NEWSLETTER ISSUE: 11 JULY 2023

DRUGLENS

Message from the Chief Executive Officer

Dr. Delese Mimi Darko

It is an honor for me to welcome you to the eleventh edition of the DrugLens.

In this year's edition of the DrugLens, we seek to focus on the key achievements of the Technical Advisory Committees responsible for the safety of medicines, vaccines and other health products., FDA's journey to Maturity Level 4 (ML4) and the ultimate realization of our dream of becoming a WHO-Listed Authority.

The Authority has made some giant strides with diverse in-country experts who have supported the safety monitoring of health products to improve consumer safety. The National Pharmacovigilance Center has worked effectively over the years with two standing committees, Technical Advisory Committee on Safety of Medicines (TAC-SM) and the Technical Advisory Committee on Safety of Vaccines and Biological Products (TAC-VBP) who have faithfully served the FDA with dedication to ensure patient safety.

Two ad hoc committees, the Joint Malaria Vaccine Committee (JMVC) and the Joint COVID-19 Vaccine Safety Committee (JCVSRC) have been established with a focus on the safety monitoring of RTS,S and COVID-19 vaccines respectively. These Committees have lived up to the highest standard during the Malaria Vaccine Implementation Program (MVIP) and the deployment of COVID-19 vaccines respectively.

The Committees have supported the FDA in the review of guidelines, and pharmacovigilance training materials and Social and Behavior Change Communication Materials for healthcare professionals and patients.

The Committees have also made recommendations for Marketing Authorization Holders (MAHs) on additional Risk Minimization Measures to be implemented to improve the benefit-risk balance of drugs and vaccines.

The JCVSRC played an important role in review of safety reports during the deployment of COVID-19 vaccines and made recommendations which helped in the safe use of the vaccines and increased confidence in on Ghana's safety surveillance system.

The JMVC reviewed all safety reports from the MVIP and contributed to the decision to expand the use of the malaria vaccine beyond the pilot districts.

Since attaining ML3, the Authority continues to improve its regulatory processes towards becoming an ML4 agency and ultimately a WHO-Listed Authority. The authority is working with partners across the globe to ensure this is achieved within the shortest possible time.

The FDA is particularly grateful to World Health Organization (WHO), Bill and Melinda Gates Foundation, European Union/German Agency for International Cooperation, Africa Union Smart Safety Surveillance (AU-3S) and USP/Promoting the Quality of Medicines Plus (PQM+) program for building capacity for staff of the Authority to transform it into a training hub for the sub-region and a reliance national regulatory agency is also acknowledged.

It's our belief that all these efforts and support from our partners will yield positive results and bring us to our goal of becoming a center of excellence and WHO-listed Authority.

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Individual Case Safety Reports Received in 2022

A total of 2,821 individual case safety reports (ICSRs) were received in 2022. There has been an increase in ICSRs received by the National Pharmacovigilance Centre since 2016. The decrease in the number of reports in 2022 compared to 2021 is attributable to adverse events following immunization (AEFI) reports from the COVID-19 vaccine deployment. Figure 1 shows the number of ICSRs received by year since 2016.

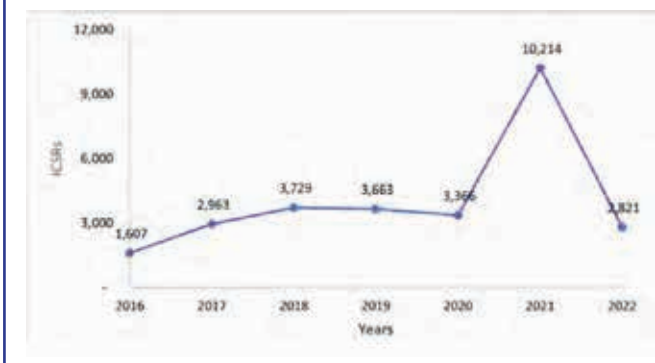

Fig 1: Number of ICSRs from 2016 to 2022

Individual case safety reports to medicines, medical devices, cosmetics and household chemical substances

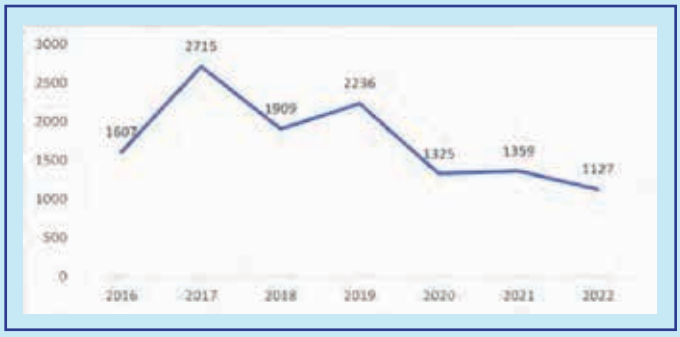

Fig 2: Number of ADRs from 2016-2022

Out of the 2,821 reports received, 1,127 were for medicines, medical devices, cosmetics and household chemical substances and 1,694 for vaccines. These reports were from healthcare professionals, pharmaceutical industries, and patients/consumers.

Figure 2 shows the number of ICSRs for medicines, medical devices, cosmetics, and household chemical substances.

Health care professionals contributed 1,022 (90.7%) reports, 95 (8.3%) from industry and 10 (1.0%) from patients.

Out of 1,127 reports, 46 (4.1%) were suspected product quality issues including substandard and falsified medicinal products, therapeutic ineffectiveness, poor labeling/packaging and defective devices.

The 1,081 reports were adverse reactions to medicines of which 731 (67.6%) were female, 325 (30.0%) male and the remaining 25 (2.4%) were not stated.

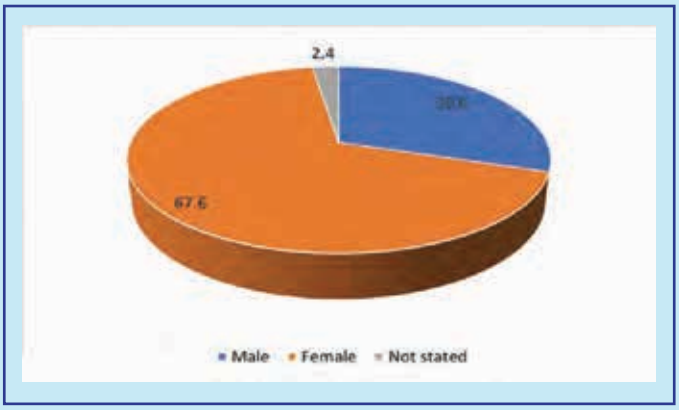

Fig 3: Sex distribution of patients who had adverse reactions

Spontaneous reports received from different reporters as shown in Figure 3.

