REPUBLIC OF KENYA

PHARMACY AND POISONS BOARD

Pharmacovigilance Summary Report: Jan 1st to Mar 31st 2026 (Q3)

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).

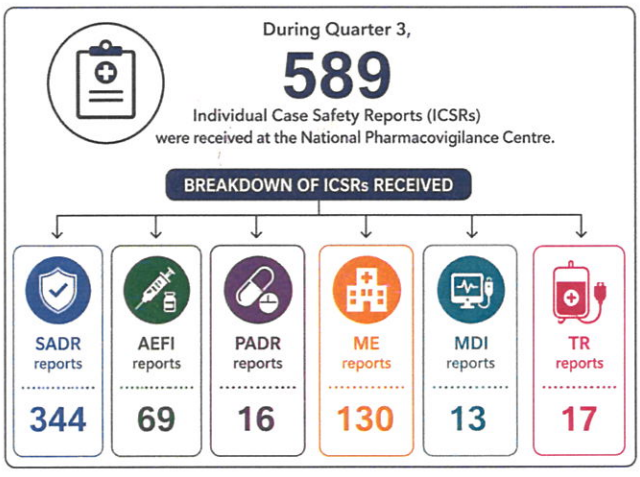
Further, Rule 5 of the Pharmacy and Poisons (Pharmacovigilance and Post-Market Surveillance) Rules, 2022 mandates the Board to establish and maintain a National Pharmacovigilance Centre responsible for coordinating the national pharmacovigilance and post-market surveillance system, including receiving, collating, assessing, and maintaining information on adverse events associated with authorized HPTs.

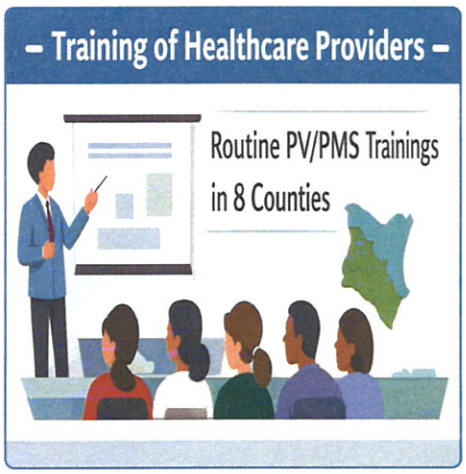
As part of this mandate, the Board provides quarterly pharmacovigilance reports to stakeholders as a feedback mechanism, aiming to enhance collaboration and encourage the timely reporting of adverse events.

In this quarter, the National Pharmacovigilance Centre 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 January 1st to March 31st 2026.

Pharmacovigilance Updates





Receiving and Processing of ICSRs

During Quarter 3, a total of 589 Individual Case Safety Reports (ICSRs) were received at the National Pharmacovigilance Centre. These included 344 suspected adverse drug reaction (SADR) reports, 69 adverse events following immunization (AEFI) reports, 16 public adverse drug reaction (PADR) reports, 130 medication error reports, 13 medical device incident reports, and 17 transfusion reaction reports.

Training of Healthcare Providers

During Quarter 3, three (3) sets pharmacovigilance trainings were conducted, including 3-day routine PV/PMS trainings in 8 Counties, 1-day PV/PMS Sensitization in 29 sentinel sites in 28 Counties, and a Qualified Person for Pharmacovigilance (QPPV) Training for 31 Marketing Authorization Holders.

Routine Trainings: Conducted in hard-to-reach counties including Isiolo, Garissa, Mandera, Wajir, Turkana, West Pokot, Kitui, and Lamu Counties

1-day PV Sensitization: Held in 29 Sentinel Sites in 28 Counties.

QPPV Training: 31 Marketing Authorization Holders (MAH) were trained on the implementation of the QPPV Role.

Stakeholder Engagements

In addition to the PV/PMS training conducted across various counties, the National Pharmacovigilance Centre carried out several stakeholder engagement activities during the reporting period. Key stakeholder engagement activities included: Participation in the coordination of pharmacy-based PrEP and HIV self-testing delivery models roll out, review of TB support supervision findings, public media engagement on medicine safety, participation in international and national scientific and public health forums, and collaboration with partners/stakeholders on TB, HIV, neglected tropical diseases commodities as well as maternal vaccines pharmacovigilance.

Safety Communication
The key safety communication issued during the quarter:

- **Right Drug, Right Dose, Right Patient: Ensuring good dispensing and administration practices to prevent medication errors**

The safety communication can be accessed on the Pharmacy and Poisons Board website via the following link:

https://web.pharmacyboardkenya.org/wp-content/uploads/2026/03/DHCP-Letter_ME.pdf

Post Marketing Surveillance Updates

Receiving and Processing of PQHPTs

During the period from January to March 2026, the National Pharmacovigilance Centre received 125 reports of suspected poor-quality medicines from14 counties All reports received undergo thorough evaluation and investigation.

Regulatory Actions

Findings from these investigations inform appropriate regulatory actions to safeguard public health. In this reporting period, several voluntary Class II recalls were implemented, including:

Budecort 100 Inhaler (5GB1889), Claxy 1.2g (09125PO12), GEMKIT (12173), Citro-Soda Regular (C134585, C134584, C130143, C127438), Cachnerve (25510456), and Utilyf Sachet (EFG24003).

For the most up-to-date information on recalls, rapid alerts, and safety communications, stakeholders are encouraged to visit: https://web.pharmacyboardkenya.org/safety-and-rapid-alerts/

Active Surveillance

In February 2026, the Board conducted a risk-based active Post-Marketing Surveillance exercise informed by market complaints and quality concerns, targeting key product categories including antibiotics, antihypertensives, antimalarials, anaesthetics, anticoagulants, supplements, antidiabetics, diagnostic kits, analgesics, emergency contraceptives, and erectile dysfunction products. 361 samples were collected from 31 counties and are currently undergoing Minilab® screening followed by confirmatory testing. The exercise aims to assess product quality and regulatory compliance and support evidence-based regulatory actions such as inspections, enforcement, and future surveillance planning.

SUSPECTED ADVERSE DRUG REACTIONS (SADRS)

During Quarter 3 of the 2025/2026 financial year (1st January – 31st March 2026), a total of **344 Suspected Adverse Drug Reaction (SADR)** reports were submitted to the National Pharmacovigilance Centre, a 10% increase from the previous quarter. Of these, **337 (97.97%)** were initial reports, while **7 (2.03%)** were follow-up reports. To avoid duplication, only one copy of each Individual Case Safety Report (ICSR) was included in the analysis, resulting in **337 reports** being analyzed in this quarterly summary. Among the 337 initial reports:

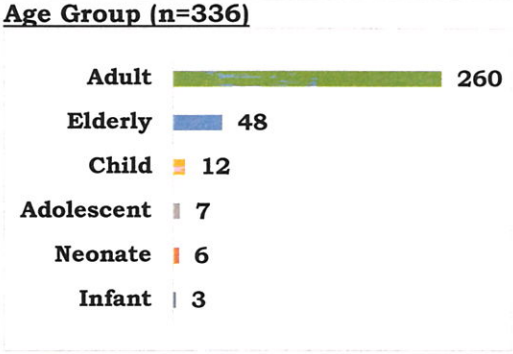
- **328 reports (97.33%)** were categorized as Suspected Adverse Drug Reactions (SADRs),
- **9 reports (2.67%)** were related solely to Therapeutic Ineffectiveness (TI).

