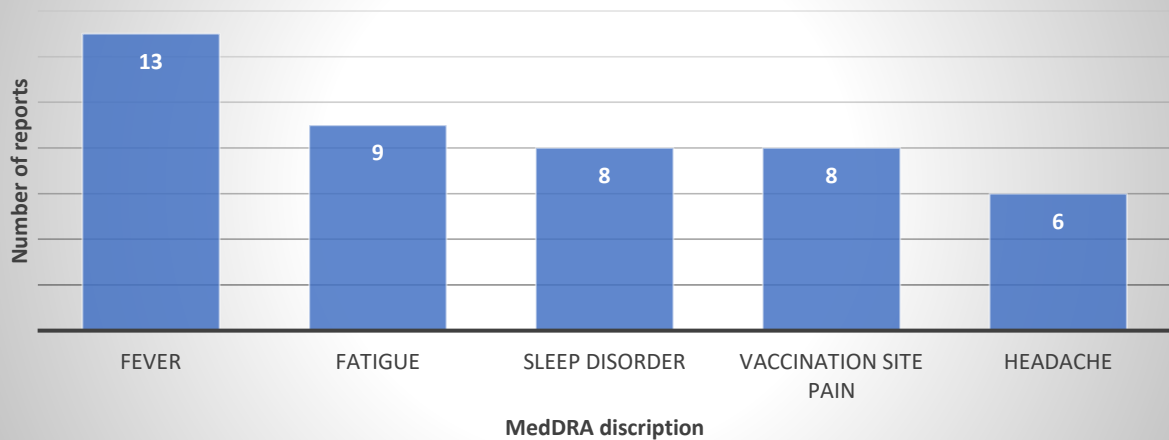


## Top 5 reported Vaccines by Trade name

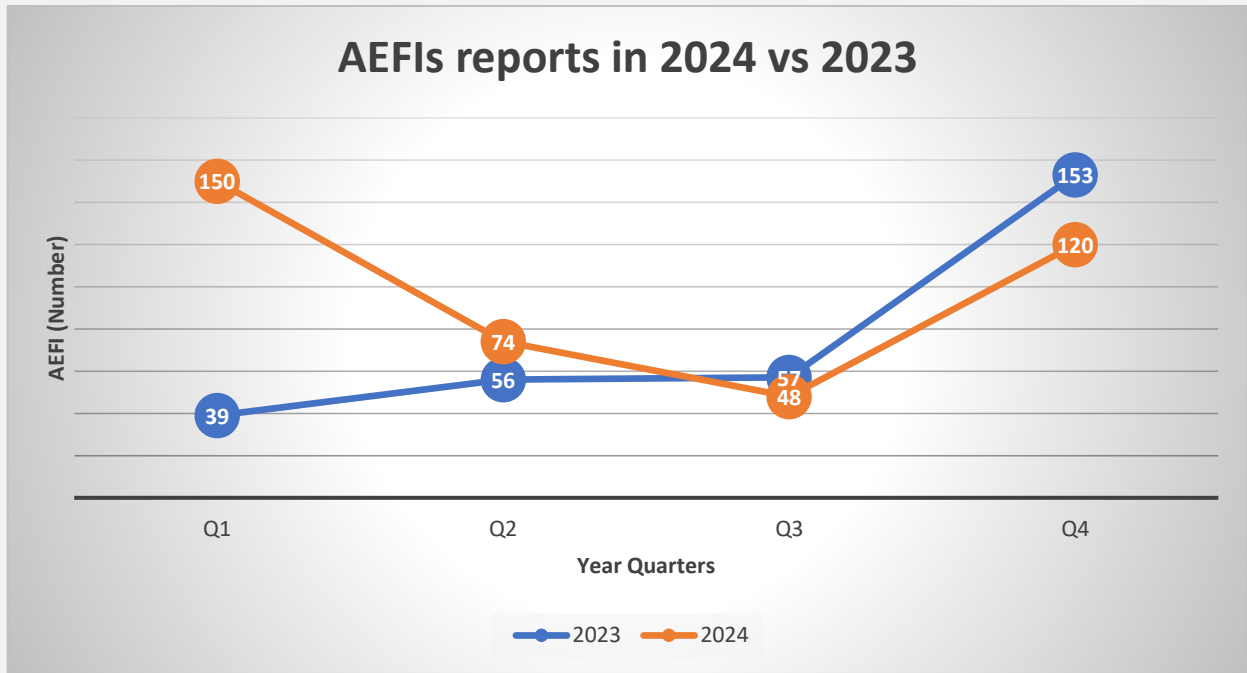


The top 5 reported vaccines by (trade name1) reported in 2024.

