



Ministry of Health

PPB Pharmacovigilance Centre

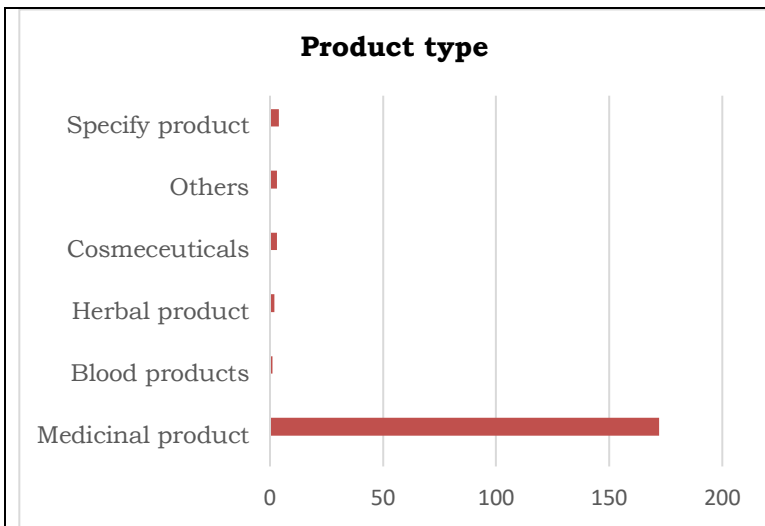
Pharmacovigilance Summary Report: **January-June 2021 (Q3 & 4)**

The Pharmacy and Poisons Board is the Drug 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 in drugs and poisons.

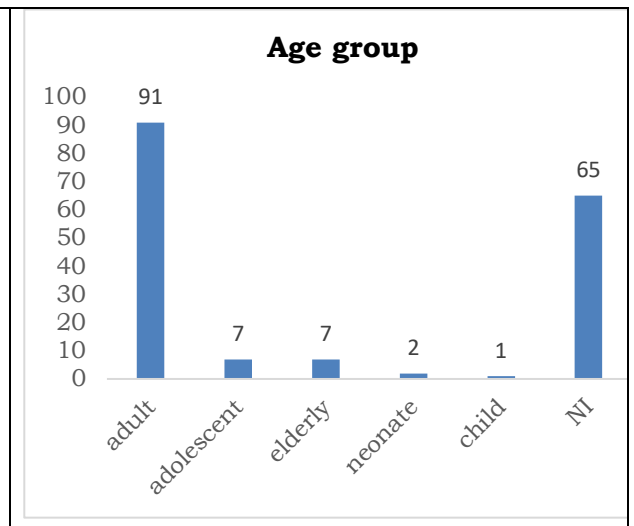
PPB has 4 directorates of which the Directorate of Medicines Information and Pharmacovigilance (MIPV) is responsible for Pharmacovigilance, Post-Market Surveillance, Clinical Trials & Medicines Information activities. MIPV shares quarterly pharmacovigilance reports with stakeholders to serve as a feedback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

Since the introduction of PV in Kenya, a total of **14,589** individual case safety reports has been submitted to the global data reports **26,863,169** (0.05%).

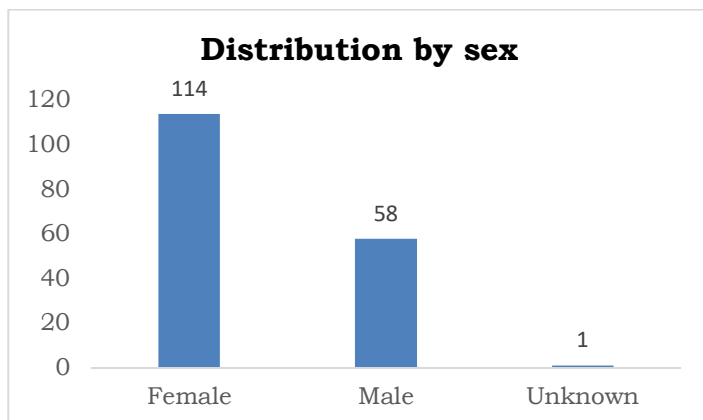
Suspected Adverse Drug Reactions (SADRs)



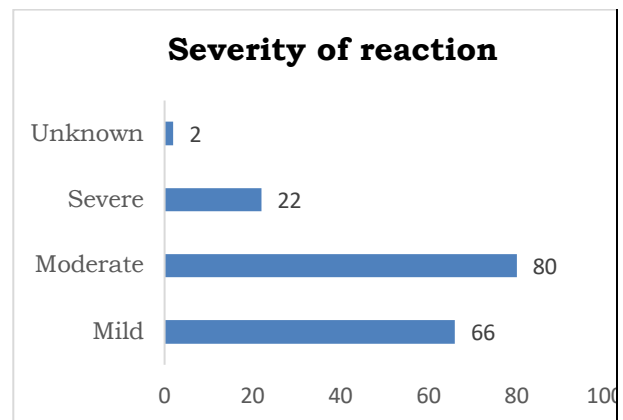
Majority of the reports (94.5%) of the reports submitted were medicinal products while 2.6 % of the products were not specified.