Product Category (n=337)

Product Category	Count	Proportion
Medicinal Product	316	93.8%
Cosmeceutical	1	0.3%
Others	2	0.6%
Not Indicated	18	5.3%

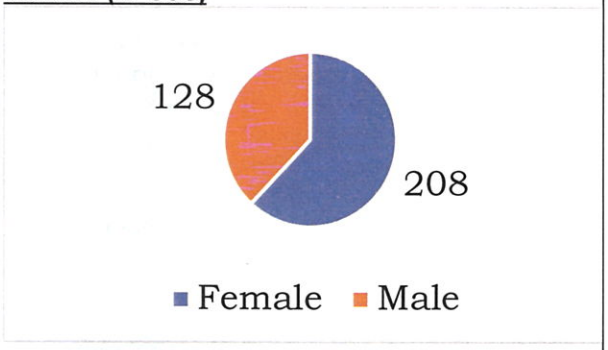
Of the 337 product category reports received, the majority involved medicinal products (316; 93.8%). Only a few reports were associated with cosmeceuticals (1; 0.3%) and other products (2; 0.6%), specifically Typhoid vaccine and Levofloxacin. In addition, 18 reports (5.3%) were classified as Not Indicated, indicating that the product category was not specified. The Typhoid vaccine report was excluded from subsequent analysis.

Age Group (n=336)



Of the 336 reports, the majority of the patients affected were associated with adults, accounting for 260 cases (77.38%). Reports involving the elderly were 48 cases (14.29%). Smaller proportions were observed among children (12; 3.57%), adolescents (7; 2.08%), neonates (6; 1.79%), and infants (3; 0.89%).

Gender (n=336)



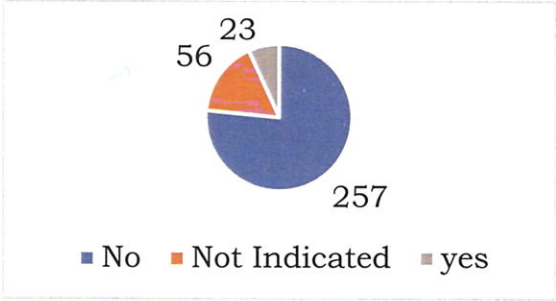
Of the 336 reports, the majority were associated with female patients, accounting for 208 cases (61.90%), while male patients accounted for 128 cases (38.10%).

Pregnancy Status (n=208)

Pregnancy Status	Count	Proportion
Not pregnant	125	60.10%
Not Applicable	41	19.71%
Not Indicated	29	13.94%
3rd Trimester	8	3.85%
2nd Trimester	4	1.92%
1st Trimester	1	0.48%
Grand Total	**208**	**100.00%**

Of the 208 reports involving female patients, most involved patients who were not pregnant (60.10%), with a smaller proportion classified as not applicable or not indicated. Among reports involving pregnant patients, 8 cases (3.85%) occurred during the third trimester, 4 cases (1.92%) during the second trimester, and 1 case (0.48%) during the first trimester.

Known Allergy (n=336)



Of the 336 reports, most patients had no known food or drug allergy (257, 76.49%).

A smaller proportion had a documented allergy (23, 6.85%), while allergy status was not specified in 16.67% (56) of reports.

Reported Allergen (n=23)

Allergen	Count	%
Sulphur	4	17.39%
Diclofenac	2	8.70%
Cotrimoxazole	2	8.70%

Among the 23 patients with a documented food or drug allergy, Sulphur was the most frequently reported allergen in 4 cases (17.39%). Diclofenac and cotrimoxazole each were reported in 2 cases (8.70%). Other allergens, each reported in 1 case (4.35%), included assorted pharmaceutical drugs, dolutegravir, fish, ibuprofen, metronidazole, Sulphonamides, eggs, isoniazid, and tetracyclines. In 6 cases (26.09%), the specific allergen was not indicated.

Suspected medicines
(n=352)

A total of 105 generic names and fixed-dose combinations (FDCs) were reported as suspected medicines during the quarter. The most frequently reported suspected medicine was RHZE (150 mg/75 mg/400 mg/275 mg), accounting for 64 reports (18.23%). This was followed by TDF/3TC/DTG (300 mg/300 mg/50 mg) with 39 reports (11.11%), and TAF/3TC/DTG (25 mg/300 mg/50 mg) with 24 reports (6.84%). Other commonly reported suspected medicines included cotrimoxazole, ceftriaxone, isoniazid/rifapentine (300 mg/300 mg), amlodipine besylate BP and nifedipine. The table above presents the most frequently reported suspected medicines during the quarter.

Suspected Medicine	***Count***	***Proportion***
RHZE (150mg/75mg/400mg/275mg)	64	18.23%
TDF/3TC/DTG (300/300/50mg)	39	11.11%
TAF/3TC/DTG (25mg/300mg/50mg)	24	6.84%
Cotrimoxazole	17	4.84%
Ceftriaxone	12	3.42%
Isoniazid/Rifapentine (300mg/300mg)	12	3.42%
Amlodipine Besilate BP	9	2.56%
Nifedipine	9	2.56%
Paracetamol	7	1.99%
Enalapril	7	1.99%
Rifampicin/Isoniazid (150mg/75 mg)	6	1.71%
Iohexol injection USP	6	1.71%
Metronidazole	5	1.42%
Lidocaine/Adrenaline	5	1.42%
Olanzapine	4	1.14%
Ferrous Sulphate /Folic Acid (200mg/0.4mg)	4	1.14%
Tenofovir Disoproxil Fumarate (300mg)	4	1.14%

