



Ministry of Health

PPB Pharmacovigilance Centre

Pharmacovigilance Summary Report: July to October 2021 (Q1)

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.

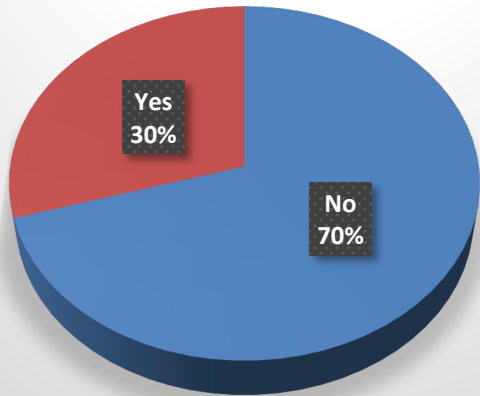
Since the introduction of PV in Kenya, a total of **15,029** individual case safety reports has been submitted to the global data reports **28,328,915** (0.05%).

Suspected Adverse Drug Reactions (SADRs)

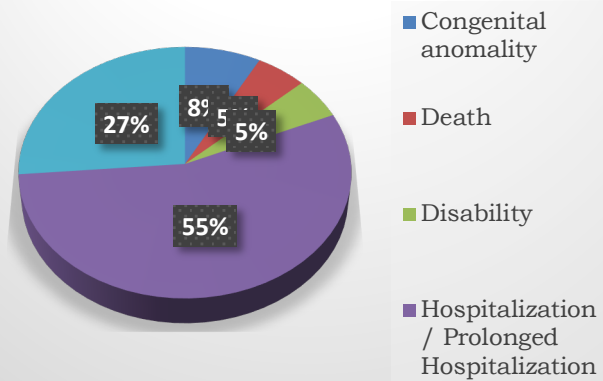
| | | | | | | | | | | | | | |
|---|---|---|-------------------|-----|----------------|---|----------------|---|----------------|---|--------|---|---|
| <table border="1"> <tr> <td>Therapeutic Ineffectiveness</td> <td>2</td> </tr> <tr> <td>Medicinal product</td> <td>166</td> </tr> <tr> <td>Blood products</td> <td>0</td> </tr> <tr> <td>Herbal product</td> <td>0</td> </tr> <tr> <td>Cosmeceuticals</td> <td>0</td> </tr> <tr> <td>Others</td> <td>1</td> </tr> </table> | Therapeutic Ineffectiveness | 2 | Medicinal product | 166 | Blood products | 0 | Herbal product | 0 | Cosmeceuticals | 0 | Others | 1 | <p style="text-align: center;">AGE</p> |
| Therapeutic Ineffectiveness | 2 | | | | | | | | | | | | |
| Medicinal product | 166 | | | | | | | | | | | | |
| Blood products | 0 | | | | | | | | | | | | |
| Herbal product | 0 | | | | | | | | | | | | |
| Cosmeceuticals | 0 | | | | | | | | | | | | |
| Others | 1 | | | | | | | | | | | | |
| <p>Most (98.2%) of the reports on suspected ADRs were caused by medicinal products</p> | <p>The incidence of SADRs was highest amongst the adult age group (45-64 and 18-44) in comparison to the others. A total of 3 reports did not have age indicated.</p> | | | | | | | | | | | | |
| <p style="text-align: center;">GENDER</p> | <p style="text-align: center;">SEVERITY</p> | | | | | | | | | | | | |
| <p>The frequency of reported SADRs was higher in female (60%) compared to male.</p> | <p>Of the total reports received in Q1, 12% were classified as severe while 2% were classified as fatal.</p> | | | | | | | | | | | | |



