

PHARMACY AND POISONS BOARD

Pharmacovigilance Summary Report: 1st January-31st March 2025 (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 regulates the Practice of Pharmacy and the manufacture and trade of drugs and poisons.

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

Since the introduction of PV in Kenya, a total of 19,754 individual case safety reports (ICSRs) have been submitted to the global database representing 2.7% of the total ICSRs submitted by African countries.

Suspected Adverse Drug Reactions (sADRs)

There were 223 suspected adverse drug reaction (sADR) reports submitted to the National Pharmacovigilance Centre within Quarter 3 (1st January – 31st March 2025). Of the 223 reports, 207 (92.83%) reports were initial reports while 16 (7.17%) reports were follow-up reports. Only one copy of each ICSR was used in the analysis to eliminate duplicity and in the case of follow up report, then the original report was disregarded hence the total number of reports included in this quarterly summary was 207. Of the 207 initial reports, 204 reports were reports on suspected adverse drug reactions (sADRs), 2 reports were on both sADRs and Therapeutic Ineffectiveness (TI), while one report was on only TI.

Product Catego	<u>ry (n=207)</u>		Age Group (n=207)	
Product Category	Count	Proportion	Age Group	
Medicinal			Adult	169
Product	187	90.34%	Elderly 28	
Not Indicated	19	9.18%	Child = 10 Neonate = 6	
Others	1	0.48%	Adolescent 6 Infant 4	
Grand Total	207	100.00%		

Most of the ADR cases reported were due to medicinal products (98.89%). In 1 (0.37%) report, the product category was marked as others. There were no herbal product, cosmeceuticals and others respectively.	The prevalen highest (75.7 adults (18-64 the other a followed by th and the chil rest of the re adolescent, in age groups as	ce of sAl 78%) amo) in comp age group he elderly dren (4.48 ports incl hfant and shown ab	DRs ngst arisc ps. (12.) 8%). udec nec	was the on to This 56%) The 1 the onate
<u>Gender (n=207)</u>	Pregnancy St	tatus (n=1	<u>34)</u>	
Gender	Pregnancy Status	Count	Propo	ortion
Gender	Not pregnant	84	6	2.69%
	Not Applicable	25	1	8.66%
73	Not Indicated	15	1	1.19%
134	1st Trimester	5		3.73%
134	3rd Trimester	3		2.24%
Eemale Male	2nd Trimester	2		1.49%
- remare - mare	Grand Total	134	100).00%
higher in female (64.73%, 134) as compared to male (35.27%, 73).	reported SAI were not preg reporting. Of women, 5 trimester, 3 trimester whil trimester. A t female cases indicate the p	DRs, 84 mant at the the 10 were in were in e 2 were in otal of 15 reported regnancy s	(62.) ne tin preg the the the (11. did statu	(ne of nant 1st 3rd ir 2 nd 19%) not 1s.
Known Allergy (n=207)	Reported Allerg	<u>en (n=10)</u>		
	Allergen	Co	unt	%
Known Allergy	Sulphur		4	40
	unspecified alle	rgy	1	10
yes 10	Aspirin Azithromycin:		1	10
Not Indicated 41	Amoxicillin Clavulanate; As Solvin Plus Zidovudine	coril;	1	10 10
No 156	NSAIDS		1	10
	Paracetamol		1	10
	Grand Total		10	100
The frequency of reported SADRs was higher in patients with no history of	Out of the 10 known aller	SADR rep gies, all	orts lergy	with to

known allergies (75.36%, 156) compared to those with known allergies (4.83%, 10) as shown above.	Sulphur and were the most reported with 4 reports (40%) as shown above.		
Suspected me	dicines		
(n=260)		
SUSPECTED DRUG NAME	COUNT	PROPORTION	
TDF/3TC/DTG (300mg/300mg/50mg)	17	6.54%	
Levofloxacin	17	6.54%	
RHZE (150mg/75mg/400mg/275mg)	15	5.77%	
Dolutegravir (50mg)	13	5.00%	
Nifedipine	12	4.62%	
Tenofovir Disoproxil Fumarate	12	4.62%	
Cycloserine Capsules USP 250 mg	10	3.85%	
Clofazimine	10	3.85%	
Pyridoxine Hydrochloride BP (Vitamin B6)	7	2.69%	
Linezolid	6	2.31%	
Ceftriaxone for Injection U.S.P.	6	2.31%	
Tetracycline HCL	5	1.92%	
Tenofovir/Lamivudine (300mg/300mg)	5	1.92%	
Bedaquiline	5	1.92%	
Amlodipine Besilate BP	5	1.92%	
Ferric carboxymaltose injection	5	1.92%	
Lamivudine (300mg)	5	1.92%	

Key:

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

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

A total of 91 generic names/fixed dose combinations (FDC) were reported as suspected medicines in this quarter. Tenofovir/Lamivudine/Dolutegravir (300mg/300mg/50mg) Fixed Dose Combination and Levofloxacin was the most frequently reported (6.54%,17).

