دائـــــرة الـصـــحـــة
DEPARTMENT OF HEALTH

ANALYSIS OF ADVERSE DRUG REACTIONS

2023 REPORT

Pharmacovigilance Program
Research and Innovation Center
Department of Health (DOH)

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Introduction

This report serves as an annual report on pharmacovigilance adverse drug reports for the year 2023 and provides comprehensive overview of the adverse events associated with pharmaceutical products reported within our pharmacovigilance system during the past year.

Suspected Adverse drug reactions are reported to DOH pharmacovigilance program by healthcare professionals/facilities, ADR's database is examined and investigated regularly by DOH pharmacovigilance team as part of routine safety monitoring to ensure that medical products used in Abu Dhabi are safe and effective.

These efforts have enabled us to monitor the safety profile of marketed drugs, identify potential risks, and take appropriate regulatory actions to ensure the continued safe use of medications.
In this report, we present a summary of the key findings, trends, and insights derived from the analysis of adverse drug reports received during the reporting period.

The aim of this analytical report is to increase the awareness of adverse drug reactions related to medicinal products amongst healthcare professionals, promote adverse event reporting related to medical products and to encourage all healthcare professionals to report ADRs experienced by patients especially those that are suspected to be associated with medical products.

We recognize the invaluable contributions of healthcare professionals, and other stakeholders in reporting adverse drug events, which are instrumental in enhancing drug safety surveillance and promoting public health.
Together, we remain committed to advancing the science of pharmacovigilance, fostering proactive risk management, and safeguarding the well-being of patients worldwide.

Methods

Source of data:

The data was obtained from adverse drug reaction reports submitted electronically through Abu Dhabi DOH pharmacovigilance E-notification system using the "Adverse drug reaction Report form "surveillance approaches", the reports were reviewed by pharmacovigilance team, this approach aim to quickly identify an adverse event once it has happened and prevent it from happening if possible. Regardless of how an adverse event is detected, the process for reporting and analyzing is the same. The serious ADR was further investigated & used ADR probability scale "Naranjo" which consists of ten questions that are answered as either "Yes", "No", or "Do not know". Different point values (-1, 0, +1 or +2) are assigned to each answer. While this scale includes all the usual features that are important in assessing causality, the scale is not weighted for the most critical elements in judging the likelihood of drug induced liver injury, such as specific

time to onset, criteria for time of recovery, and list of critical diagnoses to exclude, making the scale of limited use in assessing hepatotoxicity. As a member country of the WHO International Drug Monitoring Program, all adverse drug reactions. The reports were also submitted to the WHO-Uppsala Monitoring Centre in Sweden for collation inttheHO's VigiLyze for Potential signals of serious risks /new safety information.

Data collation and analyses:

The data used for analysis was for the period between January and December 2023. It follows the previous report of ADR data analysis for the years 2013-2022. Adverse reactions following immunizations reports are not included in this analysis.
Information to be used in this analysis was extracted in Microsoft® Excel files from DOH electronic reporting system from the reports and collated on patient's demographic information such as age, gender, hospitalization status, outcome of the adverse event, seriousness of the adverse event, profession of the reporter, type of products involved, organ system affected were collated.

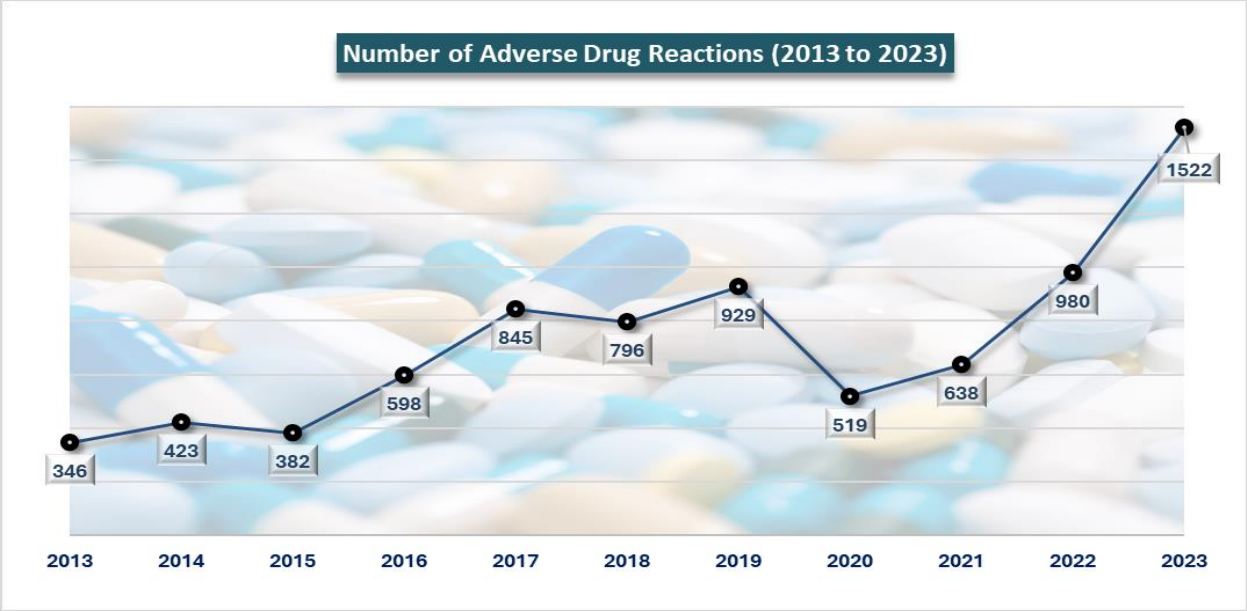
Adverse drug reaction for marketed drugs in Abu Dhabi in this report were categorized using MedDRA Terminology a single standardized international medical terminology which can be used for regulatory communication and evaluation of data pertaining to medicinal products for human use involving different system-organ classes (SOC) with the relevant “Preferred Term.”

