



Pharmacovigilance Quarterly Feedback Report

April - June 2023
(Q1)

FY 2023/2024

Ministry of Health and Social
Services

Namibia Medicines Regulatory
Council (NMRC)

Therapeutic Information and
Pharmacovigilance Centre (TIPC)

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 first quarter of the 2023/24 financial year. During this quarter, a total of **104** reports were received.

Abbreviations

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

Statistics

REPORT TYPE

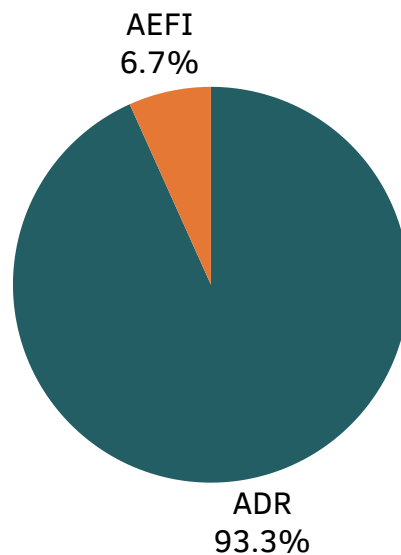


Figure 1: Report type

Of the total number reported, 7 reports (7%) were adverse events following immunization (AEFI) and 97 reports (93%) were adverse events (AEs) from medicinal product that are non-vaccine medicines.

This report will mostly focus on the adverse events (AEs) from non-vaccine medicines.

PROFESSION

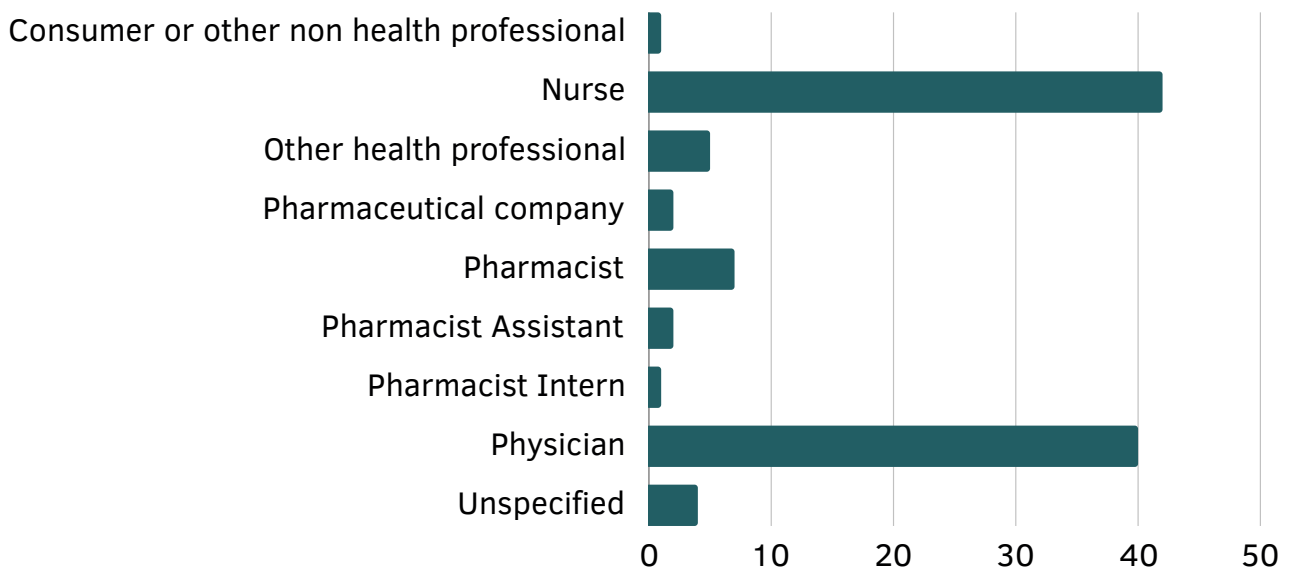


Figure 2: Number of reports received by profession

Majority of the reports received were from nurses (40.38%), followed by physicians (38.46%) and pharmacists (6.73%).

