



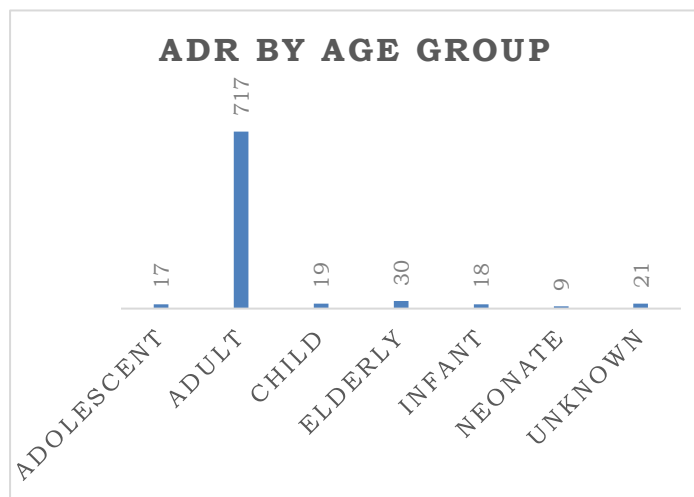
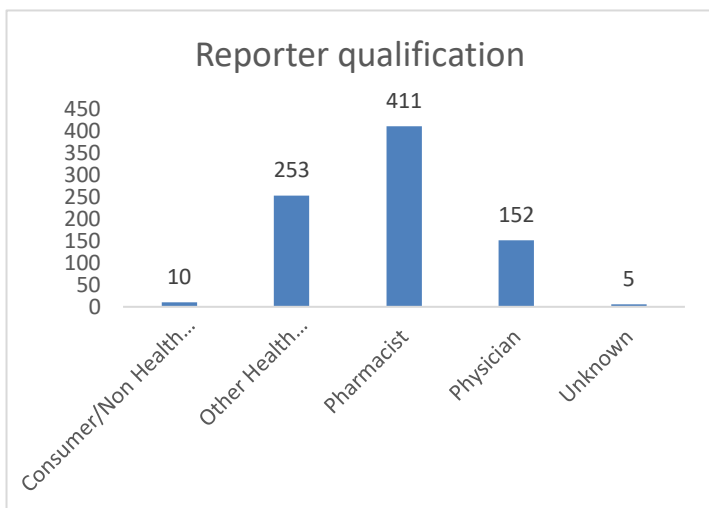
Ministry of Health, PPB Pharmacovigilance Centre

Pharmacovigilance Summary Report: April-June 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.

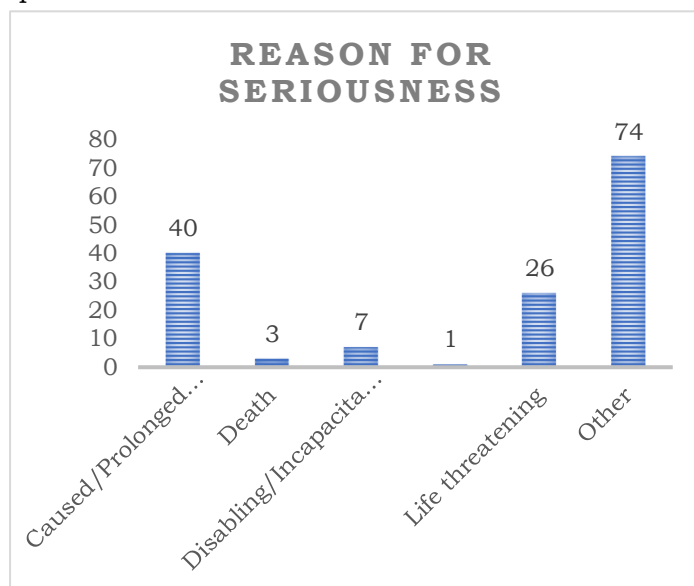
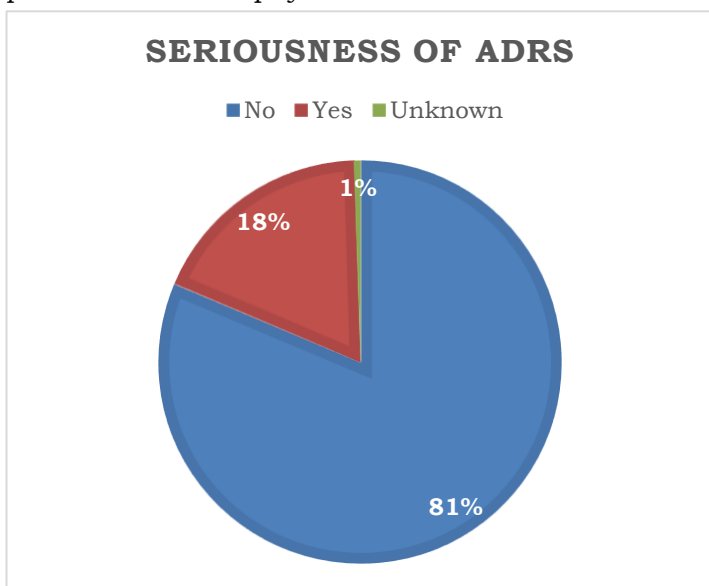
PPB has 6 directorates of which the Directorate of Medicines Information and Pharmacovigilance (MIPV) is responsible for Pharmacovigilance, Post-Market Surveillance, Clinical Trials & Medicines Information activities. MIPV shares quarterly pharmacovigilance reports with stakeholders to serve as a feedback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

