Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Descriptive Report of Adverse Event Following Immunization (AEFIs)

Data in Saudi Arabia, Q2 2026

DATA CAPTURE SECTION

NATIONAL PHARMACOVIGILANCE CENTER

General notes:

Data Report: National Pharmacovigilance Centre

- **Source:**

Dashboard and Spontaneous Reporting System, National Pharmacovigilance Centre.

- **Scope:**

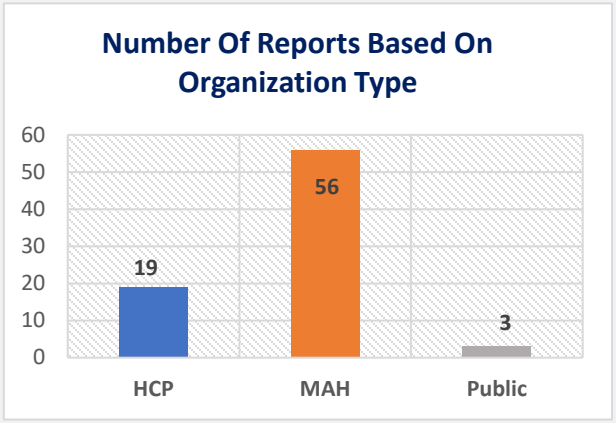
Adverse event reports following immunization. These are medical occurrences noted after the administration of a vaccine, but do not necessarily imply a direct causal link to the vaccine.

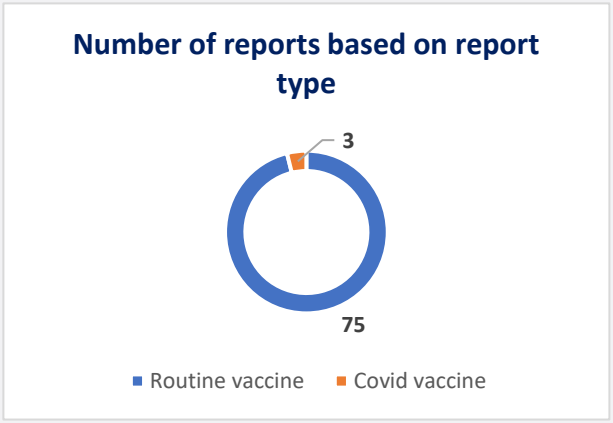
- **Parameters:**

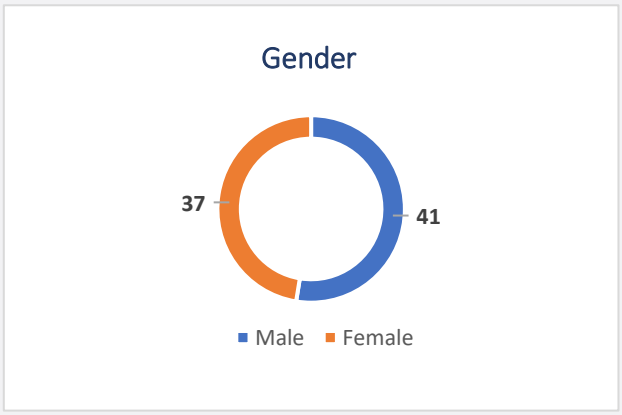
1. Routine and COVID-19 vaccine reports (Drug reports excluded)
2. Data extract from 1 April to 30 June 2026.

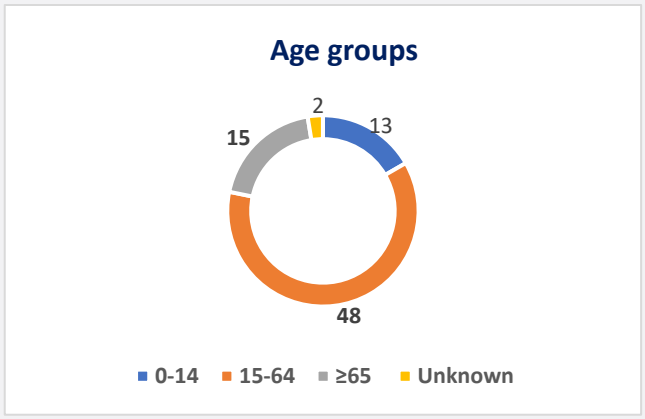
Understanding Pharmacovigilance:
The National Pharmacovigilance Centre plays a crucial role in post-market vaccine safety monitoring. By collecting and analyzing adverse event reports following immunization (AEFIs), it helps identify serious issues and facilitates interventions to protect public health.