Key

RHZE - *Rifampicin/Isoniazid/Pyrazinamide/Ethambutol*

TDF/3TC/DTG - *Tenofovir Disoproxil Fumarate/Lamivudine/Dolutegravir*

TAF/3TC/DTG - *Tenofovir Alafenamide/Lamivudine/Dolutegravir*

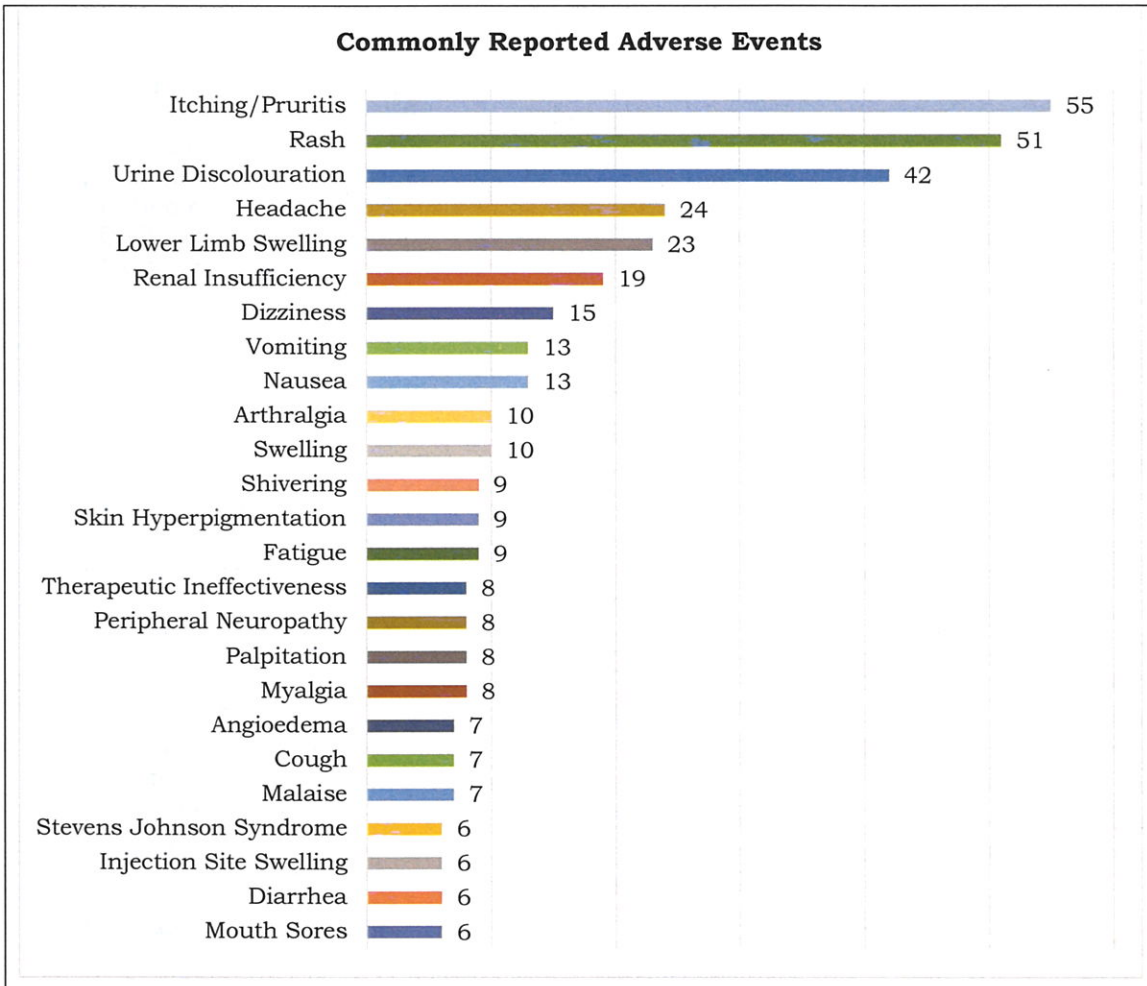
Commonly reported adverse reactions

A total of 563 adverse events were reported during the quarter, with MedDRA System Organ Class (SOC) of Skin and Subcutaneous Tissue Disorders being the most frequently observed.

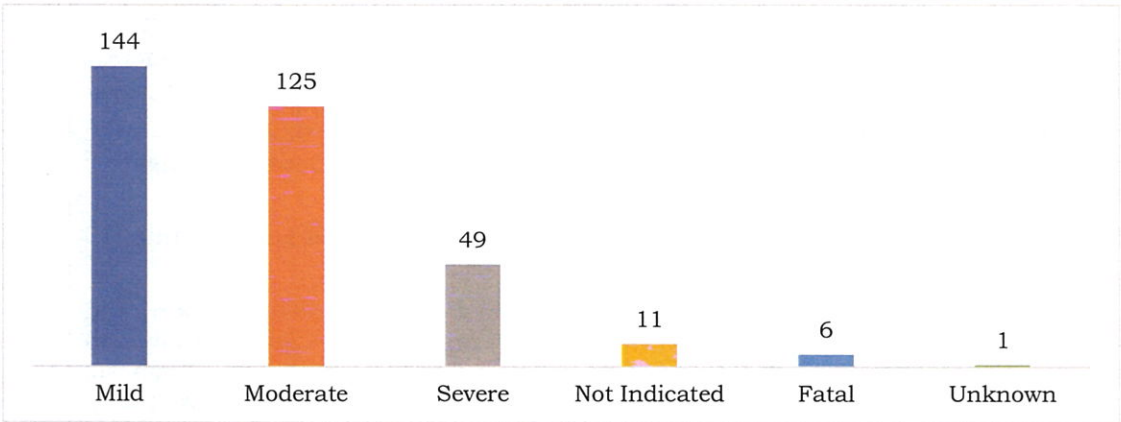
The most common events were itching/pruritus (55; 9.77%), rash (51; 9.06%), and urine discoloration (42; 7.46%), followed by headache (24; 4.26%), lower limb swelling (23; 4.09%), and renal insufficiency (19; 3.37%).

Other frequently reported events included dizziness (15; 2.66%), nausea and vomiting (13 each; 2.31%), and arthralgia and generalized swelling (10 each; 1.78%).

By MedDRA SOC classification, the majority of events clustered within Skin and Subcutaneous Tissue Disorders (e.g., pruritus, rash, angioedema, Stevens–Johnson syndrome, skin hyperpigmentation), Nervous System Disorders (e.g., headache, dizziness, peripheral neuropathy, convulsions), Gastrointestinal Disorders (e.g., nausea, vomiting, diarrhea, abdominal pain), Renal and Urinary Disorders (e.g., renal insufficiency, urine discoloration, hematuria, proteinuria), and General Disorders and Administration Site Conditions (e.g., fatigue, shivering, malaise, injection site swelling).



Severity (n=336)

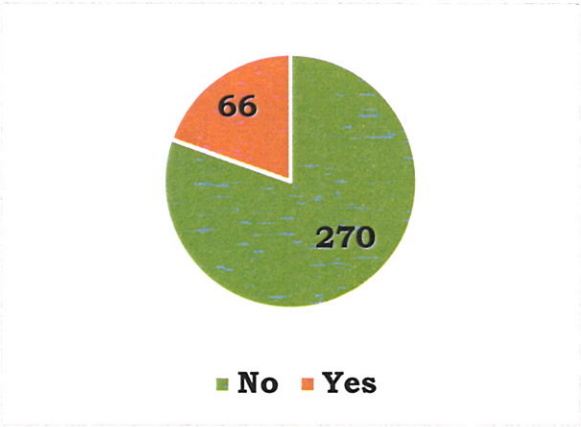


Of the 336 ADR reports received in this quarter, the majority of reports were classified as mild (144, 42.86%), followed by moderate cases with 125 reports (37.20%).

Severe reactions constituted 49 cases (14.58%), while 11 reports (3.27%) had the severity not indicated.

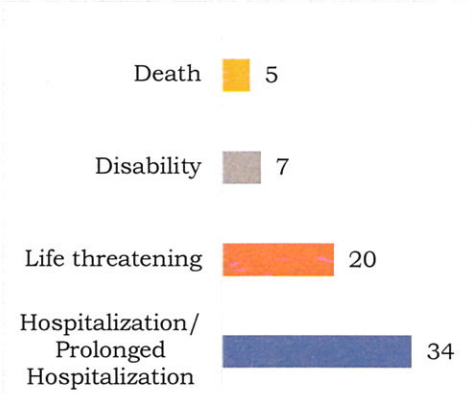
A small proportion of cases were fatal (6; 1.79%), and 1 report (0.30%) was classified as unknown.

Was the reaction serious? (n=336)



Most reports were classified as non-serious, accounting for 270 cases (80.36%), while 66 reports (19.64%) were classified as serious.

Reason for seriousness (n=66)



Among the 66 serious cases, the most common reason for seriousness was hospitalization or prolonged hospitalization (34; 51.52%), followed by life-threatening events (20; 30.30%). Disability accounted for 7 cases (10.61%), while death was reported in 5 cases (7.58%).

