NEWSLETTER ISSUE 9 OCTOBER, 2021

DRUGLENS

Message from the Chief Executive Officer

DELESE MIMI DARKO

Once again, I have the honour to welcome you to the ninth edition of the Druglens. With increasing readership, the Editorial Team is determined to provide the current and up-to-date information on safety monitoring activities to our distinguished readers.

In the 8th edition of the Druglens, I mentioned efforts by the Food and Drugs Authority to make it possible for healthcare professionals and consumers to report adverse reactions to vaccines, medicines (including herbal products) and other health products using the Med Safety App. I wish to update you that, this has gone excellently well albeit low uptake.

In order to improve uptake of the Med Safety App, a number of improvements have been made including the addition of adverse event following immunization (AEFI) reporting form.

In addition to this the FDA has also undertaken a study to determine the challenges and facilitating factors for the use of the Med Safety App in Ghana. The result of this study showed a significant level of acceptance of the App by users.

To improve reporting of safety issues by healthcare professionals in the coming years, the FDA has started a programme to decentralize pharmacovigilance to lower-level healthcare facilities in Ghana including clinics and CHPS zones. The FDA hopes this will lead to increase in reporting rate of safety issues of healthcare products and improved patient safety.

To this end, the Authority is grateful to the Access and Delivery Partnership for funding the initial phase of this programme to train 182 healthcare professionals from five regions. The FDA looks forward to funding opportunities in the coming years to further pursue this programme.

In addition to decentralization of pharmacovigilance to the lower-level facilities, the FDA shall also focus on improving consumer reporting of safety issues. In view of this, Information, Education and Communication materials are being developed to educate the general public on the importance of reporting safety issues to the FDA.

Finally, as the pandemic continues the FDA is working round the clock to make sure critical and life-saving vaccines and other health products are available to Ghanaians. Proactive safety monitoring strategies are also in place to ensure safety monitoring during the deployment of COVID-19 vaccines. It is instructive to note that COVID-19 vaccinations are ongoing with no major safety concerns and the role of the Joint COVID-19 Vaccine Safety Review Committee in this process is considered highly commendable.

Spontaneous Reporting for 2020

The National Pharmacovigilance Centre received one thousand three hundred and twenty-five (1,325) spontaneous reports in 2020. The reports were received from healthcare professionals, pharmaceutical industries and patients/consumers. Figure 1 showed the reporting trend from 2016 to 2020.

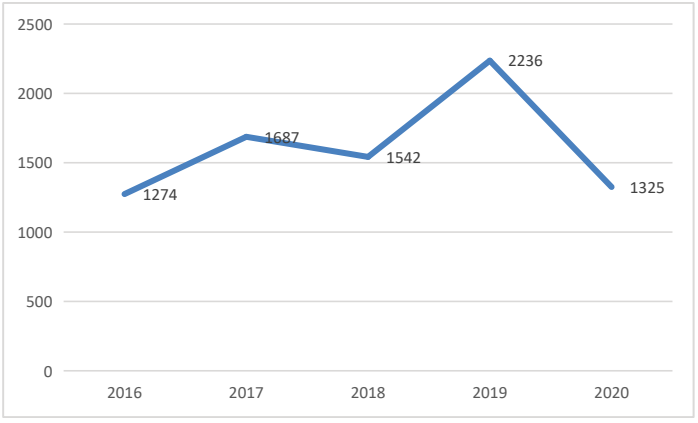

Fig. 1: Number of Reports Received from 2016-2020

Ninety-two (92) out of the 1,325 reports received were on pharmaceutical care issues. The pharmaceutical care issues ranged from pharmaceutical defect (40), medication errors (15) and poor labelling (2) to name only a few. Quality control laboratory analysis of nine (9) products with pharmaceutical defects showed only one did not meet the quality control parameters as per the British Pharmacopeia. This product was recalled from circulation and the manufacturer sanctioned. Twelve (12) reports out of the 92 were for products without marketing authorization with the FDA.

The remaining 1,233 reports were adverse reactions to drugs; 618(61.6%) and 743(33.7%) were from females and males respectively, the gender for the remaining 58(4.7%) is unknown. Refer to Fig. 2

The 1,233 reports consist of 720 from healthcare professionals, 34 through Med Safety App, 133 reports from industry and 346 by patient safety centers. The lower number of adverse reaction reports received in 2020 compared to the previous years' is likely due to COVID-19 pandemic resulting in reduced hospital visits.

