



FY2023/2024

PHARMACOVIGILANCE **QUARTERLY FEEDBACK REPORT** **OCT - DEC 2023 (Q3)**

MINISTRY OF HEALTH AND SOCIAL SERVICES

Namibia Medicines Regulatory Council (NMRC)

Therapeutic Information and Pharmacovigilance Centre (TIPC)

TIPC

INTRODUCTION

The Namibia Medicines Regulatory Council (NMRC), established in accordance with the *Medicines and Related Substances Act (Act No. 13 of 2003)*, is responsible for overseeing the regulation of medicines and related substances in the Namibian market. This oversight ensures the safety, efficacy, and quality of these products both upon authorization and throughout their shelf life.

The Therapeutics Information and Pharmacovigilance Centre (TIPC) serves as the administrative and technical arm of the Council, with the mandate to conduct pharmacovigilance activities to ensure the safe and rational use of medicines. As part of its feedback mechanism, the TIPC regularly disseminates quarterly reports to 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 **third (3rd) quarter of the 2023/2024 financial year**. In this quarter, a total of **255 reports** adverse events were received.

ABBREVIATIONS

PV	Pharmacovigilance
AEFI	Adverse Events Following Immunization
ADR	Adverse Drug Reactions
AE	Adverse Events



STATISTICS

DATA REPORT

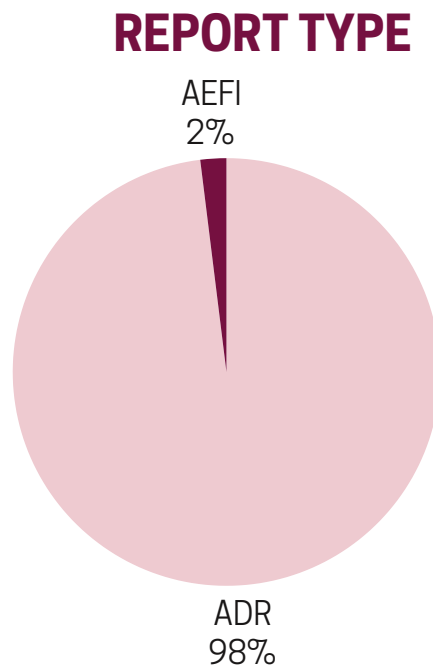


Figure 1: Report type

Out of the total number of reported cases, 5 reports (2%) were adverse events following immunization (AEFI), while 250 reports (98%) were adverse events (AEs) related to medicinal products other than vaccines.