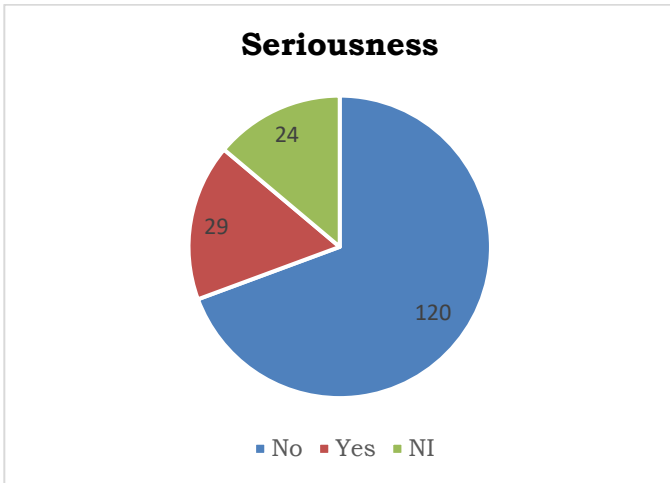
The incidence of SADRs was highest amongst the adult (52.6%) age group in comparison to the children. 37.5% of the total reports did not have age indicated.



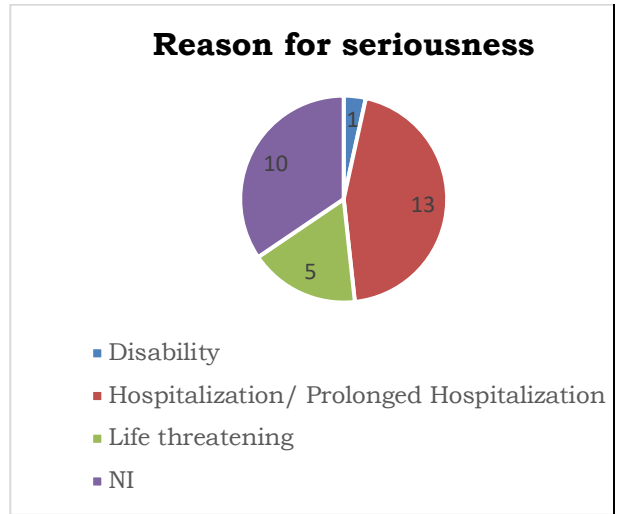
The frequency of reported SADRs was higher in female (65%) compared to male.



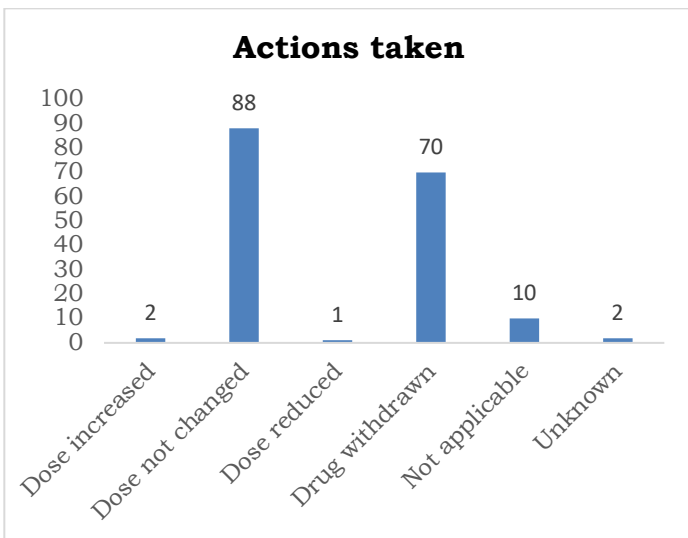
Of the total reports received on SADRs, (12.9 %) were classified as severe while majority were moderate (47%).



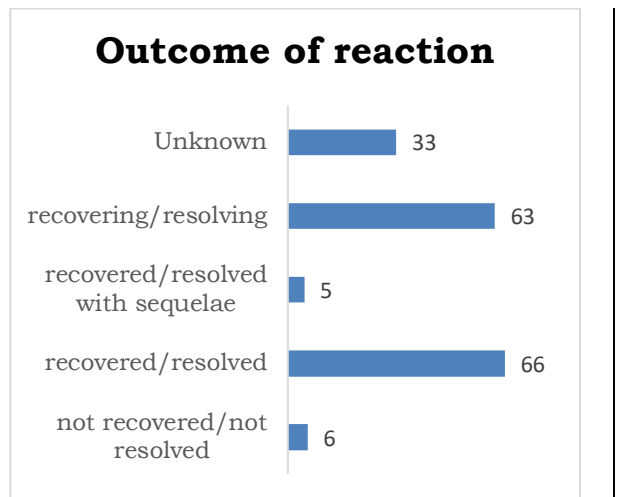
Of the total reports received in SADR, 69.4% were classified as serious.



Out of the serious reactions reported, hospitalization (44.8%) was the major reason for seriousness.



