



Ministry of Health, PPB Pharmacovigilance Centre

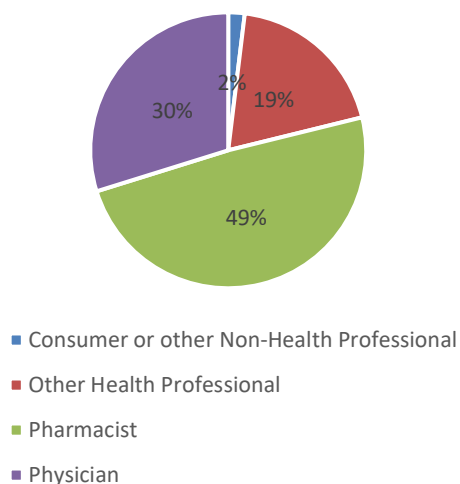
Pharmacovigilance Summary Report: January –March 2019

The Pharmacy and Poisons Board is the Drug Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board regulates the Practice of Pharmacy and the manufacture and trade in drugs and poisons.

PPB has 6 directorates of which the Directorate of Medicines Information and Pharmacovigilance (MIPV) is responsible for Pharmacovigilance, Post-Market Surveillance, Clinical Trials & Medicines Information activities. MIPV shares quarterly pharmacovigilance reports with stakeholders to serve as a feedback mechanism and also encourage all stakeholders to report.

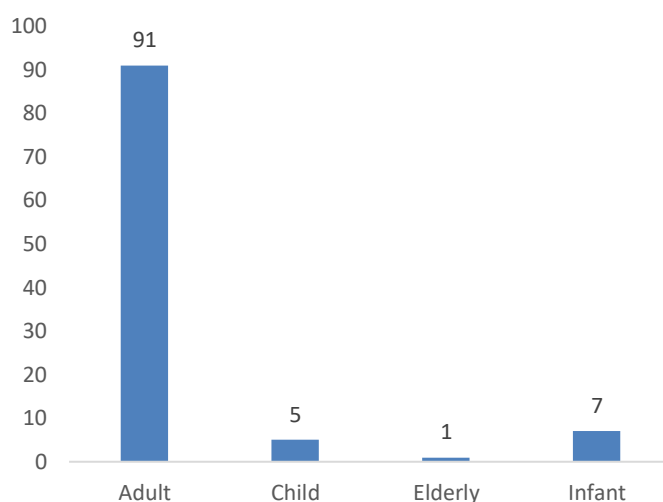
Since the introduction of PV in Kenya, a total of 11,400 individual case safety reports has been submitted to the global data base reports 19,258,758 (0.06%). This quarter three of 2018/2019, number of reports went up (104 reports) compared to previous quarter which submitted (60 reports).

Reporter qualification



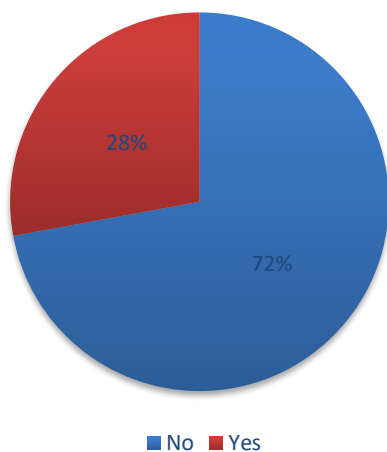
Most ADRs reported consistently by pharmacists throughout the quarter

ADR by Age

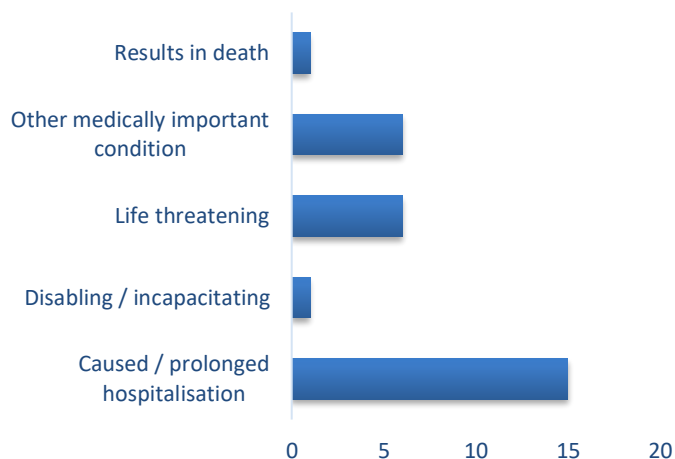


Majority of the patients that are affected by ADR are adults throughout the quarter followed by infants then children.