HEALTH FACILITY

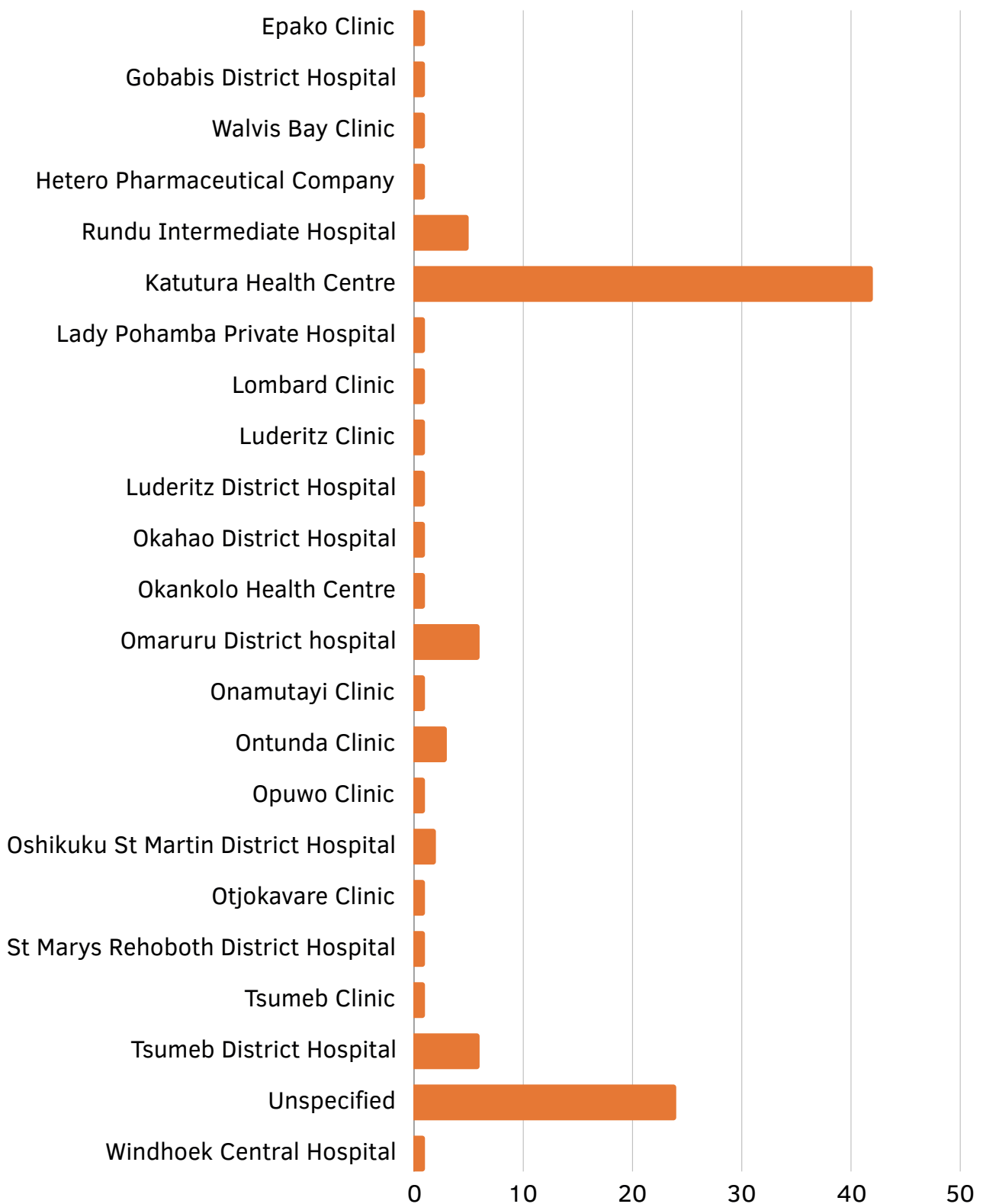


Figure 3: Number of reports received by health facility

Majority of the reports received were from Katutura Health Centre (40.38%), followed by Omaruru District Hospital and Tsumeb District Hospital (5.77%).

