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DRUGLENS

Message from the Chief Executive Officer

Delese Mimi Darko

This is to welcome you to the 10th Anniversary Edition of the DrugLens. The Food and Drugs Authority is grateful to our numerous readers and stakeholders for their patronage over the decade.

In this issue, we wish to focus on three important areas affecting the availability of good quality, safe and efficacious medicines/vaccines. These are safety monitoring of COVID-19 vaccines and therapeutics, manufacturing of vaccines and activities to attain World Health Organization (WHO) maturity level 4 (ML4) regulatory status.

First of all, the FDA continues to perform its mandate of ensuring the safety of all persons receiving COVID-19 vaccines and therapeutics granted Emergency Use Authorization (EUA) through its robust safety monitoring system. To effectively achieve this objective, the FDA received support from partners such as Promoting the Quality of Medicines Plus (PQM+) Program and the Africa Union Smart Safety Surveillance (AU-3S) project. The PQM+ program is supporting the FDA to carry out cohort event monitoring of COVID-19 vaccines whiles the AU-3S program is helping the FDA strengthen the pharmacovigilance system in general including capacity building of staff and the Joint COVID-19 Vaccine Safety Review Committee, procurement of IT equipment and upgrade of SafetyWatch System to improve management of safety reports and signal detection capacity amongst others.

Secondly, in line with the Government's 10-year plan to make Ghana a vaccine manufacturing hub in the sub-region, the FDA has received support from the German Development Cooperation (GIZ) and the European Union (EU) under the Team Europe, to support the implementation of Ghana's first ever major strategic intervention on domestic vaccine production. This partnership will facilitate the upgrade and strengthening of the FDA and contribute to the regulation of production of various vaccines. This collaboration is aimed at ensuring domestic vaccine production to prevent the inequitable supply of COVID-19 vaccines during the pandemic in Africa and other low- and middle-income countries (LMICs).

This support will lead to an upgrade of all regulatory functions of the FDA from WHO maturity level 3 regulatory status to a maturity level 4 regulatory status. The support will ensure that the FDA has the capacity in terms of facilities and personnel to ensure the quality, safety, and efficacy of locally manufactured vaccines that meet WHO and international standards.

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SPONTANEOUS REPORTING FOR 2021

The National Pharmacovigilance Centre received one thousand three hundred and fifty-nine (1,359) spontaneous reports for drugs and other products excluding vaccines in 2021. The reports were received from healthcare professionals, pharmaceutical industries and patients/consumers. Of the 1,359 reports received, 26(1.9%) were pharmaceutical care issues while 1,333 (98.1%) reports were adverse reactions to drugs.

Of the pharmaceutical care issues recieved, 19 (73.1%) were suspected product quality issues. Quality control laboratory analysis of the 19 products showed that 2 (10.5%) did not meet the quality control parameters as per the British Pharmacopoeia. The remaining pharmaceutical care issues ranged from medication errors (11.5%), therapeutic failure (7.7%) and poor labeling/packaging (7.7%). These complaints have all been addressed appropriately.

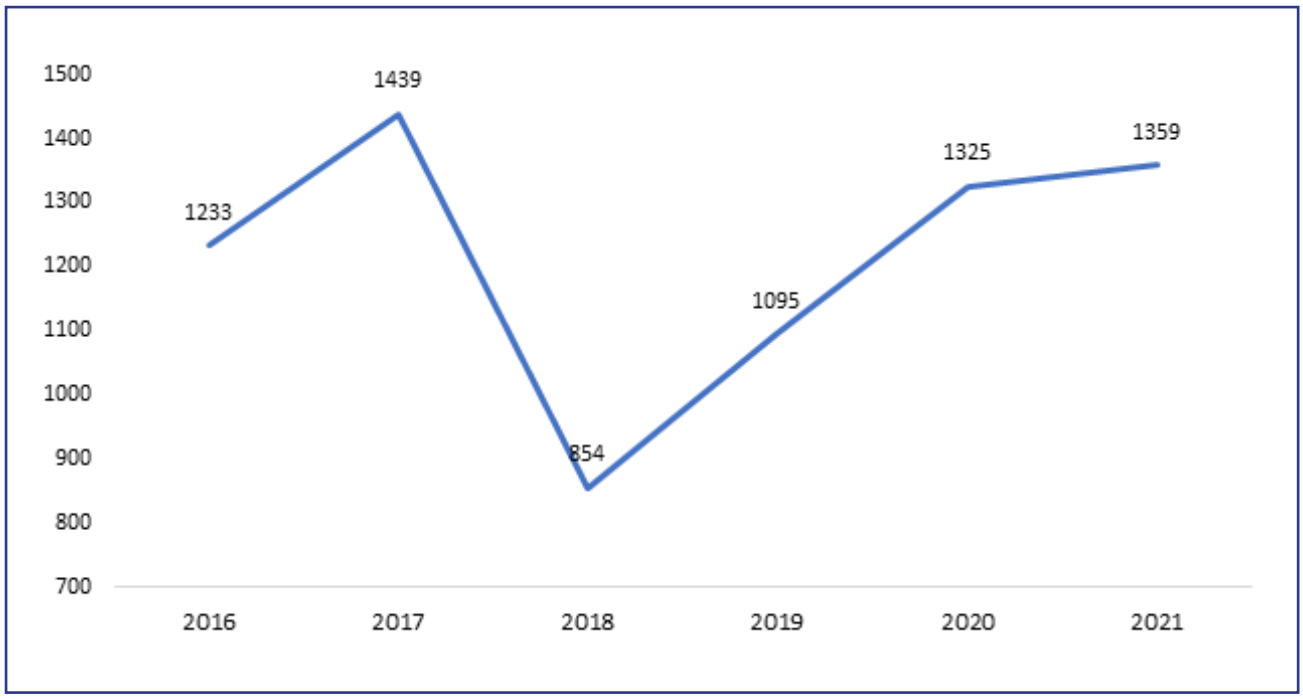


Figure 1: Number of reports received from 2016-2021

An analysis of the 1,333 adverse reaction reports showed that 768(57.6%) of those who had the reaction were females and 476 (35.7%) were males, the gender for the remaining 89 (6.7%) was not stated (refer to figure 2).