Actions taken by the health care workers included; withdrawal of the offending drug (40.4%). 50.8 % reported that no change in dosage was made while, 1.16% did not indicate the action taken.



Most of the reported SADR cases had recovered (36%). 19 % of the reports had no outcome indicated on them

Reporting facilities

Facility	Number of reports n=173	Frequency (%)
The Mater Hospital Mukuru	34	19.7

Reporting counties

County	Number of reports. n=173	Frequency (%)
Siaya	60	34.6
Nairobi County	39	22.5
Kakamega	9	5.2
Kirinyaga	9	5.2



Yala Sub-District Hospital	27	15.6
EMMAH RANDIKI	22	12.7
Taveta District Hospital	8	4.6
Kibwezi Sub District Hospital	7	4.0
Navakholo Sub-District Hospital	5	2.8
Kirinyaga county	4	2.3
Migori District Hospital	3	1.7
AMBIRA SCH	3	1.7
Kilifi District Hospital	2	1.2
Lumakanda District Hospital	2	1.2
Malindi District Hospital	2	1.2
Maralal District Hospital	2	1.2
Muhuru Health Centre	2	1.2
Njegas Dispensary	2	1.2
Sega Dispensary	2	1.2
Siaya District Hospital	2	1.2
Ambira Sub-District Hospital	1	0.6
Arombe Dispensary	1	0.6
Bahati District Hospital	1	0.6
Bristol park hospital	1	0.6
Cheptais Sub District Hospital	1	0.6
Chulaimbo Sub District Hospital	1	0.6
Dreams Center Dispensary (Lang'ata)	1	0.6
Emali Health Centre	1	0.6

Makueni	9	5.2
Migori	8	4.6
Taita Taveta	8	4.6
Kiambu	5	2.89
Kilifi	4	2.3
Mombasa	3	1.7
Nakuru	3	1.7
Embu	2	1.2
Kisii	2	1.2
Kisumu	2	1.2
Meru	2	1.2
Samburu	2	1.2
Bung'oma	1	0.6
Kericho	1	0.6
Murang'a	1	0.6
Nandi	1	0.6
Nyeri	1	0.6
West Pokot	1	0.6
Total reports	173	

SADR reports were received from 22 of the 47 counties. Siaya county submitted the highest number of SADR reports (60) followed by Nairobi (39), Kakamega (9), Kirinyaga (9) and Makueni (9). The other reporting counties with less than 3 reports were Embu, Kisii, Kisumu, Meru, Samburu, Bungoma, Kericho, Murang'a and Nandi.



Embu Provincial General Hospital	1	0.6
Gatundu District Hospital	1	0.6
Gesusu Sub-District Hospital	1	0.6
GOODLIFE PHARMACY LIMITED	1	0.6
Got Agulu Sub-District Hospital	1	0.6
IQVIA	1	0.6
Kaboi Dispensary	1	0.6
Kapenguria District Hospital	1	0.6
Kapkatet District Hospital	1	0.6
Kehancha Subcounty Hospital	1	0.6
Kenyatta University Teaching Referral and Research Hospital	1	0.6
Kiambu District Hospital	1	0.6
Kijabe (AIC) Hospital	1	0.6
Kisii Hospital (Level 5)	1	0.6
Likoni District Hospital	1	0.6
Madiany Sub District Hospital	1	0.6
Makueni District Hospital	1	0.6
Mama Lucy Kibaki Hospital - Embakasi	1	0.6
Matete Health Centre	1	0.6
Meru District Hospital	1	0.6



Miathene District Hospital	1	0.6
MUMIAS LEVEL IV HOSPITAL	1	0.6
Murang'a District Hospital	1	0.6
Mutithi Health Centre	1	0.6
Nakuru Provincial General Hospital (PGH)	1	0.6
Nazareth Hospital	1	0.6
Nguka Dispensary	1	0.6
Nyeri Provincial General Hospital (PGH)	1	0.6
Port Reitz District Hospital	1	0.6
Rongo District Hospital	1	0.6
Sagana Rural Health Demonstration Centre	1	0.6
Social service league Mp. Shah Hospital	1	0.6
St Clare Bolo Health Centre	1	0.6
St. Anthony	1	0.6
Tudor District Hospital (Mombasa)	1	0.6
Uradi Health Centre	1	0.6

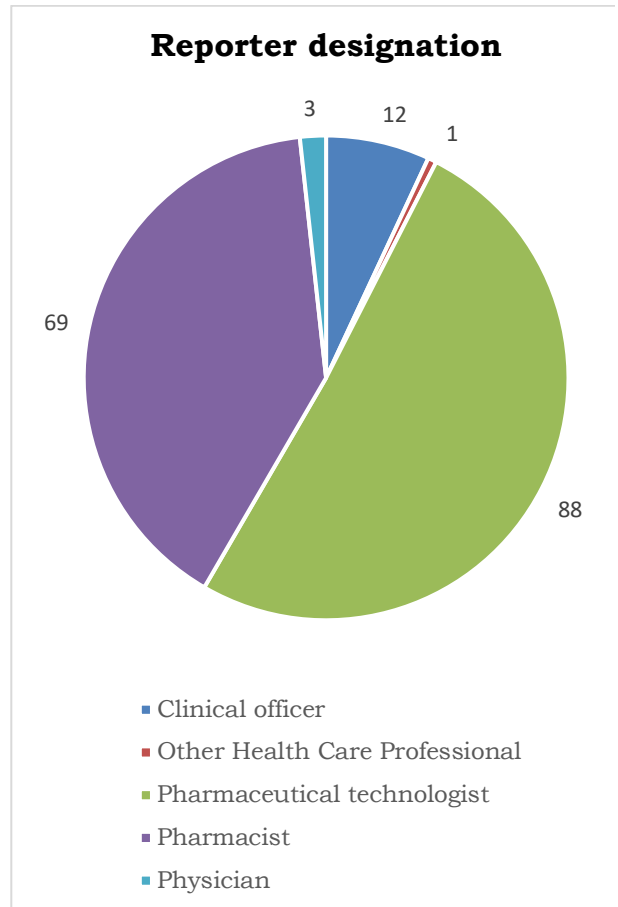
In this 3rd and 4th Quarter, only 61 facilities out of the 9,000 facilities listed in the Kenya Master facility reported SADR. 6 facilities reported at least 5 reports and above. The top leading facilities were The Mater Hospital Mukuru with 34 reports (19.7%), followed by Yala Sub-District Hospital 27 reports (15.6 %) , Emmah Randiki Hospital 22 reports (12.7%) ,Taveta District Hospital 8 reports (4.6



%), Kibwezi subdistrict Hospital 7 reports (4.0%) and Navakholo Sub-District Hospital .

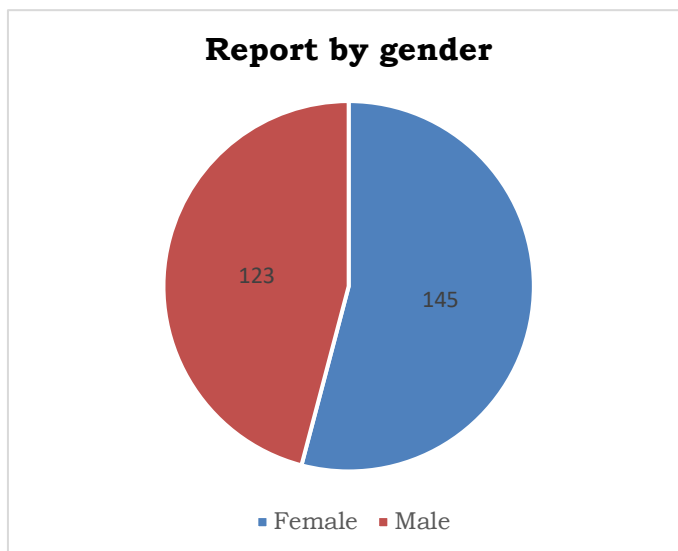
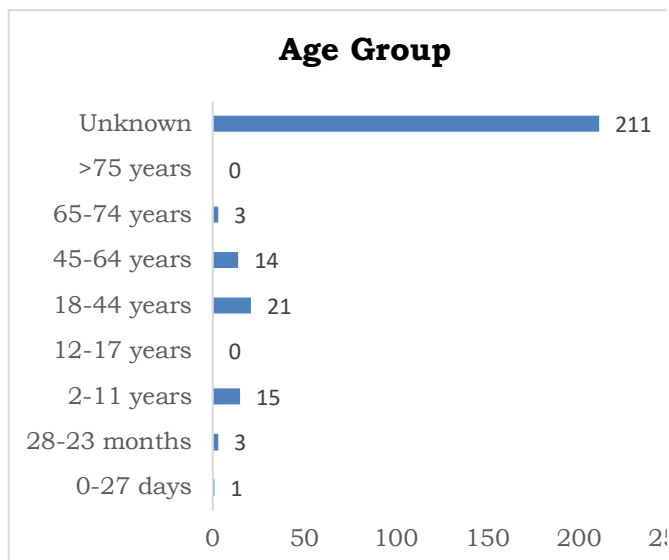
Below is a list of top 14 facilities

S/No	Facility	Reports
1	The Mater Hospital Mukuru	34
2	Yala Sub-District Hospital	27
3	EMMAH RANDIKI	22
4	Taveta District Hospital	8
5	Kibwezi Sub District Hospital	7
6	Navakholo Sub-District Hospital	5
7	Kirinyaga county	4
8	Migori District Hospital	3
9	AMBIRA SCH	3
10	Kilifi District Hospital	2
11	Lumakanda District Hospital	2
12	Malindi District Hospital	2
13	Maralal District Hospital	2
14	Muhuru Health Centre	2