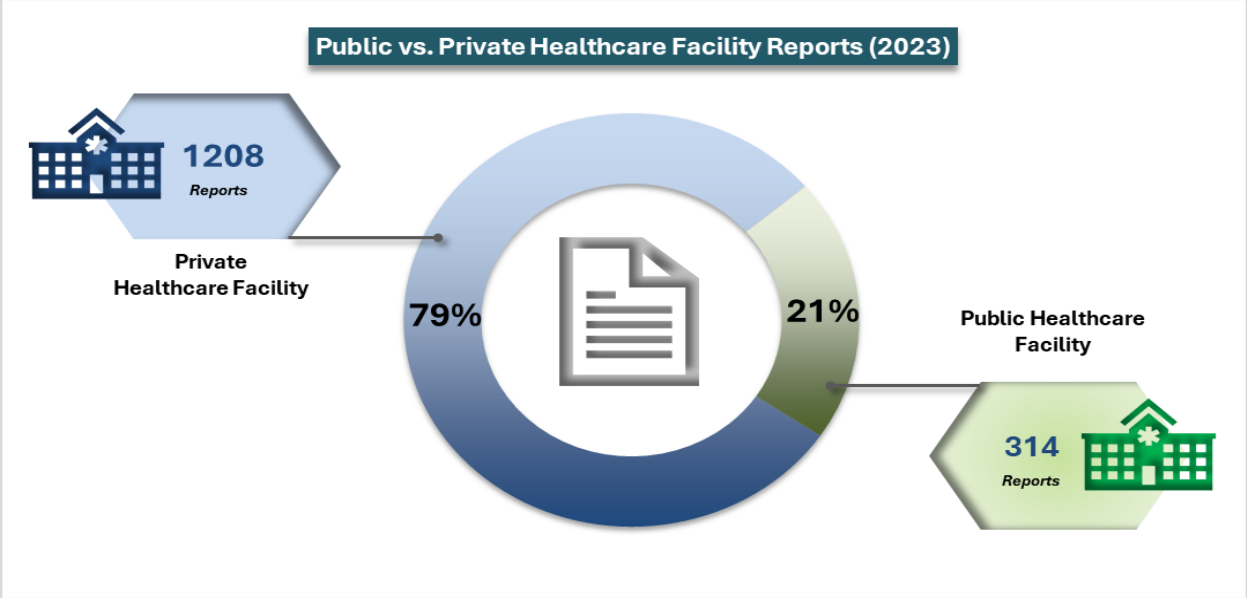
Results

Number of Reports and Mode of reporting

A total of 1522 adverse drug reaction reports were submitted to the pharmacovigilance program during the period of January - December 2023. This year's count is 235% higher than the average annual reports received for the past 10 years (645). All reports 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.