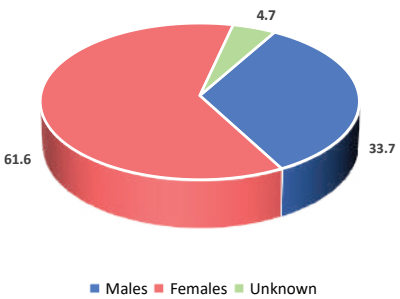

Fig. 2: Gender distribution of patients who had adverse reactions

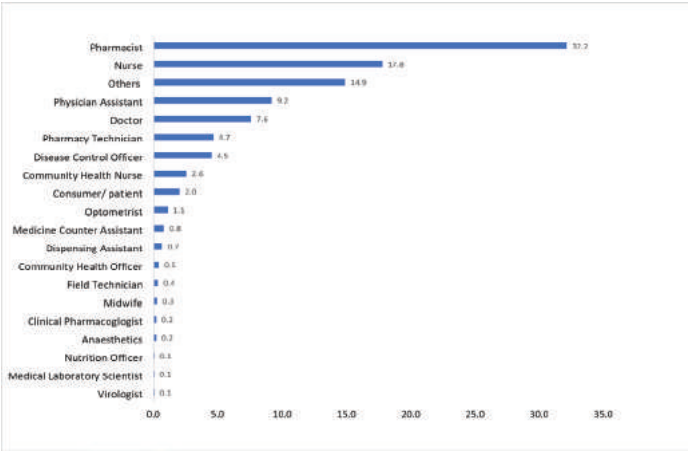

Fig. 3: Percentage reporting by healthcare professionals

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

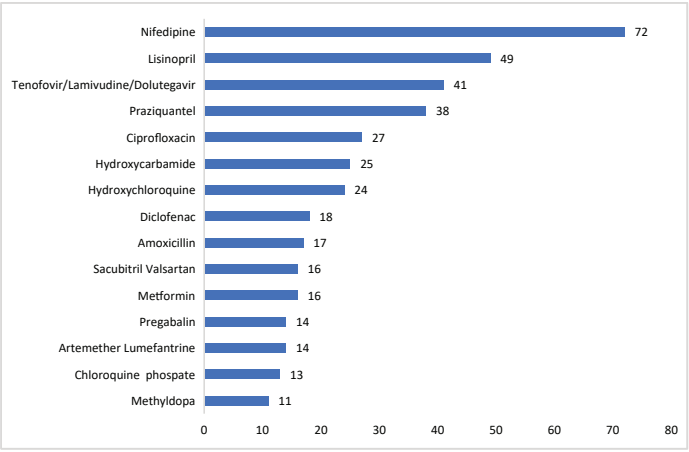

Fig. 4: Top 15 medicines with the most commonly reported adverse reactions

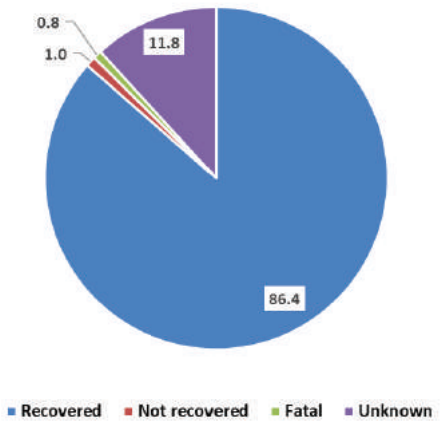

Fig. 5: Outcome of reported adverse reactions

Figure 6 is the contribution of all regions to spontaneous adverse reaction reports received per 1,000,000 population of the region.

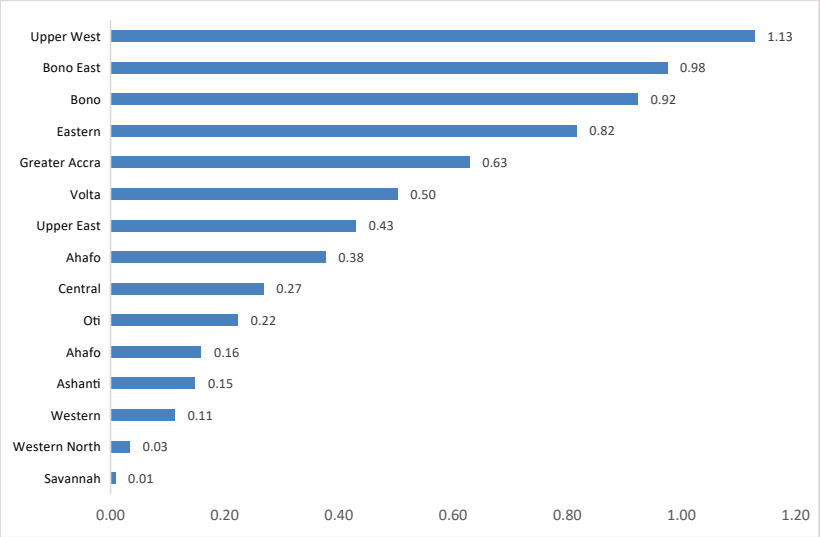

Fig. 6: Regional contribution to the spontaneous reports received per 1,000,000 population

Table 1 represents the top twenty (20) healthcare facilities which submitted reports to the National Pharmacovigilance Centre in 2020.