Actions taken (n=336)

Action Taken	Count	Proportion
Drug withdrawn	206	61.31%
Dose not changed	91	27.08%
Not applicable	26	7.74%
Dose reduced	6	1.79%
Unknown	4	1.19%
Dose increased	3	0.89%
Grand Total	**336**	**100.00%**

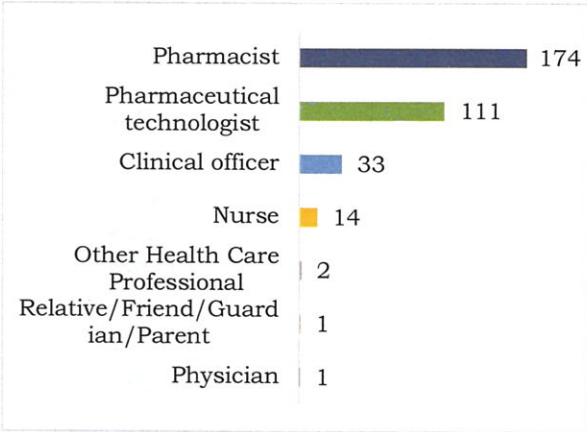
In terms of action taken by the healthcare providers, drug withdrawal was the most common action, reported in 206 cases (61.31%). This was followed by cases where the dose was not changed (91; 27.08%). Other outcomes included not applicable (26; 7.74%), dose reduction (6; 1.79%), unknown outcomes (4; 1.19%), and dose increases (3; 0.89%).

Outcome (n=336)

Outcome	Count	Proportion
Recovering/resolving	127	37.80%
Recovered/resolved	80	23.81%
Not recovered/not resolved	63	18.75%
Unknown	55	16.37%
Fatal	7	2.08%
Not Indicated	3	0.89%
Not recovered/Not resolved/Ongoing	1	0.30%
Grand Total	**336**	**100.00%**

Regarding outcomes, most of the affected patients were recovering or resolving (127; 37.80%), followed by those that had recovered or resolved (80; 23.81%) at the time of reporting. A further 63 cases (18.75%) had not recovered or remained unresolved, while 55 cases (16.37%) had an unknown outcome. Fatal outcomes were reported in 7 cases (2.08%), with a small number classified as not indicated (3; 0.89%) or not recovered/not resolved/ongoing (1; 0.30%).

Reporter designation (n=336)



Reporter designation (n=336)

Pharmacists contributed the majority of reports (174; 51.79%), followed by pharmaceutical technologists (111; 33.04%).

Clinical officers accounted for 33 reports (9.82%), while nurses submitted 14 reports (4.17%).

Reports from other health care professionals were minimal (2; 0.60%), and physicians as well as relatives/friends/guardians/parents each contributed 1 report (0.30% each).

Institution

In this quarter, adverse drug reaction reports were received from a total of 131 health facilities across the country.

The highest number of adverse drug reaction reports was submitted by Maralal District Hospital, which contributed 42 reports (12.50% of the total).

This was followed by The Mater Hospital Mukuru with 23 reports (6.85%) and Meru Teaching and Referral Hospital with 19 reports (5.65%). Below is a list of top 11 facilities with at least 5 reports and above.

Institution/Facility	Count	Proportion
Maralal District Hospital	42	12.50%
The Mater Hospital Mukuru	23	6.85%
Meru Teaching And Refferal Hospital	19	5.65%
Webuye County Hospital	16	4.76%

Kakamega County General Hospital	9	2.68%
Murang'a County Refferal Hospital	9	2.68%
Kerugoya County Refferal Hospital	7	2.08%
Kirinyaga County Referral Hospital	7	2.08%
Jumuia Hospital Huruma	6	1.79%
Kisii Teaching And Referral Hospital (Level 6)	5	1.49%
Thika Level 5 Hospital	5	1.49%

County

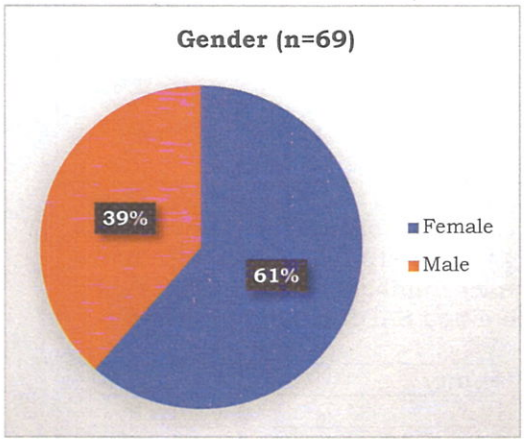
By county, most reports came from Nairobi County (57; 16.96%), followed by Kirinyaga (53; 15.77%) and Samburu (42; 12.50%). Kiambu (23; 6.85%) and Meru (20; 5.95%) also had a fair number of reports. Other counties contributed smaller numbers, each with less than 6% of the total. Below is a table of the counties that submitted SADR reports in Quarter 3.

No	County	Count	%	No	County	Count	%
1	Nairobi County	57	16.96%	18	Nyeri	4	1.19%
2	Kirinyaga	53	15.77%	19	Homa Bay	4	1.19%
3	Samburu	42	12.50%	20	Isiolo	3	0.89%
4	Kiambu	23	6.85%	21	Taita Taveta	3	0.89%
5	Meru	20	5.95%	22	Migori	3	0.89%
6	Bungoma	18	5.36%	23	Embu	3	0.89%
7	Kakamega	13	3.87%	24	Machakos	3	0.89%
8	Mombasa	11	3.27%	25	Nakuru	2	0.60%
9	Murang'a	10	2.98%	26	Makueni	2	0.60%
10	Kilifi	9	2.68%	27	West Pokot	2	0.60%
11	Kisii	8	2.38%	28	Busia	2	0.60%
12	Kisumu	6	1.79%	29	Kitui	2	0.60%
13	Nandi	6	1.79%	30	Narok	1	0.30%
14	Uasin Gishu	6	1.79%	31	Kwale	1	0.30%
15	Turkana	6	1.79%	32	Kajiado	1	0.30%
16	Siaya	5	1.49%	33	Trans Nzoia	1	0.30%
17	Kericho	5	1.49%	34	Garissa	1	0.30%

ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

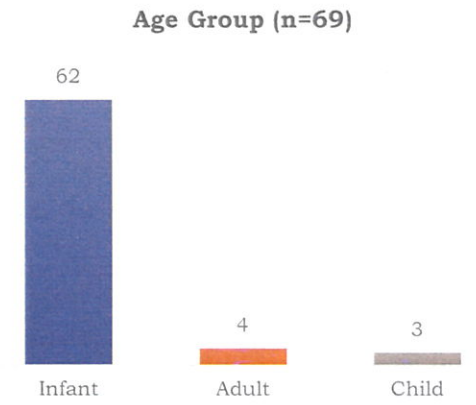
Between 1st January and 31st March 2026, the National Pharmacovigilance Centre received 69 AEFI reports, all of which were initial reports.

Gender (n=69)



Of the AEFI reports received in this quarter, it was noted that females affected were 61% (42) more than males 39% (27).

Age Group (n=69)



Majority of the AEFIs reported in this quarter affected the Infant age group (< 1year) (62). The least affected age group in this quarter were the Adults (4) (18-64years) and Child (3) (1-17 years)

