REPUBLIC OF KENYA

PHARMACY AND POISONS BOARD

Pharmacovigilance Summary Report: Oct 1st to Dec 31st 2025 (Q2)

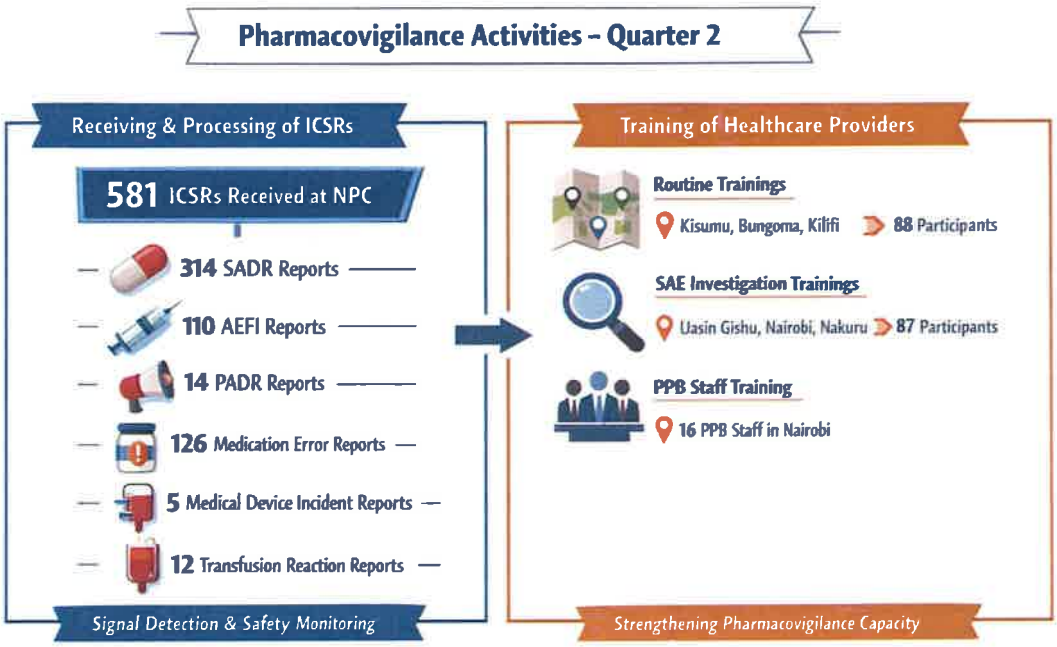
The Pharmacy and Poisons Board is the National Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board is mandated to protect and promote public health by regulating the pharmacy profession and ensuring access to quality, safe, and effective health 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 October 1st to December 31st 2025.



Receiving and Processing of ICSRs

During Quarter 2, a total of 581 Individual Case Safety Reports (ICSRs) were received at the National Pharmacovigilance Centre. These included 314 suspected adverse drug reaction (SADR) reports, 110 adverse events following immunization (AEFI) reports, 14 public adverse drug reaction (PADR) reports, 126 medication error reports, 5 medical device incident reports, and 12 transfusion reaction reports. Collectively, these reports provided critical data to support signal detection, safety monitoring, and continuous benefit-risk assessment.

Training of Healthcare Providers

During Quarter 2, six pharmacovigilance trainings were conducted, including three routine trainings and three SAE investigation trainings. These activities strengthened healthcare worker and regulator capacity in safety reporting, investigation, and regulatory compliance.

Routine Trainings: Conducted in Kisumu, Bungoma, and Kilifi in December 2025, reaching a total of 88 participants and enhancing adverse event reporting at county level.

SAE Investigation Trainings: Held in Uasin Gishu, Nairobi, and Nakuru in November 2025, training 87 participants on serious adverse event investigation, documentation, and submission for causality assessment.

PPB Staff Training: Sixteen Pharmacy and Poisons Board (PPB) staff were trained in Nairobi to strengthen internal pharmacovigilance capacity.

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 HPTs.

Key stakeholder engagement activities included:

***Joint PPB/NVIP Secretariat Meeting*:** Conducted to discuss cases that occurred during the quarter prior to being tabled to the expert committee.

***PPB/NTD Mass Drug Administration Activities*:** Collaborated with the NTD on pharmacovigilance monitoring of NTD mass drug administration exercise.

***Maternal Immunization Safety Surveillance Planning Project Leadership Workshop*:** Convened various stakeholders to as part of the strategic planning of an upcoming maternal immunization active safety surveillance.

***GAP Analysis Survey Planning and Implementation*:** Undertaken to identify gaps to reporting and inform targeted strengthening of pharmacovigilance structures and processes.

***Quarterly KAPI Meeting with PPB*:** Held to review and update pharmaceutical industry stakeholders on pharmacovigilance updates to enable alignment with regulatory priorities.

Safety Communication

During the reporting period, the Pharmacy and Poisons Board issued a safety communication regarding the safe use of Health Products and Technologies (HPTs). This communication was 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 on paracetamol uses during pregnancy**

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 2 of the 2025/2026 financial year (1st October – 31st December 2025), a total of **314 Suspected Adverse Drug Reaction (SADR)** reports were submitted to the National Pharmacovigilance Centre. Of these, **306 (97.45%)** were initial reports, while **8 (2.55%)** were follow-up reports. To avoid duplication, only one copy of each Individual Case Safety Report (ICSR) was included in the analysis, resulting in **306 reports** being analyzed in this quarterly summary. Among the 306 initial reports:

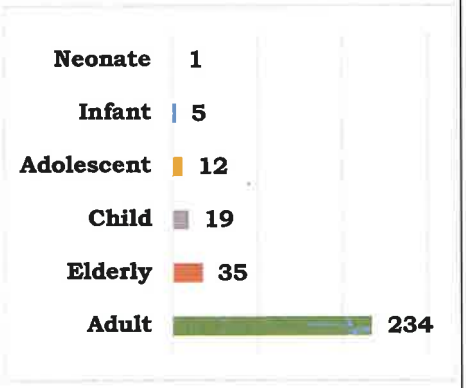
- **301 reports (98.36%)** were categorized as Suspected Adverse Drug Reactions (SADRs),

- **3 reports (0.98%)** involved both SADRs and Therapeutic Ineffectiveness (TI), and
- **2 reports (0.65%)** were related solely to Therapeutic Ineffectiveness (TI).

Product Category (n=306)

Product Category	Count	Proportion
Medicinal Product	277	90.52%
Diagnostic product	8	2.61%
Not Indicated	21	6.86%

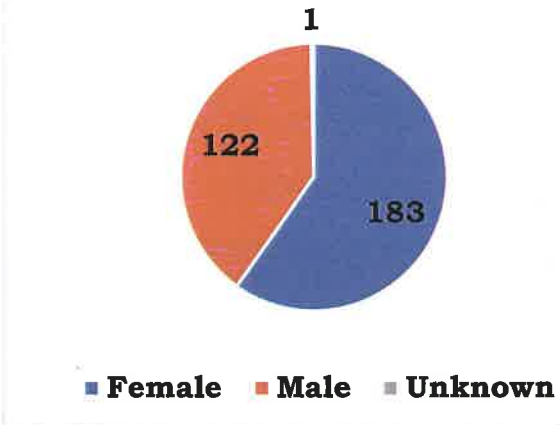
Age Group (n=306)



Of the 306 ADR reports received, the majority were associated with medicinal products, accounting for 277 cases (90.52%). A smaller number of reports involved diagnostic products, with 8 cases (2.61%). Additionally, 21 reports (6.86%) were classified as Not Indicated, where the product category was not specified.

