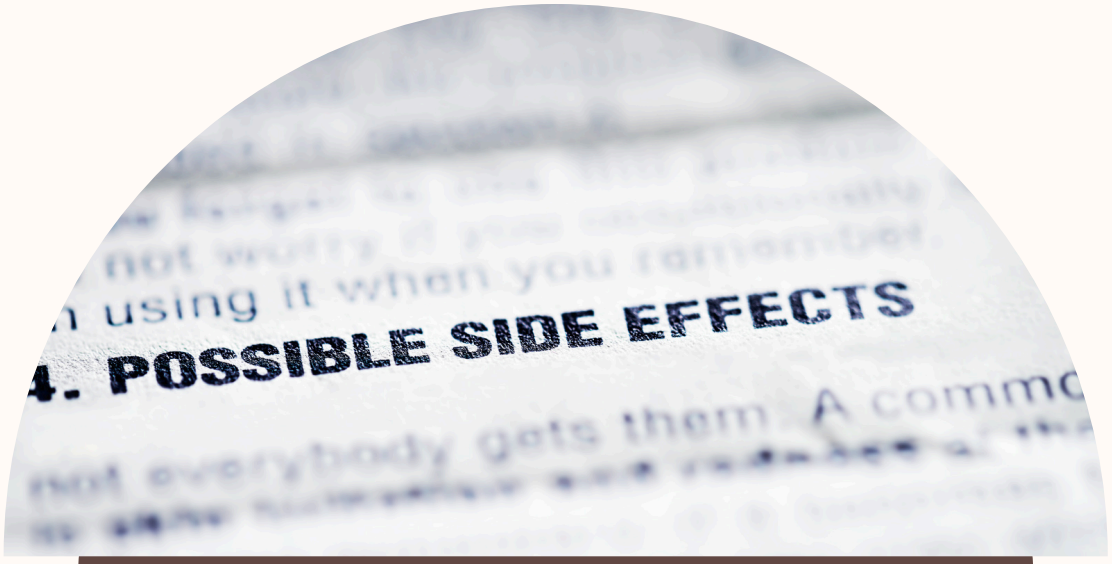
PHARMACOVIGILANCE QUARTERLY FEEDBACK REPORT



JULY - SEPTEMBER 2023 (Q2)

Ministry of Health and Social Services
Namibia Medicines Regulatory Council (NMRC)
Therapeutic Information and Pharmacovigilance Centre (TIPC)

FY 2023/2024

INTRODUCTION

The Namibia Medicines Regulatory Council (NMRC), established under the *Medicines and Related Substances Act (Act No. 13 of 2003)*, is entrusted with the responsibility of overseeing the regulation of medicines and related substances in the Namibian market. This oversight ensures that these products remain safe, effective, and of high quality both at the time of authorization and throughout their shelf life.

The Therapeutics Information and Pharmacovigilance Centre (TIPC) functions as the administrative and technical arm of the Council, tasked with carrying out pharmacovigilance duties to guarantee the safe and rational utilization of medicines. As part of a feedback mechanism, the TIPC regularly shares quarterly reports with stakeholders, encouraging them to report any adverse events.

The purpose of this report is to provide an update on the adverse events reported during the **second quarter** of the 2023/2024 financial year. During this quarter, a total of **194** reports were received.

ABBREVIATIONS

PV	Pharmacovigilance
AEFI	Adverse Events Following Immunization
ADR	Adverse Drug Reaction
AE	Adverse Event

STATISTICS

REPORT TYPE

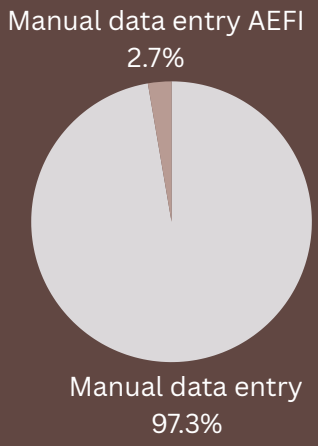


Figure 1: Report type

Of the total number reported, 5 reports (2.7%) were adverse events following immunization (AEFI) and 189 reports (97.3%) were adverse events (AEs) from medicinal product that are non-vaccine medicines.

