



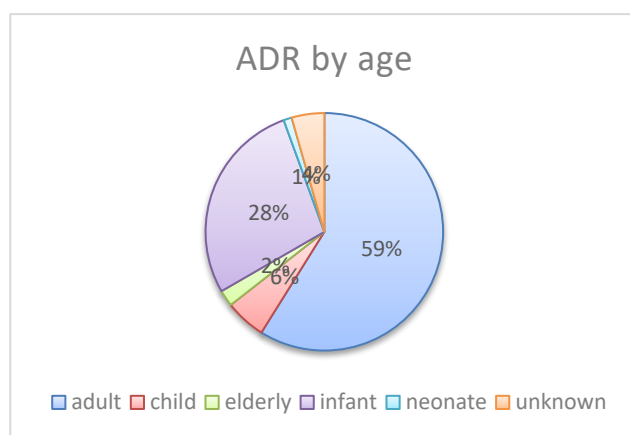
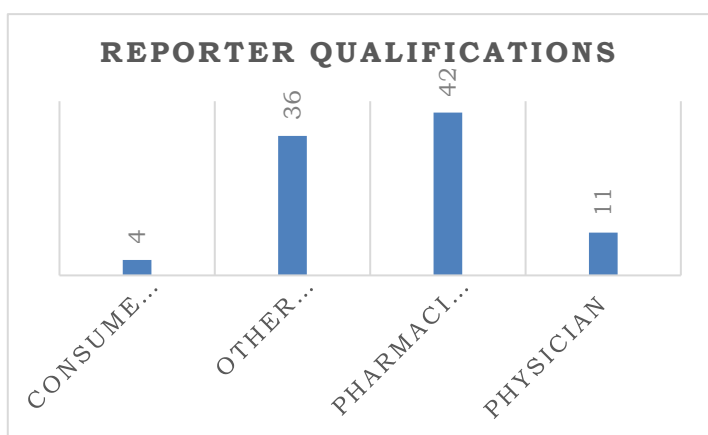
Ministry of Health, PPB Pharmacovigilance Centre

Pharmacovigilance Summary Report: July-September 2018

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.

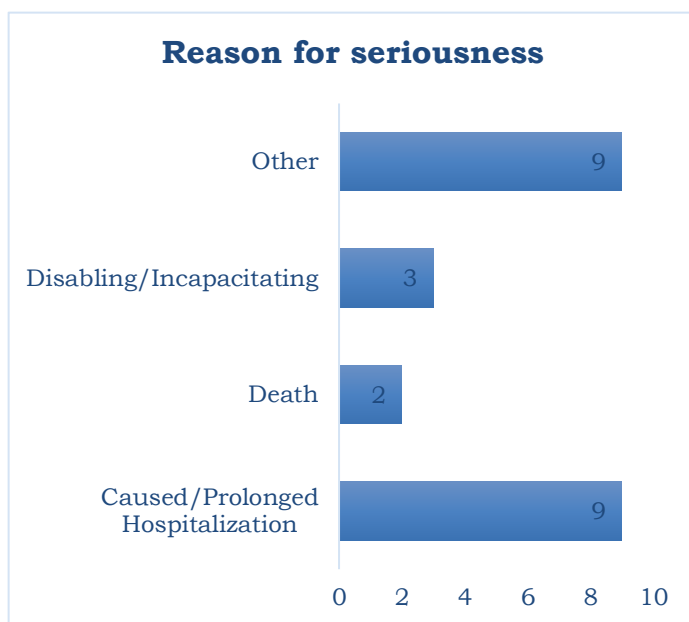
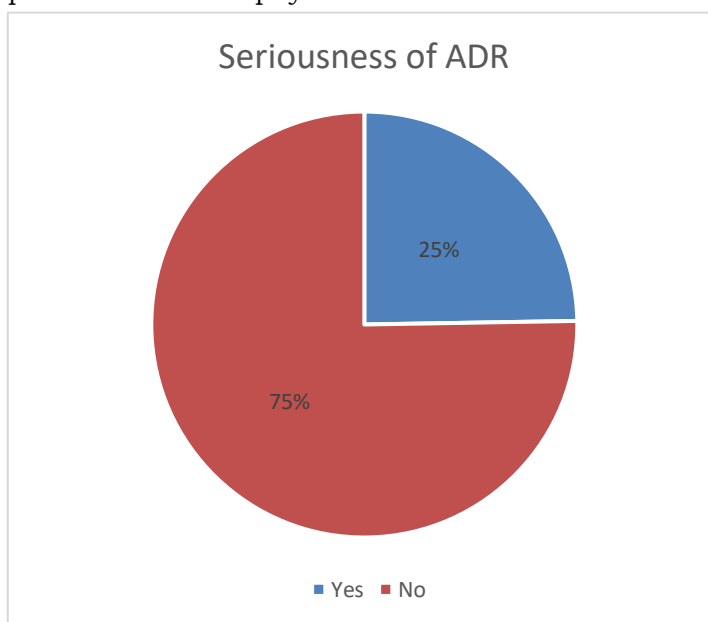
PPB has 6 directorates of which the Directorate of Medicines Information and Pharmacovigilance (MIPV) is responsible for Pharmacovigilance, Post-Market Surveillance, Clinical Trials & Medicines Information activities. MIPV shares quarterly pharmacovigilance reports with stakeholders to serve as a feedback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

Since the introduction of PV in Kenya, a total of 11,653 individual case safety reports have been submitted to the global database 18,461,044 (0.06%). This quarter one of 2018/2019, number of reports received went down (93 reports) compared to previous quarter which submitted (141 reports).