Type of Vaccine Administered

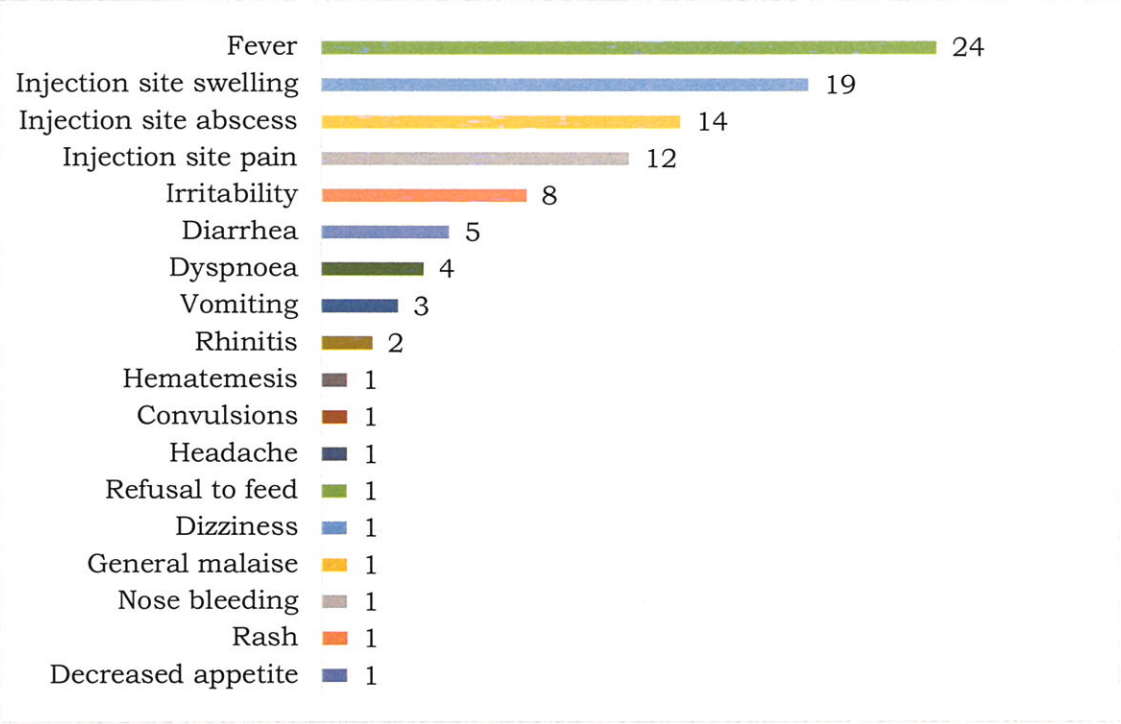
Most AEFI reports were linked to Pentavalent Vaccine (DTP-HepB-Hib) with 50 cases (31%). This was followed by Pneumococcal conjugate vaccine with 30 cases (19%) and Rotavirus vaccine with 29 cases (18%). Overall, these three vaccines accounted for the highest proportion of reported AEFIs.

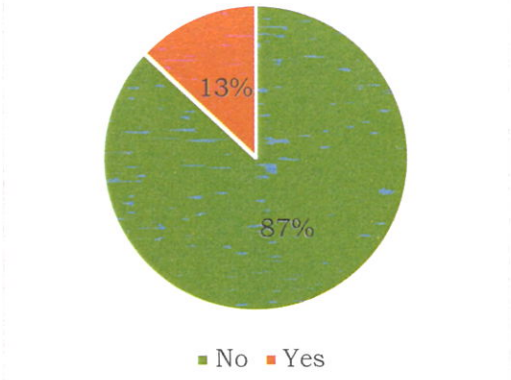
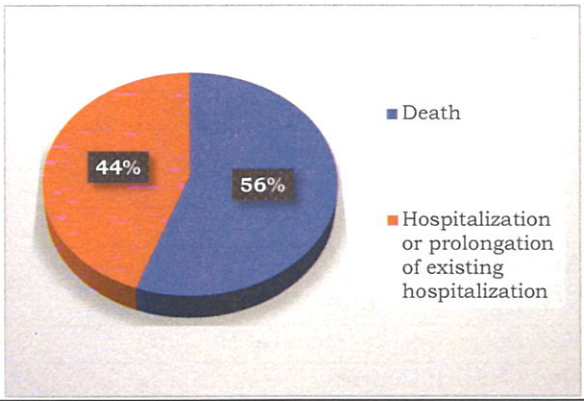
Vaccine Type	Count	Proportion
Pentavalent Vaccine (DTP-HepB-Hib)	50	31.85%
Pneumococcal conjugate vaccine	30	19.11%
Rota virus vaccine	29	18.47%
Bivalent oral Polio vaccine	28	17.83%
Inactivated polio vaccine	7	4.46%
Measles Rubella Vaccine	4	2.55%
Hepatitis B Vaccine	3	1.91%
Malaria (RTSS)Vaccine	3	1.91%
Typhoid Conjugate Vaccine (TCV)	2	1.27%
Tetanus Diptheria Vaccine	1	0.64%

Adverse Events Following Immunization

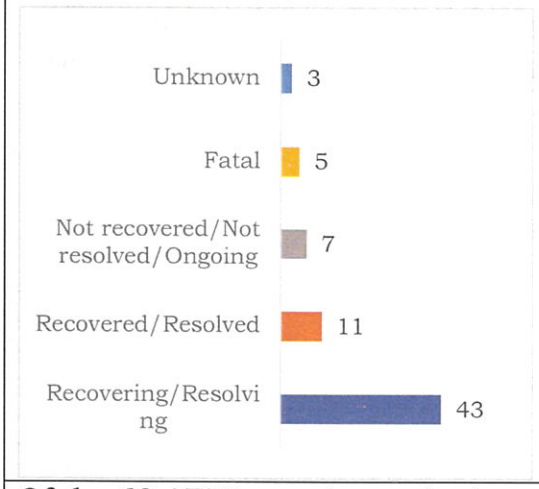
In this quarter, fever was the most commonly reported AEFI, accounting for 24% of cases.

Other frequently reported reactions included injection site reactions, particularly injection site pain (19%), injection site abscess (14%), and injection site pain (12%). The other commonly reported AEFIs were as shown in the diagram below.



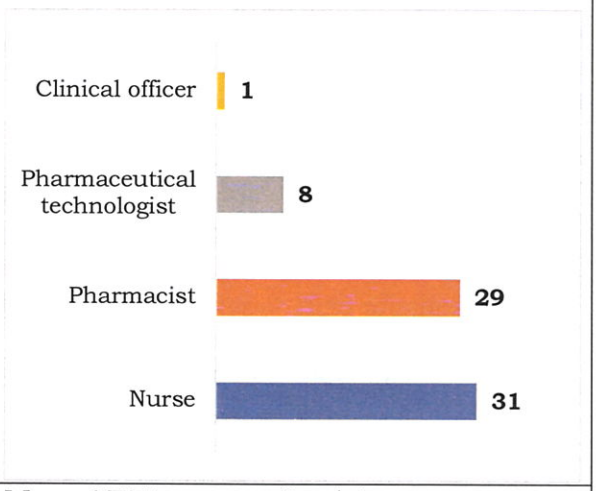
Was the reaction Serious? (n=69)	**Reason for Seriousness (n=9)**
	
Majority of the AEFI reports 87% (60) received in this quarter were reported as not serious, with 13% (9) reported as serious.	Of the 9 AEFI reports noted to be serious 56% (5) were due to death and 44% (4) were due to hospitalization or prolonged hospitalization.

Outcome (n=69)



Of the 69 AEFI reports received, most outcomes were reported as recovering or resolving (43 cases). Eleven cases had fully recovered/resolved, while 7 cases had not recovered or were still ongoing. Three cases had unknown outcomes, and 5 cases were reported as fatal.

Reporter designation (n=69)



Most AEFI reports in this quarter were submitted by nurses, who accounted for 31 reports (45%). Pharmacists submitted 29 reports (42%), while pharmaceutical technologists and clinical officers submitted 8 (12%) and 1 (1%) report, respectively.