Table 1: Top 20 reporting healthcare facilities in 2020

Facility	Region	Number of reports
Peki Dzake Health Centre	Volta	68
Atua Government Hospital	Eastern	45
St. Joseph Hospital	Eastern	44
University of Ghana Medical Centre	Greater Accra	34
Greater Accra Regional Hospital	Greater Accra	29
Akuse Government Hospital	Eastern	28
Eastern Regional Hospital	Eastern	25
Abesim Eye Clinic/ Health Center	Bono	22
Tumu District Hospital	Upper West	22
University of Ghana Hospital	Greater Accra	21
Achimota Hospital	Greater Accra	20
Suhum Government Hospital	Eastern	17
St. Francis Xavier Hospital	Central	15
Babile Polyclinic	Upper West	14
Agona Government Hospital	Ashanti	13
Daffiama Health Centre	Upper West	13
Issa Polyclinic	Upper West	13
Ussher Polyclinic	Greater Accra	13
Anafobisi Health Centre	Upper East	12
Upper West Regional Hospital	Upper West	12

UPDATES FROM PATIENT SAFETY CENTRES

Reporting by Community Pharmacies

Community Pharmacies are unarguably the first point of call for members of the general population to obtain solutions for diseases of common occurrence and refill of prescriptions. The community pharmacy practice has evolved to more wholistic patient-oriented practice where obtaining the best therapeutic outcome for clients has become the centre of care. Adverse reactions (side effects) of medicines reduce the quality of life of clients.

The FDA has therefore built on the important role of the Community Pharmacies in patient care to encourage reporting of safety issues from pharmacies designated as Patient Safety Centres.

This section features the team from Union Square Pharmacy in Cape Coast led by the Superintendent Pharmacist, Pharm. Dr. Robert Incoom.

Superintendent Pharmacist with staff of Union Square Pharmacy (left to right, Ms. Felicia Antwi Dr. Robert Incoom and Ms. Hannah Boamah)

The Team believes in a patient-centered approach to pharmaceutical care and is of the view that Pharmacists should expand their role to be leaders in patient safety in order to optimize patient outcomes.

The Pharmacy has a structured framework to follow up on patients for possible safety issues which helps optimize benefit-risk balance of medicinal products.

The FDA is appreciative of the exceptional contribution of the Team at Union Square Pharmacy and also the teams at the underlisted pharmacies to patient safety in 2020.

Table 2: List of other patient safety centres who reported in 2020

Facility	Region
Peniel Pharmacy	Greater Accra
Bubune Pharmacy	Volta
Fabby Chemist	Greater Accra
Hayat Pharmacy	Northern
Samest Drugstore	Greater Accra

VACCINE SAFETY UPDATES

Adverse Event Following Immunization Reporting

A total of 2,041 AEFI reports were received in 2020. Three hundred (300) AEFI reports were received from the passive (spontaneous) reporting system, 744 from the Phase 2B Yellow Fever Preventive Mass vaccination campaign and 997 from the Malaria Vaccine Implementation Program (MVIP).

Spontaneous AEFI reports for routine vaccines.

Figure 7 shows the regional distribution of the 300 (three hundred) AEFI reports received from the passive reporting system.

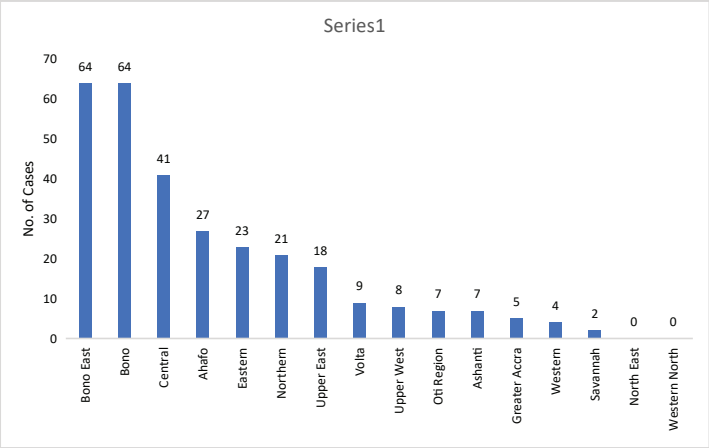

Fig. 7: Regional distribution of AEFI reports received in 2020

Out of the 300 AEFI reports received from the passive reporting system, sixty (60) were classified as serious and the results of the Causality Assessment per antigen 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.