The majority of ADR reports were from adults, accounting for 234 cases (76.47%). Elderly patients comprised 35 reports (11.44%), followed by children with 19 reports (6.21%) and adolescents with 12 reports (3.92%). Reports involving infants accounted for 5 cases (1.63%), while neonates represented the smallest proportion, with 1 report (0.33%).

Gender (n=306)

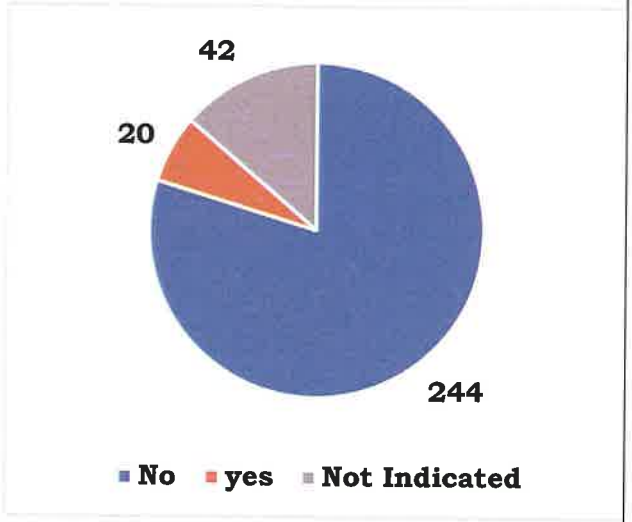


Pregnancy Status (n=183)

Pregnancy Status	Count	Proportion
1st Trimester	3	1.64%
2nd Trimester	2	1.09%
3rd Trimester	2	1.09%
Not Applicable	26	14.21%
Not pregnant	122	66.67%
Not Indicated	28	15.30%
Grand Total	**183**	**100.00%**

Most ADR reports were associated with female patients, accounting for 183 cases (59.80%). Male patients accounted for 122 reports (39.87%), while the patient's sex was unknown in 1 report (0.33%).

Among the 183 female ADR reports, most cases involved non-pregnant patients, accounting for 122 reports (66.67%). Pregnancy-related reports were uncommon, with 3 cases (1.64%) occurring in the first

	trimester, and 2 cases each (1.09%) reported in the second and third trimesters. In 26 reports (14.21%), pregnancy status was not applicable, while 28 reports (15.30%) did not indicate pregnancy status.
Known Allergy (n=306) 	**Reported Allergen (n=20)** **Allergen** / **Count** / **%** Sulphur 6 30 NSAIDS 2 10 Not Indicated 2 10 penicillin/Cotrimoxazole/ Ibuprofen 1 5 Ceftriaxone 1 5 Tramadol 1 5 Cotrimoxazole/Mara Moja 1 5 Penicillin 1 5 Diclofenac 1 5 CEFTRIAXONE 1 5 Ampicillin/Cloxacillin 1 5 Azithromycin/Amoxicillin Clavulanate/Ascoril/ Solvin Plus 1 5 Paracetamol 1 5 **Grand Total 20 100**
Most patients who experienced an adverse drug reaction did not have a known allergy, accounting for 244 reports (79.74%). A known allergy was reported in 20 cases (6.54%). In 42 reports (13.73%), the allergy status was not indicated.	Among the 20 reports in which a known allergy was documented, sulphur was the most frequently reported allergen, accounting for 6 cases (30%). NSAIDs were reported in 2 cases (10%), while in 2 cases (10%) the specific allergen was not indicated. The remaining allergens were each reported in single cases (5%) and included penicillins (alone or in combination), ceftriaxone, tramadol, diclofenac, paracetamol, ampicillin/cloxacillin, and combinations such as azithromycin with amoxicillin clavulanate and other medications.

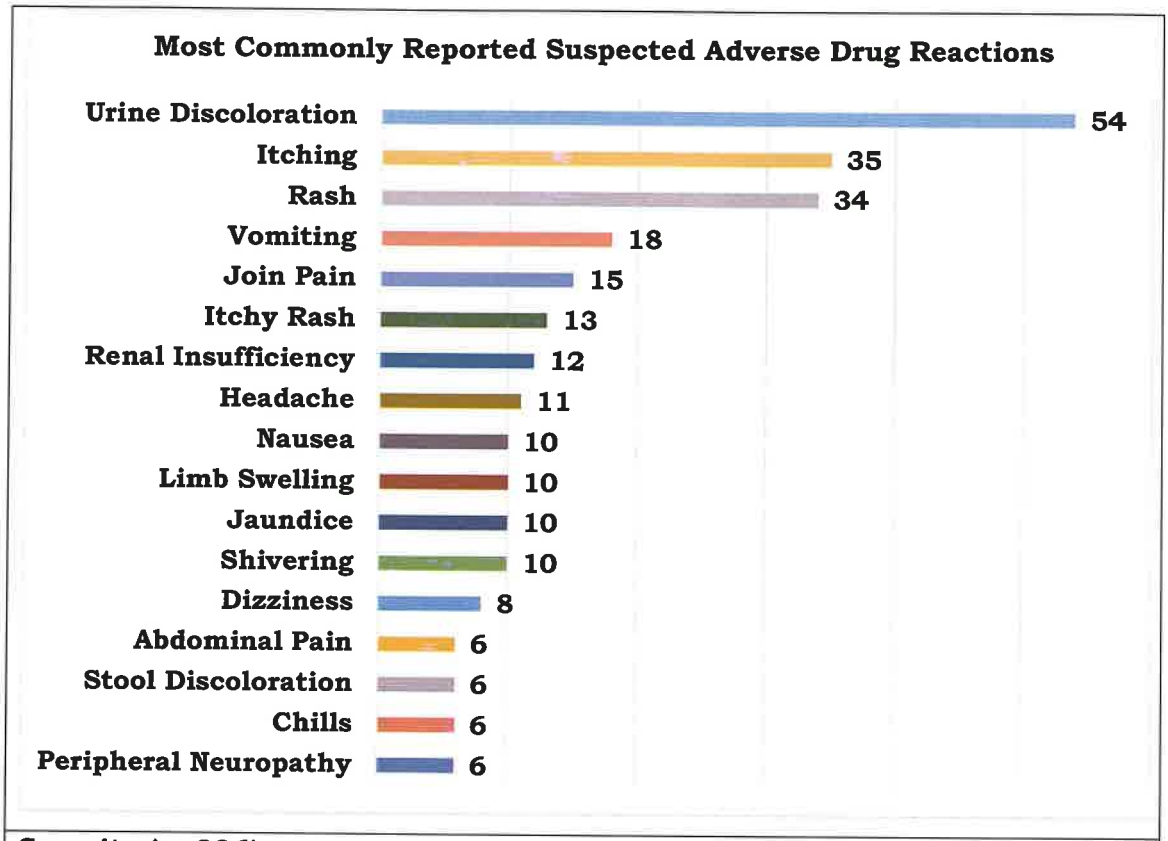
Suspected medicines (n=324)