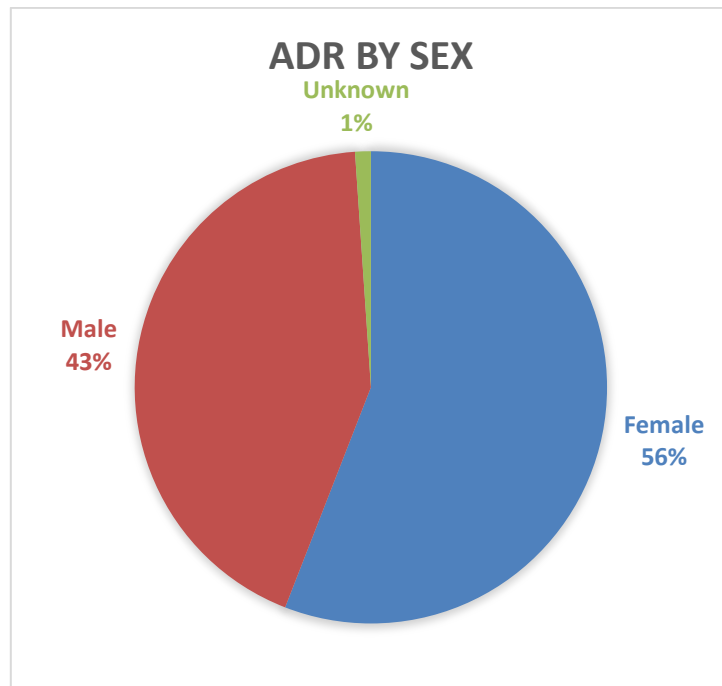
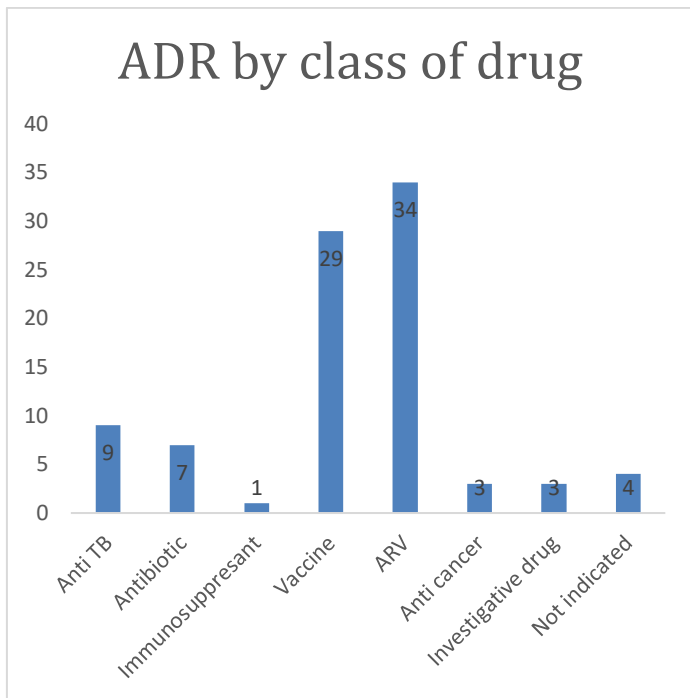
Most ADRs reported consistently by pharmacist throughout the quarter, followed by other professionals then physician.

Majority of the patients that are affected by ADR are adults throughout the quarter.



In quarter 1 of 2018, 23 (25%) serious ADR reports were reported.

Of these, 9 cases required hospitalization. 2 deaths were reported due to suspected ADR and 3 cases were disabling to the patient.

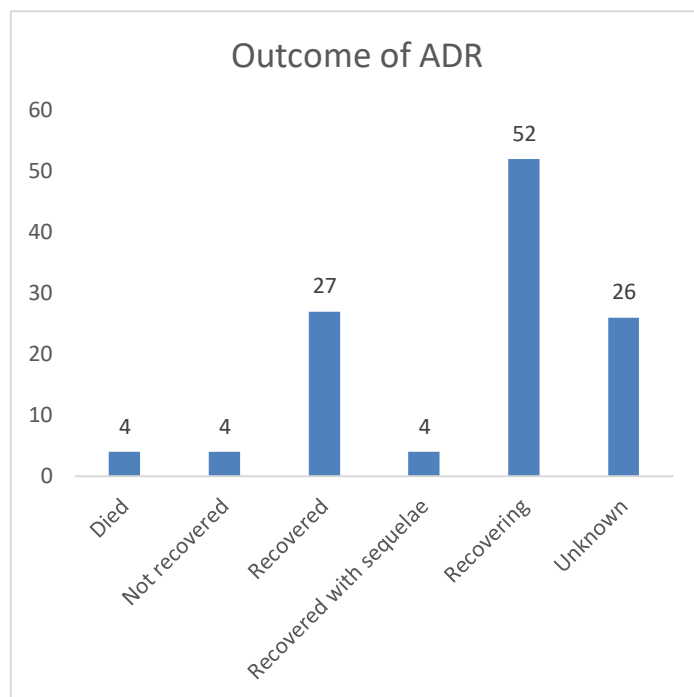


ARVs 34(38%) accounted for most of the suspected ADRs followed by vaccines 29(32%), antiTBs 9 (10%) & antibiotics 7(8%) in that order

