



دائرة الصحة  
DEPARTMENT OF HEALTH

# ANALYSIS OF ADVERSE DRUG REACTIONS *2024 REPORT*

Department of Health  
Pharmacovigilance Program



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## Introduction

This document presents the annual report on pharmacovigilance system for the year 2024. It offers a comprehensive review of adverse drug reactions (ADRs) associated with pharmaceutical products that were reported to our pharmacovigilance system throughout the year.

Adverse events suspected to be linked to medicinal products were reported by healthcare professionals and facilities across Abu Dhabi to the Department of Health's (DOH) pharmacovigilance program. The DOH pharmacovigilance team systematically evaluates and investigates these reports as part of its ongoing drug safety surveillance, ensuring that all therapeutic products available in Abu Dhabi meet high standards of safety and efficacy. This report presents the major findings, trends, and insights derived from the review of adverse drug reaction (ADR) reports received during 2024. The analysis aims to raise awareness among healthcare professionals about adverse reactions to medicinal products, reinforce the importance of ADR reporting, and encourage timely and comprehensive submissions—particularly for events suspected to be associated with pharmaceutical or biological products.

We extend our appreciation to all healthcare professionals and stakeholders for their continued collaboration. Their contributions play an essential role in strengthening our pharmacovigilance system and ensuring better therapeutic outcomes for patients. Together, we strive to advance drug safety practices, uphold regulatory standards, and protect the well-being of the community.

## Methods

### ***Source of data:***

Adverse drug reaction (ADR) data were collected through the Department of Health – Abu Dhabi's dedicated pharmacovigilance E-Notification platform. Healthcare professionals/facilities submitted ADRs using the standardized "Adverse Drug Reaction Report Form," an integral part of the pharmacovigilance surveillance framework. Once received, each case underwent preliminary screening and assessment by the DoH pharmacovigilance team to support the timely identification of adverse events and, where possible, prevent recurrence.

For serious or unexpected adverse reactions, further causality assessment was conducted using the internationally recognized Naranjo Algorithm. This tool, comprising 10 structured questions, provides a systematic method for evaluating the probability of drug-related causality, assigning numerical values to responses of "Yes," "No," or "Do Not Know." While effective for general signal detection, the algorithm has recognized limitations in assessing hepatotoxicity due to its



lack of emphasis on critical factors such as time to onset, recovery parameters, and exclusion of alternative diagnoses.

As part of its role within the World Health Organization (WHO) Program for International Drug Monitoring, all validated ADR reports were transmitted to the Uppsala Monitoring Centre (UMC) in Sweden. These reports are incorporated into the VigilLyze database to identify potential safety signals and emerging risk information.

### ***Data collation and analyses:***

The data analyzed in this report covers the period from January to December 2024 and builds upon previous ADR analyses conducted for the years 2013–2023. Reports related to adverse events following immunization (AEFI) were excluded from this analysis.

Relevant information was extracted from the Department of Health (DoH) electronic reporting system and compiled into Microsoft® Excel spreadsheets. The extracted data included patient demographics (such as age and gender), hospitalization status, outcome and seriousness of the adverse event, the type of products involved, and the affected organ systems.

Adverse drug reactions related to marketed drugs in Abu Dhabi were classified using the Medical Dictionary for Regulatory Activities (MedDRA). MedDRA is a globally standardized medical terminology used for regulatory communication and scientific evaluation of medicinal products. Each ADR was categorized under the appropriate System Organ Class (SOC) and assigned the corresponding Preferred Term (PT).



## Results

### Number of Reports

A total of 1,516 adverse drug reaction (ADR) reports were submitted to the pharmacovigilance program between January and December 2024. The volume remains significantly elevated compared to previous years, reflecting continued improvement in awareness and reporting practices. All submissions were received through the E-Notification system.

Data revealed that the proportion of reports from the private sector was higher than those from public sectors (79%, 21% respectively) this shows an increase in the private sector reporting compared to previous years.