REACTION SERIOUS



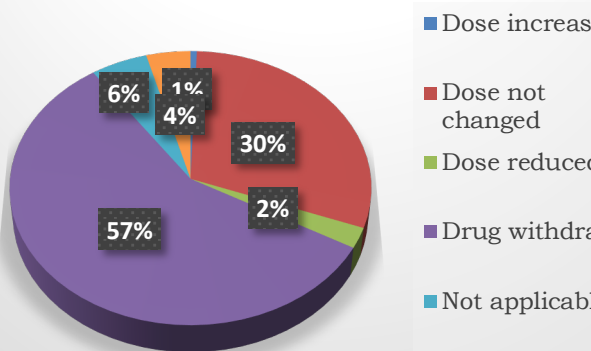
REASONS FOR SERIOUSNESS



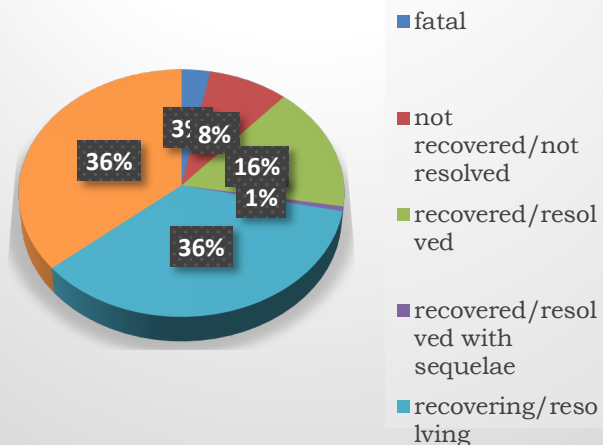
Of the total reports received in Q1, 30% were classified as serious.

Out of the serious reactions reported, congenital anomaly (55%) was the major reason for seriousness.

ACTION TAKEN



OUTCOME



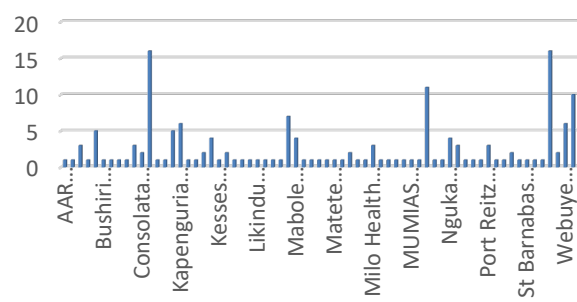
Actions taken by the health care workers included; withdrawal of the offending drug (57%). 30% reported that no change in dosage was made while, 1% did not indicate the action taken.

Out of the SADR reported in 2021, 3% were fatal and 16% had recovered. A total of 36% of the reports did not indicate the outcome.

Reporter designation

| | |
|--------------------------------|----|
| Clinical officer | 33 |
| Medical officer | 1 |
| Other Health Care Professional | 4 |
| Pharmaceutical technologist | 63 |
| Pharmacist | 64 |
| Physician | 1 |

Facility



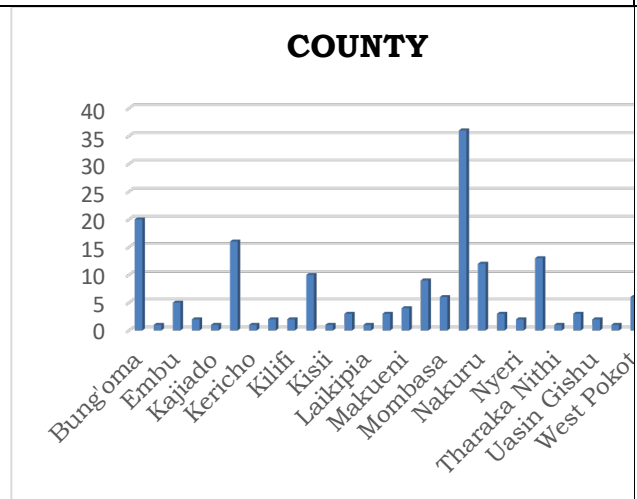
Majority of the reports (38.79% and 38.18%) of the reports were submitted by pharmacists and pharmaceutical

In this 1st Quarter, only 85 facilities out of the 9,000 facilities listed in the Kenya Master facility reported ADRs. 11 facilities reported at



technologists respectively while non healthcare professionals submitted 0.02% reports.

least 5 reports and above. The top leading facilities were Dreams Center Dispensary (Lang'ata) and The Mater Hospital Mukuru with 16 reports (7.8%), followed by Nakuru Provincial General Hospital (PGH) at 11 reports each (5.4%) and Lumakanda District Hospital, Yala Sub-District Hospital and Webuye Hospital with 10 reports each (4.9%) Below is a list of top 14 facilities.