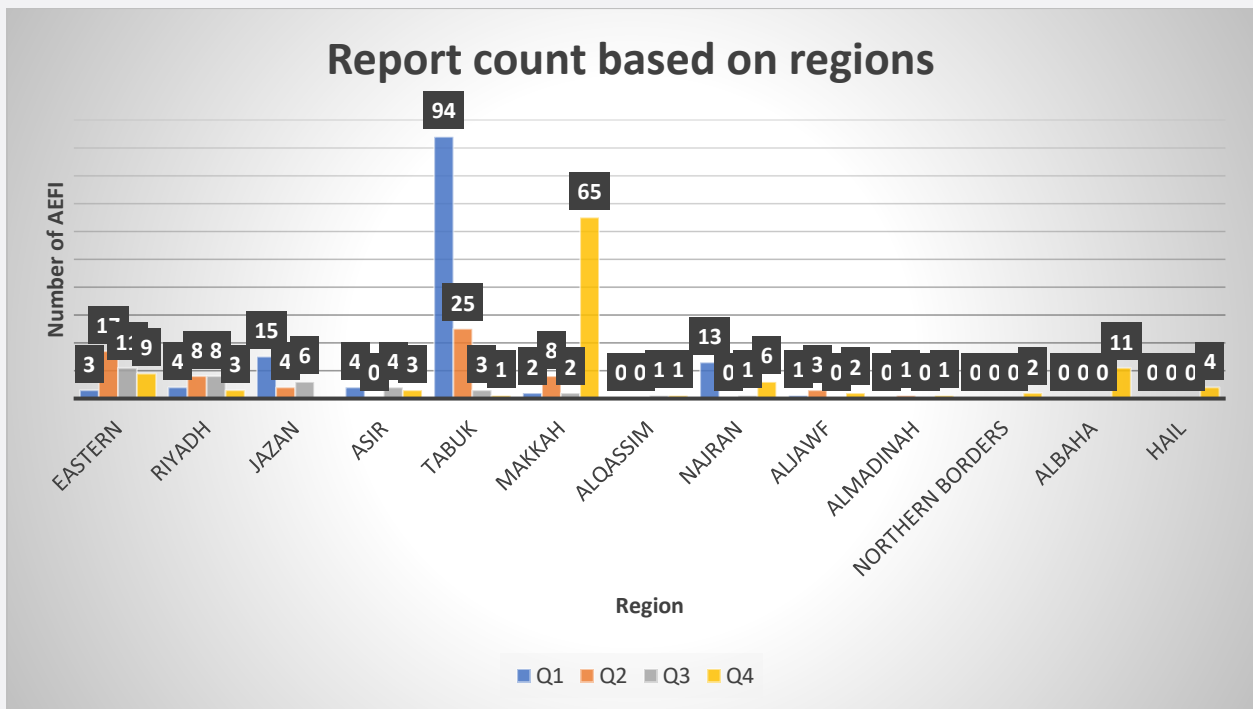
## Top reported AEFI based on MedDRA discription



The top 5 reported AEFI by (MedDRA) reported in 2024.



**Number of AEFIs reports in 2024 vs 2023**



**Reports count based on regions for year 2024, all quarters**

## **Recommendation:**

After reviewing the reports and statistics for 2023, as well as the comparisons between quarters, and based on our action plan following the visit to silent regions around the kingdom conducted in Q3, we recommend continuing the monitoring of the areas we visited, which include Tabuk, Al qassim, and Madinah. It is essential to maintain ongoing communication with these regions to identify any barriers to improving reporting. However, good improvements were observed in the regions of Albaha, Makkah and Hail regarding the reporting rate.

On the other hand, there has been a significant decline in reporting rates in certain regions. Notably, Tabuk, which previously had the highest reporting rate, has consistently decreased throughout the year, reaching a total of 1 in Q4.

## **Action plan in 2025:**

- 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.
- Virtual meetings: Convening meetings for each region after the quarter to review the extent of improvement in reporting rates.