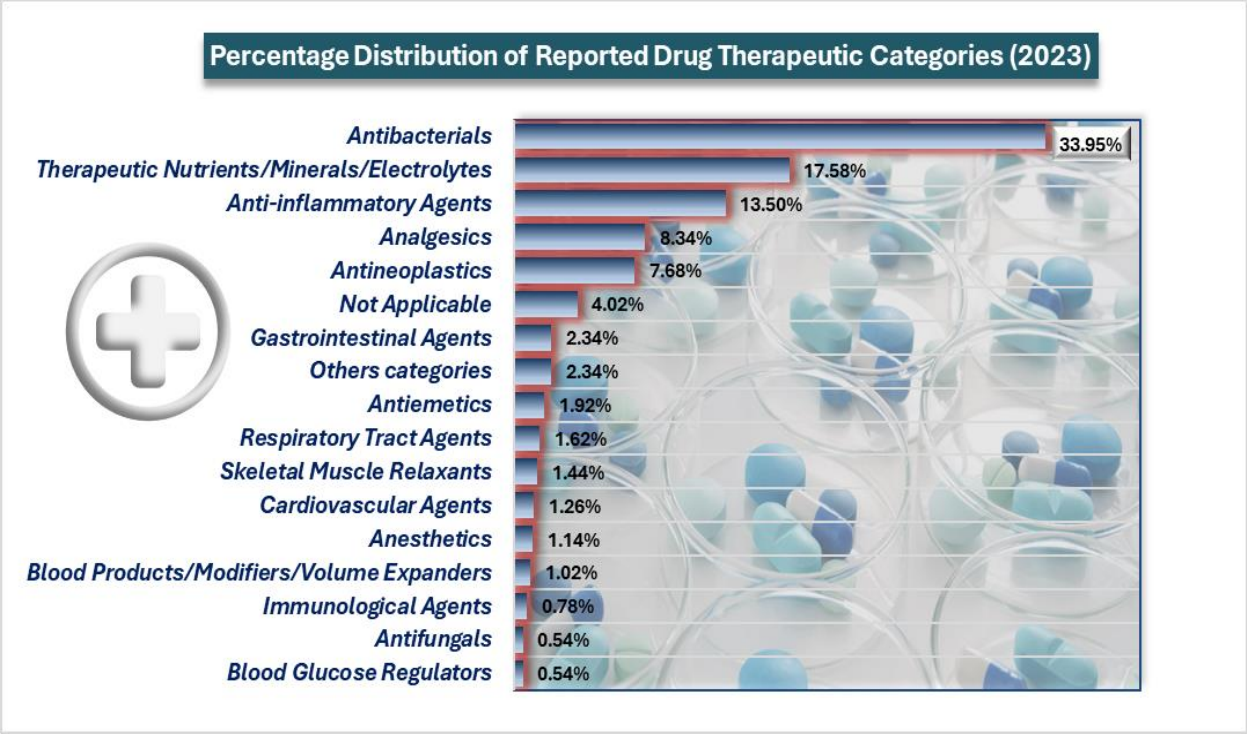


Adverse drug reactions received by drug classification:

The total number of suspected drugs reported was 1667 drug, (1091 Generic name and 576 other generic names, none from brand name as the generic and other generic names were not ever blank at any of the reports) some ADR reports had more than one suspected drug reported which explains why the number of drugs is more than the number of reports (1667 vs 1522 respectively).

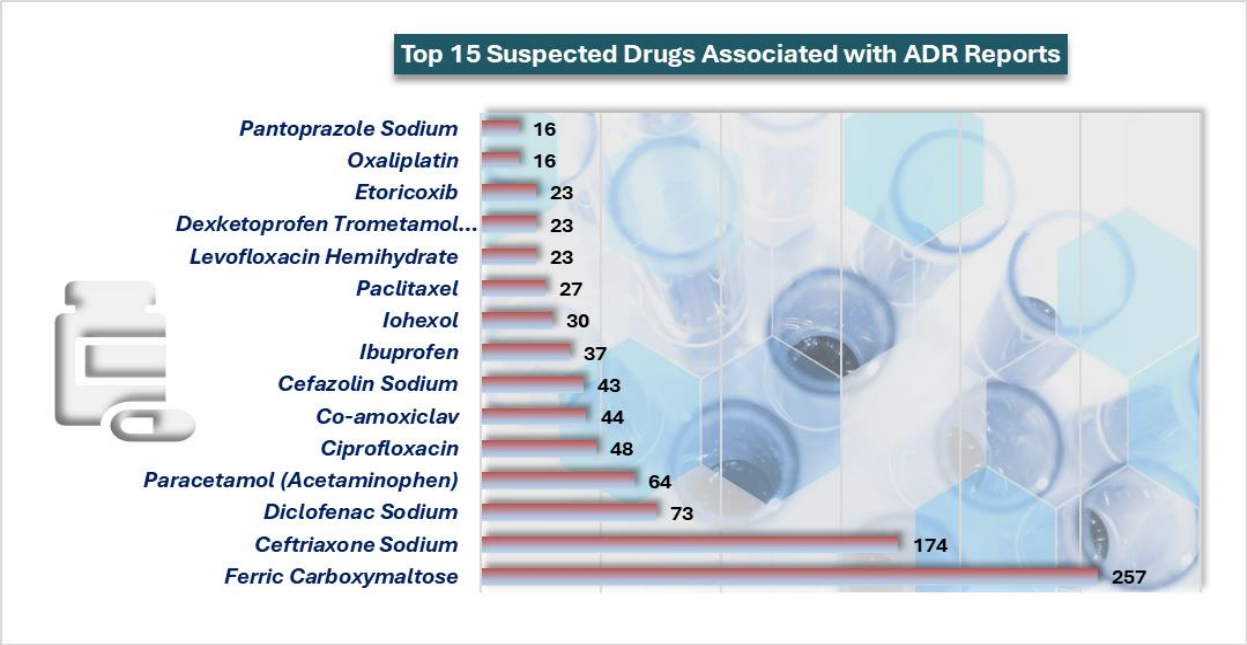
Antibacterial (Antibiotics) count is 566 represent the highest therapeutic category associated with ADR incidences with percentage of 34%, this is consistent with the previous year's results which showed that antibiotics were the highest therapeutic category of drugs associated with ADR events.
It is followed by therapeutic Nutrients/Minerals/Electrolytes count is 293 and percentage is 17.6%, followed by Anti-inflammatory Agents count is 225 and percentage of 13.5%. The number of Antineoplastic reports count was 128 representing 7.7%, this is notable compared to previous years.

