



PHARMACOVIGILANCE FEEDBACK REPORT

OCTOBER - DECEMBER 2022 (Q3)

FY 2022/2023

MINISTRY OF HEALTH AND SOCIAL SERVICES

NAMIBIA MEDICINES REGULATORY COUNCIL (NMRC)

**THERAPEUTIC INFORMATION AND
PHARMACOVIGILANCE CENTRE (TIPC)**

INTRODUCTION

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The Namibia Medicines Regulatory Council (NMRC) as established by the Medicines and Related Substances Control Act (Act No. 13 of 2003) has the mandate to regulate medicines and related substances in Namibian. This is to ensure that at authorization and throughout their shelf life, medicines continue to be safe, efficacious and of optimum quality.

The Therapeutics Information and Pharmacovigilance Centre (TIPC) is the Council's administrative and technical arm that carries out the pharmacovigilance responsibility to ensure the safe and rational use of medicines. The TIPC shares quarterly reports with stakeholders as part of a feedback mechanism and also to encourage all stakeholders to report adverse events.

This report intends to provide an update on the adverse events reported during the third quarter of the 2022/23 financial year. During this quarter, a total number of **83** reports were received.



ABBREVIATIONS

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

REPORT TYPE

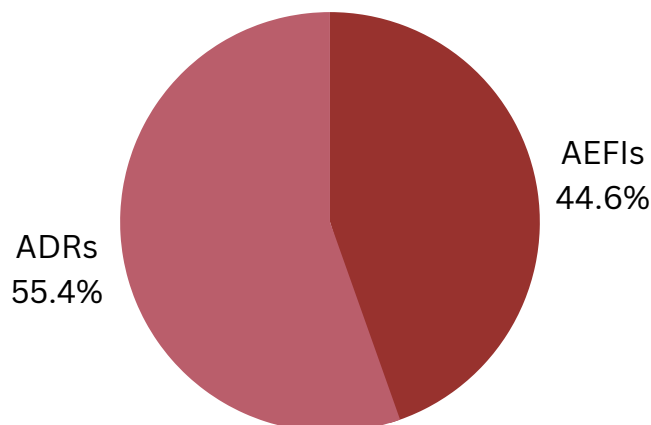


Figure 1: Report type

Of the total number reported, 46 reports (55.42%) were from non-vaccine medicinal products and 37 reports (44.58%) were adverse events following immunization (AEFI).

This report will only focus on the AEs from non-vaccine medicines.