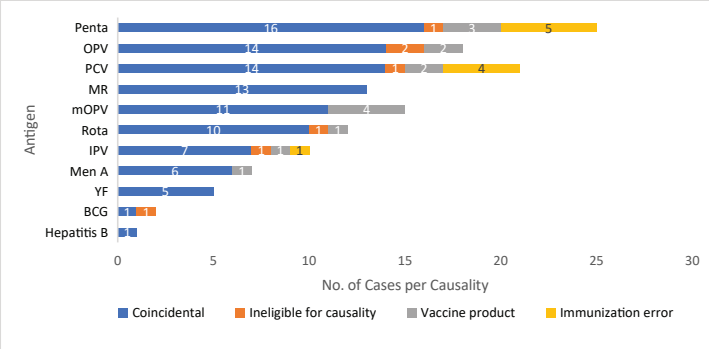

Fig. 8: Causality assessment of serious AEFI cases per vaccine received from the passive reporting system

AEFI reports from 2020 sub-national Phase 2B Yellow Fever Preventive Mass vaccination campaign

The Food and Drugs Authority in collaboration with the Expanded Programme on Immunisation employed enhanced passive surveillance system during the 2020 sub-national Phase 2B Yellow Fever Preventive Mass vaccination campaign.
A total of 744 AEFI reports were received from this campaign. Out of the 744 AEFI reports received 12 were serious. The outcome of the causality assessment of the 12 serious cases by the TAC-VBP is shown below:

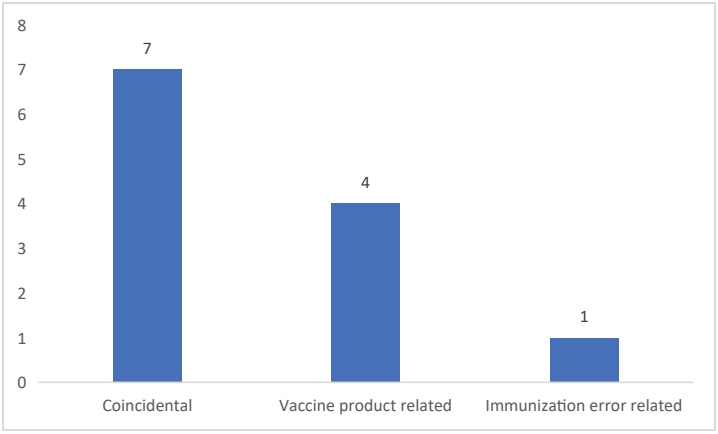

Fig 9: Outcome of causality assessment for 12 serious cases received during the YF campaign

The top 5 commonly reported events with their System Organ Classification are as shown below:

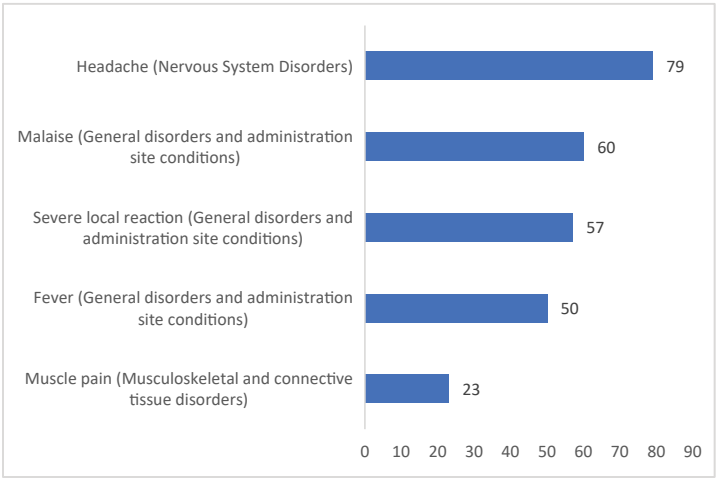

Fig 10: Top 5 commonly reported events with their System Organ Class during the YF campaign

The regional distribution of AEFI reports received through the Spontaneous Reporting System is as shown below:

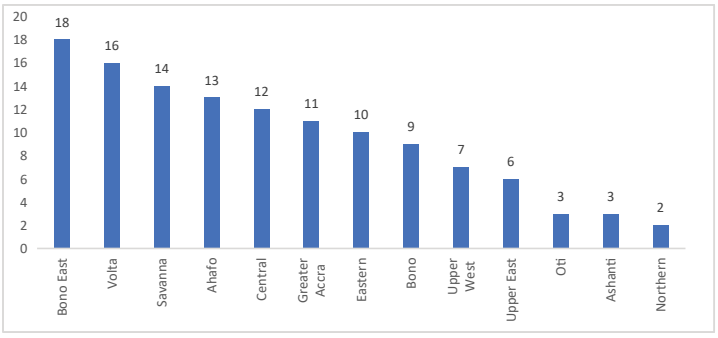

Fig 11: Regional distribution of reports received per 100,000 vaccinated during the YF campaign

AEFI Reports from the Malaria Vaccine Implementation Programme reports from MVIP

Out of the 997 AEFI reports received from the MVIP in 2020, 965 (96.8%) were received from the phase 4 study, titled A prospective study to evaluate the safety, effectiveness and impact of the RTS,S/AS01E vaccine in young children in sub-Saharan Africa (EPI-MAL-003) at Navrongo Health Research Centre and Kintampo Health Research Centre in the Upper East and Bono East regions respectively. Table 3 shows the serious AEFI reports received and the source of the reports, namely, the enhanced spontaneous reporting system (GHS/FDA), MVPE and the EPI-MAL-003.

Table 3: Number of serious AEFI reports by source

No.	Monitoring Activity	AEFI Reports by Source	Non-serious	Serious
1	EPI-MAL-003	965	804	161
2	Enhanced Spontaneous (FDA/GHS)	16	13	3
3	MVPE	16	0	16
4	**Total**	**997**	**817**	**180**

The outcome of the causality assessment of the 180 serious cases reviewed by the Joint Malaria Vaccine Committee (JMVC) is shown below:

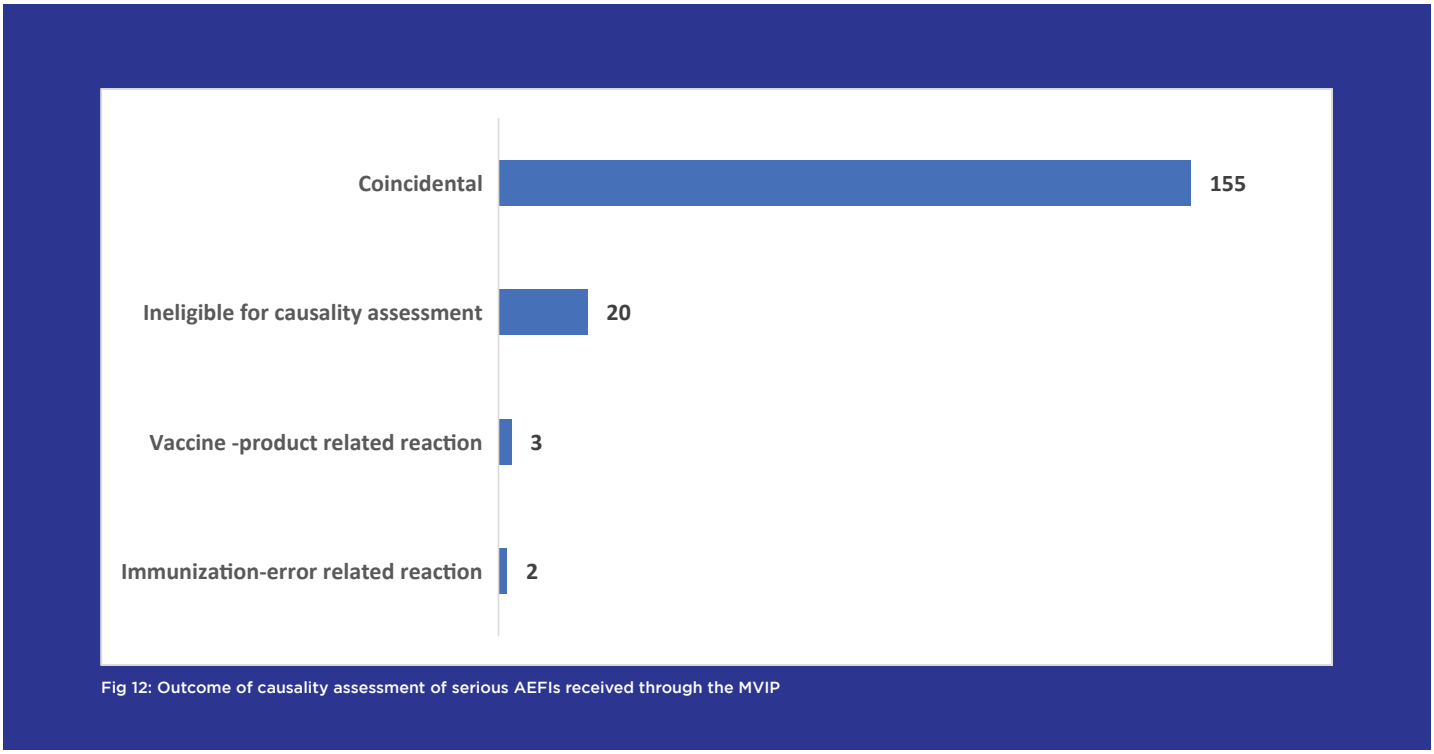

Fig 12: Outcome of causality assessment of serious AEFIs received through the MVIP

Safety Monitoring of COVID-19 Vaccines

The FDA has granted Emergency Use Authorization (EUA) to six COVID-19 vaccines on the dates indicated below at the time of publication of this newsletter.

Table 4: List of COVID-19 vaccines granted Emergency Use Authorization (EUA)

No.	Name of vaccine	Manufacturer	Date of Authorization	Storage Conditions
1.	Sputnik V (Gam-COVID-Vac)	Gameleya National Centre of Epidemiology and Microbiology, Russia	9th February, 2021	-18°C
2.	Covishield (ChAdOX1Ncov-19 Corona Virus Vaccine (Recombinant)	Serum Institute of India Pvt. Limited, India	12th February, 2021	2°C - 8°C
3.	COVID-19 Vaccine Janssen Suspension for Injection (Ad26.COV2-S [recombinant])	Janssen Vaccines & Prevention B. V, 2333 CN Leiden, The Netherlands	3rd June, 2021	2°C - 8°C
4.	Moderna's Dispersion for Injection [COVID-19 mRNA Vaccine (nucleoside modified)]	Moderna Biotech Spain, S.L.	30th June, 2021	-25°C - 15°C
5.	Comirnaty Concentrate for Dispersion for Injection [COVID-19 mRNA Vaccine (nucleoside modified)]	BioNTech Manufacturing GmbH, Germany	30th June, 2021	-80°C - 60°C (6months) and 2°C to 8°C up to 5days
6.	COVID-19 Vaccine AstraZeneca Suspension for Injection (ChAdOx1 S [recombinant])	AstraZeneca, United Kingdom	29th July, 2021	2°C - 8°C

Review of COVID-19 Vaccine Safety Information

One of the roles of the FDA during the deployment of COVID-19 vaccines is to continually monitor safety of these vaccines and keep stakeholders informed about the safety reports received. The FDA has a proactive safety monitoring strategy with dedicated staff in place for performing this activity. Review of safety reports received from the general public and healthcare professionals for all COVID-19 vaccines deployed did not show any major safety concern from the vaccinations. The FDA has both active safety surveillance and spontaneous reporting systems in place to receive safety reports for all vaccines. In the active safety surveillance strategy, vaccinees are followed up on specified days after vaccination to solicit for AEFIs. The spontaneous reporting system relies on voluntary notification of any AEFI after vaccination by the general public and healthcare professionals.

From March to August 2021, three vaccines namely, Oxford/AstraZeneca (Covishield/Vaxzevria), Sputnik V and COVID-19 Vaccine Janssen (Johnson and Johnson vaccine) had been deployed in Ghana. The total doses of the three vaccines administered is 1,404,463 consisting of 1,232,876 doses of Covishield, 107,766 doses of COVID-19 Vaccine Janssen and 63,821 doses of Sputnik V.

The total number of AEFI reports received within the same period for the three vaccines was 5,451 with the overall reporting rate of 3 to 4 reports per 1,000 doses administered. There were 3,365 AEFI reports submitted for Oxford/AstraZeneca (Covishield/Vaxzevria), 1,993 for Sputnik V and 93 for COVID-19 Vaccine Janssen. The higher reporting rate for Sputnik V was because the AEFI reports were mainly through the active safety surveillance system.

The most commonly reported AEFIs for the three vaccines were headache, fever, chills, pain at injection site and body pains which resolved within a day or two.

Out of the 5,451 AEFI reports received, 26 were considered to be serious. Consequently, causality assessment was done by the FDA's Joint COVID-19 Vaccine Safety Review Committee (JCVSRC) using the WHO's AEFI Causality Assessment procedure. This showed that there was no direct causal relationship between the vaccinations and the AEFIs except those known to be caused by the vaccine.

In addition to the local data the JCVSRC also reviewed safety information from international sources and recommended the continued use of the COVID-19 vaccines granted EUA by the FDA because these vaccines continue to be effective in reducing the risk of severe disease, hospitalization and death from coronavirus disease.