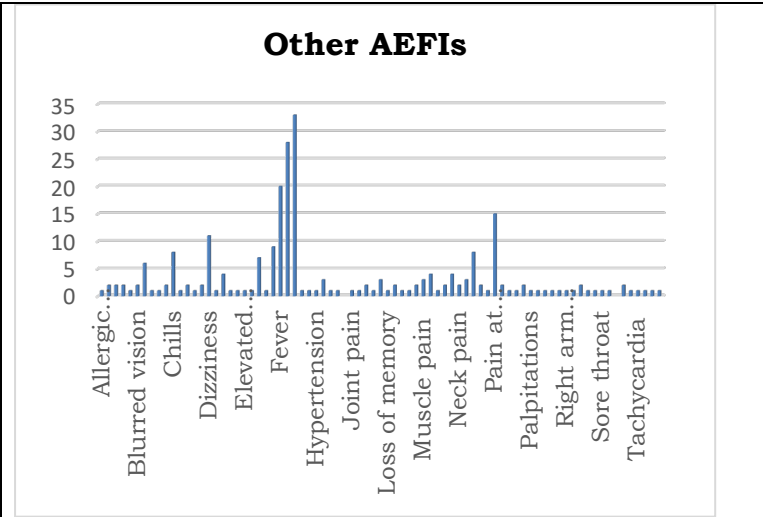
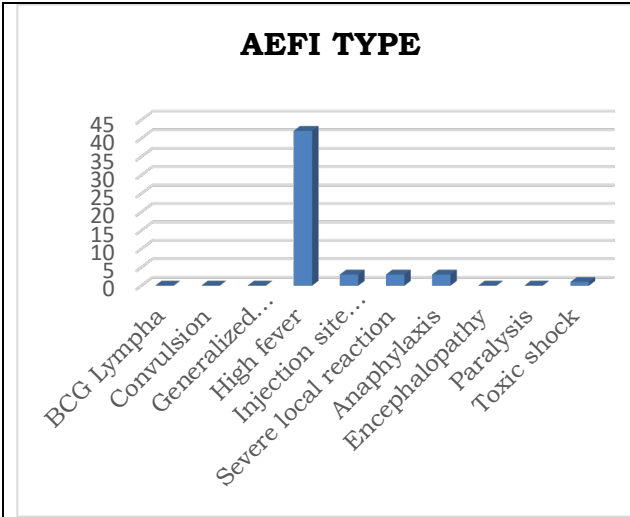
Additionally, SADR reports were received from 29 of the 47 counties. Nairobi county submitted the highest number of AEFI reports (46) followed by Bungoma (26), Kakamega (21), Siaya (19) and Nakuru (12). The other reporting counties with less than 3 reports were Meru, Kwale, Kisii, Laikipia, Tharaka Nithi, Kajiado, Kericho, Busia, Vihiga

| INSTITUTION | REPORTS | INSTITUTION | REPORTS |
|--|---------|--------------------------------------|---------|
| Dreams Center Dispensary (Lang'ata) | 16 | Kapenguria District Hospital | 7 |
| The Mater Hospital Mukuru | 16 | EMMAH RANDIKI | 5 |
| Nakuru Provincial General Hospital (PGH) | 11 | Port Reitz District Hospital | 5 |
| Lumakanda District Hospital | 10 | Bungoma District Hospital | 5 |
| Webuye Hospital | 10 | Njegas Dispensary | 4 |
| Yala Sub-District Hospital | 10 | Mama Lucy Kibaki Hospital - Embakasi | 4 |
| IQVIA | 7 | Mabole Health Centre | 4 |



