PHARMACOVIGILANCE FEEDBACK REPORT

JULY - SEPTEMBER 2022 (Q2)

MINISTRY OF HEALTH AND SOCIAL SERVICES

NAMIBIA MEDICINES REGULATORY COUNCIL (NMRC)

THERAPEUTIC INFORMATION AND PHARMACOVIGILANCE CENTRE (TIPC)

INTRODUCTION

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

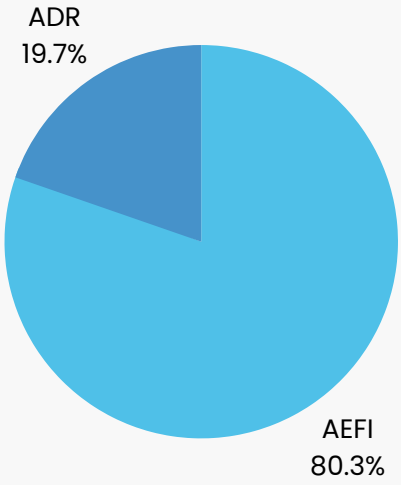
This report intends to provide an update of the adverse events reported during the second quarter of the 2022/23 financial year.

ABBREVIATIONS

PV	Pharmacovigilance
AEFI	Adverse Event Following Immunization
ADR	Adverse Drug Reaction
AE	Adverse Event
C	Clinic
HC	Health Centre
H	Hospital
DH	District Hospital
PH	Private Hospital
SH	State Hospital
IH	Intermediate Hospital

STATISTICS

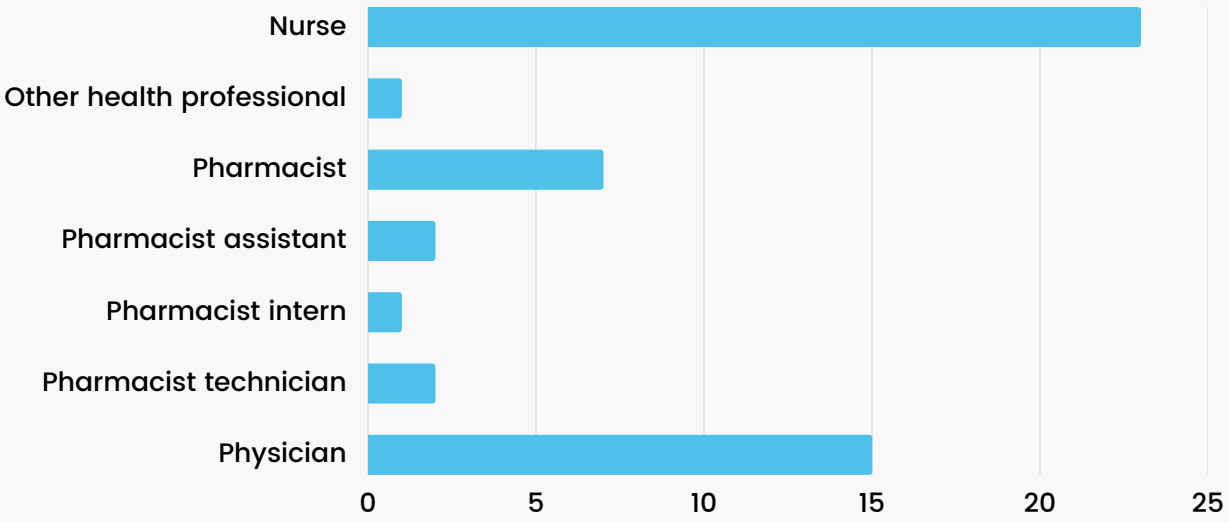
TYPE OF REPORT



In this quarter, the number of reports received were 259. Of the total number reported, 208 reports were adverse events following immunization (AEFI) and 51 were adverse drug reactions (ADR) from non-vaccine medicines.