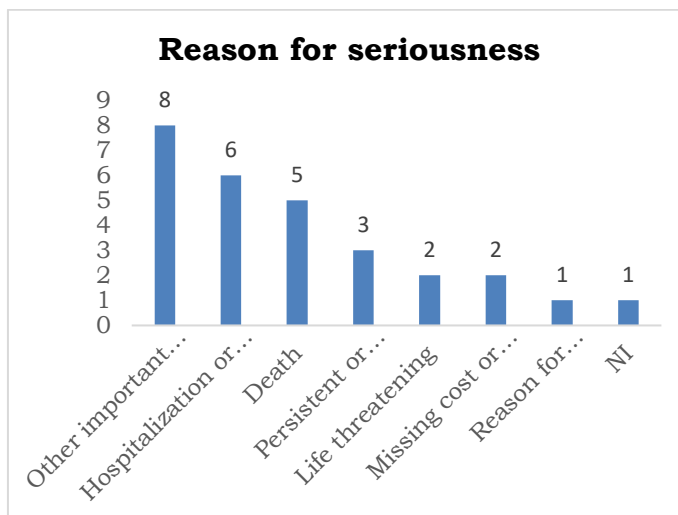
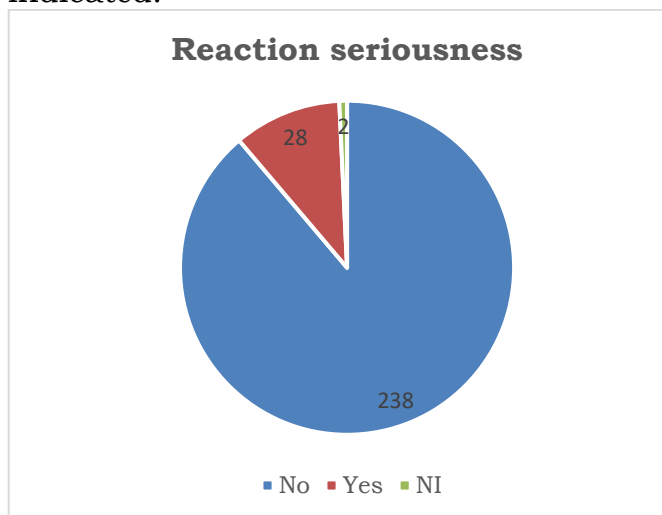
Majority of the reports (50.8%) of the reports were submitted by Pharmaceutical technologists while non-health professionals submitted 0.6% of the reports.

Adverse Events Following Immunizations (AEFIs)



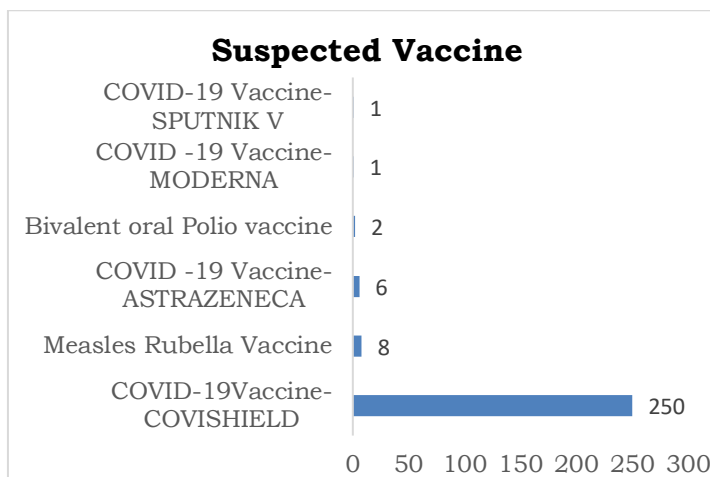
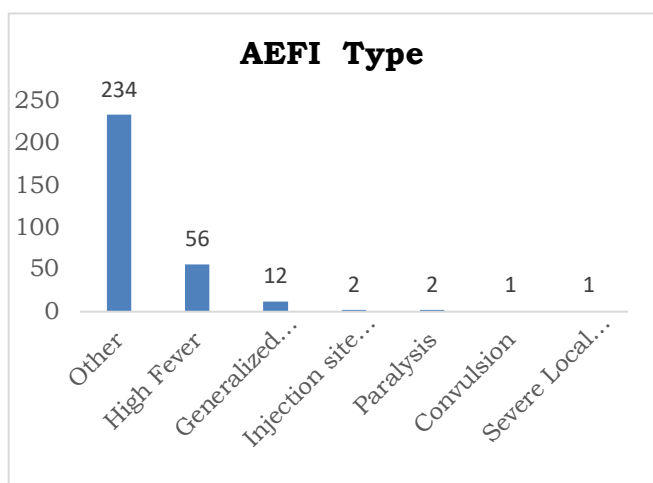
The incidence of AEFIs was highest amongst the adult age group (18-44 and 45-64) in comparison to the others. 78.7 % of the total reports did not have age indicated.

The frequency of reported AEFIs was higher in female (54%) compared to male.



Of the total reports received in AEFI, 10.4 % were classified as serious.