In this report adverse reactions due to drug-herb interactions have not been recognized. This could be attributed to the fact that the physician or other health professional was not aware if the patient was concomitant use of herbal products. Therefore, it is recommended that the patients and their healthcare providers communicate openly about the usage of herbal products along with pharmaceutical products.



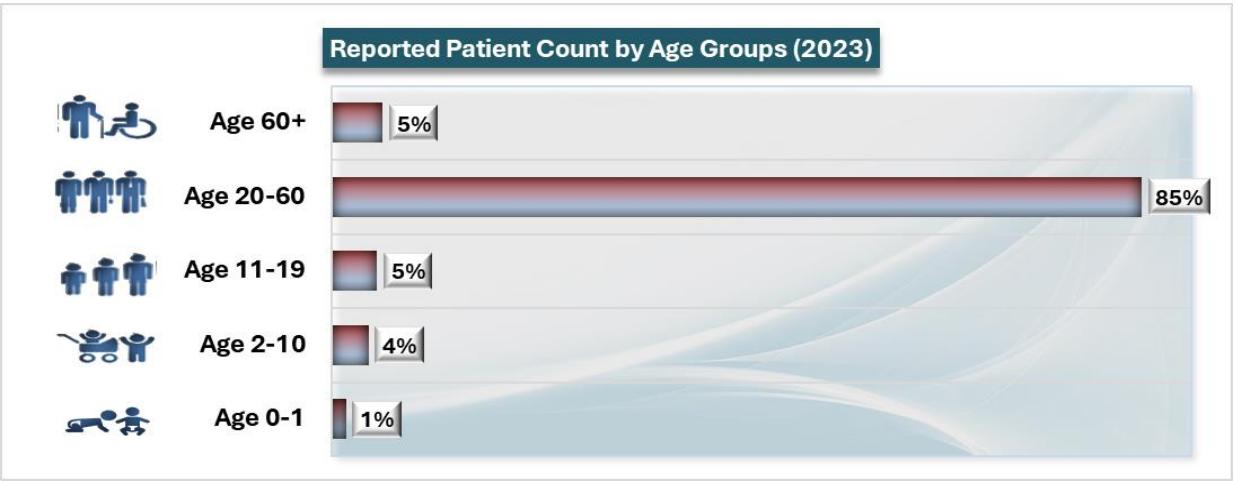
Suspected Drugs in ADR Reports:

Ferric Carboxy maltose was the most reported drug suspected to be associated with an adverse drug reaction by 257 reports resembling for 15.4% of the total reported suspected drugs during 2023. Ceftriaxone comes next with 174 reports (10.4%), followed by Diclofenac Sodium 73 (4. 4%) and paracetamol 64 (3.8%).



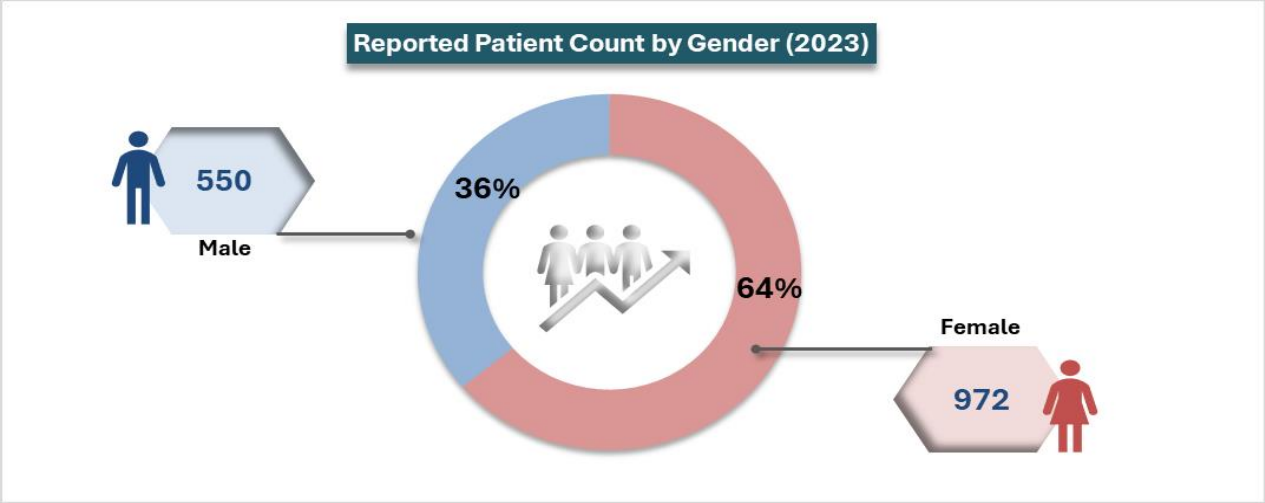
Adverse drug reactions received by patients' Age Group:

The below figure shows the estimated percentage of reports in each age group. The age of the patients in the ADR reports ranged from 0 to 93 years old. The highest number of reports was found to be in the patients' age range between 20-60 years by 1291 representing 85% of the reports, while the age group range from 0 to 1 year resembled the smallest number by 22 reports and the percentage of 1%.