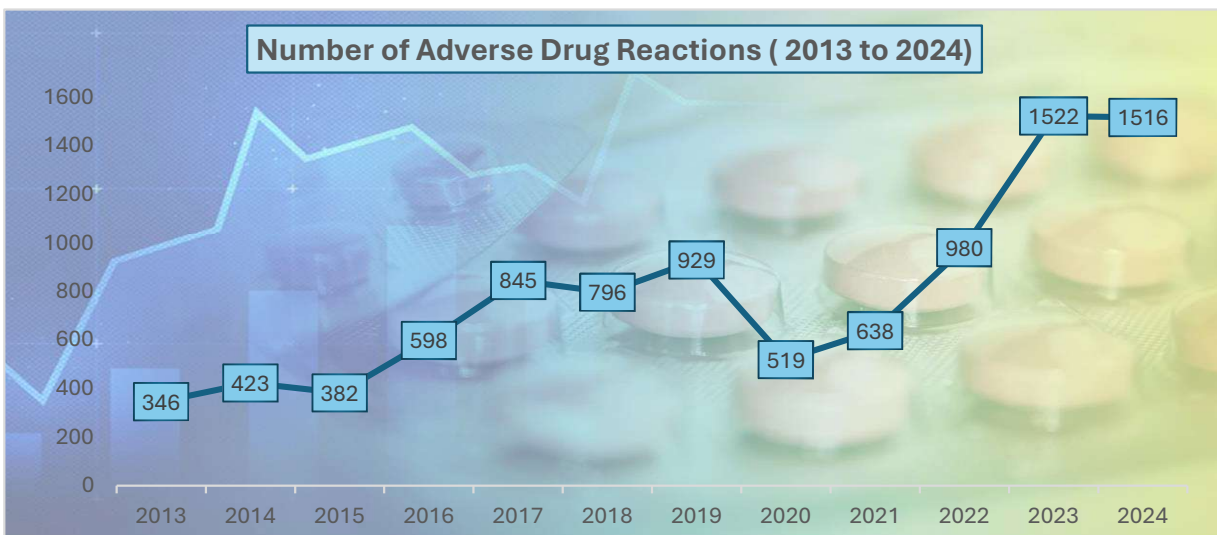


Figure 1: Number of Adverse Drug Reaction Reports.

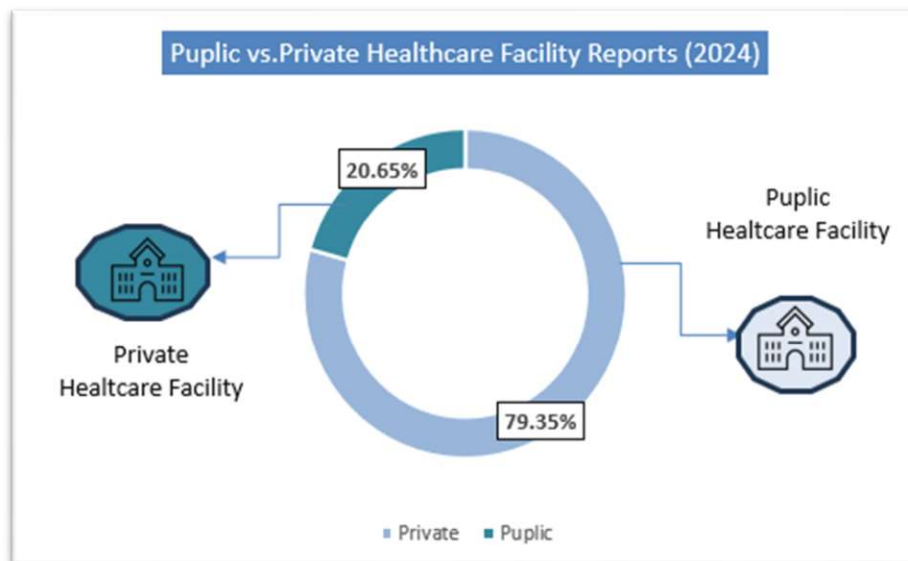


Figure 2: Public vs. Private Healthcare Facility Reports



### Adverse drug reactions received by drug classification:

The total number of suspected drugs reported was 1645 drug, some ADR reports had more than one suspected drug reported which explains why the number of drugs is more than the number of reports (1645 vs 1516 respectively).

In 2024, Antibacterial (Antibiotics) remained the leading therapeutic class associated with ADR reports, accounting for 551 cases, which represents 33.5% of all reported ADRs. This finding aligns with the 2023 data, where antibiotics similarly topped the list reinforcing their continued prominence in ADR trends. Therapeutic nutrients, minerals, and electrolytes ranked second in 2024, with 285 reports (17.3%), closely mirroring the previous year's figure. Anti-inflammatory agents followed with 201 reports (12.2%). Analgesics accounted for 178 reports (10.8%), while antineoplastic agents were involved in 106 ADRs (6.4%). Overall, the data show consistent therapeutic patterns over the two-year period, with slight variations across categories.

In this report, no adverse drug reactions related to drug-herb interactions were identified. This may be due to limited awareness among physicians or other healthcare professionals regarding patients' concurrent use of herbal products. To address this gap, it is recommended that patients and healthcare providers engage in open communication about the use of herbal remedies alongside prescribed pharmaceutical treatments.