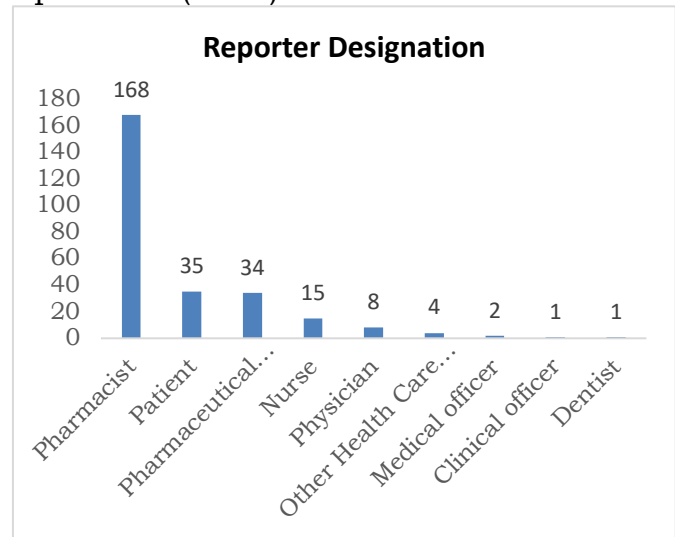
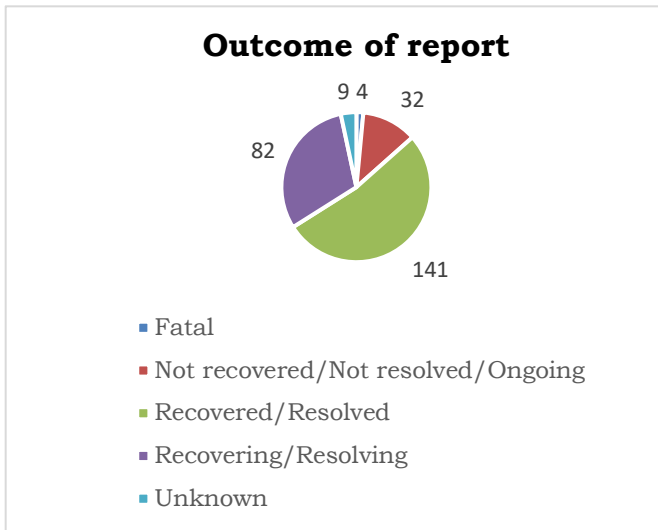
Out of the serious reactions reported, hospitalization (21.4%) was the major reason for seriousness.





Most commonly reported AEFIs type were high fever and urticaria.

The most commonly reported vaccine causing adverse reactions was Covid-19 Vaccine-Covishield (93%), Measles Rubella Vaccine (2.98%) followed by Covid -19 Vaccine- Astrazeneca (2.2%), Bivalent oral Polio vaccine (0.8%), Covid -19 Vaccine-Moderna (0.3%) and Covid-19 Vaccine-Sputnik V (0.3%).



Most of the reported AEFIs cases had either recovered 52.6 % or were e recovering 30.5% respectively. 3.4 % of the reports had no outcome indicated on them.

Majority of the reports (62.6%) were submitted by pharmacists while non-health professionals submitted 1.49 % of the reports submitted.

Facilities	Frequency n=268	Proportion (%)
Embu Provincial General Hospital	49	18.3
Webuye Hospital	27	10.1
Kakamega Provincial General Hospital (PGH)	20	7.5
Uasin Gishu District Hospital	18	6.7
Kilifi District Hospital	12	4.5

County	Number of reports n=268	Frequency (%)
Kakamega	55	20.6
Embu	49	18.4
Nairobi County	32	12.0
Bung'oma	28	10.5
Uasin Gishu	27	10.1
Kilifi	12	4.5
Kirinyaga	11	4.1
Machakos	11	4.1
Kiambu	10	3.7
Mombasa	5	1.9
Turkana	5	1.9
Garissa	3	1.1
Kisumu	3	1.1
Nyeri	3	1.1
Kajiado	2	0.7



Lumakanda District Hospital	12	4.5
Machakos Level 5 Hospital	8	3.0
Kerugoya District Hospital	7	2.6
National Vaccines program	6	2.2
Kijabe (AIC) Hospital	5	1.9
Mama Lucy Kibaki Hospital - Embakasi	5	1.9
Burnt Forest RHDC (Eldoret East)	4	1.5
Coast General Teaching & Referral Hospital	4	1.5
Iguhu District Hospital	4	1.5
Kiambu District Hospital	4	1.5
Kirinyaga county	4	1.5
Likuyani Sub-District Hospital	4	1.5
Lopiding Sub-District Hospital	4	1.5
Mumias Dispensary	4	1.5
Kayole II Sub-District Hospital	3	1.1
Kesses Health Centre	3	1.1
Malava District Hospital	3	1.1

Murang'a	2	0.7
Siaya	2	0.7
Homa Bay	1	0.4
Kisii	1	0.4
Laikipia	1	0.4
Makueni	1	0.4
Nakuru	1	0.4
Taita Taveta	1	0.4
Wajir	1	0.4

Additionally, AEFIs reports were received from 24 of the 47 counties. Kakamega county submitted the highest number of AEFI reports (55) followed by Embu (49), Nairobi County (32), Bungoma (28) and Uasin Gishu (27). The other reporting counties with less than 3 reports were Kajiado, Murang'a, Siaya, Homabay, Kisii, Laikipia, Makueni, Taita Taveta, Wajir and Nakuru.