Adverse drug reactions received by patients' Gender:

There were more ADR reports received for female patients the count was 972 representing 64% while reports for male patients counted 550 representing 36% of total reports received, same findings with close figures were seen in the previous years.



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 2023 revealed that most of reports included more than one MedDRA at same time, this explains why 2825 MeDRA were reported by 1522 notification reports.

It is worth mentioning that 12 of MeDRA were reported without SOC. This resulted in discrepancy between 2825 count of MedDRA and 2813 count of SOC.

The difference between number of MeDRA and SOC was due to misreporting in 8 reports, these missing were filled manually by corresponding suitable SOC and analyzed to reveal the following results.

The table below shows the SOC classification of ADR associated with the use of medicinal products. 2825 count of MedDRA preferred term were used to unify the reported ADR symptoms and 2813 count of SOC. The three major SOC reported were "Skin and subcutaneous tissue disorders" 1907 (67.5%) followed by "Respiratory, thoracic and mediastinal disorders" 223 (7.9%) and "General disorders and administration site conditions" 145 (5.1%). These proportions are very close to last year's.

SOC	MedDRA PT	No. of reports
Skin and subcutaneous tissue disorders		**1907**
	Pruritus	609
	Rash	497
	Erythema	303
	Urticaria	161
	Pruritus generalised	85
	Rash generalised	81
	Rash erythematous	61
	Angioedema	26
	Swelling face	16
	Rash pruritic	11
	Rash maculopapular	9
	Hyperhidrosis	8
	Drug eruption	5
	Blister	3
	Erythema multiforme	3
	Acne	2
	Dermatitis	2
	Dermatitis allergic	2
	Eczema	2
	Fixed eruption	2
	Hypersensitivity	2
	Lip pruritus	2
	Skin irritation	2
	Skin reaction	2
	StevensJohnson syndrome	2
	Dermatitis bullous	1
	Dermatitis contact	1
	Dry Skin	1
	Lip swelling	1
	Papule	1
	Red man syndrome	1
	Skin discolouration	1
	Skin oedema	1
Respiratory, thoracic and mediastinal disorders		**223**
	Dyspnoea	137
	Cough	34
	Throat irritation	10
	Wheezing	9
	Bronchospasm	6

SOC	MedDRA PT	No. of reports
	Tachypnoea	5
	Oropharyngeal discomfort	4
	Hypoxia	4
	Dysphonia	3
	Oropharyngeal pain	3
	Respiratory distress	3
	Nasal congestion	2
	Respiratory depression	1
	Sinonasal obstruction	1
	Sneezing	1
General disorders and administration site conditions		**145**
	Chest discomfort	38
	Swelling	18
	Chills	16
	Chest pain	11
	Pain	12
	Feeling hot	7
	Injection site erythema	7
	Pyrexia	6
	Induration	4
	Injection site pruritus	4
	Asthenia	3
	Discomfort	3
	Face oedema	3
	Oedema	3
	Injection site reaction	2
	Foaming at mouth	1
	Hot flush	1
	Injection site hypersensitivity	1
	Injection site rash	1
	Injection site swelling	1
	Mucosal Erosion	1
	Oedema peripheral	1
	Pruritus	1
Gastrointestinal disorders		**119**
	Vomiting	27
	Lip swelling	26
	Nausea	22
	Abdominal pain	15
	Diarrhoea	7

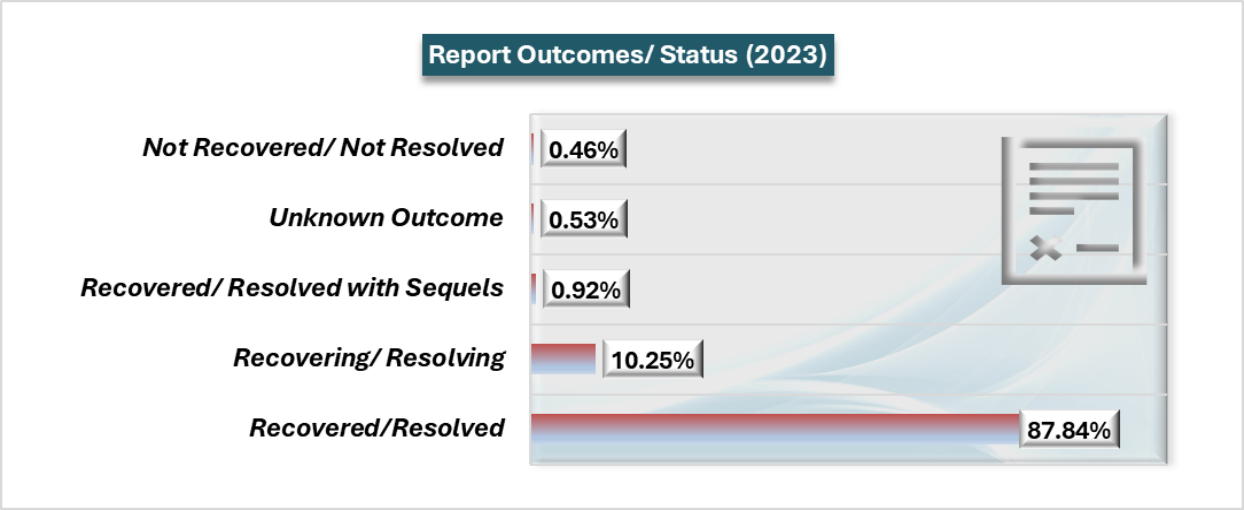
SOC	MedDRA PT	No. of reports
	Swollen tongue	6
	Abdominal discomfort	5
	Abdominal pain upper	4
	Dyspepsia	1
	Dysphagia	1
	Lip blister	1
	Lip erosion	1
	Lip oedema	1
	Oral discomfort	1
	Tongue oedema	1
Eye disorders		**80**
	Eye swelling	24
	Swelling of eyelid	13
	Periorbital swelling	10
	Ocular hyperaemia	8
	Periorbital oedema	8
	Eye oedema	4
	Eye pruritus	4
	Eyelid oedema	3
	Vision blurred	2
	Conjunctival hyperaemia	1
	Glaucoma	1
	Visual impairment	1
Nervous system disorders		**75**
	Dizziness	35
	Hypoaesthesia	9
	Headache	8
	Burning sensation	8
	Extrapyramidal disorder	4
	Unresponsive to stimuli	2
	Loss of consciousness	2
	Dysarthria	1
	Paraesthesia	1
	Syncope	1
	Cerebrovascular accident	1
	Dyskinesia	1
	Meningitis cryptococcal	1
	Somnolence	1
Immune system disorders		**66**
	Hypersensitivity	53

SOC	MedDRA PT	No. of reports
	Anaphylactic reaction	10
	Anaphylactic shock	4
Vascular disorders		**57**
	Hypotension	31
	Flushing	16
	Hot flush	7
	Hypertension	3
Cardiac Disorders		**47**
	Palpitations	20
	Tachycardia	15
	Bradycardia	7
	Cardiac arrest	2
	Cyanosis	2
	Dyspnoea	1
General system disorders NEC		**33**
	Infusion related reaction	33
Investigations		**27**
	Allergy Test	7
	Oxygen saturation decreased	5
	Blood pressure decreased	4
	Heart rate increased	4
	Blood pressure increased	3
	Liver function test abnormal	1
	Skin test positive	1
	Blood uric acid increased	1
	Haemoglobin Decrease	1
Psychiatric disorders		**17**
	Agitation	8
	Restlessness	3
	Anxiety	1
	Mood swings	1
	Nervousness	1
	Aggression	1
	Insomnia	1
	Irritability	1
Musculoskeletal and connective tissue disorders		**16**
	Back pain	13
	Muscle spasms	1
	Rhabdomyolysis	1
	Pain in extremity	1

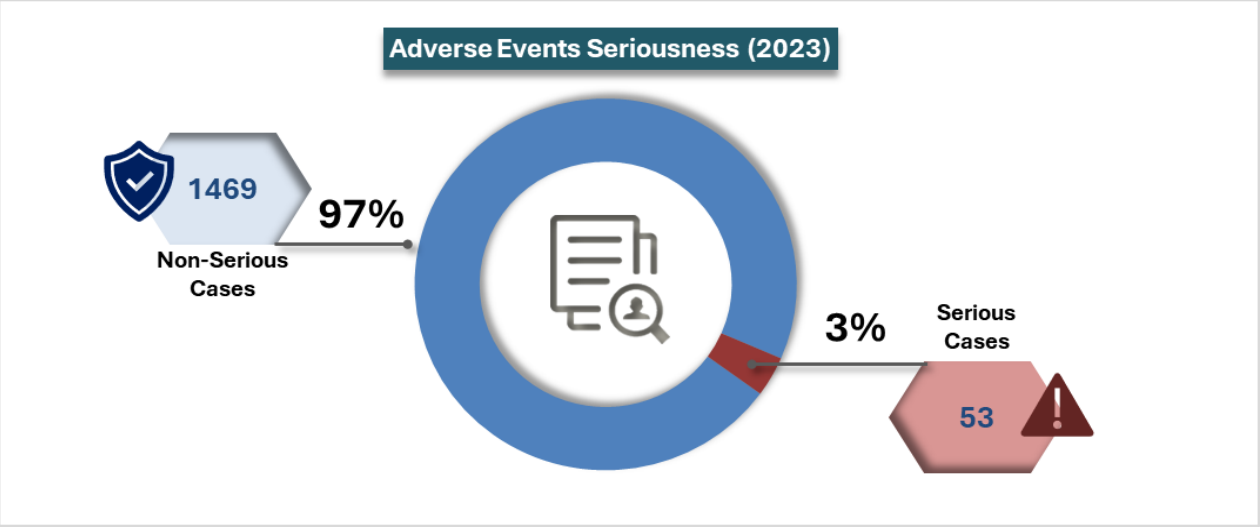
SOC	MedDRA PT	No. of reports
Renal and urinary disorders		**4**
	Renal tubular acidosis	1
	Urinary retention	1
	Urinary incontinence	1
	Proteinuria	1
Blood and lymphatic system disorders		**3**
	LYMPHADENITIS	1
	Haemolytic anaemia	1
	Leukopenia	1
Reproductive system and breast disorders		**2**
	Erectile dysfunction	1
	Scrotal swelling	1
Eat and labyrinth disorders		**2**
	Tinnitus	1
	Ear Pruritus	1
Metabolism and nutrition disorders		**1**
	Diabetic ketoacidosis	1
Product issues		**1**
	Suspected product quality issue	1
Grand Total		**2825**

Outcome and Seriousness of the Adverse Events

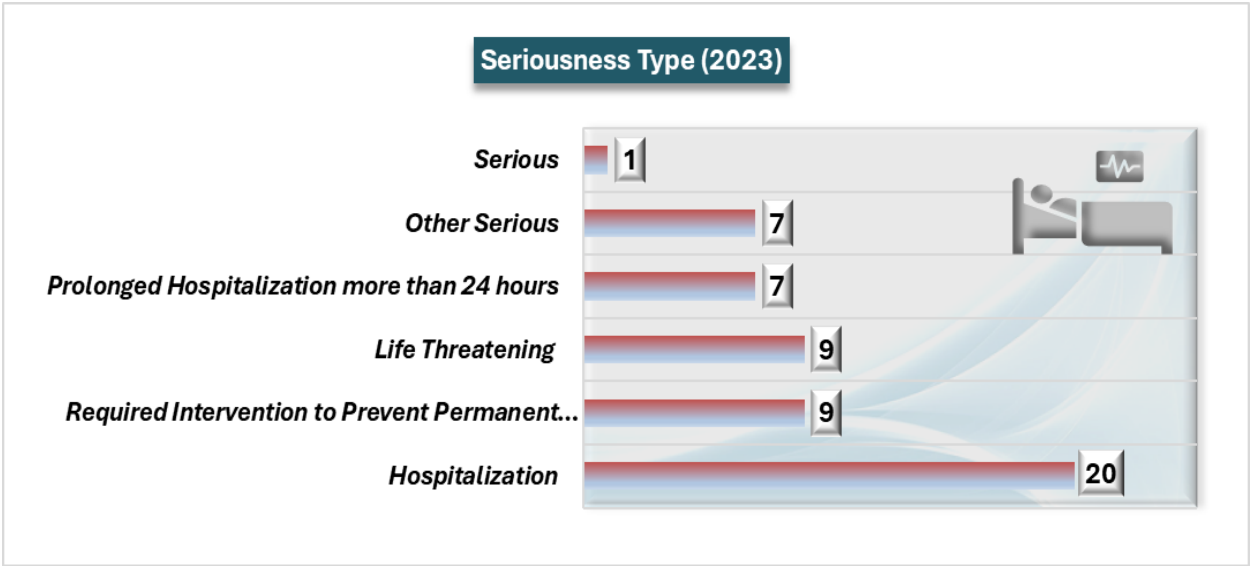
In 1337 (87.84%) of the submitted reports, patients had recovered from the adverse drug reaction symptoms. 156 patients (10.25%) were still recovering at the time of report submission. 14 patients (0.92%) Recovered with sequelae while 8 (0.53%) patients had an unknown outcome. Only 7 patients (0.45%) showed no recovery for the adverse drug reactions.



Most of the submitted reports were non-serious 1469 (96.5%). Healthcare professionals and providers are required to report all ADRs whether serious or non-serious as per DoH standard aiming to capture all adverse known and unknown drug reactions.



The 53 serious adverse reactions reported resembling around 3.5% of the total reports were then included in a further analysis to provide close insights into the type of seriousness. For those 53 reports categories and reports count of seriousness type are shown in the below graph. Those which required "*Hospitalization*" were the most reported in 20 cases. This was followed by "*Required Intervention to prevent permanent harm/impairment/damage*" reported in 9 cases," Life *Threatening*" were also reported in 9 cases, "*Other Seriousness* "as well as "*Prolonged Hospitalization more than 24 hours*" were reported in 7 cases, while just "serious "was reported in 1 case.