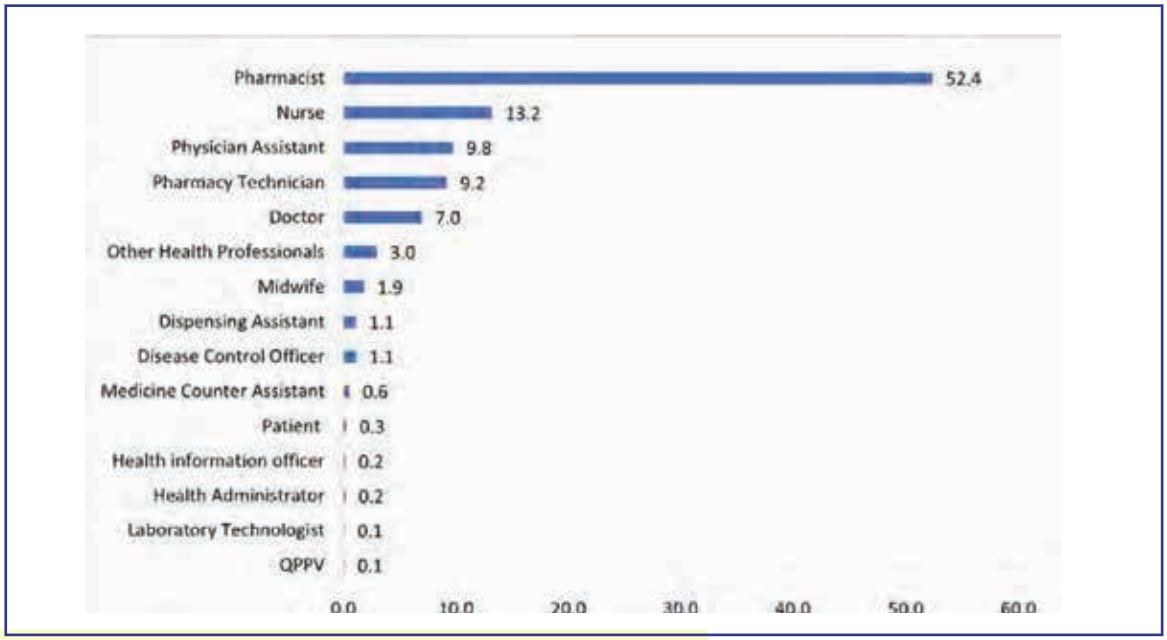

Fig 4: Percentage of ICSRs from different reporters

The top 15 medicines with the most reported adverse reactions are shown in Figure 5

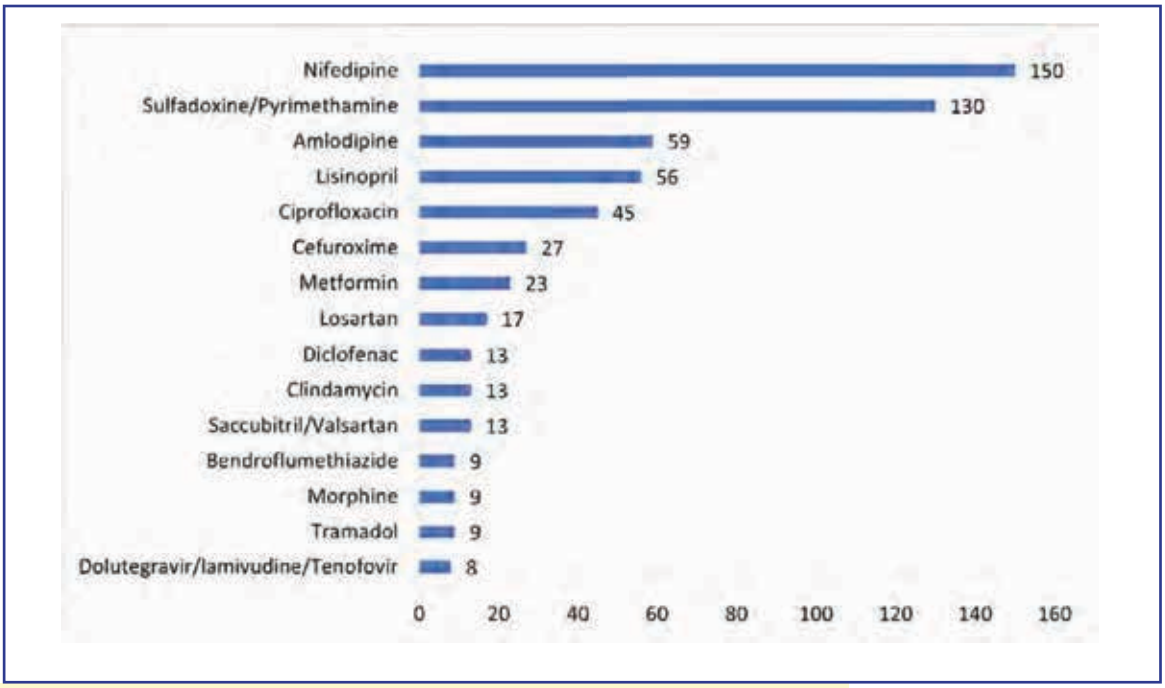

Fig 5: Top 15 medicines with the most reported adverse reactions.

The outcome of reactions at the time reports were received is shown in Figure 6.