The FDA will continue to proactively monitor the safety of all vaccines issued EUA being deployed during the pandemic and keep all stakeholders informed about any safety issues.

Strengthening Haemovigilance in Ghana

The World Health Organization defines haemovigilance as a continuous process of data collection and analysis of transfusion-related adverse events and reactions in order to investigate their causes and outcomes and prevent their occurrence or recurrence.

The FDA received 48 adverse reaction reports to blood and blood between 2018 and 2020. All the reports were classified as non- serious reports and did not lead to any major reviews in policy.

The FDA and the National Blood Service are working together with support from the Paul Ehrlich Institute, Germany to strengthen the haemovigilance system in Ghana.

The 3 institutions have worked together to develop the Haemovigilance Framework in Ghana and Guidelines for Reporting Adverse Reactions and Adverse Events in the Blood Transfusion Chain for Ghana which is to be launched in the near future.

New safety information or signals identified by FDA through the adverse reaction reporting system in 2020

Below is the list of signals identified by the FDA in 2020 through the spontaneous adverse reaction reporting system and actions taken to protect patients.

Product Name: Brand (Active Ingredient)	Signal / New Safety Information	Regulatory Action taken
Bupivacaine Hydrochloride Injection	Therapeutic Ineffectiveness of Bupivacaine Hydrochloride Injection	Dear Healthcare Professional letter to Anesthesiologists and Anesthetists
Paraconica (Paracetamol 10mg/ml) Solution	Crystallization and Discoloration of Paracetamol 1000mg IV	Healthcare professionals were advised about the proper storage condition of the product. Manufacturer informed to amend the label to clarify the storage condition of the product.

Rare Events of Thrombosis and Thrombocytopenia Following Vaccination with Covid-19 Vaccine AstraZeneca

This publication was targeted towards healthcare professionals to provide information on the safety signal of rare events of thrombosis and thrombocytopenia following vaccination with COVID-19 Vaccine AstraZeneca (Covishield) in Ghana. The communication is a result of reports received in Europe and other countries and recommendation by the Pharmacovigilance Risk Assessment.

These rare reports consisted of blood clots associated with thrombocytopenia, with or without bleeding, including rare cases of cerebral venous sinus thrombosis (CVST) i.e. clots in the vessels draining blood from the brain.

Whilst no causal link has been found between the reported thrombotic events and the AstraZeneca Covid-19 vaccine, the FDA advised healthcare professionals to closely monitor persons vaccinated and ask them to seek immediate medical attention if they develop any of the underlisted after vaccination:

- Shortness of breath, chest pain, leg swelling, persistent abdominal pain
- Neurological symptoms including severe or persistent headaches or blurred vision, headache for more than 4 days after vaccination, or experiences skin bruising (petechia) beyond the site of vaccination after a few days.

Suspected Therapeutic Ineffectiveness of Bupivacaine Hydrochloride Injection

Anesthesiologists and anesthetists were informed of a total of nineteen (19) suspected therapeutic failure reports of Bupivacaine hydrochloride Injection used for anesthesia in a three-year period (i. e. 2017 to 2020).

The FDA notified healthcare professionals that analysis conducted by the Quality Control Laboratory on quality and sterility of these products revealed that physicochemical and microbiological parameters were not compromised.

Advice to anesthesiologists and anesthetists were:

- Bupivacaine hydrochloride by intrathecal anesthesia should be given only by Anesthesiologists and Anesthetists with the necessary training, knowledge and experience to avoid failure of therapy.
- Patients requiring anesthesia should be adequately prepared as per the standard operative procedures includ ing but not limited to preoperative assessment, appropriate hydration and pre-medication.
- Anesthesiologists and anesthetists must ensure availability of emergency medi cations needed for the treatment of possible adverse effects when they occur.

Reporting Medication Errors

This publication reminded healthcare professionals that medication errors and circumstance or information capable of leading to medication errors are reportable events. These should therefore be reported to the FDA using the Adverse Reaction Reporting Form. These reports are reviewed by the FDA for appropriate regulatory action to be taken when necessary.

Healthcare professionals were also reminded that these reports should be reviewed by the Drugs and Therapeutic Committees (DTCs) at the facility level, when available, and lessons learnt used for system improvement and modifying behaviour to prevent future occurrence.

The FDA wishes to assure all healthcare professionals that reports on medication errors and circumstance or information capable of leading to medication errors received are used to implement regulatory actions to prevent future occurrence.

Healthcare professionals are therefore requested to submit all reports on medication errors and all other adverse reactions to the FDA.