Seriousness of ADR



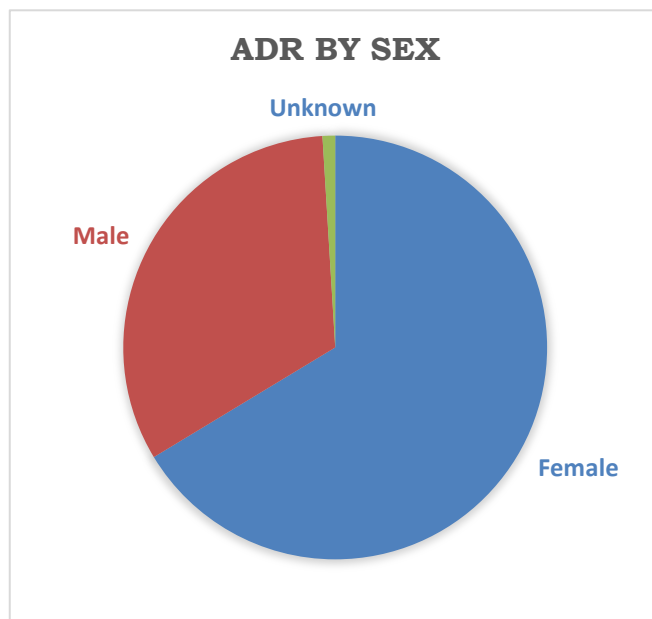
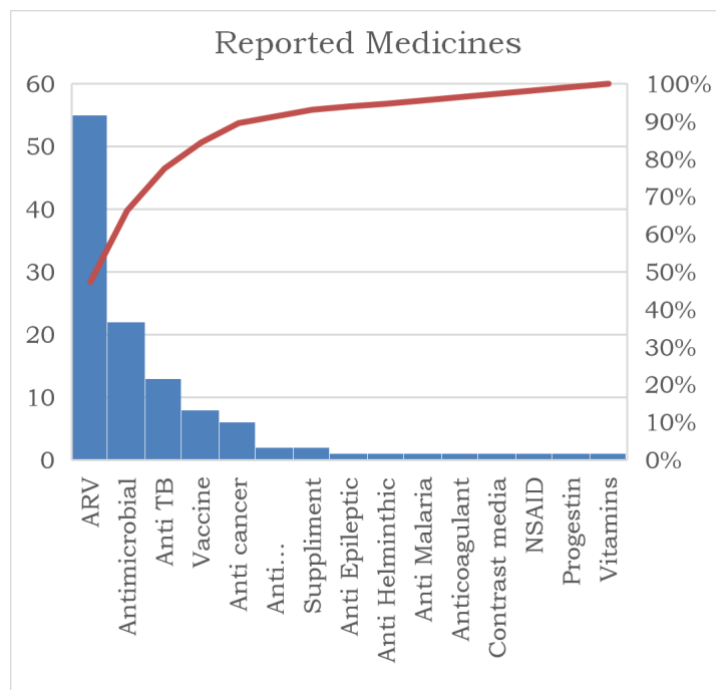
Reason for Seriousness





In quarter 3 of 2018/2019, 29 (28%) serious ADR reports were reported.

Out of the 29 (28%) serious reports received, 15(52%) of the cases caused/prolonged hospitalizations, 6 (21%) cases were both life-threatening and causing other medically important conditions.