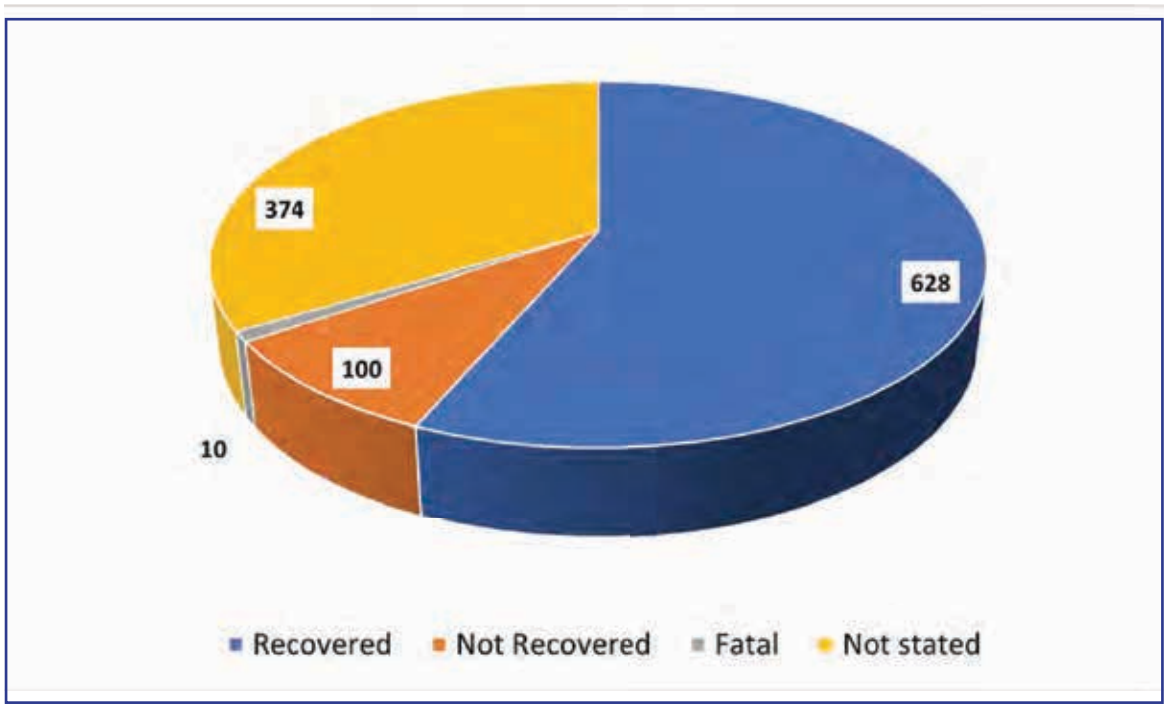

Fig 6: Outcome of reported adverse reactions

Figure 7 is the contribution of 16 regions to the spontaneous reports received per 100,000 population based on the 2021 Population and Housing Census.

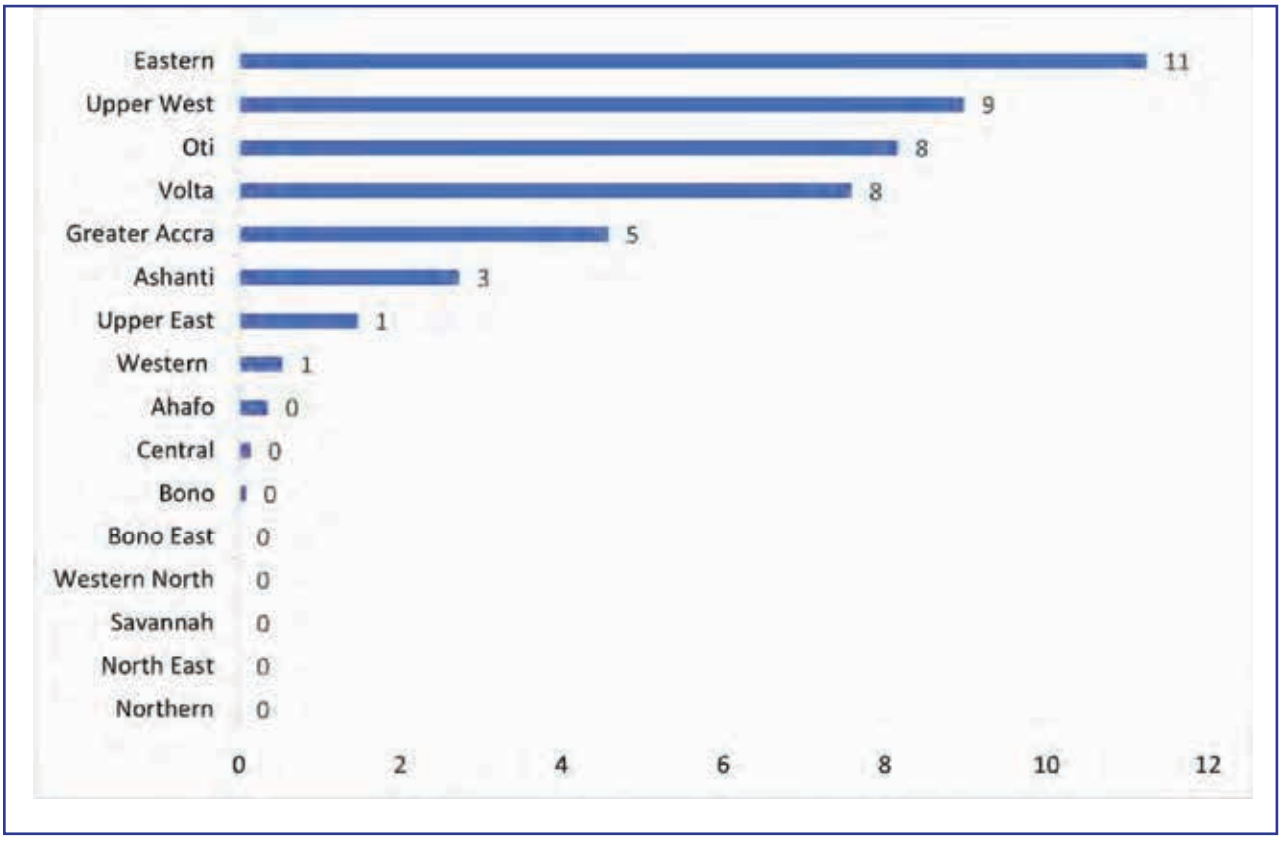

Fig 7: Regional distribution of the spontaneous reports received per 100,000 population

From Figure 5, the Eastern Region emerged as the region with the highest number of reports. The outstanding performance of the region is due largely to the excellent working relationship between healthcare professionals and the FDA Regional Office.

Table 1 represents the top twenty healthcare facilities that submitted reports to the National Pharmacovigilance Centre in 2022 with 8 (40.0%) facilities from the Eastern Region.