Suspected Medicine	Count	Proportion
Rifampicin/Isoniazid/Pyrazinamide/Ethambutol Hydrochloride (150mg/75mg/400mg/275mg)	89	27.47%
Tenofovir/Lamivudine/Dolutegravir (300mg/300mg/50mg)	26	8.02%
Carbamazepine	10	3.09%
Nifedipine	9	2.78%
Iohexol usp	8	2.47%
Rifapentine/Isoniazid (300mg/300mg)	8	2.47%
Paracetamol	7	2.16%
Ceftriaxone	6	1.85%
Linezolid	6	1.85%
Iron sucrose injection USP	6	1.85%
Rifampicin/Isoniazid/Pyrazinamide (75mg/50mg/150mg)	5	1.54%
Tenofovir Disoproxil Fumarate	5	1.54%
Amlodipine	5	1.54%
Rifampicin/Isoniazid (150mg/75mg)	5	1.54%
Nitrofurantoin	4	1.23%
Vancomycin Hydrochloride	4	1.23%
Tenofovir Alafenamide/Lamuvidine/Dolutegravir (50mg/300mg/25mg)	4	1.23%
Metronidazole	4	1.23%

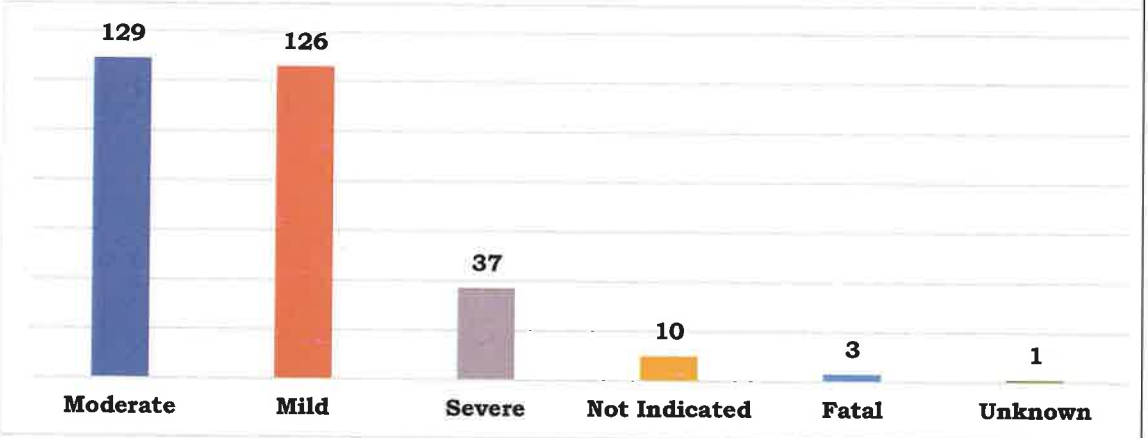
A total of 98 generic names and fixed-dose combinations (FDCs) were reported as suspected medicines during the quarter. The most frequently reported suspected medicine was Rifampicin/Isoniazid/Pyrazinamide/Ethambutol hydrochloride (150mg/75mg/400mg/275mg), accounting for 89 reports (27.47%). This was followed by Tenofovir/Lamivudine/Dolutegravir (300mg/300mg/50mg) with 26 reports (8.02%). Other commonly reported suspected medicines included carbamazepine with 10 reports (3.09%), Nifedipine with 9 reports (2.78%), and Iohexol Injection USP with 8 reports (2.47%). The table above presents the most frequently reported suspected medicines during the quarter.

Commonly reported adverse reactions

The most frequently reported suspected adverse drug reaction was urine discoloration, with 54 reports (11.49%). This was followed by itching in 35 cases (7.45%) and rash in 34 cases (7.23%). Vomiting was reported in 18 cases (3.83%), while joint pain accounted for 15 reports (3.19%). Other commonly reported reactions included itchy rash (13 reports; 2.77%), renal insufficiency (12 reports; 2.55%), headache (11 reports; 2.34%), and nausea, shivering, limb swelling, and jaundice, each reported in 10 cases (2.13%). Less frequently reported reactions included dizziness (8 reports; 1.70%), and stool discoloration, peripheral neuropathy, abdominal pain, and chills, each reported in 6 cases (1.28%).



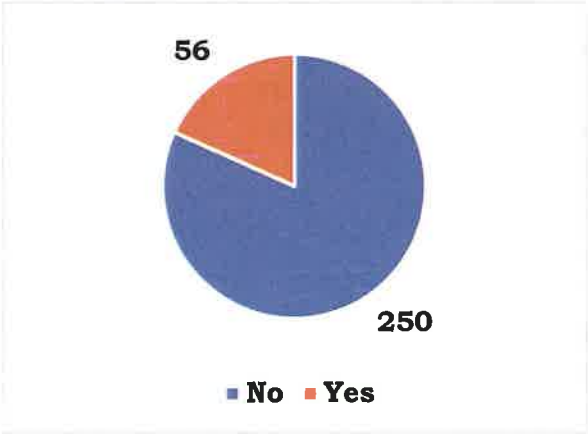
Severity (n=306)



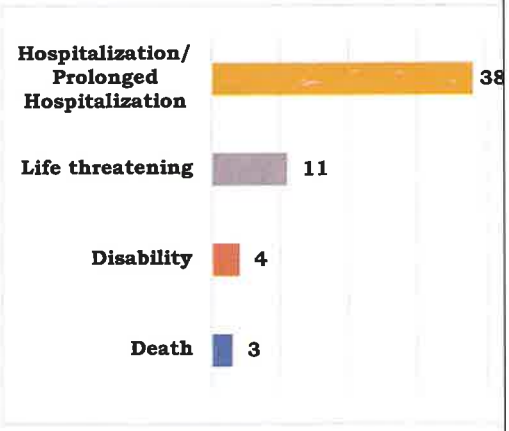
Most adverse drug reactions were classified as moderate in severity, accounting for 129 reports (42.16%), closely followed by mild reactions with 126 reports (41.18%). Severe reactions were reported in 37 cases (12.09%). In 10 reports (3.27%), severity was not indicated, while 1 report (0.33%) was classified as unknown.

Fatal outcomes were rare, with 3 reports (0.98%).

Was the reaction serious? (n=306)



Reason for seriousness (n=56)



The majority of adverse drug reactions were not serious, accounting for 250 reports (81.70%). Serious reactions were reported in 56 cases (18.30%).

Among the 56 serious adverse drug reaction reports, hospitalization or prolonged hospitalization was the most common reason for seriousness, accounting for 38 cases (67.86%). Life-threatening reactions were reported in 11 cases (19.64%), while disability was reported in 4 cases (7.14%). Death was reported in 3 cases (5.36%).