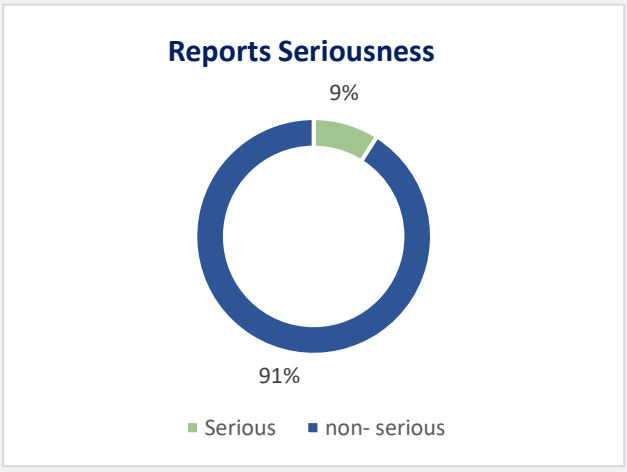
Important Notes:
Reports of adverse events following immunization (AEFIs) do not automatically prove that the vaccine caused the event. Careful assessment is necessary to establish any potential relationship.

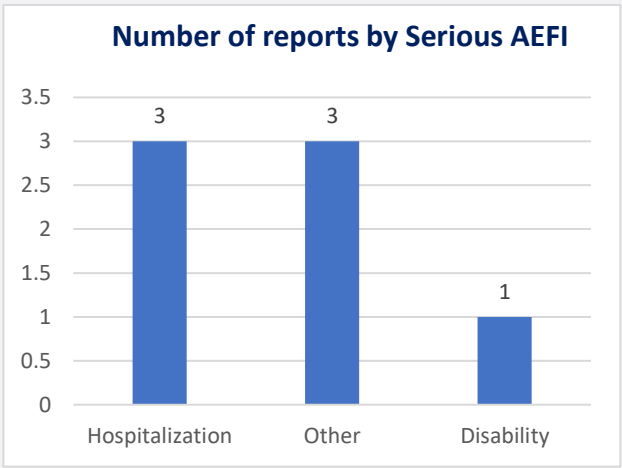

Number Of Reports Based On Organization Type
60
50
40
30
20
10
0
19
56
3
HCP
MAH
Public