PROFESSION

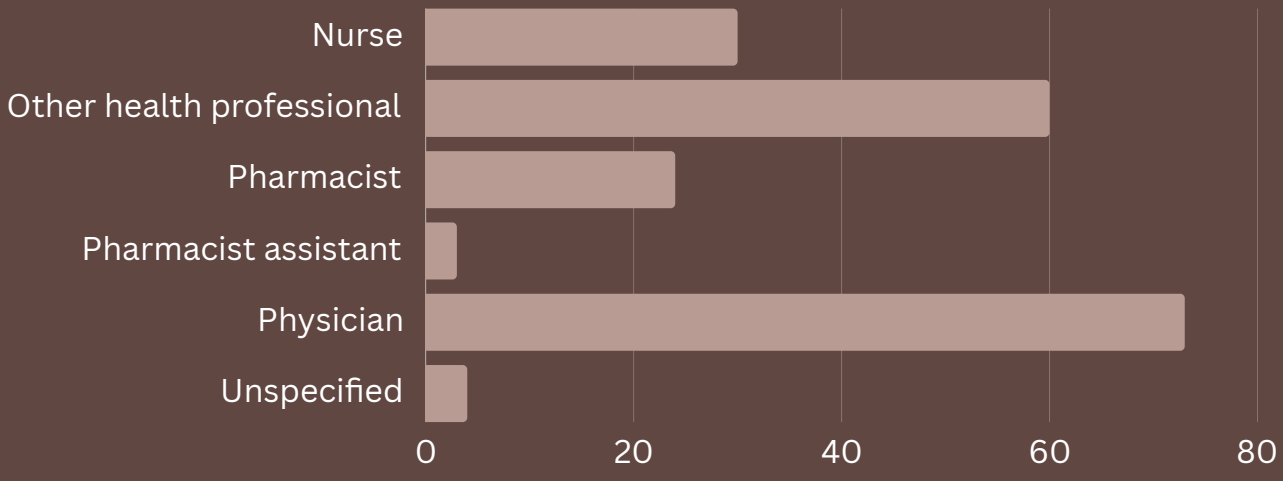


Figure 2: Number of reports received by profession

Majority of the reports received were from physicians (37.6%), followed by other healthcare professionals (30.9%) and nurses (15.5%).