Reporting institution (n=30)

In this Quarter, only 30 facilities out of the over 9,000 facilities listed in the Kenya Master facility reported AEFIs. The top leading facility was Maralal District Hospital with 18 reports followed by Limuru Cottage Hospital and Kangu Dispensary with 7 reports each. The table below shows the top ten reporting facilities in this quarter

Facility	Count	Proportion
Maralal District Hospital	18	25.71%
Limuru Cottage Hospital	7	10.00%
Kangu Dispensary	7	10.00%
Limuru Health Centre	4	5.71%
Kirinyaga county	3	4.29%
Wangige Sub County Hospital	2	2.86%
Kakamega County General Hospital	2	2.86%
Gede Health Centre	2	2.86%
Tudor District Hospital (Mombasa)	2	2.86%
Webuye Hospital	2	2.86%

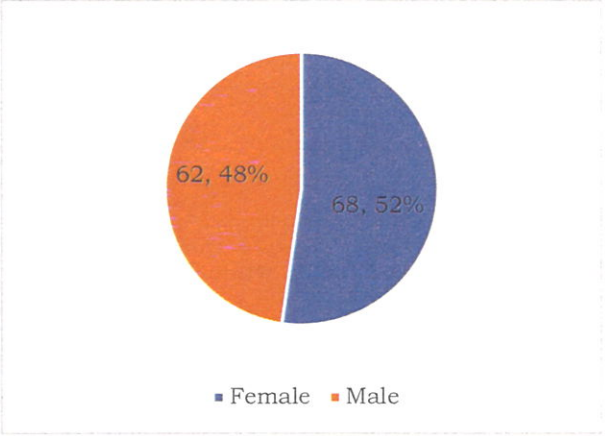
Reporting counties (n=16)

AEFI reports were received from 16 of the 47 counties. Samburu County submitted the highest number of reports (18), followed by Kiambu (13) and Kirinyaga (12). The remaining counties submitted fewer reports as shown in the table above.

County	Count	Proportion
Samburu	18	25.71%
Kiambu	13	18.57%
Kirinyaga	12	17.14%
Nairobi County	4	7.14%
Kakamega	5	7.14%
Bungoma	3	4.29%
Siaya	3	4.29%
Kilifi	2	2.86%
Mombasa	2	2.86%
Uasin Gishu	2	2.86%
Busia	1	1.43%
Meru	1	1.43%
Kwale	1	1.43%
Kisii	1	1.43%
Kisumu	1	1.43%

MEDICATION ERRORS (MEs)

Gender (n=130)



A total of 130 medication errors were reported in Quarter 3. Of this, 52% (68) involved the female gender while 48% (62) involved the male gender.

Age Group (n=130)

Age Group	Count	Percentage
Adult	71	54.62%
Elderly	21	16.15%
Child	16	12.31%
Not Indicated	10	7.69%
Infant	7	5.38%
Neonate	3	2.31%
Adolescent	2	1.54%
Grand Total	**130**	**100.00%**

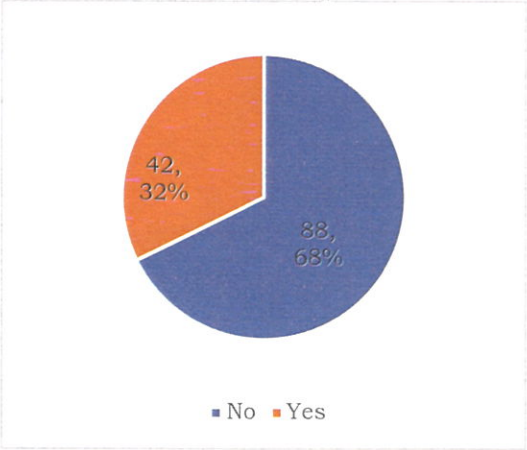
Adults accounted for the majority of patients affected by medication errors received this quarter (54.62%), followed by the elderly (16.15%) and children (12.31%), while the remaining cases were distributed across other age groups. In 10 reports, the age groups was not indicated.

Reporter Designation

Cadre	No. of Reports	Percentage
Pharmacist	116	89.23%
Pharmaceutical technologist	12	9.23%
Other Health Care Professional	2	1.54%
Grand Total	**130**	**100.00%**

Most medication errors were reported by Pharmacists 116 (89.23%), followed by pharmaceutical technilogisits 12 (9.23%), and other healthcare professionals 2 (1.54%)

Did the Error reach the patient?



In Quarter 3, 88 (68%) of the reported medication errors did not reach patients while 42 (32%) reached patients.

Medication Error Outcome

Outcome	No. of Reports	Percentage
Actual error-did not reach patient	70	53.85%
Actual error-caused no harm	18	13.85%
Potential error, circumstances/events have potential to cause incident	18	13.85%
Additional monitoring required-caused no harm	18	13.85%
Treatment /intervention required-caused temporary harm	4	3.08%
Initial/prolonged hospitalization-caused temporary harm	1	0.77%
Death	1	0.77%
Grand Total	**130**	**100.00%**

Most of the medication errors 70 (53.85%) did not reach patients, 18 (13.85%) reached patients but caused no harm, 18 (13.85%) had potential to cause harm, while 18 (13.85%) had additional monitoring which resulted in no harm.

Number of medication errors per product

Drug	No. of Reports	Percentage
Metronidazole	6	4.80%
Zidovudine	5	4.00%
Flucloxacilln	5	4.00%
Amoxicillin	5	4.00%
Amlodipine	4	3.20%
Carvedilol	3	2.40%
Bisacodyl	3	2.40%
Digoxin	2	1.60%
Meropenem	2	1.60%
Bisacodyl	2	1.60%
Furosemide	2	1.60%

Of the reported errors, 6 (4.80%) were associated metronidazole followed by zidovudine 5 (4.00%), and Flucloxacillin 5 (4.00%). Other medication errors are as shown in the table

Process Where the Error Occurred

Process	No. of Reports	Percentage
Prescribing	101	77.69%
Administration	19	14.62%
Dispensing (includes filling)	9	6.92%
Others	1	0.77%
Grand Total	**130**	**100.00%**

In quarter 3, most medication errors 101 (77.69%) occurred during prescription, followed by 19 (14.62%), administration errrors and 9 (6.92%) as dispensing errors.

Description of the Error

Error Description	No. of Reports	Percentage
Prescribed overdose	24	14.12%
Prescribed underdose	19	13.07%
Wrong drug combination	14	11.61%
Non-adherence to medication	14	11.61%
Not Indicated	13	5.04%
Dispensed wrong medication	11	4.38%
Polypharmacy	9	4.32%
Irrational antibiotic prescribing	9	3.51%
Prescribed wrong dose	7	3.51%
Dose not specified	5	3.51%
Not a medication error	5	3.51%

Of the reports received, majority involved prescription overdose 24(14.12%), followed by prescription underdose 19 (13.07%), wrong drug combination 14 (11.61%) as well as non-adherence to medication. The frequency of other errors is as captured in the table.

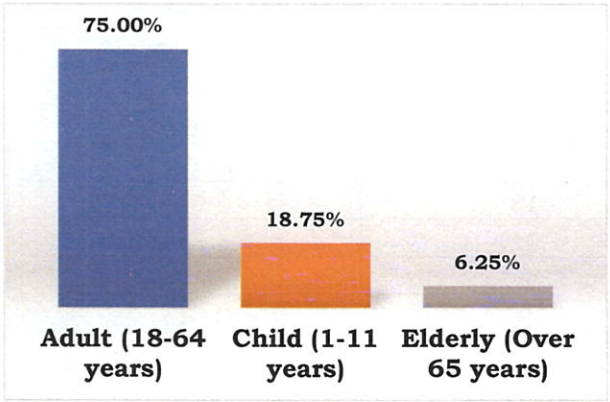
Factors Contributing to the Error Occurrence

Contributing Factor	No. of Reports	Percentage
Heavy workload	45	20.45%
Distraction	33	15.00%
Peak hour	30	13.64%
Inexperienced personnel	27	12.27%
Inadequate knowledge	26	11.82%
work procedure	10	8.18%
Use of abbreviations	8	5.45%
Look alike medication	6	4.55%
Wrong labelling	6	3.64%
Others	6	2.73%
Incorrect computer entry	5	2.27%

The most commonly reported contributing factor was heavy workload 45 (20.45%), followed by distraction 33 (15.00%), and peak hour 30 (13.64%). The impact of other contributing factors is as shown.