Rifampicin/Isoniazid/Pyrazinamide/Ethambutol(150mg/75mg/400mg/27 5mg) regimen was reported as the suspected medicine in 15 cases (5.77%), while Dolutegravir (50mg) was reported in 13 reports (5.00%). The table above consists of a list of the most reported medicines in Quarter 3.

Commonly reported adverse reactions

The following adverse drug reactions were commonly reported in Quarter 3: Itching 21(6.21%), Rash 17 (5.03%); and headache 16 (4.73%). The figure below shows adverse drug reactions reported in at least 6 reports.





<u>Actions taken (n=207)</u>		
<u>Action Taken</u>	<u>Count</u>	<u>Proportion</u>
Drug withdrawn	134	64.73%
Dose not changed	47	22.71%
Not applicable	12	5.80%
Dose reduced	9	4.35%
Unknown	5	2.42%

Among the actions taken by the health care workers following the occurrence of the adverse drug reaction included withdrawal of the offending drug in 64.73% (134) cases and dose reduction (4.35%, 9). A total of 47 reports (22.71%) indicated that the dose of the suspect medicine was not changed.

<u>Outcome (n=207)</u>

Outcome	Count	Proportion
Recovering/Resolving	82	39.61%
Recovered/Resolved	62	29.95%
Unknown	34	16.43%
Not Recovered/Not Resolved	12	5.80%
Not Indicated	10	4.83%
Fatal	4	1.93%
Recovered/Resolved with Sequelae	2	0.97%
Not Recovered/Not Resolved/Ongoing	1	0.48%
Grand Total	207	100 00%

Out of the 207 SADR reports received in Q3, four cases were fatal. A total of 39.61% (82) of the cases were reported to be recovering/resolving at the time of reporting while 29.95% (62) of the cases were already recovered or resolved at the time of reporting. The outcome was unknown in 16.43% (34) of the cases reported.



Institution

In this Quarter, only 93 facilities out of the 9,000 facilities listed in the Kenya Master facility reported SADRs. 22 facilities reported at least 3 reports and above. The top leading facilities were Likoni District Hospital with 11 reports (5.31%) followed by Mihang'o Community Health Centre with 10 reports (4.83%). Tumutumu (PCEA) Hospital, Joshua Memorial Mbai Dispensary, Kilifi County Hospital, Coast General Teaching and Referral Hospital and The Mater Hospital Mukuru were third most reporting facilities in this quarter with 8 reports (3.86%) each. Below is a list of top 22 facilities with at least 3 reports and above.

<u>No</u>	<u>Institution</u>	<u>Count</u>	<u>%</u>	<u>No</u>	<u>Institution</u>	<u>Count</u>	<u>%</u>
1	Likoni District Hospital	11	5.31%	12	Kakamega County General Hospital	4	1.93%
2	Mihang'o Community Health Centre	10	4.83%	13	Mama Lucy Kibaki Hospital - Embakasi	4	1.93%
3	Tumutumu (PCEA) Hospital	8	3.86%	14	Kerugoya County Refferal Hospital	4	1.93%
4	Joshua Memorial Mbai Dispensary	8	3.86%	15	Bungoma County Referral Hospital	3	1.45%
5	Kilifi County Hospital	8	3.86%	16	KUTRRH	3	1.45%
6	Coast General Teaching and Referral Hospital	8	3.86%	17	Mvita Health Center	3	1.45%
7	The Mater Hospital Mukuru	8	3.86%	18	Machakos County Referral Hospital	3	1.45%
8	Nyeri Provincial General Hospital (PGH)	7	3.38%	19	P.C.E.A CHOGORIA HOSPITAL	3	1.45%
9	Karumandi Health Centre	7	3.38%	20	Gathigiriri Health Centre	3	1.45%
10	Dreams Center Dispensary (Lang'ata)	5	2.42%	21	Kenya Ports Authority Medical clinic	3	1.45%
11	Gatundu District Hospital	4	1.93%	22	Kikoko Mission Hospital	3	1.45%
Cou	ntv	1	1		1	I	L

SADR reports were received from 30 of the 47 counties. Nairobi county submitted the highest number of SADR reports (43, 20.77%) followed by

Kirinyaga (41, 19.81%) and Mombasa (29, 14.01%) Counties. Below is a table of the counties that submitted SADR reports in Quarter 3.

