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:**

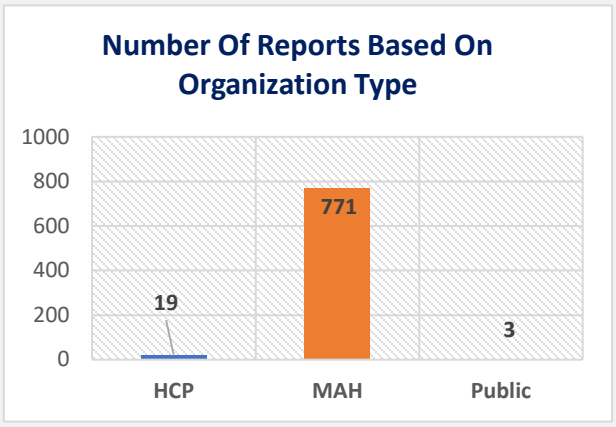
Adverse event reports following immunization. These are medical occurrences noted after the administration of a vaccine, but do not necessarily imply a direct causal link to the vaccine.

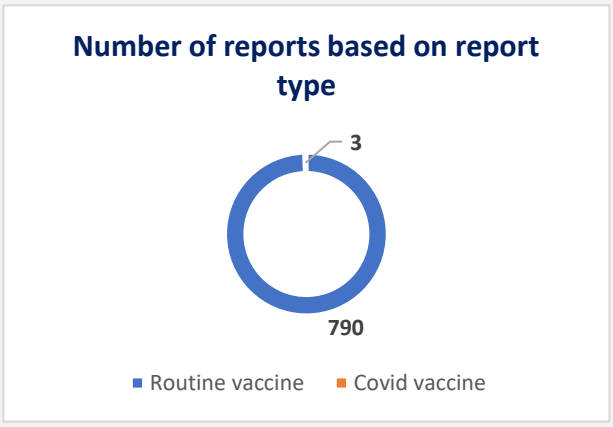
- **Parameters:**

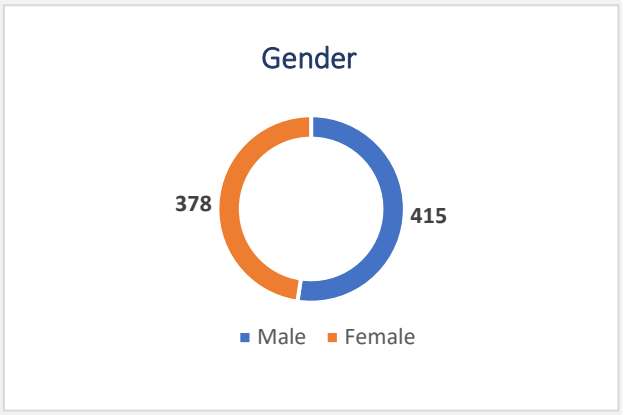
1. Routine and COVID-19 vaccine reports (Drug reports excluded)
2. Data extract from 1 April to 30 June 2026.

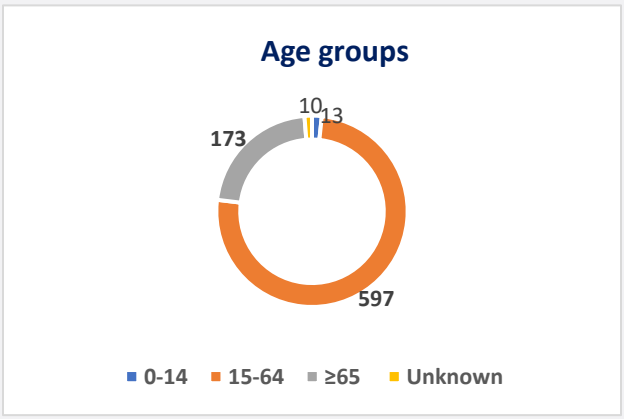
Understanding Pharmacovigilance:
The National Pharmacovigilance Centre plays a crucial role in post-market vaccine safety monitoring. By collecting and analyzing adverse event reports following immunization (AEFIs), it helps identify serious issues and facilitates interventions to protect public health.