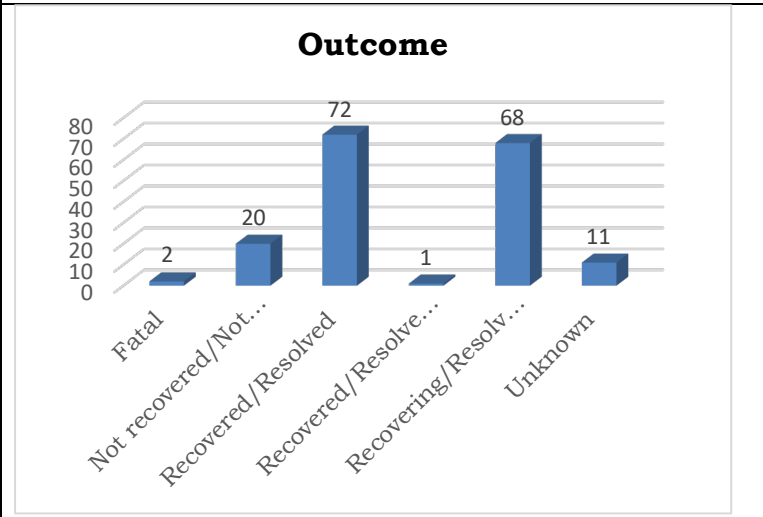
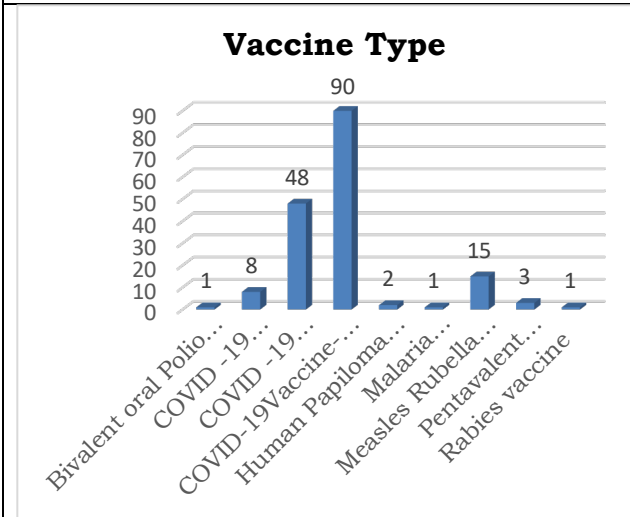
Adverse Events Following Immunizations (AEFIs)