Mumias Sub-District Hospital (Matungu)	3	1.1
Special Treatment Clinic	3	1.1
Butere District Hospital	2	0.7
Kajiado District Hospital	2	0.7
Navakholo Sub-District Hospital	2	0.7
Nyeri Provincial General Hospital (PGH)	2	0.7
Umoja Health Centre	2	0.7
UNON Joint Medical Service	2	0.7
bliss medical center	1	0.4
Bondo District Hospital	1	0.4
Cheptais Sub District Hospital	1	0.4
Chiga Dispensary	1	0.4
Garissa Provincial General Hospital (PGH)	1	0.4
Gatundu District Hospital	1	0.4
Hagadera Hospital	1	0.4
Henry Amdany	1	0.4
International Rescue Committee	1	0.4



Kakuma Health Centre	1	0.4
Kalala Dispensary	1	0.4
Kangundo District Hospital	1	0.4
Karen surgery	1	0.4
Kemri wellcome trust research programme	1	0.4
Kigumo Health Centre (Muranga South)	1	0.4
Kisii Hospital (Level 5)	1	0.4
Kombewa District Hospital	1	0.4
Madiany Sub District Hospital	1	0.4
Makueni District Hospital	1	0.4
Mama Vero Clinic	1	0.4
Mathare North Health Centre	1	0.4
Matuu District Hospital	1	0.4
Mautuma Sub-District Hospital	1	0.4
Mbagathi District Hospital	1	0.4
Mogotio RHDC	1	0.4
Murang'a District Hospital	1	0.4



Nanyuki District Hospital	1	0.4
Provide International Kayole Clinic	1	0.4
Rangwe subcounty hospital	1	0.4
Ruaraka Uhai Neema Hospital	1	0.4
self	1	0.4
Sex Workers Operation Project (SWOP)	1	0.4
social service league Mp. Shah Hospital	1	0.4
St Elizabeth Chiga Health Centre	1	0.4
Taveta District Hospital	1	0.4
Tridem Pharma Kenya Limited	1	0.4
Tudor District Hospital (Mombasa)	1	0.4
Tumutumu (PCEA) Hospital	1	0.4
Wajir District Hospital	1	0.4
Ziwa Sub-District Hospital	1	0.4
Total Reports	268	

In this 3rd Quarter, only 70 facilities out of the 9,000 facilities listed in the Kenya Master facility reported AEFIs. 11 facilities reported at least 5 reports and above. The top leading facilities were Embu Provincial General

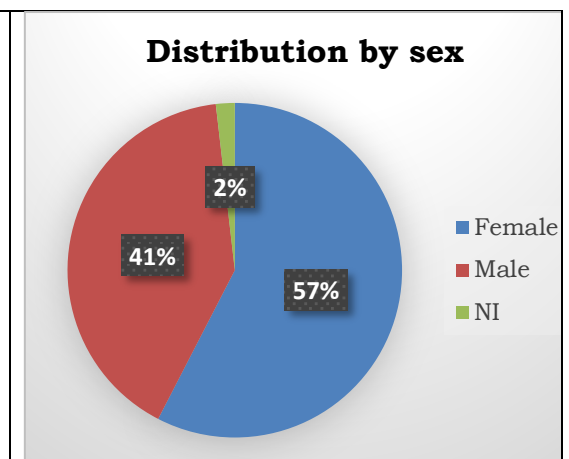
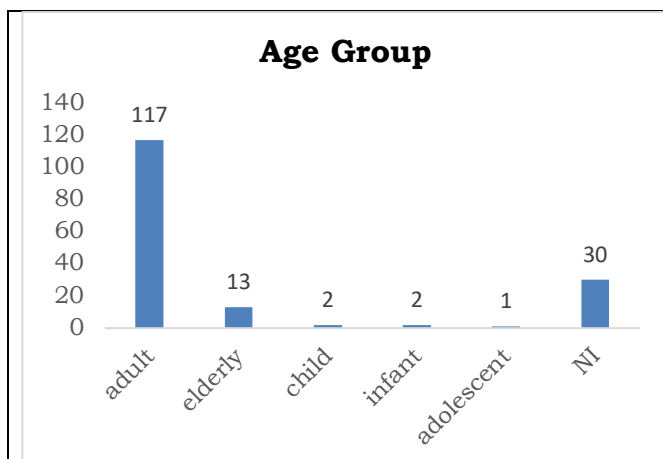


Hospital 49 reports (18.3%), Webuye Hospital 27 Reports (10.1%), Kakamega Provincial General Hospital (PGH) 20 reports (7.5%), Uasin Gishu District Hospital 18 reports (6.7%), Kilifi District Hospital and Machakos Level 5 Hospital 12 reports each (4.5%).

