PHARMACY AND POISONS BOARD

Pharmacovigilance Summary Report: April 1st to June 30th 2025 (Q4)

The Pharmacy and Poisons Board is the National 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 of drugs and poisons.

The PPB has 4 directorates of which the Directorate of Product Safety (PDS) is responsible for Pharmacovigilance, Post-Marketing Surveillance, Clinical Trials & Medicines Information activities. PDS shares quarterly pharmacovigilance reports with stakeholders to serve as a feedback mechanism and also encourage all stakeholders to report adverse events.

Since the introduction of PV in Kenya, a total of 22,255 individual case safety reports (ICSRs) have been submitted to the global database representing 0.05% of the total ICSRs submitted globally.

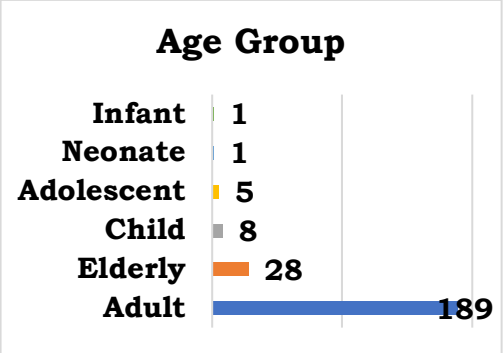
Suspected Adverse Drug Reactions (SADRs)

There were 237 suspected adverse drug reaction (SADR) reports submitted to the National Pharmacovigilance Centre within Quarter 4 (1st April – 30th June 2025). Of the 237 reports, 232 (97.89%) reports were initial reports while 5 (2.11%) reports were follow-up reports. Only one copy of each ICSR would be used in the analysis to eliminate duplicity hence the total number of reports included in this quarterly summary was 232. Of the 232 initial reports, there are 223 reports categorized as suspected adverse drug reactions (SADRs), 2 reports were on both SADRs and Therapeutic Ineffectiveness (TI), while 7 report was on only TI.

Product Category (n=232)

Product Category	Count	Proportion
Medicinal product	218	93.97%
Blood products	0	0.00%
Herbal product	0	0.00%
Cosmeceuticals	0	0.00%
Others	1	0.43%

Age Group (n=232)



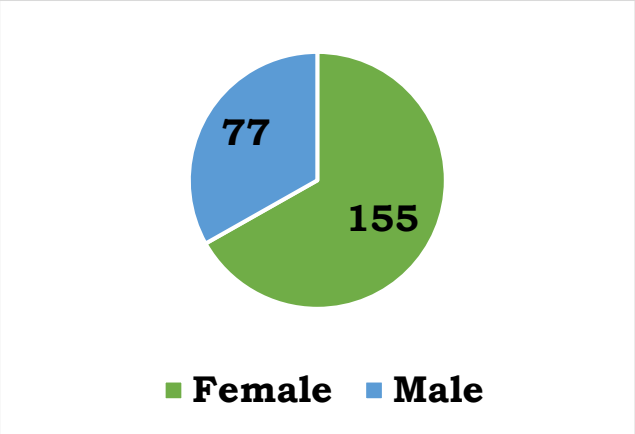
Most of the ADR cases reported were due to medicinal products (93.97%). In 1

The prevalence of SADRs was highest (81.47%) amongst the

(0.37%) report, the product category was marked as others which involved Alpha-Hyper-Methrin. The rest of the reports did not indicate the product category. In this Quarter, there were no SADR reports on Blood Products, Herbal Products and Cosmeceuticals

adults (18-64) in comparison to the other age groups. This followed by the elderly (12.07%) and the children (3.45%). The rest of the reports included the adolescent, infant and neonate age groups as shown above.

Gender (n=232)



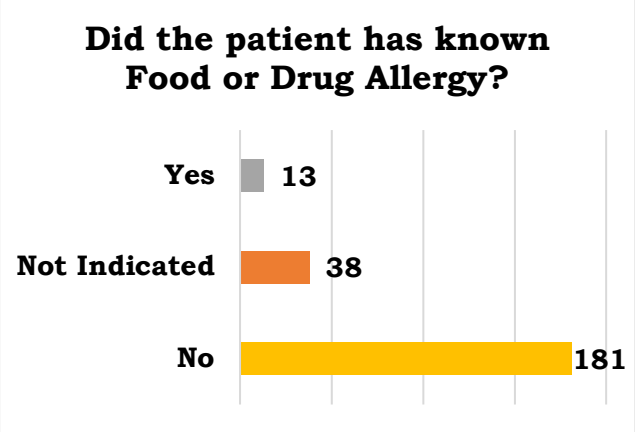
The frequency of reported SADRs was higher in female (66.81%, 155) as compared to male (33.19%, 77).

Pregnancy Status (n=155)

Pregnancy Status	Count	Proportion
Not pregnant	88	56.77%
Not Applicable	31	20.00%
Not Indicated	28	18.06%
2nd Trimester	4	2.58%
3rd Trimester	3	1.94%
1st Trimester	1	0.65%
Grand Total	**155**	**100.00%**

Out of the 155 females with reported SADRs, 88 (56.77%) were not pregnant at the time of reporting. Of the 8 pregnant women, one was in her 1st trimester, 4 were in their 2nd trimester while 3 were in their 3rd trimester. A total of 28 (18.06%) female cases reported did not indicate the pregnancy status.

Known Allergy (n=232)



Reported Allergen (n=13)

Allergen	Count	Proportion
Not Indicated	6	46.15%
Sulphur	4	30.77%
Proteins	1	7.69%
Diclofenac	1	7.69%
Asthma	1	7.69%
Grand Total	**13**	**100.00%**

The frequency of reported SADRs was higher in patients with no history of known allergies (78.02%, 181) compared to those with known allergies (5.60%, 13) as shown above.	Out of the 13 SADR reports with known allergies, allergy to Sulphur and were the most reported with 4 reports (30.77%) as shown above.

