



PHARMACOVIGILANCE FEEDBACK REPORT: APRIL - JUNE 2022 (Q1)



MINISTRY OF HEALTH AND SOCIAL SERVICES

NAMIBIA MEDICINES REGULATORY COUNCIL

THERAPEUTIC INFORMATION AND
PHARMACOVIGILANCE CENTRE (TIPC)

02

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 circulating on the Namibian market. This is to ensure that at authorization and throughout their market 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 safe and rational use of medicines. The TIPC shares quarterly reports with stakeholders to serve as a feedback mechanism as well as to encourage stakeholders to report. This report intends to provide an update of the adverse events reported during the first 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

03

STATISTICS

Number of case reports in VigiBase

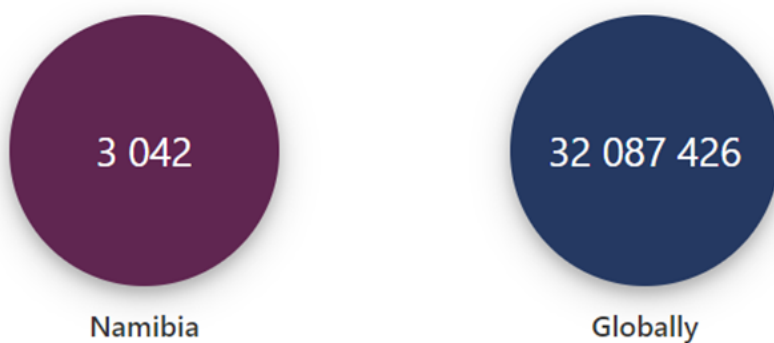


Figure 1: Number of case reports in VigiBase

Since the introduction of pharmacovigilance in Namibia, a total of 3 042 individual case study reports have been submitted to the global data base (i.e. Vigibase) contributing 0.009% to the total number of reports worldwide. In this quarter, the number of reports received were 177.

TYPE OF REPORT

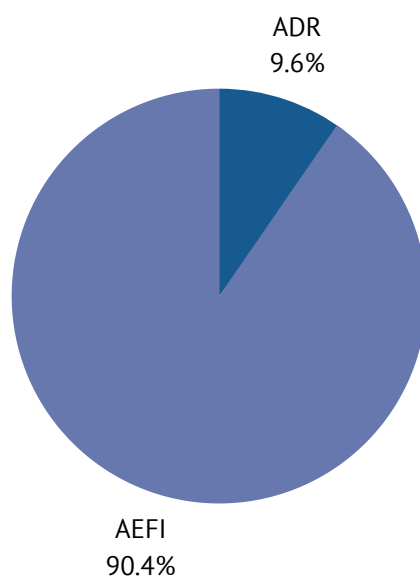


Figure 2: Percentage of ADRs and AEFIs received for Quarter 1 (April - June 2022)

Of the total number reported, 160 reports were AEFIs and 17 were ADRs from non-vaccine medicines.