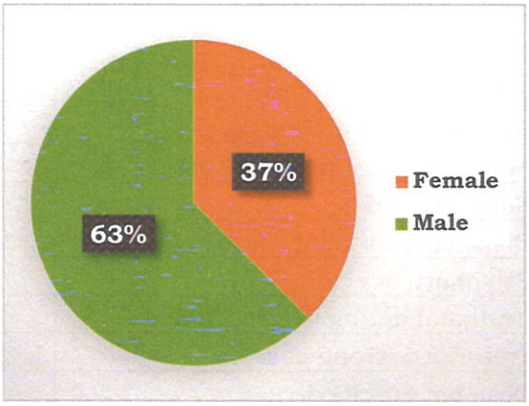
PUBLIC ADVERSE DRUG REPORTING (PADRS)

Age Group (n=16)



Most PADR cases were highest amongst adults, with 12 out of 16 cases (75%). Children had 3 cases out of 16 (18.75%), and the elderly had 1 case out of 16 (6.25%).

Gender (n=16)



PADRs were more common in males, who accounted for 10 out of 16 cases (63%). Females made up 6 out of 16 cases (37%).

Suspect Health Product and Technologies

The table below presents the distribution of drugs implicated in Public Adverse Drug Reactions (PADRs) reports, showing the frequency and proportion of each reported drug.

No	Drug	Count	%	No	Drug	Count	%
1	Rifampicin, Isoniazid, Pyrazinamide, Ethambutol	1	6.25%	7	Ceftriaxone	1	6.25%
2	Artemether Lumefantrine	1	6.25%	8	Tenofovir/Lamivudine/Dolutegravir	1	6.25%
3	Vitamin D drops 400IU	1	6.25%	9	Deflazacort	1	6.25%
4	Cefixime	1	6.25%	10	Delased Dry Cough	1	6.25%
5	Beecox MR (celecoxib 200mg, paracetamol 325mg and chlorzoxazone 250mg tablets	1	6.25%	11	Inclisiran	1	6.25%
6	Jadelle	1	6.25%				

Commonly Reported Public Adverse Drug Reactions Reports

The most commonly reported PADRs were vomiting (14.29%), dizziness (11.90%), rash (9.52%), and headache (9.52%). The other reported reactions are highlighted in the table below.

No	Reaction	Count	Proportion	No	Reaction	Count	Proportion
1	Vomiting	6	14.29%	9	Thirsty	1	2.38%
2	Dizziness	5	11.90%	10	Shortness of breath	1	2.38%
3	Rash	4	9.52%	11	Heartburn	1	2.38%
4	Headache	4	9.52%	12	Delirium	1	2.38%
5	Red/ painful eyes	3	7.14%	13	Tongue sores	1	2.38%
6	Pain in the stomach	3	7.14%	14	Seizures	1	2.38%
7	Joints and muscle pain	2	4.76%	15	Diarrhea	1	2.38%
8	Feeling weak	1	2.38%	16	Leaking cap	1	2.38%

County

PADRs were reported from 9 of the 47 counties. Nairobi County submitted the highest number of reports (6, 37.5%). Uasin Gishu and Kiambu each submitted 2 reports (12.5%), while the remaining counties—Tharaka Nithi, Kitui, Turkana, Mombasa, Homa Bay, and Siaya—each submitted 1 report (6.3%), as shown in the table below.

No	County	Count	Proportion	No	County	Count	Proportion
1	Nairobi County	6	37.5%	6	Turkana	1	6.3%
2	Uasin Gishu	2	12.5%	7	Mombasa	1	6.3%
3	Kiambu	2	12.5%	8	Homa Bay	1	6.3%
4	Tharaka Nithi	1	6.3%	9	Siaya	1	6.3%
5	Kitui	1	6.3%				

MEDICAL DEVICE INCIDENCE REPORTS

In the past quarter, there were 13 reports of medical device incidents (MDIs). Most cases occurred in female patients (10), while 3 were reported in male patients. The incidents were classified as serious (6), moderate (4), mild (1), and unknown (2). Regarding patient outcomes, 7 patients recovered, 4 were recovering, and 2 had unknown outcomes.

During the reporting period, the following medical devices were associated with incidents reported from healthcare facilities. The details of these incidents are presented in the table below.

No	Medical Device	Manufacturer	Incident (Event)
1.	Blood Glucose Test Meter	Green Cross Medis Corp	The device produced inconsistent and inaccurate random blood sugar (RBS) readings compared to repeat tests and a replacement device. This could have led to a risk of misdiagnosis or inappropriate treatment.
2.	Haemocent Haemodialysis Catheter Kit	Poly medicure Ltd	Guidewires were found to be brittle and resistant during removal, posing procedural challenges and potential risk to patients.
3.	I.V. Cannula 24G	Bio-Med Health Care Products	The catheter surface is rough, causing inflammation at the injection site. Additionally, the catheter tears during needle removal, posing a risk to patient safety.
4.	Infusion giving set	Revital	Giving sets reported to be malfunctional, compromising infusion administration.
5.	IV Flow Regulator	Eraser Medikal	The giving set was missing a flow regulator, which is essential for controlling the rate of drug administration over the prescribed period.
6.	Latex gloves	Tan Sin Lian Industries Sdn.Bhd	Gloves were fragile and tore easily during donning, affecting usability and protection.
7.	Oxygen Flow meter	Boehringer	Breakage observed at the humidifier attachment, affecting functionality.
8.	Safety Box	Not Indicated	A healthcare worker sustained a needle-stick injury from a needle protruding from a suspected poor-quality safety box while dressing a wound in the outpatient department. The staff member was subsequently initiated on post-exposure prophylaxis (PEP)
9.	Syringe 5cc with needle	Revital	Syringes reported to be malfunctional, affecting intended use.
10.	Umbilical cord clamp	Nthope Industry &Trade Co Ltd	Cord clamps reported to be malfunctional, compromising proper cord clamping.

The reports were primarily made by pharmaceutical technologists (7,53.85%), Pharmacists (5,38.46%) and a Clinical officer (1,7.69%).

Reporting Counties

These reports were received from 7 of the 47 counties, with Mombasa County submitting the highest number (4, 30.77%) as shown in the table below.

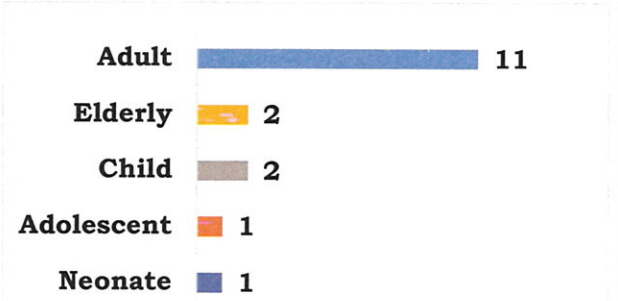
No	County	Count	Proportion	No	County	Count	Proportion
1	Mombasa	4	30.77%	5	Bomet	1	7.69%
2	Migori	2	15.38%	6	West Pokot	1	7.69%

3	Kakamega	2	15.38%	7	Meru	1	7.69%
4	Kilifi	2	15.38%				

TRANSFUSION REACTION

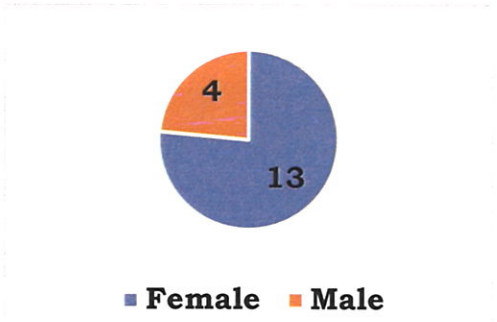
During Quarter 3 of the 2025/2026 financial year (1st January – 31st March 2026), a total of **21 transfusion reactions** reports were submitted to the National Pharmacovigilance Centre. Of these, **4 reports were duplicates**. To avoid duplication, only one copy of each Individual Case Safety Report (ICSR) was included in the analysis, resulting in **17 reports** being analyzed in this quarterly summary.