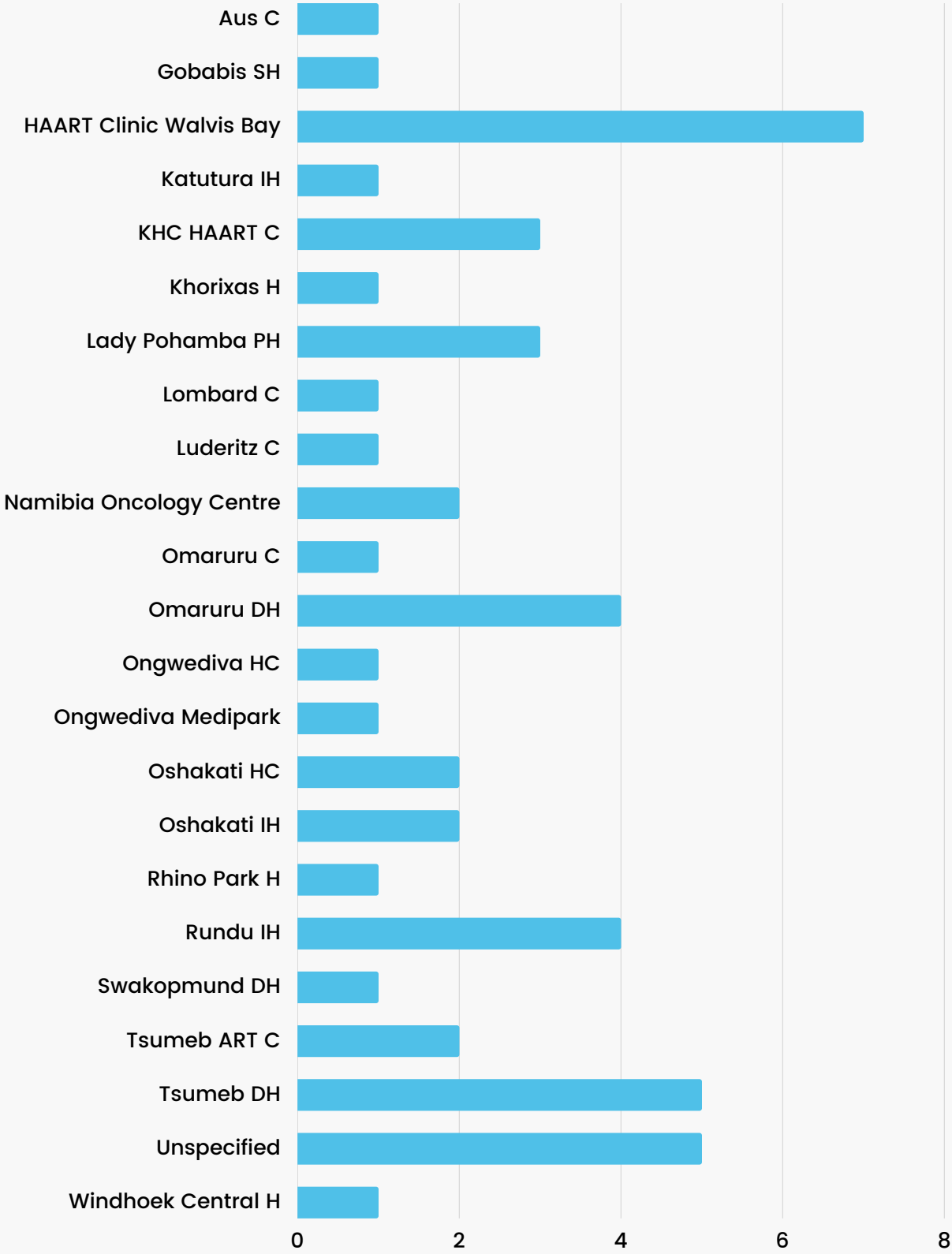
This report will only focus on the ADRs from non-vaccine medicines.