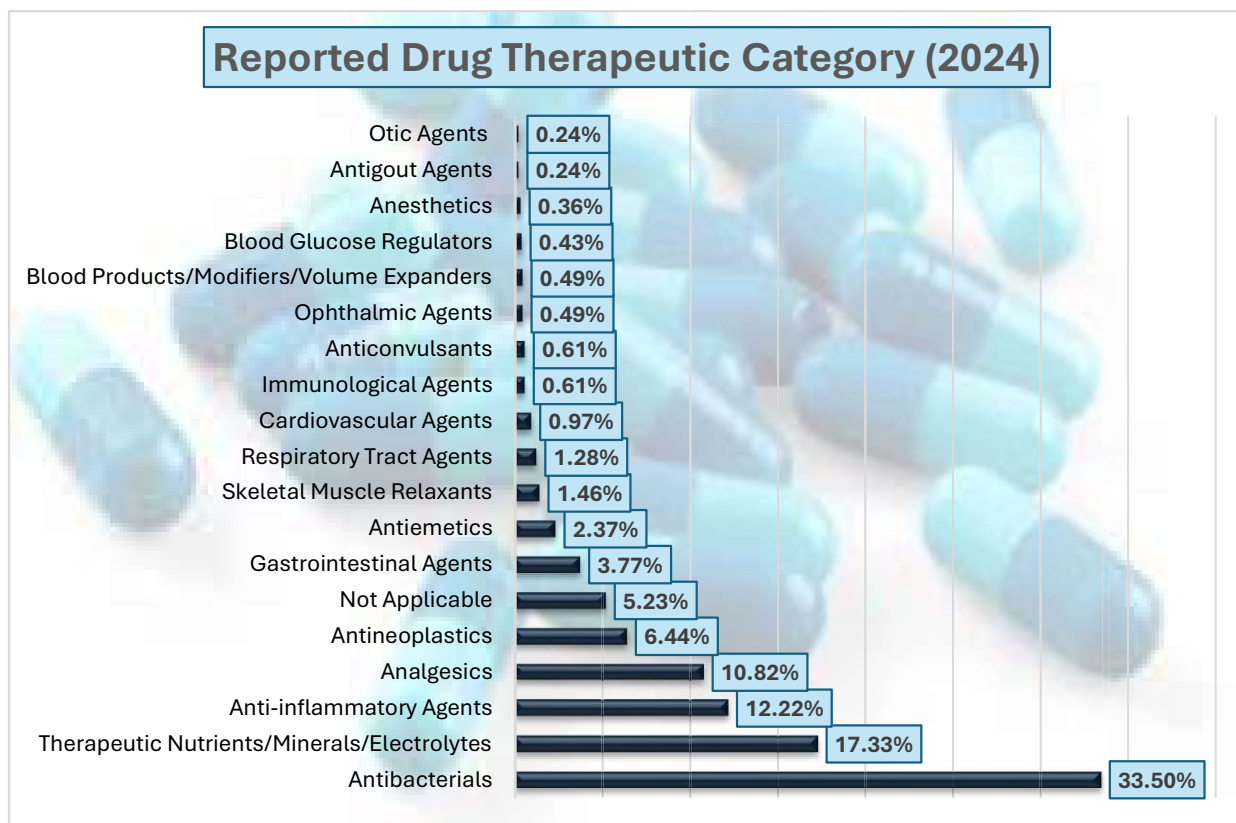


Figure 3: Reported Drug Therapeutic Category



### **Suspected Drugs in ADR Reports:**

In 2024, Ferric Carboxy maltose remained the most frequently reported suspected drug associated with adverse drug reactions, accounting for 246 reports, representing 14.9% of all suspected drug-related cases. This aligns with the 2023 findings, in which Ferric Carboxy maltose also ranked highest, with 257 reports (15.4%). Ceftriaxone was the second most commonly reported drug with 155 ADR reports (9.4%). Diclofenac followed with 102 reports (6.2%), marking an increase from 73 reports (4.4%) in the previous year. Paracetamol and Ciprofloxacin each accounted for 65 reports (3.9%). These trends underscore the continued prominence of certain widely used medications in ADR reporting and highlight the importance of ongoing pharmacovigilance to ensure their safe use in clinical practice.

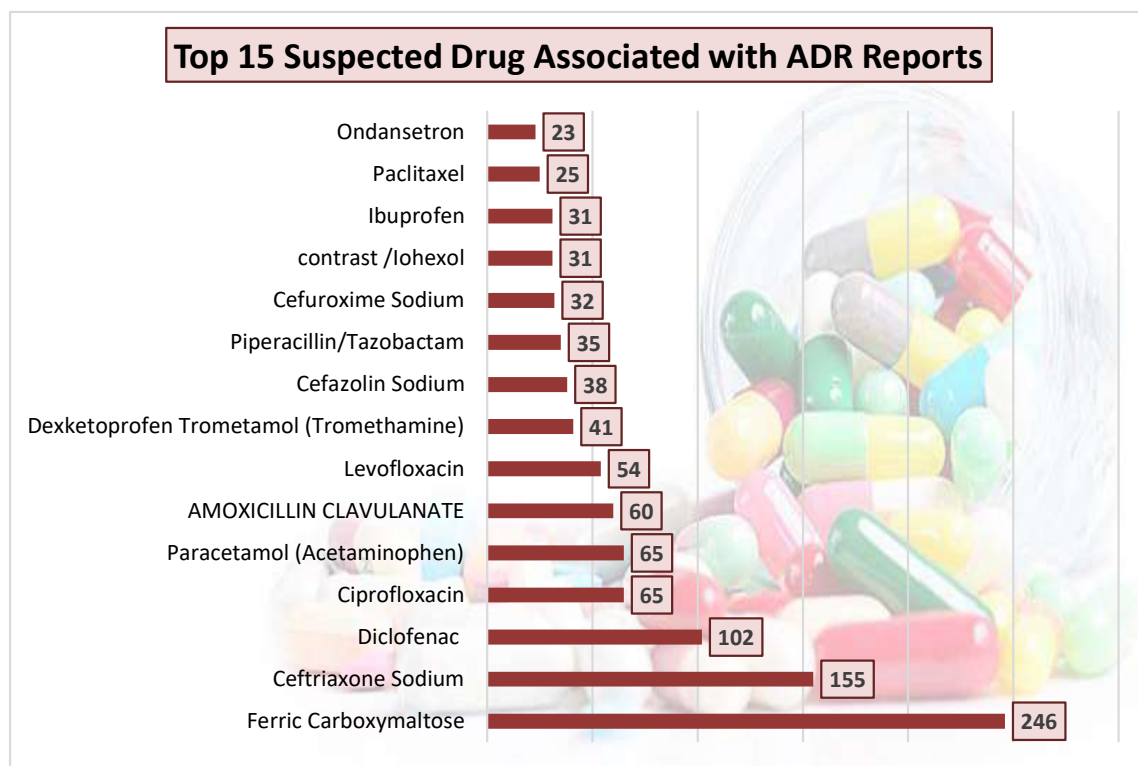


Figure 4: Top 15 Suspected Drug Associated with ADR Reports.