PROFESSION

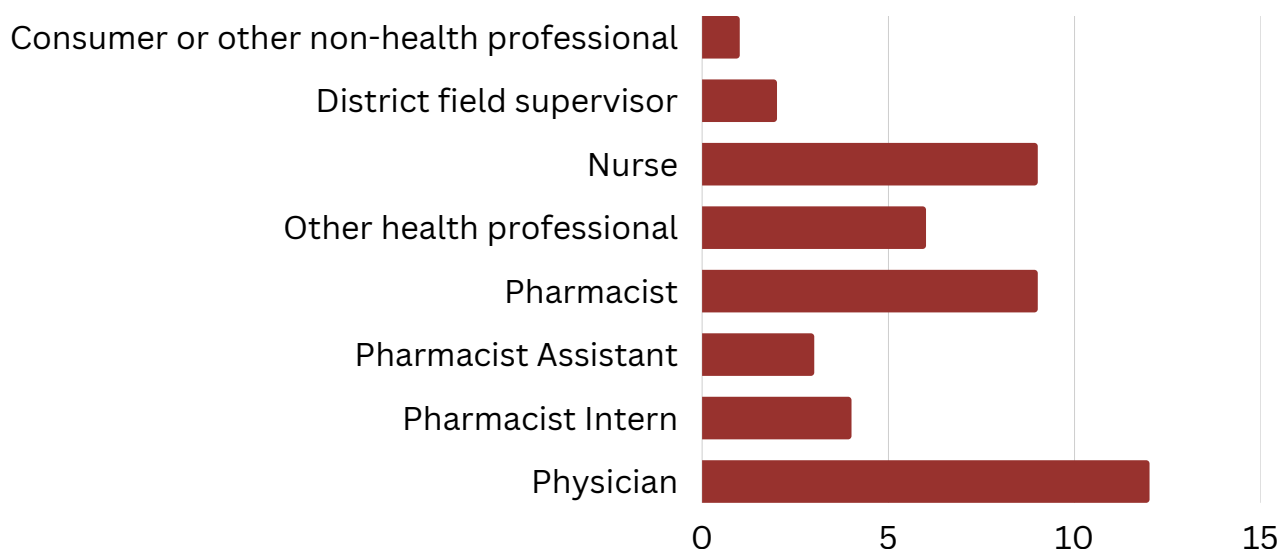


Figure 2: Number of reports received by profession

Majority of the reports received were from physicians (26.09%), followed by nurses and pharmacists (19.57%).

HEALTH FACILITY

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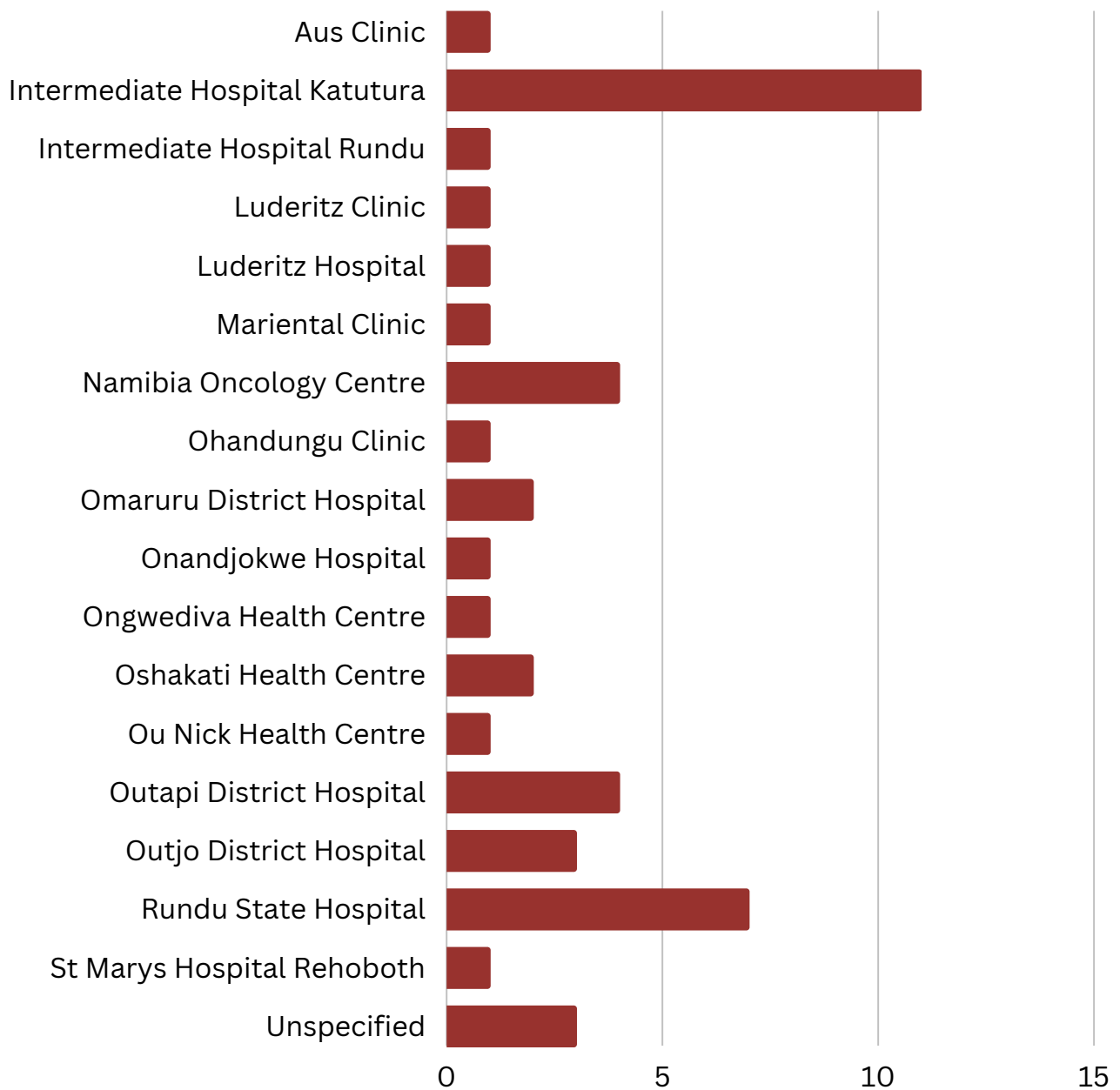


Figure 3: Number of reports received by health facility

Majority of the reports received were from Intermediate Hospital Katutura (23.91%), followed by Rundu State Hospital (15.22%) and then Namibia Oncology Centre and Outapi District Hospital (8.7%).