PROFESSION



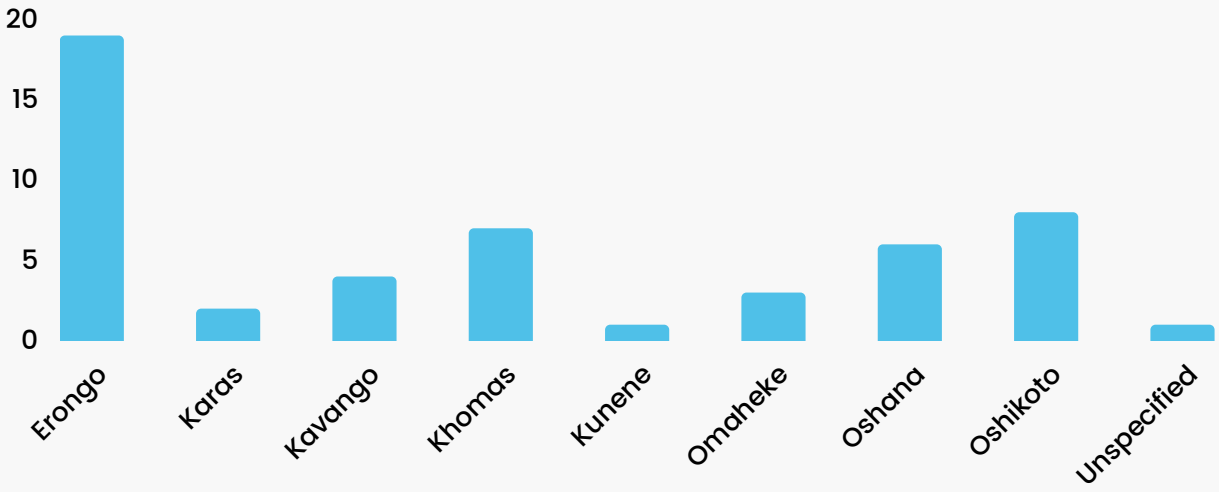
The majority of reports received were from nurses (45.1%), followed by physicians (29.41%) and then pharmacists (13.73%).

HEALTH FACILITY



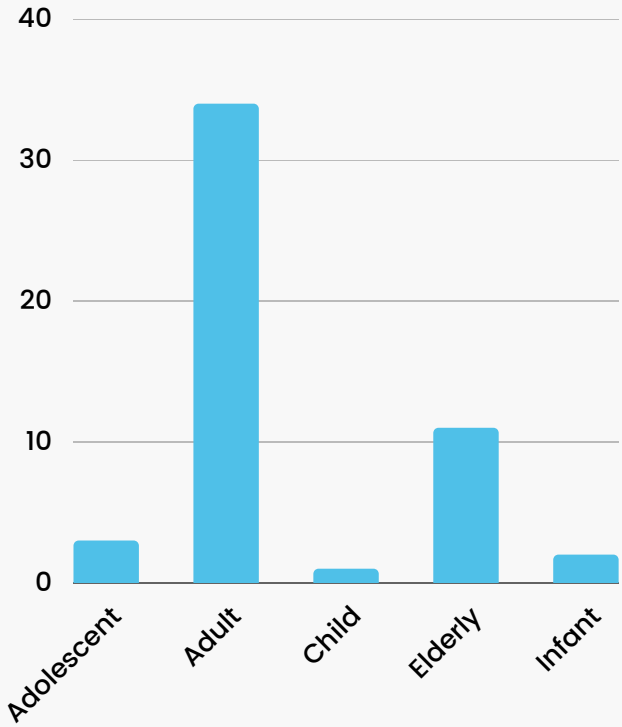
Majority of the reports received were from Walvis Bay HAART Clinic (13.73%), followed by Tsumeb District Hospital (9.8%), Rundu Intermediate Hospital and then Omaruru District Hospital (7.84%).

