



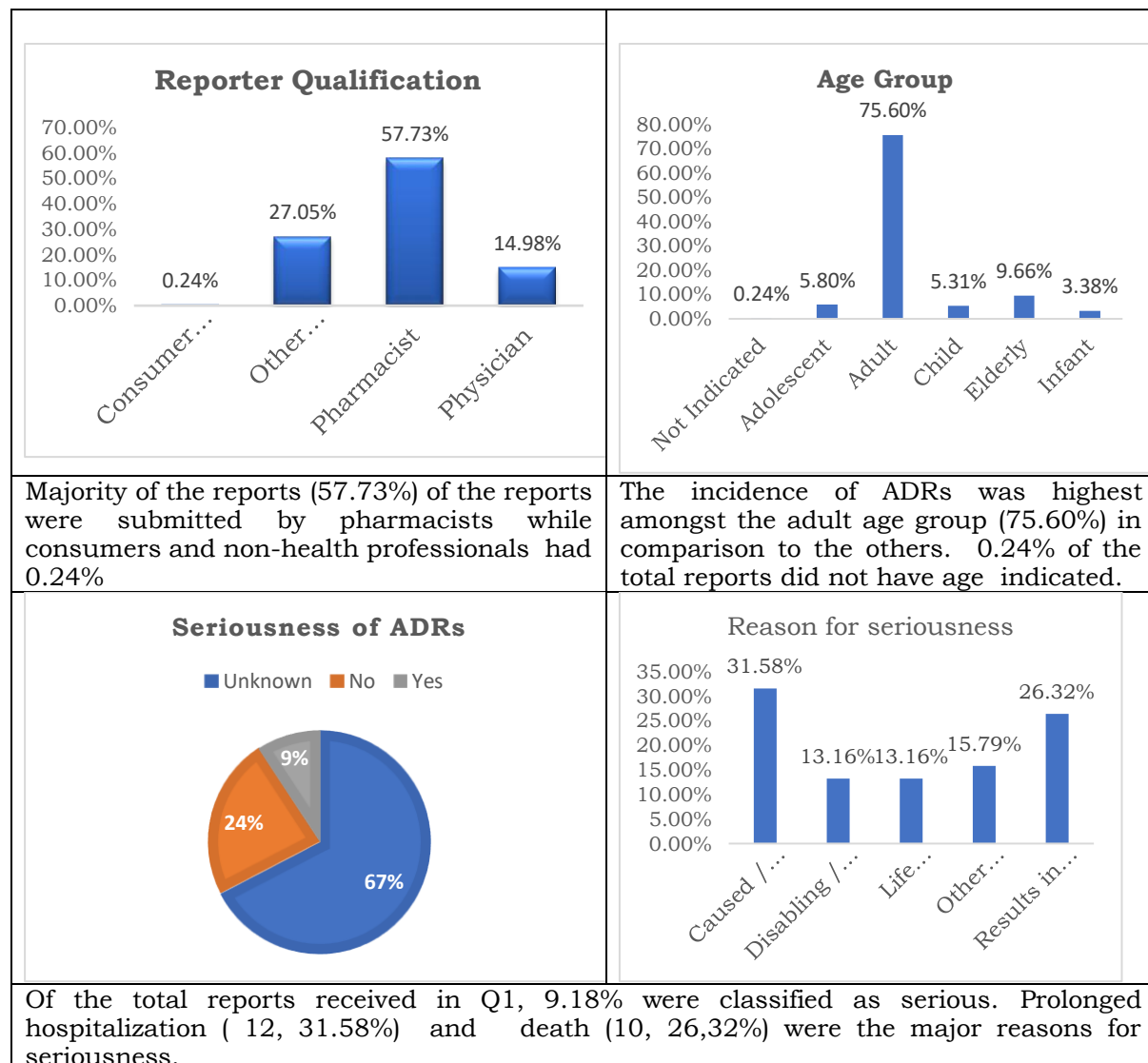
Ministry of Health, PPB Pharmacovigilance Centre

Pharmacovigilance Summary Report: July-September 2020 (Q1)

The Pharmacy and Poisons Board is the National Medicines 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 Department of Product Safety is responsible for Pharmacovigilance, Post-Market Surveillance, Clinical Trials & Medicines Information activities. Pharmacovigilance division shares quarterly 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 **14,403** individual case safety reports have been submitted to the global data base Vigibase contributing to 0.06% of the total reports (n=23,609,664). In this Quarter number of reports received were **414**.





Suspected	Frequency	Proportion
Tenofovir	30	12.40%
Imatinib	30	12.40%
DTG/TDF/3TC	22	9.09%
Cotrimoxazole	15	6.20%
Dolutegravir	12	4.96%
Nifedipine	9	3.72%
Isoniazid	6	2.48%
Efavirenz	6	2.48%
EFV/3TC/TDF	6	2.48%
Zidovudine	5	2.07%
RHZE	5	2.07%
Rifampicin	5	2.07%
Others	24	9.92%

The most common reported suspected agents causing adverse reactions were tenofovir 30 (12.4%), followed by Imatinib 30(12.4%), combination of dolutegravir/tenofovir/lamivudine 22(9.09%), cotrimoxazole 15(6.2%) and dolutegravir 12(4.96%)

sex

The frequency of reported ADRs was higher in female(60%)compared to male.

System Organ Classification	Frequency	Proportion
Skin and subcutaneous tissue disorders	107	25.85%
General disorders and administration site conditions	55	13.29%
Nervous system disorders	43	10.39%
Psychiatric disorders	29	7.00%
Gastrointestinal disorders	26	6.28%
Reproductive system and breast disorders	22	5.31%
Renal and urinary disorders	20	4.83%
Musculoskeletal and connective tissue disorder	14	3.38%

The skin and subcutaneous tissue disorders were the most commonly reported reactions (25.85%) followed by, general disorders and administration site conditions (13.29%) Nervous system Disorders (10.39)% and Psychiatric disorders (7%).

OUTCOME

Most of the reported ADRs were either recovering/resolving or recovered/resolved at 57.25%. 31.40% of the reports had no outcome indicated on them.



Actions Taken		Reaction MeDRA	Frequency	Proportion	
<p> ■ Dose Increased ■ Dose not Changed ■ Dose Reduced ■ Drug Withdrawn ■ Not Applicable ■ Unknown </p>		Suspected therapeutic ineffectiveness	22	5.31%	
		Headache	13	3.14%	
		Rash	12	2.90%	
		Itchy rash	11	2.66%	
		Toxicity renal	11	2.66%	
		Erectile dysfunction	9	2.17%	
		Jaundice	9	2.17%	
		Arthralgia	7	1.69%	
		Peripheral neuropathy	7	1.69%	
		Hyperglycaemia	7	1.69%	
		Insomnia	7	1.69%	
		Others	52	1.45%	
<p>Actions taken by the health care workers included; withdrawal of the offending drug (.48%). 37% reported that no change in dosage was made while .10% did not indicate the action taken.</p>		<p>Most commonly reported ADR terms were suspected therapeutic ineffectiveness 5.31%, followed by headache 3.14%, rash, 2.99% itchy rash and renal toxicity at 2.66% each.</p>			
Facilities	Frequency	Proportion	Counties	Frequency	Proportion
Nairobi Hospital	27	6.52%	Nairobi	130	31.40%
Kuria District Hospital	19	4.59%	Migori	51	12.32%
Kenyatta National Hospital	17	4.11%	Bungoma	31	7.49%
St Camillus Mission Hospital	16	3.86%	Kakamega	29	7.00%
Kibwezi Sub-District Hospital	15	3.62%	Kirinyaga	22	5.31%
The Mater Hospital Mukuru	14	3.38%	Makueni	20	4.83%
Kimbimbi Sub-District Hospital	14	3.38%	Kiambu	19	4.59%
Naivasha (AIC) Medical Centre	12	2.90%	Siaya	19	4.59%
Karungu Sub-District Hospital	10	2.42%	Nakuru	12	2.90%
Webuye Hospital	10	2.42%	Kilifi	10	2.42%
			Mombasa	10	2.42%
			Kisumu	10	2.42%
			Others	36	7.97%
<p>In this 1st Quarter, only 169 facilities out of the 9,000 facilities listed in the Kenya Master facility reported ADRs, 13 facilities reported at least 8 reports and above. The top leading facilities was Nairobi Hospital with 27 reports (6.52%), followed by Kuria(19,4.5%), Kenyatta National Hospital(16,4.11%) and St Camilla's mission hospital (16, 3.86%). Meru district hospital, Ruiru sub-district hospital, Nabongo dispensary among others facilities reported less than 8 reports each.</p>			<p>sADR reports were received from 33 of the 47 counties. Nairobi county submitted the highest number of ADRS reports 130 followed by Migori 51 reports, Bungoma 31, Kakamega 29 and Kirinyaga who submitted 22 reports. The other reporting counties with less than 5 reports were Muranga, Machakos, Meru, Kitui, Laikipia and Taita Taveta.</p>		



Abbreviations: PPB = Pharmacy & Poisons Board; PV = Pharmacovigilance; sADR = suspected Adverse Drug Reaction; PVERS = PV Electronic Reporting System, SOC = System Organ Classification, TDF=Tenofovir, 3TC=Lamivudine, EFV=Efavirenz, DTG=Dolutegravir

*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