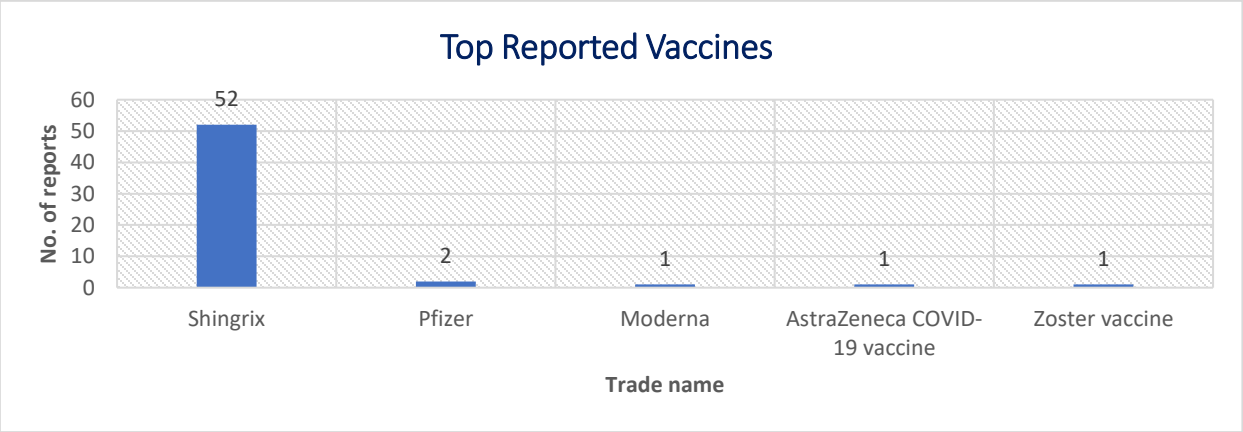

Number of reports based on report type
3
75
Routine vaccine
Covid vaccine


Gender
37
41
Male
Female

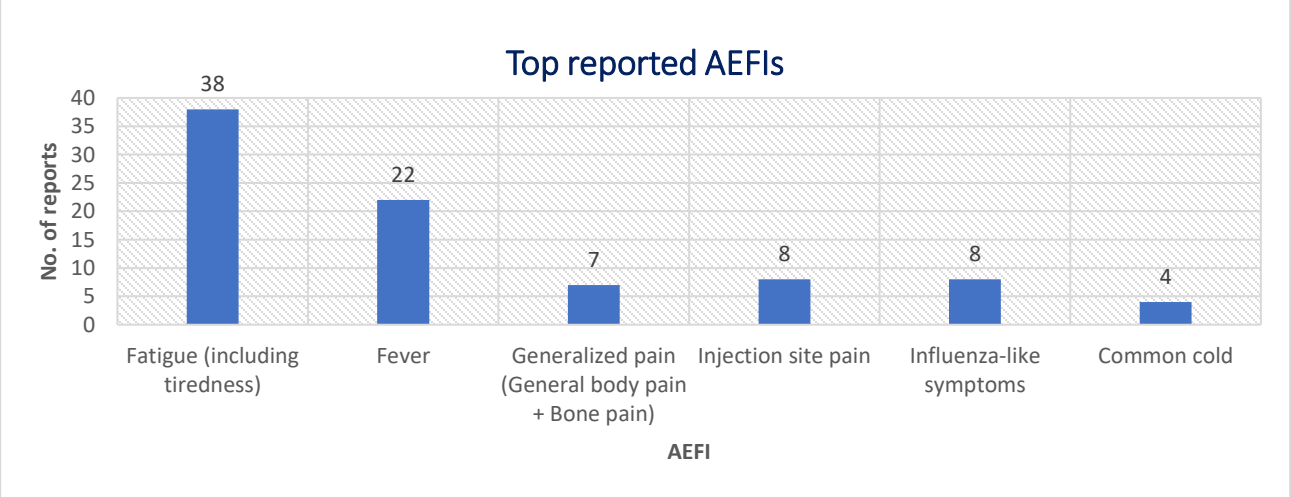

Age groups
2
13
15
48
0-14
15-64
≥65
Unknown


Reports Seriousness
9%
91%
Serious
non- serious

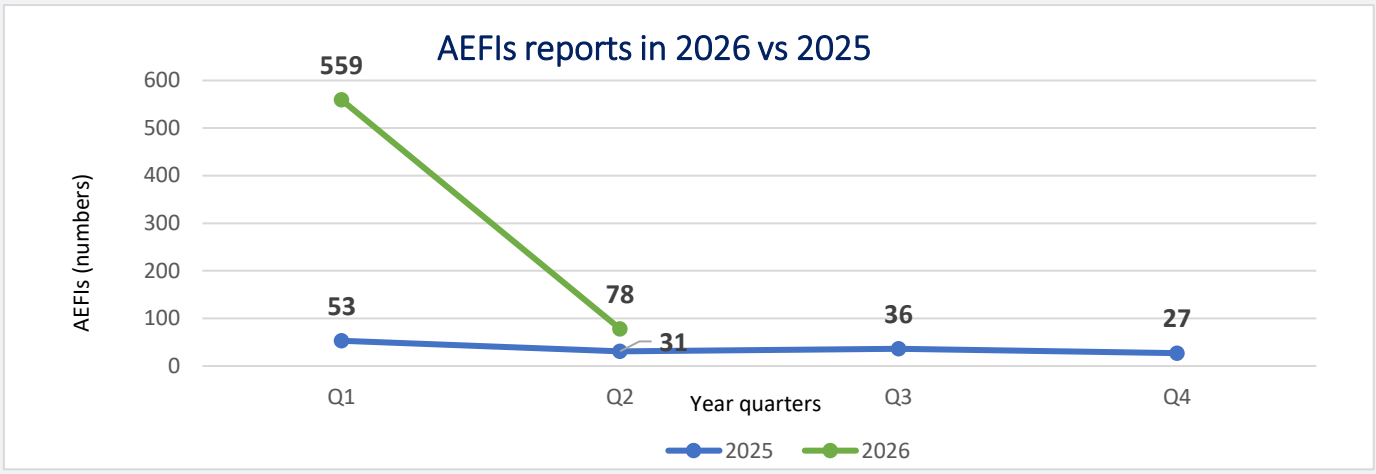

Number of reports by Serious AEFI
3.5
3
2.5
2
1.5
1
0.5
0
3
3
1
Hospitalization
Other
Disability