REGION



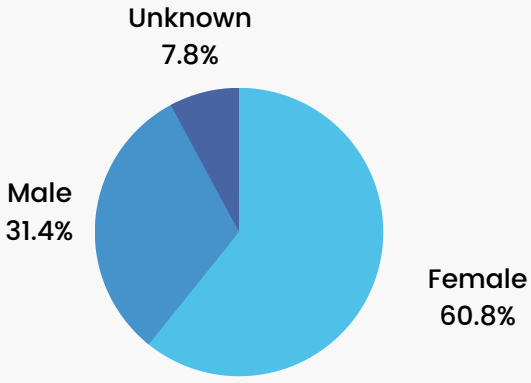
ADR reports were received from 8 out of the 14 regions in Namibia. The majority of the reports received were from Erongo region (37.25%), followed by Oshikoto region (15.69%) and then Khomas region (13.73%).

AGE GROUP



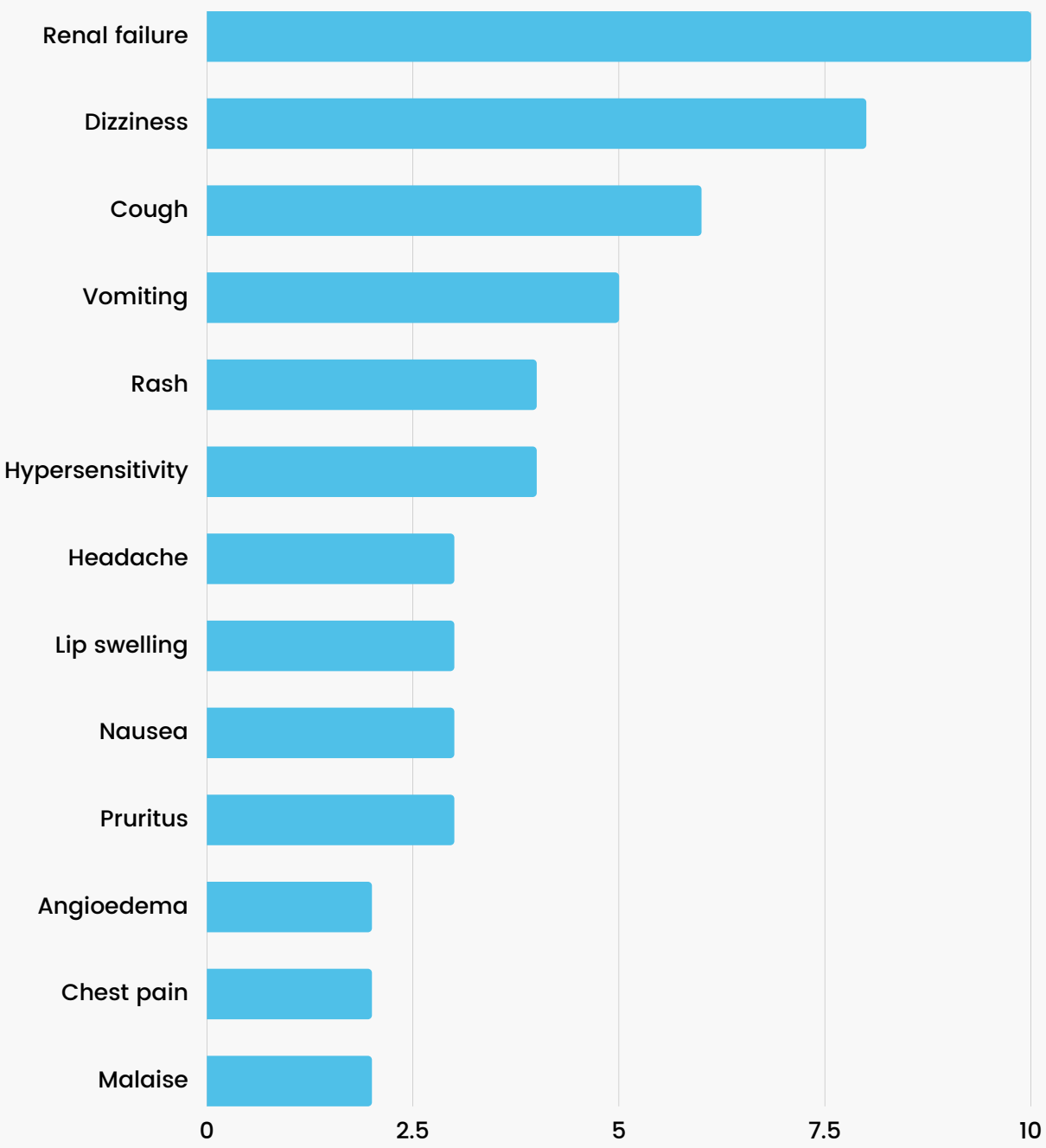
The incidence of AEs was highest amongst the adult age group (66.67%), followed by the elderly (21.57%) and then the adolescent (5.88%).

