



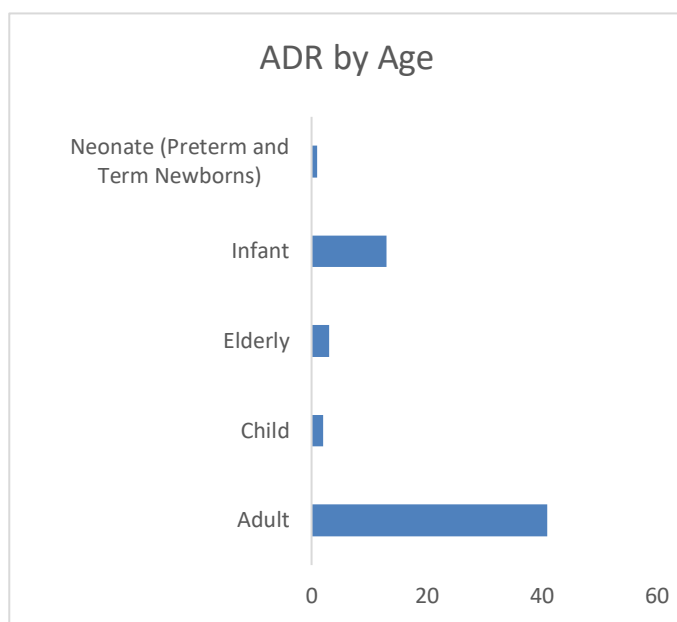
# Ministry of Health, PPB Pharmacovigilance Centre

## Pharmacovigilance Summary Report: October –December 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.

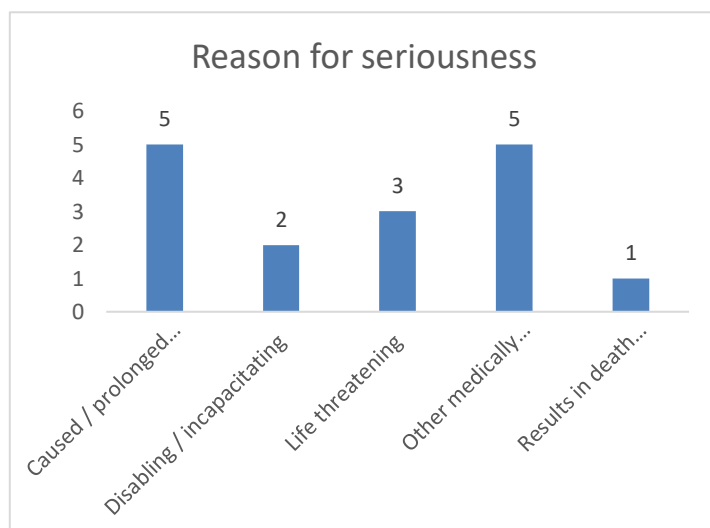
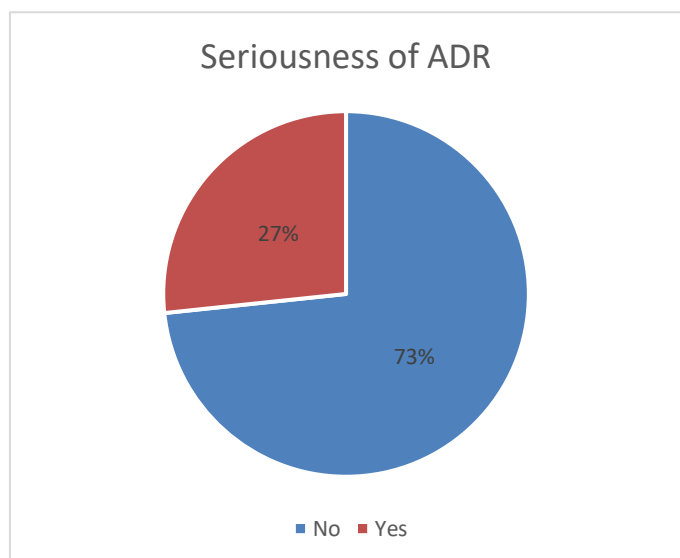
PPB has 6 directorates of which the Directorate of Medicines Information and Pharmacovigilance (MIPV) is responsible for Pharmacovigilance, Post-Market Surveillance, Clinical Trials & Medicines Information activities. MIPV shares quarterly pharmacovigilance reports with stakeholders to serve as a feedback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

Since the introduction of PV in Kenya, a total of 11,373 individual case safety reports has been submitted to the global data base reports 18,873,573 (0.06%). This quarter two of 2018/2019, number of reports went down (60 reports) compared to previous quarter which submitted (93 report).



Most ADRs are reported consistently by pharmacists throughout the quarter.