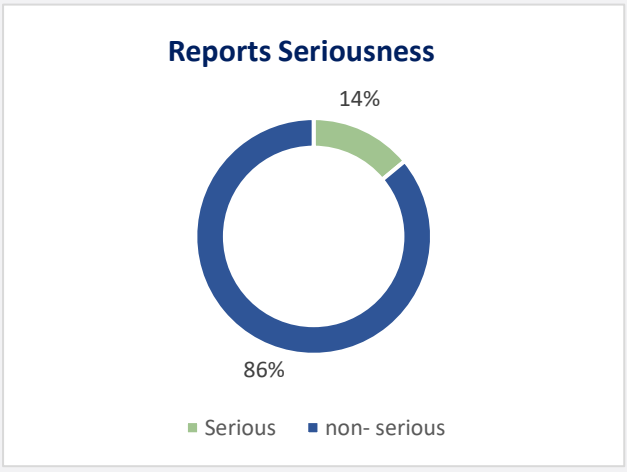
Important Notes:
Reports of adverse events following immunization (AEFIs) do not automatically prove that the vaccine caused the event. Careful assessment is necessary to establish any potential relationship.

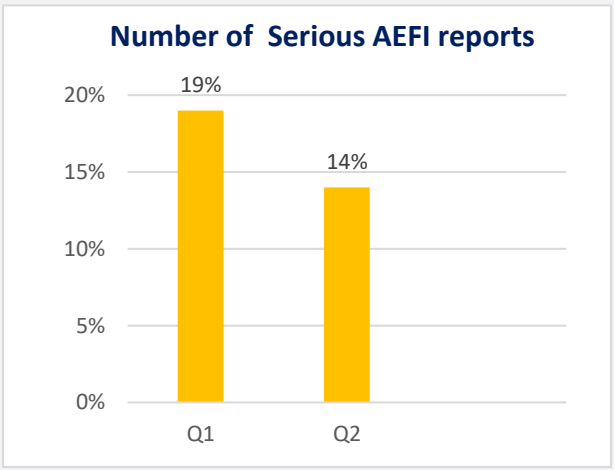

Number Of Reports Based On Organization Type
1000
800
600
400
200
0
19
771
3
HCP
MAH
Public