SEX



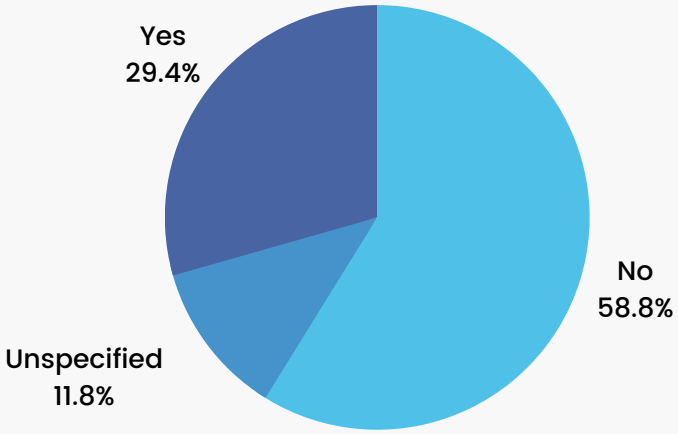
The frequency of reported adverse events (AE) was higher in females (61%) compared to males (31%).

COMMONLY REPORTED AEs

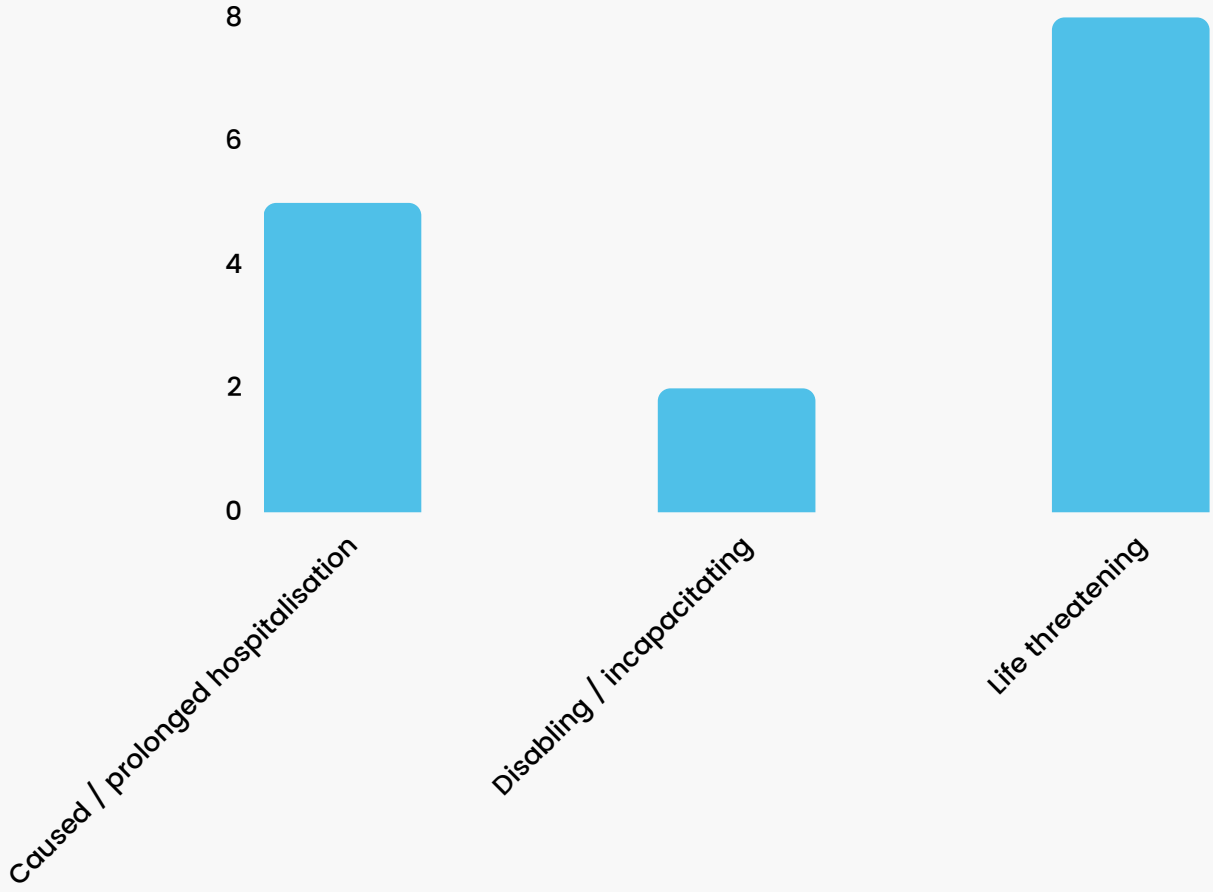


Most commonly reported AEs were renal failure (12.82%), dizziness (10.26%) and cough (7.69%).