### **Adverse drug reactions received by patients' Age Group:**

The figure below illustrates the distribution of adverse drug reaction (ADR) reports across different age groups. Patient ages ranged from 0 to 93 years. The majority of reports—1,279 cases, accounting for 84%—were associated with individuals aged 20 to 60 years.



In contrast, the 0 to 1-year age group recorded the fewest reports, with only 21 cases, representing 1.39% of the total.

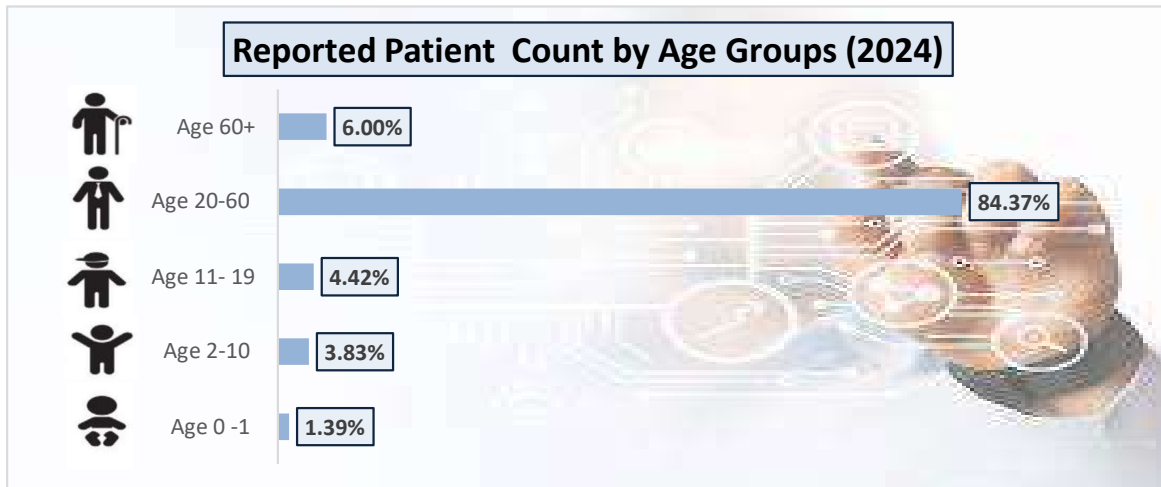


Figure 5: Reports received by Age Groups.

#### **Adverse drug reactions received by patients' Gender:**

A higher number of adverse drug reaction (ADR) reports were associated with female patients, totaling 912 reports (60%), compared to 604 reports (40%) for male patients. Similar trends with comparable figures have been consistently observed in previous years.

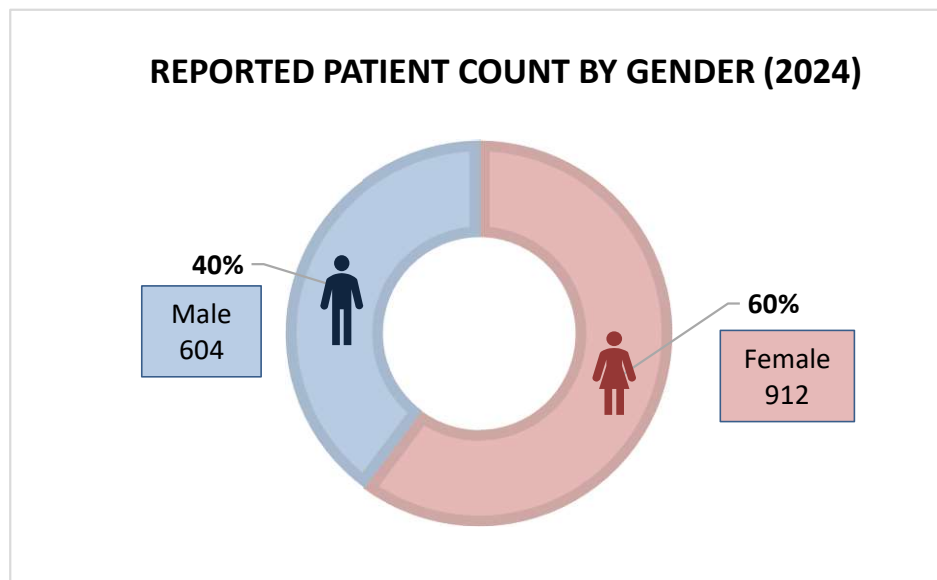


Figure 6: Reports received by Gender.



### **ADR grouped according to system organ class (SOC) classification:**

In the realm of pharmacovigilance, the term SOC stands for System Organ Class which provides a structured framework for classifying adverse events and medical conditions, facilitating consistent reporting and analysis in pharmacovigilance processes while MedDRA is the Medical Dictionary for Regulatory Activities and an international medical terminology with an emphasis on use for data entry, retrieval, analysis, and display.

The analysis of MedDRA received during year 2024 revealed that most of reports included more than one MedDRA at same time, this explains why 2748 MedDRA were reported by 1516 notification reports.