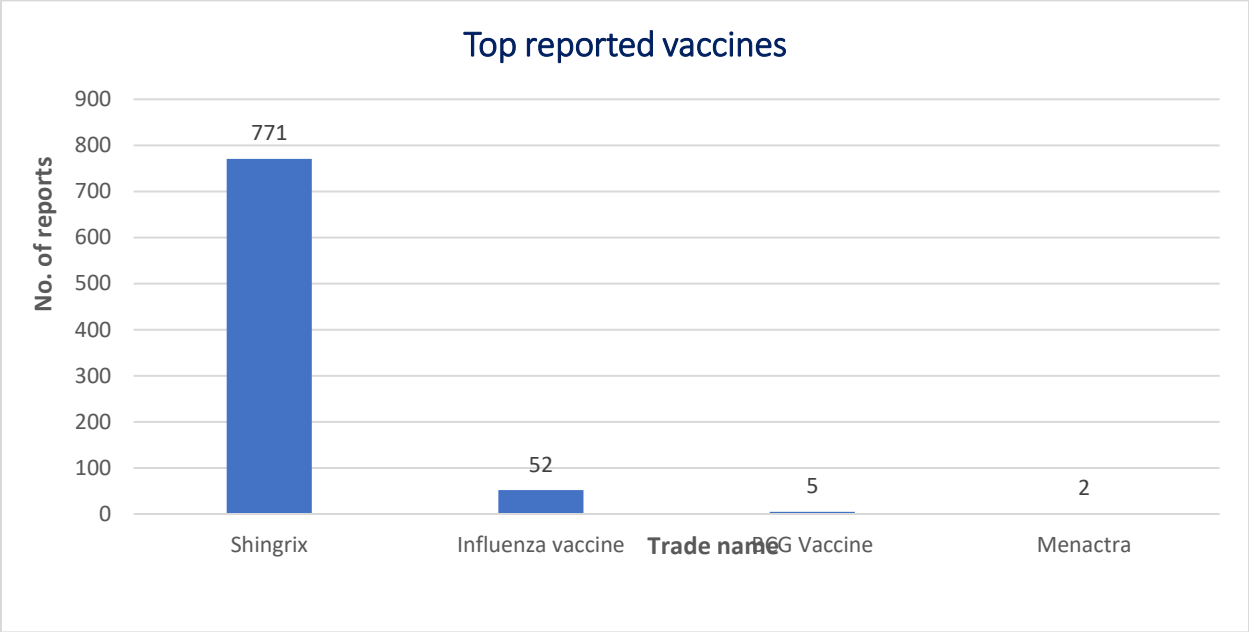

Number of reports based on report type
3
790
Routine vaccine
Covid vaccine

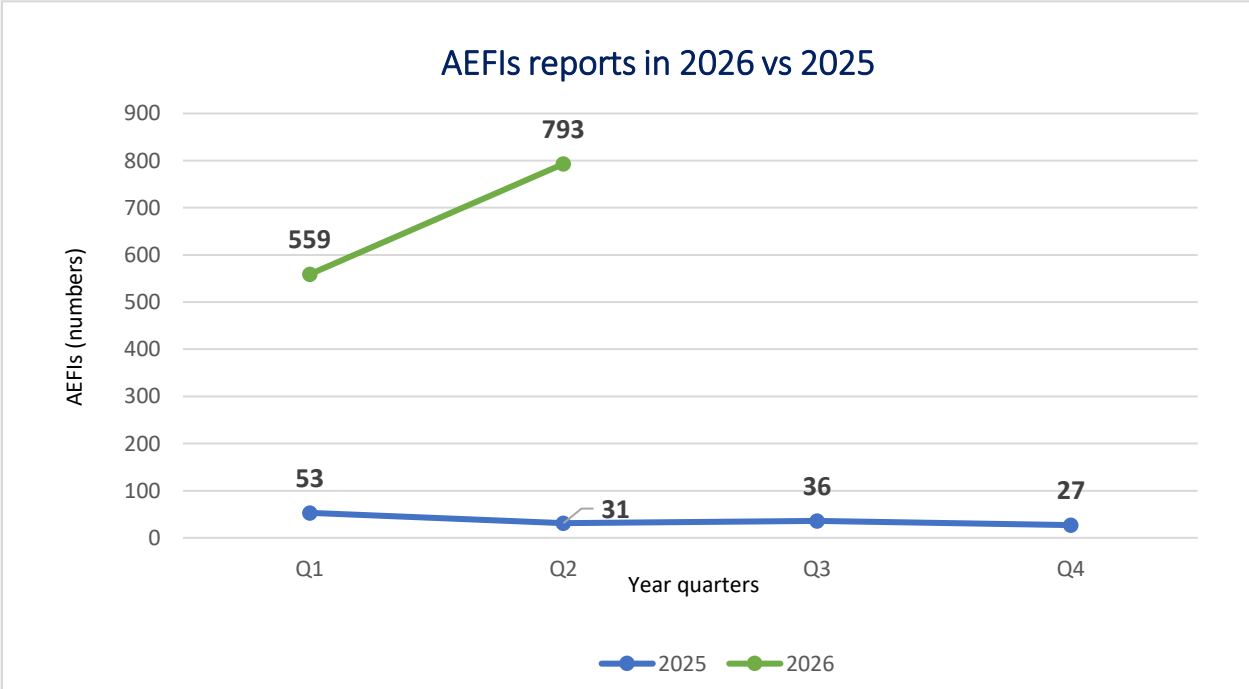

Gender
378
415
Male
Female


Age groups
10
13
173
597
0-14
15-64
≥65
Unknown

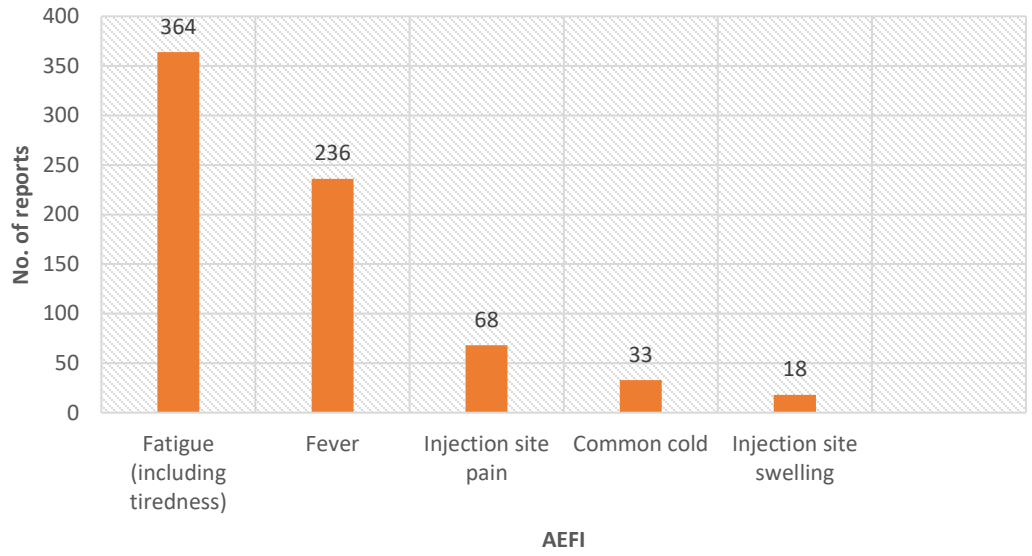

Reports Seriousness