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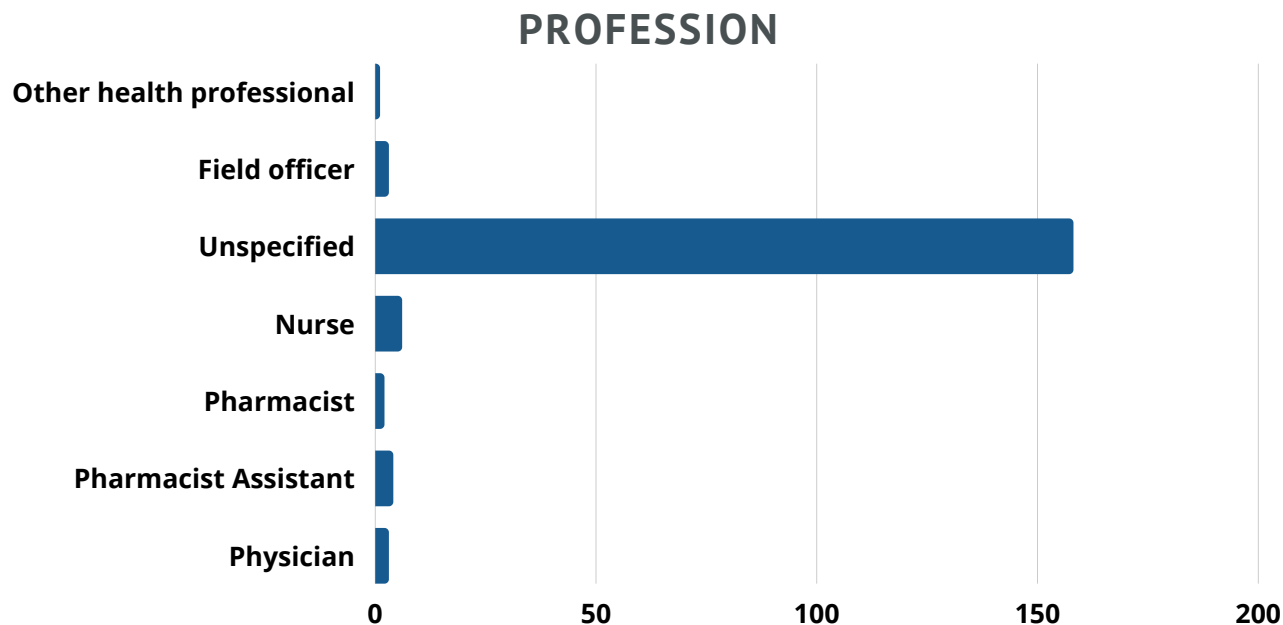


Figure 3: Number of reports received by profession

For majority of the reports received the reporter profession was not indicated thus unspecified (89.27%) was the highest, followed by nurses (3.39%) and then pharmacist assistants (2.26%).

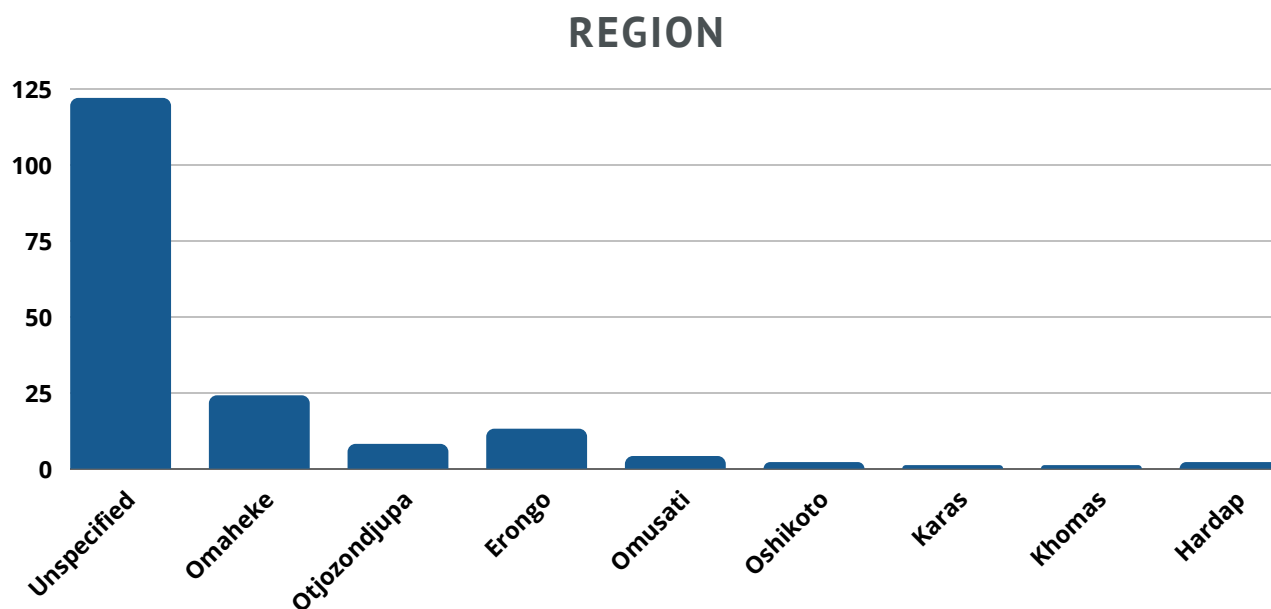


Figure 4: Number of reports received by region

AE reports were received from 8 out of the 14 regions in Namibia. For majority of the reports received the region was not indicated thus unspecified (69%) was the highest, followed by Omaheke region (14%) and then Erongo region (7%).