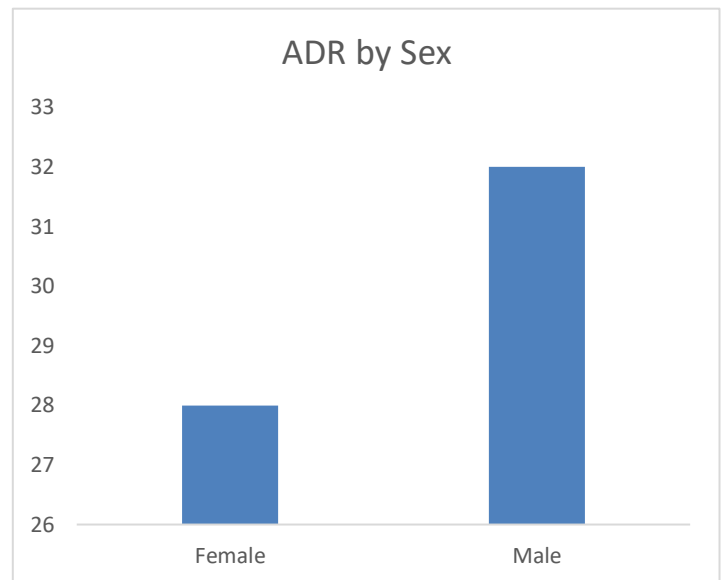
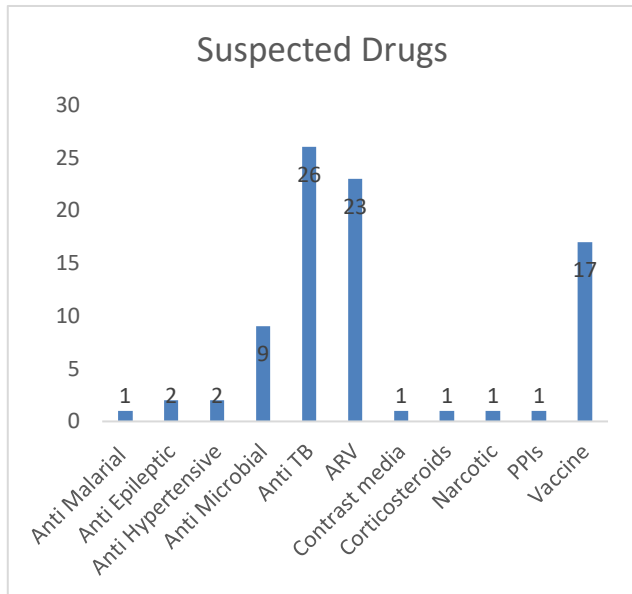
Majority of the patients that are affected by ADR are adults throughout the quarter, followed by infants then elderly patients.





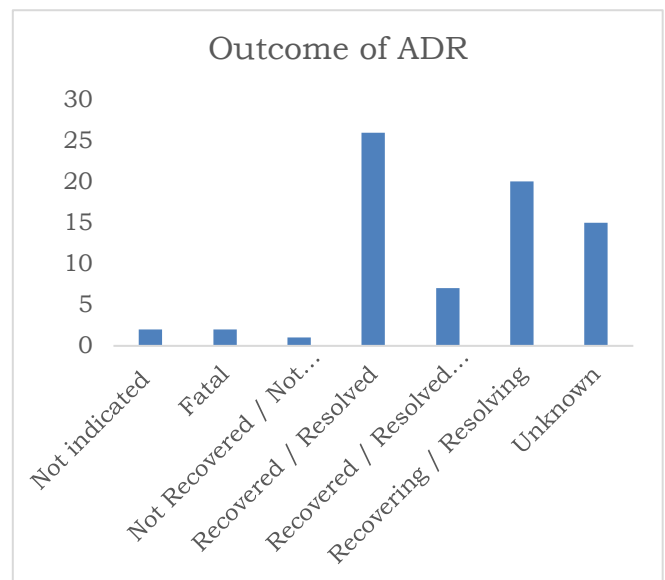
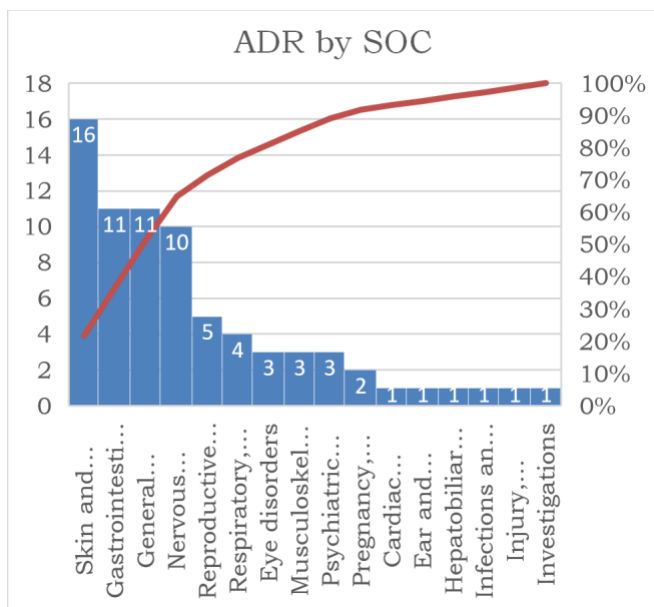
In quarter 2 of 2018/2019, 16 (36%) serious ADR reports were reported.