14%
86%
Serious
non- serious


Number of Serious AEFI reports
20%
15%
10%
5%
0%
19%
14%
Q1
Q2

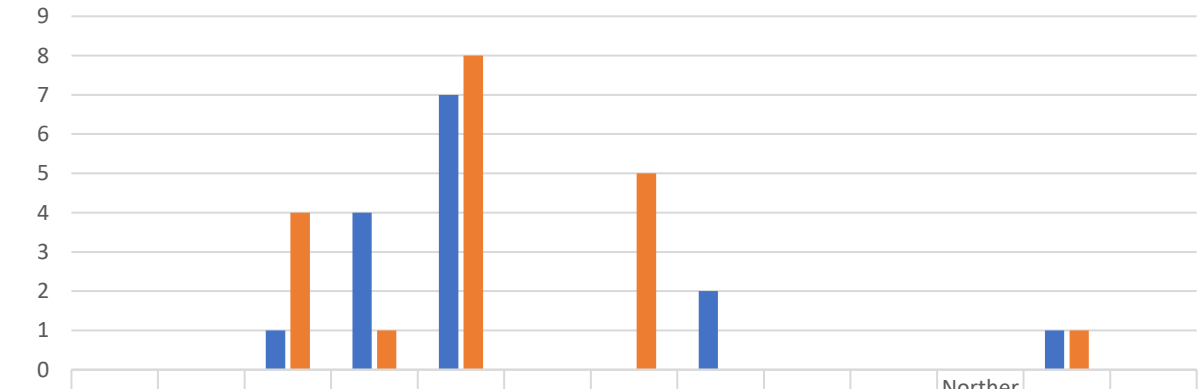

Top reported vaccines
No. of reports
900
800
700
600
500
400
300
200
100
0
771
52
5
2
Shingrix
Influenza vaccine
BCG Vaccine
Menactra
Trade name