05

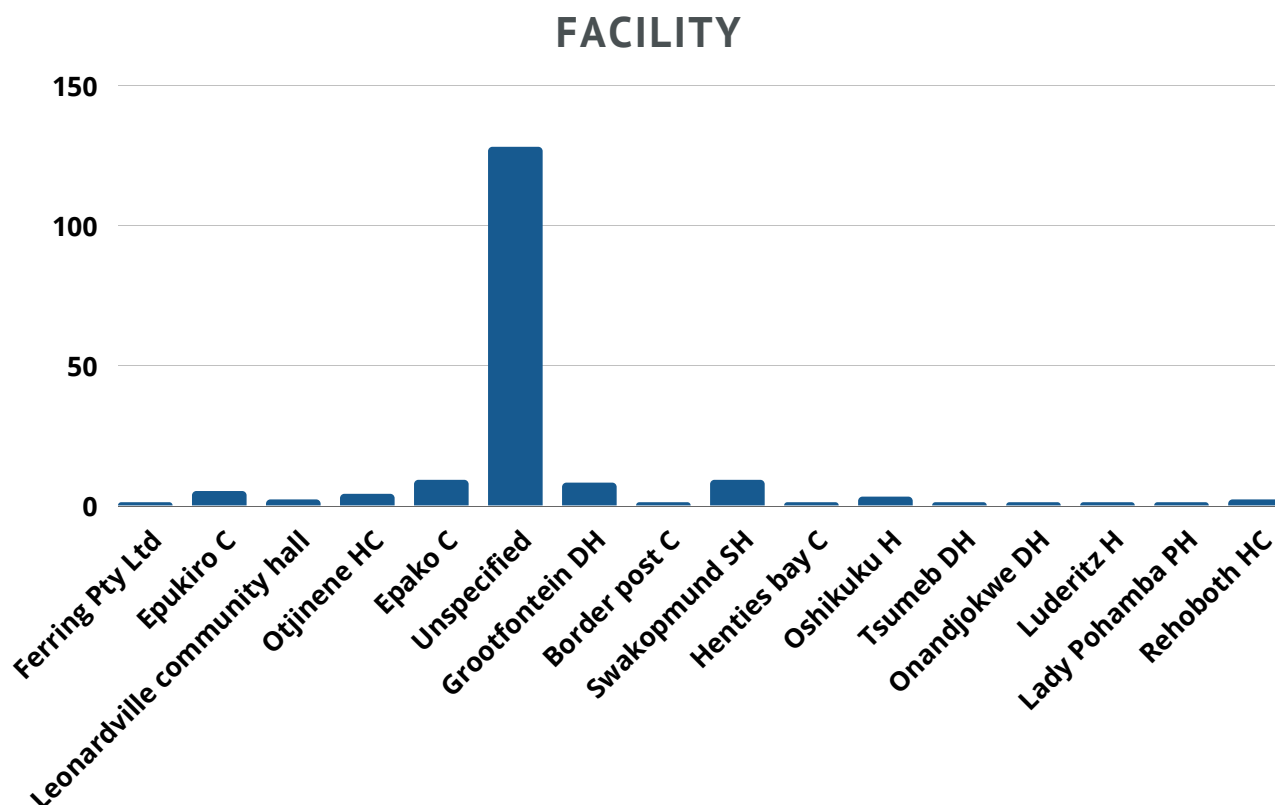


Figure 5: Number of reports received by healthcare facility

For majority of the reports received the facility was not indicated thus unspecified (72%) was the highest, followed by Swakopmund State Hospital (5%) and Epako Clinic (5%).