Actions taken (n=306)

Action Taken	Count	Proportion
Drug withdrawn	152	49.67%
Dose not changed	115	37.58%
Not applicable	19	6.21%
Dose reduced	14	4.58%
Unknown	6	1.96%
Grand Total	**306**	**100.00%**

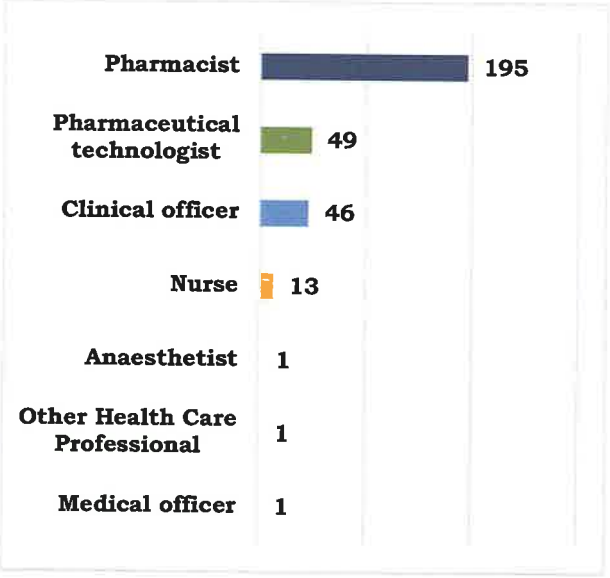
In response to the reported adverse drug reactions, the suspected drug was withdrawn in nearly half of the cases, accounting for 152 reports (49.67%). In 115 cases (37.58%), the dose was not changed. Other actions taken included no applicable action in 19 reports (6.21%) and dose reduction in 14 reports (4.58%). In 6 reports (1.96%), the action taken was unknown.

Outcome (n=306)

Outcome	Count	Proportion
Recovering/Resolving	101	33.01%
Recovered/Resolved	91	29.74%
Not Recovered/Not Resolved	67	21.90%
Unknown	41	13.40%
Fatal	3	0.98%
Recovered/Resolved with Sequelae	3	0.98%
Grand Total	**306**	**100.00%**

Regarding patient outcomes, most cases were either recovering or resolving, accounting for 101 reports (33.01%), or had fully recovered or resolved, with 91 reports (29.74%). Not recovered or not resolved outcomes were reported in 67 cases (21.90%). In 41 reports (13.40%), the outcome was unknown. Fatal outcomes were rare, with 3 reports (0.98%), and an additional 3 cases (0.98%) had recovered or resolved with sequelae.

Reporter designation (n=306)



Reporter designation (n=306)

Most adverse drug reaction reports were submitted by pharmacists, accounting for 195 reports (63.73%). Pharmaceutical technologists contributed 49 reports (16.01%), followed by clinical officers with 46 reports (15.03%).

Nurses submitted 13 reports (4.25%). Medical officers, anesthetists, and other health care professionals each accounted for 1 report (0.33%).

Institution

In this quarter, adverse drug reaction reports were received from a total of 110 health facilities across the reporting period. The highest number of adverse drug reaction reports was submitted by Maralal District Hospital, accounting for 57 reports (18.63%). This was followed by Aga Khan Hospital with 24 reports (7.84%). Kilifi County Hospital and Kakamega County General Hospital contributed 13 (4.25%) and 11 reports (3.59%), respectively. Below is a list of top 11 facilities with at least 5 reports and above.

Facility/Institution	Count	Proportion
Maralal District Hospital	57	18.63%
Aga Khan Hospital	24	7.84%
Kilifi County Hospital	13	4.25%
Kakamega County General Hospital	11	3.59%
Meru Teaching and Refferal Hospital hospital	10	3.27%
Port Reitz District Hospital	7	2.29%
Kenyatta National Hospital	7	2.29%
TOPSTONE PHARMA LIMITED	6	1.96%
Difathas Health Centre	5	1.63%
Mlaleo Health Centre (MOH)	5	1.63%
Mweiga Health Centre	5	1.63%

County

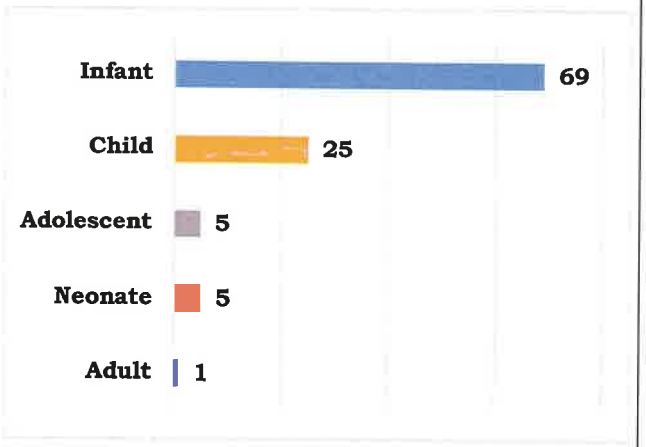
SADR reports were received from 31 out of the 47 counties during the quarter. Nairobi County contributed the highest number of reports with 62 cases (20.26%), followed closely by Samburu with 57 reports (18.63%). Kirinyaga accounted for 27 reports (8.82%), while Mombasa contributed 24 reports (7.84%). Below is a table of the counties that submitted SADR reports in Quarter 2.

No	County	Count	%	No	County	Count	%
1	Nairobi County	62	20.26%	17	Murang'a	3	0.98%
2	Samburu	57	18.63%	18	Isiolo	3	0.98%
3	Kirinyaga	27	8.82%	19	Laikipia	3	0.98%
4	Mombasa	24	7.84%	20	Siaya	2	0.65%
5	Kiambu	17	5.56%	21	Kisii	2	0.65%
6	Kilifi	16	5.23%	22	Turkana	2	0.65%
7	Meru	14	4.58%	23	Kitui	2	0.65%
8	Kakamega	12	3.92%	24	Nandi	2	0.65%
9	Nyeri	10	3.27%	25	Taita Taveta	1	0.33%
10	Bungoma	8	2.61%	26	Kericho	1	0.33%
11	Makueni	7	2.29%	27	Migori	1	0.33%
12	Nakuru	7	2.29%	28	Garissa	1	0.33%
13	Kisumu	7	2.29%	29	Kajiado	1	0.33%
14	Homa Bay	4	1.31%	30	Embu	1	0.33%
15	Uasin Gishu	4	1.31%	31	Machakos	1	0.33%
16	Vihiga	4	1.31%				

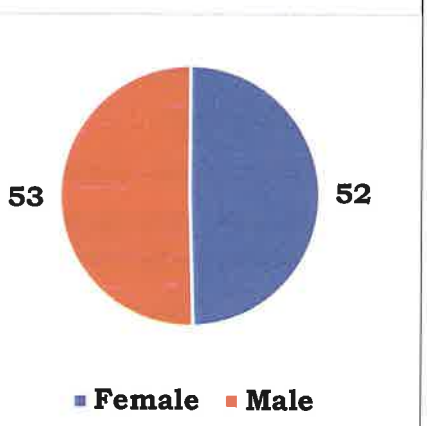
ADVERSE EVENTS FOLLOWING IMMUNIZATION

During Quarter 2 of the 2025/2026 financial year (1st October – 31st December 2025), a total of **110 Adverse Events following immunization (AEFIs)** reports were submitted to the National Pharmacovigilance Centre. A total of 110 adverse events following immunization (AEFIs) were reported during the period, the majority of which were initial reports, accounting for 105 cases (95.45%). Follow-up reports were few, with 5 cases (4.55%). To avoid duplication, only one copy of each Individual Case Safety Report (ICSR) was included in the analysis, resulting in **105 reports** being analyzed in this quarterly summary.