Since the introduction of PV in Kenya, a total of 12,231 individual case safety reports has been submitted to the global data reports 20,322,506 (0.06%). This quarter four of 2018/2019, number of reporting went up (831 reports) compared to previous quarter which submitted (104 reports). This could be explained by the fact that vigiflow system was undergoing maintenance for some period and therefore reports could not be uploaded at the time. This are therefore backlog reports for the entire year.



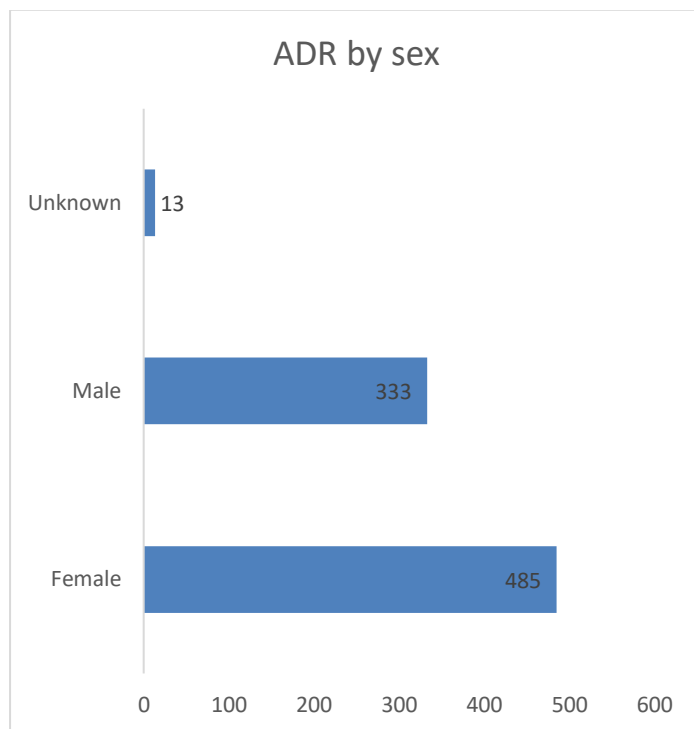
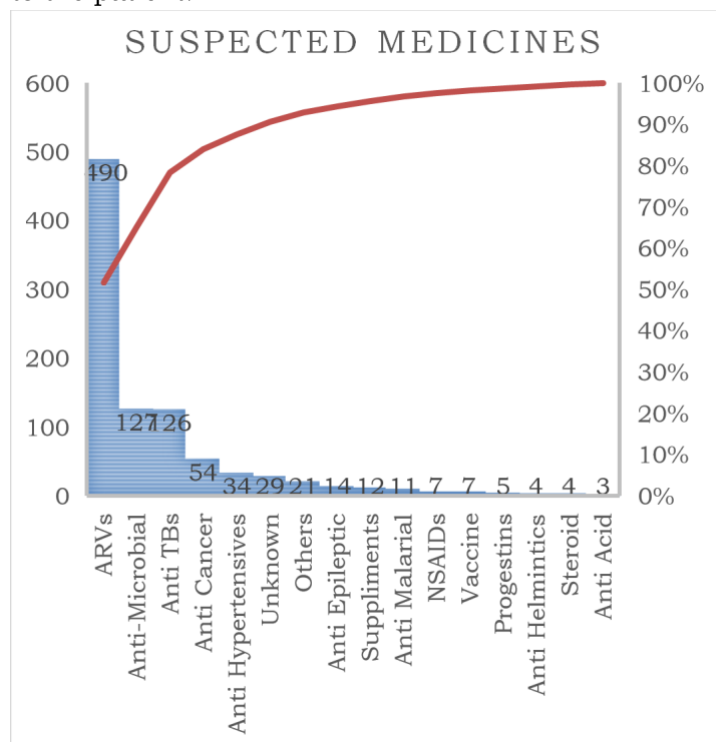
Most ADRs reported consistently by other pharmacists throughout the quarter, followed by other professionals then physician.