<u>No</u>	<u>County</u>	<u>Count</u>	<u>%</u>	<u>No</u>	<u>County</u>	<u>Count</u>	<u>%</u>
1	Nairobi County	43	20.77%	19	Isiolo	2	0.97 %
2	Kirinyaga	41	19.81%	20	Kajiado	2	0.97 %
3	Mombasa	29	14.01%	21	Meru	2	0.97 %
4	Nyeri	16	7.73%	22	Laikipia	2	0.97 %
5	Kilifi	11	5.31%	23	Taita Taveta	1	0.48 %
6	Makueni	9	4.35%	24	Murang'a	1	0.48 %
7	Kiambu	9	4.35%	25	Turkana	1	0.48 %
8	Homa Bay	5	2.42%	26	Kitui	1	0.48 %
9	Bungoma	5	2.42%	27	Elgeyo/Marakwet	1	0.48 %
10	Machakos	4	1.93%	28	Embu	1	0.48 %
11	Nakuru	4	1.93%	29	Kisii	1	0.48 %
12	Kakamega	4	1.93%	30	Garissa	1	0.48 %
13	Tharaka Nithi	3	1.45%	31	Kisumu	1	0.48 %
14	Uasin Gishu	3	1.45%	32	Nyamira	1	0.48 %
15	Narok	2	0.97%	33	Nyandarua	1	0.48 %

ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)					
Type of Report (n=36) 6% • Initial • FollowUp 94%			The National Phan Centre received a reports in the per January 2025 and 94% (34) of the re this quarter were only 6% (2) of the follow-up report.	rmacovig total of iod betw d 31 st Ma ports re- initial re total be	gilance 36 AEFI reen 1 st arch 2023. ceived in eports with ing a
Type of Vaccine (n=12)		Of the total AEI	FI repor	ts received,
Vaccine Type Count %		most events we	re caus	sed by the	
DTP-HepB-Hib	21	32.81%	Pentavalent Vacc	ine (DTI	P-HepB-Hib)
PCV	15	23.44%	% (17), Pneum	nococcal	conjugate
IPV	7	10.94%	vaccine at 21% (10) and Rota virus		
Rota virus vaccine	5	7.81%	vaccine at 9% (6). The table above		
TD Vaccine	4	6.25%	shows the vaccines and their		
MR Vaccine	4	6.25%	proportions of AFFIs		
Malaria (RTSS)Vaccine	2	3.13%	Key:	110.	
Bivalent oral Polio vaccine	2	3.13%	DTP-HepB-Hib: Penta PCV: Pneumococcal co	valent Vao oniugate v	ccine accine
BCG	1	1.56%	IPV: Inactivated polio	vaccine	
Rota virus vaccine	1	1.56%	TD: Tetanus Diptheric	a Vaccine	
nOPV2	1	1.56%	MR: Measles Rubella		
OPV	1	1.56%	nOPV2: Novel oral pol	lio vaccine	type 2
Gender	(n=51)		Outcome	Count	Proportion
			Recovering/		
			Resolving	25	49.02%
			Recovered/		
	47.9/		Resolved	17	33.33%
45% #Female 55%		Not recovered/Not resolved/Ongoing	5	9.80%	
			Unknown	2	3.92%
			Fatal	2	3.92%



Reporter Designation	Count	%
Nurse	18	52.94%
Pharmacist	13	38.24%
Clinical officer	2	5.88%
Pharmaceutical technologist	1	2.94%

Majority of the AEFIs in this quarter were reported by Nurses who submitted 18 (52%) reports. Pharmacists submitted 13 (38%) reports, Clinical Officers 2 (5%) and pharmaceutical technologist 1 (2%),



Majority of the AEFIs reported in this quarter affected the Infant age group (< 1year) (22) and Child (1-11 years) (7). The least affected age group in this quarter were the Neonates and Adolescents (18-65 years) with only (2) reports.

Reporting	Count	%	Reporting	Count	%
Lang'ata Health Centre	6	17.65	Fitc Dispensary	1	2.94%
(Ruiru)		%			
Mwariki Community	4	11.76	Likoni District	1	2.94%
Dispensary		%	Hospital		
Ngecha Health Centre	2	5.88	Gathambi	1	2.94%
		%	Health Centre		
Fitc Dispensary	2	5.88	Mailwa	1	2.94%
		%	Dispensary		
Kangu Dispensary	2	5.88	Uhuyi	1	2.94%
		%	Dispensary		
Kerugoya County Refferal	2	5.88	Mutituni Level 4	1	2.94%
Hospital		%	Hospital		
Haven Hospital	1	2.94	Kitengela	1	2.94%
		%	Medical Services		
Mikindani Hospital	1	2.94	Jamia Medical	1	2.94%
		%	Centre		
Limuru Cottage Hospital	1	2.94	Kitui County	1	2.94%
		%	Referral		
			Hospital		
Kabati Dispensary	1	2.94	Cheptais Sub	1	2.94%
(YMCA)		%	County Hospital		
Iftin Sub-District	1	2.94	Kikopey	1	2.94%
Hospital		%	dispensary		

Reporting institution (n=35)

In this Quarter, only 22 facilities out of the 9,000 facilities listed in the Kenya Master facility reported AEFIs. The top leading facility was Lang'ata Health Centre with 6 reports followed by Mwariki Community Dispensary with 4 reports. The table above shows the facilities and the number of reports submitted by each.

Reporting counties

County	Count	Proportion
Kiambu	9	26.47%
Nakuru	9	26.47%
Kirinyaga	5	14.71%
Mombasa	2	5.88%
Siaya	2	5.88%
Kajiado	2	5.88%
Machakos	1	2.94%
Garissa	1	2.94%
Bungoma	1	2.94%
Kakamega	1	2.94%
Kitui	1	2.94%

Additionally, AEFI reports were received from 11 of the 47 counties. Kiambu and Nakuru counties submitted the highest number of AEFIs reports (9) each. Five counties submitted 1 report each as shown in the table above.

Adverse Events

Event	Count	%	Event	Count	%
Fever	11	20.75%	Bleeding at injection site	1	1.89%
Inflammation at injection site	9	16.98%	General malaise	1	1.89%
Pain at injection site	4	7.55%	Fever	1	1.89%
Vomiting	3	5.66%	Redness of site of injection	1	1.89%
Itchiness	3	5.66%	Anaphylaxis	1	1.89%
Injection site abscess	2	3.77%	Swelling of the face	1	1.89%
Irritability	2	3.77%	Loss of appetite	1	1.89%
Lower limb weakness	2	3.77%	Swollen wrist joints	1	1.89%

Death following anaphylaxis	1	1.89%	Diarrhea	1	1.89%
Shortness of breath	1	1.89%	Weakness generalized	1	1.89%
Paralysis	1	1.89%	Nose bleeding	1	1.89%
Convulsion	1	1.89%	Crying	1	1.89%
Swollen elbow joint	1	1.89%			

Of the AEFIs reported in this quarter, fever was the most reported with an incidence of 31.34%. Other most reported AEFIs were diarrhea (10.45%), Generalized urticaria and Vomiting with an incidence of (7.46%) each and Rash (5.97%). The other most reported AEFIs are listed above.

Medication Errors (MEs)

Institution	No. of Reports	Proportion
Kenyatta National Hospital	14	16.5
Port Reitz District Hospital	13	15.3
Ruiru Sub-County Hospital	10	11.8
Kiambu County Referral Hospital	8	9.4
Embu Provincial General Hospital	7	8.23
Malindi District Hospital	5	5.88
Kimbimbi Sub-County Hospital	5	5.88
Siaya County Referral Hospital	3	3.52

A total of 85 reports were received during the quarter 3. Kenyatta National Hospital submitted the highest number of reports 14 (16.5%) followed by Port Reitz District Hospital 13 (15.3%). Reporting from other facilities is as shown in the table above.



Medication Error Outcome

Error Outcome	No. of Reports	Percentage
Actual error-did not reach patient	47	55.3
Potential error, circumstances/events have potential to cause incident	19	22.4
Actual error-caused no harm	10	11.8
Treatment /intervention required-caused temporary harm	3	3.5
Not Indicated	2	2.35
Additional monitoring required-caused no harm	2	2.35
Initial/prolonged hospitalization-caused temporary harm	1	1.17
Death	1	1.17
Grand Total	85	100

Most of the medication errors 47 (55.3%) did not reach the patient, while 19 (22.4%) had potential to cause harm and 10 (11.8%) reached the patient but caused no harm. Other error outcos are as captured in the table.