| <p style="text-align: center;">Age group</p> <table border="1"> <thead> <tr> <th>Age group</th> <th>Number of reports</th> </tr> </thead> <tbody> <tr> <td>Unknown</td> <td>3</td> </tr> <tr> <td>>75 years</td> <td>1</td> </tr> <tr> <td>65-74 years</td> <td>23</td> </tr> <tr> <td>45-64 years</td> <td>100</td> </tr> <tr> <td>18-44 years</td> <td>31</td> </tr> <tr> <td>12-17 years</td> <td>0</td> </tr> <tr> <td>2-11 years</td> <td>6</td> </tr> <tr> <td>28-23 months</td> <td>1</td> </tr> <tr> <td>0-27 days</td> <td>0</td> </tr> </tbody> </table> | Age group | Number of reports | Unknown | 3 | >75 years | 1 | 65-74 years | 23 | 45-64 years | 100 | 18-44 years | 31 | 12-17 years | 0 | 2-11 years | 6 | 28-23 months | 1 | 0-27 days | 0 | <p style="text-align: center;">GENDER</p> <table border="1"> <thead> <tr> <th>Gender</th> <th>Number of reports</th> </tr> </thead> <tbody> <tr> <td>Female</td> <td>94</td> </tr> <tr> <td>Male</td> <td>80</td> </tr> </tbody> </table> | Gender | Number of reports | Female | 94 | Male | 80 |
|--|---|-------------------|---------|----|-----------|-----|---|------------------------|-------------|-------|-------------|---|-------------|------------------|------------|-------------------------------|--------------|-------------|-----------|---|--|--------|-------------------|--------|----|------|----|
| Age group | Number of reports | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Unknown | 3 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| >75 years | 1 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 65-74 years | 23 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 45-64 years | 100 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 18-44 years | 31 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 12-17 years | 0 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2-11 years | 6 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 28-23 months | 1 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 0-27 days | 0 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Gender | Number of reports | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Female | 94 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Male | 80 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>The incidence of AEFIs was highest amongst the adult age group (45-64 and 18-44) in comparison to the others. A total of 3 reports did not have age indicated</p> | <p>The frequency of reported AEFIs was higher in female (54%) compared to male.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p style="text-align: center;">Reaction Serious</p> <table border="1"> <thead> <tr> <th>Reaction Serious</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Yes</td> <td>9%</td> </tr> <tr> <td>No</td> <td>91%</td> </tr> </tbody> </table> | Reaction Serious | Percentage | Yes | 9% | No | 91% | <p style="text-align: center;">Reasons for seriousness</p> <table border="1"> <thead> <tr> <th>Reason for seriousness</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Death</td> <td>11%</td> </tr> <tr> <td>Hospitalization or prolongation of existing hospitalization</td> <td>28%</td> </tr> <tr> <td>Life threatening</td> <td>6%</td> </tr> <tr> <td>Other important medical event</td> <td>33%</td> </tr> <tr> <td>Unspecified</td> <td>22%</td> </tr> </tbody> </table> | Reason for seriousness | Percentage | Death | 11% | Hospitalization or prolongation of existing hospitalization | 28% | Life threatening | 6% | Other important medical event | 33% | Unspecified | 22% | | | | | | | | |
| Reaction Serious | Percentage | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Yes | 9% | | | | | | | | | | | | | | | | | | | | | | | | | | |
| No | 91% | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Reason for seriousness | Percentage | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Death | 11% | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hospitalization or prolongation of existing hospitalization | 28% | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Life threatening | 6% | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Other important medical event | 33% | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Unspecified | 22% | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Of the total AEFI reports received in Q1, 9% were classified as serious.</p> | <p>Out of the serious reactions reported, other important medical event (33%) was the major reason for seriousness.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | |



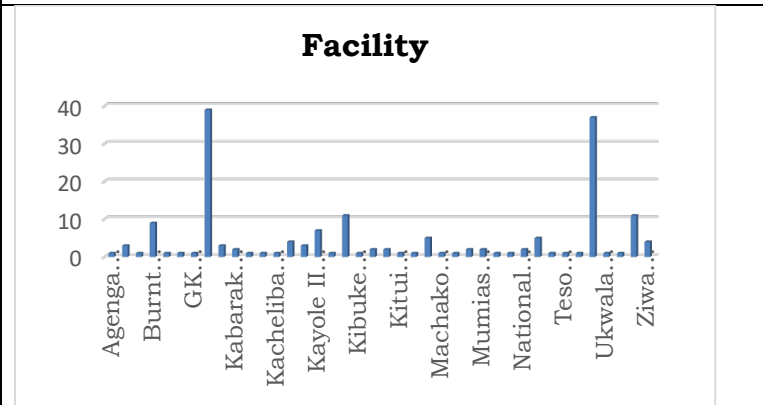
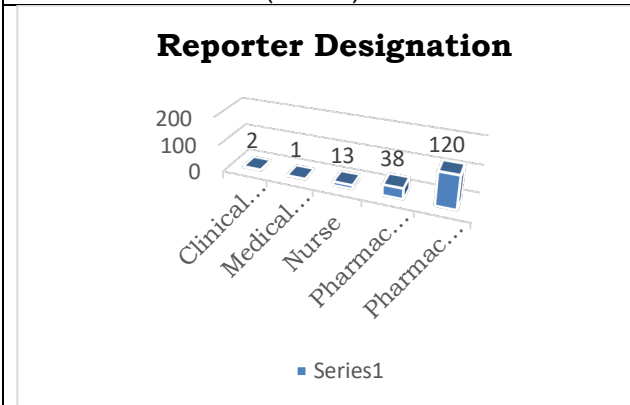
Most commonly reported AEFI type was High fever.