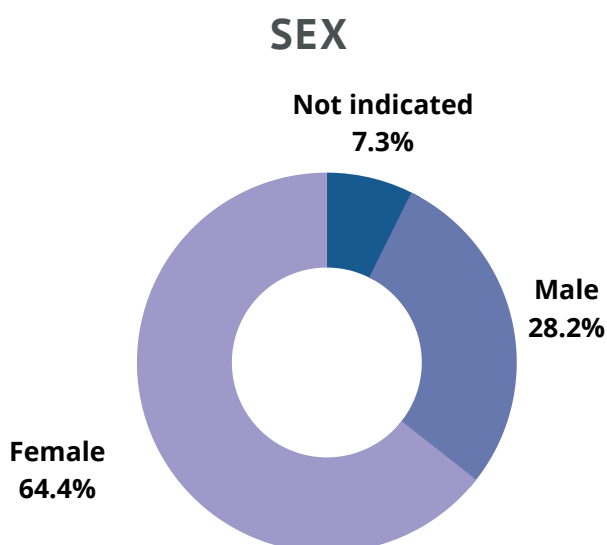


Figure 6: Number of reports received by sex

The frequency of reported AEs were higher in females (64.4%) compared to males (28.2%).

06

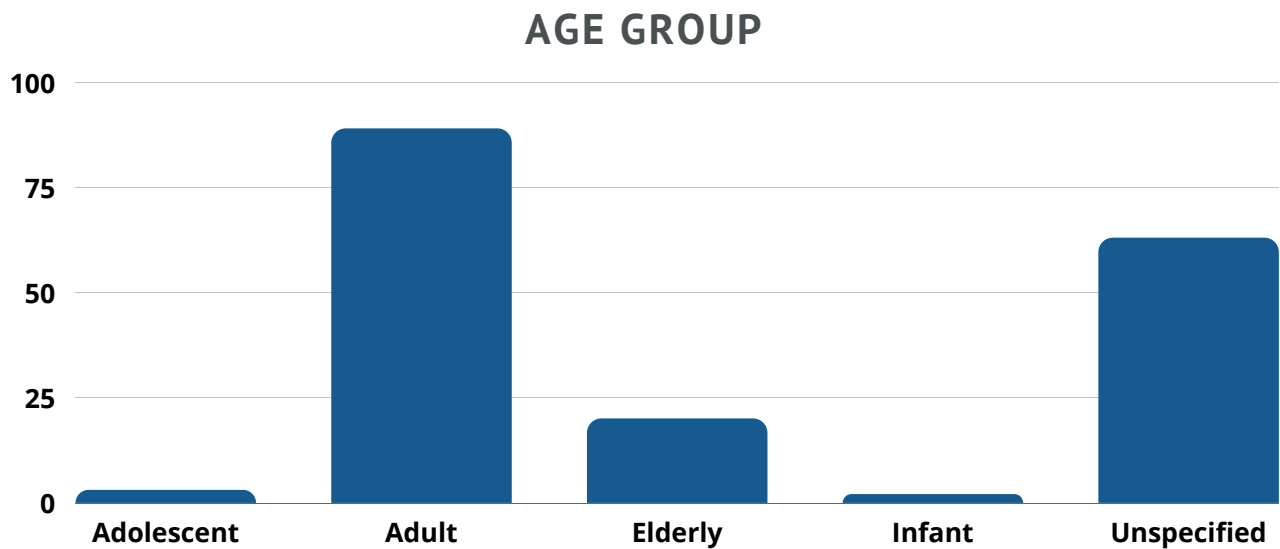


Figure 7: Number of reports received by age group

The incidence of AEs was highest amongst the adult age group (50%), followed by the elderly age group (11%). 36% of the reports did not have age indicated.