Age Group (n=105)



Gender (n=105)



Of the 105 AEFI reports, the majority occurred among infants aged 1 month to 12 months, accounting for 69 cases (65.71%). Children aged 1 to 12 years accounted for 25 reports (23.81%). Adolescents aged 13 to 17 years and neonates aged 0 to 28 days each accounted for 5 reports (4.76%). Only 1 report (0.95%) involved an adult aged 18 to 65 years.

Among the 105 AEFI reports, cases were almost equally distributed by gender. Males accounted for 53 reports (50.48%), while females accounted for 52 reports (49.52%).

Suspected Vaccines

Among the 105 AEFI reports, the Pentavalent vaccine (DTP-HepB-Hib) was the most frequently reported suspected vaccine, accounting for 24 cases (22.86%). This was closely followed by the Typhoid Conjugate Vaccine (TCV) with 23 reports (21.90%). Combinations of the Pentavalent vaccine with the pneumococcal conjugate vaccine were also common, contributing 16 reports (15.24%). Additionally, 11 reports (10.48%) involved co-administration of the Pentavalent vaccine, pneumococcal conjugate vaccine, bivalent oral polio vaccine, and rotavirus vaccine.

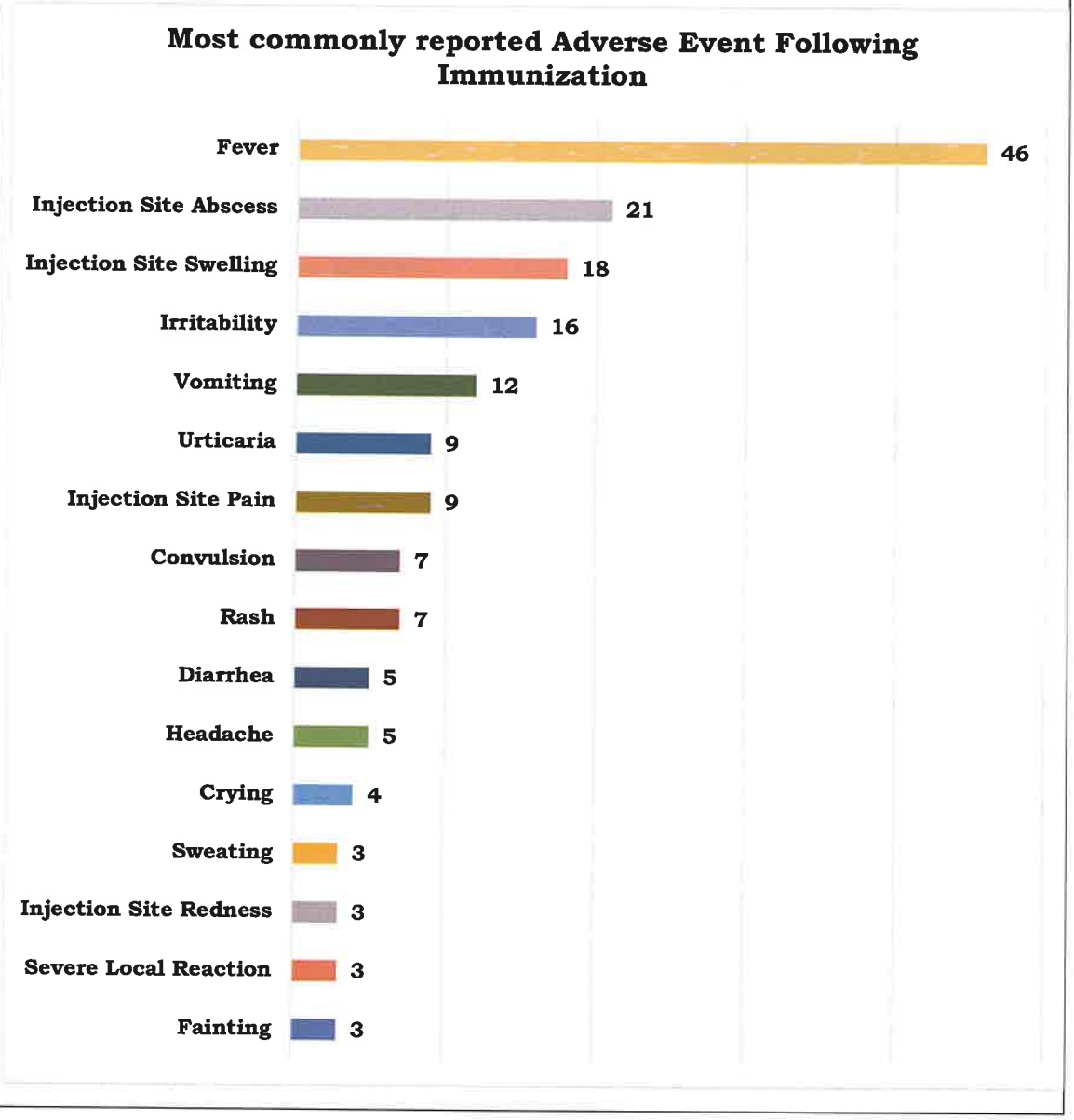
Other notable combinations included Measles Rubella vaccine with TCV, which accounted for 7 reports (6.67%), and the malaria (RTSS) vaccine with 4 reports (3.81%). Smaller proportions of reports involved single vaccines or less common combinations such as pneumococcal conjugate vaccine, measles rubella vaccine alone, tetanus diphtheria vaccine, hepatitis B vaccine, rotavirus vaccine, inactivated polio vaccine, and various multi-vaccine combinations.

Suspected Vaccines/Vaccine Combination	Count	Proportion
Pentavalent Vaccine (DTP-HepB-Hib)	24	22.86%
Typhoid Conjugate Vaccine (TCV)	23	21.90%
Pentavalent Vaccine (DTP-HepB-Hib); Pneumococcal conjugate vaccine	16	15.24%
Pentavalent Vaccine (DTP-HepB-Hib); Pneumococcal conjugate vaccine; Bivalent oral Polio vaccine; Rota virus vaccine	11	10.48%
Measles Rubella Vaccine; Typhoid Conjugate Vaccine (TCV)	7	6.67%
Malaria (RTSS)Vaccine	4	3.81%
Pneumococcal conjugate vaccine	3	2.86%
Pentavalent Vaccine (DTP-HepB-Hib); Pneumococcal conjugate vaccine; Inactivated polio vaccine	2	1.90%
BCG; Bivalent oral Polio vaccine	2	1.90%
Bivalent oral Polio vaccine; Inactivated polio vaccine; Pneumococcal conjugate vaccine; Rota virus vaccine; Pentavalent Vaccine (DTP-HepB-Hib)	2	1.90%
Measles Rubella Vaccine	2	1.90%
Tetanus Diptheria Vaccine	1	0.95%
Pneumococcal conjugate vaccine; Pentavalent Vaccine (DTP-HepB-Hib); Inactivated polio vaccine	1	0.95%
Inactivated polio vaccine	1	0.95%
Inactivated polio vaccine; Bivalent oral Polio vaccine; Pneumococcal conjugate vaccine; Rota virus vaccine; Pentavalent Vaccine (DTP-HepB-Hib)	1	0.95%
Rota virus vaccine	1	0.95%
Bivalent oral Polio vaccine; Inactivated polio vaccine	1	0.95%
Hepatitis B Vaccine	1	0.95%
Malaria (RTSS)Vaccine; Measles Rubella Vaccine	1	0.95%
BCG; Pentavalent Vaccine (DTP-HepB-Hib); Pneumococcal conjugate vaccine	1	0.95%
Grand Total	**105**	**100.00%**