Age Group (n=17)



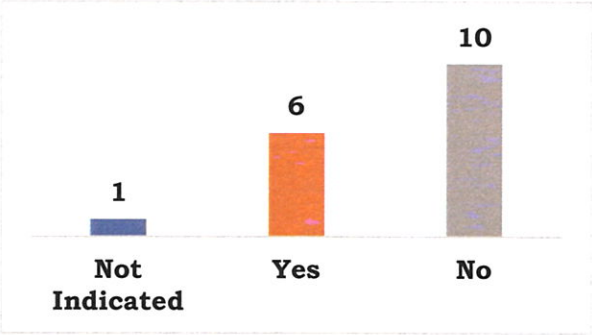
Most transfusion reactions were reported in adults (11 cases). Elderly people and children had 2 cases each, while neonates and adolescents had 1 case each.

Gender (n=17)



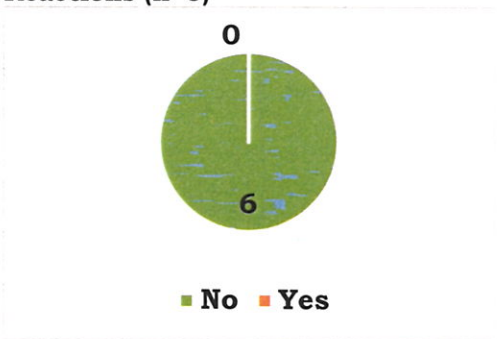
Most transfusion reactions were reported in females (13 cases), while males accounted for 4 cases.

History of Previous Transfusion (n=17)



Most patients had no previous transfusion (10 cases). Six patients had a history of transfusion, while for one case this information was not indicated. Overall, most reactions occurred in patients without a prior transfusion history.

History of Previous Transfusion Reactions (n=6)



All patients with a history of previous transfusion (6 cases) had no record of prior transfusion reactions.

Reason for Transfusion and Blood Components Transfused (n=17)

Most transfusions were given due to low hemoglobin/anemia (14 cases). A few cases also involved other conditions such as low platelets and pancytopenia, either alone or alongside anemia.

Most transfusion reactions were associated with packed red cells (15 cases). Platelets and fresh frozen plasma were each involved in 1 case.

Blood Component Type	Count	Proportion
Packed Red Cells	15	88.24%
Platelets	1	5.88%
Fresh Frozen Plasma	1	5.88%
Grand Total	**17**	**100.00%**

POST MARKETING SURVEILLANCE UPDATES

During the period from January to March 2026, the National Pharmacovigilance Centre received 125 reports of suspected poor-quality medicines from across the country. This represents a decrease compared to the 200 reports received between October and December 2025.

Reporting Counties (n=14)

No.	County	Suspected Poor Quality Reports Submitted to PPB		
		Oct-Dec 2025	Jan-March 2026	Total
1.	Nairobi	45	30	75
2.	Mombasa	21	8	28
3.	Kiambu	10	10	20
4.	Kilifi	18	1	19
5.	Kirinyaga	7	11	18
6.	Kakamega	3	11	15
7.	Kisumu	9	5	14
8.	Siaya	7	5	12
9.	Bungoma	3	9	12
10.	Nakuru	8	3	11
11.	Meru	8	4	11
12.	Uasin Gishu	8	1	9
13.	Taita Taveta	6	3	9
14.	Other counties	47	24	71
	Total	**200**	**125**	**324**

Regulatory Actions

All reports received by the Pharmacy and Poisons Board undergo thorough evaluation and investigation, which may include laboratory testing of submitted samples. Where necessary, expanded investigations are conducted to assess other batches and distribution areas of the affected products.

Findings from these investigations inform appropriate regulatory actions to safeguard public health.

The following voluntary product recalls were implemented from January 2026:

Table 2: Recalls implemented by PPB from January – March 2026

Date initiated	Class of Recall	Product Name	INN	Batch No.	MAH	Reason for Recall
30/03/2026	Class II	Budecort 100 Inhaler	Budesonide	5GB1889	Cipla limited	The actuator used is not compatible with the Bespak valve
30/03/2026	Class II	Claxy 1.2g	Amoxicillin Trihydrate BP and Clavulanate Potassium	09125PO12	Scott Edil Advance Research Laboratories and Education Ltd	An observation upon reconstitution of the dry powder that the solution exhibited an immediate color ranging from pale yellow to dark yellow
30/03/2026	Class II	GEMKIT	Gemifloxacin 320mg / Amoxicillin 1g / Rabeprazole 20mg	12173	Healthcare Formulations Pvt Ltd	A discrepancy in the stated dosing frequency of Gemifloxacin 320 mg. According to the Patient Information Leaflet (PIL), the medication is indicated to be taken twice daily, rather than

						the once-daily dosage
30/03/2026	Class II	Citro-Soda Regular	Sodium Bicarbonate, Tartaric acid, Citric acid, Sodium citrate	C134585 C134584 C130143 C127438	Adcock Ingram Healthcare Ltd	The detection of possible foreign material contamination during an inspection of the factory by the SAHPRA Inspectorate
30/03/2026	Class II	Cachnerve	Alpha Lipoic Acid, Gamma Linolenic Acid, Pyridoxine Hcl, Methylcobalamine Hcl & Chromium	25510456	Cachet Pharmaceuticals PVT	Variation in the size of the capsules, causing shrinkage
30/03/2026	Class II	Utilyf sachet	Potassium Magnesium citrate, D-Mannose, and Cranberry Extract Sachet	EFG24003	Cachet Pharmaceuticals PVT	Formation of lumps within the sachets

For the most up-to-date information on recalls, rapid alerts, and safety communications, stakeholders are encouraged to visit: https://web.pharmacyboardkenya.org/safety-and-rapid-alerts/

Active Post-Marketing Surveillance Updates

In February 2026, the Pharmacy and Poisons Board carried out a risk-based active Post-Marketing Surveillance exercise guided by market complaints, historical quality concerns, and other risk factors.

The surveillance focused on selected product categories, including antibiotics, antihypertensives, antimalarials, anaesthetics, anticoagulants, supplements, antidiabetics, rapid diagnostic test kits, analgesics, emergency contraceptives, and erectile dysfunction products.

A total of 361 samples were collected from 31 counties nationwide. The samples are currently undergoing Minilab® screening, followed by confirmatory compendial testing.

The exercise aims to verify product quality and regulatory compliance, assess conformity to marketing authorization requirements, and generate evidence to support risk-based regulatory decisions such as targeted inspections, enforcement actions, and future surveillance planning.

For any queries, please contact the PV department on pv@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*)

Signature:

Report Approved By: Dr Ahmed I. Mohamed
Ag. Chief Executive Officer
Pharmacy and Poisons Board

Date: 20th April 2026