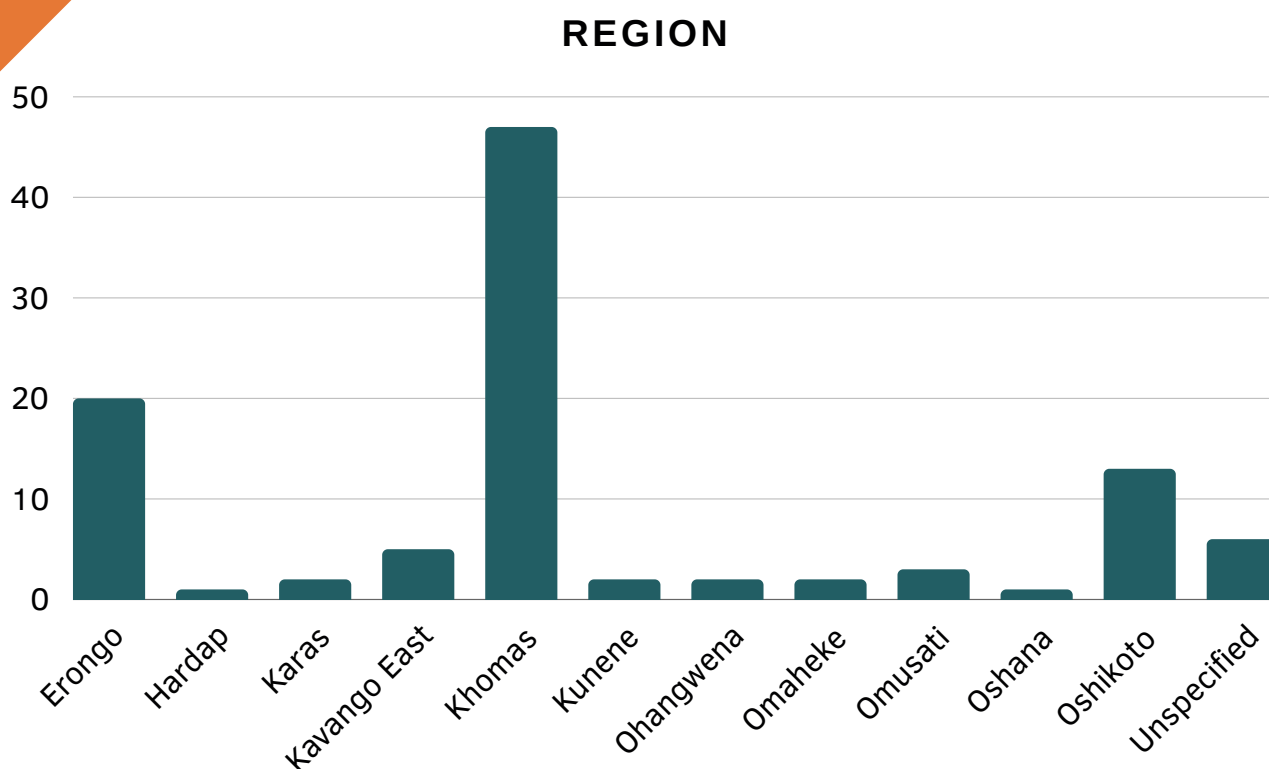


Figure 4: Number of reports received by region

AE reports were received from 11 out of the 14 regions in Namibia. Majority of the reports received were from Khomas region (45.19%), followed by Erongo region (19.23%) and Oshikoto region (12.50%).

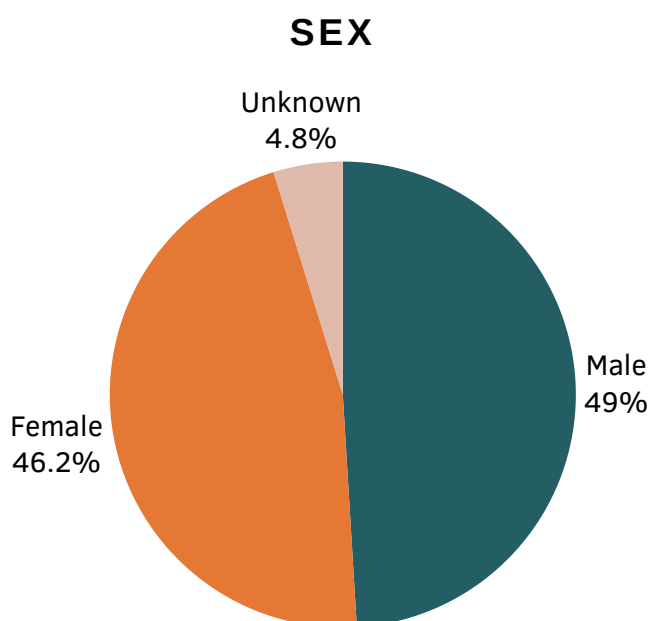


Figure 5: Number of reports received by sex

The frequency of reported AE was higher in males (49.04%) compared to females (46.15%).