SERIOUSNESS

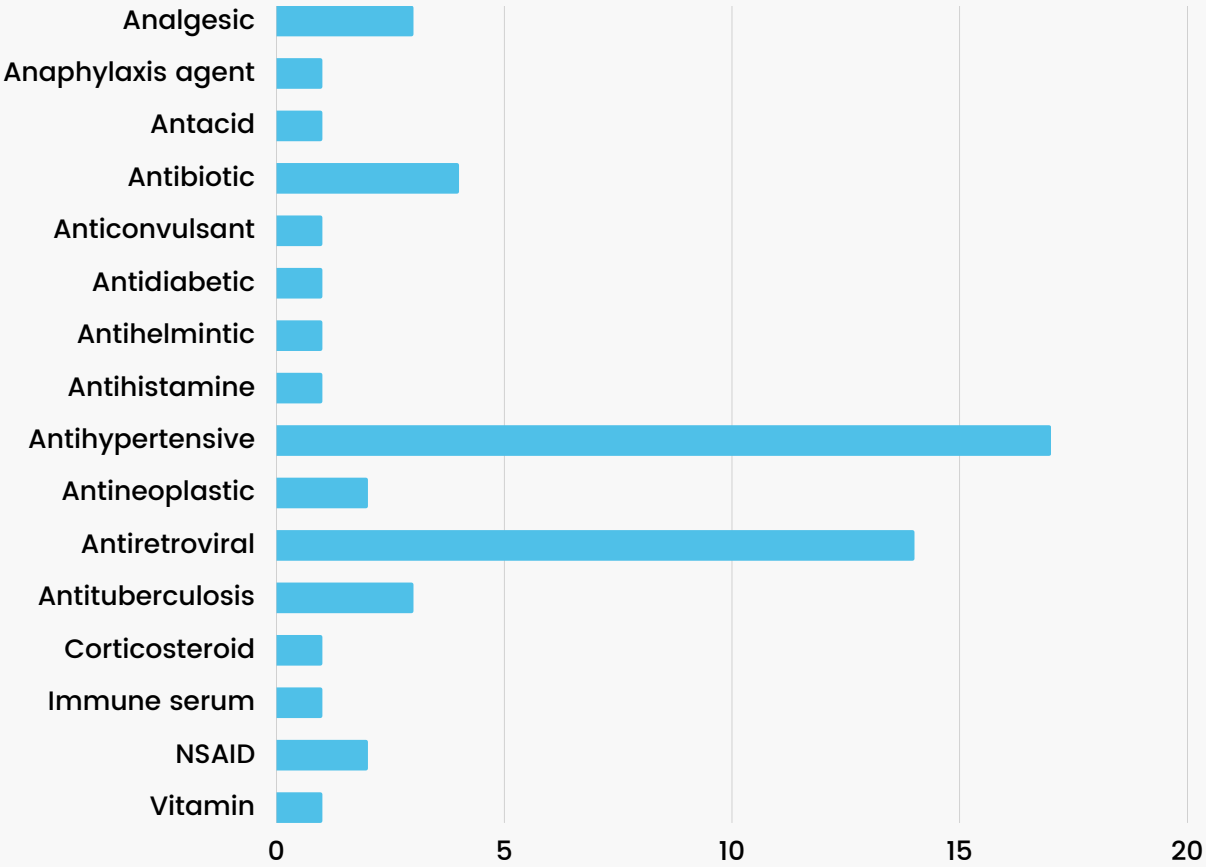


REASON FOR SERIOUSNESS



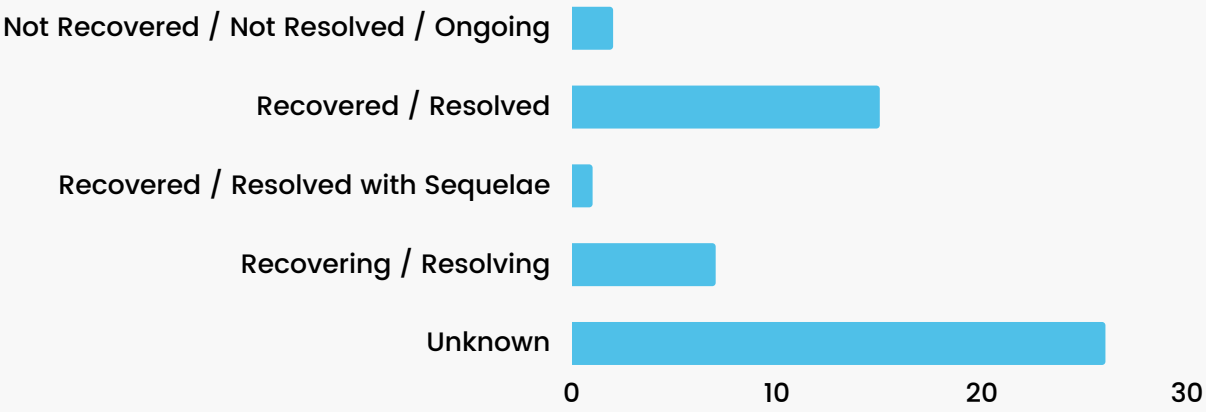
Of the total ADR reports received, 29% were classified as serious. Five (5) reports indicated the reason for seriousness as caused/prolonged hospitalization, two (2) indicated disabling/incapacitating and eight (8) indicated life-threatening.

THERAPEUTIC CLASS



The antihypertensives (31.48%), followed by antivirals (25.93%) and antibiotics (7.41%) were the top reported therapeutic classes suspected to have caused a high number of the AEs.

OUTCOME



For most of the reported AEs the outcome was unknown (50.98%), 29.41% of the reported AEs were recovered/resolved, and 13.73% were recovering/resolving.

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. A special thanks to the top three regions who submitted a high number of reports (Erongo, Oshikoto and Khomas) as well as the top four health facilities (Walvis Bay HAART Clinic, Tsumeb District Hospital, Rundu Intermediate Hospital and Omaruru District Hospital).

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

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