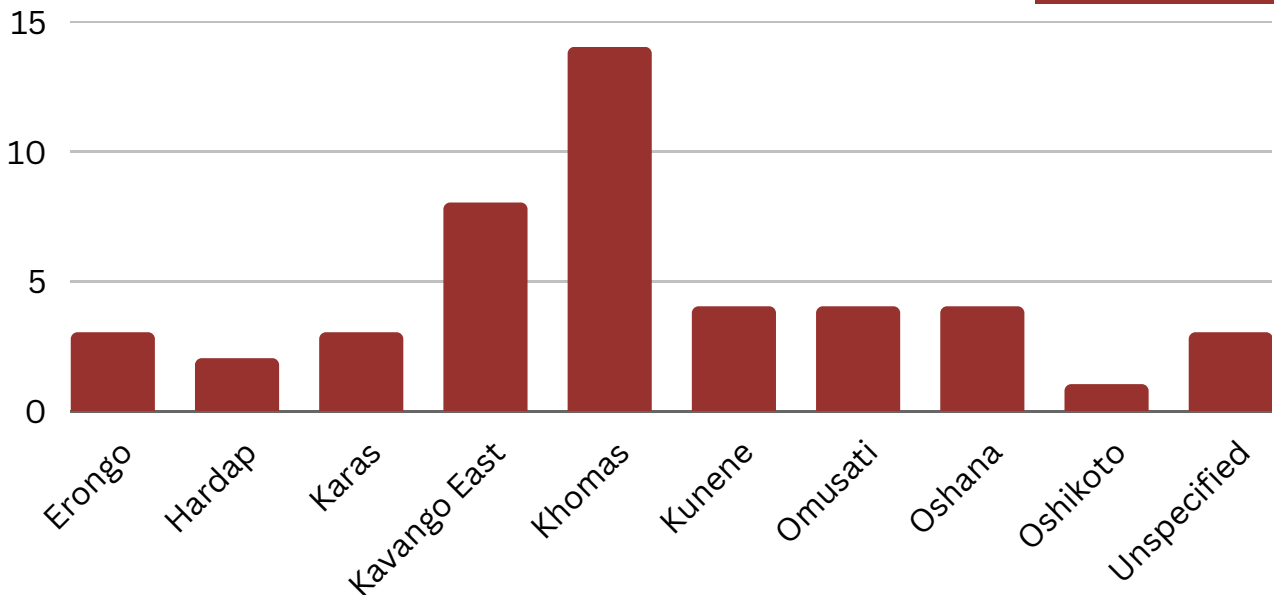
REGION

Figure 4: Number of reports received by region

AE reports were received from 9 out of the 14 regions in Namibia. Majority of the reports received were from Khomas region (30.43%), followed by Kavango East region (17.39%).

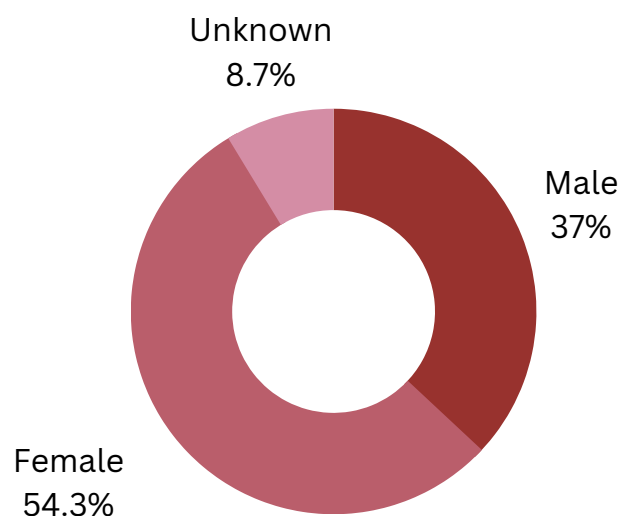
SEX

Figure 5: Number of reports received by sex

The frequency of reported AEs was higher in females (54.35%) compared to males (36.95%).