HEALTH FACILITY

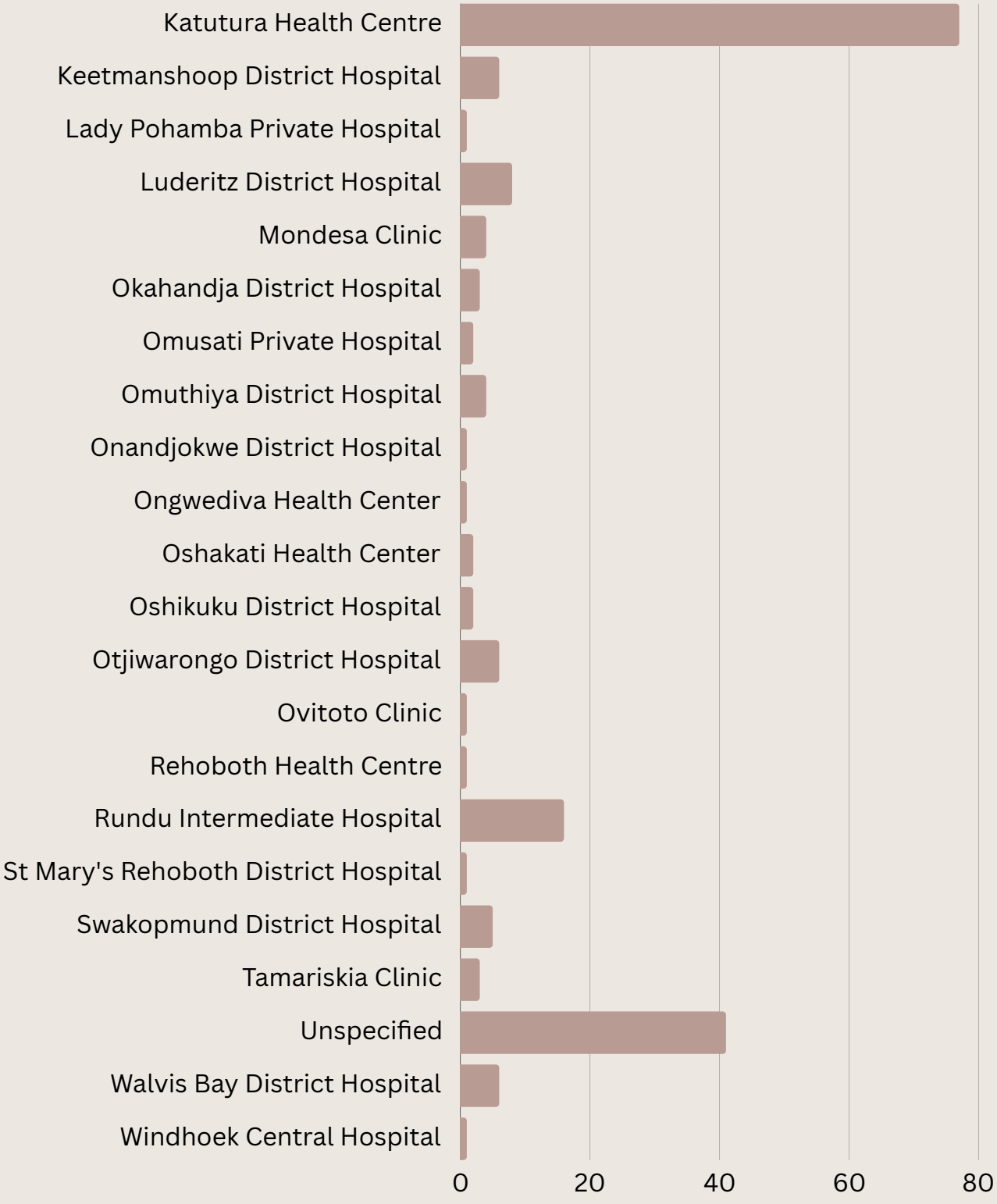


Figure 3: Number of reports received by health facility

Majority of the reports received were from Katutura Health Centre (39.69%), followed by Rundu Intermediate Hospital (8.25%) and Luderitz District Hospital (4.12%).