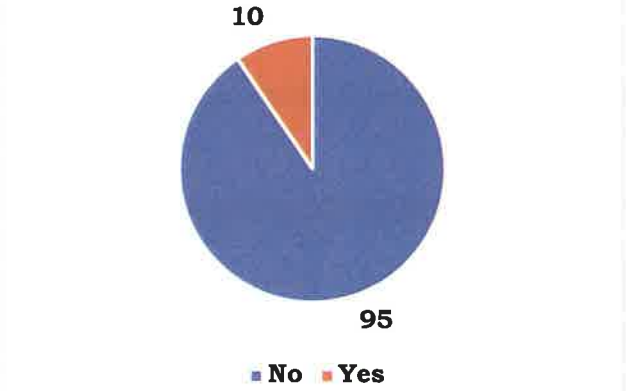
Commonly reported adverse events following immunization

The most frequently reported adverse reactions were fever, accounting for 46 cases (22.66%), followed by injection site abscess with 21 reports (10.34%), and injection site swelling in 18 cases (8.87%). Other common reactions included irritability (16 reports, 7.88%), vomiting (12 reports, 5.91%), urticaria and injection site pain (each 9 reports, 4.43%), and rash and convulsion (each 7 reports, 3.45%). Less frequent reactions included diarrhea and headache (each 5 reports, 2.46%), crying

(4 reports, 1.97%), and injection site redness, severe local reaction, fainting, and sweating (each 3 reports, 1.48%). Below is a summary of the commonly reported AEFIs this quarter.

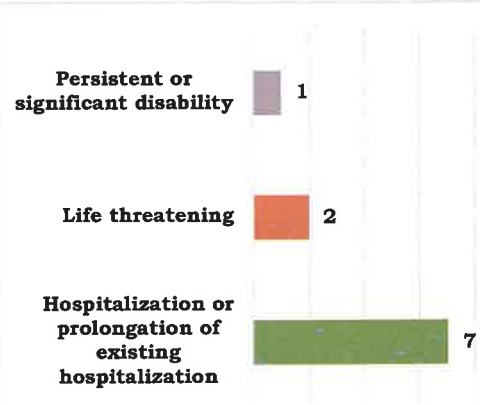


Was the reaction serious? (n=105)



The majority of reactions were not serious, accounting for 95 reports (90.48%). Serious reactions were reported in 10 cases (9.52%).

Reason for seriousness (n=10)



Among the serious reactions, the most common reason was hospitalization or prolongation of existing hospitalization, reported in 7 cases (70.00%). Life-threatening reactions were reported in 2 cases (20.00%), while persistent or significant disability occurred in 1 case (10.00%).

Actions taken (n=105)

Action Taken	Count	Proportion
Drug withdrawn	152	49.67%
Dose not changed	115	37.58%
Not applicable	19	6.21%
Dose reduced	14	4.58%
Unknown	6	1.96%
Grand Total	**306**	**100.00%**

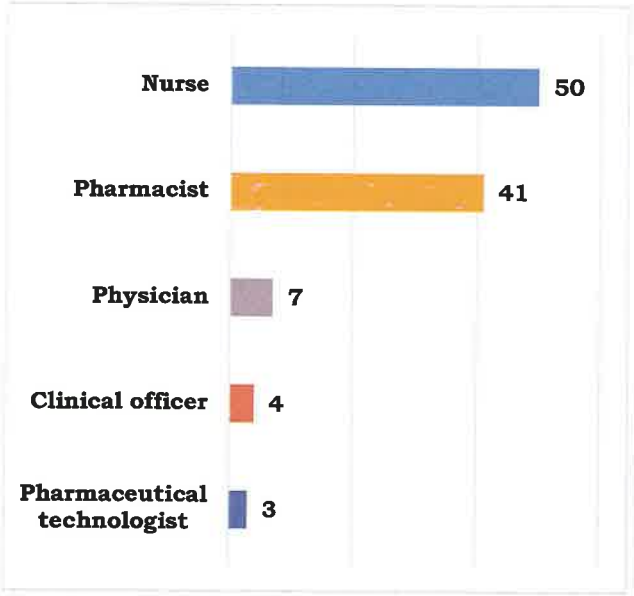
In response to the reported adverse drug reactions, the suspected drug was withdrawn in nearly half of the cases, accounting for 152 reports (49.67%). In 115 cases (37.58%), the dose was not changed. Other actions taken included no applicable action in 19 reports (6.21%) and dose reduction in 14 reports (4.58%). In 6 reports (1.96%), the action taken was unknown.

Outcome (n=105)

Outcome	Count	Proportion
Recovered/Resolved	54	51.43%
Recovering/Resolving	43	40.95%
Unknown	4	3.81%
Not recovered/Not resolved/Ongoing	2	1.90%
Fatal	1	0.95%
Recovered/Resolved with sequelae	1	0.95%
Grand Total	**105**	**100.00%**

Regarding patient outcomes, most cases had recovered or resolved, accounting for 54 reports (51.43%), or were recovering or resolving, with 43 reports (40.95%). Outcomes were not recovered/not resolved/ongoing in 2 cases (1.90%), and unknown in 4 reports (3.81%). Fatal outcomes were rare, with 1 report (0.95%), and an additional 1 case (0.95%) had recovered/resolved with sequelae.

Reporter designation (n=105)



Reporter designation (n=105)

Regarding reporter designation, most reports were submitted by nurses, accounting for 50 reports (47.62%), followed by pharmacists with 41 reports (39.05%). Reports from physicians accounted for 7 cases (6.67%), while clinical officers and pharmaceutical technologists submitted 4 (3.81%) and 3 reports (2.86%), respectively.

Institution

In this quarter, adverse events following immunization reports were received from a total of 54 health facilities across the reporting period. The highest number of reports was submitted by Ngecha Health Centre, accounting for 18 reports (17.14%), followed by Maralal District Hospital with 17 reports (16.19%). Masogo Sub County Hospital contributed 4 reports (3.81%), while Chepngombe Health Centre, Kilifi County Hospital, Kangu Dispensary, and Tudor District Hospital (Mombasa) each submitted 3 reports (2.86%). Below is a list of top 11 facilities with at least 3 reports and above.