	County		Process Whe	ere the Erro	r Occurred	
County	No. of Reports	%		No. of		
Kiambu	19	22.3	Process	Reports	Percentage	
Mombasa	15	17.6				
Nairobi County	15	17.6	Prescribing	60	70.6	
Kirinyaga	10	11.8	lincludes			
Embu	7	8.23	filling)	18	21.2	
Kilifi	5	5.9	8/	10		
Isiolo	3	3.5				
Nyeri	3	3.5	Administration	5	5.9	
Siaya	3	3.5				
Migori	2	2.4	Others	2	2.4	
Kisumu	2	2.4		I		
Kitui	1	1.2				
Grand			Grand Total	85	100	
Total	Total 85 100					
Most of the reports submitted were			In Quarter 3, most of the medication			
from Kiam	from Kiambu County 19 (22.3%),			errors occurred during the prescribing		

followed by Mombasa County at 15	process 60 (70.6%), followed by	y
(17.6%). Other counties reported	Dispensing 18 (21.2%). Other error	s
as shown in the table.	occurred during administration.	

Clinic where Error Occurred

Clinic	No. of Reports	Proportion (%)
Not Indicated	32	37.6
Outpatient	29	34.1
Diabetic clinic	14	16.5
Inpatient	2	2.35
Post-natal ward	2	2.35
Prevention of Mother-to-Child Transmission (PMTCT)	2	2.35
Medical specialist	1	1.17
Psychiatry	1	1.17
Renal Unit	1	1.17
Comprehensive Care Clinic (CCC)	1	1.17
Grand Total	85	100

Most medication errors were reported from the outpatient (34.1%) followed by the diabetic clinic 14 (16.5%). Of note, 32 (37.6%) did not indicate where the error occurred. Other errors that occurred in the various clinics are as shown in the table above.

Drugs with Medication Errors						
Drug	No. of Reports	Proportion (%)				
Not indicated	15	17.6				
Metronidazole	4	4.7				
Atorvastatin	3	3.5				
Metformin 500MG	3	3.5				
Amoxiclav	2	2.24				
Sitaglipti50mg/metformin500mg	2	2.24				
Hydralazine	2	2.24				
Cefixime	2	2.24				
Montelukast	2	2.24				
Celecoxib 200mg	2	2.24				
Clotrimazole	2	2.24				
Gliclazide	2	2.24				

In Q3, most errors were associated with metronidazole 4 (4.7%), Artovastatin 3 (3.5%) metformin 3 (3.5%). Most of the reports 15 (17.6%) did not indicate the suspected drugs.

Description of the Error						
Description of error	No. of Reports	Proportion (%)				
Prescribed wrong dose	43	50.58				
Prescribed wrong duration	17	20%				
Administered wrong dose	8	9.4%				
Dispensed wrong drug	5	5.6%				
Prescribed wrong frequency	3	3.53%				

Of the reports received, the most frequent errors were prescription errors with wrong dose 43 (50.58%), followed by Prescriptions with wrong duration 17 (20%). Other medication errors are as shown in the table above.

	No. of	
Contributing Factor	Reports	Proportion (%)
Inadequate knowledge	40	47.05
Heavy workload	28	32.9
Inexperienced personnel	24	28.2
Peak hour	14	16.5
Distraction	12	14.1
Look alike packaging	7	8.2
Look alike medication	4	4.7
Sound alike medication	3	3.52
Stock arrangements	2	2.35

In quarter 3, 40 (47.05%) cited that inadequate knowledge was a contributing factor for medication errors followed by 28 (32.9%) who cited heavy workload, and 24 (28.2%) who cited inexperienced personnel. Other contributing factors are as shown in the table above.



