Ministry of Health

PPB Pharmacovigilance Centre

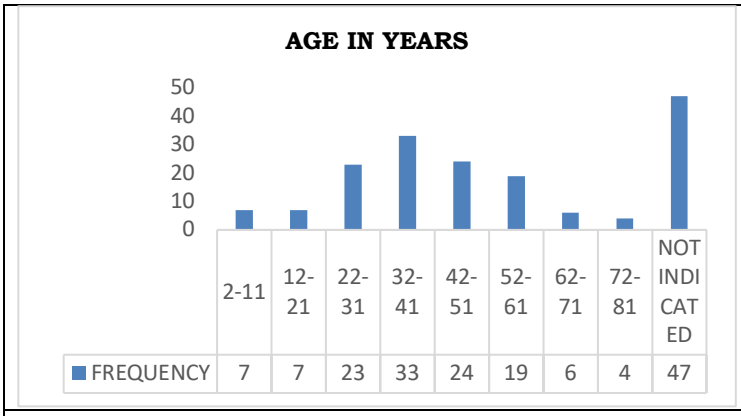
Pharmacovigilance Summary Report: October-December 2021 (Q2)

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.

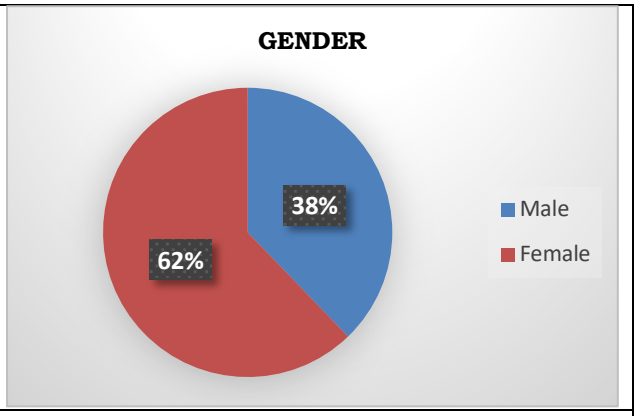
PPB has 4 directorates of which the Directorate of Medicines Information and Pharmacovigilance (MIPV) is responsible for Pharmacovigilance, Post-Market Surveillance, Clinical Trials & Medicines Information activities. MIPV shares quarterly pharmacovigilance reports with stakeholders to serve as a feedback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

*Since the introduction of PV in Kenya, a total of **15,271** individual case safety reports has been submitted to the global data reports **29,758,222** (0.05%).*

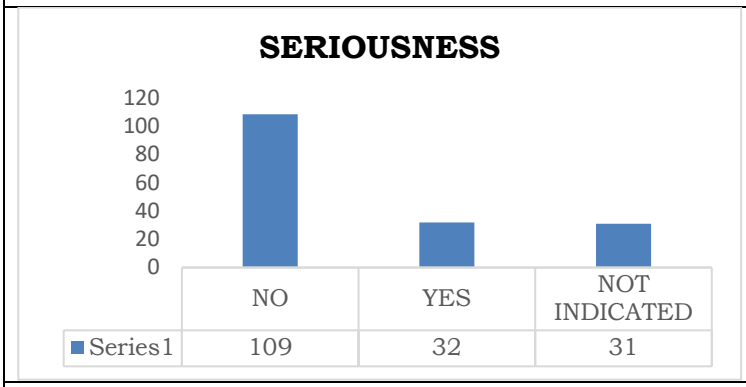
Suspected Adverse Drug Reactions (SADRs)



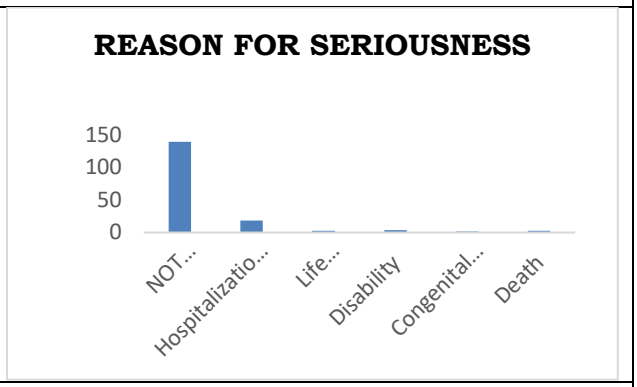
The incidence of ADRs was highest amongst the adult age group (42-51 and 32-41) in comparison to the others. 24.8% of the total reports did not have age indicated.