Report completeness:

99% of the reports were complete while only 1% were submitted incomplete. Converting the important information to be "obligatory / necessary to fill" before the reporter can submit it can effectively boost the completeness rate of the reports. Some reports were in need for more investigation information due to unclarity this was followed by investigation by the pharmacovigilance team.

Reporting Facilities:

A Total of 89 different healthcare facilities (including different healthcare facility branches) had reported ADR during the year 2023. The accumulative percentage of reporting facilities to PV program increased during 2023 (97%) compared to previous year (2022 was 93%).
Below table reflects the top 15 reporting facilities\Branches.

Facility Name	Number of Reports
N M C SPECIALTY HOSPITAL LTD	124
NEW MEDICAL CENTRE SPECIALTY HOSPITAL LTD-ABU DHABI In-Patient Pharmacy	104
TAWAM HOSPITAL	97
MEDEOR 24X7 HOSPITAL IN-PATIENT PHARMACY	75
LLH HOSPITAL PHARMACY- LLC	70
N M C ROYAL HOSPITAL LTD	55
BURJEEL HOSPITAL IN-PATIENT PHARAMCY	53
BURJEEL HOSPITAL PHARMACY L.L.C.	52
AL AHLI HOSPITAL COMPANY INPATIENT PHARMACY LLC	46
AL AHLI HOSPITAL COMPANY LLC - BRANCH 1 INPATIENT PHARMACY	46
KANAD HOSPITAL In-Patient Pharmacy	46
MEDICLINIC PHARMACY - ALNOOR - BRANCH 1	44

Facility Name	Number of Reports
NMC ROYAL WOMENS HOSPITAL LTD In-Patient Pharmacy	41
PHOENIX HOSPITAL L.L.C. INPATIENT PHARMACY	38
BURJEEL MEDICAL CITY IN-PATIENT PHARMACY L.L.C	34

Limitations

Several limitations were noticed while preparing this report, this might lead to doubts regarding the data's utility and reduces the chances to detect safety signals. Each of these factors are discussed separately:

- *Missing data*: since this retrospective analysis is based on the healthcare facilities/professionals' reports of adverse drug reaction, some important data were often lacking in the reports. Missing data included indications, route of administration, concomitant drug administration, use of herbal products, and other relevant information regarding the patient's medications.

- *Inaccurate documentation*: was also noticed in the collected data, where inconsistent information could be found within the same report. 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 the manual filling of these missing data is time and effort consuming meanwhile it does not ensure accuracy all the time .

- *Unverified patient self-reports*: patients might have been unwilling to share certain information that they deemed sensitive.

- *Underreporting:* are still major challenges facing the pharmacovigilance program. A significant problem lies with under-reporting and biases inherent in clinicians' decisions to report ADRs. A range of factors have been found to contribute to under-reporting including lack of awareness on the purpose of ADR monitoring and how to report ADRs; uncertainty of reactions being caused by drugs; considering ADRs to be too common to report; and time constraints on clinicians.

- *Observed Association or Causal Association*: The terminology "association rather than causation" can be expressed literally when reviewing ADR data, since some ADRs signs and symptoms can be attributed and explained to patient's diseases rather than the drugs usage. The true question of interest is often whether taking the drug causes the event, which cannot be established solely because an association is observed. Observed association (the event occurs after taking the drug) is not equivalent to causal association (the event is caused by taking the drug).

Recommendations

- Pharmacovigilance endeavors to uphold the safety of medications and vaccines by facilitating the reliable and timely exchange of safety-related information, promoting pharmacovigilance initiatives within organizations, and encouraging participation in reporting to the Department of Health (DOH) pharmacovigilance team.

- The analysis of reported adverse drug reactions is crucial for monitoring the safety of medical products. The DOH Pharmacovigilance team is committed to supporting healthcare professionals in adhering to DOH reporting standards, streamlining reporting procedures, and enhancing data completeness. To achieve this, targeted strategies should be implemented, including simplifying reporting processes, providing clear guidelines, and conducting regular training sessions to emphasize accurate reporting and address any queries or concerns.

- Fostering collaboration and communication among healthcare professionals, patients, and regulators is paramount to safeguarding the quality and safety of medical products while maximizing their benefits. In addition to the collaboration between the Health Care Facilities Quality Division and Pharmacovigilance teams, incorporating pharmacovigilance reporting as a key performance indicator for healthcare facilities, underscores the obligation of all healthcare professionals to integrate pharmacovigilance principles into their daily practices and actively report suspected adverse drug reactions.

- Recognizing the significance of this data at regional, national, and global levels in ensuring medication safety further incentivizes healthcare professionals to report diligently. Healthcare professionals should remain vigilant in identifying potential adverse drug reactions, particularly with newly introduced medications, and advise patients to report any medication-related side effects promptly.

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