It is worth noting that two MedDRA terms were reported without an associated SOC, and one MedDRA term was linked to an incorrect SOC. These discrepancies, which resulted from manual data entry, were corrected by assigning the appropriate SOCs before proceeding with the analysis that produced the following results.

The table below presents the SOC classification of ADRs associated with the use of medicinal products. A total of 2,748 MedDRA Preferred Terms were mapped to corresponding 2,748 SOC entries to standardize the reported ADR symptoms. The three most frequently reported SOCs in 2024 were: “Skin and subcutaneous tissue disorders” with 1,787 reports (65%), followed by “Respiratory, thoracic and mediastinal disorders” with 238 reports (8.6%), and “General disorders and administration site conditions” with 231 reports (8.4%). This distribution mirrors the pattern observed in 2023, where the same three SOCs were also the most frequently reported.

SOC	MedDRA PT	No. of reports
<b>Skin and subcutaneous tissue disorders</b>		<b>1787</b>
	Pruritus	566
	Rash	562
	Erythema	259
	Urticaria	123
	Pruritus generalised	78
	Rash generalised	64
	Rash pruritic	27
	Angioedema	18
	Swelling face	18
	Rash erythematous	13
	Rash maculo-papular	9
	Generalised erythema	7
	Hyperhidrosis	6
	Skin lesion	6
	Blister	3



SOC	MedDRA PT	No. of reports
	Stevens-Johnson syndrome	3
	Skin reaction	2
	Drug eruption	2
	Macule	2
	Lip pruritus	2
	Toxic epidermal necrolysis	2
	Purpura	2
	Fixed eruption	1
	Rash macular	1
	Petechiae	1
	Dermatitis	1
	Skin irritation	1
	Rash papular	1
	Periorbital dermatitis	1
	Erythema multiforme	1
	Prurigo	1
	Skin discolouration	1
	Skin exfoliation	1
	Eczema	1
	Dermatitis allergic	1
<b>Respiratory, thoracic and mediastinal disorders</b>		<b>238</b>
	Dyspnoea	146
	Cough	34
	Throat irritation	11
	Wheezing	8
	Bronchospasm	5
	Hypoxia	5
	Oropharyngeal pain	4
	Nasal congestion	4
	Tachypnoea	3
	Throat tightness	3
	Dysphonia	3
	Oropharyngeal discomfort	3
	Stridor	2
	Sneezing	2
	Choking sensation	2
	Dry throat	1
	Respiratory tract congestion	1
	Pharyngeal oedema	1
<b>General disorders and administration site conditions</b>		<b>231</b>



SOC	MedDRA PT	No. of reports
	Chest discomfort	42
	Injection site erythema	28
	Chills	27
	Swelling	23
	Injection site rash	22
	Injection site pruritus	18
	Chest pain	12
	Pyrexia	10
	Pain	8
	Discomfort	6
	Injection site swelling	4
	Face oedema	4
	Induration	4
	Feeling hot	3
	Oedema	3
	Malaise	3
	Fatigue	2
	Asthenia	2
	Peripheral swelling	1
	Injection site pain	1
	Injection site reaction	1
	Infusion site erythema	1
	Generalised oedema	1
	Local swelling	1
	Injection site induration	1
	Injection site oedema	1
	Nodule	1
	Injection site irritation	1
<b>Gastrointestinal disorders</b>		<b>146</b>
	Lip swelling	43
	Vomiting	31
	Nausea	21
	Abdominal pain	17
	Diarrhoea	5
	Abdominal discomfort	5
	Lip oedema	4
	Swollen tongue	3
	Epigastric pain	3
	Mouth ulceration	2
	Hypoaesthesia oral	2



SOC	MedDRA PT	No. of reports
	Paraesthesia oral	1
	Abdominal pain lower	1
	Constipation	1
	Abdominal distension	1
	Oral mucosal eruption	1
	Lip pain	1
	Glossodynia	1
	Dry mouth	1
	Lip erosion	1
	Dyspepsia	1
<b>Eye disorders</b>		<b>80</b>
	Swelling of eyelid	20
	Eye swelling	19
	Erythema of eyelid	7
	Ocular hyperaemia	6
	Eye pruritus	5
	Eye irritation	4
	Eyelid oedema	4
	Periorbital swelling	3
	Periorbital oedema	3
	Vision blurred	2
	Conjunctival oedema	2
	Eye pain	2
	Eye inflammation	1
	Lacrimation increased	1
	Eye oedema	1
<b>Vascular disorders</b>		<b>66</b>
	Hypotension	26
	Hot flush	18
	Flushing	16
	Hypertension	3
	Circulatory collapse	1
	Thrombophlebitis	1
	Pallor	1
<b>Nervous system disorders</b>		<b>64</b>
	Dizziness	28
	Burning sensation	12
	Headache	4
	Dyskinesia	3
	Paraesthesia	3