REGION

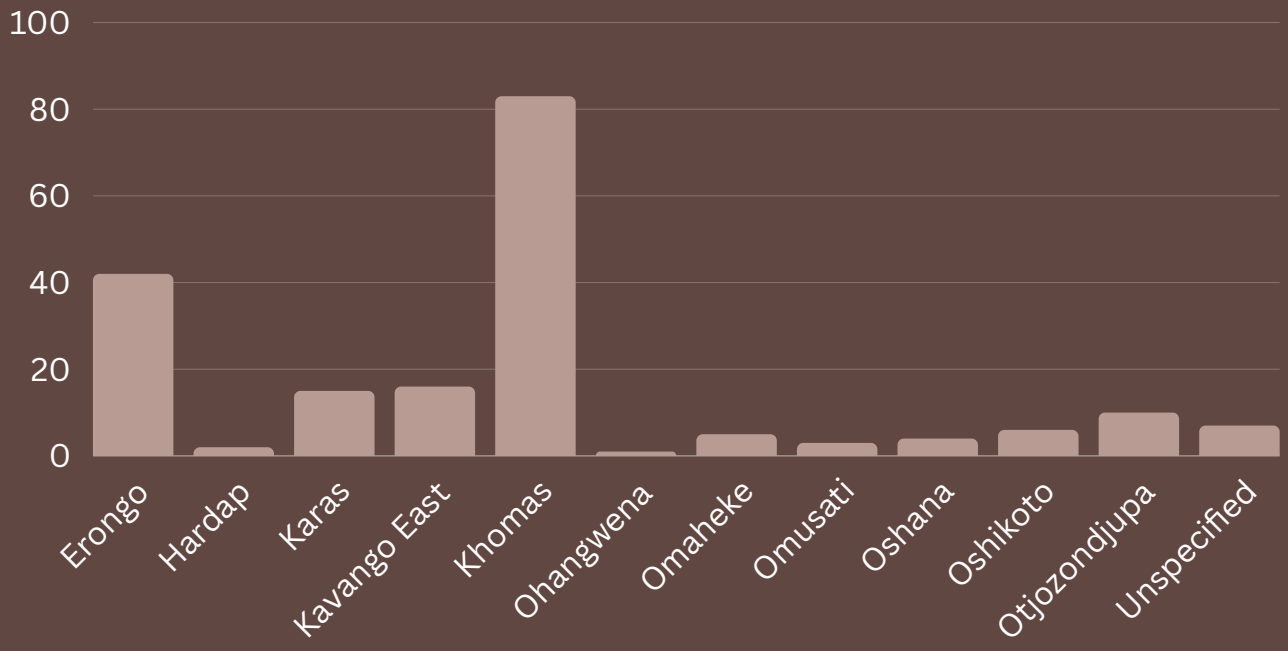


Figure 4: Number of reports received by region

AE reports were received from 11 out of the 14 regions in Namibia. The majority of reports were from the Khomas region (42.78%), followed by the Erongo region (21.65%) and the Kavango East region (8.25%).

SEX

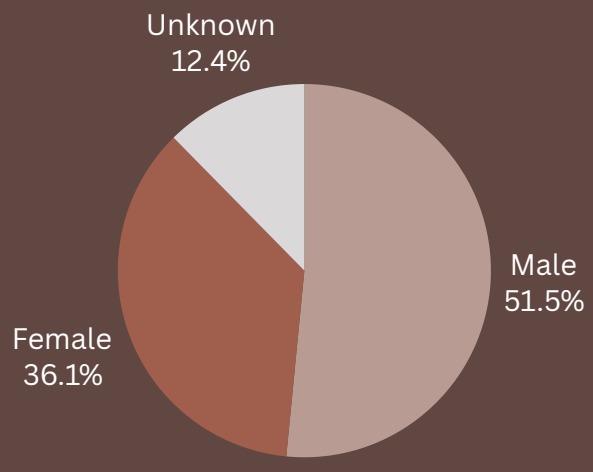


Figure 5: Number of reports received by sex

The incidence of reported AEs was greater among males (51.5%) than females (36.1%).

AGE GROUP

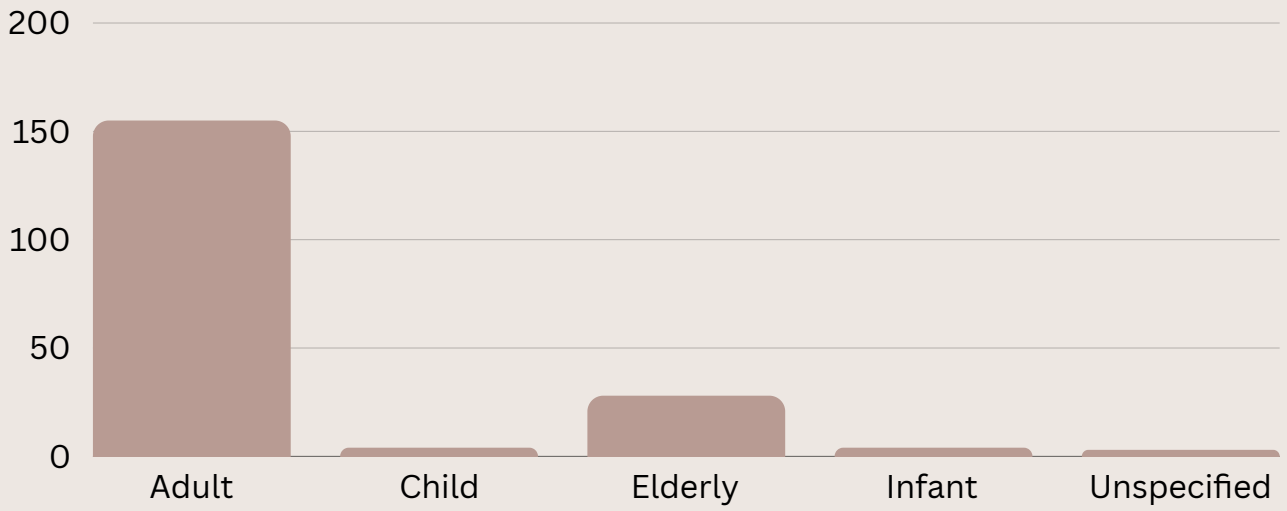


Figure 6: Number of reports received by age group

The occurrence of adverse events was most prominent among the adult age group (79.90%), followed by the elderly (14.43%), and then children and infants (2.06%).

SERIOUSNESS AND REASON FOR SERIOUSNESS

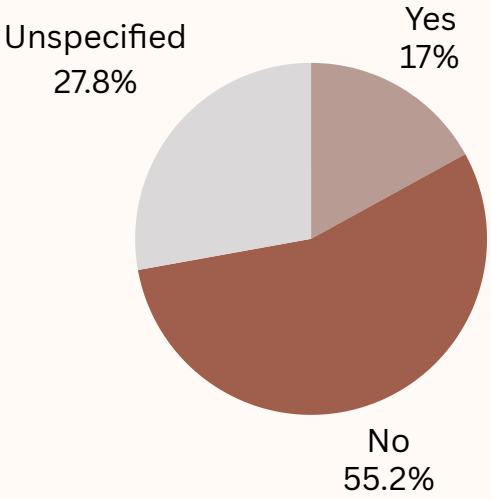


Figure 7: Seriousness of reported AEs

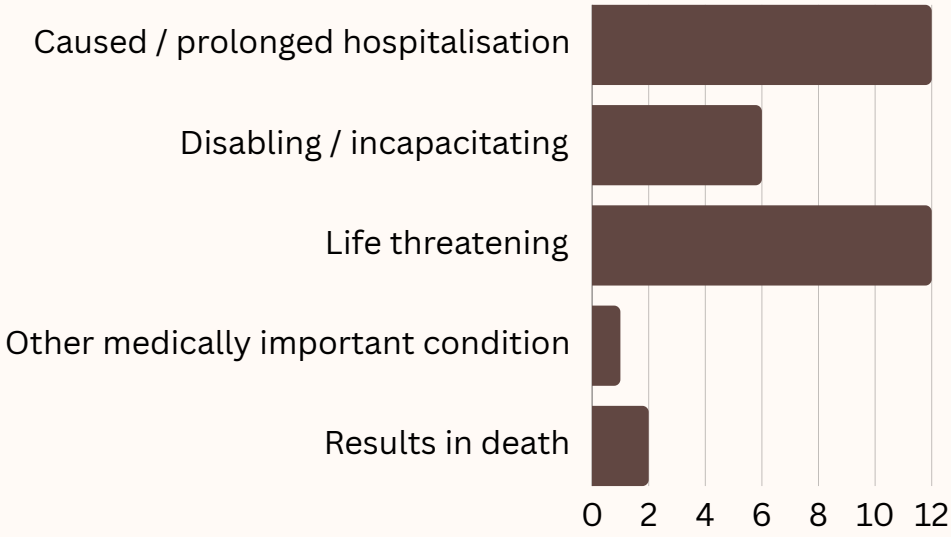


Figure 8: Reason for seriousness of reported AEs

Out of all the AE reports received, 55.2% were labeled as non-serious, 17% were labeled as serious, and the remaining reports did not specify the seriousness of the AE. Twelve (12) reports indicated hospitalization as the reason for seriousness, another twelve (12) indicated the AE as life-threatening, and six (6) reports mentioned it as causing disability or incapacitation.