AEFIs reports in 2026 vs 2025
AEFIs (numbers)
900
800
700
600
500
400
300
200
100
0
793
559
53
31
36
27
Q1
Q2
Q3
Q4
Year quarters
2025
2026

Top reported AEFIs



AEFI report counts by HCP region for Q1&Q2 2026



	Tabuk region	Jazan region	Najran region	Riyadh region	Eastern region	Asir region	Makkah region	Al Jouf region	Madinah region	Hail region	Northern Borders region	Al-Baha region	Al-Qassim region
Q1	0	0	1	4	7	0	0	2	0	0	0	1	0
Q2	0	0	4	1	8	0	5	0	0	0	0	1	0

Recommendation:

Most AEFI reports (771/793; 97.2%) were submitted by Marketing Authorization Holders (MAHs), while 19 reports (2.4%) were submitted by healthcare professionals (HCPs). Consequently, geographical information was limited for a considerable proportion of reports. Therefore, the regional distribution presented in this report is based only on reports submitted by HCPs with available geographical information.

Although the overall reporting rate increased, reporting from healthcare professionals remained limited. Therefore, it is recommended to strengthen collaboration with the Public Health Authority (PHA) and regional coordinators to improve reporting rates and encourage active participation through the national vigilance system.

Following the transition of vaccination responsibilities from the Ministry of Health (MOH) to the PHA, continued coordination is important to address reporting challenges, clarify responsibilities, and ensure the sustainability of AEFI reporting activities.

Additionally, it is recommended to continue monitoring serious AEFI reports, strengthen causality assessment activities, and implement monthly key performance indicators (KPIs) to evaluate regional reporting performance.

Action Plan for Q2 2026

- Improve Vaccine Reporting Rates: Continue implementing monthly KPIs to monitor AEFI reporting rates, particularly reports submitted by healthcare professionals, and encourage reporting from all regions.
- Increase Causality Assessment Meetings: Ensure that the Causality Assessment Committee meets at least once every quarter to review serious AEFI cases, particularly those involving hospitalization and death, and maintain consistent evaluation processes.
- Identify Silent Reporting Regions: Continue applying the established criteria to identify regions with low or absent reporting:
    1. Regions that do not meet the minimum reporting target of at least one report per month.
    2. Regions with zero reporting for three consecutive months.
    3. Regions with no login activity in the reporting system by regional coordinators or healthcare professionals.

- Target Silent Regions: Based on the Q2 2026 reporting statistics, Tabuk, Jazan, Asir, Al Jouf ,Hail, Madinah , AL-Qassim and Northern Borders regions recorded zero HCP reports. These regions should be prioritized for follow-up activities in coordination with the PHA.
- Improve Reporting in Low-Reporting Regions: Additional attention should be given to Riyadh, Al Baha, which recorded only one HCP report each during Q2 2026. Najran, Eastern region, and Makkah regions should also be monitored to support continued improvement.
- Arrange Training and Awareness Sessions: Coordinate with the PHA and regional coordinators to organize training sessions in silent and low-reporting regions, focusing on AEFI reporting requirements, data quality, and the use of the national vigilance system.
- Review Reporting Barriers: Identify and address challenges affecting reporting performance, including technical issues, limited awareness, and coordination difficulties between relevant stakeholders.
- Conduct Quarterly Follow-up Meetings: Arrange virtual meetings with regional coordinators after each quarter to review reporting performance, discuss challenges, share best practices, and evaluate improvements.
- Enhance Serious AEFI Monitoring: Continue reviewing serious AEFI reports and ensure that cases requiring further investigation are appropriately followed up and referred for causality assessment.
- Monitor Reporting Performance: Continue using the AEFI dashboard to monitor monthly reporting trends, evaluate the effectiveness of interventions, and identify regions requiring additional support.



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