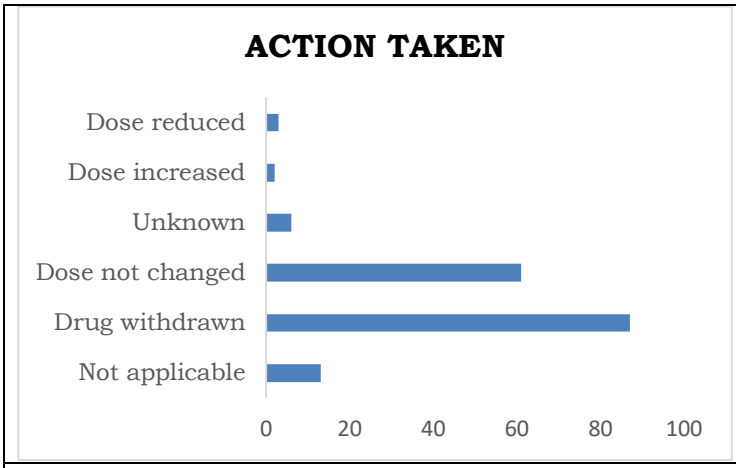
The frequency of reported ADRs was higher in females (62%) compared to males.

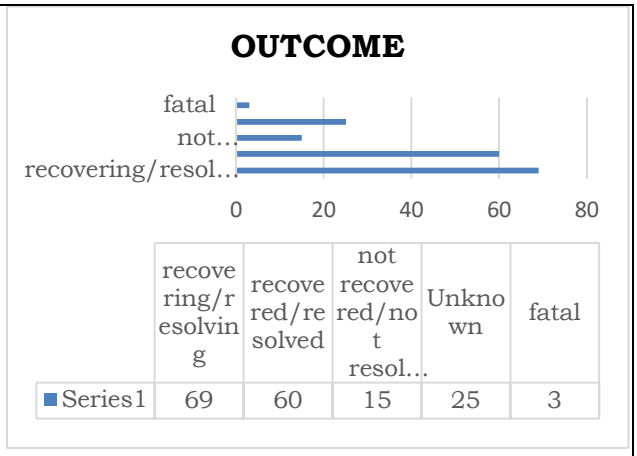


Of the total reports received in Q2, 18.6% were classified as serious, with 18% not indicated.



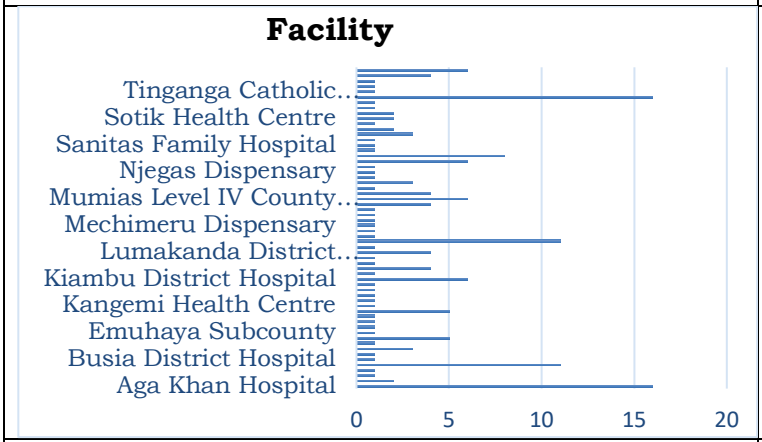
Out of the serious reactions reported, hospitalization (11%) was the major reason for seriousness.

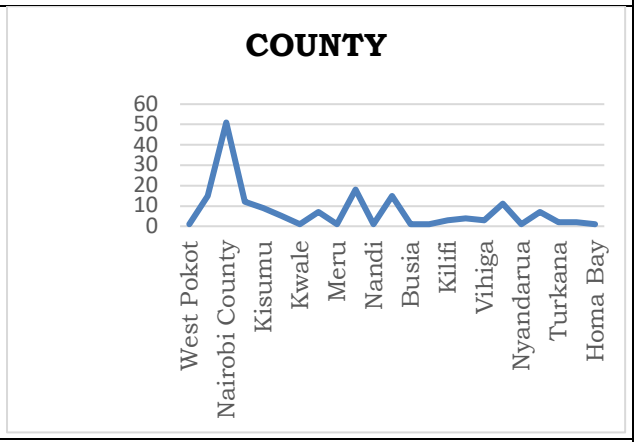




Actions taken by the health care workers included; withdrawal of the offending drug (50.5%). 35.4% reported that no change in dosage was made while, 3.5% did not indicate the action taken.

Most of the reported ADR cases were either recovering or had recovered at 40.1% and 34.8% respectively. 14.5% of the reports had no outcome indicated on them.





In this 2nd Quarter, only 146 facilities out of the 9,000 facilities listed in the Kenya Master facility reported ADRs. 22 facilities reported at least 5 reports and above. The top leading facilities were The Mater Hospital Mukuru with 70 reports, followed by Yala Sub- District hospital with 53 reports (3.8%). Below is a list of top 14 facilities.

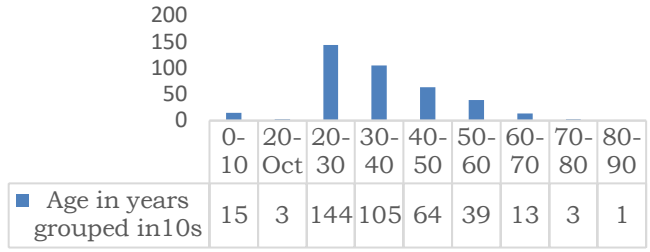
Additionally, ADR reports were received from 38 of the 47 counties. Nairobi county submitted the highest number of ADR reports (219) followed by Siaya (121), Bungoma (76), Kirinyaga (13) and Kakamega (65). The other reporting counties with less than 3 reports were Nyamira, Kitui, Baringo and Tana River.

Institution	Number of reports	Proportion
The Mater Hospital Mukuru	70	12%
Yala Sub-District Hospital	53	9%
EMMAH RANDIKI	27	5%
Dreams Center Dispensary (Lang'ata)	19	3%
Aga Khan Hospital	19	3%
IQVIA	18	3%
Lumakanda District Hospital	16	3%
Bungoma District Hospital	16	3%
Webuye Hospital	14	2%

Mama Lucy Kibaki Hospital - Embakasi	14	2%
Port Reitz District Hospital	13	2%
Nakuru Provincial General Hospital (PGH)	12	2%
Kirinyaga county	12	2%
Kiambu District Hospital	10	2%

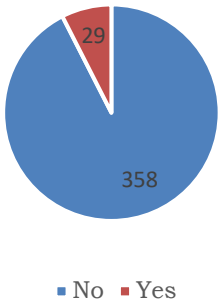
Adverse Events Following Immunizations (AEFIs)

Age Group



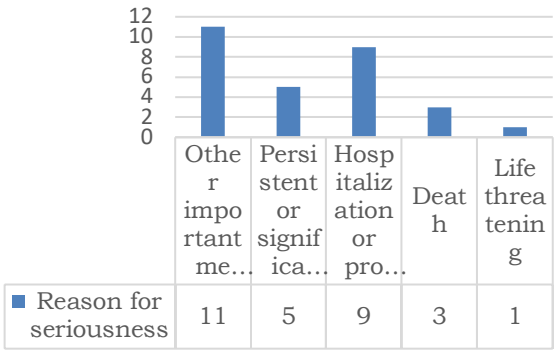
The incidence of AEFIs was highest amongst the adult age group (20-29 and 30-39) in comparison to the others.

Seriousness



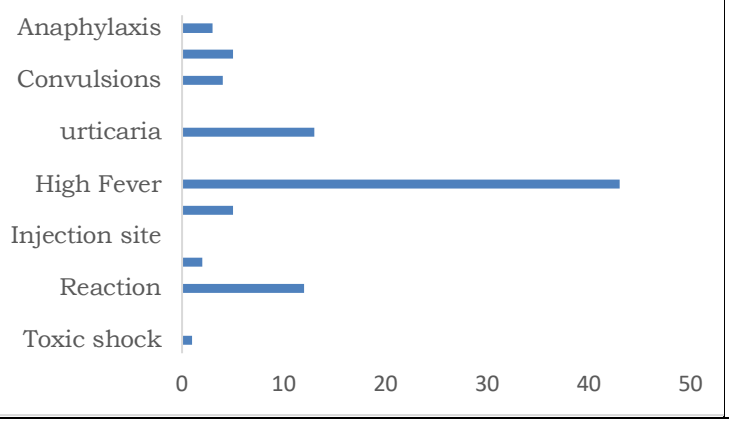
Of the total reports received in Q2, 29% were classified as serious.

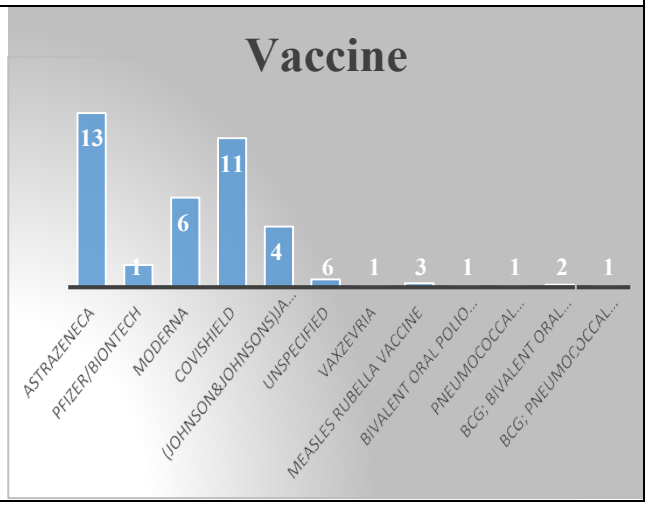
Reason for seriousness

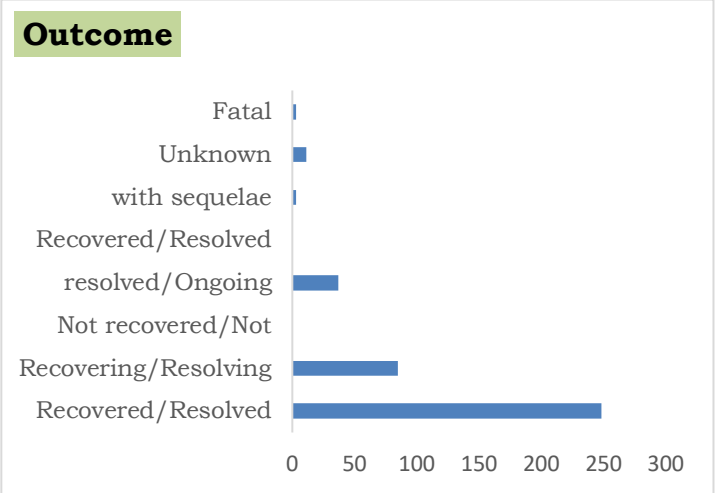
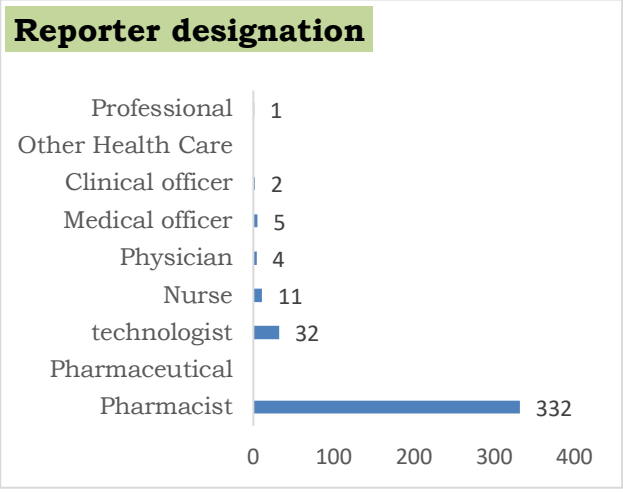
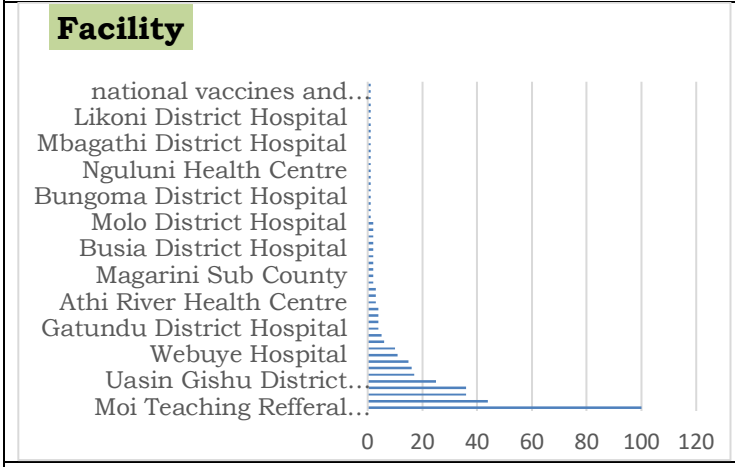
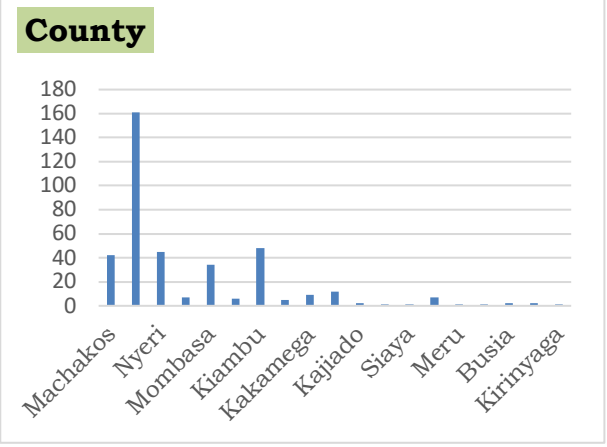


Out of the serious reactions reported, other important medical conditions (37.9%) were the major reason for seriousness.

AEFI type

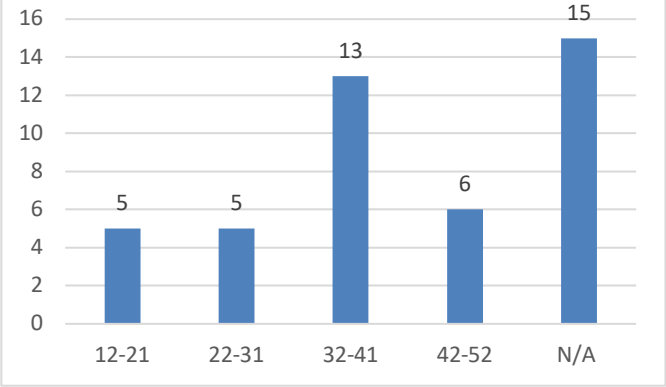




Most commonly reported AEFI types were high fever, urticaria, pain and anaphylaxis.	Most commonly administered Vaccines were Astrazeneca, Covishield, Moderna, and Johnson and johnson.
Outcome 	**Reporter designation** 
Most of the reported AEFI outcome cases were either recovered or recovering at 64.1% and 29.6% respectively. 2.8% of the reports had no outcome indicated on them.	Majority of the reports (85.8%) of the reports were submitted by pharmacists while non health professionals submitted 14.2% reports.
Facility 	**County** 
In this 2nd Quarter, only 188 facilities out of the 9,000 facilities listed in the Kenya Master facility reported ADRs. 21 facilities reported at least 5 reports and above. The top leading facilities were Moi Teaching Referral and Research Hospital with 649 reports (12%) , followed by Nyeri provincial general hospital with 249 reports (6%).	Additionally, AEFI reports were received from 35 of the 47 counties. Uasin Gishu submitted the highest number of AEFIs reports (887) followed by Nyeri (261), Nairobi county (139), Kirinyaga (116) and Machakos (106).The other reporting counties with less than 3 reports were Nyamira, Trans Nzoia, Nandi, West Pokot, Wajir, Taita Taveta, Makueni and Baringo.

Public Adverse Drug Reactions (PADRs)

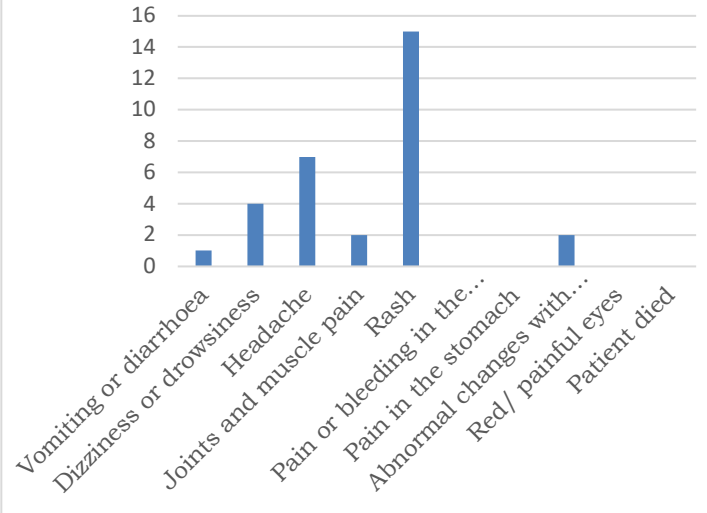
Age groups in 10s



The incidence of ADRs was highest amongst the adult age group (32-41 and 42-52) in comparison to the others. of the total reports (34.1%) did not have age indicated.

PADR type	Times reported
Vomiting or diarrhoea	1
Dizziness or drowsiness	4
Headache	7
Joints and muscle pain	2
Rash	15
Pain or bleeding in the mouth	0
Pain in the stomach	0
Abnormal changes with urination	2
Red/ painful eyes	0
Patient died	0

PADR type



MEDICATION	REPORTS
johnson & johnson covid vaccine	1
vaccine covid	1
praziquantel; mebendazole	1
covishield	1
dolutegravir 50mg lamivudine 300mg tenofovir 300mg	5
ceftriaxone	1
heavy mercaine	1
not indicated	9
dihydroartemisinin /piperaquine phosphate	1
covid-19 vaccine	1
astrazeneca	3
moderna	6
dtg	1
tenofovir/ emtricitabine	2
covid 19	1
oxford	1
moderna moderna	2
moderna2	1
pfizer	1
morna	1
rhze	2
moderna;	2
dolutegravir	1
chlorpheniramine	1

Most commonly reported PADR type was rash, headache and dizziness or drowsiness.

Majority of the PADR reports were from dolutegravir 50mg lamivudine 300mg tenofovir 300mg with 5 reports, moderna vaccine 6 reports and astrazeneca with 3

reports. Of the 47 PADR reports, (19%) were not indicated.

Other Side effects	
difficult of breathing	2
fatigue	2
very weak	2
bloating	2

Medicine source	No.
kinondo health services	1
dispensary ng'ombe la ziwa	2
not indicated	25
agakhan kisumu	2
kemsa	3
meds	1
health center	1
meru teaching and referral hospital	1
kiambu hospital	4
kanunga chief office	2
kiambu referral hospital	4

Other PADR side effects reported included difficulty in breathing, fatigues, weakness and bloating.

Majority of the reports indicated most of the medicines source from Kiambu hospital (4) and from KEMSA. However, 25 of the reports did not indicate the source.

County	Number of PADRs
Kwale	2
Mombasa	2
Trans Nzoia	1
Siaya	1
Kisumu	5
Nakuru	1
Kilifi	1
Nairobi County	13
Homa Bay	3
Meru	1
Kericho	1
Kiambu	12
Baringo	1
Kajiado	1
Machakos	1

Additionally, PADR reports were received from 15 of the 47 counties. Nairobi county submitted the highest number of PADR reports (13) followed by Kiambu (12), and Kisumu (5). Other reporting counties with less than 2 reports were Baringo, Kajiado, Machakos, Kilifi, Siaya, Trans Nzoia, Nakuru, Meru, and Kericho.

Medical device incidence

8 events were reported, 7 from Nairobi hospital and 1 from Kilifi County. 6 females and 2 males were affected. Events were classified as 5 moderate and 3 were mild and all the patients recovered from the events. All the reports were submitted by pharmacist.
Events as described by reporter;

Description of event	
The sieve on the blood burette does not allow smooth flow causing blockage.	1

Tearing of the eyes	1
Teary eyes	1
Irritation of eyes	1
Nausea	2
Stuffy nose	2
Burning of the eyes	2
Nasal blockage	1
Dry eyes	2
Dizziness	1
Reddening of eyes and nose	1
Headache	2
Abdominal discomfort	1
Flu-like symptoms	1
Stomach discomfort	2
Red eyes	1
Diarrhea	2

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*)