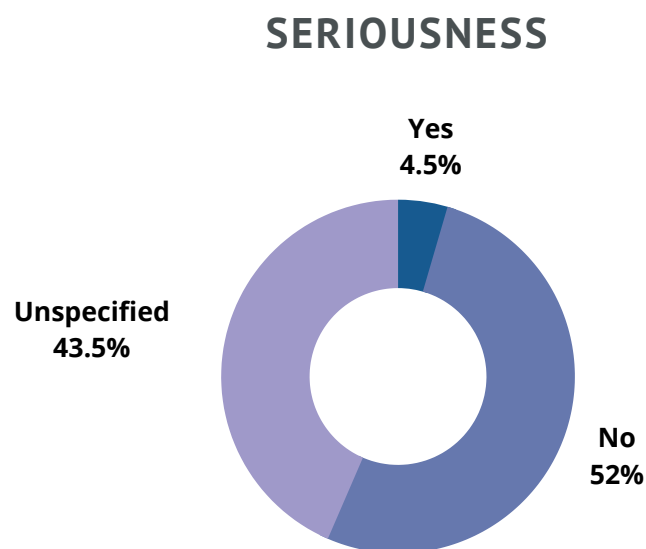


Figure 8: Seriousness of the reported AEs

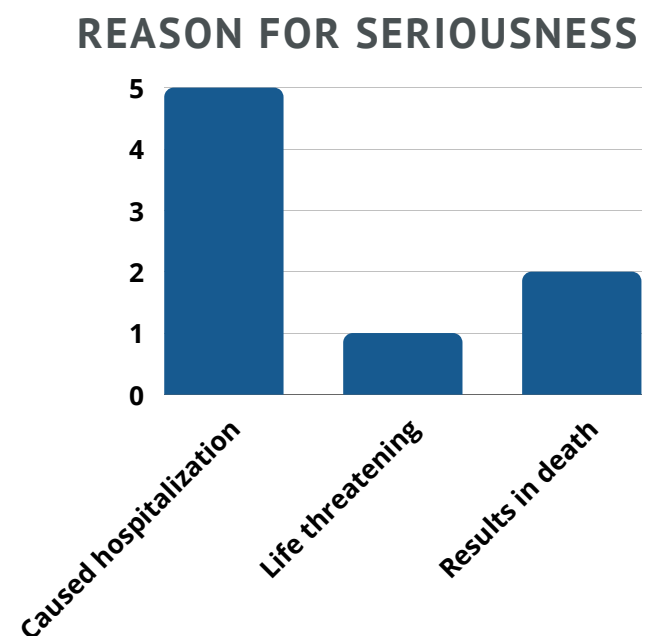


Figure 9: Reason for seriousness of the reported AEs

Of the total reports received, 4.5% were classified as serious. Five (5) reports indicated the reason for seriousness as caused/prolonged hospitalization, two (2) indicated death and one (1) indicated life threatening.