Below is a list of top 14;

	Name of facility	Frequency	Proportion
1	Embu Provincial General Hospital	49	18.3
2	Webuye Hospital	27	10.1
3	Kakamega Provincial General Hospital (PGH)	20	7.5
4	Uasin Gishu District Hospital	18	6.7
5	Kilifi District Hospital	12	4.5
6	Lumakanda District Hospital	12	4.5
7	Machakos Level 5 Hospital	8	3.0
8	Kerugoya District Hospital	7	2.6
9	National Vaccines program	6	2.2
10	Kijabe (AIC) Hospital	5	1.9
11	Mama Lucy Kibaki Hospital - Embakasi	5	1.9
12	Burnt Forest RHDC (Eldoret East)	4	1.5
13	Coast General Teaching & Referral Hospital	4	1.5
14	Iguhu District Hospital	4	1.5

Public Adverse Reactions (PADRs)



The frequency of reported PADRs was higher in female (57%) compared to male.



The incidence of PADRs was highest amongst the adult age group (70.9%) in comparison to the others. 18.1% of the total reports did not have age indicated

Suspected medicine	Frequency (n=165)	Proportion (%)
AstraZeneca Astra	52	31.5
CovidshieldAs	63	38.2
ALTEPLASE	1	0.6
Amoxicillin+ Flucloxacillin	1	0.6
Azithromycin; Zinc Sulfate; Vitamin C; Vitamin D; Paracetamol; Ascard; Montel	1	0.6
cotrimoxazole; TDF/3TC/ATVr	1	0.6
cotrimoxazole 240MG/5M SYRUP	1	0.6
COTRIMOXAZOLE 960MG	2	1.2
COTRIMOXAZOLE; TDF/3TC/DTG	2	1.2
DOLUTEGRAVIR	2	1.2
flagyls	1	0.6
FLUCONAZOLE TABS	1	0.6
Gresiovulvin	1	0.6
Isonizid,Ethambutol,Pyrazinamide,Rifampicin	2	1.2
MYOCOR	2	1.2
myospaz,rilif MR (chlorzoxazone)	1	0.6
OMNISCON CONTRAST MEDIA	2	1.2
oninjecti Ceftriaxone	1	0.6
Oral Polio Monovalent	1	0.6
PLAZO(AZITHROMYCIN 500 MG)	1	0.6
Profen 400	1	0.6
RHZE/Pyridoxine	1	0.6
sucrafil o gel	1	0.6
TdfTeno	1	0.6
VANCOLON-vancomycin	2	1.2
VEDROX 500	1	0.6
VENTAB XL 75	1	0.6
NI	18	10.9
TOTAL	165	

Commonly reported PADRs	
Vomiting or diarrhea	18
Dizziness or drowsiness	61
Headache	81
Joints and muscle pain	81
Rash	38
Pain or bleeding in the mouth	3
Pain in the stomach	28
Abnormal changes with urination	4
Red/ painful eyes	12
Patient died	4
	330

Most commonly reported PADR reactions were joint and muscle pain, headache, dizziness or drowsiness, rash and pain in the stomach.

The most commonly reported suspected medicine causing adverse reactions was Covidshield (38.2 %) and AstraZeneca Astra (31.5 %)

County	Number of	Frequency (%)
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	report s	
Nairobi County	83	50.3
Kisumu	10	6.1
Nakuru	10	6.1
Kiambu	9	5.5
Machakos	8	4.8
Siaya	9	5.5
Nyeri	7	4.2
Kilifi	5	3.0
Mombasa	3	1.8
Migori	3	1.8
Uasin Gishu	3	1.8
Bung'oma	3	1.8
Kajiado	2	1.2
Kakamega	1	0.6
Kirinyaga	2	1.2
Narok	1	0.6
Busia	1	0.6
Embu	1	0.6
Kericho	1	0.6
Laikipia	1	0.6
Murang'a	1	0.6
Vihiga	1	0.6
TOTAL	165	100.0

Additionally, PADR reports were received from 23 of the 47 counties. Nairobi county submitted the highest number of PADR reports (83) followed by Kisumu (10), Nakuru (10), Kiambu (9) and Machakos (8). The other reporting counties with less than 3 reports were Kajiado, Kakamega, Kirinyaga, Narok, Busia, Embu, Kericho, Laikipia, Murang'a and Vihiga.

Medication Errors

5 reported events, 2 from Kenyatta National Hospital, 2 from Yala-Sub District Hospital and 1 from Lodwar.

Event affected 3 adults and the other 2 were unknown. 4 of the errors occurred at prescribing stage and 1 at administration. 4 errors did not reach the patient as they were intercepted.

Medical device incidence

3 reported events from Laikipia

2 females and 1 male had mild reaction to intravenous canula product defect.

2 are recovering 1 has unknown outcome.

Transfusion reactions (Hemovigilance)

1 reported event



Male adolescent who had visceral leishmaniasis and was being transfused to raise hemoglobin levels do as to start Kal Azar treatment.

Abbreviations: PPB = Pharmacy & Poisons Board; PV = Pharmacovigilance; sADR = suspected Adverse Drug Reaction; PQMP = Poor Quality Medicinal Product; PVERS = PV Electronic Reporting System, SOC = System Organ Classification

*For any queries please contact PV department on pv@pharmacyboardkenya.org 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*)