COMMONLY REPORTED AES

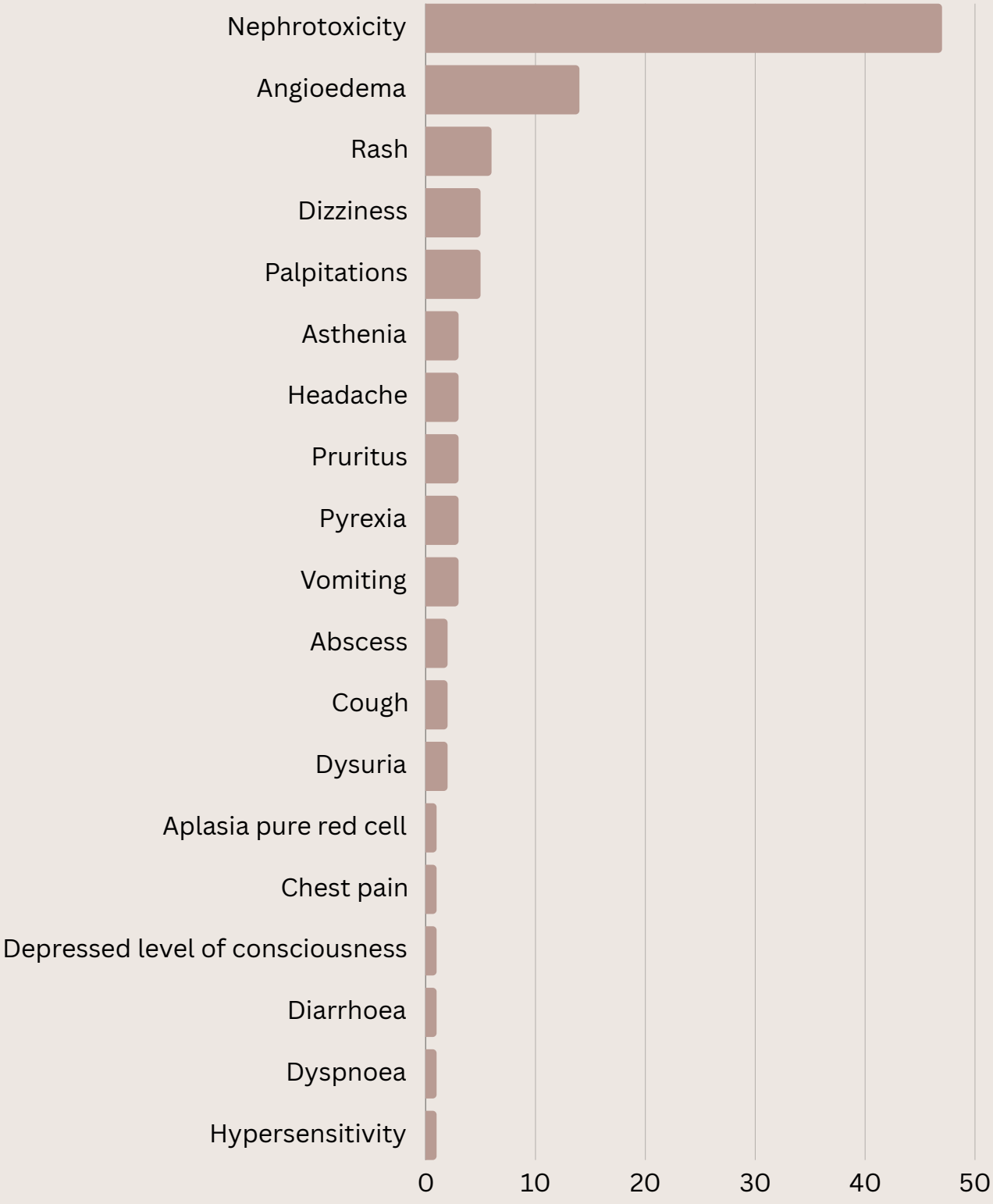


Figure 9: Common AEs reported

The AEs most frequently reported were nephrotoxicity (38.84%), angioedema (11.57%), and rash (4.98%).