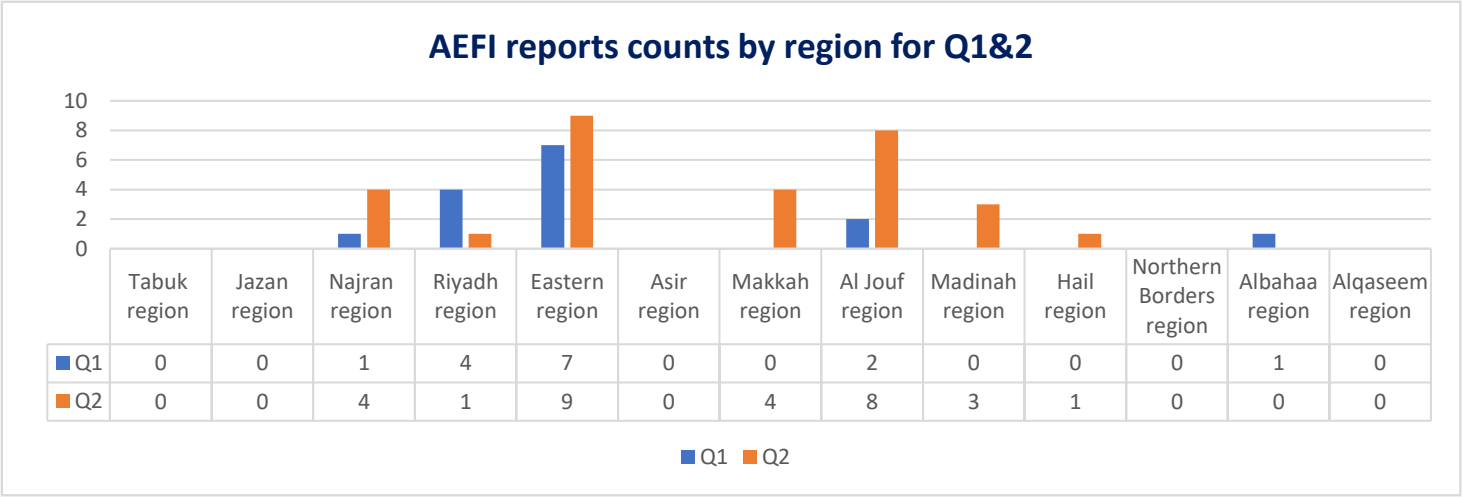
Top 5 Vaccines reported in Q2 ,2026



The Top 5 AEFIs reported in Q2, 2026



AEFI reports in 2026(Q1&Q2) compared with 2025



	Tabuk region	Jazan region	Najran region	Riyadh region	Eastern region	Asir region	Makkah region	Al Jouf region	Madinah region	Hail region	Northern Borders region	Albahaa region	Alqaseem region
Q1	0	0	1	4	7	0	0	2	0	0	0	1	0
Q2	0	0	4	1	9	0	4	8	3	1	0	0	0

AEFI report counts by region for Q1&Q2 in 2026

Most AEFI reports (56/78; 71.8%) were submitted by Marketing Authorization Holders (MAHs). Consequently, the reporting region was unavailable for a considerable proportion of reports. Therefore, the regional distribution presented in this report is based only on reports with available geographical information

Recommendation:

After reviewing the reports and statistics for the 2nd quarter of 2026, it is recommended to conduct in-person visits or remote meetings in the silent regions of the Kingdom of Saudi Arabia. This approach will support the continued achievement of the goals outlined in the reporting process.

The purpose of these meetings is to share best practices, address any remaining challenges, and highlight successes. **It is also important to note that one of the major challenges during this period has been the transition of vaccination responsibilities from the Ministry of Health (MOH) to the Public Health Authority (PHA)**.

Additionally, it is recommended to implement monthly key performance indicators (KPIs) to measure and monitor vaccine reporting rates, ensuring continuous improvement and sustained engagement.

Action Plan for 2026 Quarters:

- **Improve Vaccine Reporting Rates:** Enhance reporting performance by implementing monthly key performance indicators (KPIs) to monitor and track vaccine reporting rates throughout 2026, ensuring continuous improvement and sustained engagement.
- **Increase Meeting Frequency:** Ensure that the Causality Assessment Committee convenes at least once every quarter to review reported cases and maintain consistent evaluation processes**.**
- **Establish Criteria for Identifying Silent Reporting Regions:** Define and apply clear criteria to identify regions with low or absent reporting, including:
    1. Areas that do not meet the minimum reporting target (at least one report per month).
    2. Areas with zero reporting for three consecutive months.
    3. Regions with no login activity in the system by regional coordinators or healthcare workers.

- After reviewing the reporting KPIs and statistics for Q2 2026 through the dashboard, the following regions were identified as silent: Northern Borders Region, , Jazan Region, Asir Region, Tabuk Region, and Al-Qassim Region. Additionally, low reporting was observed in Madinah Region , Hail Region, Makkah and AlBahaa Region . The Public Health Authority (PHA) will be notified, and meetings will be scheduled with these targeted regions to discuss barriers and potential interventions.
- **Arrange Training Meetings:** Coordinate with the PHA and regional coordinators to schedule appropriate training sessions and carry out all necessary activities in the identified silent regions.
- **Review Barriers:** Identify and assess the challenges and obstacles that hinder effective reporting through the vigilance system.
- **Conduct Virtual Meetings:** Hold meetings for each region after every quarter to review the extent of improvement in reporting rates.