Majority of the patients that were affected by ADRs were adults 86% (717 reports) throughout the quarter.





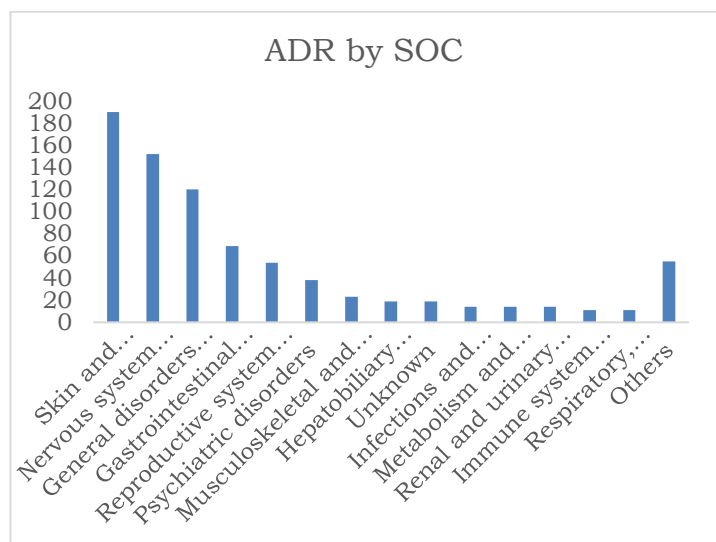
In quarter 4 of 2018/19, 151 (18%) serious ADR reports were reported. Of these, 26 cases were life-threatening and 40 cases required hospitalization. 3 deaths were reported due to suspected ADR and 7 cases were disabling to the patient.



ARVs 490(59%)accounted for most of the suspected ADRs followed by anti-microbials 127(15%), anti-TBs 126(15%), anti-cancer 54(6%) in that order

Female 485(58%) mostly affected by ADRs compared to their male counterparts.

ADR by system organ classification

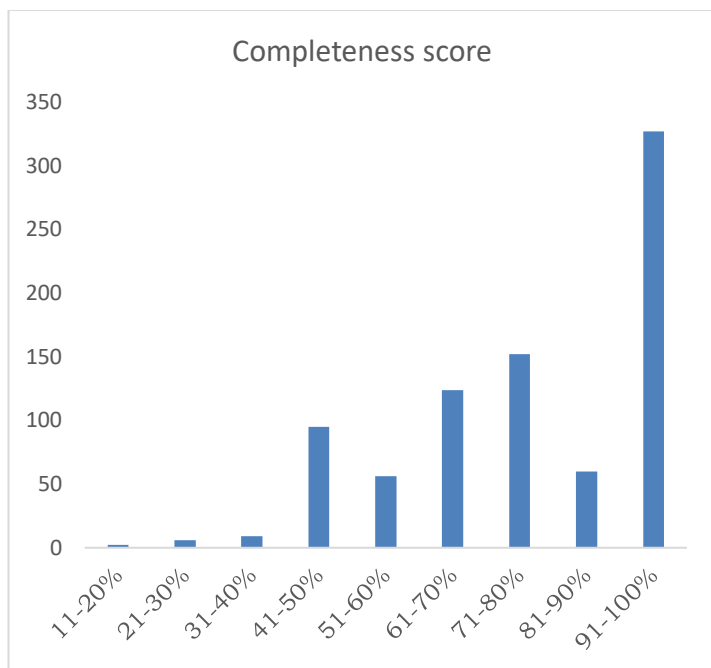


Outcome of the ADRs

Outcome	No. of reports
Unknown	322
Recovering	291
Recovered	171
Recovered with sequelae	31
Not recovered	21
Died	2
Total	838

System organ mostly affected by ADRs is the skin and subcutaneous tissue, followed by nervous system, general disorders and psychiatric in that order.

Outcome of most of the ADRs were unknown 322 (38%), 462(55%) of the total ADRs reported either recovered/resolved or were either recovering or resolving.

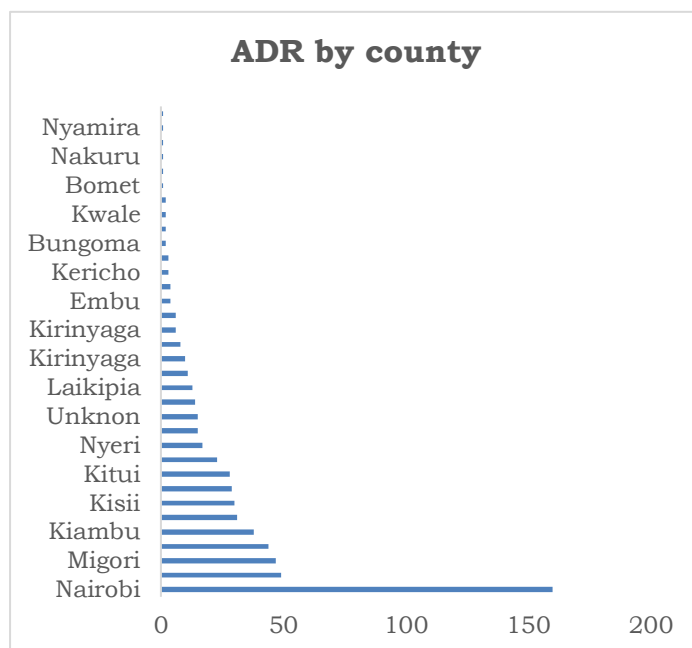


MeDRA Mapped Term	Count
Dizziness	74
Rash	58
Headache	53
Drug ineffective	46
Gynaecomastia	45
Pruritus	40
Insomnia	27
Not Mapped	23
Fatigue	20
Abdominal pain	19
Jaundice	19
Neuropathy peripheral	19
Stevens-Johnson syndrome	19
Somnolence	18
Drug eruption	17
Nausea	17
Malaise	16
Rash pruritic	14
Hallucination	13
Diarrhoea	12
Erectile dysfunction	10
Vomiting	10
Others	424
Total	1013

This is a measure of how complete an ADR report is filled as assessed by UMC. Quarter 4 had an average completeness score of 77%.

Most reported ADR terms were either dizziness, rash, headache, drug ineffective, gynecomastia and pruritus among others.

Facility	No. of reports
Nairobi Hospital	38
Kenyatta National Hospital	23
The Mater Hospital Mukuru	19
Karungu Sub-District Hospital	15
Kitui County Referral Hospital	15
Iyabe District Hospital (Kisii South)	13
Moi Teaching Referral Hospital	13
Unknown	15
Consolata Hospital	11
Dreams Center Dispensary	11
EDARP Donholm	10
Machakos Level 5 Hospital	10
Makueni District Hospital	10
Nyanza Provincial General Hospital (PGH)	10
Others	410
Total	623



All the reports in quarter were submitted by 169 health facilities in the country. 15 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 MTRH in Uasin Gishu county.

sADR reports were received from 33 of the 47 counties. Nairobi county submitted the highest number of ADRS reports 160 followed by Kisumu 49 reports, Migori 47, Siaya 44 and Kiambu who submitted 38 reports.



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

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