AGE GROUP

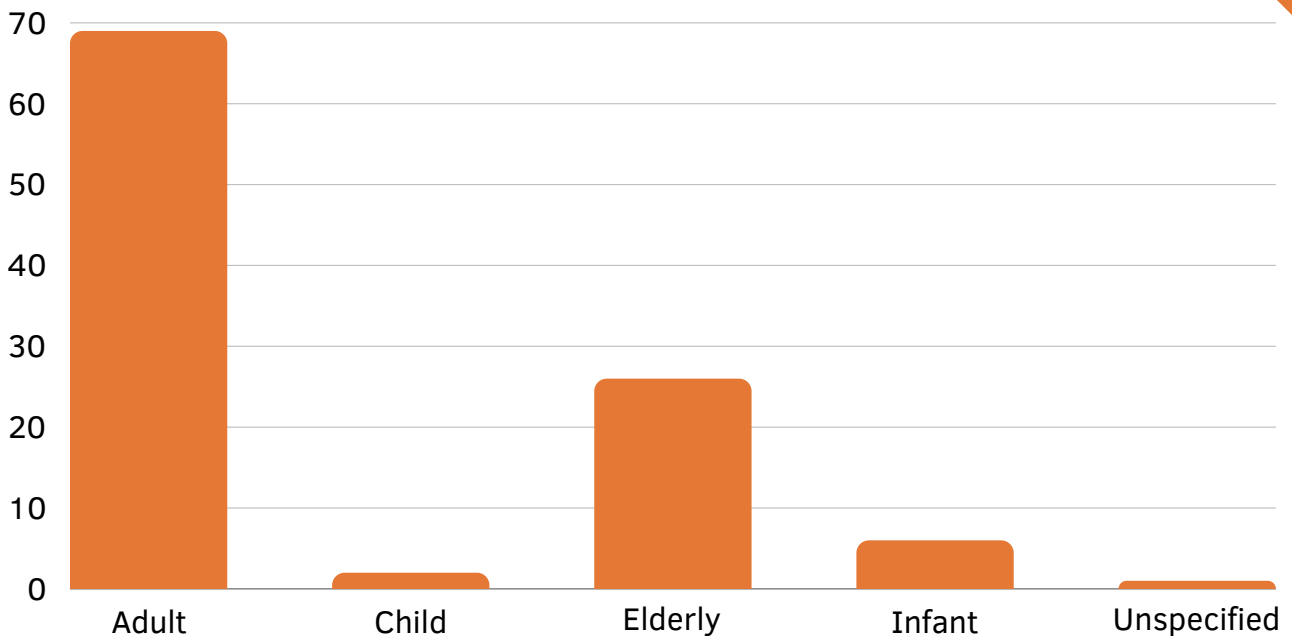


Figure 6: Number of reports received by age group

The incidence of AEs was highest amongst the adult age group (66.35%), followed by the elderly (25%) and then the infants (5.77%).