AGE GROUP

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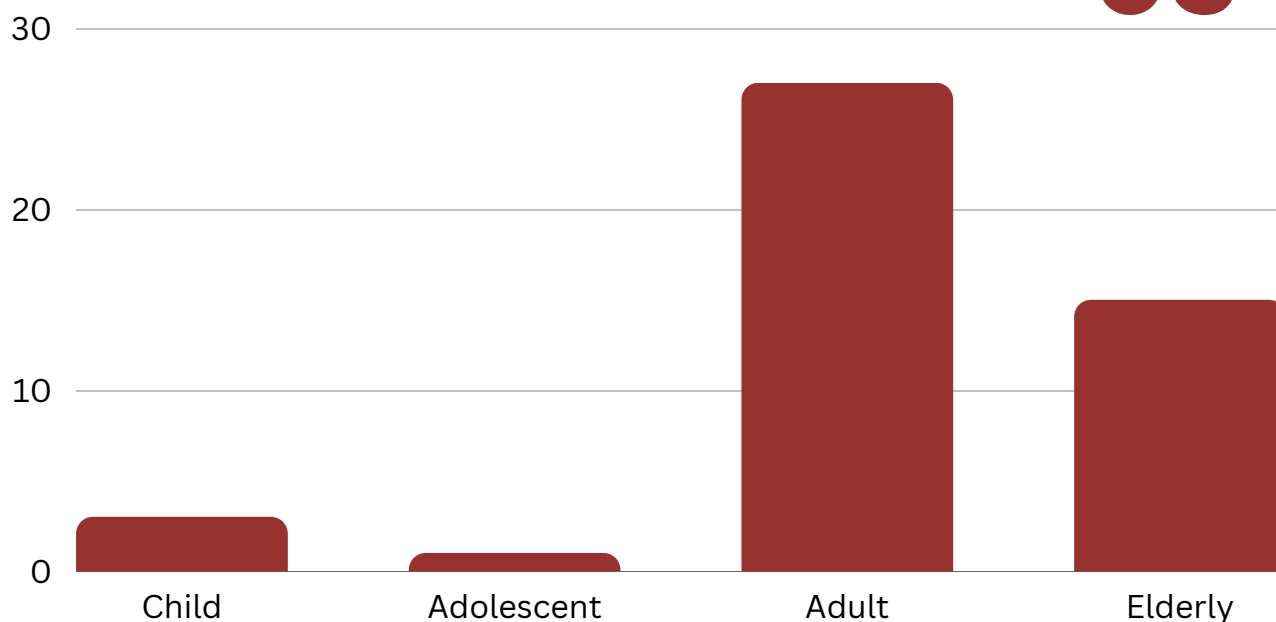


Figure 6: Number of reports received by age group

The incidence of AEs was highest amongst the adult age group (58.70%), followed by the elderly (32.61%) and then the child (6.52%).

SERIOUSNESS

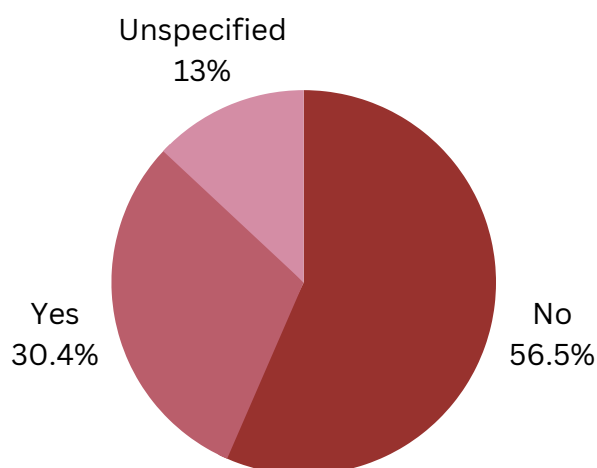


Figure 7: Seriousness of reported AEs

Of the total ADR reports received, 56.52% were classified as non-serious and 30.43% were classified as serious. Nine (9) reports indicated the reason for seriousness as caused/prolonged hospitalization, four (4) indicated other medically important conditions and one (1) indicated life threatening.