THERAPEUTIC CLASS

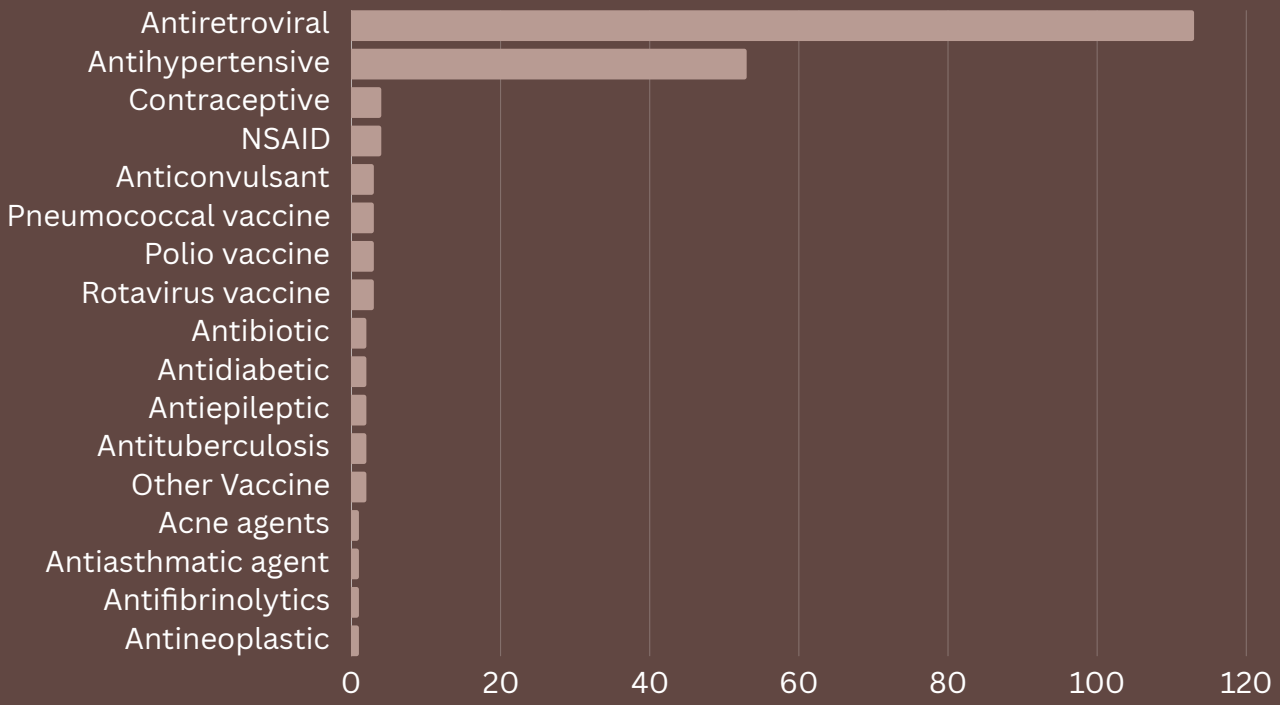


Figure 10: Number of reports by therapeutic class

The most frequently implicated therapeutic classes suspected of causing a high number of AEs were antiretroviral agents (54.85%), followed by antihypertensives (25.73%), and contraceptives (1.94%).