Female (56%) mostly affected by ADRs compared to their male (43%) counterparts.

ADR by system organ classification

System organ classification	No. of reports
General disorders and administration site conditions	23
Skin and subcutaneous tissue disorders	22
Gastrointestinal disorders	16
Nervous system disorders	14
Infections and infestations	5
Musculoskeletal and connective tissue disorders	5
Psychiatric disorders	5
Respiratory, thoracic and mediastinal disorders	5
Injury, poisoning and procedural complications	4
Reproductive system and breast disorders	4
Blood and lymphatic system disorders	3
Hepatobiliary disorders	2
Immune system disorders	2
Metabolism and nutrition disorder	2
Eye disorders	1



System organ mostly affected by ADRs is the general disorders and site administration disorders followed by skin and subcutaneous tissue, gastrointestinal disorders system, nervous system disorders and infection and infestations in that order.

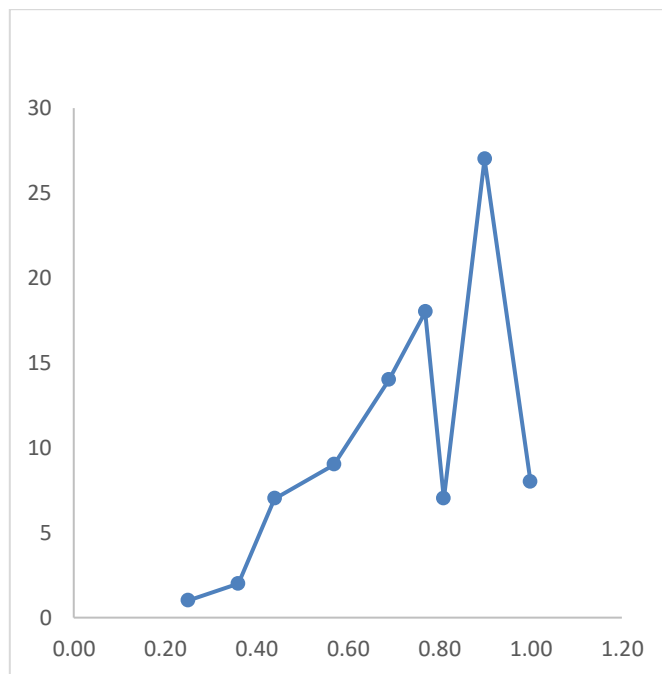
Most ADRs either recovered or were recovering 79 (68%). Outcome of 26 (22%) ADRs were unknown.



Completeness score of the report

Commonly reported ADRs/MeDRA Reported terms

MedDRA, preferred term(s)	No. of reports
Rash	11
Not indicated	10
Gynaecomastia	4
Anaemia	3
Diarrhoea	3
Maternal exposure before pregnancy	3
Neuropathy peripheral	2
Pyrexia Diarrhoea	2
Rash pruritic	2
Therapeutic response unexpected	2
Vomiting	2
Others	49
Total	93



Most reported ADR terms were either rash, gynaecomastia, anaemia, diarrhea and maternal exposure before pregnancy.

This is a measure of how complete an ADR report is filled as assessed by UMC. Quarter 1 had an average completeness score of 62%.

Reporting facility

Reporter inst.	No. of reports
Not Indicated	13
Machakos Level 5 Hospital	11
National Vaccines and Immunization Programme	9
Gatundu District Hospital	5
Nduru District Hospital	5
Mama Lucy Kibaki Hospital - Embakasi	4
Tenwek hospital	4
Bungoma District Hospital	3
Coast Province General Hospital	3
Kijabe (AIC) Hospital	2
Mbagathi District Hospital	2
Shalom Community Hospital (Machakos)	2
Siaya District Hospital	2
Yala Sub-District Hospital	2
Others	23
Total reports	90

Reporting county

County	No. of reports
Siaya	4
Others	23
Nairobi	15
Machakos	13
Not indicated	13
Kiambu	7
Nyamira	5
Bomet	4
Mombasa	3
Bungoma	3
Totals	90



All the reports in quarter were submitted by just 37 health facilities in the country. 13 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). Top reporting facility in the country is this quarter 1 of 2018 was Machakos level 5 hospital (11).

sADR reports were received from 23 of the 47 counties. Nairobi County submitted the most ADRS reports (15) followed by Machakos (13) then Kiambu (7).

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*)