SERIOUSNESS & REASON FOR SERIOUSNESS

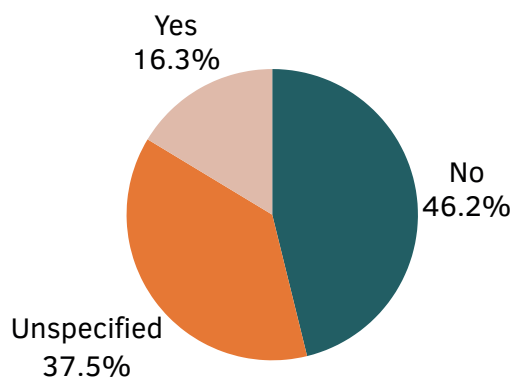


Figure 7: Seriousness of reported AEs

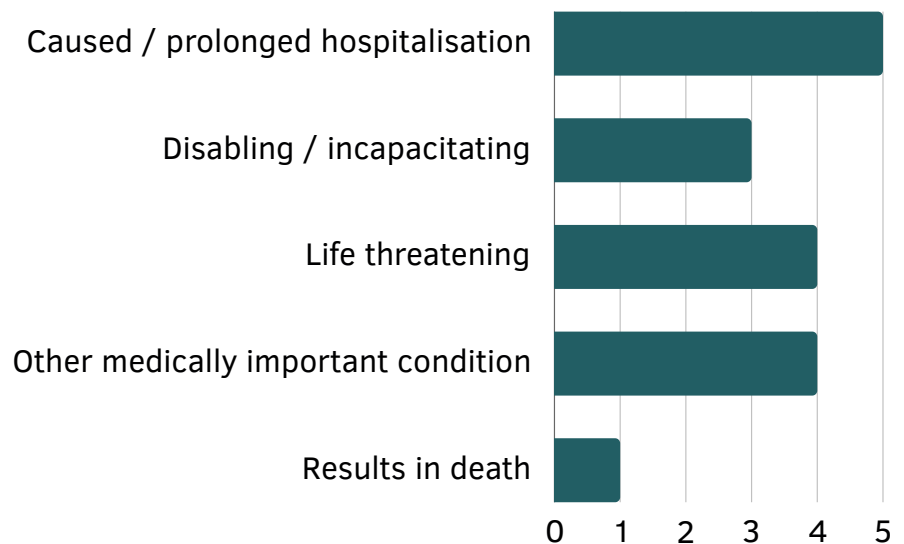


Figure 8: Reason for seriousness of reported AEs

Of the total AE reports received, 46.15% were classified as non-serious and 16.35% were classified as serious. Five (5) reports indicated the reason for seriousness as caused/prolonged hospitalization, four (4) indicated other medically important conditions and four (4) indicated life threatening.