OUTCOME

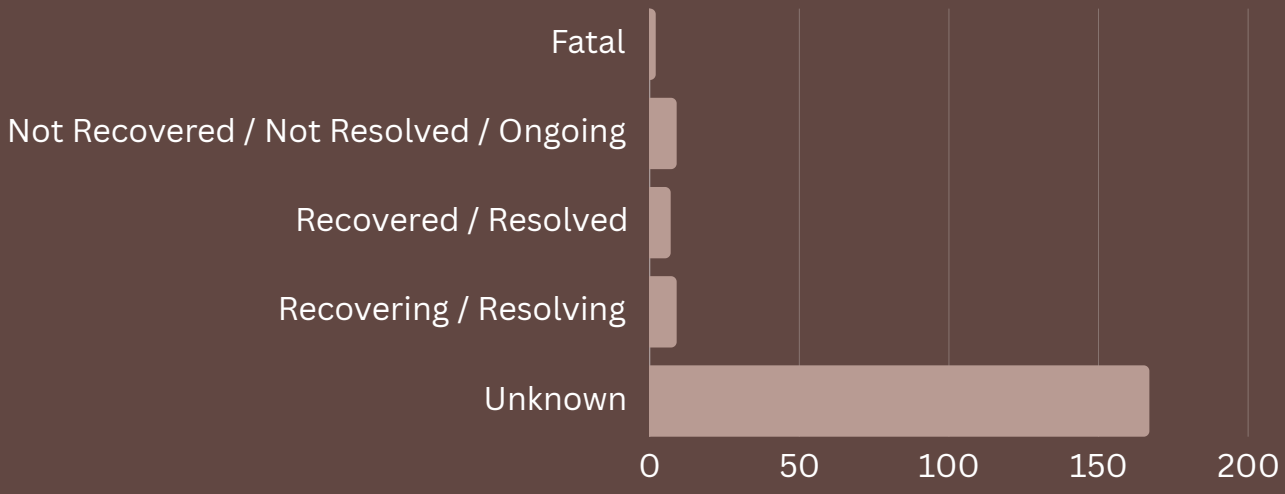


Figure 11: Number of reports by outcome

The outcome for the majority of reported AEs was unspecified (86.08%). In 4.64% of cases, the AEs were not recovered/not resolved/ongoing. For another 4.64% of reported AEs, the outcome was recovering/resolving, and for 3.61%, the outcome was recovered/resolved.

ACKNOWLEDGEMENT

THANK YOU!

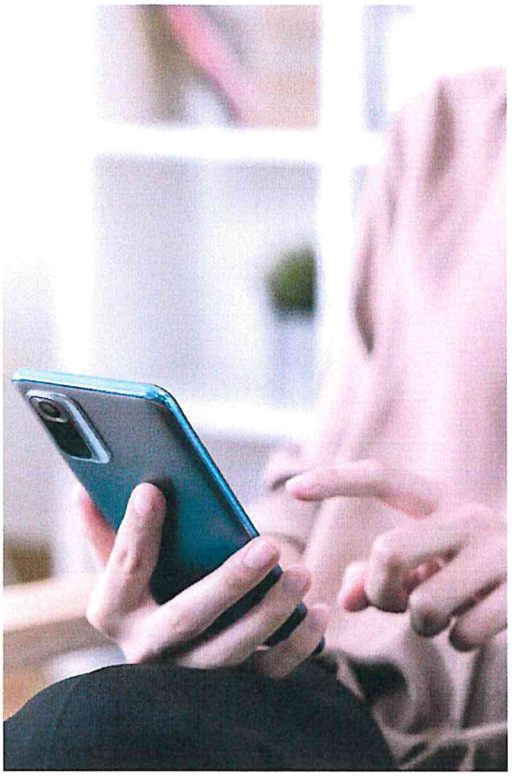
TIPC extends its sincerest gratitude to all the healthcare professionals for your unwavering dedication and invaluable contributions to the national medicines safety monitoring system (i.e. pharmacovigilance) through your vigilant reporting of suspected adverse events (AEs). Your commitment to pharmacovigilance not only ensures the safety and well-being of countless individuals but also plays a crucial role in advancing healthcare practices and safeguarding public health.

WELL DONE!

Congratulations to the top three regions and healthcare facilities for their outstanding dedication in submitting a significant number of reports. Your commitment to pharmacovigilance is truly commendable and plays a vital role in ensuring the safety of patients nationwide. Keep up the excellent work!

Top three regions: Khomas, Erongo, Kavango East

Top three healthcare facilities: Katutura Health Centre, Rundu Intermediate Hospital, Luderitz District Hospital



STAY IN TOUCH WITH US

You are welcome to contact TIPC for any inquiries related to medications, and we encourage you to promptly inform us of any adverse events.
Below are our contact details for your reference.

Phone Number	**061 203 2468**
Email Address	**info.TIPC@mhss.gov.na**
WhatsApp Number	**+264 81 146 5406**
e-Reporting link	**https://primaryreporting.who-umc.org/NA**
Office Address	**15 Ruhr Street, Northern Industrial Area, Windhoek, Namibia**

e-Reporting QR code

Fransina Nambahu
REGISTRAR OF MEDICINES