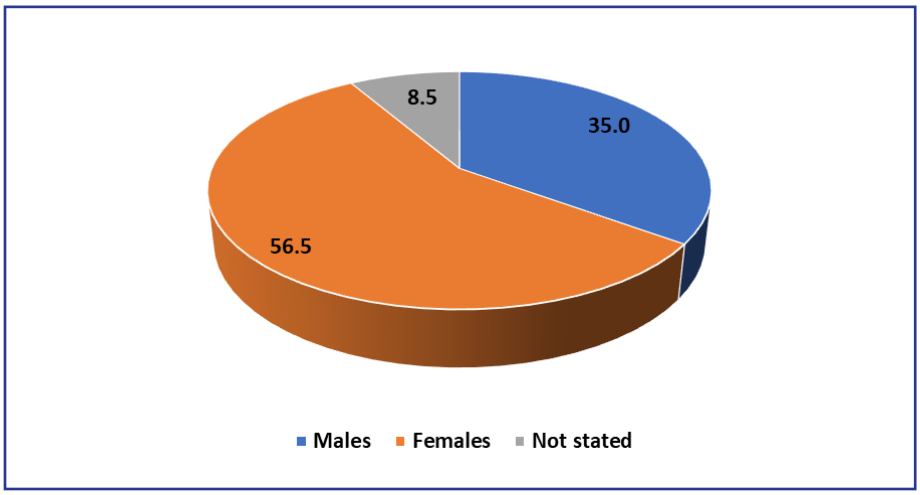


Figure 2: Gender distribution of patients who had adverse reactions

The source of the 1,359 reports were 1,116 (82.1%) from healthcare professionals, 225 (16.6%) reports from industry and 18 (1.3%) from patient safety centers.

The spontaneous reports received were from different categories of healthcare professionals as shown in Figure 3.

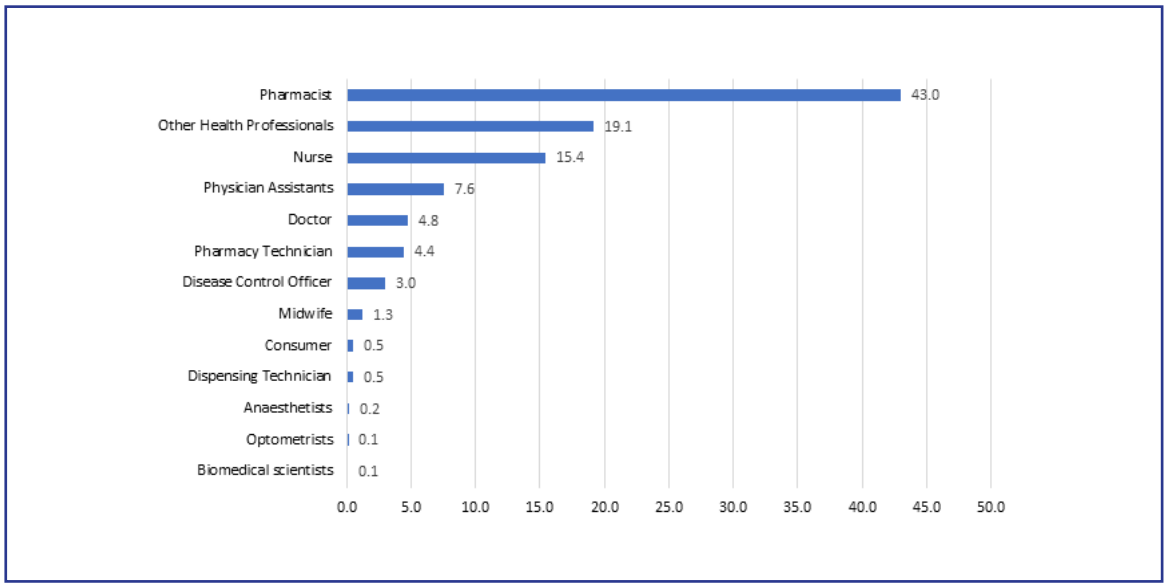


Figure 3: Percentage reporting by healthcare professionals

The top 15 medicines with the most reported adverse reactions are shown in Figure 4