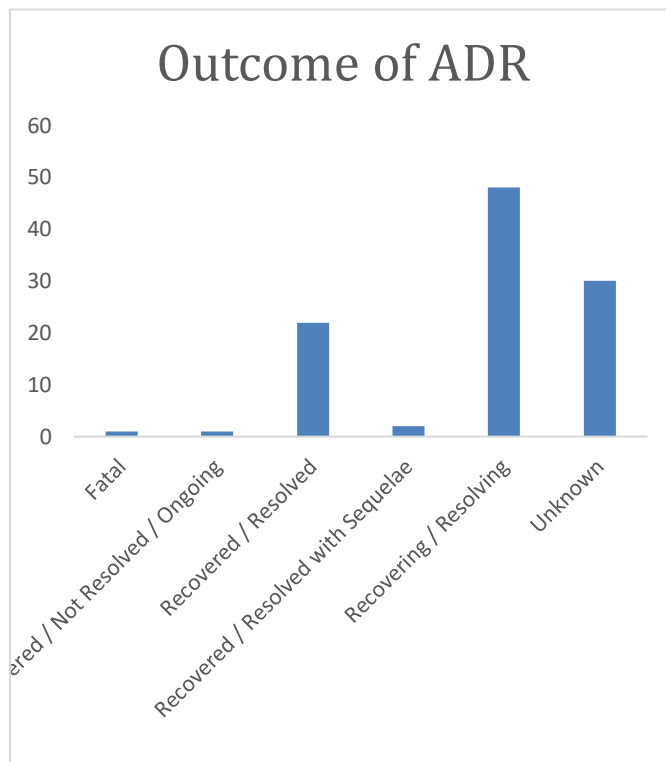
Total molecules suspected of causing ADRs were 116. ARVs accounted for most of the suspected ADRs (46%) followed by anti-Microbial (19%), anti-TBs medicines (11%), vaccines (7%) then anti-cancers at (5% each) in that order.

More female 69(66%) affected by ADRs in quarter 3.

System organ mostly affected by ADRs

Outcome of the reported ADRs

System Organ Classification	No. of reports
Nervous system disorders	29
Skin and subcutaneous tissue	28
General disorders and	17
Gastrointestinal disorders	15
Reproductive system and breast	7
Psychiatric disorders	5
Renal and urinary disorders	5
Hepatobiliary disorders	4
Eye disorders	3
Immune system disorders	2
Blood and lymphatic system disorders	1
Ear and labyrinth disorders	1
Investigations	1
Metabolism and nutrition	1
Musculoskeletal and connective tissue disorders	1





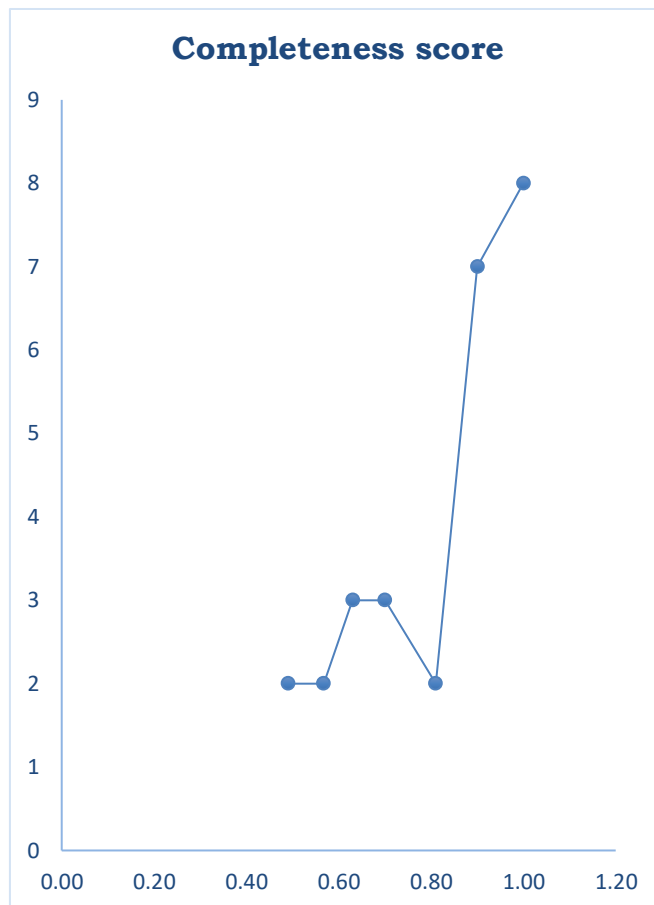
System organ mostly affected by ADRs was the nervous system disorders, followed by skin and subcutaneous tissues, general disorders and site administration, gastrointestinal disorders, reproductive and psychiatric disorders among others in a descending manner.

Most of the ADRs either recovered/resolved or were recovering/resolving (70 of the reported cases). The outcome of 30(29%) of the ADRs reported was unknown.