SOC	MedDRA PT	No. of reports
	Hypoaesthesia	2
	Depressed level of consciousness	2
	Somnolence	2
	Lethargy	1
	Neuropathy peripheral	1
	Tremor	1
	Dystonia	1
	Syncope	1
	Extrapyramidal disorder	1
	Akathisia	1
	Head discomfort	1
<b>Immune system disorders</b>		<b>36</b>
	Hypersensitivity	26
	Anaphylactic reaction	5
	Anaphylactic shock	3
	Acute generalised exanthematous pustulosis	2
<b>Cardiac Disorders</b>		<b>34</b>
	Tachycardia	18
	Palpitations	12
	Bradycardia	2
	Cyanosis	2
<b>Musculoskeletal and connective tissue disorders</b>		<b>23</b>
	Back pain	13
	Pain in extremity	2
	Myalgia	2
	Muscle spasms	1
	Flank pain	1
	Joint swelling	1
	Torticollis	1
	Limb discomfort	1
	Muscle Rigidity	1
<b>Investigations</b>		<b>18</b>
	Allergy Test	9
	Oxygen saturation decreased	6
	Blood uric acid increased	2
	Body temperature increased	1
<b>Psychiatric disorders</b>		<b>14</b>
	Restlessness	4
	Irritability	2



SOC	MedDRA PT	No. of reports
	Confusional state	2
	Agitation	2
	Insomnia	1
	Sleep terror	1
	Anxiety	1
	Hallucination	1
<b>Eat and labyrinth disorders</b>		<b>4</b>
	Ear swelling	2
	Tinnitus	1
	Ear Pruritus	1
<b>Metabolism and nutrition disorders</b>		<b>3</b>
	Decreased appetite	1
	Hyponatraemia	1
	Hypokalemia	1
<b>Renal and urinary disorders</b>		<b>1</b>
	Urinary retention	1
<b>General system disorders NEC</b>		<b>1</b>
	Infusion related reaction	1
<b>Blood and lymphatic system disorders</b>		<b>1</b>
	Methaemoglobinaemia	1
<b>Infections and infestations</b>		<b>1</b>
	Meningitis aseptic	1
<b>Grand Total</b>		<b>2748</b>

Table 1: SOC classification of ADRs with MedDRA PT.

### ***Outcome and Seriousness of the Adverse Events***

Of the submitted reports, 1,397 cases (92%) indicated that patients had fully recovered from the adverse drug reaction symptoms. In 102 cases (6.7%), patients were still recovering at the time of report submission. 11 cases (0.73%) showed no recovery, while two patients (0.13%) experienced recovery with sequelae. The outcome was unknown in 4 reports (0.26%).

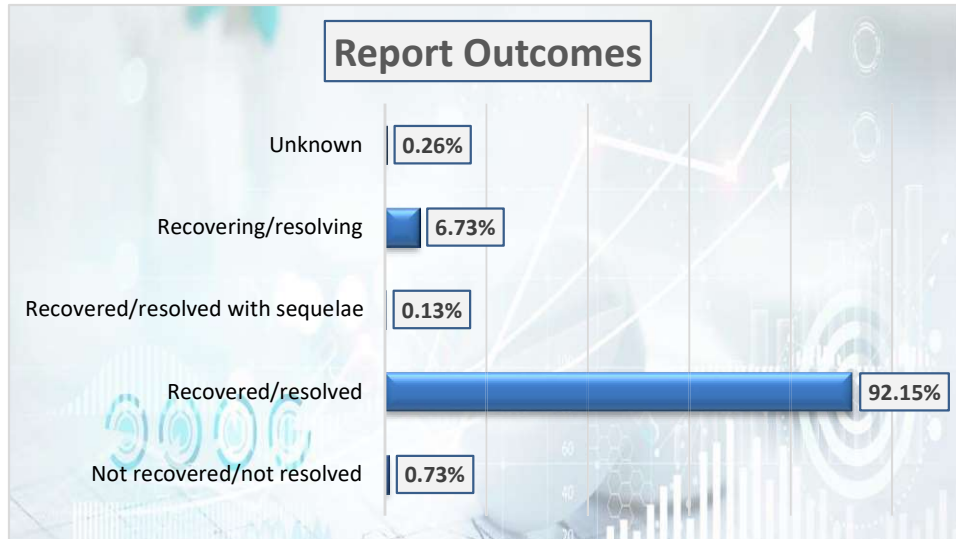


Figure 7: Reports Outcome

The majority of submitted adverse drug reaction reports—1,471 cases (97%)—were classified as non-serious. In accordance with DoH standards, healthcare professionals are required to report all ADRs, regardless of severity, to ensure comprehensive monitoring of both known and previously unrecognized drug-related risks.

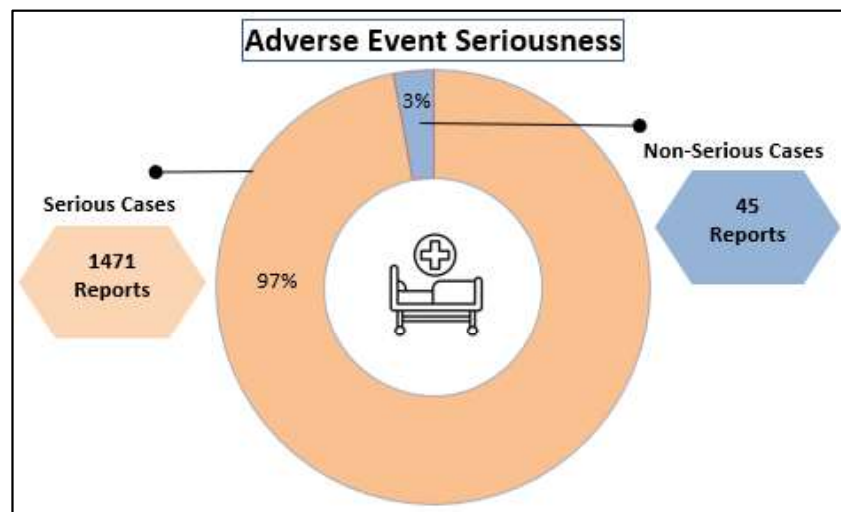


Figure 8: ADR reports seriousness

A total of 45 serious adverse drug reactions, representing approximately 3% of all submitted reports, underwent further analysis to categorize the type of seriousness involved. The breakdown is presented in the graph below. The most frequently reported category was required “Hospitalization”, accounting for 27 cases. This was followed by “Life-Threatening” events (9 cases), “Prolonged Hospitalization more than 24 hours” (4 cases), “Other Seriousness” (3 cases), and “Required Intervention to Prevent Permanent Harm” (2 cases).

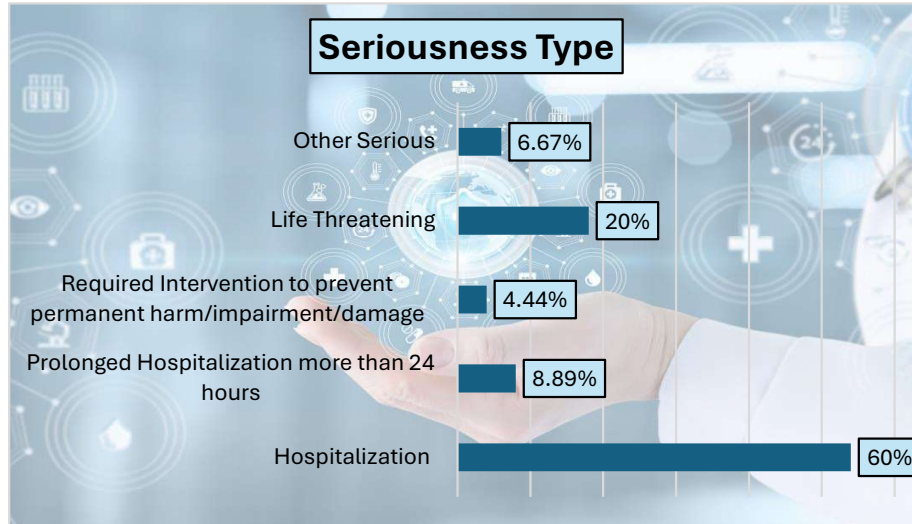


Figure 9: Type of seriousness.

### Report completeness:

99% of the submitted reports were complete, while only 1% were submitted with incomplete information. The majority of these incomplete reports required further investigation or additional clarification, often prompting follow-up questions regarding the nature and development of the reported adverse reaction and to improve the overall quality of the data, ensuring greater accuracy and effectiveness in supporting pharmacovigilance efforts.

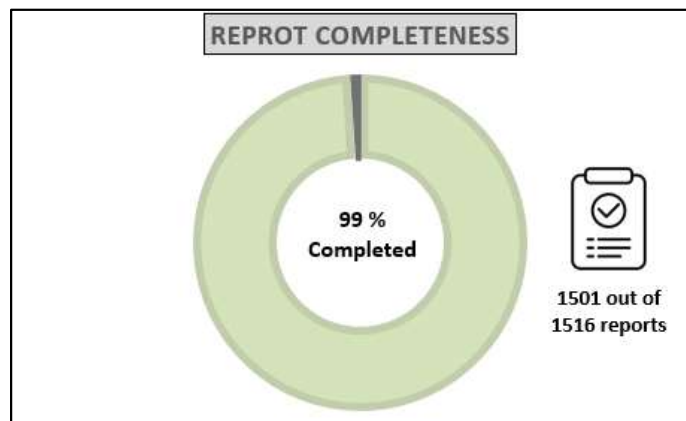


Figure 10: Status of ADR reports

### Reporting Facilities:

In 2024, a total of 95 different healthcare facilities (including their respective branches) actively reported adverse drug reactions to the pharmacovigilance program. This marks a notable improvement, achieving a 100% participation rate, up from 97% in 2023 and 93% in 2022,



indicating strengthened engagement and awareness across the healthcare sector. Table 2 highlights the top 15 reporting facilities or branches.

Facility Name	Number of Reports
NEW MEDICAL CENTRE SPECIALTY HOSPITAL LTD-ABU DHABI In-Patient Pharmacy	113
LLH HOSPITAL PHARMACY- LLC	107
N M C SPECIALTY HOSPITAL LTD	99
AL AHLI HOSPITAL COMPANY LLC - BRANCH 1 INPATIENT PHARMACY	95
AL AHLI HOSPITAL COMPANY L L C In-Patient Pharmacy	86
MEDEOR 24X7 HOSPITAL IN-PATIENT PHARMACY	86
TAWAM HOSPITAL	76
N M C ROYAL HOSPITAL LTD	47
PHOENIX HOSPITAL L.L.C. INPATIENT PHARMACY	42
Sheikh Shakbout Medical City L.L.C.-O.P.C.	40
AL DHAFRA HOSPITALS	40
MEDICLINIC PHARMACY - ALNOOR - BRANCH 1	39
NMC ROYAL WOMENS HOSPITAL LTD In-Patient Pharmacy	37
BURJEEL HOSPITAL IN-PATIENT PHARAMCY	36
LLH HOSPITAL AL MUSAFFAH IN-PATIENT PHARMACY	36

Table 2: Top 15 reporting facilities/branches

## Limitations

While the 2024 ADR reporting process demonstrated significant improvements, certain limitations persist that may affect data interpretation and signal detection.