Most commonly reported other AEFIs were Headache, general body malaise, fever, pain at injection site and dizziness.



The most commonly reported suspected Vaccine type causing AEFIs was Covid-19 covishield vaccine (53%), covid-19 moderna vaccine (28%) and measles rubella vaccine (8.9%).

Out of the AEFIs reported in Q1 of 2021, 11.5% did not recover and 41.3% recovered. A total of 6.3% of the reports did not indicate the outcome.



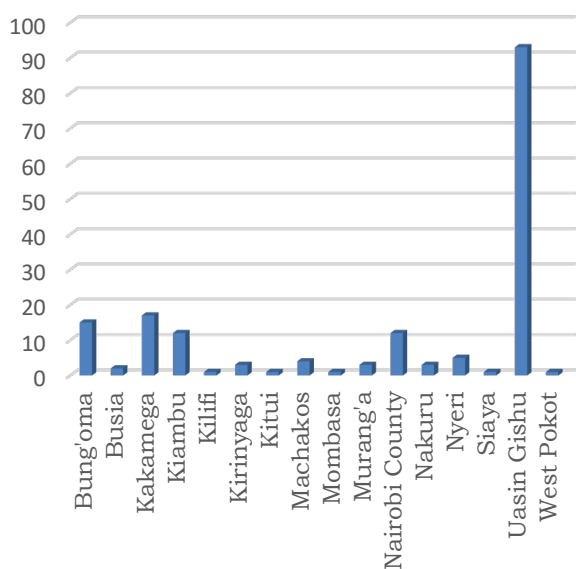
Majority of the reports (69%) of the reports were submitted by pharmacists.

In this 1st Quarter, only 55 facilities out of the 9,000 facilities listed in the Kenya Master facility reported AEFIs. 12 facilities reported at



least 5 reports and above. The top leading facilities were Uasin Gishu District Hospital with 49 reports (19.4%), followed by Huruma District Hospital with 29 reports (11.5%) and Tigoni District Hospital at 18 reports (7.14%). Below is a list of top 14 facilities.

COUNTY



Additionally, AEFI reports were received from 18 of the 47 counties. Uasin Gishu county submitted the highest number of AEFI reports (110) followed by Kiambu (35), Bungoma (20), Machakos and Kakamega (18 each) and Nairobi (14). The other reporting counties with less than 3 reports were Nyamira, Turkana, West pokot, Kitui and Siaya

Top 14 facilities that reported AEFIs

| FACILITY | REPORTS | FACILITY | REPORTS |
|--|---------|--|---------|
| Uasin Gishu District Hospital | 49 | Ziwa Sub-District Hospital | 6 |
| Huruma District Hospital | 29 | Othaya Sub-District. Hospital | 6 |
| Tigoni District Hospital | 18 | Lumakanda District Hospital | 5 |
| Webuye Hospital | 16 | Kakamega Provincial General Hospital (PGH) | 4 |
| Machakos Level 5 Hospital | 14 | Coast Province General Hospital | 3 |
| Kiambu District Hospital | 13 | Athi River Health Centre | 3 |
| Burnt Forest RHDC (Eldoret East) | 11 | Kirinyaga county | 3 |
| Huruma District Hospital ⁰⁷ | 11 | Iguhu District Hospital | 3 |
| Kayole II Sub-District Hospital | 7 | Kapteldon Health Centre | 3 |



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*)