Table 1: Top twenty reporting healthcare facilities

Facility	***Region***	***Number of Reports***
Atua Government Hospital	Eastern	77
Komfo Anokye Teaching Hospital	Ashanti	63
Anlo-Afiadenyigba Health Center	Volta	59
Korle Bu Teaching Hospital	Greater Accra	54
University of Ghana Medical Center	Greater Accra	34
Suntreso Government Hospital	Ashanti	33
Eastern Regional Hospital	Eastern	29
Tetteh Quarshie Memorial Hospital	Eastern	24
Suhum Government Hospital	Eastern	22
Eyiresi Government Hospital	Eastern	22
St Joseph Hospital, Koforidua	Eastern	21
Weija-Gbawe Municipal Hospital	Greater Accra	19
Poase Cement Health Center	Oti	18
Jasikan District Hospital	Oti	18
Ho Teaching Hospital	Volta	17
Peki-Dzake Health Center	Volta	14
Kade Government Hospital	Eastern	14
Damako Health Center	Oti	13
The Bank Hospital	Greater Accra	13
Kwahu Government Hospital	Eastern	13

Adverse Event Following Immunization (AEFI) Reports

One thousand six hundred and ninety-four (1,694) AEFI reports were received in 2022. Of these 1,276 (75.3%) were from the spontaneous monitoring whilst 418 (24.7%) reports were through active monitoring of Novel Oral Polio Vaccine type 2 (nOPV2) and Phase IV study of RTS,S (Mosquirix).

The results of the causality assessment by the TAC-VBP for 27 serious AEFIs received for routine vaccines using the process outlined in the WHO User Manual on Revised Classification of AEFI is shown in Figure 8.

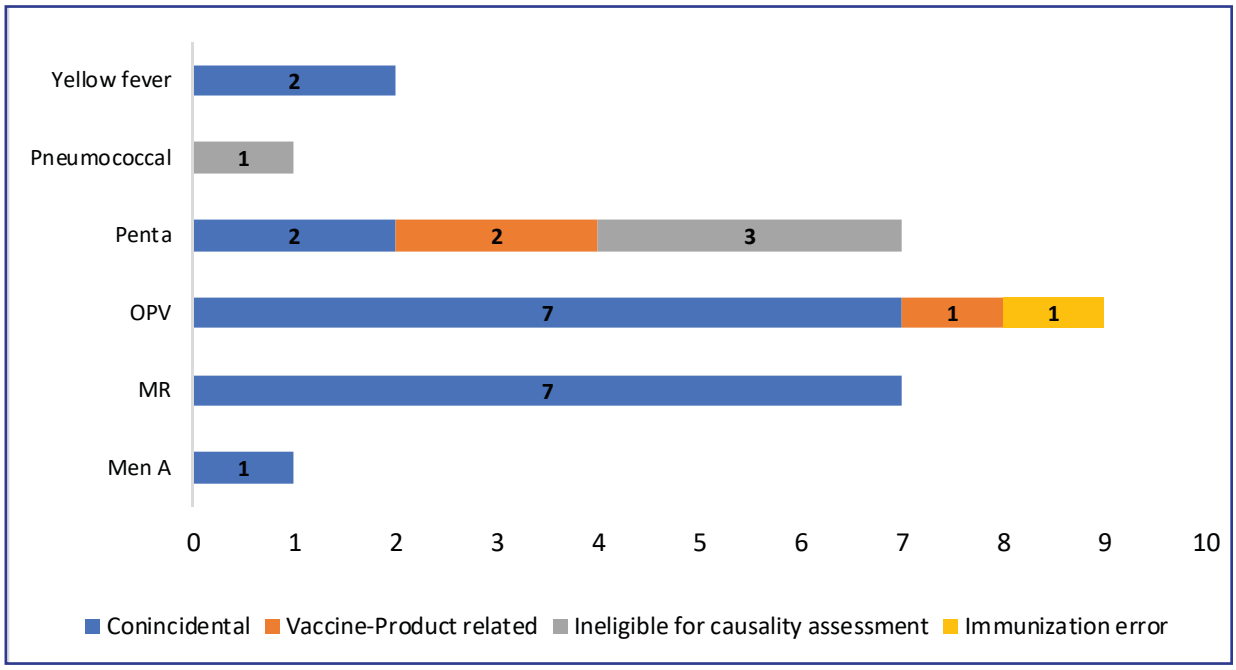

Fig 8: Causality assessment of serious AEFI cases per antigen received through the passive reporting system.

OPV –	Bivalent Type 1&3 Oral Poliomyelitis Vaccine (bOPV)
Penta -	Pentavalent vaccine (Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B and Haemophilus influenza vaccine, Adsorbed)
MR –	Measles and Rubella vaccine
Men A –	Meningococcal A conjugate vaccine (lyophilized)
Pneumococcal -	Pneumococcal-13 valent Conjugate vaccine

The regional distribution (no. of AEFI cases and AEFI rate per 100,000 surviving infants of reports received through the GHS reporting pathway is as shown in Figure 9.