07

THERAPEUTIC CLASS

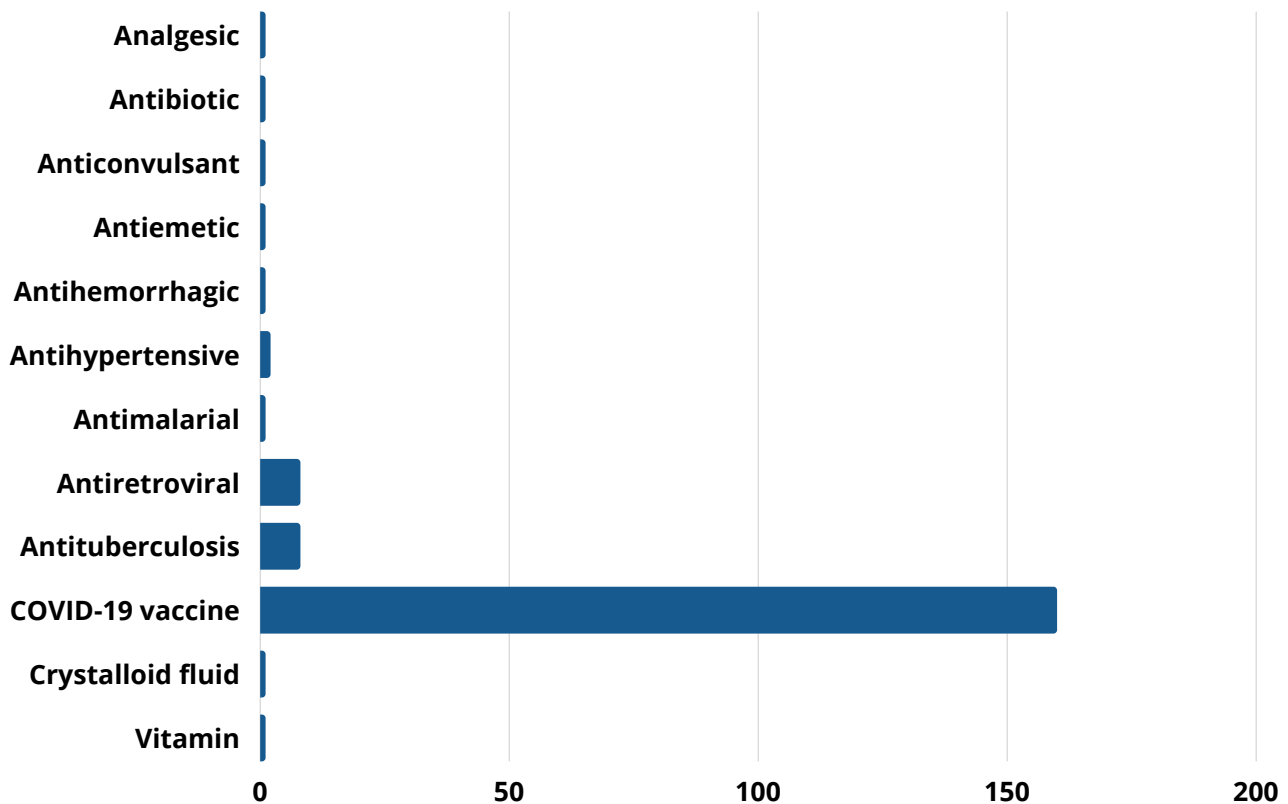


Figure 10: Number of reports by therapeutic class

The COVID-19 vaccine (86%), followed by antivirals (4%) and antituberculosis (4%) were the top reported therapeutic classes suspected to have caused a high number of the AEs.