REASON FOR SERIOUSNESS

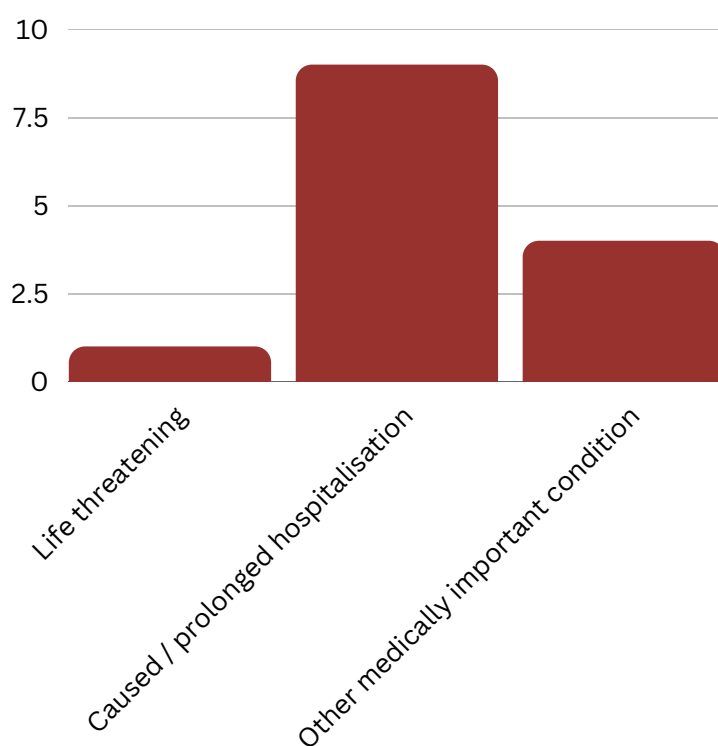


Figure 8: Reason for seriousness of reported AEs

COMMONLY REPORTED AES

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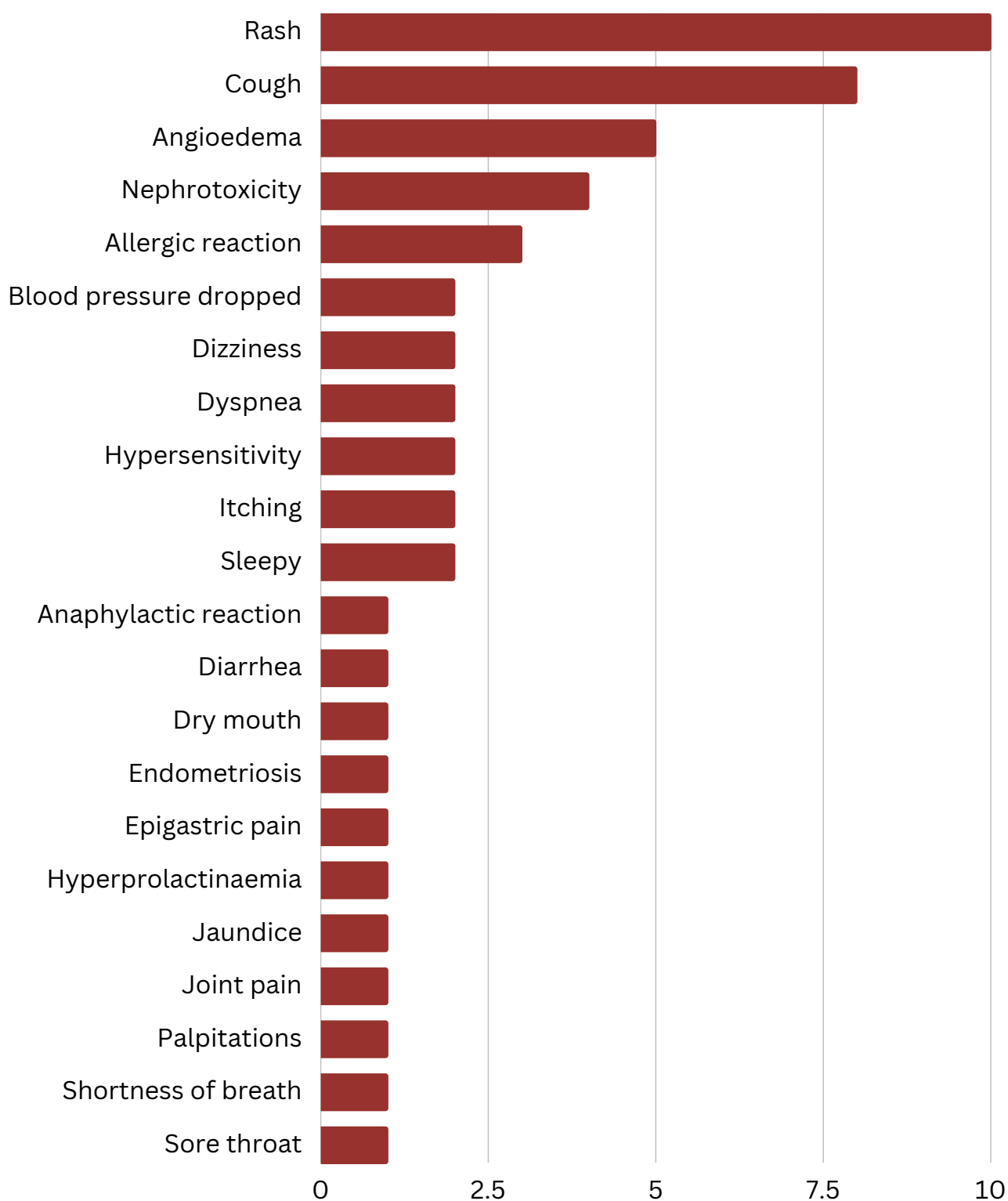