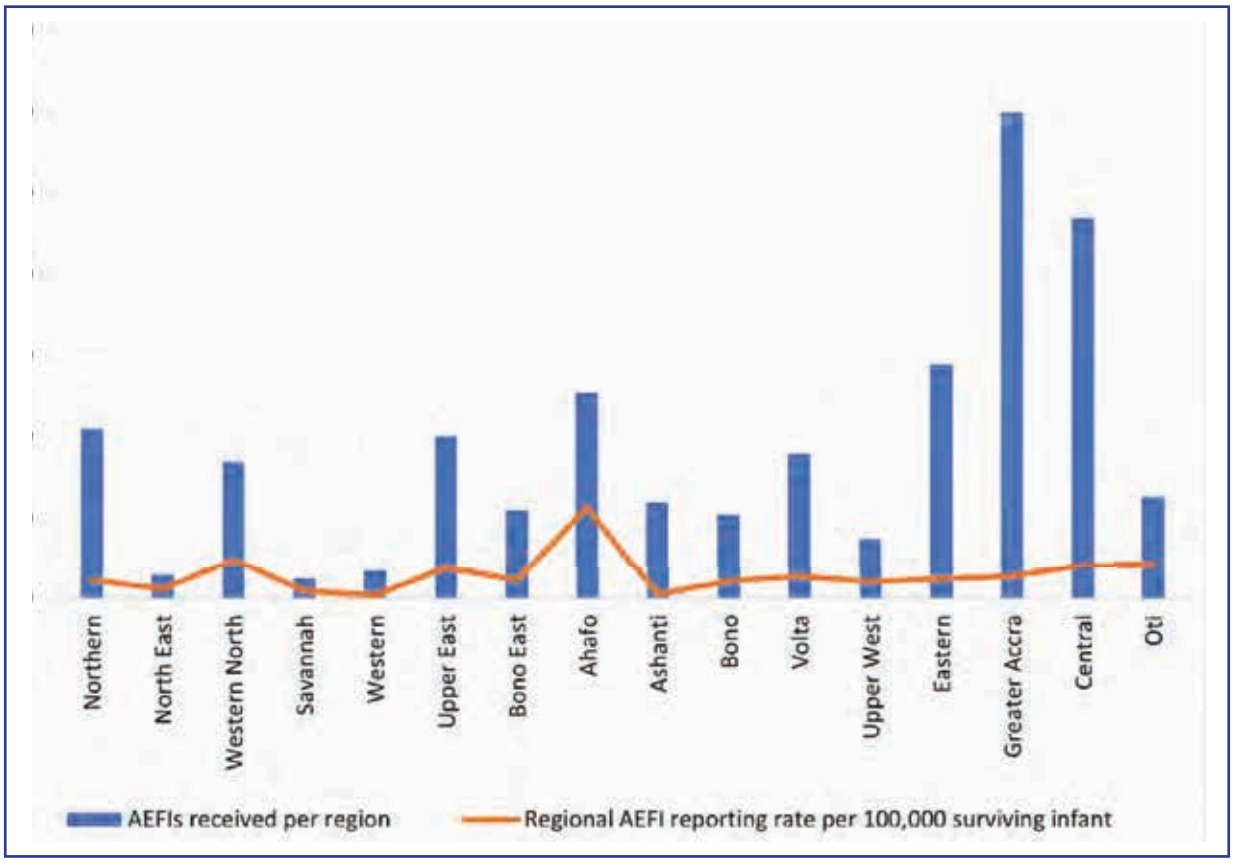

Fig 9: Regional AEFI reporting rate per 100,000 surviving infants for all vaccines administered in 2022.

One hundred and five AEFI reports were from the MVIP in 2022 with 100 from the Phase IV study, 3 from Enhanced spontaneous reporting and 2 from the malaria vaccine pilot evaluation (MVPE).

The outcome of the causality assessment of the 37 out of 71 serious cases by the JMVC is shown in figure 10.

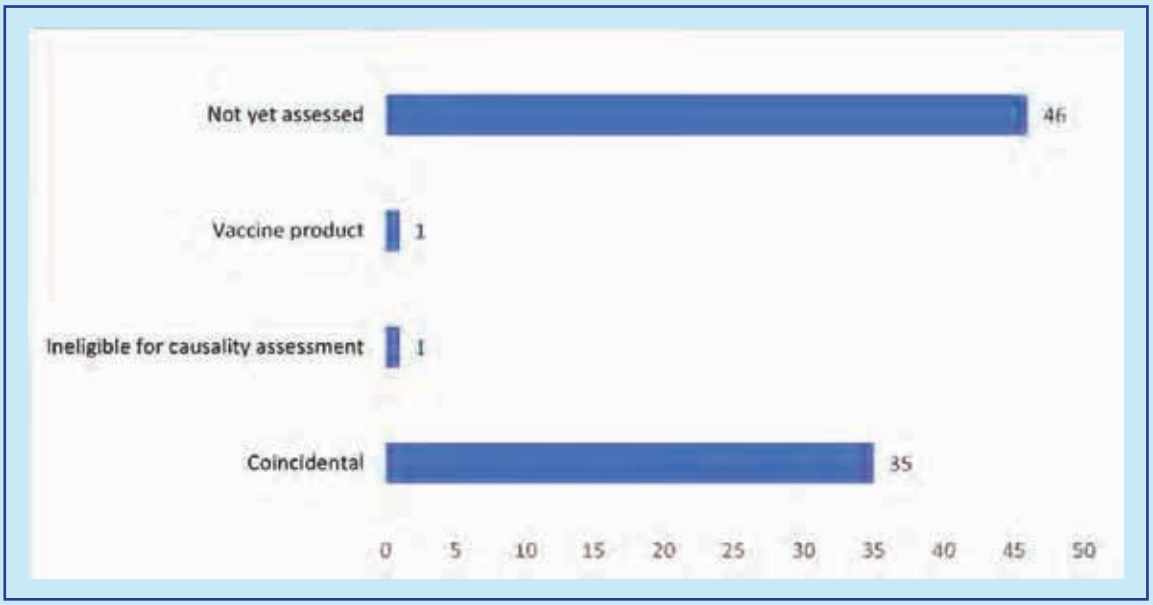

Fig 10: Outcome of causality assessment of 37 serious AEFIs received through the MVIP

Safety Monitoring of COVID-19 Vaccines

A total of 23,676,290 doses of the five vaccines (Covishield/ Vaxzevria, COVID-19 vaccine Janssen, Moderna COVID-19 vaccine, Pfizer BioNTech COVID-19 vaccine, Sputnik V) have been deployed in Ghana since 1st March 2021.

The FDA's Joint COVID-19 Vaccine Safety Review Committee (JCVSRC) reviewed the 9,521 AEFI reports and carried out causality assessment for 63 serious AEFIs reports. The outcome of the causality assessment is shown in Figure 11.

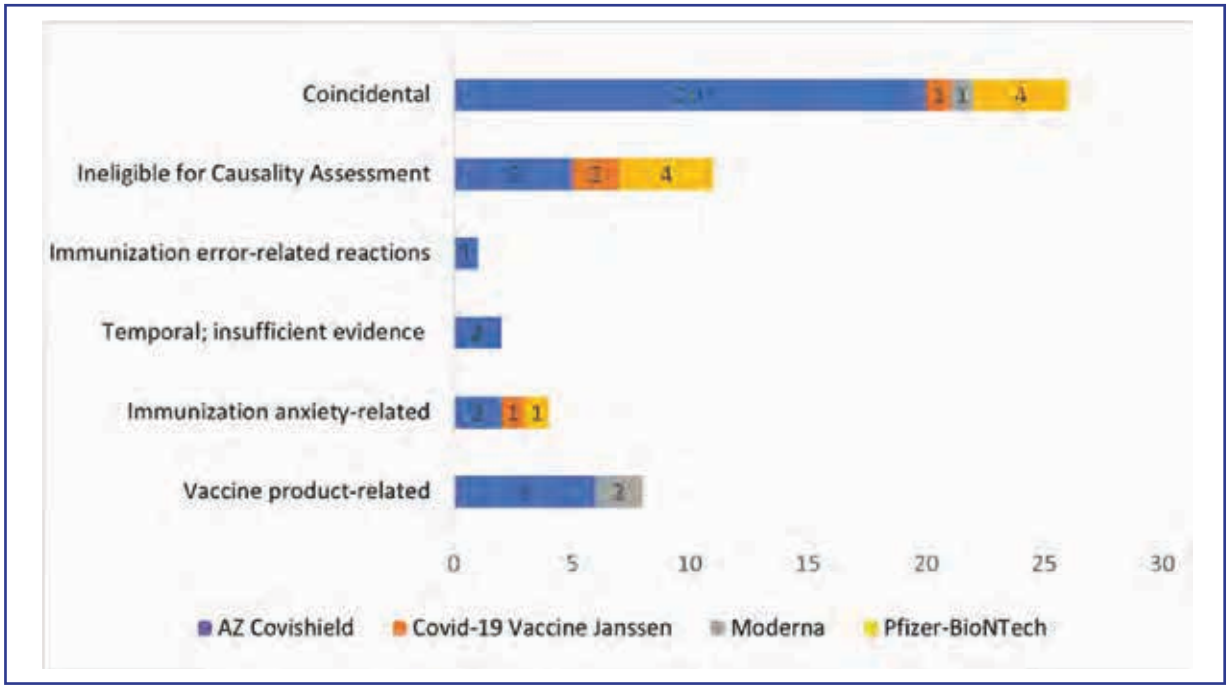

Fig. 11: Causality assessment for COVID-19 vaccines

Reporter of the Year 2022

Pharm. Dr. Derrick Kyei Baffour used to run errands for his grandfather who needed reminders on the names of his medicines. His desire and curiosity to know the details of medicines at the time pushed him to pursue a career in pharmacy. Derrick developed interest in patient safety during his housemanship period under the mentorship of Pharm Edward Abeasi at St Joseph Orthopedic Hospital, Koforidua. As a pharmacist at Atua Government Hospital, his passion is to educate clients on adherence and medicine safety issues.

PATIENT SAFETY CENTER UPDATES

The year 2022 marked the 6th anniversary of the Patient Safety Centre (PSC) initiative launched by the FDA to promote direct patient reporting of medicine safety issues through community pharmacies.

Over 700 community pharmacies have been designated as PSCs since the launch of the program with more than 300 reports received from these pharmacies. Figure 12 provides the percentage contribution of safety reports from each of the regions in Ghana.

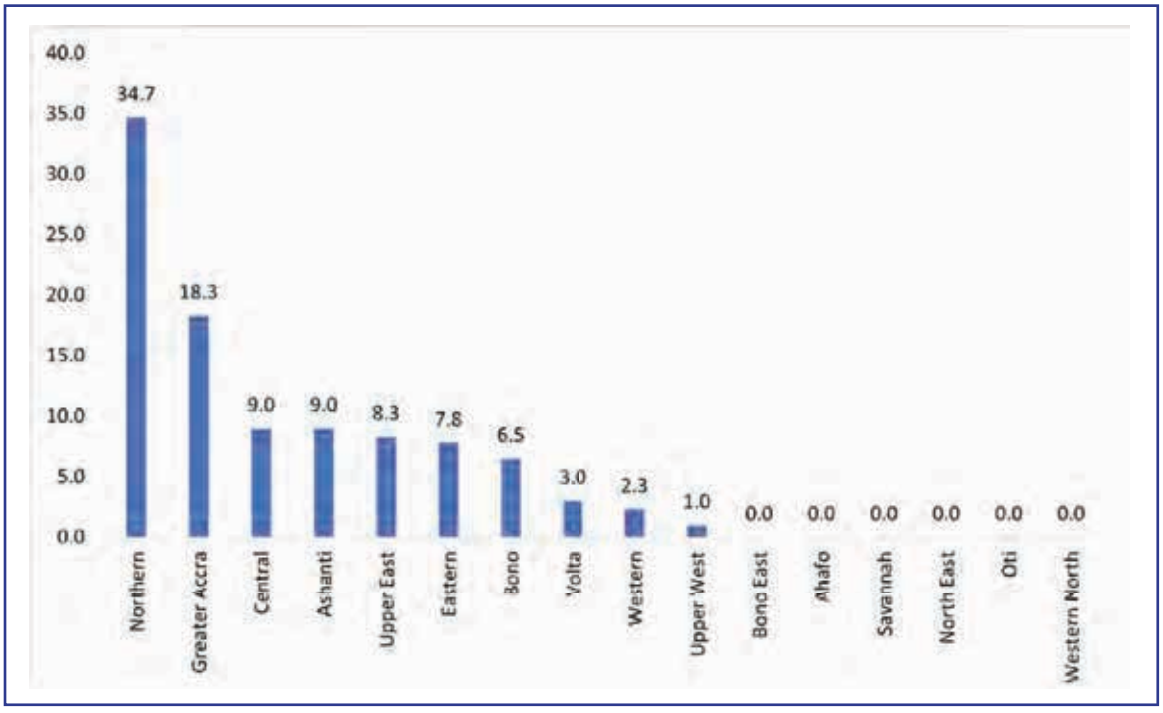

Fig. 12: Regional Performance (%) of Patient Safety Centers across Ghana 2016 - 2022.

The FDA awarded eighteen community pharmacies (Table 2), at the 2022 Annual General Meeting of the Pharmaceutical Society of Ghana held in Tamale for their commitment to patient safety.

Table 2: PSC Awarded at 2022 Pharmacists AGM

NO.	LIST OF FACILITY	REGION
1	Peniel Pharmacy	Greater Accra
2	Cape Pill Pharmacy	Central Region
3	Union Square Pharmacy	Central Region
4	Obrasi Pharmacy	Northern Region
5	Super Light Pharmacy	Northern Region
6	Equity Pharmacy	Greater Accra
7	Trust Care Pharmacy	Northern Region
8	Smart Chemist	Northern Region
9	Open Arms Pharmacy	Northern Region
10	Mauplaus Pharmacy	Northern Region
11	Fabby Chemist	Greater Accra
12	Gina Pharma	Northern Region
13	Royal Avenue Pharmacy	Ashanti Region
14	Barzila Pharmacy	Brong Ahafo
15	G & E Health Service	Volta Region
16	Honsal Pharmacy	Central Region
17	Smart Chemist	Northern Region
18	City Care Pharmacy Ltd.	Greater Accra

Fig 12: Photos of award recipients

Patient Safety Centre 2022

Fig. 13: Patient Safety Centre reporter of the year, 2022

The FDA received 8 ADR reports from PSCs in 2022 with Losab Pharmacy in the Eastern Region submitting the highest number of reports as shown in Table 3.

Pharm Dr. Affum Jeffrey Baah led his team to submit the reports from Losab Pharmacy and believes that community pharmacies are uniquely positioned to provide comprehensive pharmaceutical care to clients.

Table 3: Reporting Patient Safety Centres in 2022

Facility	***Region***	***No. of Report***	***Reporter***
Losab Pharmacy	Eastern	3	Dr. Affum Jeffery Baah
Peniel Pharmacy	Greater Accra	1	Dr. Josephine Mensah
Patient Safety Report	Ashanti	1	Ms. Cynthia Amoako
Kab Pharmacy	Greater Accra	1	Ms. Priscilla Okyere
Bc Bencyn Pharmacy Ltd	Upper East	1	Mr. Henry Anyanah
Mosan Fontlife Pharmacy	Western	1	Mr. Moses Adjei

Medicines with Additional Risk Minimization Measures

Additional Risk Minimization Measures (aRMM) have been implemented for three medicinal products to improve their benefit-risk profile.

Paracetamol IV: Paraconica and Paracetamol Sandoz

Indication:

- For short-term treatment of mild to moderate pain when oral administration is not possible (e.g. immediately post-operatively when non-steroidal anti-inflammatory agents are often contraindicated).
- For short-term treatment of fever.

Safety Concern:

Medication error (overdose due to confusion between ml and mg in underweight adult patients)

aRMM: Dosing card.

The dosing card will be distributed to healthcare workers with the aim of reducing the risk of medication errors that occur due to confusion between ml and mg, particularly in underweight patients. It will give healthcare professionals convenient tool for calculating the correct dose of IV paracetamol.

In the case of Paracetamol Sandoz, a poster will also be distributed.

Axaban-Denk (Apixaban) Tablet

Indication:

- Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery.
- Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥ 75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class ≥ II).
- Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

Safety Concern:

Bleeding

aRMM: Patient Alert Card

The patient alert is provided to patients via the package, the Denk Pharma webpage and the prescribing physician to inform the patient about the risk of bleeding and to advise in case of imminent surgery.

Hydroxycarbamide (Hydroxyurea) Tablet

Indication

Prevention of recurrent painful vaso-occlusive crises including acute chest syndrome in adults, adolescents and children older than 2 years suffering from symptomatic Sickle Cell Syndrome

Safety Concern

- Male fertility (spermatogenesis and spermatozoa function)
- Effect on embryogenesis, teratogenic potential, breast-feeding and post-natal development of progeny
- Handling of tablets
- Medication error

aRMM: Educational Materials

- Dosing Sheet
- Patient guide
- Physician guide

These additional risk minimization activities aim to ensure the safe and effective use of hydroxycarbamide, 100 mg and 1000 mg, film-coated tablets. The educational materials for prescriber and patients is communication tool designed to inform, educate and mitigate the important risks.

Safety Monitoring of New Chemical Entities

Novel Oral Polio Vaccine Type 2 (nOPV2)

The Ghana Health Service (GHS) was notified by the Noguchi Memorial Institute for Medical Research (NMIMR) on 20th May 2022 of the detection of circulating vaccine-derived poliovirus type 2 (cVDPV2) in environmental samples from Koblimahgu and Nyanshegu in Tamale Metropolis, Northern Region. The GHS and its partners responded by investigating the outbreak, assessing the risk, and conducting a vaccination campaign using the WHO recommended vaccine, novel Oral Polio Vaccine Type 2 (nOPV2). The nOPV2 was deployed to target children age 0 to 5 years.

The FDA in collaboration with the GHS used both active and spontaneous monitoring strategies during the deployment of the vaccine. As part of the active monitoring strategy, 16 sentinel sites were established with one in each region with 3,313 children followed up.

Figure 14 provides the number of participants enrolled in the active follow up per region.

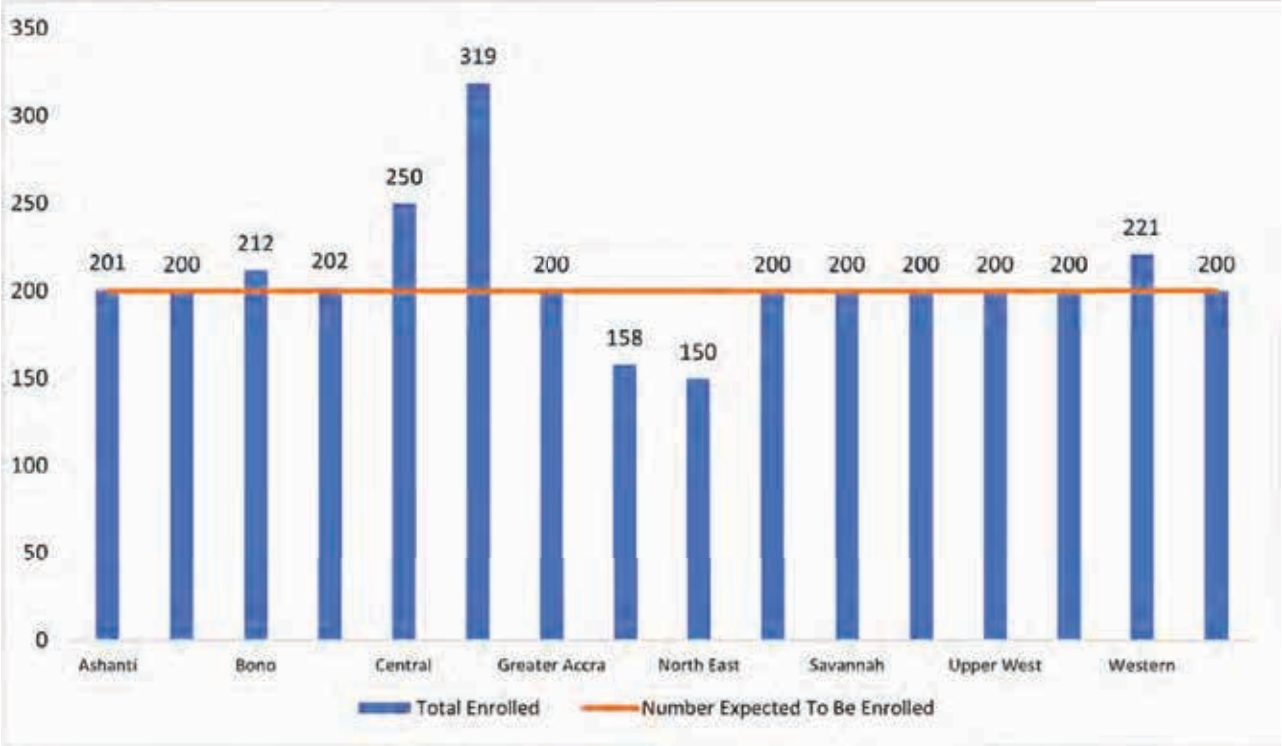

Fig.14 provides the number of participants enrolled in the active follow up per region.

The campaign involved two rounds of vaccination with 14,420,744 doses administered.