Rea	ction						
No	Reaction	Count	Proportion	No	Reaction	Count	Proportion
1	Rash	3	17.65%	7	Joints and muscle pain	1	5.88%

7.69%

7.69%

1

1

IBUPROFEN

Intrauterine

device

4

Isoniazid, Pyrazinamid

Ethambutol

Lamivudine

Dolutegravir

Tenofovir

1

1

7.69%

7.69%

e,

8

2	Dizziness or drowsiness	2	11.76%	8	Red/ painful eyes	1	5.88%
3	The color is changing	2	11.76%	9	The label looks wrong	1	5.88%
4	The smell is unusual	2	11.76%	10	The medicine/devi ce is not working	1	5.88%
5	Vomiting or diarrhoea	2	11.76%	11	The packet or bottle does not seem to be usual	1	5.88%
6	Has unusual material in it	1	5.88%				

The most commonly reported PADRs were rash, dizziness or drowsiness and vomiting or diarrhea. Other reported PADRs were related to product quality such as; the color is changing and the smell is unusual. The other incidences of the reported adverse effects are highlighted in the table above.

County

Public Adverse Drug Reactions (PADRs) were received from 10 of the 47 counties. Nairobi County submitted the highest number of PADRs (4, 31%.

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

No	County	Count	Proportion	No	County	Count	Proportion
1	Nairobi			6			
	County	4	30.77%		Marsabit	1	7.69%
2	Busia	1	7.69%	7	Meru	1	7.69%
3	Kirinyaga	1	7.69%	8	Migori	1	7.69%
4	Kisumu	1	7.69%	9	Mombasa	1	7.69%
5	Makueni	1	7.69%	10	Nyeri	1	7.69%

Blood Transfusion Reactions

There were eleven reports of blood transfusion reactions received in Quarter 3 (Q3). The reports were mostly submitted by pharmacists (58%,7), Laboratory technologist (33%,3) and a nurse (8%,1).

Eight incidents of Blood transfusion reactions involved adult (18-64 years) patients and three incidents in Adolescent (12-17 years) patients. Most

transfusion reaction were noted in female patients (9) compared to male patients (2).

Seven of the patients had received a blood transfusion due to severe anaemia, Two patients due to severe anemia in pregnancy and one due to low haemoglobin levels. One patient had received a transfusion of fresh frozen plasma (FPP). Five of the patients had previously received a blood transfusion and none of the patients had experienced a previous reaction.

The reported blood transfusion reactions had the following incidences;

No	Reaction	Count	%	No	Reaction	Count	%
1	Fever	7	21.88%	8	Dizziness	1	3.13%
2				9			
	Chills/Rigors	6	18.75%		Excessive sweating	1	3.13%
3				10	Haemoglobinuria-		
	Chest pain	3	9.38%		Dark urine	1	3.13%
4	Flushing	3	9.38%	11	Headache	1	3.13%
5	Dyspnoea	2	6.25%	12	Hypertension	1	3.13%
6	Tachycardia	2	6.25%	13	Hypotension	1	3.13%
7				14			
	Urticaria	2	6.25%		Nausea/ Vomiting	1	3.13%
	Urticaria	2	6.25%		Nausea/ Vomiting	1	3.

Medical Device Incidence Reports

In the past quarter, there were three reports of medical device incidents (MDI) submitted. These reports originated from Nairobi (1), Kisumu (1) and Kitui (1) County.

The incidents involved (2) adult male patients and (1) adult female patient. According to the MDI reports, it was noted that one of the devices had an issue that had been previously identified by the reporters. The details of the reported medical device incidents are presented in the table below:

Medical Device	Manufacturer	Incident (Event)
Zinc Oxide adhesive	ALI SONS	The strapping intended for securing
strapping		intravenous branulas/cannulas and
		wound gauzes, exhibited inadequate
		adhesive strength. As a result, the
		strapping failed to hold
		branulas/cannulas in place, leading to
		their dislodgement shortly after
		application. Additionally, wound
		dressings became unsecured within
		hours, exposing the wounds.

Blood Pressure	Contec	The device recorded high blood pressure			
Machine	manufacturer	readings in a patient and when another			
		machine was used the blood pressure			
		reading was normal.			
SURE, TEST HIV	NANTONG	A client reported purchasing a SURE			
TEST KIT	DIAGNOS	TEST HIV test kit that was missing the			
	BIOTECHNOLOGY	diluent solution which is a critical			
		component required for the test to			
		function. This rendered the test			
		unusable and delayed diagnostic			
		procedures.			
The reports were primarily made by a pharmaceutical technologist,					
medical officer and physician and the incidents were classified as mild,					

medical officer and physician and the incidents were classified as mild, moderate and one was unknown. The outcome in one of the patients was recovered and two were unknown.

If you have any questions, don't hesitate to get in touch with the PV department at pv@ppb.go.ke or call **0795743049.**

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