Suspected medicines (n=246)

Suspected Drug Name	Count	Proportion
TDF/3TC/DTG (300mg/300mg/50mg)	40	16.26%
RHZE (150mg/75mg/400mg/275mg)	24	9.76%
Tenofovir Disoproxil Fumarate (300mg)	16	6.50%
Ceftriaxone for injection USP 1000mg	8	3.25%
Metronidazole	8	3.25%
Rifapentine/Isoniazid (300mg/300mg)	6	2.44%
Isoniazid	6	2.44%
Dolutegravir	4	1.63%
Iron sucrose injection USP	4	1.63%
Sulfadoxine & Pyrimethamine	4	1.63%
Rifampicin	4	1.63%
Rifampicin/Isoniazid (150mg/75mg)	4	1.63%
Nifedipine 20mg	4	1.63%
Heparin Injection BP 5000 IU/ML	4	1.63%
Amoxicillin	3	1.22%
Losartan potassium & Hydrochlorothiazide.	3	1.22%
Bupivacaine Hydrochloride & Dextrose	3	1.22%
Cycloserine Capsules USP 250 mg	3	1.22%
Nifedipine Extended-Release Tablets USP 20 mg	3	1.22%
Docetaxel Trihydrate	3	1.22%
Azithromycin Tablets 500 mg	3	1.22%
Enalapril	3	1.22%
Amlodipine Besilate BP	3	1.22%

Key:

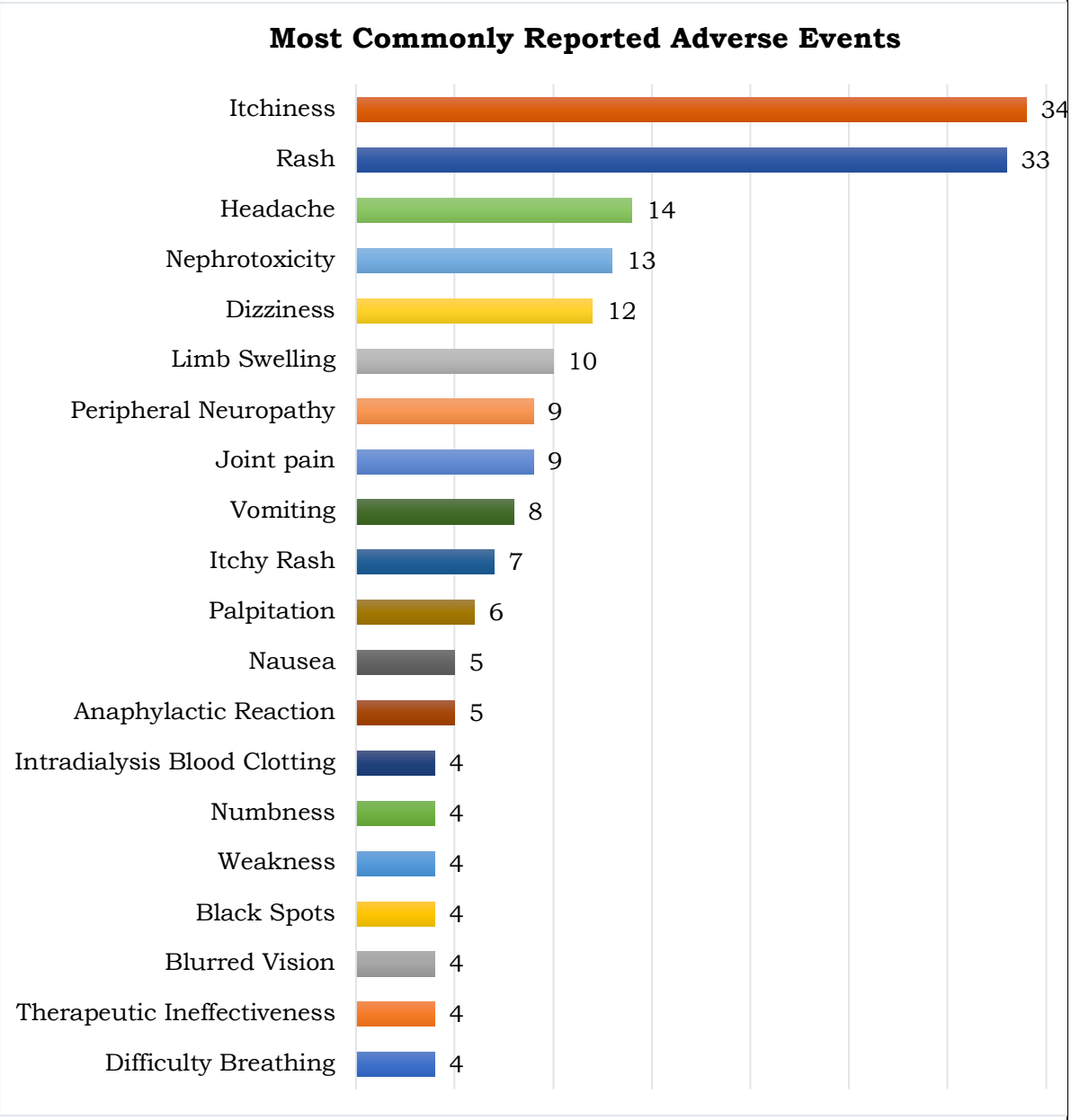
TDF/3TC/DTG*: Tenofovir/Lamivudine/Dolutegravir (300mg/300mg/50mg)*

RHZE*: Rifampicin/Isoniazid/Pyrazinamide/Ethambutol (150mg/75mg/400mg/275mg)*

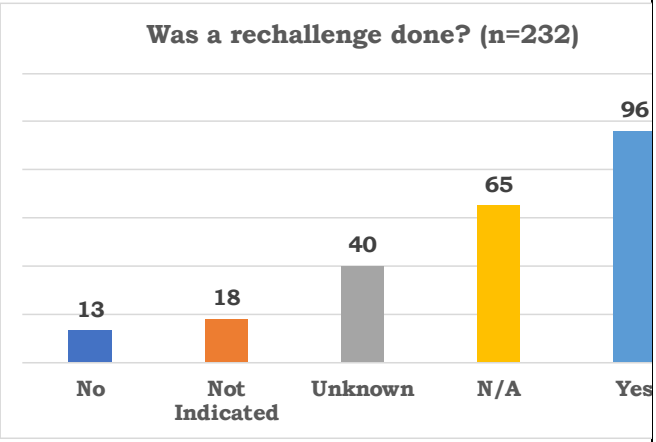
A total of 95 generic names/fixed dose combinations (FDC) were reported as suspected medicines in this quarter. Tenofovir/Lamivudine/Dolutegravir (300mg/300mg/50mg) Fixed Dose Combination was the most frequently reported (16.26%,40). The Rifampicin/Isoniazid/Pyrazinamide/Ethambutol (150mg/75mg/400mg/275mg) regimen was reported as the suspected medicine in 24 cases (9.75%), while Tenofovir Disoproxil Fumarate (300mg) was reported in 16 reports (6.50%). The table above consists of a list of the most reported medicines in Quarter 4.

Commonly reported adverse reactions

The following adverse drug reactions were commonly reported in Quarter 4: Itching 10.30%), Rash (10.00%); and headache (4.24%). The figure below shows adverse drug reactions reported in at least 4 reports.



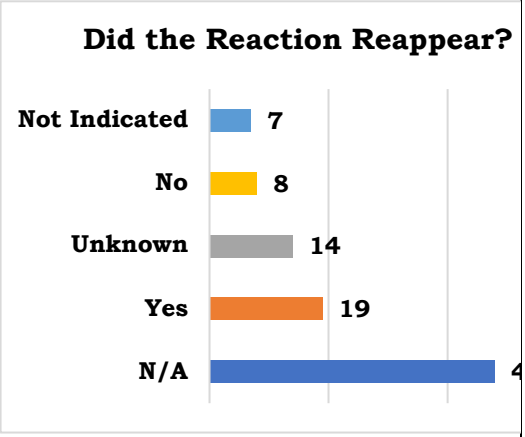
Rechallenge (n=232)



A rechallenge was conducted in 41.38% (96) of the 232 cases reported. In 5.60% (13) of the reported cases, rechallenge was not conducted.

The rechallenge status in 40 reports (17.24%) were marked as **unknown** and **not applicable** in 28.02% (65) of the reports. 7.76% (18) of the reports did not indicate if a re-challenge was done or not.

Reaction Reappear (n=96)



The suspected ADR reappeared in only 19.79% (19) of the cases where a rechallenge was done. However, in 8.33% of the cases (8), the suspected ADR did not reappear following a rechallenge.

In most of the cases, the rechallenge outcome was marked as either **unknown**, **not indicated** or **not applicable** as shown in the table above.

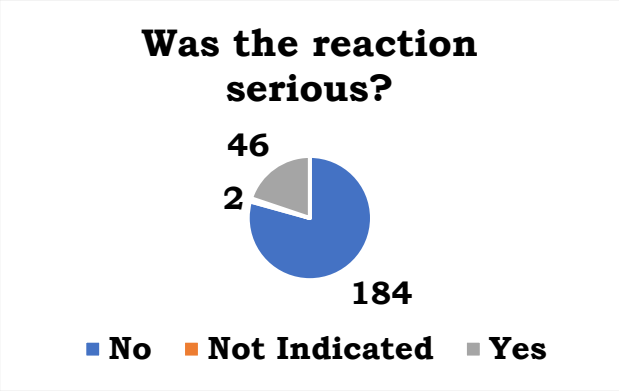
Severity (n=232)

Severity	Count	Proportion
Moderate	111	47.84%
Mild	81	34.91%
Severe	33	14.22%
Not Indicated	5	2.16%
Fatal	2	0.86%
Grand Total	**232**	**100.00%**

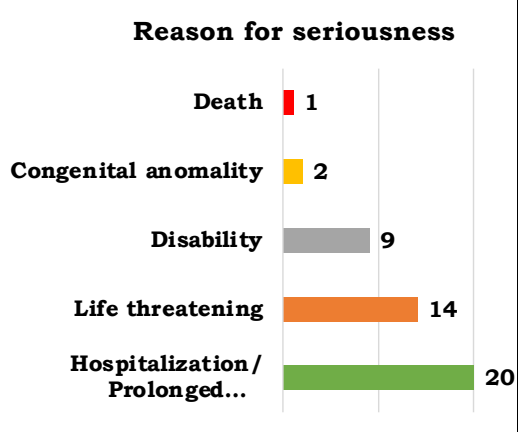
Of the 232 suspected adverse drug reaction reports received in Quarter 4, 14.22% (33) were classified as severe, 0.86% (2) were classified as fatal while 2.16% (5) of the reports did not indicate the severity.

Most of the reports (47.84%, 111) were graded as being of moderate severity whereas 34.91% (81) of the reports were graded as mild.

Was the reaction serious? (n=232)



Reason for seriousness (n=46)



Of the 232 SADR reports received in Q4, 19.83% (46) were classified as serious while most of the received reports (79.31%, 184) were classified as not serious. Two reports did not indicate whether they were serious or not.

Out of the 46 serious SADR reports received, hospitalization/ prolonged hospitalization was the major reason for seriousness (43.48%, 20) followed by life threatening with 14 reports (30.43%). In one report, the reason for seriousness was death. The other reason for seriousness marked by the reporters was disability as shown in the figure above.

Actions taken (n=232)

Action Taken	***Count***	***Proportion***
Drug withdrawn	149	64.22%
Dose not changed	63	27.16%
Not applicable	11	4.74%
Dose increased	5	2.16%
Unknown	2	0.86%
Dose reduced	2	0.86%

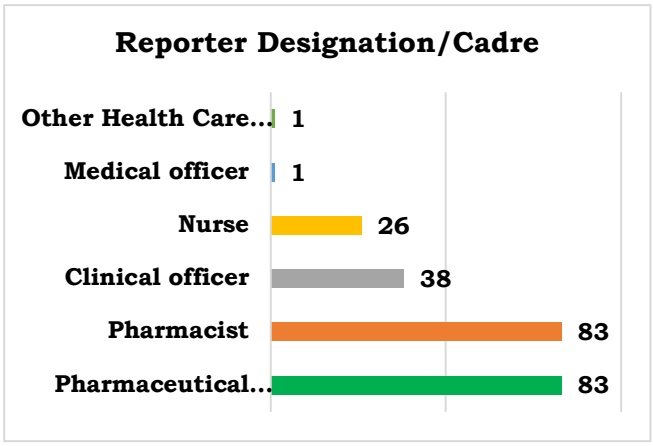
Among the actions taken by the health care workers following the occurrence of the adverse drug reaction included withdrawal of the offending drug in 64.22% (149) cases and dose reduction (0.86%, 2). A total of 63 reports (27.16%) indicated that the dose of the suspect medicine was not changed.

Outcome (n=232)

Outcome	Count	Proportion
Recovering/Resolving	90	38.79%
Recovered/Resolved	78	33.62%
Unknown	45	19.40%
Not recovered/Not resolved	13	5.60%
Recovered/Resolved with sequelae	4	1.72%
Fatal	2	0.86%
Grand Total	**232**	**100.00%**

Out of the 232 SADR reports received in Q4, two cases were fatal. A total of 38.79% (90) of the cases were reported to be recovering/resolving at the time of reporting while 33.62% (78) of the cases were already recovered or resolved at the time of reporting.

The outcome was unknown in 19.40% (45) of the cases reported.



Reporter designation (n=232)

Majority of the SADR reports received by the national pharmacovigilance center in Quarter 4 were submitted by Pharmacists and Pharmaceutical Technologists (35.78%, 83) each.

Clinical officers submitted 16.38% (38) of the total reports followed by Nurses and Medical officers as shown in the table on the left.

Institution

In this Quarter, only 122 facilities out of the 9,000 facilities listed in the Kenya Master facility reported SADRs. 24 facilities reported at least 3 reports and above. The top leading facilities were Siaya County Referral Hospital with 10 reports (4.31%) followed by Dreams Center Dispensary (Lang'ata) with 9 reports (3.88%). Kangu Dispensary and Gathigiriri Health Centre were third most reporting facilities in this quarter with 7 reports (3.45%) each. Below is a list of top 24 facilities with at least 3 reports and above.

No	Institution	Count	%	No	Institution	Count	%
1	Siaya County Referral Hospital	10	4.31%	13	Mutithi Health Centre	4	1.72%
2	Dreams Center Dispensary (Lang'ata)	9	3.88%	14	Mbooni District Hospital	3	1.29%
3	Kangu Dispensary	8	3.45%	15	Likoni District Hospital	3	1.29%
4	Gathigiriri Health Centre	8	3.45%	16	Ukwala Sub County Hospital	3	1.29%
5	Nyandiwa Level IV Hospital	7	3.02%	17	Murang'a District Hospital	3	1.29%
6	Coast General Teaching and Referral Hospital	7	3.02%	18	Coast Province General Hospital	3	1.29%
7	Nguluni Health Centre	5	2.16%	19	Kerugoya County Refferal Hospital	3	1.29%
8	Kenyatta National Hospital	5	2.16%	20	St Joseph Catholic Dispensary (Ruiru)	3	1.29%
9	Malindi District Hospital	5	2.16%	21	Nanyuki Teaching & Referral Hospital	3	1.29%
10	Sigomere Health Centre	4	1.72%	22	Meru Teaching and Refferal Hospital hospital	3	1.29%
11	Kathiani Sub County Hospital	4	1.72%	23	Bungoma County Referral Hospital	3	1.29%
12	Yala Sub County Hospital	4	1.72%	24	Lodwar County Referral Hospital	3	1.29%

County

SADR reports were received from 34 of the 47 counties. Kirinyaga county submitted the highest number of SADR reports (37, 15.95%) followed by Nairobi (24, 10.34%) and Siaya (23, 9.91%) Counties. Below is a table of the counties that submitted SADR reports in Quarter 4.

No	***County***	***Count***	***%***	***No***	***County***	***Count***	***%***
1	Kirinyaga	37	15.95%	**18**	Tharaka Nithi	4	1.72%
2	Nairobi County	24	10.34%	**19**	Migori	4	1.72%
3	Siaya	23	9.91%	**20**	Vihiga	4	1.72%
4	Mombasa	21	9.05%	**21**	Kajiado	3	1.29%
5	Kilifi	11	4.74%	**22**	Nyeri	3	1.29%
6	Machakos	10	4.31%	**23**	Nakuru	3	1.29%
7	Kiambu	8	3.45%	**24**	Kisumu	2	0.86%
8	Homa Bay	8	3.45%	**25**	Marsabit	2	0.86%
9	Turkana	8	3.45%	**26**	Trans Nzoia	2	0.86%
10	Makueni	7	3.02%	**27**	Nyandarua	2	0.86%
11	Kakamega	6	2.59%	**28**	Uasin Gishu	2	0.86%
12	Bungoma	6	2.59%	**39**	Kisii	2	0.86%
13	Laikipia	5	2.16%	**30**	Kericho	2	0.86%
14	Kitui	5	2.16%	**31**	Narok	2	0.86%
15	Meru	5	2.16%	**32**	Isiolo	1	0.43%
16	Nandi	4	1.72%	**22**	Samburu	1	0.43%
17	Murang'a	4	1.72%	**34**	Embu	1	0.43%

ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

The National Pharmacovigilance Centre received a total of 26 AEFI reports in the period between 1st April 2025 and 30th June 2025. 100% of the reports received in this quarter were initial reports.

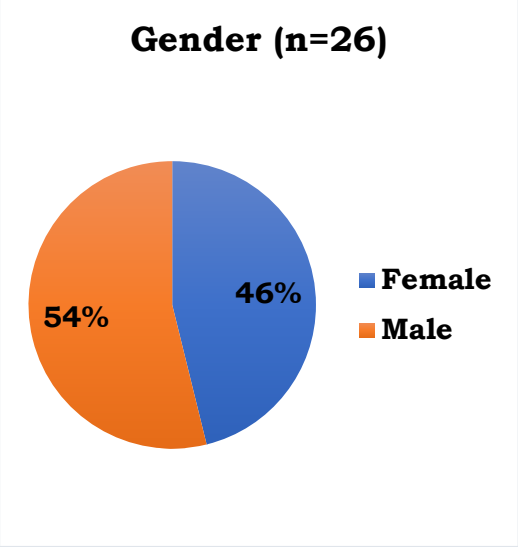
Type of Vaccine

Vaccine Type	Count	%
Pentavalent Vaccine (DTP-HepB-Hib)	10	26.32
Malaria (RTSS)Vaccine	6	15.79

Of the total AEFI reports received, most events were caused by the Pentavalent Vaccine (DTP-HepB-Hib) 26.32% (10), Pneumococcal conjugate vaccine at 21% (10) and Rota virus vaccine at 9% (6). The

Pneumococcal conjugate vaccine	6	15.79
Rota virus vaccine	4	10.53
Measles Rubella Vaccine	4	10.53
Bivalent oral Polio vaccine	3	7.89
Tetanus Diptheria Vaccine	2	5.26
BCG	1	2.63
Vaxigrip	1	2.63
Inactivated polio vaccine	1	2.63

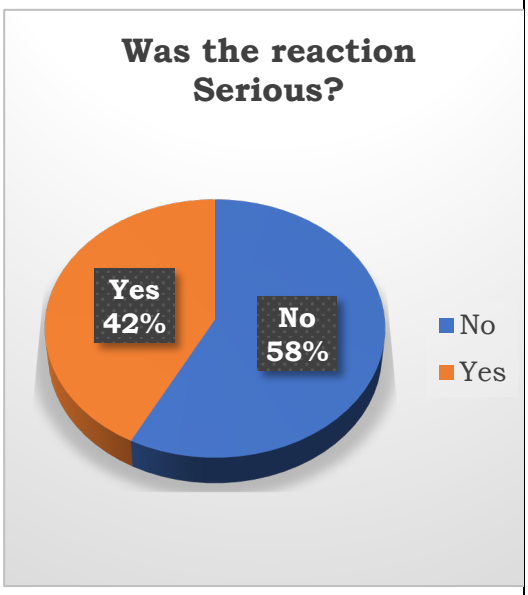
table above shows the vaccines and their proportions of AEFIs.



Outcome	Count	Proportion
Recovering/Resolving	13	50.00%
Recovered/Resolved	7	26.92%
Fatal	5	19.23%
Not recovered/Not resolved/Ongoing	1	3.85%

Of the AEFI reports received in this quarter, it was noted that males affected were 54% (14) more than females 46% (12).

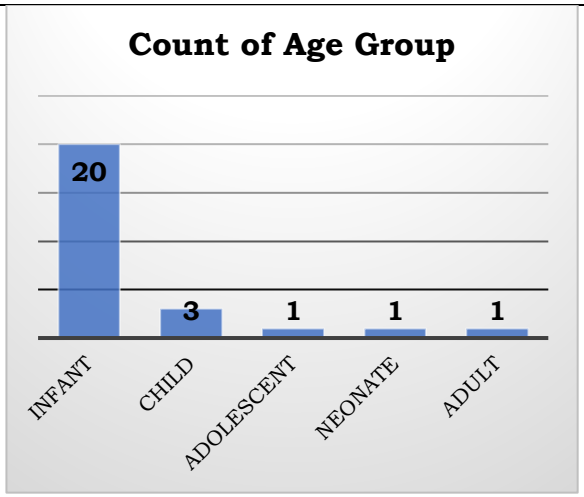
Of the 26 AEFI reports received, 13 indicated the outcome as either recovering/resolving. 7 of the reported cases were noted to have recovered/resolved while one (1) report was reported to have not recovered. Unfortunately, there were five (5) fatal outcomes in the reporting period



Majority of the AEFI reports 58% (15) received in this quarter were reported as not serious, with 42% (11) reported as serious.

Of the 11 AEFI reports noted to be serious 45.45% (5) were due to death. Three (3) were due to hospitalization or prolonged hospitalization, two (2) were due to other important medical events while one (1) was due to life threatening.

Reporter Designation	Count	Proportion
Nurse	13	50.00%
Pharmacist	6	23.08%
Pharmaceutical technologist	3	11.54%
Clinical officer	3	11.54%
Paediatrician	1	3.85%



Majority of the AEFIs in this quarter were reported by Nurses who submitted 13 (50%) reports. Pharmacists submitted 6 (23.08%) reports. Pharmaceutical technologist and Clinical officers submitted three (3) reports each while Pediatrician submitted one (1) report.

Majority of the AEFIs reported in this quarter affected the Infant age group (< 1year) (20) and Child (1-11 years) (3). The least affected age group in this quarter were the Neonates and Adolescents and Adults with only one (1) report each.

Reporting institution (n=35)

Facility	Count	Proportion
Ukwala Sub County Hospital	2	7.69%
Machwele Dispensary	2	7.69%
Kangu Dispensary	2	7.69%
Difathas Health Centre	2	7.69%
Ebusiratsi Health Centre	2	7.69%
Haven Hospital	2	7.69%
Kayole II Sub-County Hospital	1	3.85%
Kapsabet County Referral Hospital	1	3.85%
Mechimeru Dispensary	1	3.85%
Mtwapa Sub County Hospital	1	3.85%
Karati Health Centre	1	3.85%
Nazareth Hospital	1	3.85%
Embakasi Health Centre	1	3.85%
Cheptais Sub County Hospital	1	3.85%
Gertrudes Childrens Hospital	1	3.85%
Ematsuli Dispensary	1	3.85%
Sachangwan Health Centre	1	3.85%
Igegania Sub-County Hospital	1	3.85%
Ambira Sub-County Hospital	1	3.85%
Kangemi Health Centre	1	3.85%

In this Quarter, only 20 facilities out of the 9,000 facilities listed in the Kenya Master facility reported AEFIs. The highest reporting facilities included Ukwala Sub-County Hospital, Machwele Dipsenasry, Kangu Dispensary, Diftathas Health Centre, Ebusiratsi Health Centre and Haven Hospital, each with 2 reports each. The rest of the facilities reported one report each as shown in the table above.

Reporting counties

County	Count	Proportion
Siaya	5	19.23%
Bungoma	4	15.38%
Kirinyaga	4	15.38%
Nairobi County	4	15.38%
Vihiga	3	11.54%
Kiambu	2	7.69%
Nakuru	2	7.69%
Kilifi	1	3.85%
Nandi	1	3.85%

Additionally, AEFI reports were received from 9 of the 47 counties. Siaya county submitted the highest number of AEFIs reports (5) while the rest of the counties submitted the number of AEFI reports as tabulated above.

Adverse Events

Event	Count	Proportion
Fever	14	28.57%
Convulsions	6	12.24%
Injection site abscess	6	12.24%
Injection site swelling	5	10.20%
Coughing	3	6.12%
Injection site pain	2	4.08%
Sudden infant death	2	4.08%
Injection site bleeding	2	4.08%
Hallucination	2	4.08%
Chest congestion	1	2.04%
Severe local reaction	1	2.04%
Refusal to feed	1	2.04%
Diarrhea	1	2.04%
Buldging anterior fontanelle	1	2.04%
Difficulty in breathing	1	2.04%
Severe local reaction	1	2.04%

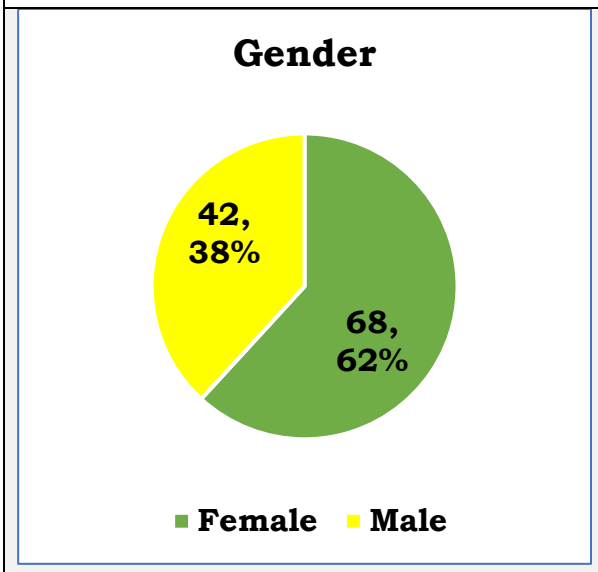
Of the AEFIs reported in this quarter, fever was the most reported with an incidence of 28.57%. Other most reported AEFIs were convulsion and injection site abscess at (12.24%) each). Other reported AEFIs are listed above.

MEDICATION ERRORS (MEs)

Institution	No. of Reports	Percentage
Coast General Teaching and Referral Hospital	37	33.64%
Siaya County Referral Hospital	16	14.55%
Nanyuki Teaching & Referral Hospital	12	10.91%
Kiambu County Referal Hospital	11	10.00%
Mbale Rural Health Training Centre	4	3.64%
Embu Provincial General Hospital	4	3.64%

Difathas Health Centre	3	2.73%
Kirinyaga county referral hospital	3	2.73%
Meteitei Sub-District Hospital	2	1.82%
Thika Level 5 Hospital	2	1.82%
Kimbimbi Sub-County Hospital	2	1.82%
Kenyatta National Hospital	2	1.82%

A total of 110 reports were received during the quarter. Coast Province General Hospital submitted the highest number of reports 37 (33.64%) followed by Siaya County Referral Hospital 16 (14.55%). Reporting from other facilities is as shown in the table above.

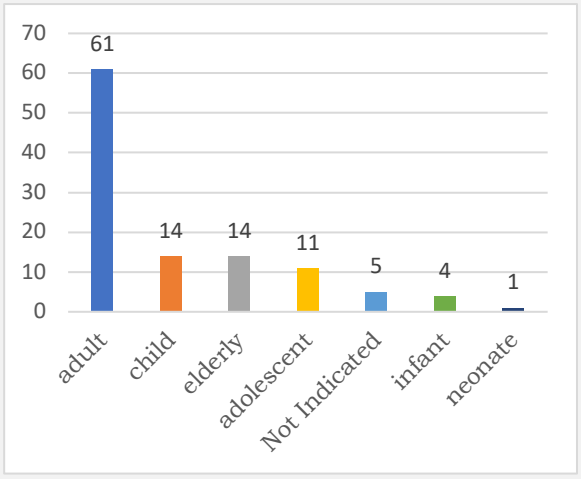


Cadre	No. of Reports	Percentage
Pharmacists	79	71.82%
Pharmaceutical technologists	27	24.55%
Clinical officers	2	1.82%
Nurses	2	1.82%
Grand Total	**110**	**100.00%**