COMMONLY REPORTED AES

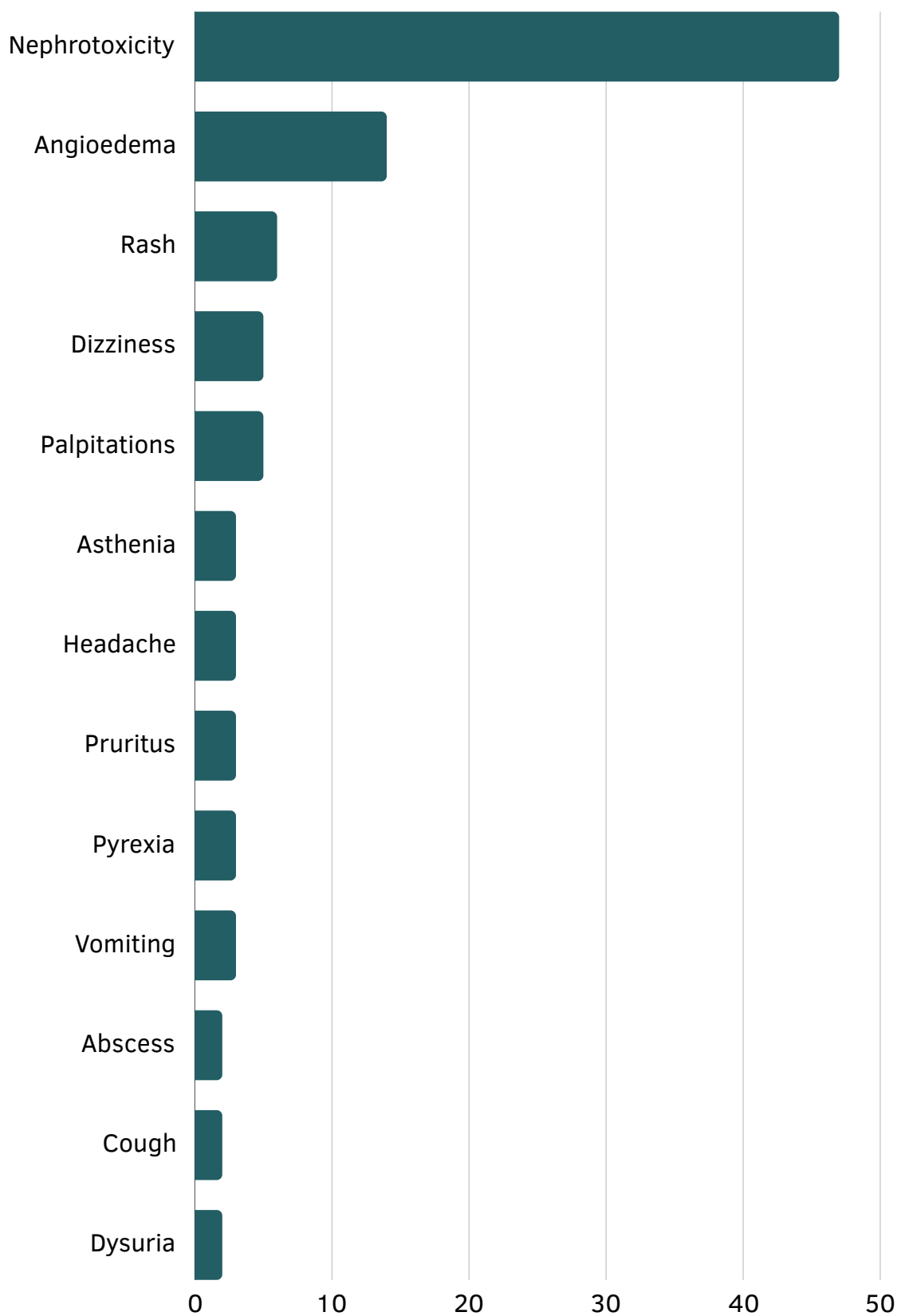


Figure 9: Common AEs reported

Most commonly reported AEs were nephrotoxicity (30.58%), angioedema (11.57%) and toxicity to various agents (8.26%).

THERAPEUTIC CLASS

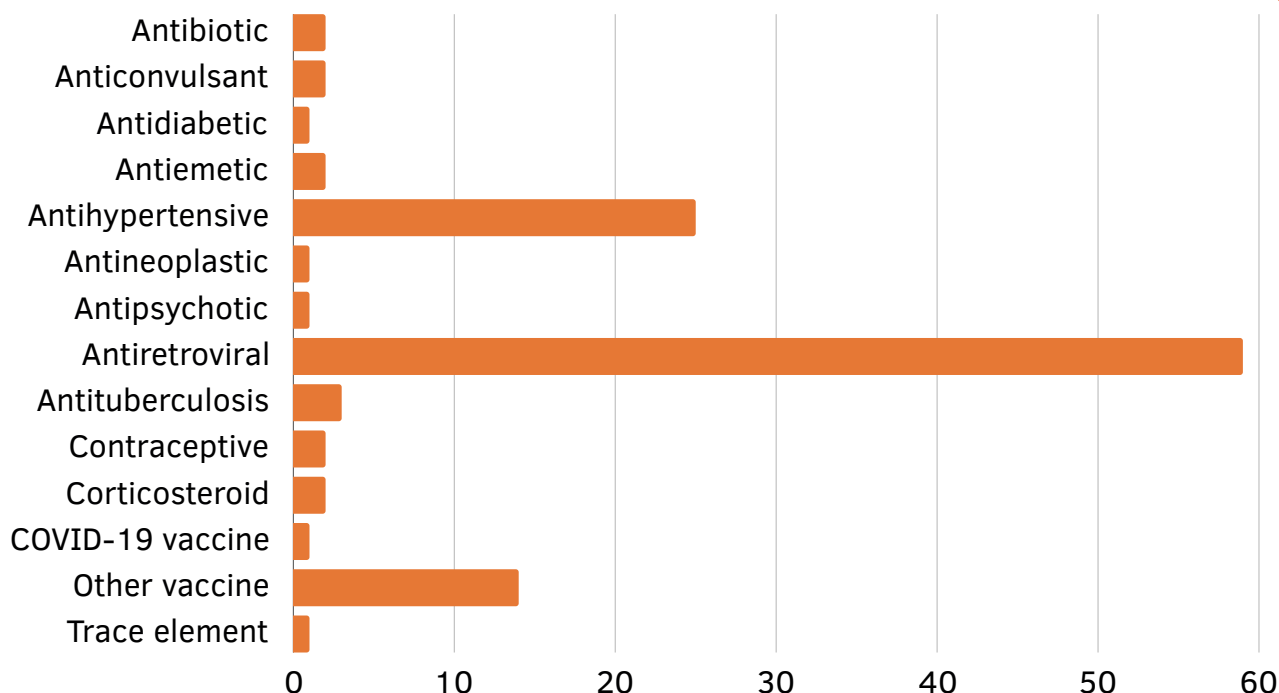


Figure 10: Number of reports by therapeutic class

The antiretroviral agents (50.86%), followed by antihypertensives (21.55%) and other vaccines (12.07%) were the top reported therapeutic classes suspected to have caused a high number of the AEs.

OUTCOME

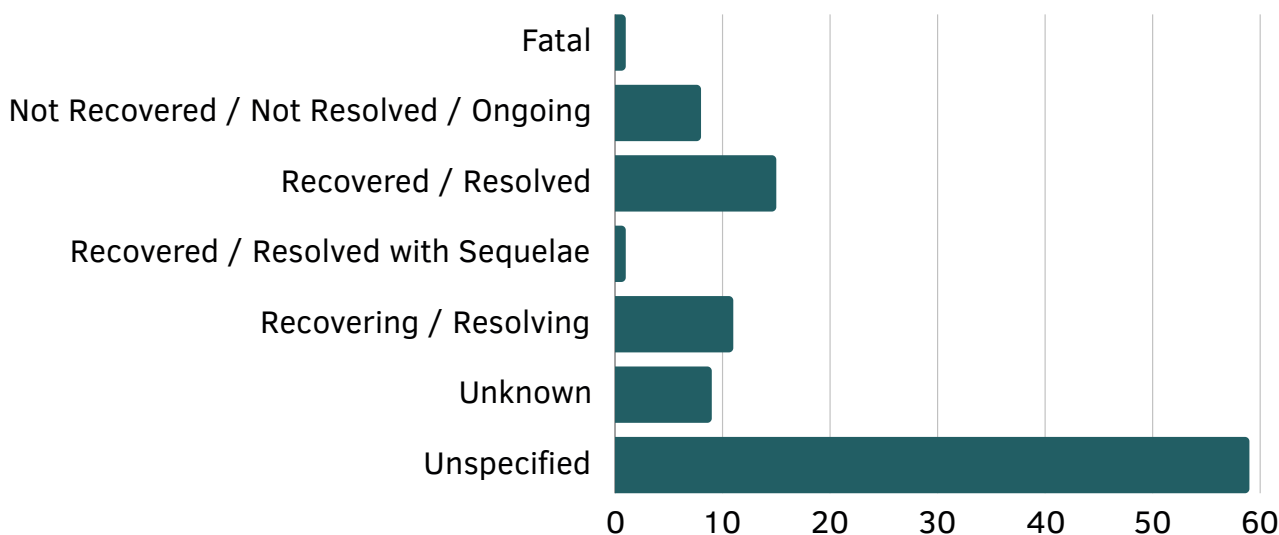


Figure 11: Number of reports by outcome

The outcome for most of the reported AEs were unspecified (56.73%), 14.42% of the reported AEs were recovered/resolved, and for 10.58% of the reported AEs the outcome was recovering/resolving.

Thank You

The TIPC team expresses gratitude to healthcare professionals for their ongoing contributions to the National Medicines Safety Monitoring System (Pharmacovigilance) through the reporting of suspected adverse events (AEs). Congratulations to the top three regions and the top three health facilities that have submitted a significant number of reports. Well done!



Top 3 regions:

Khomas
Erongo
Oshikoto

Top 3 health facilities:
Katutura Health Centre
Omaruru District Hospital
Tsumeb District Hospital



WELL DONE

Please feel free to reach out to TIPC with any inquiries related to medications, and please promptly notify TIPC of any adverse events through email, fax2mail, or e-Reporting. We value your input and welcome your thoughts or suggestions on enhancing our feedback reports. To share your feedback, please click on the link below.

<https://forms.gle/DHkTkAnk6uFhxZRQA>



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e-Reporting QR code



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