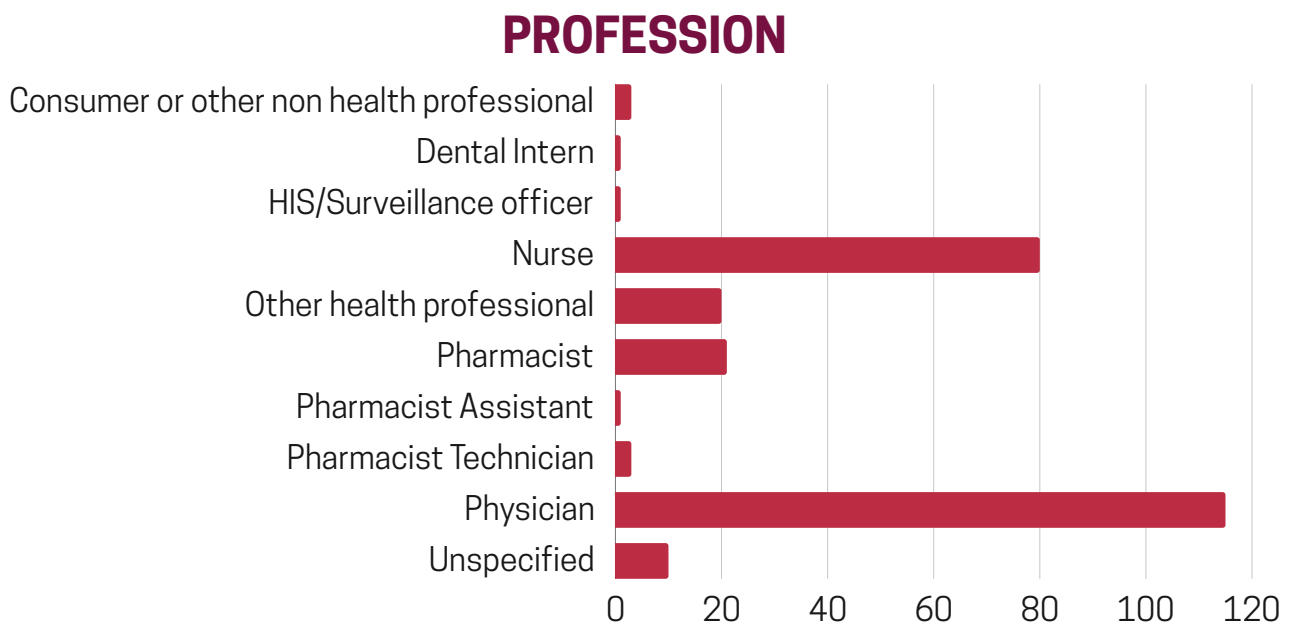


Figure 2: Number of reports received by profession

The majority of received reports came from physicians (45%), followed by nurses (31%), and pharmacists (8%).