Figure 9: Common AEs reported

Most commonly reported AEs were rash (16.95%), cough (13.56%) and angioedema (8.47%).

THERAPEUTIC CLASS

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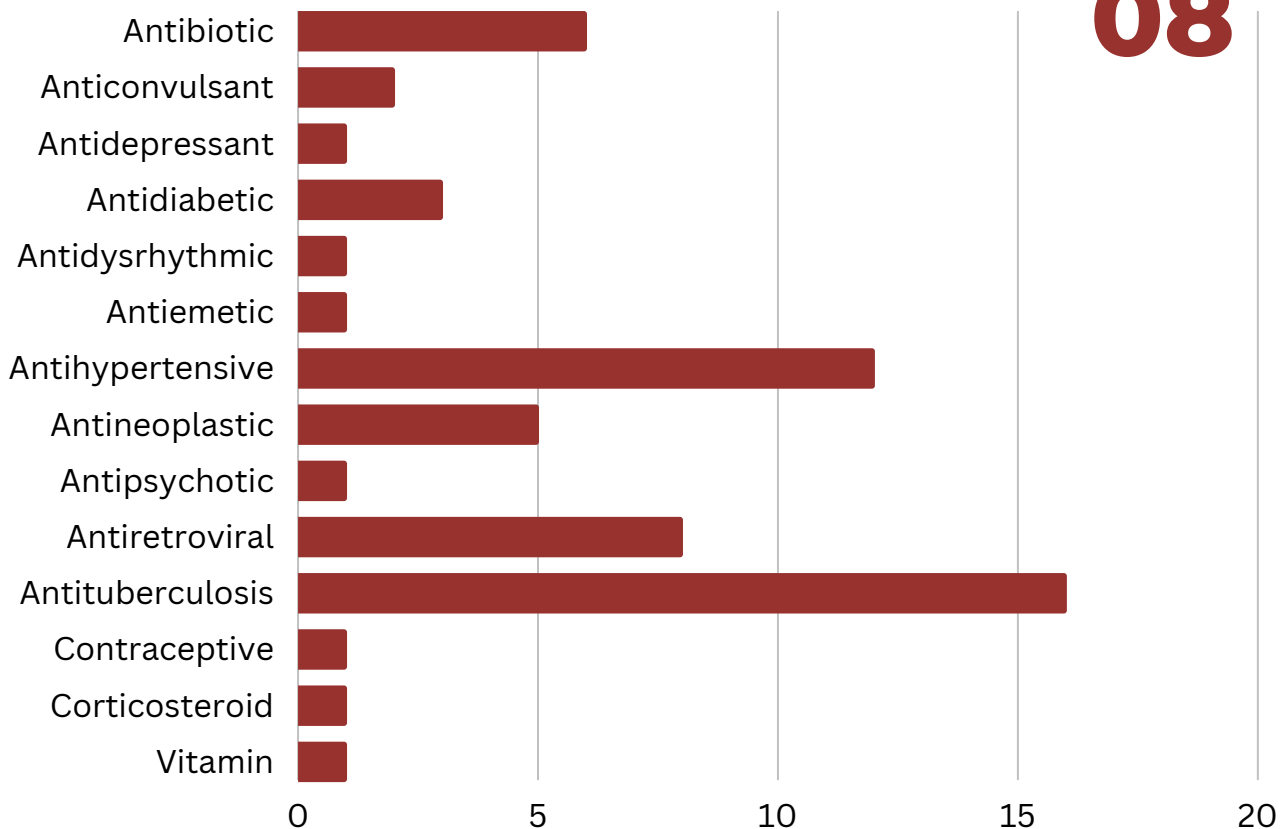