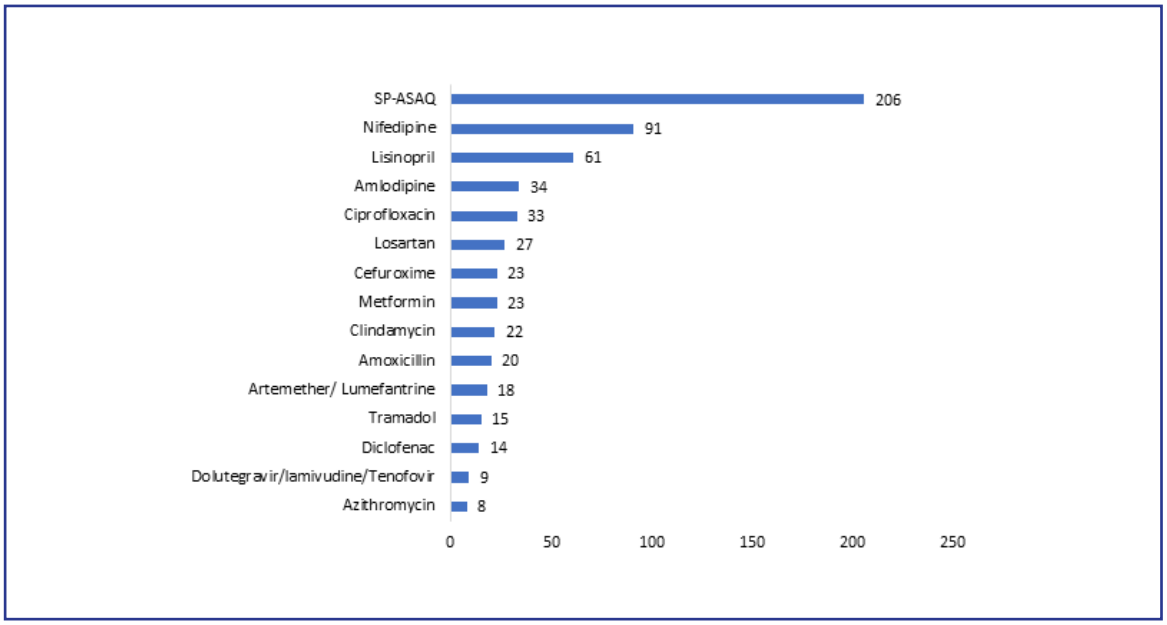


Figure 4: Top 15 medicines with the most commonly reported adverse reactions

The outcome of the reported reactions is shown in Figure 5

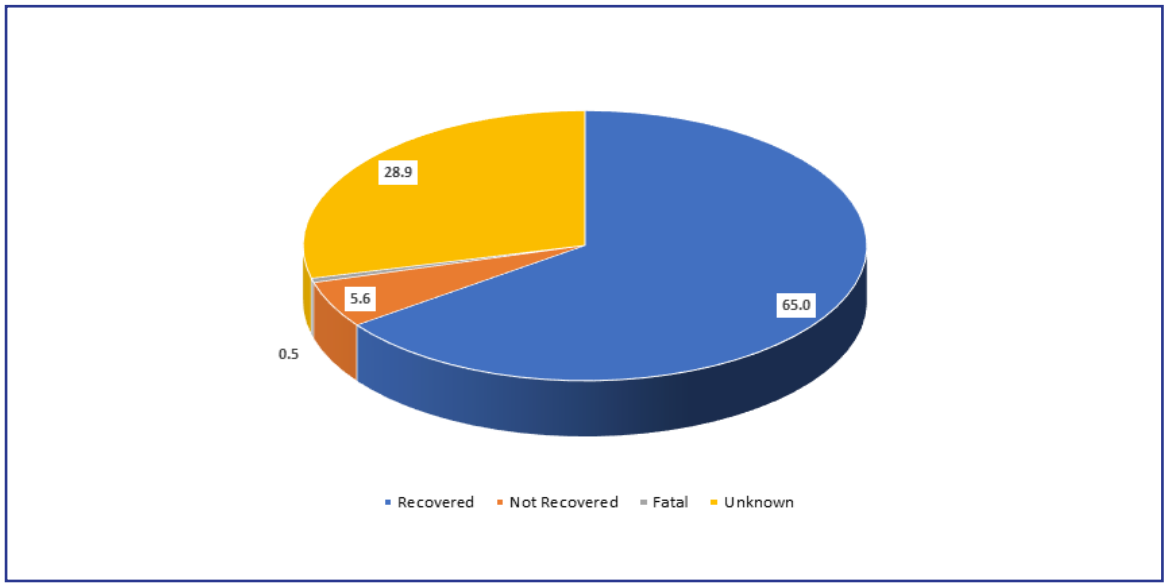


Figure 5: Outcome of reported adverse reactions

The contribution of regions to the ADR reports received per 100,000 population using data from the 2021 Ghana Population and Housing Census is as shown in Figure 6.

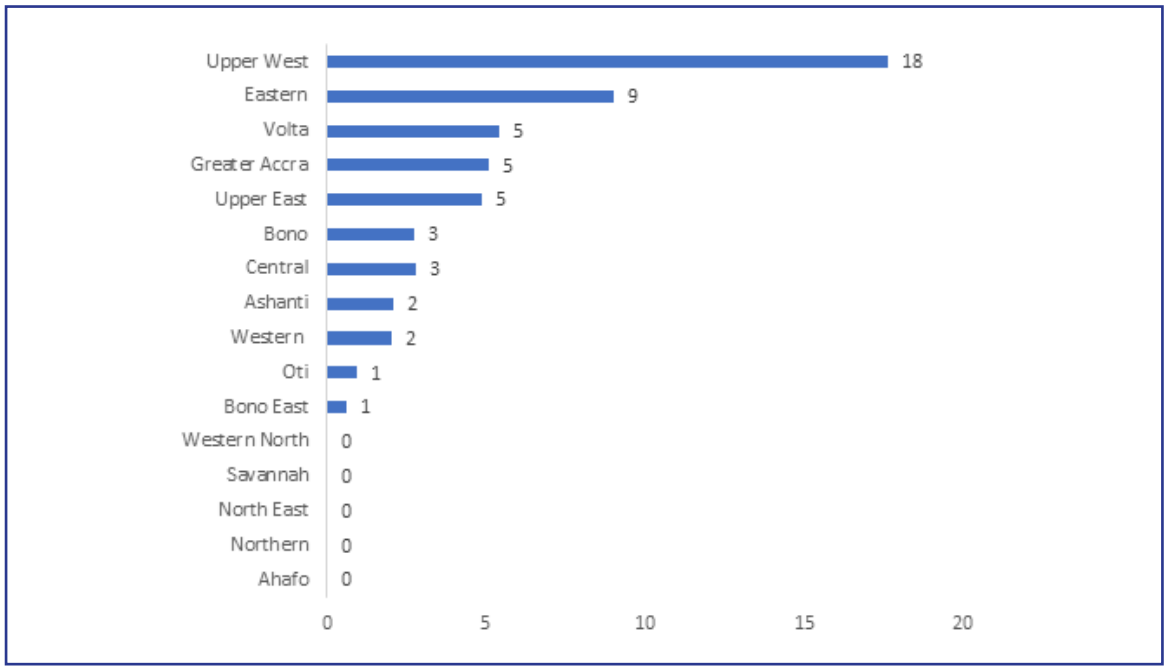


Figure 6: ADR reports received per 100,000 population.

Table 1 represents the top 20 healthcare facilities that submitted reports to the National Pharmacovigilance Centre in 2021.

Table 1: The top 20 reporting healthcare facilities.

Facility	Region	Number of Reports
Korle Bu Teaching Hospital	Greater Accra	122
Peki Dzake Health Center	Volta	64
Eastern Regional Hospital	Eastern	62
Atua Government Hospital	Eastern	49
Cape Coast Teaching Hospital	Central	43
Komfo Anokye Teaching Hospital	Ashanti	20
Agona Government Hospital	Ashanti	20
Abesim Eye Clinic	Bono	15
Kwahu Government Hospital	Eastern	15
Asamankese Government Hospital	Eastern	14
Enyiresi Government Hospital	Eastern	14
Asesewa Government Hospital	Eastern	13
Upper East Regional Hospital	Upper East	11
Kwesimintsim Government Hospital	Western	11
Akuse Government Hospital	Eastern	10
Jasikan District Hospital	Oti	10
Peki Adzokoe CHPS Compound	Volta	10
Duakwa Polyclinic	Central	7
Dormaa West District Hospital	Bono	6
LEKMA Polyclinic	Greater Accra	5

OUR PATIENT SAFETY FOCAL PERSON FOR THE YEAR, 2021

Dr. Josephine Mensah (National)

We celebrate Dr. Josephine Mensah, a pharmacist at University of Ghana Medical Centre (UCMG), Legon in the Greater Accra Region.

At the University of Ghana Medical Centre, Josephine works with a team of other healthcare professionals to offer pharmaceutical care with commitment.

Josephine dedicates this recognition to her team and the Director of Pharmacy at the UGMC Pharmacy Directorate.

REGIONAL PATIENT FOCAL PERSONS

Dr. Samuel Kwakye Afram (Ashanti Region)

Dr. Samuel Kwakye Afram is the pharmacist in charge of Suntreso Government hospital in the Ashanti Region.

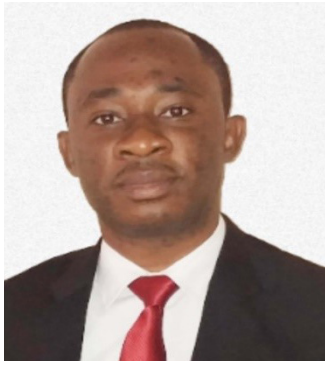
Samuel believes that monitoring the safety of medicines helps promote medicine safety by identification of manufacturing, substandard and falsified medications.

Pharm. Stella Sellasie Ahiati (Greater Accra)

Pharm. Stella Selassie Ahiati is a young pharmacist at the Anti-Retroviral Therapy (ART) Pharmacy of the Korle-bu Teaching Hospital. She is passionate about patient safety and the rational use of drugs.

Selassie believes that the role of a pharmacist is to ensure that patients obtain the best therapeutic outcome from their treatment.

Dr. Courage Edem Ketor (Volta Region)



Dr. Courage Edem Ketor is a Clinical Pharmacist at the Jasikan District Hospital in the Oti Region of Ghana.

His interest in patient safety dates back as 2012 while training as an Intern Pharmacist at the Ho Teaching Hospital. He has ever since contributed to pharmacovigilance and patient safety by consistently reporting to the Authority on issues of drug and vaccine safety.

Pharm. Samuel Amoateng Saffoh (Upper East Region)

Pharm. Samuel Amoateng Saffoh is a Pharmacist at Bolgatanga Regional Hospital in the Upper East Region.
Monitoring and reporting of medication errors as well as adverse drug reactions within the hospital and the municipality during mass drug administration exercises are his passion.

Pharm. Angela Owusu (Central Region)

Pharm. Angela Owusu, Pharmacist - Cape Coast Teaching Hospital Central Region and assistant lecturer at the Department of Pharmaceutical Science, Kumasi Technical University.
Her interest in promoting patient safety has been the driving force for carrying out her duty as a PV contact person in the hospital.

Pharm. Kwaku Nimoh-Boakye (Bono Region)

Pharm. Kwaku Nimoh-Boakye is the Head of Pharmacy Department at Sene District Hospital in the Bono East Region where he has been the Institutional Contact Person for Pharmacovigilance since 2012.

Pharm. Nimoh-Boakye has passion for Pharmacovigilance and strongly believes that Pharmacovigilance is the responsibility of every health care professional.

REGIONAL PATIENT FOCAL PERSONS

Pharm. Fauzia Salifu (Northern Region)

Pharm. Fouzia Salifu, pharmacist at Tamale Teaching Hospital, Northern Region.

She has been working together with other Pharmacists to create awareness and the need to strengthen Pharmacovigilance efforts in and around the hospital.

Dr. Ivan An-Ichie Muanah (Ahafo Region)

Dr. Ivan An-Ichie Muanah, Medical Director, St. Elizabeth Hospital, Hwidiem – Ahafo region and specialist ENT surgeon.

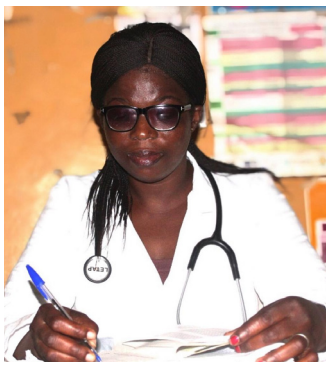
In Dr. Muanah's view, pharmacovigilance is very essential in medical practice and every medical practitioner should be concerned with it by looking out for and promptly reporting adverse drug reactions.

Pharm. Grace Grant (Western Region)

Pharm. Grace is a pharmacist at the Kwesimintsim District Hospital in the Western Region.

She believes pharmacovigilance plays a major role in improving health outcomes.

Mad. Esther Deme-Der (Upper West Region)



Mad. Esther Deme-Der, Principal Physician Assistant, Immaculate Conception Health Centre, Upper West Region.

Esther is a principal physician assistant at the Immaculate conception health centre. She is passionate about patient safety and acknowledges the contribution of pharmacovigilance in improving the clinical outcome of her patients. She believes pharmacovigilance plays a pivotal role in health care delivery in providing quality care for her clients.

PATIENT SAFETY CENTRE OF THE YEAR 2021

The Food and Drugs Authority in 2016 launched an intervention to increase patient involvement in medicine safety by encouraging direct patient reporting of adverse reactions and adverse events following immunization.

Community pharmacists were identified as key stakeholders for the success of this initiative because community pharmacies are the closest to the people and hence the first point of call for the medical needs of the population.

Community pharmacies that volunteered to support this initiative were branded by the FDA as "Patient Safety Centres" with the responsibility to educate patients on how to identify side effects of medicine and vaccines and to report these to the FDA.

With the commencement of Pharmacist in Immunization Programme and the requirement for these pharmacies to be Patient Safety Centres, the FDA looks forward to more community pharmacies to be designed as Patient Safety Centres.

In this edition of the DrugLens, the FDA would like to acknowledge the efforts of Pharm. Dr. Joseph Kizzie-Hayford and his team at Cape Pill Pharmacy Limited, Cape Coast for their continued dedication to patient safety.

From Left to Right: Ms. Nancy Wilson, Pharm. Dr. Joseph Kizzie-Hayford, Mrs. Grace Otoo, Mr. Ebenezer Baiden.

Cape Pill Pharmacy Ltd. is declared the patient safety centre of the year based on the quality, number and timeliness of reporting.

The team at Cape Pill Pharmacy Ltd believes in individualizing care for their clients because each person is unique.

The FDA also aknowledges the efforts of Alpha Deta Pharmacy in Greater Accra Region for their commitment to patient safety.

SAFETY MONITORING OF NEW CHEMICAL ENTITIES

COVID-19 Vaccines and Therapeutics

The objective of pharmacovigilance is to improve public health and safety by accessing benefit/ risk of medicines. The two pharmacovigilance methods employed to monitor the safety of medicines in Ghana are; spontaneous and active monitoring - Cohort Event Monitoring (CEM). In 2021, the FDA granted Emergency Use Authorization (EUA) to six COVID-19 to vaccines listed below:

- Sputnik V (Gam-COVID-Vac)
- Covishield (ChAdOX1Ncov-19 Corona Virus Vaccine (Recombinant)
- COVID-19 Vaccine Janssen Suspension for Injection (Ad26.COV2-S [recombinant])
- Moderna's Dispersion for Injection [COVID-19 mRNA Vaccine (nucleoside modified)]
- Comirnaty Concentrate for Dispersion for Injection [COVID-19 mRNA Vaccine (nucleoside modified)]
- COVID-19 Vaccine AstraZeneca Suspension for Injection (ChAdOx1 S [recombinant])

The FDA employed a robust safety monitoring strategy including spontaneous and active monitoring during the deployment of these vaccines. As part of the active monitoring of these vaccines, seven sentinel sites were established across the country to follow up on those who received the COVID-19 vaccines. Pregnant women who received the mRNA COVID-19 vaccines were also followed up. Per FDA's EUA guidelines, Marketing Authorization Holders were required to have a system to monitor the safety of their products. This involved the submission of Risk Management Plans (RMPs), Period Benefit Risk Evaluation Reports (PBRERs) and conduct of post approval studies and report to the FDA. The FDA has issued EUA for two COVID-19 Therapeutics namely Molnupiravir and Regkirona. As per WHO requirements, the FDA has planned for the active safety monitoring of these therapeutics.

Molnupiravir is indicated for COVID-19 patients with non-severe disease who are at higher risk of hospitalization.

Regkirona (Regdanvimab) a monoclonal antibody used for treating COVID-19 in adults who do not require supplemental oxygen and are at increased risk of the disease becoming severe.

Reports from Routine Vaccination Program

A total of eight thousand, three hundred and twenty-five (8,325) adverse events following immunization (AEFI) reports were received in 2021. Four thousand, six hundred and seventeen (4,617) AEFI reports were received through the passive reporting system in 2021 and three hundred and eighty-three (383) AEFI reports were through the Malaria Vaccine Implementation Program (MVIP); Out of the AEFIs received through the passive system, 4,470 were COVID-19 vaccine AEFIs whiles 147 were AEFIs arising from routine vaccination at healthcare facilities in Ghana.

Figure 7 shows the regional distribution of the 147 AEFI reports received through routine immunization program in Ghana in in 2021.

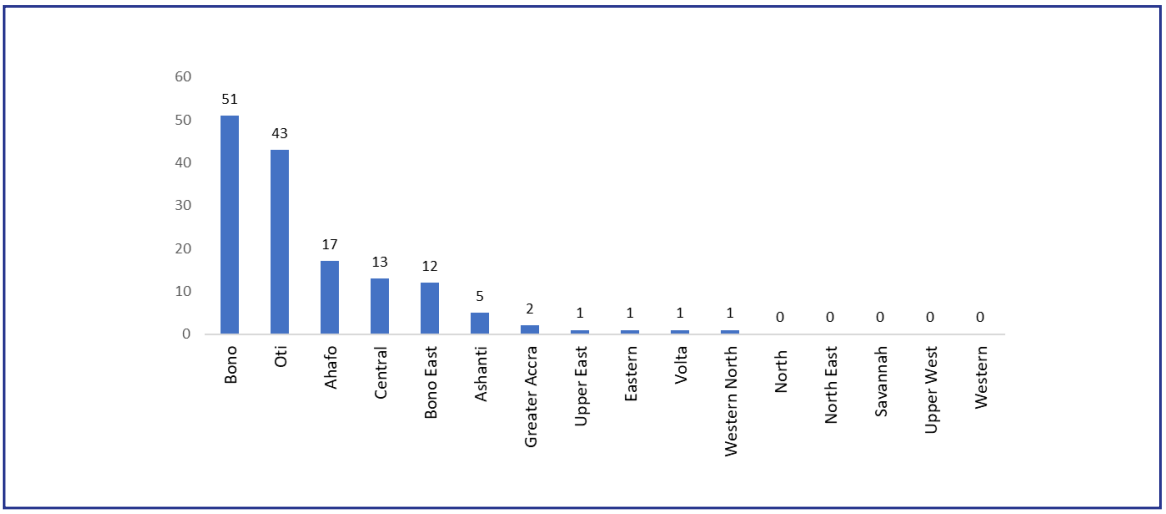


Figure 7: Regional distribution of AEFI reports received through routine immunization program in 2021

Of the 147 routine AEFI reports received through routine immunization program in 2021, 88 (59.9%) were serious. The outcome of Causality Assessment per antigen for 82 SAEFIs by the Technical Advisory Committee on Safety of Vaccines and Biological Products (TAC-VBP) using the process outlined in the WHO User Manual on Revised Classification of AEFI is shown in Figure 8.

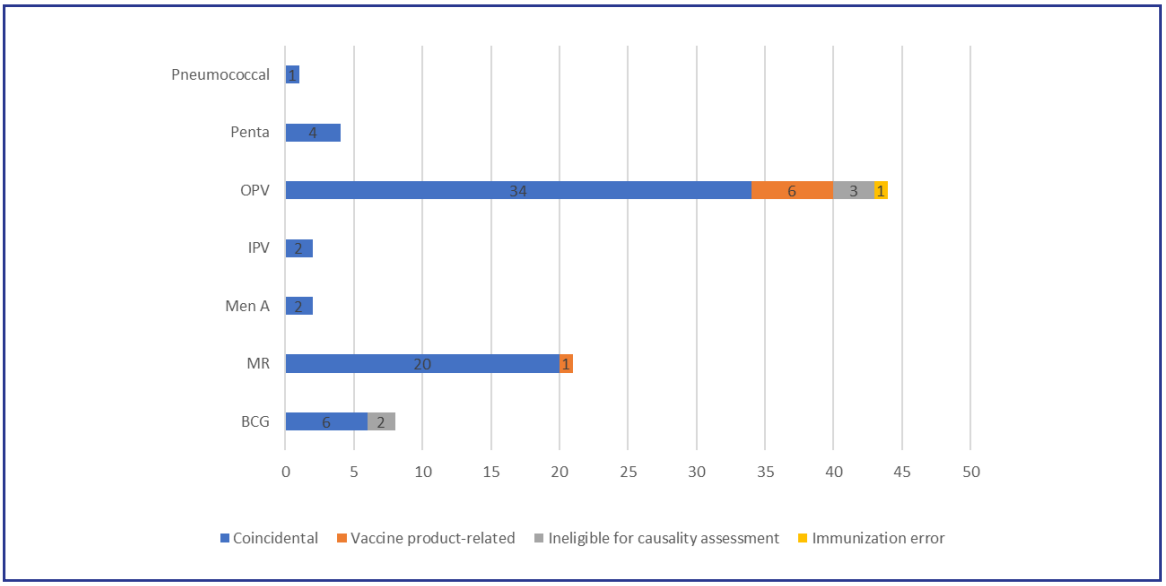


Figure 8: Causality assessment of serious AEFI cases per antigen received through routine immunization program in 2021

The regional distribution (number of AEFI reports and AEFI rate per 100,000 doses administered) of AEFI reports received through the sponteneous reporting pathway is as shown below:

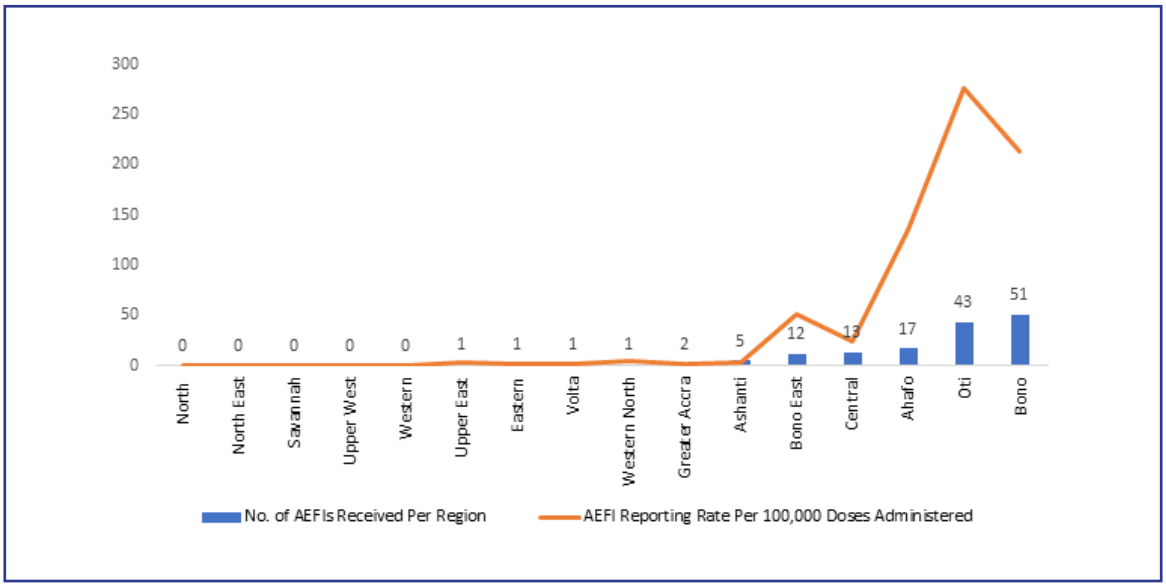


Figure 9: Regional distribution of AEFI reports received through the sponteneous reporting pathway

Updates from the Malaria Vaccine Implementation Programme (MVIP)

The Food and Drugs Authority in collaboration with the Ghana Health Service-Expanded Programme on Immunization has successfully monitored the safety of the malaria vaccine, Mosquirix (RTS,S) for three years since the Malaria Vaccine Implementation Programme was launched on 30th April 2019.

In monitoring the safety of the vaccine, the Food and Drugs Authority's Joint Malaria Vaccine Safety Committee reviewed safety data from three sources; namely, enhanced spontaneous reporting system, GSK-led Phase IV studies and WHO led sentinel hospital surveillance (MVPE).

As of 30th April 2022, a total of 1,170,181 doses of the vaccine had been administered to eligible children with 370,000 children receiving at least one dose.

The FDA received a total of 2,165 adverse event following immunization (AEFI) reports from the 3 data sources shown in Table 2.

Table 2: Number of AEFI reports received between 1st May 2019 – 31st May 2022

No.	Monitoring System	AEFI by source	Non-serious	Serious
1	GSK-led Phase IV studies	2090	1,785	305
2	Enhanced Spontaneous	42	32	10
3	MVPE	34	0	34
	Total	**2,166**	**1,817**	**349**

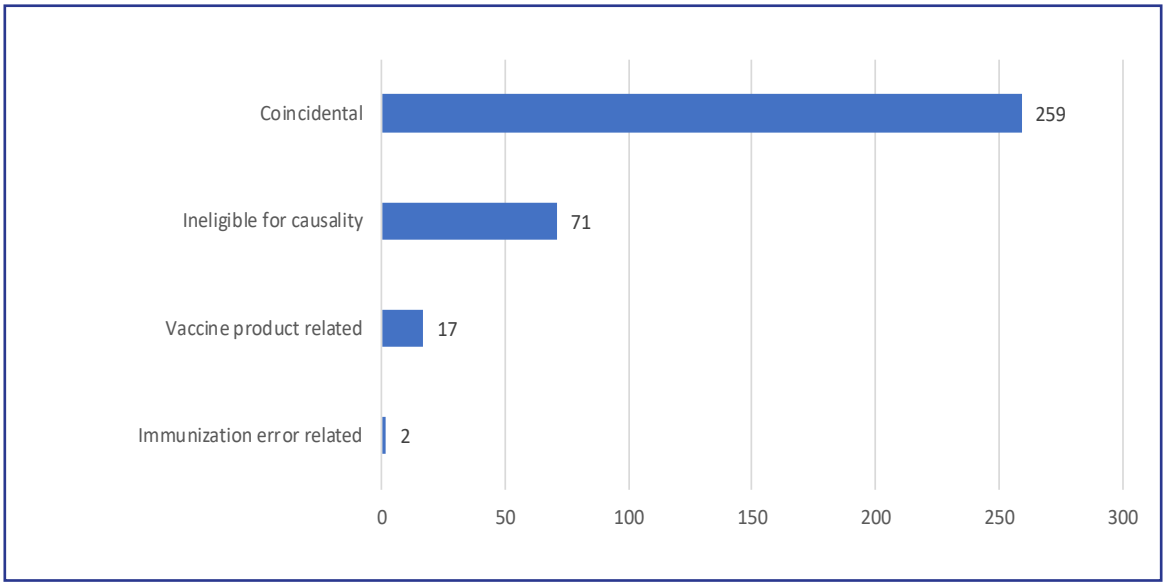


Figure 10: Outcome of causality assessment of RTS,S serious AEFI reports, Ghana, 1st May 2019 – 31st May 2022

WHO recommendation on widespread use of RTS,S in children living in high endemic regions

October 2021 marked an important milestone in efforts to control malaria in children with WHO's announcement of the recommendation of widespread use of the RTS,S malaria vaccine among children in sub-Saharan Africa and other regions of moderate to high P. falciparum malaria transmission. The recommendation is based on results from an ongoing pilot programme in Ghana, Kenya and Malawi that has reached more than 900,000 children since 2019. Data from the pilot programme has shown that the vaccine is feasible to implement through routine vaccination programme, has a satisfactory impact in reducing malaria death in children, and acceptable safety profile. Another significant success in the fight against malaria is the announcement by GAVI, the Vaccine Alliance to support the rollout of RTS,S malaria vaccine expansion in the three pilot countries and beyond in sub-Saharan Africa in a phased approach.

Ghana's National Immunization Technical Advisory Group (NITAG) following the announcements has been reviewing this WHO recommendation and will soon provide technical recommendations to the Ministry of Health to inform the country policy

Safety Monitoring of COVID-19 Vaccines

Ghana has been deploying COVID-19 vaccines since March 2021 and as of 31st May 2022, approximately 15,496,852 doses of the five vaccine types (AstraZeneca COVID-19 Vaccine, COVID-19 vaccine Janssen, Moderna COVID-19 vaccine, Pfizer BioNTech COVID-19 vaccine and Sputnik V) have been administered to various segments of the target population. These vaccines have been issued emergency use authorization (EUA) in Ghana by the Food and Drugs Authority.

The FDA's Joint COVID-19 Vaccine Safety Review Committee (JCVSRC) has reviewed the safety data from both the active and spontaneous reporting systems that have been implemented to ensure complete safety data is available for assessment. Table 1 provides the number of AEFIs per doses of vaccines administered

The cumilative AEFI reporting rate per 10,000 doses of all vaccines administered is 6.

Table 3: AEFI reporting per vaccine

Name of Vaccine	Cumulative Dose Administered	Method of Detection	No. of AEFIs
AstraZeneca COVID-19 Vaccine	9,471,006	Active Spontaneous	4,093
Sputnik V	17,982	Active	2458
COVID-19 Vaccine Janssen	1,755,751	Active Spontaneous	1668
Moderna COVID-19 Vaccine	1,065,357	Active Passive	826
Pfizer-BioNTech COVID-19 Vaccine	3,186,756	Active Passive	379

The JCVSRC has performed causality assessment for 49 serious AEFIs as at its 16th Meeting held on 22nd June 2022 as shown in figure 10 below

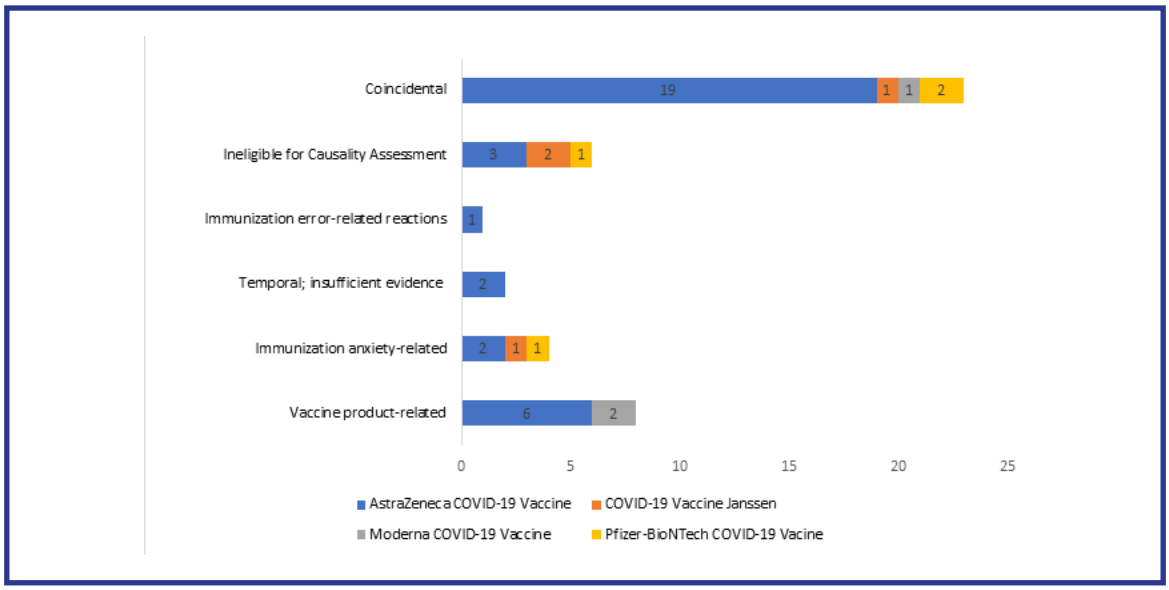


Figure 11: Causality assessment for COVID-19 vaccines

Following the extension of vaccination to persons 15 years and above and pregnant women, in addition to booster doses, the FDA has been monitoring the safety of the vaccines in these categories of persons. An active follow-up of pregnant women exposed to mRNA COVID-19 vaccines is being conducted at 7 sentinel hospitals in 6 regions with the objective to get Ghana specific data to answer local safety questions that may arise.

As at the end of May 2022, 12,389 pregnant women have been vaccinated with mRNA COVID-19 vaccines. The FDA has followed up on 430 pregnant women exposed to mRNA COVID-19 vaccines with 1.9% of the women experiencing AEFI after the 1st dose of the vaccine. The AEFIs were similar to those reported by non-pregnant vaccinees including headache, chills and dizziness. Twenty-one (4.1%) of the pregnant women have delivered and there were no reported untoward events on both mother and baby.

The JCVSRC based on the review of both local and international data maintains that the COVID-19 vaccines under monitoring are still safe for the public and pregnant women and recommended their continuous deployment. The Committee also encourages pregnant women to get their vaccinations because available evidence indicates that the benefits of receiving the mRNA COVID-19 vaccines during pregnancy far outweigh any potential risks.

Products With Additional Risk Minimization Measures (aRMMs)

Risk minimisation measures are interventions intended to prevent or reduce the occurrence of adverse reactions. Risk minimization measures could either be routine (e.g Summary of product characteristics, Product information leaflet) or additional measures. Additional measures are used to improve benefit-risk profile of medicines and may include selection of patients, restriction of access and educational programmes.

Three products with additional risk minimization measures being implemented are shown in Table 4.

Table 4: Products with additional Risk Minimization Measures

Product Name	Indication	Safety Concern	Additional Risk Minimization Measure
Etanercept (Enbrel)	• Rheumatoid arthritis • Psoriatic arthritis • Ankylosing spondylitis • Non-radiographic axial spondylarthritis • Plaque psoriasis • Juvenile idiopathic arthritis	Congestive heart failure in adult subjects is an identified important risk	Patient card to be distributed to patient by etanercept prescribing physicians aimed at reducing the risk of serious infections and congestive heart failure and ensuring the traceability of Enbrel drug product. The card will provide the following important safety information to the patients: • Etanercept treatment may increase the risk of infection and congestive heart failure in adults. • Signs or symptoms of infection and congestive heart failure and when to seek attention from a healthcare professional Instructions to record the brand name and batch number of the medication to ensure traceability. Contact details of the Prescriber.
Rituximab (MabThera)	• Non-Hodgkin's Lymphoma (NHL) • Chronic Lymphocytic Leukaemia (CLL) • Rheumatoid Arthritis • Granulomatosis with polyangiitis and microscopic polyangiitis • Pemphigus vulgaris	MabThera is available in two formulations for the respective indications listed below • MabThera solution for subcutaneous injection (MabThera SC): Non-Hodgkins Lymphoma ONLY • MabThera concentrate for solution for infusion: All MabThera approved indications Administration Route Error: Risk of administration error between subcutaneous and intravenous rituximab formulations	Educational materials for healthcare professionals with the objective to educate them about use of the SC formulations to reduce the likelihood of accidental product substitution and ensure that the SC formulation is injected correctly. The educational material comprises of a comparison card which focuses on package differentiation, and step by step guide which aims to educate on correct injection technique.