Out of the 16 (36%) serious reports received, 5(31%) of the cases were due to other medically important condition and caused prolonged hospitalizations respectively, 3 (19%) cases were life-threatening and 2(13%) disabling cases.



Total molecules suspected of causing ADRs were 84. Anti-TBs accounted for most of the suspected ADRs (31%) followed by ARVs (27%), Vaccines, (20%), Antimicrobials (12%) & Anti hypertensives and Anti epileptics respectively at (2% each).

More males were affected by ADRs in quarter 2.

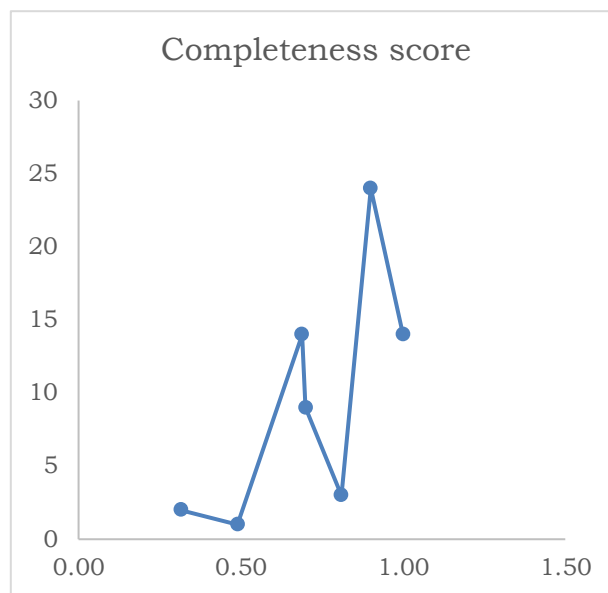
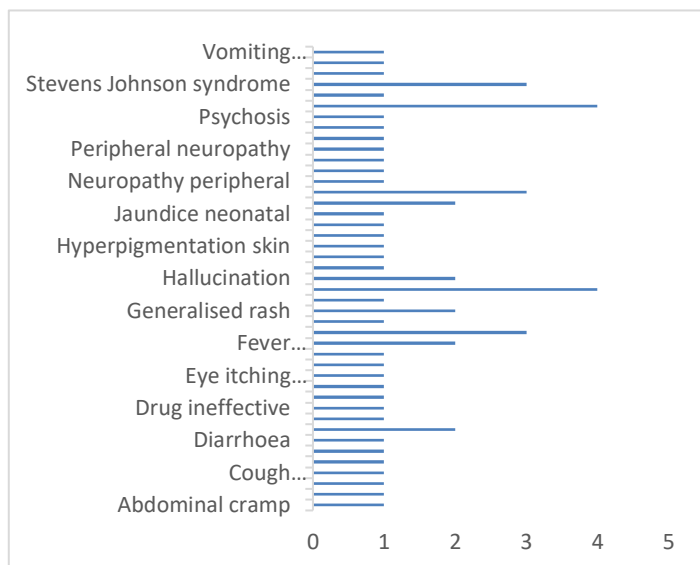


System organ mostly affected by ADRs is the skin and sub-cutaneous tissues disorders, followed by gastrointestinal disorders and general disorders and administration site conditions respectively, nervous system disorders ,reproductive system and breast disorders among others in a descending manner.

Most of the ADRs either recovered/resolved or were recovering/resolving (46 of the reported cases). The outcome of 21% (15 reports) of the ADRs reported was unknown.



**Commonly reported ADRs/MeDRA Reported Completeness score of the reports terms**



Most reported ADR terms were either rash, gynecomastia, SJS, nausea, dizziness, fever and convulsions among others.

This is a measure of how complete an ADR report is filled as assessed by UMC. Quarter 2 had an average completeness score of 81%.

**Reporting facilities**

Facility	No.
National Vaccines and Immunization Programme	6
Aga Khan Hospital	4
Ahero Sub-District Hospital	4
Chuka District Hospital	3
Holy Family Oriang Mission Dispensary	3
Malindi District Hospital	3
Moticho Health Centre	3
Nduru District Hospital	3
Self	3
The Mater Hospital Mukuru	3
Kariobangi Health Centre	2
Mbagathi District Hospital	2
Ruiru Sub-District Hospital	2
St Camillus Mission	2
Unknown	2
Waitthaka Health Centre	2
Others	13
<b>Total</b>	<b>60</b>

**Reporting County**

County	No. of facilities
Homa bay	1
Kakamega	1
Kiambu	2
Kilifi	1
Kisii	1
Kisumu	2
Meru	1
Migori	1
Mombasa	2
Nairobi	11
Nyamira	2
Siaya	3
Unknown	1
<b>Total</b>	<b>30</b>



All the reports in the quarter were submitted by 30 health facilities in the country. 2 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 12 of the 47 counties in quarter 2. Nairobi County, with 11 facilities reporting followed by Siaya 3 facilities. Majority of the counties had one facility reporting e.g. Homabay, Kakamega, Kilifi, Kisii, Meru and Migori.

*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*)