Three hundred and sixty-six AEFIs were reported giving an AEFI reporting rate of 2.5 per 100,000 doses administered.

Table 4 provides details of doses administered and AEFIs received during the campaign.

Table 4: Details of doses administered and AEFIs

Details of AEFIs (n, %)				Method of Detection	
Round	Doses administered	Number of AEFIs	AEFI reporting Rate per 100,000 doses administered	Active	Passive
1	6,554,790	174 (47.53)	2.65	137	37
2	7,653,922	192 (52.47)	2.51	142	50
Mop up	209,032	0	0	0	0
Total	14,420,744	366	2.54	279	87
Seriousness of AEFI					
Non-serious				316 (86.3)	
Serious				50 (13.7)	

AEFIs received post doses 1 and 2 were fever, diarrhea, vomiting, cold, cough, headache etc. which were mild to moderate mostly occurring same day and day 2 after vaccination. The study helped to gather local data to support the safety of the use of nOPV2 vaccines Ghana. Overall, there were no safety concerns that could hinder the continuous use of the vaccine as part of routine vaccinations in Ghana.

SAFETY COMMUNICATIONS

Recall of Pfizer's Accupril (Quinapril Hydrochloride)

The safety alert was sent to healthcare professionals and consumers following a voluntary recall by Pfizer of five (5) batches of the antihypertensive drug Accupril (Quinapril Hydrochloride).

Quinapril is indicated for the treatment of hypertension, to lower blood pressure and in management of heart failure as an adjunctive therapy when added to conventional therapy including diuretics and /digitalis.

The purpose of the safety notification was to alert consumers and healthcare professionals about the cancer-causing contaminant N-Nitroso Quinapril that was found in some batches of Accupril. Patients were encouraged to seek medical counsel from their healthcare providers in cases where they were on any of the affected batches. Healthcare professionals with patients taking the affected batches were advised to assess if their products were affected and provide alternatives.

Risk of Serious, Life-Threatening Adverse Event - *Bradycardia, Associated with the use of Sevoflurane in Down Syndrome Patients*

The aim of this Dear Healthcare Professional Letter was to notify healthcare professionals of bradycardia, a serious life-threatening adverse event associated with the use of sevoflurane in patients with Down syndrome.

This safety update followed a recommendation by the Ghana Food and Drugs Authority's Technical Advisory Committee on Safety of Medicines (TAC-SM) after review of regulatory safety action by the United States Food and Drugs Administration (US FDA). The US FDA assessed and classified bradycardia as a serious, life-threatening adverse event with reasonable causal association with the use of sevoflurane in patients with Down syndrome. The safety issue is not adequately described in terms of the events or steps to decrease its likelihood or minimize its severity in the product information.

At the time that this Dear Healthcare Professional Letter was published, FDA Ghana had not received any report of bradycardia following the use of sevoflurane in patients with Down syndrome, which could be due to the probability of few patients being operated on. However, a regulatory action was needed to ensure the safety of these patients due to the severity of the event.

Newsworthy Activities

The African Union Smart Safety Surveillance (AU-3S) programme

The African Union Smart Safety Surveillance (AU-3S) programme was launched in 2020. It is led by AUDA-NEPAD and aims to create a sustainable continental safety monitoring system to improve the safety of priority medical products for patients across Africa. The programme aim to achieve this through efficiencies like technological innovation, pooling of resources, and work sharing.

The AU-3S is currently piloting its approach on the safety surveillance of COVID-19 vaccines in five countries: Ethiopia, Ghana, Nigeria, South Africa and Kenya.

Some achievements of AU-3S Programme include:

- Formation of at the Joint Signal Management Group (JSMG) for signal assessment of priority medicines
- Implementation of the Data Integration and Signal Detection (DISD) system for pooled safety data from participating countries
- Capacity strengthening of pharmacovigilance and communication staff of participating countries.


Decentralization of pharmacovigilance to lower-level healthcare focal persons

The Safety Monitoring Department in a bid to improve patient safety with regards to use of medicines and vaccine organized 16 training workshops for healthcare workers in 8 selected regions in Ghana. A total of 414 healthcare workers from lower-level healthcare facilities were trained in collaboration with the Regional and District Health Directorates of the Ghana Health Service. The cadre of professionals included physician assistants, public health nurses, disease control officers within practicing in CHIPS compounds and health centers. The objectives of the training was to introduce the healthcare workers to use the Med Safety App to reports safety issues of medicines and explore ways to improve safety monitoring of drugs, vaccines and other health products facilities. This activity was funded by the Promoting the Quality of Medicines Plus (PQM+) Programme under the U.S. Agency for International Development (USAID).

WHO workshop on the strategic planning for improved maturity in pharmacovigilance for the Anglophone ECOWAS Member states

The World Health Organization to ensure vaccine safety supported country visits in 2022 with the aim of peer reviewing the surveillance and management of Adverse Events Following Immunizations (AEFIs). The review revealed the gaps as well as the best practices with the AEFI surveillance system.

Following the peer review, two workshops; one for francophone countries and another for anglophone countries were planned. Ghana hosted the workshop for anglophone countries form in Accra from 8th to 12th May 2023. The expected outcome of the workshop was for countries to develop a roadmap to help increase countries' pharmacovigilance maturity levels as per the WHO Global Benchmarking Tool and enhance collaboration among pharmacovigilance stakeholders for optimal utilization of capacity and resources.

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In our attempt to improve on our information sharing on safety issues relating to medicines through our newsletter, the DrugLens, we wish to collect your view on any edition of the newsletter you recieve.

Name (optional): .....
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E-mail (optional): .....
1. Has the newsletter been beneficial to you? .....
2. Do you plan to share the newsletter with other colleagues, friends? Yes ☐ No ☐
3. Any other comments: .....
.....
.....

EDITORIAL TEAM

What to report?

The FDA encourages the reporting of all suspected adverse reaction to medicines, including vaccine, Over-the-Counter medicine and herbal, traditional or alternative remedies. We particularly request reports of:

- All suspected ADR's whether known or not which cause concern in the caregiver/the patient.
- Lack of efficacy/therapeutic failure
- Suspected pharmaceutical defect
- Counterfeit pharmaceuticals.
- Mediation errors

You don't need to be certain, just be suspicious!

Report maybe submitted using the FDA "BlueForm" available at hospitals and pharmacies and also available at the FDA website https://fdaghana.gov.gh/ or the Med Safety app available from the Google play store on android or App store for IOS. You may also contact the National Pharmacovigilance Centre on Mobile No: 0244310279 or Email: drug.safety@fda.gov.gh or any of the FDA regional Offices.