Figure 10: Number of reports by therapeutic class

The antituberculosis agents (27.12%), followed by antihypertensives (20.39%) and antiretrovirals (13.56%) were the top reported therapeutic classes suspected to have caused a high number of the AEs.

OUTCOME

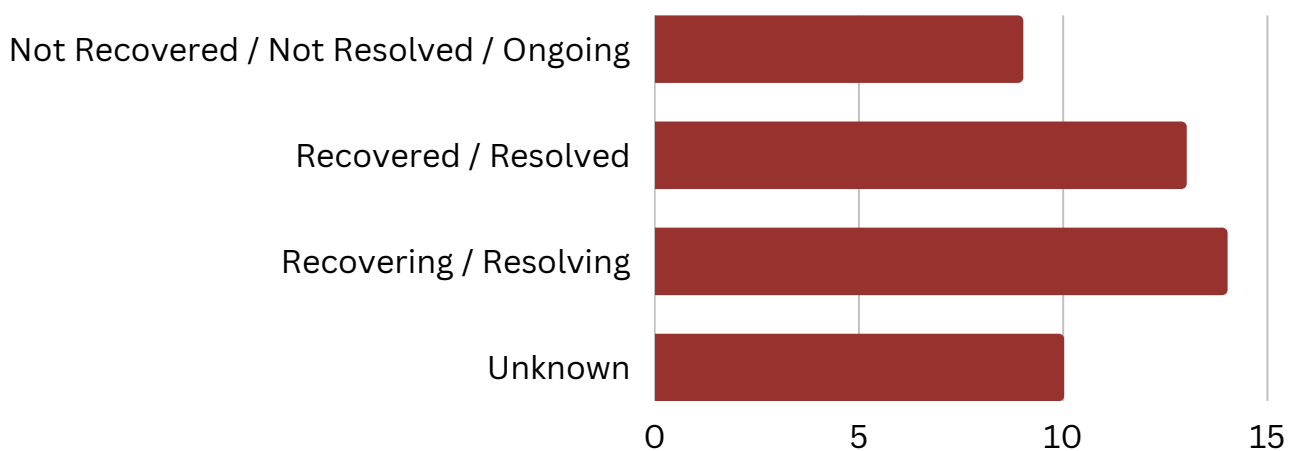


Figure 11: Number of reports by outcome

Most of the reported AEs were recovering/resolving (30.43%), 28.26% of the reported AEs were recovered/resolved, and for 21.74% of the reported AEs the outcome was unknown.

THANK YOU

The TIPC team would like to thank all the healthcare professionals for their continuous contribution to the National Medicines Safety Monitoring System (i.e. pharmacovigilance) by reporting suspected AEs. Well done to the top two regions who submitted a high number of reports (Khomas and Kavango East) as well as the top four health facilities (Intermediate Hospital Katutura, Rundu State Hospital, Namibia Oncology Centre and Outapi District Hospital).

Please do not hesitate to contact TIPC for any medicine-related query, and kindly report adverse events to TIPC via email, fax2mail or e-Reporting.



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