HEALTH FACILITY

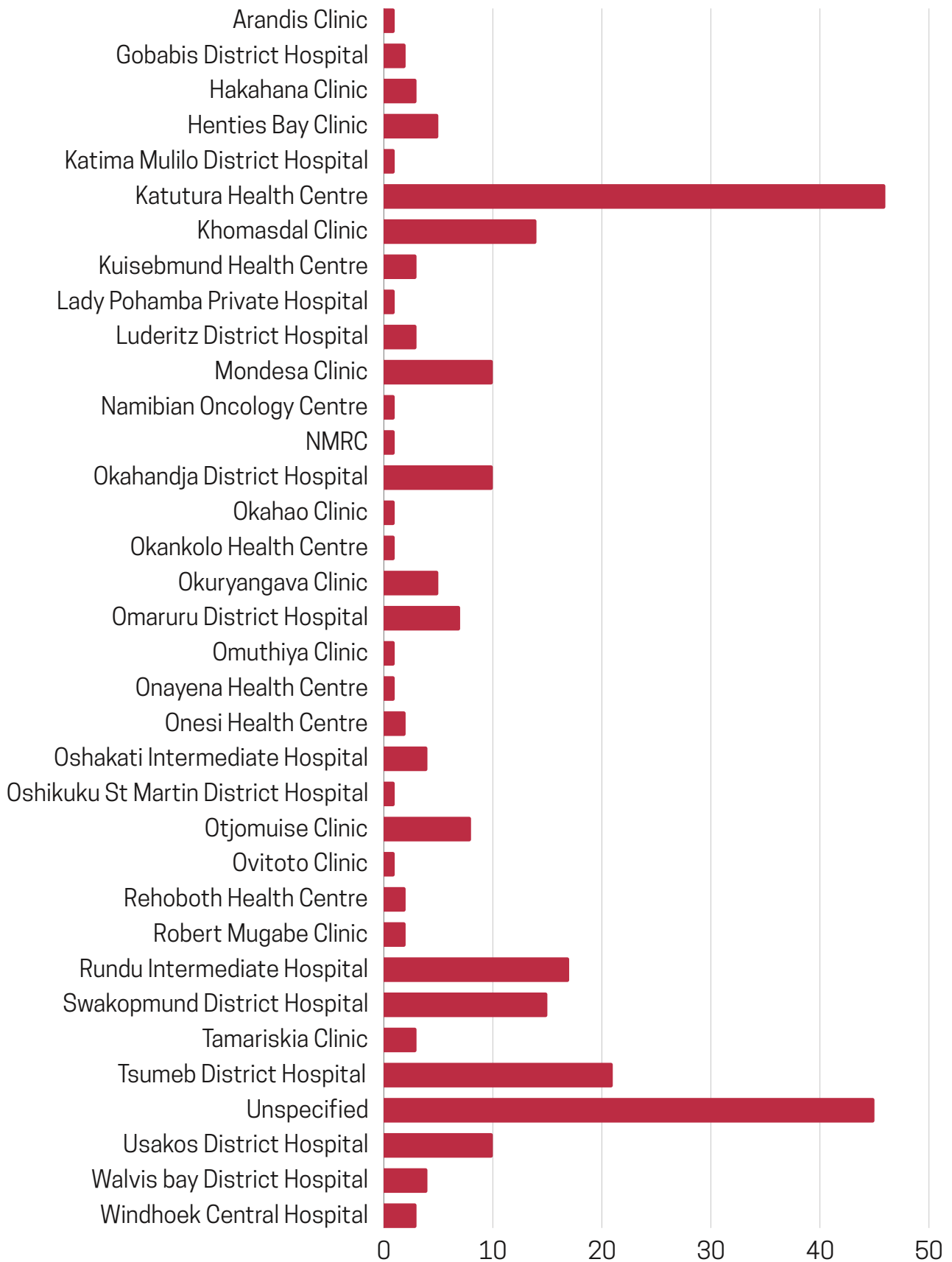


Figure 3: Number of reports received by health facility

The majority of the reports were received from Katutura Health Centre (18%), followed by Tsumeb District Hospital (8%) and Rundu Intermediate Hospital (7%).

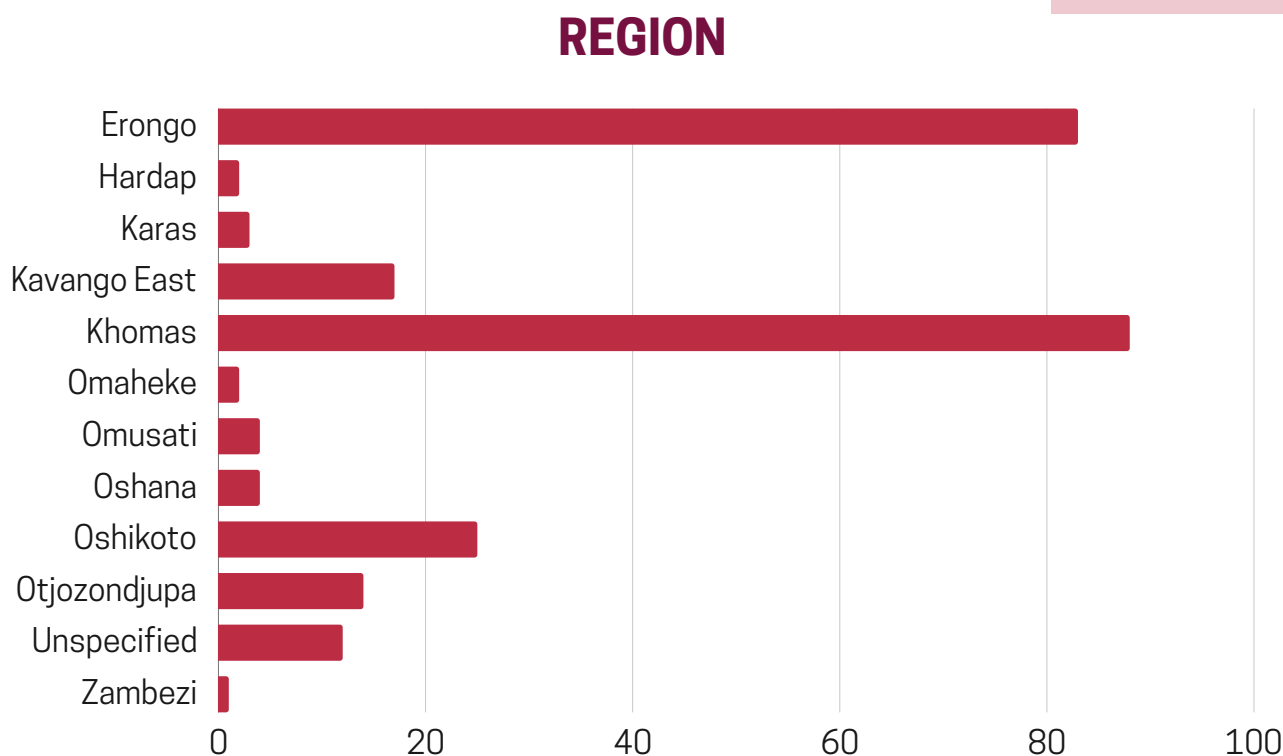


Figure 4: Number of reports received by region

Adverse event reports were received from 11 out of the 14 regions in Namibia. Most of the reports came from the Khomas region (35%), followed by the Erongo region (33%) and the Oshikoto region (10%).

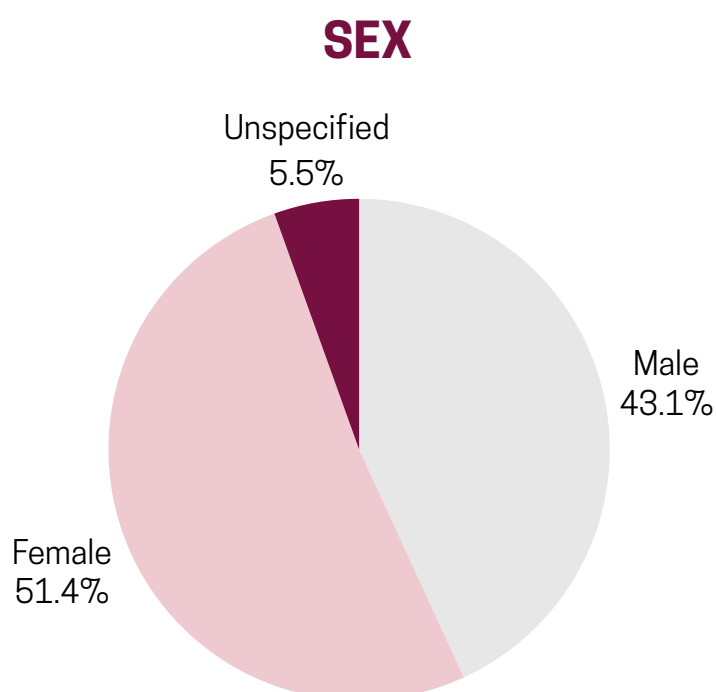


Figure 5: Number of reports received by sex

The incidence of reported adverse events was higher among females (51.4%) compared to males (43.1%).



AGE GROUP

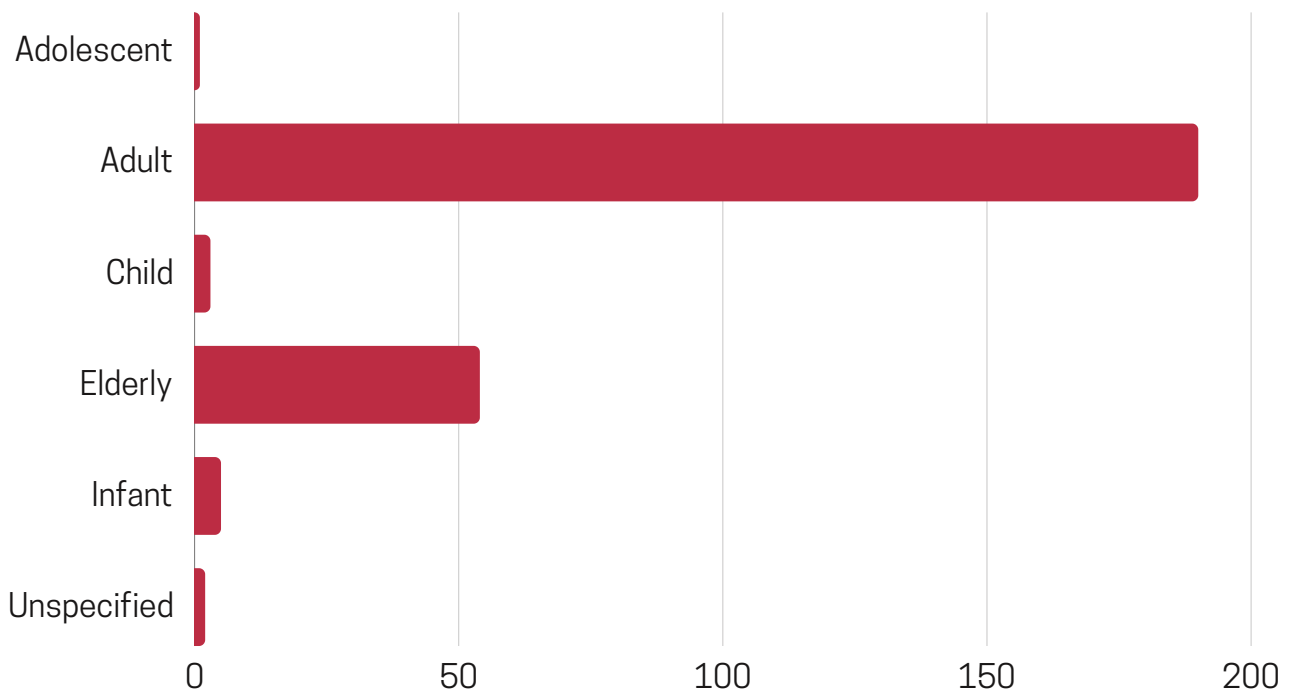


Figure 6: Number of reports by age group

Adverse events were most prevalent in the adult age group (75%), followed by the elderly (21%) and infants (2%).

SERIOUSNESS AND REASON FOR SERIOUSNESS

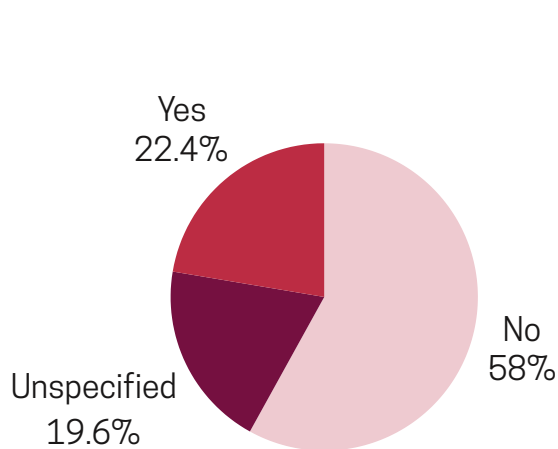


Figure 7: Seriousness of reported AEs

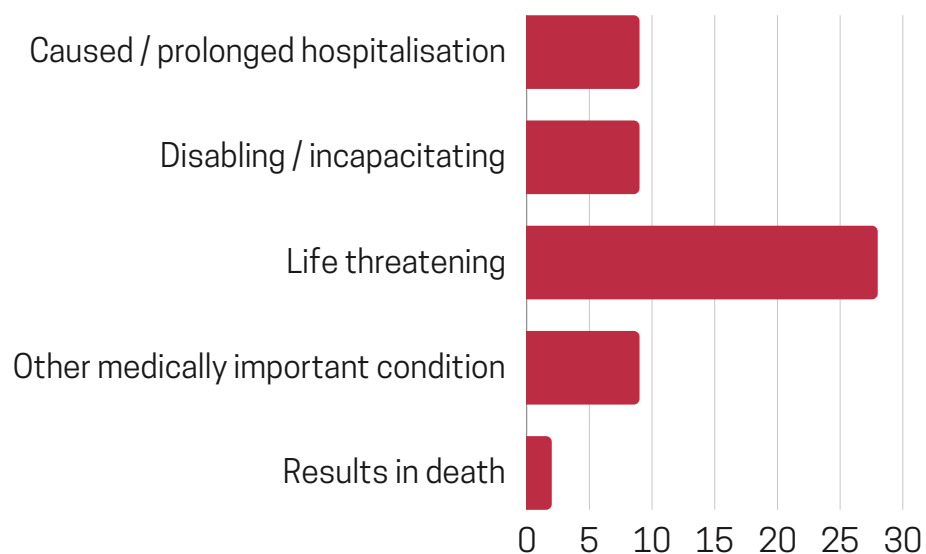


Figure 8: Reason for seriousness of serious reported AEs

Among all the AE reports received, 58% were classified as non-serious, 22.4% as serious, and the remaining reports did not specify the severity of the AE. Of the serious AEs, 28 reports cited life-threatening conditions, nine indicated hospitalization, and another nine mentioned disability or incapacitation as the reasons for seriousness.

COMMONLY REPORTED AES

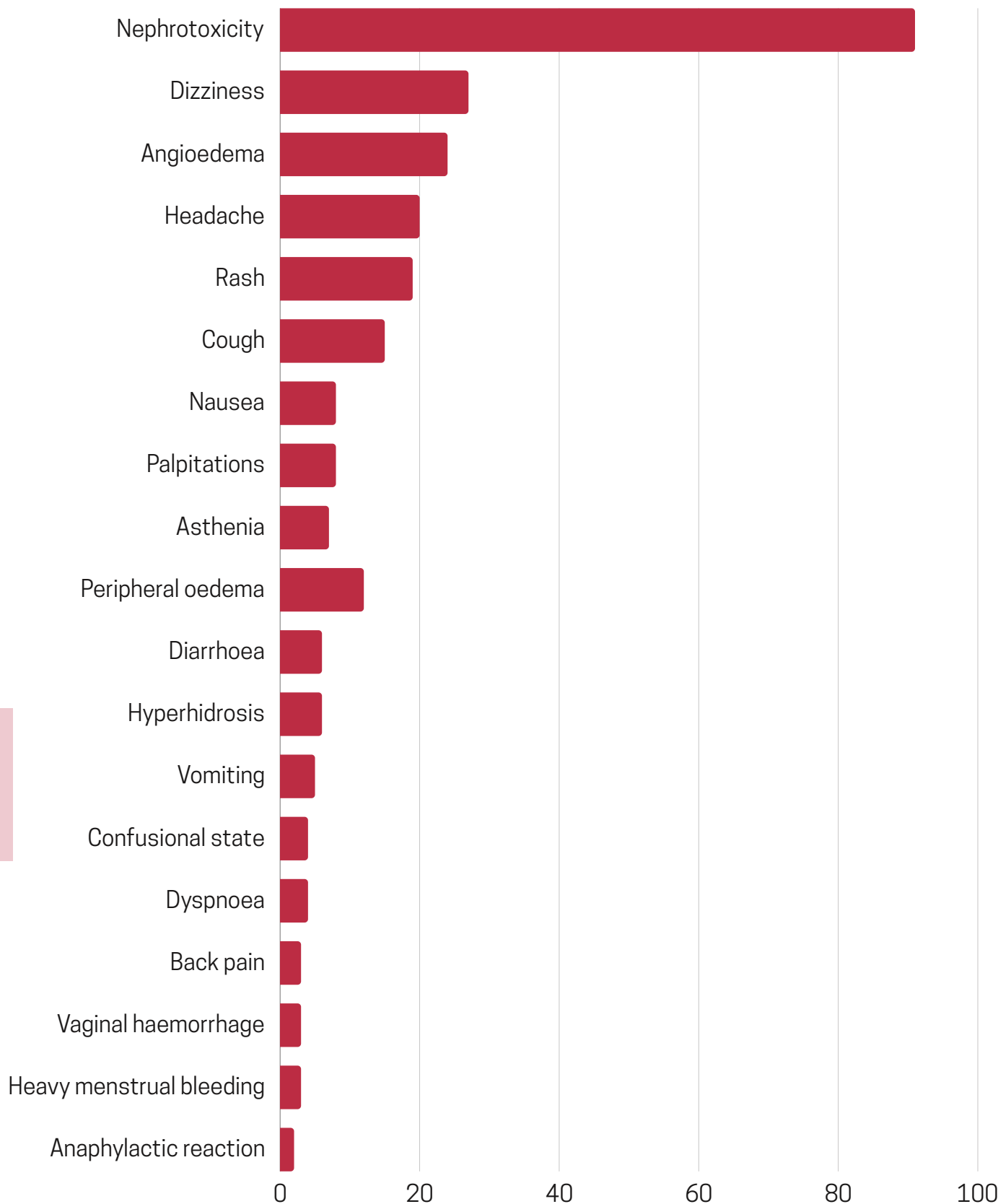


Figure 9: Common AEs reported

The most frequently reported AEs were nephrotoxicity (31.71%), dizziness (9.41%), and angioedema (8.36%).



THERAPEUTIC CLASS

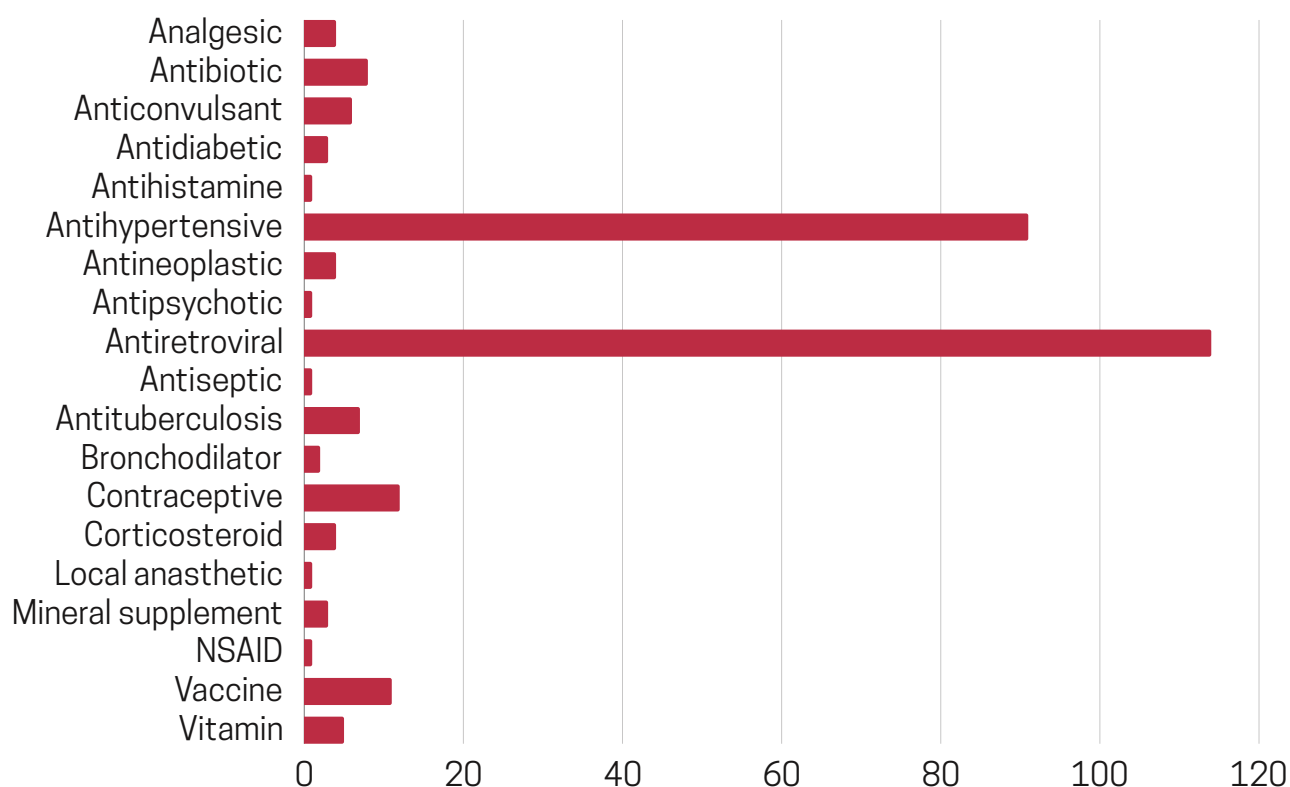


Figure 10: Number of reports received by therapeutic class

The therapeutic classes most frequently suspected of causing a high number of AEs were antiretroviral agents (41%), followed by antihypertensives (33%), and contraceptives (4%).

OUTCOME

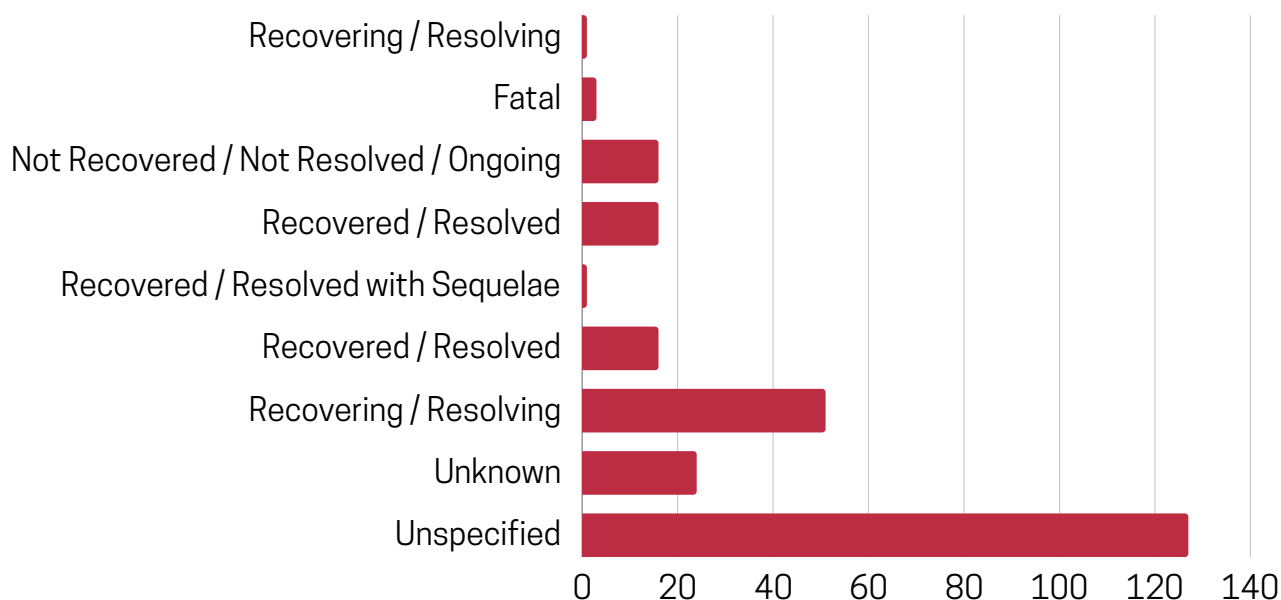


Figure 11: Number of reports by outcome

The outcome for most reported AEs was unspecified (50%). In 20% of cases, the AEs were recovering/resolving. The outcome was unknown for 9% of reported AEs, while 6% had recovered/resolved.

ACKNOWLEDGEMENT & APPRECIATION

A heartfelt thank you to all healthcare professionals for your unwavering dedication, support, and invaluable contributions to pharmacovigilance. Your commitment is truly appreciated and plays a crucial role in ensuring medication safety and improving healthcare practices. TIPC extends its deepest gratitude for your ongoing efforts in safeguarding public health.

WELL DONE!!

Congratulations to the top three regions and the top three healthcare facilities for their outstanding achievement in submitting a significant number of reports. Your dedication and proactive approach to pharmacovigilance are commendable and greatly contribute to medication safety and public health. Keep up the excellent work!

Top three regions:

1. Khomas
2. Erongo
3. Oshikoto

Top three healthcare facilities:

1. Katutura Health Centre
2. Tsumeb District Hospital
3. Rundu Intermediate Hospital



CONTACT US

Feel free to reach out to TIPC for any inquiries regarding medications, and we strongly encourage you to promptly notify us of any adverse events. Please find our contact details below for your reference.



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e-Reporting link

<https://primaryreporting.who-umc.org/NA>



e-Reporting QR code

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REGISTRAR OF MEDICINES