- Data Completeness:** the implementation of periodic report reviews by the pharmacovigilance team, coupled with IT system enhancements mandating the completion of essential fields. This proactive approach effectively addressed previous issues of missing data in mandatory fields such as DOB, outcome and reporter details. While still issue of missing other data such as indications, route of administration, concomitant drug administration, use of herbal products, and other relevant information regarding the nature and the development of the reported adverse reaction.
- Documentation Accuracy:** inconsistent information remains in few reports. For example, Seriousness Adverse Reaction in few reports were chosen as non-serious while the comments suggest it is serious. Other reports were missing SOC and MedDRA Preferred Term (PT) linked to an incorrect SOC. These discrepancies were manually corrected by the PV team. Such issues highlight the need for ongoing training and system checks to ensure data accuracy



- *Underreporting*: continues to be a global challenge in pharmacovigilance. Factors contributing to underreporting include time constraints, uncertainty about the causality of reactions, and lack of awareness about reporting systems and purpose of ADR monitoring. These factors can lead to biases in the data, affecting the detection of safety signals
- *Causality Assessment Challenges*: Determining a causal relationship between a drug and an adverse event remains complex. Adverse events may be attributed to the underlying disease or other medications, making it difficult to establish causality based solely on spontaneous reports. This limitation underscores the importance of comprehensive clinical evaluations and, where possible, the use of standardized causality assessment tools.



## Recommendations

- **Enhance Training and Awareness Programs**

Continuous education for healthcare professionals is vital to maintain high reporting standards. Regular training sessions should be conducted to update reporters on the importance of accurate ADR reporting, correct usage of MedDRA terminology, and the implications of incomplete or inaccurate data. Emphasizing the significance of reporting both serious and non-serious ADRs can lead to a more comprehensive safety profile of medicinal products.

- **Promote a Culture of Reporting**

Underreporting remains a global challenge in pharmacovigilance. To address this, fostering a culture that encourages reporting is essential. This can be achieved by integrating ADR reporting metrics into healthcare facility performance indicators, recognizing and rewarding diligent reporting practices, and simplifying the reporting process to reduce the burden on healthcare professionals. Such initiatives have been effective in countries like Singapore, where active participation in ADR reporting has been linked to improved medication safety outcomes.

- **Leverage Technology for Signal Detection**

Adopting advanced data analytics and signal detection tools can enhance the identification of potential safety concerns. Implementing algorithms, AI that analyze reporting patterns can aid in early detection of adverse events, allowing for prompt regulatory actions.

- **Encourage Patient Involvement**

Patients are valuable contributors to pharmacovigilance. Encouraging patient-reported ADRs can uncover issues that may not be captured through healthcare professional reports alone. Educational campaigns aimed at patients, informing them about the importance of reporting side effects and the available channels to do so, can enhance the depth and breadth of ADR data collected.

- **Continuous System Improvements**

Regular assessments of the electronic reporting system should be conducted to identify and rectify technical issues promptly. Feedback mechanisms can be established to gather user experiences, facilitating iterative improvements to the system's usability and functionality.



## References

1. Department of Health (DoH), Abu Dhabi. Adverse Drug Reaction Pharmacovigilance Reporting System.
2. MedDRA MSSO. Medical Dictionary for Regulatory Activities (MedDRA®). Version accessed on May 22, 2025. Available from: <https://tools.meddra.org/wbb/>
3. World Health Organization. The importance of pharmacovigilance – Safety monitoring of medicinal products. Geneva: WHO; 2002. Accessed on May 22, 2025. Available from: <https://www.who.int/publications/i/item/10665-42493>
4. Molokhia M, Tanna S, Bell D. Improving reporting of adverse drug reactions: Systematic review. *Clin Epidemiol*. 2009 Aug 9;1:75–92. doi: 10.2147/cep.s4775. PMID: 20865089; PMCID: PMC2943157. Available from: <https://pubmed.ncbi.nlm.nih.gov/20865089/>
5. Health Product Safety Information Summary – May 2025 (Vol. 27, No. 1). Published: May 2025. Accessed: May 22, 2025. Available from: [https://www.hsa.gov.sg/docs/default-source/announcements/adverse-drug-reaction-news-bulletin/adr\\_news\\_may2025\\_vol27\\_no1.pdf](https://www.hsa.gov.sg/docs/default-source/announcements/adverse-drug-reaction-news-bulletin/adr_news_may2025_vol27_no1.pdf)
6. Analysis of Adverse Event (AE) Reports for Year 2017. *ADR News Bulletin*. 2018 May; Vol. 20(1). Accessed on May 22, 2025. Available from: [https://www.hsa.gov.sg/docs/default-source/announcements/adverse-drug-reaction-news-bulletin/analysis-of-ae-reports-for-year-2017\\_may2018\\_vol-20\\_no1.pdf](https://www.hsa.gov.sg/docs/default-source/announcements/adverse-drug-reaction-news-bulletin/analysis-of-ae-reports-for-year-2017_may2018_vol-20_no1.pdf)