Commonly reported ADRs/MeDRA Reported terms

Average completeness score of the reports submitted

MeDRA term	No. of reports
Drug ineffective	10
Rash	10
Hepatotoxicity	9
Drug interaction	5
Hallucinations	5
Stevens-Johnson syndrome	5
Vomiting	5
Acute kidney failure	4
Febrile convulsion	3
Renal failure	3
Allergy	2
Anaemia	2
Diarrhoea	2
Dizziness	2
Ear pain	2
Gynecomastia	2
Injection site swelling	2
Jaundice	2
Lipodystrophy	2
Throbbing headache	2
Tingling teeth	2
Not indicated	1
Others	37
Total	118



This is a measure of how complete a report is filled and uploaded to vigiflow. The average completeness score for all the reports submitted in the quarter was 81% or 0.81

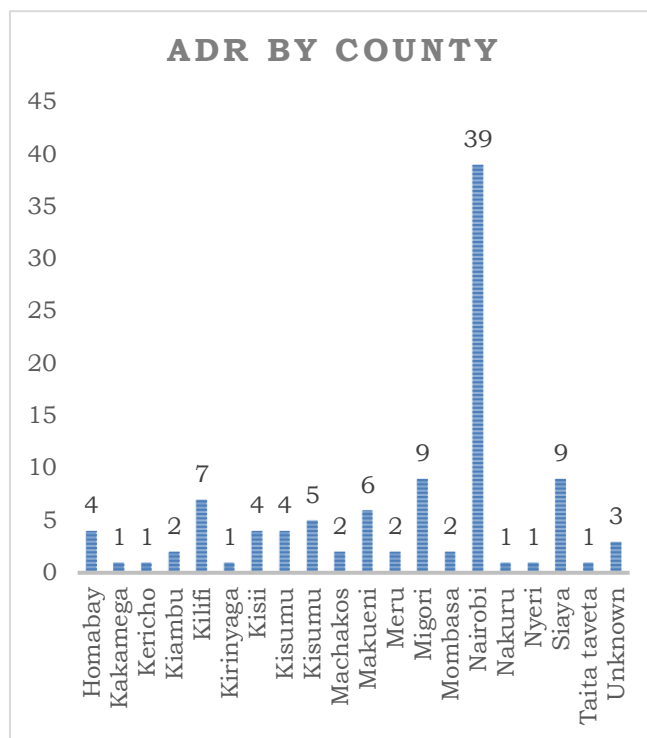
Most reported ADR terms were either drug ineffective, rash, hepatotoxicity, drug interactions, hallucinations, SJS, vomiting among others as shown on the table above



Reporting facilities

Facility	No. of Reports
The Mater Hospital Mukuru	21
St Camillus Mission Hospital	7
Dreams Center Dispensary (Langata)	5
Makueni District Hospital	4
Malindi District Hospital	4
MIGOSI SUB-COUNTY HOSPITAL	4
Nairobi Hospital	4
National Vaccines and Immunization Programme	4
Kilifi District Hospital	3
Siaya District Hospital	3
St Elizabeth Chiga Health Centre	3
Unknown	3
Others	39
Total	104

Reporting counties



All the reports in the quarter were submitted by 43 health facilities in the country. 3 reports had no facility indicated on them. To put this in context, there are over 9,000 health facilities listed in the Kenya Master Facility List (MFL)

sADR reports were received from 19 of the 47 counties. Nairobi County, with 8 facilities reporting 39 ADRs, followed by Siaya & Migori 2 and 5 facilities respectively (9 ADRs) and Kilifi 2 facilities reporting (7 ADRs). Majority of the counties had one facility reporting e.g. Kakamega, Kericho, Kirinyaga, Nakuru, Nyeri and Taita Taveta.

Abbreviations: PPB = Pharmacy & Poisons Board; PV = Pharmacovigilance; sADR = suspected Adverse Drug Reaction; PQMP = Poor Quality Medicinal Product; PVERS = PV Electronic Reporting System, SOC = System Organ Classification

*For any queries please contact PV department on **0795743049**.*

This document is produced by the Pharmacovigilance Center at PPB.

Data sources: PPB PV Center; WHO VigiLyze Database (NB: the information does not represent the opinion of the World Health Organization)