Facility/Institution	Count	Proportion
Ngecha Health Centre	18	17.14%
Maralal District Hospital	17	16.19%
Masogo Sub County Hospital	4	3.81%
Chepngombe Health Centre	3	2.86%
Kilifi County Hospital	3	2.86%
Kangu Dispensary	3	2.86%
Tudor District Hospital (Mombasa)	3	2.86%

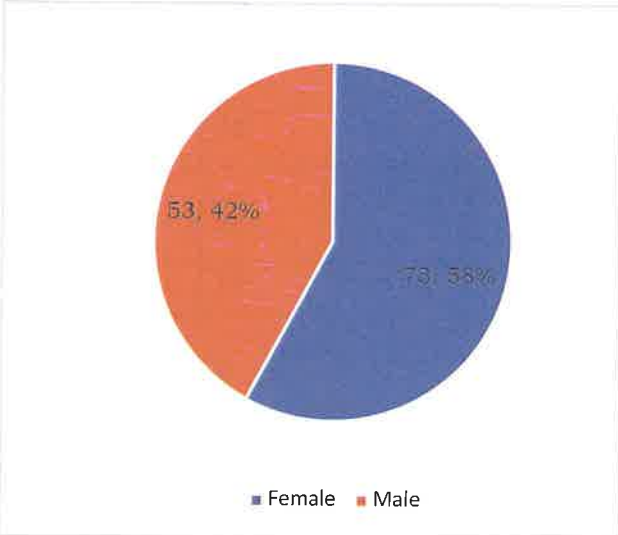
County

AEFI reports were received from 26 out of the 47 counties during the quarter. Kiambu County contributed the highest number of reports with 26 cases (24.76%), followed by Samburu with 17 reports (16.19%). Kisumu accounted for 9 reports (8.57%), while Kirinyaga contributed 7 reports (6.67%). Below is a table of the counties that submitted AEFI reports in this quarter.

No	***County***	***Count***	***%***	***No***	***County***	***Count***	***%***
1	Kiambu	26	24.76%	**17**	Kakamega	2	1.90%
2	Samburu	17	16.19%	**18**	Embu	2	1.90%
3	Kisumu	9	8.57%	**19**	Bungoma	1	0.95%
4	Kirinyaga	7	6.67%	**20**	Meru	1	0.95%
5	Nyamira	6	5.71%	**21**	Kwale	1	0.95%
6	Siaya	4	3.81%	**22**	Turkana	1	0.95%
7	Kilifi	4	3.81%	**23**	Kericho	1	0.95%
8	Baringo	4	3.81%	**24**	Uasin Gishu	1	0.95%
9	Vihiga	3	2.86%	**25**	Kisii	1	0.95%
10	Mombasa	3	2.86%	**26**	Isiolo	1	0.95%
11	Nakuru	3	2.86%	**27**	Kajiado	1	0.95%
12	Nyeri	2	1.90%	**28**	Nandi	1	0.95%
13	Nyandarua	2	1.90%	**29**	Kitui	1	0.95%

MEDICATION ERRORS (MEs)

Gender (n=126)



Age Group (n=126)

Age Group	No. of Reports	Percentage
adult	82	66.13%
child	21	16.94%
elderly	9	7.26%
adolescent	6	4.84%
infant	4	3.23%
neonate	2	1.61%
Not Indicated	2	0.00%
Grand Total	**126**	**100.00%**

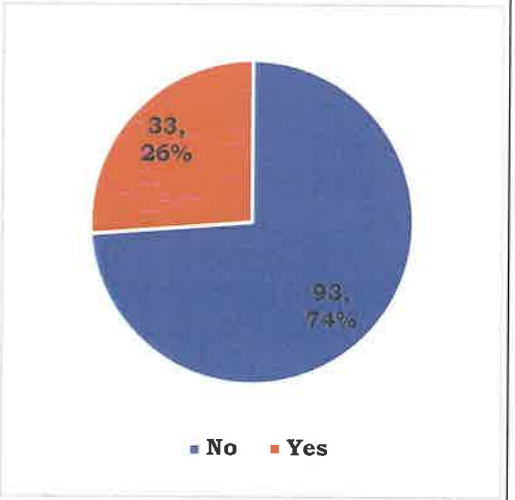
A total of 126 medication errors were reported in Quarter 2. Of this, 58% (73) involved the female gender while 42% (53) involved the male gender.

Of the reported medication errors, about 66% (82) involved adults while 21 (16.94%) occurred in children.

Reporter Designation

Cadre	No. of Reports	Percentage
Pharmacist	103	81.75%
Pharmaceutical technologist	22	17.46%
Clinical officer	1	0.79%
Grand Total	**126**	**100.00%**

Did the Error Reach the Patient?



Most medication errors were reported by Pharmacists 103 (81.75%), followed by pharmaceutical technilogisits 22 (17.46%), and clinical officers 1 (0.79%)	In Quarter 2, 93 (74%) errors did not reach patients while 33 (26%) reached patients.

Medication Error Outcome

Error Outcome	No. of Reports	Percentage
Potential error, circumstances/events have potential to cause incident	58	46.03%
Not Indicated	21	16.67%
Actual error-did not reach patient	21	16.67%
Additional monitoring required-caused no harm	12	9.52%
Actual error-caused no harm	11	8.73%
Treatment /intervention required-caused temporary harm	3	2.38%
Grand Total	**126**	**100.00%**

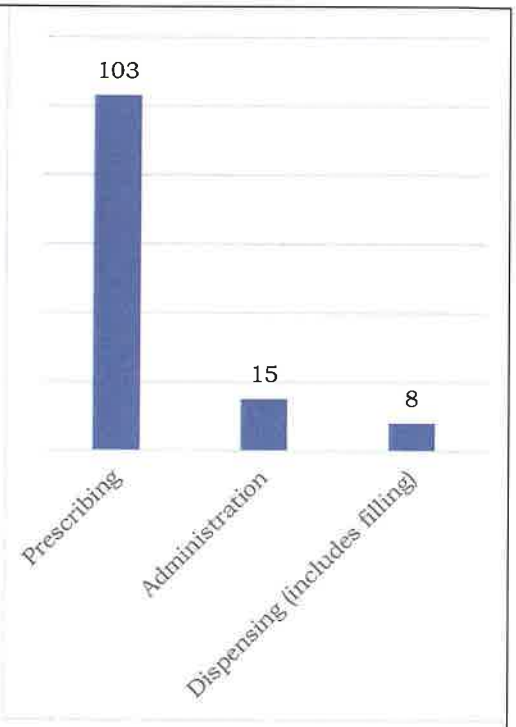
Most of the medication errors 58 (46.03%) did not reach patients but had potential to cause harm if they would have reached patients. Moreover, 21 (16.67%) errors did not reach the patient and for those that reached the patient, they caused no harm 11 (8.73%), while 3 (2.38%) caused temporary harm.

Number of medication errors per product

Reported Drug	No. of Reports	Percentage
Aceclofenac/serratiopeptidase	7	5.56%
Ceftriaxone	3	2.38%
Amlodipine	3	2.38%
Amoxicillin	3	2.38%
Potassium chloride	2	1.59%
Phenytoin; Amlodipine 5mg; Asprin	2	1.59%
Ampicillin/cloxacillin	2	1.59%
Tenofovir disoproxil fumarate, lamivudine, dolutegravir	2	1.59%
Atorvastatin 20mg Nocte	2	1.59%
Losartan-H 1 OD; Atorvastatin 20mg N	2	1.59%

Process Where the Error Occurred

Azithromycin	1	0.79%



Of the reported errors, 7 (5.56%) were associated Aceclofenac/serratiopeptidase followed by ceftriaxone 3 (2.38%), and Amoxicillin 3 (2.38%).