Product Name	Indication	Safety Concern	Additional Risk Minimization Measure
Xarelto (Rivarobaxan)	*Adults* Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack. Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. (See section 4.4 for haemodynamically unstable PE patients.) *Paediatric population* Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing more than 50 kg after at least 5 days of initial parenteral anticoagulation treatment.	Potential risk of bleeding	Patient cards to be distributed to patients by prescribing physicians aimed at educating the patient on the potential risk of bleeding. The card will provide advice to patients on signs and symptoms that need to be immediately reported to the physician if noticed.

New safety information or signals identified by FDA through the adverse reaction reporting system in 2021

Chlorhexidine digluconate gel is indicated for neonatal umbilical cord care as an antimicrobial to prevent cord sepsis. The National Pharmacovigilance Centre reviewed the SafetyWatch System (FDA's national safety database) as part of its routine signal management processes and identified 8 adverse reaction reports of cord infection (including laceration and haemorrhage) associated with the use of chlorhexidine gel between July 2019 to December 2021. The reports were non-serious and there were no concomitant medicines. Cord infection has not been stated as an adverse reaction in the product information of chlorhexidine digluconate gel, however, review of literature showed that cord infection could occur whilst using the product.

The FDA's Technical Advisory Committee on Safety of Medicines reviewed the signal report for chlorhexidine digluconate gel and cord sepsis. The Committee concluded that based on available information, the reaction could possibly be associated with inappropriate application of the product in newborns at home and recommended the following;

- midwives should educate mothers and caregivers on the correct application of the product at home.
- the FDA should inform the Family Health Division of the Ghana Health Service to facilitate the implementation of this recommendation.

SAFETY COMMUNICATIONS PUBLISHED BETWEEN JANUARY 2021 TO JUNE 2022

Contamination of Losartan Active Substance with Mutagenic Azido Impurities

This publication sought to bring to the attention of the general public information from European health authorities about detection of previously unknown Azido impurity, 4-chlor-azidomethyltetrazole in some sartan medicines. The azido impurity is considered a mutagen which may increase the risk of cancer, however, the specific risk for this azido impurity to cause cancer in humans is unknown.

The FDA collaborated with Denk Pharma GmbH & Co. KG to recall losartan-containing products, namely, Colosar-Denk (losartan potassium/hydrochlorothiazide) and Losar-Denk tablets from the Ghanaian market as a precautionary measure due to the presence of the azido impurity.
In the publication, patients were advised not to stop taking their Colosar-Denk, Losar-Denk or other sartan containing anti-hypertensive products unless this has been discussed with their healthcare professionals. This is because suddenly stopping medication for high blood pressure could be risky.

Information on the Risks of Valproate Use in Female Patients and Pregnant Women

The FDA approved a healthcare professional guide as part of the valproate Pregnancy Prevention Programme for distribution by Sanofi. The objective of the guide was to provide information about the teratogenic risk associated with the use of valproate during pregnancy, actions necessary to minimize the risk to patients and ensure adequate level of understanding of the risk by patients. The guide also provided new information on the risk of hearing impairment or deafness and updates related to the risk of Attention Deficit Hyperactivity Disorder (ADHD).

Safety Advisory - Constipation: a Potentially Serious Side Effect

Product Information (PI) and Consumer Medicine Information (CMI) for clozapine have been updated to strengthen warnings about potential severe gastrointestinal side effects, including constipation.
Clozapine is used to treat schizophrenia when other antipsychotic medicines either have not worked or have caused severe side effects.
Clozapine may also affect the bowels by slowing them down and can cause severe constipation. This condition is known as clozapine-induced gastrointestinal hypomotility. If untreated, it can lead to serious problems.

FDA Engages Chief Executive Officers and Managers of Pharmaceutical Industries in Ghana

The FDA organized the 2nd Product Safety Forum for Chief Executive Officers (CEOs) and Managers of pharmaceutical industries to provide a platform to discuss issues concerning the implementation of pharmacovigilance requirements per the Public Health Act 2012, Act 851. At the end of the meeting, the managers had a better understanding of the role of Qualified Persons for Pharmacovigilance (QPPV) and the need for management support for successful implementation of the pharmacovigilance requirement.

The Product Safety Forum was followed by the 4th Forum for QPPVs which was attended by 76 participants. The forum is an annual engagement with the QPPVs to discuss progress of implementation of PV requirement, identify challenges and propose recommendations to improve their work and promote public health and safety.

SAVING Consortium News

SAVING (Sustainable Access and Delivery of New Vaccines in Ghana) consortium led by the University of Health and Allied Sciences (UHAS) is building capacity of multiple stakeholders; Ghana Food and Drugs Authority, Ministry of Health and the Ghana Health Service to identify and address implementation challenges for the efficient and effective delivery and uptake of new medical interventions. The work of the SAVING consortium led by Prof. Mrs. Margret Gyapong, Director of Institute of Health Research, UHAS, builds on the framework of the Access and Delivery Partnership value chain. The consortium is using Implementation Research (IR) as the guiding principle for its work and building technical and IR capacity in partner institutions to facilitate the delivery and update of new medical interventions in Ghana. The FDA component of the consortium, Work Package 4, seeks to promote pharmacovigilance and is currently undertaking an IR around the deployment of the Med Safety App as an adverse reaction reporting tool.

A section of SAVING Management Board with some representatives of the various Work Packages

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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): .....
Organization (Optional): .....
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: .....
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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.

THE MED SAFETY APP
FOR REPORTING SAFETY ISSUES

safety of medicines and vaccines in your hands

- Submit reports on adverse reactions even while offline
- View and submit updates to previously submitted reports
- See immediate acceptance of your reports
- Create a watch list of medications, to recieve personalized news and alerts

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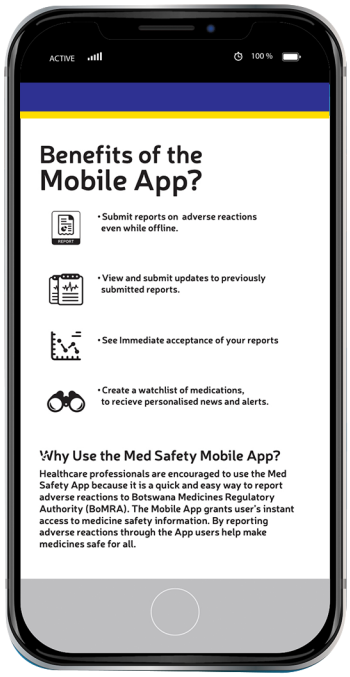

Why USE the MED SAFETY APP?

Consumers, patients and healthcare professionals are encouraged to use the Med Safety App because it is quick and easy way to report adverse reactions to the Food and Drugs Authority.

The Mobile App grants users instant access to medicine safety information.
By reporting adverse reactions through the App, users help make medicines safe for all.

Scan to download for free

GET IT ON Google Play
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