OUTCOME

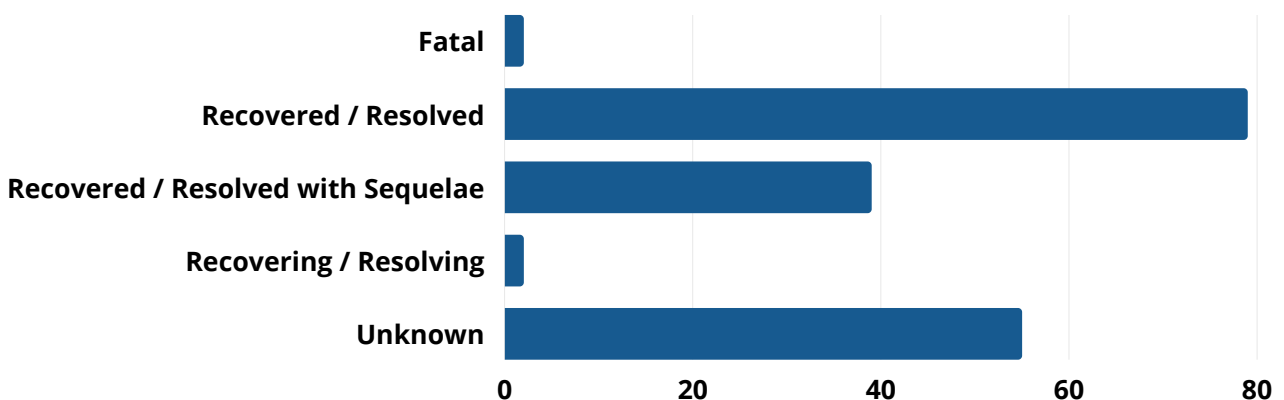
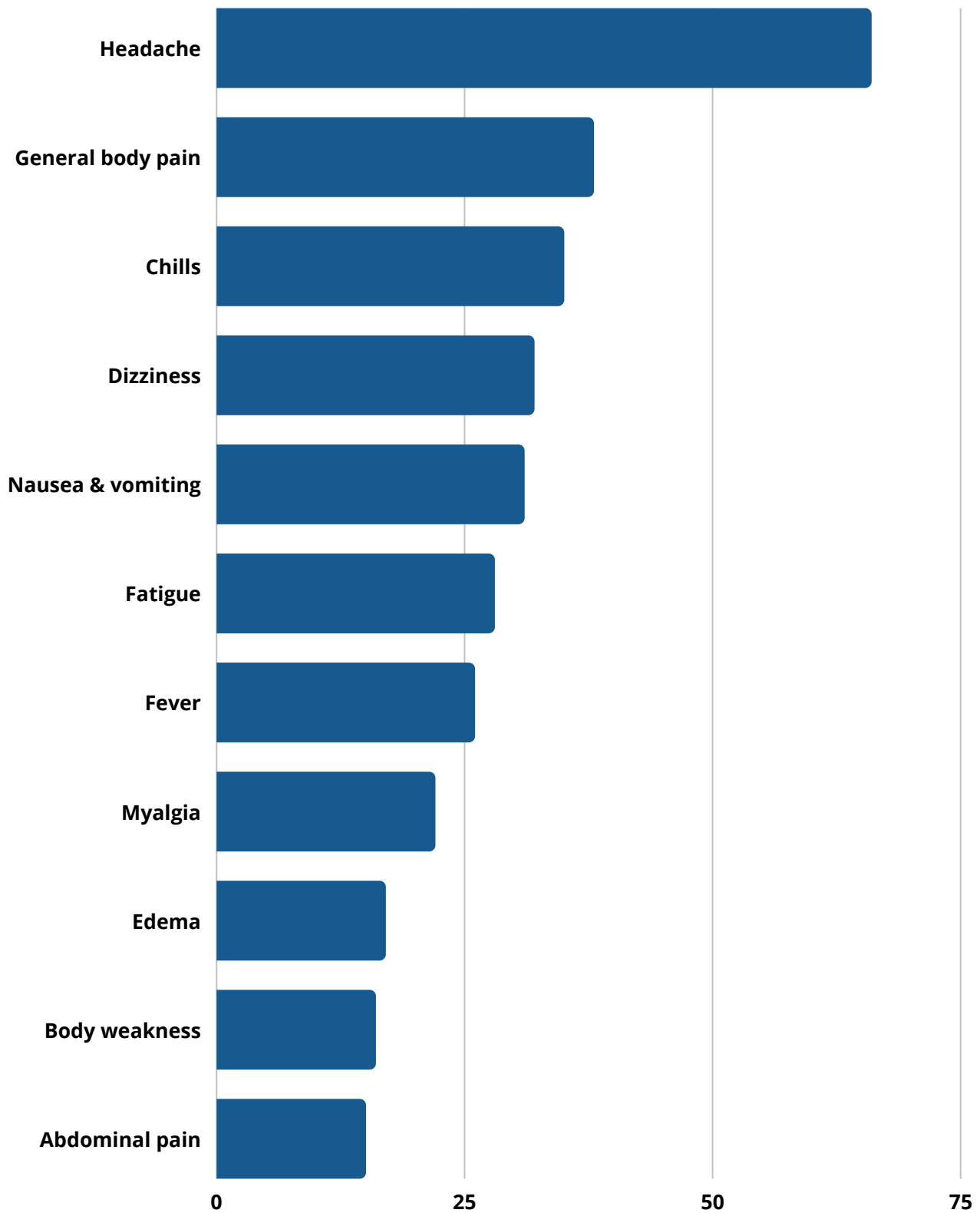


Figure 11: Reported outcomes of the reported AEs

Most of the reported AEs were recovered/resolved (45%), for 31% of them the outcome was not indicated, and 22% were recovered/resolved with sequelae.

08

COMMONLY REPORTED AEs

*Figure 12: Common AEs reported*

Most commonly reported AEs were headache, general body pain and chills.

09

ACKNOWLEDGMENT

The TIPC team would like to thank all healthcare workers for their continuous contribution to the National medicines safety monitoring system (i.e. pharmacovigilance) by reporting suspected ADRs and AEFIs. A special thanks to the top three regions who submitted a high number of reports (Omaheke, Erongo and Otjozondjupa) as well as the top three health facilities (Swakopmund State Hospital, Epako Clinic and Grootfontein District Hospital).

As observed in the statistics there are a number of reports where the region and/or health facility were not indicated. All healthcare workers are encouraged to extensively complete the reporting forms.

Please do not hesitate to contact TIPC for any medicine-related query, and kindly report adverse drug reactions to TIPC through any of the following routes:

Email: **info.TIPC@mhss.gov.na**

Tel: **061 203 2406**

Fax2mail: **088 660 6781**

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



e-Reporting QR code



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REGISTRAR OF MEDICINES