In quarter 2, most medication errors 103 (81.7%) occurred during prescription, followed by 15 (12%), administration errrors and 8 (6.3%) as dispensing errors.

Description of the Error

Error Description	No. of Reports	Percentage
Prescribed overdose	19	15.20%
Prescribed underdose	18	14.40%
Prescribed wrong drug combination	11	8.80%
Non-adherence to medication	10	8.00%
Not Indicated	5	4.00%
Dispensed wrong medication	4	3.20%
Polypharmacy	4	3.20%
Irrational antibiotic prescribing	4	3.20%
Prescribed wrong dose	3	2.40%
Dose not specified	3	2.40%
Not a medication error	3	2.40%

Of the reports received, majority involved prescription overdose 19 (15.20%), prescription underdose 18 (14.40%), prescribed wrong drug combination 11 (8.8%). The frequency of other errors is as captured in the table.

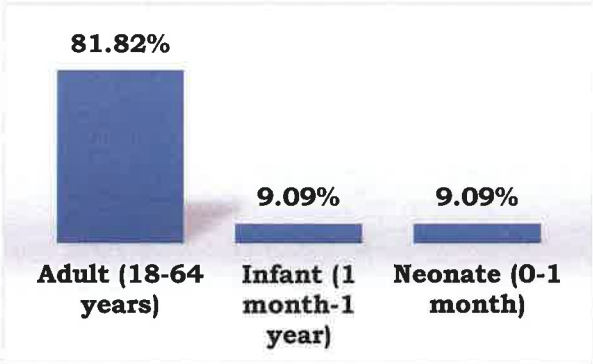
Factors Contributing to the Error Occurrence

Contributing Factor	No. of reports	Percentage
Inadequate knowledge	50	31.44
Inexperienced personnel	38	23.9
Heavy workload	21	13.2
Distraction	14	8.8
Peak hour	11	6.9
Others	11	6.9
Work procedure	8	5
Look Alike Packaging	6	3.8

The most commonly reported contributing factor was inadequate knowledge 50 (31.44%), followed by Inexperienced personnel 38 (23.9%), and heavy workload 21 (13.2%). The impact of other contributing factors is as shown.

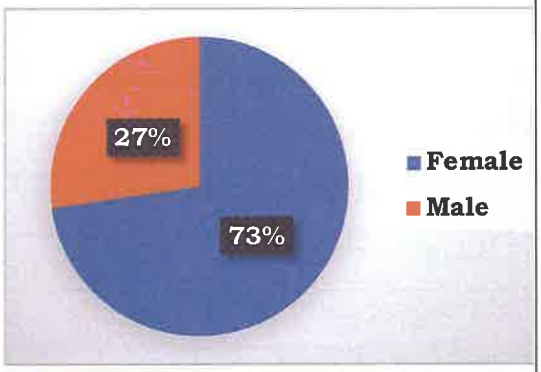
PUBLIC ADVERSE DRUG REACTIONS (PADRS)

Age Group (n=11)



The incidence of PADRs was highest amongst adults at 81.82% followed by infants (9.09%) and neonates (9.09%)

Gender (n=11)



The incidences of PADRs were highest amongst females at 73% (8). Male reporters constituted 27% (3) of all the PADRs.

Suspect medicine

The most commonly reported suspected medicine are as shown in the table below:

No	Drug	Count	Proportion	No	Drug	Count	Proportion
1	Vitamin A	1	9.09%	5	Aceclofenac, Paracetamol and Chlorzoxazone	1	9.09%
2	Semaglutide	1	9.09%	6	Amlodipine and Losartan Potassium	1	9.09%
3	Paclitaxel	1	9.09%	7	Not indicated	5	45.05%
4	AZITHROMYCIN	1	9.09%				

Reaction

The most commonly reported PADRs were rash (17.64%), headache (11.76%) and palpitations (11.76%) The other reported reactions (each less than 6%) are highlighted in the table below.

No	Reaction	Count	Proportion	No	Reaction	Count	Proportion
1	Rash	3	17.64%	7	Bulging fontanelle after getting Vitamin A	1	5.88%
2	Headache	2	11.76%	8	Joints and muscle pain	1	5.88%
3	Palpitations	2	11.76%	9	Haemorrhoid	1	5.88%
4	Unusual packet or bottle	2	11.76%	10	Lack of sleep	1	5.88%
5	Dizziness or drowsiness	1	5.88%	11	Empty box and not sealed	1	5.88%
6	decrease blood pressure	1	5.88%				

County

PADRs were received from 8 of the 47 counties. Nairobi County submitted the highest number of PADRs (4, 36.36%).

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	4	36.36%	5	Machakos	1	9.09%
2	Garissa	1	9.09%	6	Nakuru	1	9.09%
3	Kakamega	1	9.09%	7	Nyeri	1	9.09%
4	Kiambu	1	9.09%	8	Vihiga	1	9.09%

Blood Transfusion Reactions

During Quarter 2(Q2), a total of twelve (12) reports of blood transfusion reactions were received. All the reports were submitted by pharmacists.

Seven incidents of blood transfusion reactions involved adult (18-64 years) patients, three elderly (above 64 years) patients, one incident in an adolescent (12-17 years) patient and one incident in a child (1-11 years). Most transfusion reaction were noted in female patients (7) compared to male patients (5).

Eight of the patients had received a blood transfusion due to severe anemia and four patients were transfused due to low hemoglobin levels.

Five of the patients had a history of prior transfusions; two 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	6	24%	6	Other skin rash	2	8%
2	Fever	6	24%	7	HEADACHE	1	4%
3	Tachycardia	4	16%	8	Tachycardia and Involuntary nodding of the head	1	4%

4	Nausea/ Vomiting	3	12%				
5	Flushing	2	8%				

Medical Device Incidence Reports

In the past quarter, there were three reports of a medical device incident (MDI) which was received from Meru (1), Mombasa (1) and Uasin Gishu (1) County

The incidents involved (1) adult male patient, (1) neonate female patient and (1) neonate male patient.

During the reporting period, the following medical devices were associated with incidents reported from healthcare facilities:

The details of the reported medical device incidents are presented in the table below:

Medical Device	Manufacturer	Incident (Event)
HIV Self-Test	Revital Healthcare LTD	The HIV self-test kits (Serial/Lot No HIVST 250604) yield false positive results. The observed issues include the appearance of **up to three test lines** and, in some cases, **merging of two lines**, leading to result misinterpretation. Upon follow-up with testing using alternative HIV test kits produced **negative results** after initial positive outcomes with these devices.
CORD CLAMP	BTHOPE INDUSTRY& TRADE CO. LTD	The cord clamp (Serial/Lot No HIVST 240557) **unexpectedly opened after application**, resulting in **bleeding of the newborn.**
CORD CLAMP	REVITAL HEALTHCARE (EPZ)	The cord clamps (Serial/Lot No HIVST 041123) **fail to lock as required during the delivery procedure** compromising proper cord clamping.

The reports were primarily made by a pharmaceutical technologist and (2) pharmacists. The incidents were classified as mild (2) and moderate. The outcome of the patients was (2) recovered and one was unknown.

For any queries, please contact the PV department on pv@pharmacyboardkenya.org or call ***0795743049.***

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. CEO, Pharmacy and Poisons Board

Date: 29th January 2026

Signature: