REPUBLIC OF KENYA

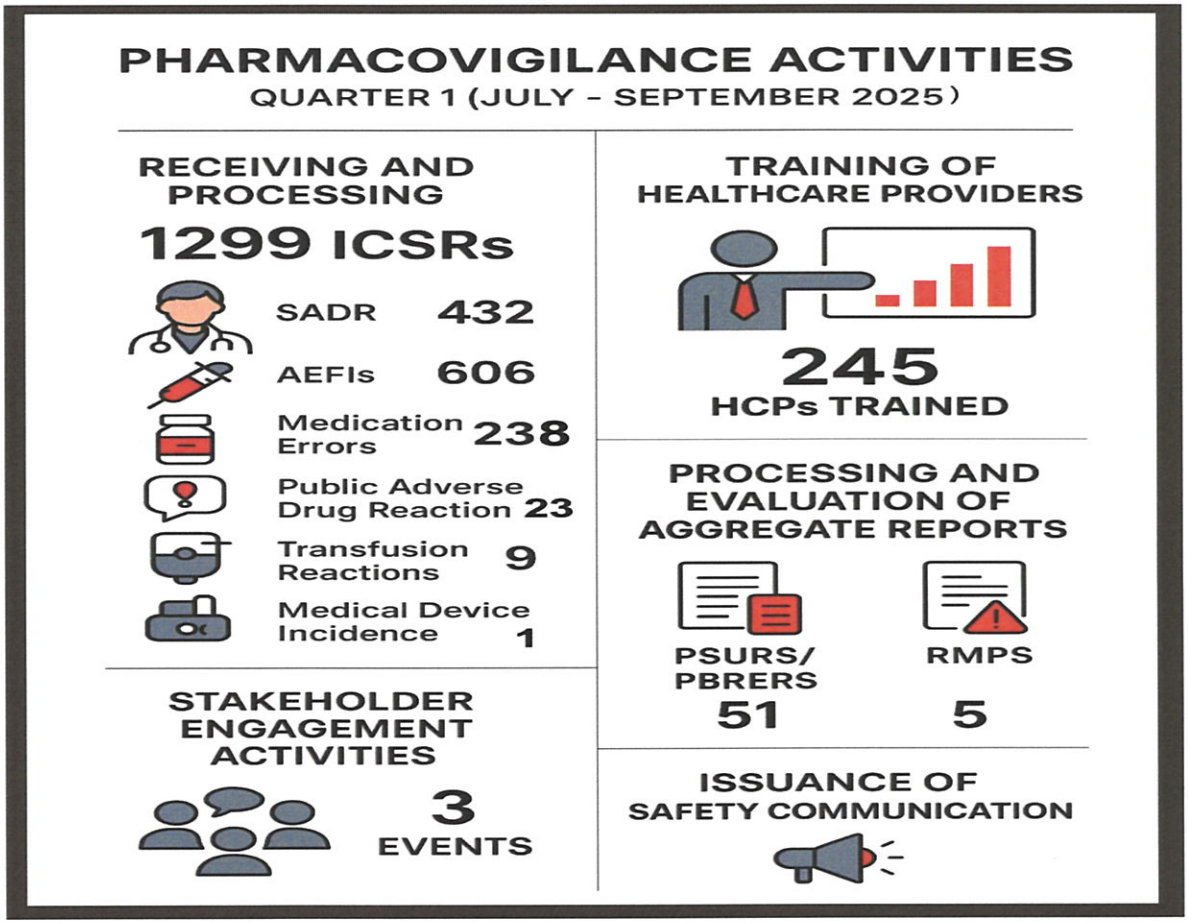
PHARMACY AND POISONS BOARD

PV/PMS Quarterly Summary Report: July 1st to Sept 30th 2025 (Q1)

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 is mandated to protect and promote public health by regulating the pharmacy profession and ensuring access to quality, safe, and effective health products and technologies (HPTs).

The Department of Product Safety (PDS) provides quarterly pharmacovigilance reports to stakeholders as part of its feedback mechanism, aiming to enhance collaboration and encourage the timely reporting of adverse events.

In this quarter, the pharmacovigilance division as part of its mandate engaged in several pharmacovigilance activities in an effort to ensure the quality, safety and efficacy of Health products and Technologies. Below is a summary of Pharmacovigilance activities conducted between July 1st to September 30th 2025.



Receiving and Processing of ICSRs

During the reporting period, the Pharmacy and Poisons Board received a total of 1,299 Individual Case Safety Reports (ICSRs), encompassing Suspected Adverse Drug Reactions (SADRs) and Medical Device Incident Reports. All reports were reviewed and processed in accordance with established pharmacovigilance procedures. Where applicable, investigations were initiated to verify and assess the reported events.

Three expert committee meetings were convened during the quarter — one by the **National Vaccine and Safety Advisory Committee (NVSAC)** and two by the **Pharmacovigilance Expert Review and Advisory Committee (PERAC)**. Cumulatively, over 40 investigated cases were presented for causality assessment, and appropriate feedback was subsequently provided to the respective stakeholders.

Training of Healthcare Providers

During the reporting period, the Pharmacy and Poisons Board conducted routine three-day Pharmacovigilance (PV) training sessions across eight counties. A total of 245 healthcare providers were trained, enhancing their capacity to identify, manage, and report adverse events related to health products and technologies. The trainings were conducted in the following counties: Siaya, Homa Bay, Embu, Meru, Kiambu, Mombasa, Kericho, and Nairobi.

Receiving and Processing of Aggregate Reports

During the reporting period, the National Pharmacovigilance Centre received a total of 56 aggregate reports, comprising 51 Periodic Safety Update Reports/Periodic Benefit-Risk Evaluation Reports (PSURs/PBRERs) and 5 Risk Management Plans (RMPs).

All submitted reports were reviewed and processed in accordance with established pharmacovigilance procedures to ensure continued assessment

of the safety profiles and benefit–risk balance of health products in the Kenyan market.

Stakeholder Engagements

In addition to the routine pharmacovigilance training conducted across various counties, the National Pharmacovigilance Centre carried out several stakeholder engagement activities during the reporting period. These activities were aimed at strengthening collaboration, promoting shared responsibility, and enhancing the overall safety of Health Products and Technologies (HPTs).

Key stakeholder engagement activities included:

- **Joint PPB/NVIP Secretariat Meeting:** Convened to review and discuss serious Adverse Events Following Immunization (AEFIs) that occurred during the Typhoid Conjugate Vaccine/Measles-Rubella (TCV/MR) Campaign.
- **Internal PPB Stakeholder Engagement Meeting and Routine PV Training:** Held to explore strategies through which various PPB departments can contribute to strengthening the safety monitoring of HPTs.
- **3rd Annual County Pharmacovigilance Focal Persons Meeting:** Organized to discuss the pivotal role of County Pharmacovigilance Focal Persons in promoting the safety of HPTs and improving pharmacovigilance activities at the county level.

Safety Communication

During the reporting period, the Pharmacy and Poisons Board issued several safety communications regarding the safe use of Health Products and Technologies (HPTs). These communications were intended to inform stakeholders of emerging safety concerns and to promote the appropriate use of medical products in order to minimize potential risks.

Key safety communication issued during the quarter:

- **Public Alert and Dear Healthcare Professional (DHCP) Communication on Semaglutide.**

The safety communication can be accessed on the Pharmacy and Poisons Board website via the following link:
https://web.pharmacyboardkenya.org/safety-communication-2025/

SUSPECTED ADVERSE DRUG REACTIONS (SADRS)

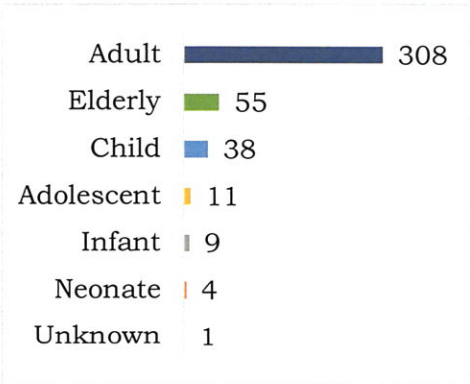
During Quarter 1 of the 2025/2026 financial year (1st July – 30th September 2025), a total of 432 Suspected Adverse Drug Reaction (SADR) reports were submitted to the National Pharmacovigilance Centre. Of these, 426 (98.61%) were initial reports, while 6 (1.39%) were follow-up reports. To avoid duplication, only one copy of each Individual Case Safety Report (ICSR) was included in the analysis, resulting in 426 reports being analyzed in this quarterly summary. Among the 426 initial reports:

- **420 reports (98.59%)** were categorized as Suspected Adverse Drug Reactions (SADRs),
- **4 reports (0.94%)** involved both SADRs and Therapeutic Ineffectiveness (TI), and
- **2 reports (0.47%)** were related solely to Therapeutic Ineffectiveness (TI).

Product Category (n=426)

Product Category	Count	Proportion
Medicinal product	393	92.25%
Blood products	0	0.00%
Herbal product	0	0.00%
Cosmeceuticals	2	0.47%
Others	3	0.70%
Not Indicated	28	6.57%

Age Group (n=426)



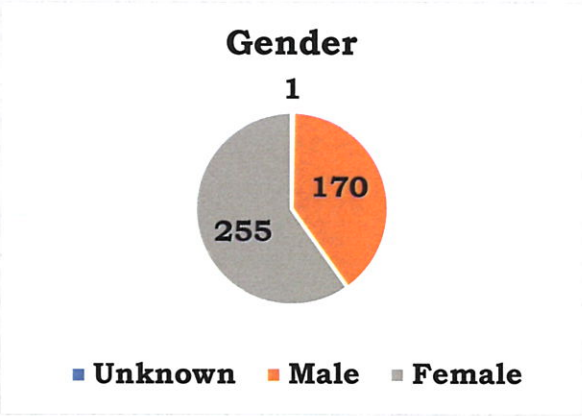
Most of the ADR cases reported were associated with medicinal products (92.25%). In 2 reports (0.47%), the product category was marked as cosmeceuticals, while in 3 reports, the product category was marked as others, which included reactions to vape, Iohexol Injection USP, and backstreet

The prevalence of SADRs was highest among adults aged 18–64 years (72.30%), followed by the elderly (12.91%) and children (8.92%). The remaining reports involved adolescents, infants, and neonates, as shown above. Only one report

drugs. Additionally, in this quarter, 28 reports did not specify the product category.

corresponded to an unknown age group.

Gender (n=426)



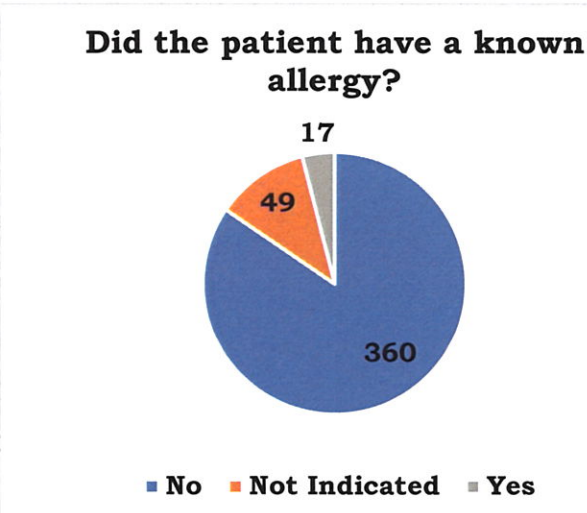
Pregnancy Status (n=255)

Pregnancy Status	Count	Proportion
Not pregnant	167	65.49%
Not Applicable	48	18.82%
Not Indicated	29	11.37%
3rd Trimester	9	3.53%
1st Trimester	2	0.78%
Grand Total	**255**	**100.00%**

Out of the total SADRs received, the prevalence was highest among females (59.9%), followed by males (39.9%). Only one report (0.2%) was of unknown sex.

With regard to pregnancy status among female individuals, the majority of reports were from those who were not pregnant (167; 65.49. Reports from pregnant individuals were few, with 9 (3.53%) in the third trimester and 2 (0.78%) in the first trimester.

Known Allergy (n=426)



Reported Allergen (n=17)

Reported Allergens	Count	Proportion
Not Indicated	5	29.41%
Penicillins	3	17.65%
Seasonal Allergies	1	5.88%
Zidovudine	1	5.88%
Quinine	1	5.88%
NSAIDS	1	5.88%
Sulphonamides	1	5.88%
Sugary foods	1	5.88%
Ceftriaxone	1	5.88%
Asthmatic	1	5.88%
Proteins	1	5.88%
Grand Total	**17**	**100.00%**

With regard to allergy status, the majority of reports were from patients without a known allergy (360; 84.51%),

Among the 17 reports involving patients with a known allergy, the most frequently reported

followed by those where allergy status was not indicated (49; 11.50%). Only 17 reports (3.99%) involved patients with a known allergy.	allergens were penicillins (3; 17.65%). The remaining cases each accounted for one case and included seasonal allergies, zidovudine, quinine, NSAIDs, sulphonamides, sugary foods, ceftriaxone, asthmatic triggers, and proteins. Five reports (29.41%) did not indicate a specific allergen.

Suspected medicines

(n=475)

Suspected Medicine	Count	Proportion
TDF/3TC/DTG (300mg/300mg/50mg)	86	18.11%
RHZE (150mg/75mg/400mg/275mg)	75	15.79%
Nifedipine	20	4.21%
Co-Trimoxazole	15	3.16%
Amoxicillin	10	2.11%
Rifapentine/Isoniazid (300/300mg)	10	2.11%
Enalapril Maleate	10	2.11%
Sulfadoxine/Pyrimethamine	9	1.89%
Vancomycin Hydrochloride	9	1.89%
Linezolid	8	1.68%
Amlodipine	8	1.68%
Metronidazole	8	1.68%
Dolutegravir	7	1.47%
Rifampicin/Isoniazid (150mg/75mg)	7	1.47%
Iron sucrose injection USP	7	1.47%
Ceftriaxone Sodium	7	1.47%
Clofazimine	7	1.47%
Tenofovir Disoproxil Fumarate	7	1.47%
Rifampicin	7	1.47%

Key:

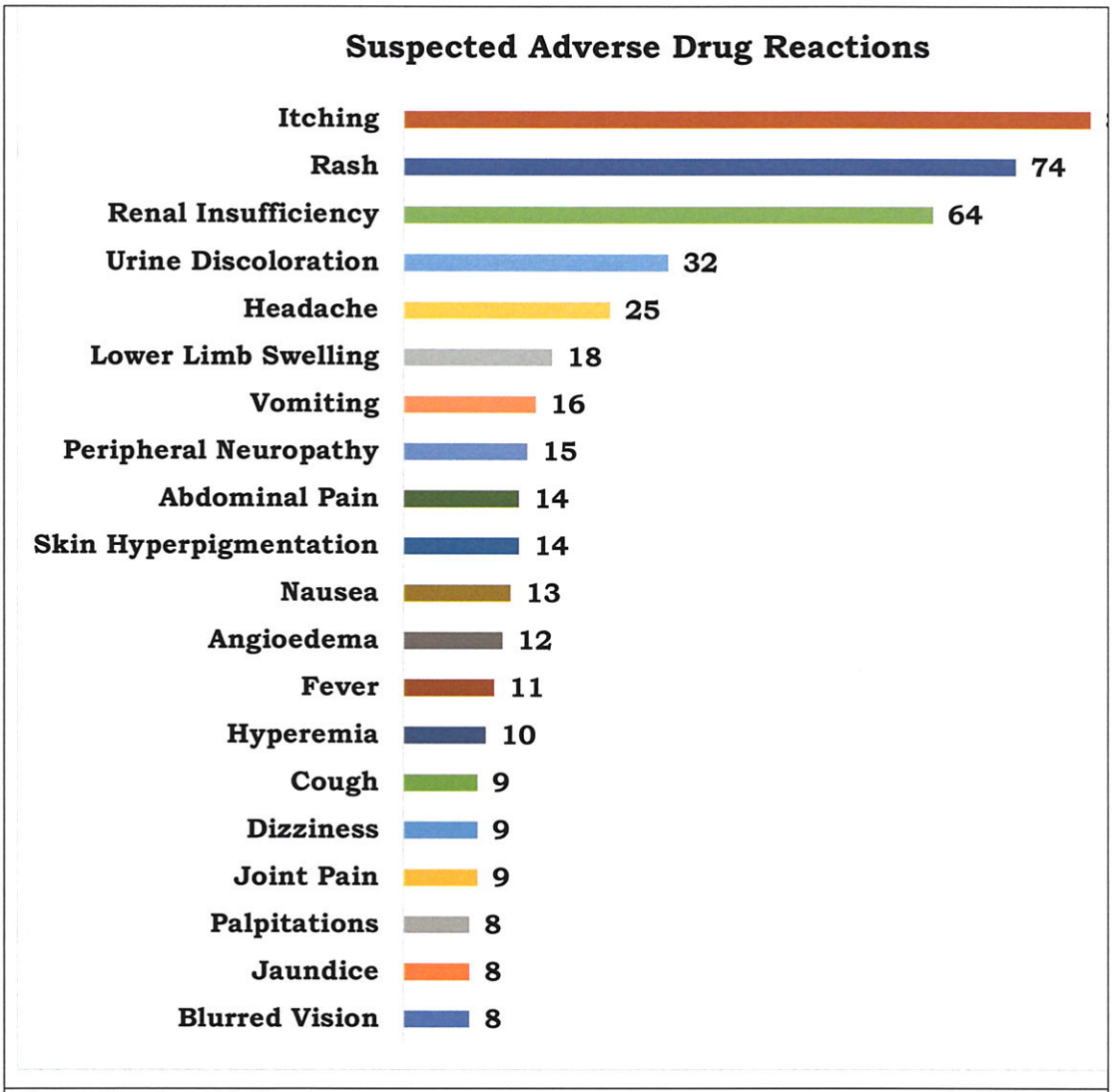
***TDF/3TC/DTG**: Tenofovir/Lamivudine/Dolutegravir (300mg/300mg/50mg)*

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

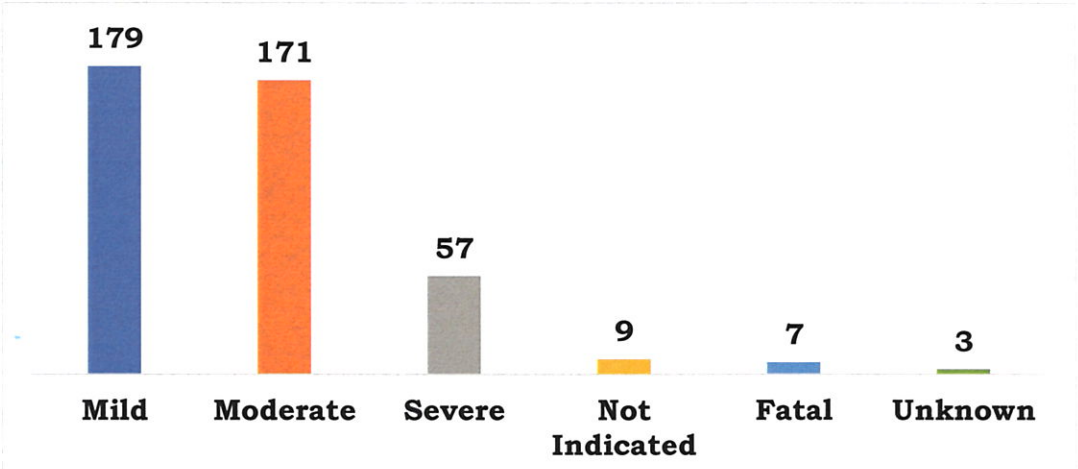
A total of 118 generic names and fixed-dose combinations (FDCs) were reported as suspected medicines during the quarter (n = 475). The most frequently reported suspected medicine was Tenofovir/Lamivudine/Dolutegravir (TDF/3TC/DTG 300mg/300mg/50mg) with 86 reports (18.11%), followed by Rifampicin/Isoniazid/Pyrazinamide/Ethambutol (150mg/75mg/400mg/275mg) with 75 reports (15.79%). Nifedipine accounted for 20 reports (4.21%), while Co-trimoxazole was reported in 15 cases (3.16%). The table above presents the most frequently reported suspected medicines for Quarter 1.

Commonly reported adverse reactions

The most frequently reported suspected adverse reaction was itching (83; 11.37%), followed by rash (74; 10.14%) and renal insufficiency (64; 8.77%). Other commonly reported reactions included urine discoloration (32; 4.38%), headache (25; 3.42%), and lower limb swelling (18; 2.47%). Less frequently reported reactions were vomiting (16; 2.19%), peripheral neuropathy (15; 2.05%), skin hyperpigmentation (14; 1.92%), abdominal pain (14; 1.92%), nausea (13; 1.78%), and angioedema (12; 1.64%).



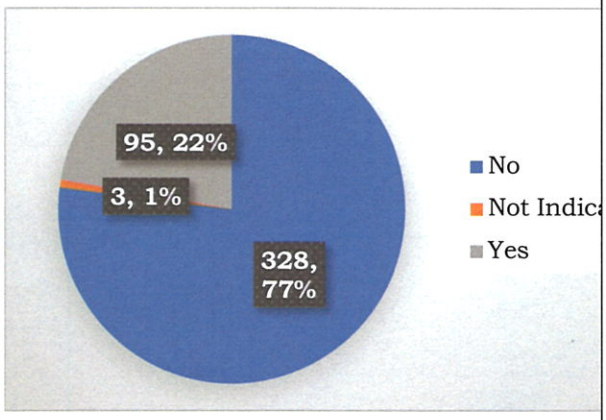
Severity (n=426)



In terms of severity, most of the reported SADRs were classified as mild (179; 42.02%) and moderate (171; 40.14%). Severe reactions accounted for 57 reports (13.39%), while 9 (2.11%) were not indicated.

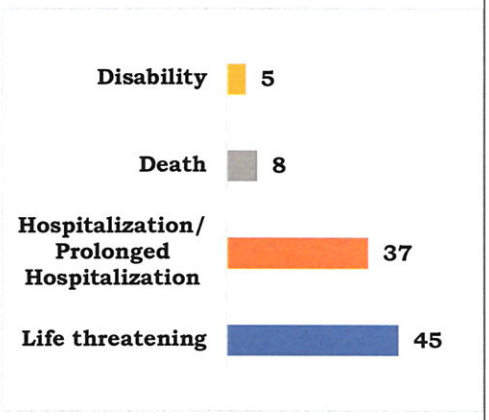
Fatal outcomes were reported in 7 cases (1.64%), and 3 reports (0.70%) had unknown severity.

Was the reaction serious? (n=426)



Regarding seriousness, the majority of reported SADRs were classified as non-serious (328; 77.00%), while 95 reports (22.30%) were considered serious. In 3 cases (0.70%), the seriousness of the reaction was not indicated.

Reason for seriousness (n=95)



Among the 95 reports classified as serious, the most common reason for seriousness was life-threatening conditions (45; 47.37%), followed by hospitalization or prolonged hospitalization (37; 38.95%). Death was reported as the reason for seriousness in 8 cases (8.42%), while 5 reports (5.26%) involved disability.

Actions taken (n=426)

Action Taken	Count	Proportion
Drug withdrawn	258	60.56%
Dose not changed	136	31.92%
Not applicable	21	4.93%
Dose increased	5	1.17%
Unknown	3	0.70%
Dose reduced	3	0.70%
Grand Total	**426**	**100.00%**

In response to the reported SADRs, the most common course of action was withdrawal of the suspected medicine (258; 60.56%). In 136 cases (31.92%), the treatment dose was maintained without adjustment, while in 21 cases (4.93%) no specific action was applicable. Dose modifications were infrequent—five reports (1.17%) noted an increase, and three (0.70%) a reduction. Likewise, three reports (0.70%) did not specify the action taken.

Outcome (n=426)

Outcome	Count	Proportion
Recovering/Resolving	162	38.03%
Recovered/Resolved	112	26.29%
Unknown	83	19.48%
Not Recovered/Not Resolved	51	11.97%
Fatal	8	1.88%
Recovered/Resolved with sequelae	7	1.64%
Not Indicated	3	0.70%
Grand Total	**426**	**100.00%**

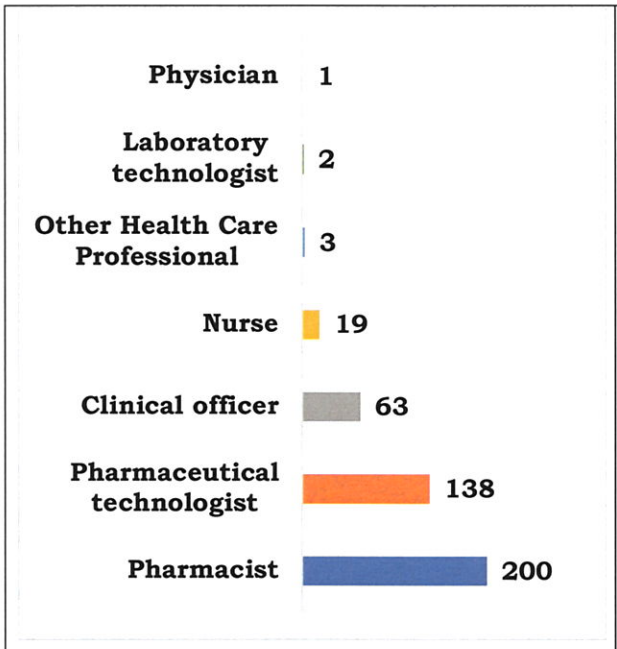
Regarding the outcomes of the reported SADRs, most patients were either recovering or resolving at the time of reporting (162; 38.03%), while 112 cases (26.29%) had fully recovered or resolved. Outcomes were unknown in 83 reports (19.48%), and 51 cases (11.97%) had not yet recovered or resolved. Fatal outcomes were documented in 8 cases (1.88%), while 7 reports (1.64%) indicated recovery with sequelae. In 3 instances (0.70%), the outcome was not specified.

Reporter designation (n=426)

Reporter designation (n=426)

In terms of reporter designation, pharmacists contributed the majority of the reports (200; 46.95%), followed by pharmaceutical technologists (138; 32.39%) and clinical officers (63; 14.79%).

Reports from nurses accounted for 19 cases (4.46%), while a few were submitted by other healthcare professionals (3; 0.70%), laboratory technologists



(2; 0.47%), and physicians (1; 0.23%).

Institution

In this quarter, only 155 facilities out of the 9,000 facilities listed in the Kenya Master Facility List submitted ADR reports to the National Pharmacovigilance Centre. The Mater Hospital Mukuru recorded the highest number of reports (43; 10.09%), followed by Maralal District Hospital (34; 7.98%) and Maragua District Hospital (28; 6.57%). Other notable contributors included Port Reitz District Hospital (12; 2.82%), Kilifi County Hospital (11; 2.58%), and Kangu Dispensary (9; 2.11%). Below is a list of top 11 facilities with at least 7 reports and above.

Facility/Institution	Count	Proportion
The Mater Hospital Mukuru	43	43
Maralal District Hospital	34	34
Maragua District Hospital	28	28
Port Reitz District Hospital	12	12
Kilifi County Hospital	11	11
Kangu Dispensary	9	9
Meru Teaching and Refferal Hospital hospital	8	8
Mweiga Health Centre	7	7
Kipkelion Sub District Hospital	7	7
KUTRRH	7	7
Joshua Memorial Mbai Dispensary	7	7

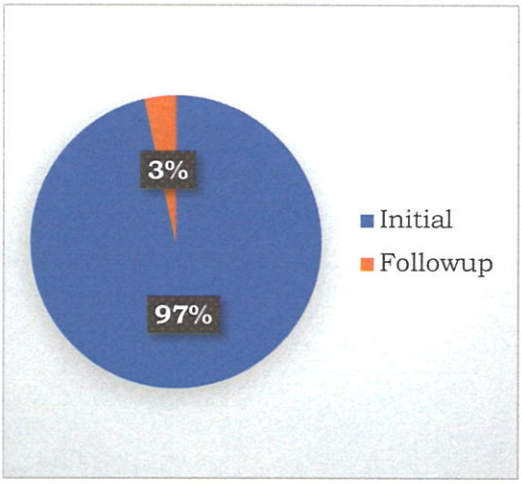
County

SADR reports were received from 35 out of the 47 counties during the quarter. Nairobi County contributed the highest number of reports (78; 18.31%), followed by Kirinyaga (50; 11.74%), Mombasa (39; 9.15%), Samburu (34; 7.98%), and Murang'a (30; 7.04%). Below is a table of the counties that submitted SADR reports in Quarter 1.

No	***County***	***Count***	***%***	***No***	***County***	***Count***	***%***
1	Nairobi County	78	18.31%	**19**	Migori	7	1.64%
2	Kirinyaga	50	11.74%	**20**	Kisumu	6	1.41%
3	Mombasa	39	9.15%	**21**	Uasin Gishu	4	0.94%
4	Samburu	34	7.98%	**22**	Vihiga	3	0.70%
5	Murang'a	30	7.04%	**23**	Taita Taveta	3	0.70%
6	Kilifi	19	4.46%	**24**	Nakuru	3	0.70%
7	Kiambu	18	4.23%	**25**	Nandi	2	0.47%
8	Kericho	14	3.29%	**26**	Laikipia	2	0.47%
9	Nyeri	13	3.05%	**27**	Narok	2	0.47%
10	Turkana	13	3.05%	**28**	Kwale	1	0.23%
11	Meru	12	2.82%	**39**	Kajiado	1	0.23%
12	Bungoma	11	2.58%	**30**	Trans Nzoia	1	0.23%
13	Kisii	11	2.58%	**31**	Isiolo	1	0.23%
14	Kakamega	10	2.35%	**32**	Embu	1	0.23%
15	Siaya	9	2.11%	**22**	Machakos	1	0.23%
16	Kitui	9	2.11%	**34**	Elgeyo/Marakwet	1	0.23%
17	Homa Bay	8	1.88%	**35**	Nyandarua	1	0.23%
18	Makueni	8	1.88%				

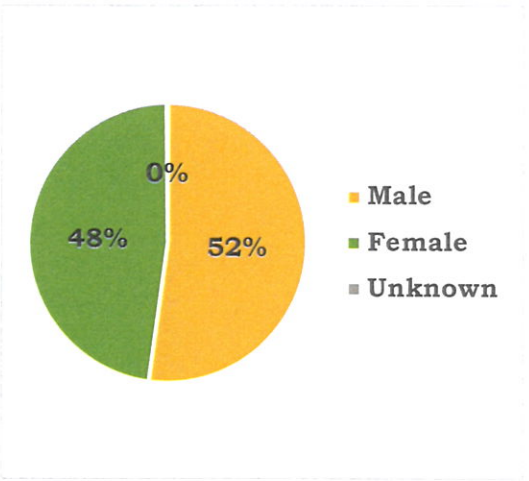
ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

Type of report (n=606)



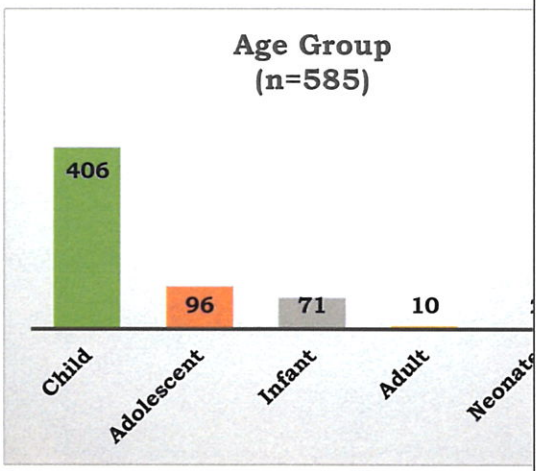
The National Pharmacovigilance Centre received a total of 606 AEFI reports in the period between 1st July 2025 and 30th September 2025. 97% (585) of the reports received in this quarter were initial reports while 3% (21) were follow up reports.

Gender (n=585)



The frequency of reported AEFIs was higher in males (52%, 305) compared to females (48%, 279). In one report (0.17%), the patient's gender was unknown.

Age Group (n=585)



Age Group

Majority of the AEFIs reported in this quarter affected the Child age group (1-11years) (69%). The Adolescent and Infant age groups were moderately affected at 16% and 12% respectively. The least affected age group in this quarter were the Neonates and Adults (18-65 years) with 2 and 10 reports respectively.

Type of Vaccines Administered

Vaccine	Count	Proportion
Typhoid Conjugate Vaccine (TCV)	334	57.09%
Measles Rubella Vaccine; Typhoid Conjugate Vaccine (TCV)	172	29.40%
Pentavalent Vaccine (DTP-HepB-Hib); Pneumococcal conjugate vaccine	33	5.64%
Measles Rubella Vaccine	13	2.22%

Pentavalent Vaccine (DTP-HepB-Hib)	8	1.37%
MPOX Vaccine	7	1.19%
Pneumococcal conjugate vaccine; Pentavalent Vaccine (DTP-HepB-Hib); Rota virus vaccine; Bivalent oral Polio vaccine	4	0.68%
Rota virus vaccine	2	0.34%
Malaria (RTSS) Vaccine	2	0.34%
BCG; Pentavalent Vaccine (DTP-HepB-Hib); Pneumococcal conjugate vaccine	1	0.17%
BCG; Pentavalent Vaccine (DTP-HepB-Hib); Pneumococcal conjugate vaccine; Bivalent oral Polio vaccine	1	0.17%
Pentavalent Vaccine (DTP-HepB-Hib); Bivalent oral Polio vaccine; Pneumococcal conjugate vaccine	1	0.17%
BCG	1	0.17%
Pentavalent Vaccine (DTP-HepB-Hib); Pneumococcal conjugate vaccine; Inactivated polio vaccine	1	0.17%
BCG; Bivalent oral Polio vaccine	1	0.17%
Tetanus Diptheria Vaccine	1	0.17%
Hepatitis B Vaccine	1	0.17%
Influenza vaccine	1	0.17%
Human Papiloma virus vaccine	1	0.17%

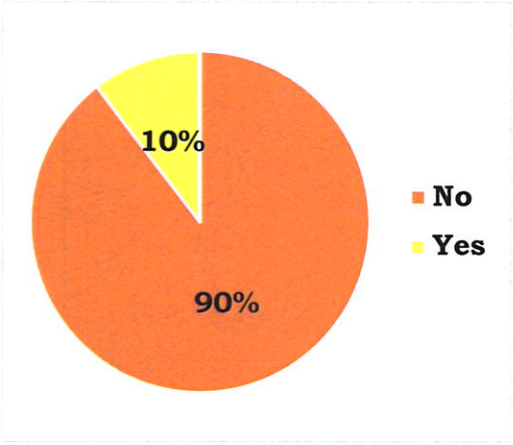
Of the total AEFI reports received, most events occurred following administration of the Typhoid Conjugate Vaccine (TCV), which accounted for 57% (334) of all reports. Administration of both the Measles-Rubella and Typhoid Conjugate Vaccines contributed 29% of the reported AEFIs, while combined administration of the Pentavalent and Pneumococcal Conjugate Vaccines accounted for 5%. The remaining AEFIs were associated with other vaccines as detailed in the table above.

Adverse Events

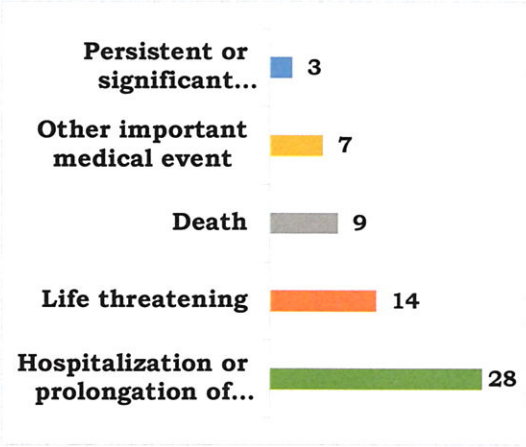
Event	Count	Proportion
Fever	230	18.30%
Rash	123	9.79%
Urticaria	93	7.40%
Vomiting	70	5.57%
Injection Site Swelling	61	4.85%
Headache	59	4.69%
Convulsion	48	3.82%
Itching	46	3.66%
Injection Site Abscess	42	3.34%
Diarrhea	34	2.70%

Of the AEFIs reported in this quarter, fever was the most reported with an incidence of 18.30%. Other most reported AEFIs were rash urticaria and vomiting. The other most reported AEFIs are listed above.

Was the reaction serious? (n=585)



Reason For Seriousness (n=61)



Majority of the AEFI reports 90% (524) received in this quarter were reported as not serious, with only 10% (61) reported as serious.

Of the 61 AEFI reports noted to be serious 45% (28) were due to hospitalization or prolonged hospitalization. One report was due to another important medical event. This was followed by life-threatening situations, which were noted in 14 reports (22%). Nine reports categorized death as the reason for seriousness. Additionally, other important medical event and persistent/significant disability were also reported as a reason for seriousness, as illustrated in the figure above.

Outcome (n=585)

Outcome	Count	Proportion
Recovering/Resolving	266	45.47%
Recovered/Resolved	255	43.59%
Not recovered/Not resolved/Ongoing	29	4.96%
Unknown	21	3.59%
Fatal	13	2.22%

Reporter designation (n=585)

Reporter Designation	Count	Proportion
Nurse	222	37.95%
Pharmacist	195	33.33%
Other Health Care Professional	62	10.60%
Pharmaceutical technologist	61	10.43%
Clinical officer	34	5.81%

Recovered/Resolved with sequelae	1	0.17%

Health Records and Information Officer	10	1.71%
Physician	1	0.17%

Of the 585 AEFI reports received, 266 indicated the outcome as either recovering/resolving while 255 of the reported cases were noted to have recovered/resolved. Unfortunately, 13 reports had a fatal outcome while one report recovered with sequelae.

The NPC received the majority of AEFI reports from nurses, who submitted 37.95% (222 reports). Pharmacists and pharmaceutical technologists submitted 33.33% and 10.43% of the reports respectively while Health records and information officers submitted 1.71%. Physicians submitted 0.17% of the reports while other healthcare professionals submitted 10.60%.

Reporting institution (n=319)

Facility	Count	Proportion
Ngecha Health Centre	38	6.50%
Mtwapa Sub County Hospital	10	1.71%
Kaiyaba Dispensary	10	1.71%
Karindundu dispensary	8	1.37%
Oloosirkon Dispensary	8	1.37%
Madiany Sub County Hospital	7	1.20%
Njenga Hospital	7	1.20%
Uasin Gishu District Hospital	7	1.20%
Subukia Sub County Hospital	7	1.20%

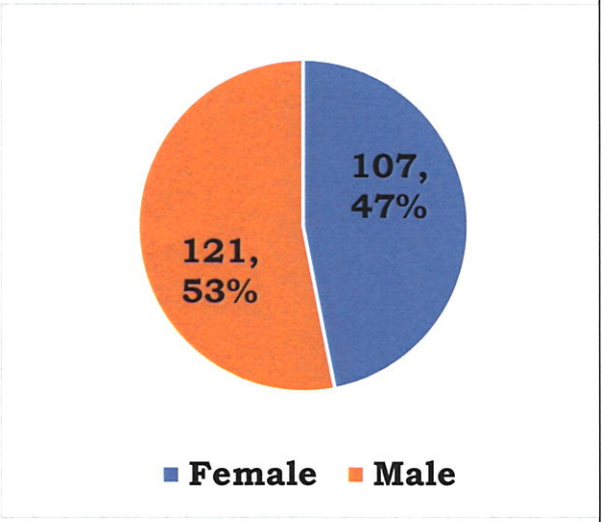
In this Quarter, only 319 facilities out of the 9,000 facilities listed in the Kenya Master facility reported AEFIs. The top leading facility was Ngecha Health Centre with 38 reports followed by Mtwapa Sub County Hospital and Kaiyaba Dispensary with 10 reports each. The table above shows the top reporting facilities and the number of reports submitted by each.

County	Count	Proportion
Kiambu	64	10.94%
Nairobi County	53	9.06%
Nyeri	41	7.01%
Nakuru	36	6.15%
Busia	32	5.47%
Kilifi	29	4.96%
Siaya	28	4.79%
Kitui	27	4.62%
Kisumu	22	3.76%
Uasin Gishu	20	3.42%

Additionally, AEFI reports were received from 39 of the 47 counties. Kiambu and Nairobi counties submitted the highest number of AEFIs reports, 64 and 53 reports each. The table above represents the top ten reporting counties.

MEDICATION ERRORS (MES)

Gender



A total of 228 medication errors were reported in Quarter 1. Of this, 53% (121) involved the female gender while 47% (107) involved the male gender.

Age Group (n=228)

Age Group	No. of Reports	Proportion
Adults	140	61.40%
Children	40	17.54%
Infants	16	7.02%
Adolescents	12	5.26%
Neonates	8	3.51%
Elderly	8	3.51%
Not Indicated	4	1.75%
Grand Total	**228**	**100.00 %**

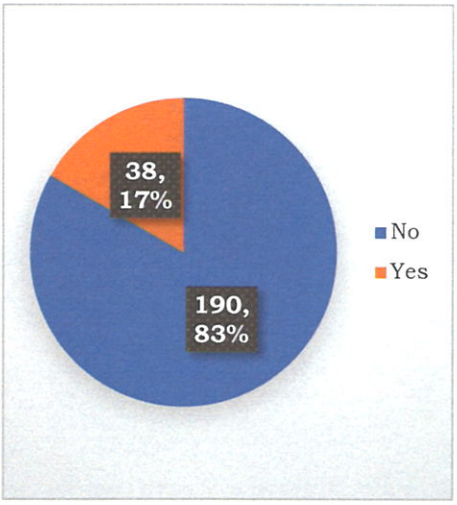
Of the reported medication errors, about 61% (140) involved adults, 40 (17.54%) children.

Reporter Designation

Designation	No. of Errors Reported	Proportion
Pharmacist	209	91.67%
Pharmaceutical technologist	17	7.46%
Physician	1	0.44%
Clinical officer	1	0.44%
Grand Total	**228**	**100.00%**

Most medication errors were reported by Pharmacists, followed by pharmaceutical technilogisits, physicians, and clinical officers.

Did the error reach the Patient?



In Quarter 1, 190 (83%) errors did not reach patients while 38 (17%) reached patients.

Medication Error Outcome

Outcome	No. of Reports	Percentage
Not Indicated	119	52.19%
Actual error-did not reach patient	69	30.26%
Error has potential to cause harm	17	7.46%
Actual error-caused no harm	11	4.82%
Additional monitoring required-caused no harm	8	3.51%
Intervention required-caused temporary harm	4	1.75%
Grand Total	**228**	**100.00%**

Most of the medication errors 69 (30.26%) did not reach the patient and for those that reached the patient, 17 (7.46%) had potential to cause harm, 11 (4.82%) while 8 (3.51%) caused no harm but required additional monitoring. However, 119 (52.19%) did not indicate the outcome.

Number of medication errors per product

Product	No. of reports	%
Not Indicated	91	39.91%
Amoxiclav	7	3.07%
Aceclofenac/paracetamol/chlorzoxazone	6	2.63%
Metronidazole	5	2.19%
Paracetamol	4	1.75%
Amlodipine	4	1.75%
Atorvastatin	4	1.75%
Typhoid Conjugate vaccine	3	1.32%
metformin	3	1.32%
Ibuprofen	3	1.32%
Cefuroxime	3	1.32%
TDF 300MG/3TC 300MG/DTG 50MG	3	1.32%

Of the reported errors, 7 (3.07%) were associated with amoxiclav, Aceclofenac/paracetamol/chlorzoxazone followed by 6 (2.63%). Of note is that 91 (39.9%) did not indicate the product.

Process Where the Error Occurred

Process	No. of Reports	Percentage
Prescribing	171	75.00%
Dispensing	37	16.23%
Administration	11	4.82%
Transcribing	6	2.63%
Others	3	1.32%
Grand Total	**228**	**100.00%**

In quarter 1, most medication errors 171 (75%) occurred during prescription, followed by 37 (16%), andministration errrors 11 (4.82%).

Description of the Error

Error Description	No. of Reports	Proportion
Incomplete details on prescription	32	34.78%
Wrong dose	25	27.17%
Wrong drug prescribed	6	6.54%
Wrong frequency	3	3.27%
Look alike	2	2.17%
Wrong combination	2	2.17%
Wrong timing to take medication	1	1.09%
Wrong route of administration	1	1.09%
Wrong formulation	1	1.09%
Over writing on the prescription	1	1.09%

Of the reports received, majority involved incomplete details on the prescription 32 (34.78%), wrong dose 25 (27.17%), wrong drug prescribed 6 (6.54%). The frequency of other errors is as captured in the table.

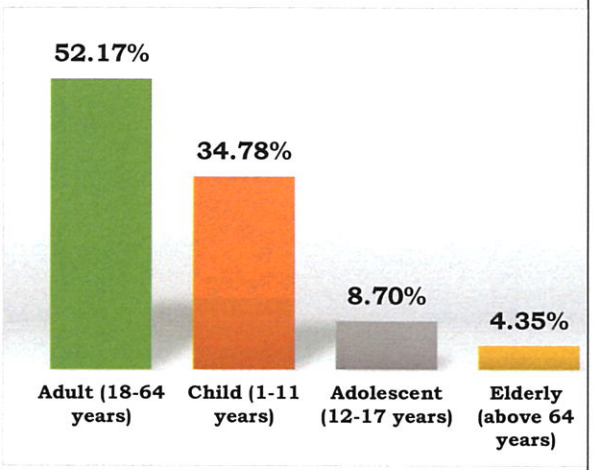
Contributing Factors

Contributing Factor	No. of reports	Proportion
Failure to follow Work Procedures/Guidelines	32	15.2
Heavy Workload	28	13.3
Peak Hour	27	12.9
Illegible Prescriptions	24	11.4
Inadequate Knowledge	23	11.0
Inaccurate Information	19	9.0
Inexperienced Personnel	16	7.6
Distraction	12	5.7
Use of Abbreviations	7	3.3
Sound Alike Medication	6	2.9
Look Alike Packaging	6	2.9

The most commonly reported contributing factor was Failure to follow Work Procedures 32 (15.2%), followed by failure to adhere to Heavy Workload 28 (13.3%), and Peak Hour 27 (12.9%). The impact of other contributing factors is as shown.

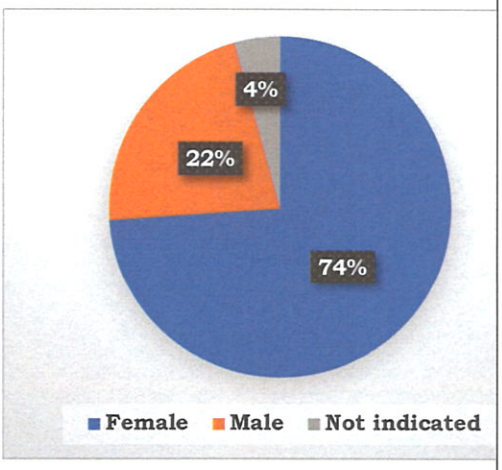
PUBLIC ADVERSE DRUG REPORTING (PADRS)

Age Group (n=23)



The incidence of PADRs was highest amongst adults at 52.17% followed by

Gender (n=23)



The incidences of PADRs were highest amongst females at 74% (17). Male reporters constituted

children (34.78%), adolescent (8.70%) and elderly at 4.35%.	22% (5) of all the PADRs and one report did indicate the gender.

Suspect medicine

The most commonly reported suspected medicine causing adverse drug reactions was Typhoid Conjugate Vaccine and Measles Rubella Vaccine.

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

No	***Drug***	***Count***	***Proportion***	***No***	***Drug***	***Count***	***Proportion***
1	Typhoid Conjugate Vaccine and Measles Rubella Vaccine	3	13.04%	7	Moxifloxacin Hydrochloride 400mg; Pretonamid 200 mg; LINEZOLID 600 mg	1	4.35%
2	Isoniazid/Rifapentine (300mg/300mg)	2	8.70%	8	Nebivolol 5mg	1	4.35%
3	Linezolid 600mg	2	8.70%	9	Nifedipine	1	4.35%
4	Dolutegravir	1	4.35%	10	Oral polio vaccine	1	4.35%
5	Fluconazole 200mg	1	4.35%	11	Typhoid conjugate vaccine	1	4.35%
6	Influenza vaccine	1	4.35%				

Reaction

The most commonly reported PADRs were rash (21.7%), headache (10.9% and joint and muscle pain (8.7%)

The other reported reactions (each less than 5%) are highlighted in the table below.

No	**Reaction**	**Count**	**Proportion**	**No**	**Reaction**	**Count**	**Proportion**
1	Rash	10	21.74%	7	Abnormal changes with urination	1	2.17%
2	Headache	5	10.87%	8	Body aches	1	2.17%
3	Joints and muscle pain	4	8.70%	9	Body weakness	1	2.17%
4	Dizziness	2	4.35%	10	Cough	1	2.17%
5	Fever	2	4.35%	11	Drowsy eyes	1	2.17%

6	Pain in the stomach	2	4.35%	12	Dryness of mouth and throat	1	2.17%

County

PADRs were received from 9 of the 47 counties. Nairobi County submitted the highest number of PADRs (10, 43.48%)

The rest of the counties submitted 1 report as shown in the table below.

No	County	Count	Proportion	No	County	Count	Proportion
1	Nairobi County	10	43.48%	**6**	Kakamega	1	4.35%
2	Mombasa	3	13.04%	**7**	Lamu	1	4.35%
3	Kiambu	2	8.70%	**8**	Machakos	1	4.35%
4	Nakuru	2	8.70%	**9**	Nandi	1	4.35%
5	Uasin Gishu	2	8.70%				

Blood Transfusion Reactions

During Quarter 1, a total of nine reports of blood transfusion reactions were received. All the reports were submitted by pharmacists.

Five incidents of blood transfusion reactions involved adult (18-64 years) patients, two incidents in children (1-11 years), one incident in an adolescent (12-17 years) patient and one in an elderly (above 64 years) patient. Most transfusion reaction were noted in female patients (6) compared to male patients (3).

Seven of the patients had received a blood transfusion due to severe anaemia and two patients were transfused due to low haemoglobin levels.

Five of the patients had a history of prior transfusions; however, none of the patients had experienced a previous transfusion reaction.

The reported blood transfusion reactions had the following incidences;

No	Reaction	Count	Proportion	No	Reaction	Count	Proportion
1	Chills/Rigors	5	25%	6	HEADACHE	1	5%
2	Fever	4	20%	7	Nausea	1	5%
3	Skin rash	4	20%	8	Tachycardia	1	5%
4	Chest pain	2	10%	9	Vomiting	1	5%
5	Dyspnoea	1	5%				

Medical Device Incidence Reports

In the past quarter, one report of a medical device incident (MDI) was received from Turkana County.

The incident involved an adolescent male patient where it was noted that the blood failed to drip from the blood bag through the giving set into the patient's vein. The identified medical device was a medimax blood giving set manufactured by Shailesh Surgical.

The report was made by a pharmaceutical technologist and the incident was classified as mild. The outcome of the patient was they recovered.

Suspected Poor Quality HPT Reports (PQHPT)

There were 109 suspected Poor Quality HPT Reports submitted to the National Pharmacovigilance Centre within Quarter 1 (July 1st to September 30th 2025).

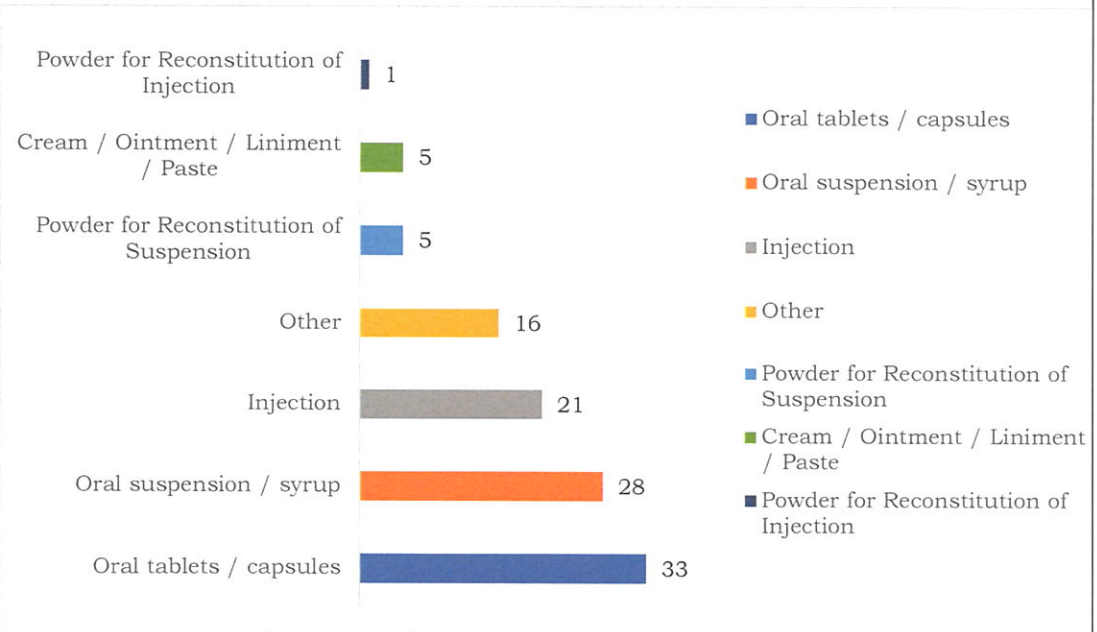
Product Category (n=109)

Product Category	Count	Proportion
Medicinal product	88	80.73%
Medical device	18	16.51%
Herbal product	1	0.92%
Vaccine	1	0.92%
Others	1	0.92%

Most of the suspected PQHPT reported were medicinal products (88, 80.73%), followed by medical devices (18, 16.51%). Herbal products, vaccines, and others are each represented by a single report, contributing 0.92% each to the overall count.

Product Formulation

As indicated below, among the 109 products reported, oral tablets/capsules were the most common formulation reported, representing 30.28% of the total. This was followed by oral suspensions/syrups at 25.69%, and injectable formulations at 19.27%. Topical preparations such as creams/ointments/ liniments/pastes accounted for 4.59%, while powders for reconstitution of suspension and injection represented 4.59% and 0.92%, respectively.



Suspected Medicines and Medical Devices

The most frequently reported medicines included Ibuprofen (13, 11.93%), Paracetamol (7, 6.42%), Amoxicillin & Potassium Clavulanate (6, 5.50%), Metronidazole (4, 3.67%), and Furosemide (3, 2.75%). Among medical devices, syringes were the most commonly reported, also accounting for 11.93% as shown in the table below.

	Generic Name	**Count**	**Proportion**
1.	Ibuprofen	13	11.93%
2.	Syringe	13	11.93%
3.	Paracetamol	7	6.42%
4.	Amoxicillin & Potassium Clavulanate	6	5.50%
5.	Metronidazole	4	3.67%
6.	Furosemide	3	2.75%
7.	Methyldopa	2	1.83%
8.	Griseofulvin 500mg	2	1.83%
9.	Fosfomycin	2	1.83%
10.	Others (One complaint each)	57	52.31%
	Grand Total	**109**	**100.00%**

Suspected quality defects reported

Of the reports received this quarter, color change, caking, therapeutic ineffectiveness, and labelling discrepancy were the most commonly reported quality defects, with a proportion of 14.29%, 13.45%, 10.08% and 9.24% respectively. Other suspected quality defects reported in this quarter are listed in the table below.

	Reported Quality Defects	**Count**	**Proportion**
1.	Colour change	17	14.29%
2.	Caking	16	13.45%
3.	Therapeutic ineffectiveness	12	10.08%
4.	Labelling discrepancy	11	9.24%
5.	Incomplete pack	9	7.56%
6.	Crystallization	8	6.72%
7.	Powdering/Crumbling	6	5.04%
8.	Change of odour	6	5.04%
9.	Product leakage	6	5.04%
10.	Capless needles	5	4.20%
11.	Bent needles	5	4.20%
12.	Presence of particulate matter	3	2.52%
13.	Breaking syringe	3	2.52%
14.	SADR	2	1.68%
15.	Look-alike medicine	2	1.68%

16.	Others (One defect each)	8	6.74%
	Grand Total	**109**	**100.00%**

Counties

A total of 109 reports were received from 26 out of 47 counties. Kilifi County contributed the highest number of reports, accounting for 22.02% of the total, followed by Nairobi at 18.35% and Mombasa at 17.43%. Kakamega and Nyandarua counties reported 6.42% and 5.50% respectively. Below is a table of counties that submitted reports in quarter 1.

	County	Count	Proportion		County	Count	Proportion
1.	Kilifi	24	22.02%	14.	Embu	2	1.83%
2.	Nairobi	20	18.35%	15.	Tana River	2	1.83%
3.	Mombasa	19	17.43%	16.	Kajiado	1	0.92%
4.	Kakamega	7	6.42%	17.	Kwale	1	0.92%
5.	Nyandarua	6	5.50%	18.	Meru	1	0.92%
6.	Turkana	3	2.75%	19.	Mandera	1	0.92%
7.	Vihiga	3	2.75%	20.	Trans Nzoia	1	0.92%
8.	Isiolo	2	1.83%	21.	Kirinyaga	1	0.92%
9.	Kiambu	2	1.83%	22.	Murang'a	1	0.92%
10.	Kisii	2	1.83%	23.	Siaya	1	0.92%
11.	Taita Taveta	2	1.83%	24.	Busia	1	0.92%
12.	Kericho	2	1.83%	25.	Kisumu	1	0.92%
13.	Kitui	2	1.83%	26.	Laikipia	1	0.92%

Institutions

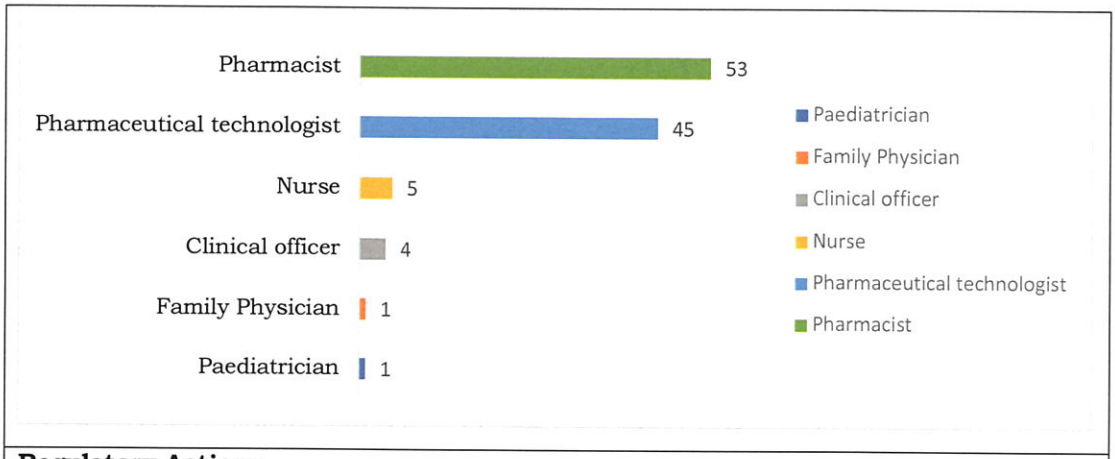
61 facilities submitted reports in this quarter, with Coast General Teaching and Referral Hospital leading with 8 reports (7.34%), followed by Matsangoni Model Health Centre, Port Reitz Sub County Hospital, and Engineer County Hospital with 5 reports (4.59%) each as shown in the table below.

	Institution	Count	Proportion
1.	Coast General Teaching and Referral Hospital	8	7.34%
2.	Matsangoni Model Health Centre	5	4.59%
3.	Port Reitz Sub County Hospital	5	4.59%
4.	Engineer County Hospital	5	4.59%

5.	Kenyatta University Teaching Refferal and Research Hospital	4	3.67%
6.	Gede Sub-County Hospital	4	3.67%
7.	Gertrudes Childrens Hospital Junction Mall Clinic	4	3.67%
8.	Novartis Kenya	3	2.75%
9.	Mtwapa Sub County Hospital	3	2.75%
10.	Mariakani District Hospital	3	2.75%
11.	Kakamega County General Hospital	3	2.75%
12.	Moi District Hospital Voi	2	1.83%
13.	Embu Level 5 Hospital	2	1.83%
14.	Hola referral hospital	2	1.83%
15.	Kitui County Referral Hospital	2	1.83%
16.	Mbale Rural Health Training Centre	2	1.83%
17.	Lodwar Hills Medical Centre	2	1.83%
18.	Butere Sub County Hospital	2	1.83%
19.	Marereni Dispensary	2	1.83%
20.	Isiolo County Referral Hospital	2	1.83%
21.	Tigoni Sub County Hospital	2	1.83%
22.	Kenyatta National Hospital	2	1.83%
23.	Not Indicated	2	1.83%
24.	Others (One report each)	38	34.90%
	Grand Total	**109**	**100.00%**

Reporter Designation

The majority of reports were submitted by pharmacists (48.62%, 53), followed by pharmaceutical technologists (41.28%, 45). Nurses and clinical officers contributed 4.59% and 3.67% respectively, while a family physician and a paediatrician submitted one report each.



Regulatory Actions

The Board investigates each of the reports and takes the necessary regulatory actions so at to protect public health. Please see the link below for the current ongoing public alerts and recall.

https://web.pharmacyboardkenya.org/safety-and-rapid-alerts/

For any queries, please contact PV Division on pv@ppb.go.ke and pms@ppb.go.ke or call ***0795743049.***

This document is produced by the National Pharmacovigilance Center

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

Report approved by: Dr. Ahmed I. Mohamed

Ag. CHIEF EXECUTIVE OFFICER

Date: 16th October 2025

Signature: .....