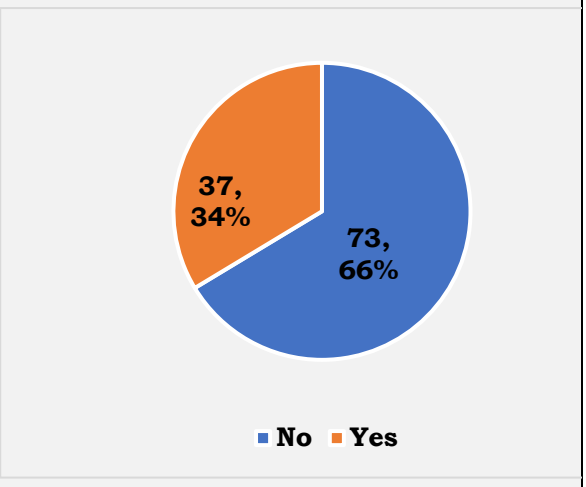
There were more reports of medication errors among female patients 68 (62%) compared to male patients 42 (38%).

The reporting cadres were pharmacists 79 (71.82%) and pharmaceutical technologists 27 (24.55%), clinical officers and nurses at 2 (1.82%), respectively.

Medication Errors and Age



Did Error Reach Patient?



Medication errors were highest among adults 61 (55.45%), followed by children 4 (12.72%) and elderly 4 (12.72%). The distribution among other age groups is as shown in the table.

In Quarter 4, 73 (66%) errors did not reach patients while 37 (34%) reached patients.

Medication Error Outcome

Error Outcome	No. of Reports	Percentage
Actual error-did not reach patient	55	50.00%
Additional monitoring required-caused no harm	25	22.73%
Potential error, circumstances/events have potential to cause incident	11	10.00%
Actual error-caused no harm	7	6.36%
Not Indicated	5	4.55%
Treatment /intervention required-caused temporary harm	4	3.64%
Initial/prolonged hospitalization-caused temporary harm	2	1.82%
Death	1	0.91%
Grand Total	**110**	**100.00%**

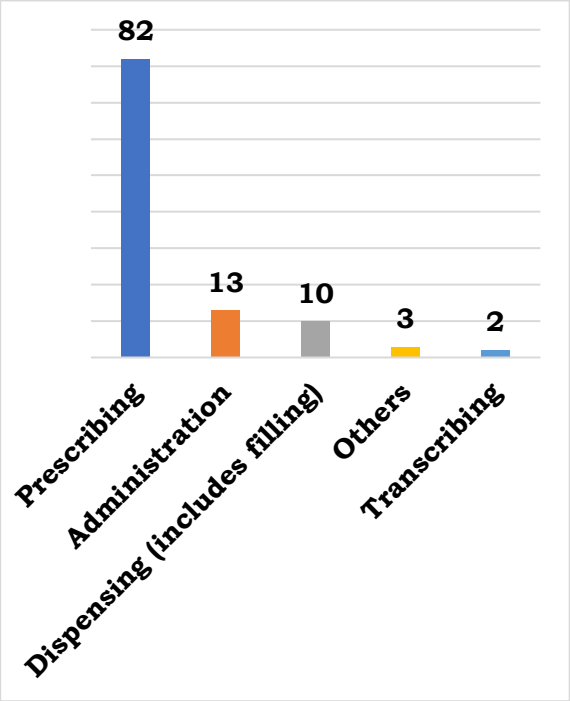
Most of the medication errors 55 (50%) did not reach the patient and for those that reached the patient, they caused no harm 25 (22.73%), while 11 (10%) had potential of causing harm.

County

County	No. of Reports	Percentage
Mombasa	38	34.55%
Siaya	18	16.36%
Kiambu	13	11.82%
Laikipia	12	10.91%
Kirinyaga	9	8.18%
Vihiga	4	3.64%
Embu	4	3.64%
Nandi	3	2.73%
Turkana	3	2.73%
Kilifi	2	1.82%
Nairobi	2	1.82%
Kakamega	1	0.91%

Process Where the Error Occurred

Migori	1	0.91%
Grand Total	**110**	**100.00%**



Most of the reports submitted were from Mombasa County 38 (34.55%), followed by Siaya County at 18 (16.36%). Other counties reported as shown in the table above.

In Quarter 4, most of the medication errors occurred during the prescribing process 82 (74.54%), followed by Administration process 13 (11.81%). Other errors occurred during dispensing 10 (9.09%).

Clinic where Error Occurred

Clinic	No. of Reports	Percentage
Outpatient	36	32.73%
Diabetic Outpatient clinic	12	10.91%
Special Clinic	9	8.18%
Inpatient	5	4.55%
CCC	3	2.73%
Eye	1	0.91%
Psychiatric	1	0.91%
Dental Clinic	1	0.91%
Tuberculosis clinic	1	0.91%
CCC	1	0.91%
Grand Total	**110**	**100.00%**

Most medication errors were reported from the outpatient clinic 36 (32.73%) and the Diabetic Outpatient Clinic 12 (10.91%). Of note, 40 (36.36%) of the reports did not indicate the clinic where the errors occurred. Other errors that occurred in the various clinics are as shown in the table above.

Drugs with Medication Errors

Drug	No. of Reports	Percentage
Metronidazole	8	7.27%
Amoxicillin	4	3.64%
Ibuprofen	3	2.73%
Aceclofenac /chlorzoxazone/ paracetamol	3	2.73%
Paracetamol	3	2.73%
flucloxacillin	2	1.82%
Atorvastatin 20mg Nocte	2	1.82%
Artemether/Lumefantrine	2	1.82%
clindamycin	2	1.82%
dexamethasone	2	1.82%
benzathine penicillin	2	1.82%
TAF/3TC/ DTG	2	1.82%
Ciprofloxacin	2	1.82%
Abacavir/Lamivudine	2	1.82%

The drugs with the highest incidence of medication errors were metronidazole 8 (7.27%) amoxicillin 4 (3.64%), Aceclofenac /chlorzoxazone/ paracetamol 3 (2.73%), paracetamol 3 (2.73%). Other reports are as shown in the table.

Description of the Error

Description of error	No. of Reports	Percentage
Prescribed wrong dose	24	21.81
Administer wrong route	13	11.81
Prescribed wrong combination	10	9.09
Administered wrong dose	8	7.27
Prescribed wrong duration	8	7.27
Dispensed wrong drug	7	6.36
Administered wrong combination	6	5.45
Prescribed wrong formulation	6	5.45

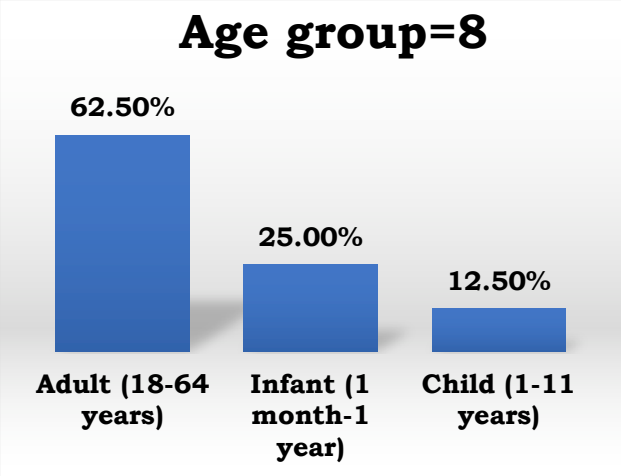
Of the reports received, the most frequent errors were prescription errors with wrong dose 24 (21.81%), followed by administration in wrong route 13 (11.81%). Other medication errors are as shown in the table.

Contributing Factor	No. of Reports	Percentage
Inadequate knowledge	51	46.36
Heavy workload	40	36.36

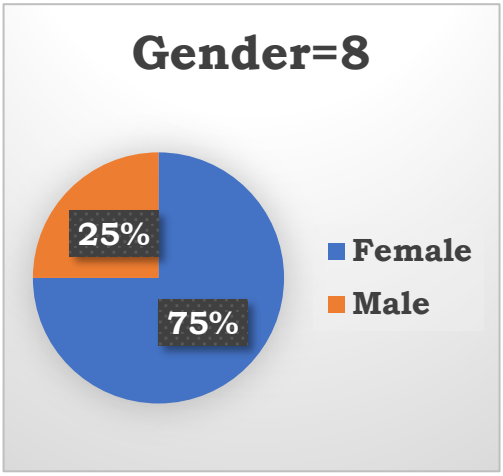
Inexperienced personnel	23	20.91
Distraction	22	20
Peak hour	18	16.36
Work procedure	17	15.45
Illegible prescriptions	11	10
Incorrect computer entry	7	6.36
Others	5	4.45

The contributing factors were inadequate knowledge 51 (46.36%), heavy workload 40 (36.36%), inexperienced personnel 23 (20.91%) while other factors are as shown in the table

PUBLIC ADVERSE DRUG REPORTING (PADRS)



The incidence of PADRs was highest amongst adults at 62.5% followed by infants (25%) and children at 12.5%.



The incidences of PADRs were highest amongst females at 78% (7). Male reporters constituted 22% (2) of all the PADRs.

Suspect medicine

The most commonly reported suspected medicine causing adverse drug reactions was Measles Rubella Vaccine with 2 reports.

The rest of the suspected medicines reported are as shown in the table below:

No	***Drug***	***Count***	***Proportion***
1	Measles Rubella Vaccine	2	25.00%
2	Black castor oil	1	12.50%

3	Bupivacaine Hydrochloride & Dextrose	1	12.50%
4	Trimethoprim & Sulphamethoxazole	1	12.50%

Reactions reported

No	Reaction	Count	%	No	Reaction	Count	%
1	Rash	4	16%	**10**	Joints and muscle pain	1	4%
2	Dizziness or drowsiness	3	12%	**11**	Sore throat	1	4%
3	Fever	2	8%	**12**	Swollen tongue	1	4%
4	Red/ painful eyes	2	8%	**13**	Vomiting or diarrhoea	1	4%
5	Body malaise	1	4%	**14**	The color is changing	1	4%
6	Chills	1	4%	**15**	The font size on the leaflet is unreadable and therefore not useful	1	4%
7	Concussion and reduced level of consciousness	1	4%	**16**	The label looks wrong	1	4%
8	Dry cough	1	4%	**17**	The packet or bottle does not seem to be usual	1	4%
9	Hives	1	4%	**18**	The bottle top of medical syrup is of poor quality resulting to rust just after a few days of opening	1	4%

The most commonly reported PADRs were rash, dizziness or drowsiness, fever and red/ painful eyes. Other reported PADRs were related to product quality such as the color is changing and the font size on the leaflet is unreadable and therefore not useful. The other incidences of the reported adverse effects are highlighted in the table above.

County

Public Adverse Drug Reactions (PADRs) were received from 5 of the 47 counties. Nairobi County submitted the highest number of PADRs (3, 37.5%). The rest of the counties submitted 1 report as shown in the table below.

No	County	Count	Pro
1	Nairobi County	3	37.
2	Kericho	1	12.
3	Nakuru	1	12.
4	Nandi	1	12.
5	Nyandarua	1	12.

For any questions, please get in touch with the PV department at pv@ppb.go.ke or call ***0795743049.***

The Kenya National Pharmacovigilance Center prepared this document

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