Potential Carcinogenic Effect of Gentian Violet

This publication sought to bring to the attention of the general public that the Technical Advisory Committee on Safety of Medicine (TAC-SM) of the FDA has completed review of safety concerns regarding the potential carcinogenic effect of oral exposure to gentian violet in animal and human products. Gentian violet is a non-prescription antiseptic dye used to treat fungal infections. It also has weak antibacterial effects and may be used on minor cuts and scrapes to prevent infection. The TAC-SM's review concluded that currently there is no evidence that gentian violet can cause cancer in humans.

The conclusion was based on the fact that FDA has not received any adverse reaction report to gentian violet use in humans and there is no evidence from the literature that gentian violet can cause cancer in humans.

The review follows Health Canada's withdrawal of all products containing gentian violet from the Canadian market triggered by the Codex Alimentarius Commission's recommendation to regulatory authorities to prevent exposure to gentian violet in food residues because of its potential to cause cancer. The FDA will continue to monitor the situation and inform the general public when new information becomes available.

Public Statement on the Withdrawal of Johnson and Johnson Brand of Baby Talcum Powder from North American Market

This publication was to address discussions on social media that has gone viral which linked the use of Johnson's baby talcum powder with ovarian cancers.

The FDA assured the public that it has since 2018 increased its regulatory activities and put in place appropriate measures to ensure public safety in the use of all cosmetic products containing talcum powder.

Talc as a product naturally found near asbestos, has the potential to become contaminated during the mining process. Over-exposure to such contaminated talc has been linked to cases of ovarian and lung cancers. All talc-containing powders including Johnson's Baby Powder registered for use in Ghana are rigorously evaluated to ensure that they are asbestos-free.

FDA undertakes the underlisted regulatory activities on all talc-based products to ensure they are free from asbestos.

- Stringent evaluation of documentation submitted for registration to ensure that talc in these products are certified from the country of origin as asbestos-free.
- Rigorous Quality Control Laboratory analysis to verify that indeed the talc-containing powders submitted do not contain asbestos.
- Targeted biennial market surveillance activi ties to verify that products being marketed continue to be free of asbestos. In the last market surveillance activity in 2018 a total of 50 different talc based cosmetic powders were tested.
- Periodic evaluation of available peer-reviewed publications and scientific data from studies by the FDA's expert Technical Advisory Committee on Safety of Products.

The general public was informed that the FDA will continue to analyze cosmetic powders that contain talc for asbestos contamination, monitor closely and review any new safety data related to the use of talc in these products, take appropriate action and inform the public accordingly.

Crystallization and Discoloration of Paracetamol 100mg IV

This publication was to alert healthcare professionals on reports of pharmaceutical defects presenting in the form of crystallization and discoloration with Paraconica (Paracetamol 10mg/ml) Solution for Infusion when stored under refrigerated conditions (2°C-8°C).

Healthcare professionals were informed that the reports of the pharmaceutical defects reported was as a result of the underlisted reasons.

- Storage of the product under refrigerated condition because of ambiguous storage conditions on the primary package which indicated "Do not store above 30°C"
- Paraconica Solution contains an inactive ingredient, mannitol, which crystalizes when stored at refrigerated conditions or lower temperatures. The storage of the samples in the fridge resulted in the colour change and crystals observed.

The FDA has since informed the manufacturer of Paraconica IV Solution and other Paracetamol IV Solutions containing mannitol as an inactive ingredient to revise the storage conditions on the product labels to include the instruction "Do not refrigerate or freeze" and also list all excipients on the product labels.

Advice to Healthcare Professionals:

Healthcare professionals are therefore advised not to refrigerate or freeze Paracetamol IV Solution containing mannitol

Preliminary findings from stimulated spontaneous reporting of adverse drug reactions during COVID-19 pandemic: An experience from Ghana.

The Food and Drugs Authority published the manuscript with the above title in the Ghana Medical Journal in 2020. The abstract is reproduced below, readers can read the full article at
DOI: 10.4314/gmj.v54i4s.10

Background: The novel coronavirus disease 2019 (COVID-19) is an ongoing pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and there is limited information on the safety of drugs used for treatment of COVID-19.

Objective: Objective of this study is to describe the pattern of stimulated spontaneous adverse drug reaction (ADR) reports received from healthcare professionals for SARS-CoV-2 positive patients in Ghana and lessons learnt particularly for low- and middle-income
countries.

Methods: This is a study of individual case safety reports (ICSRs) received from healthcare professionals between 1st April 2020 to 31st July 2020 in SARS-CoV-2 positive patients in Ghana. The ICSRs were retrieved from the SafetyWatch System and descriptive statistics used to describe the ADRs by System Organ Classification and Preferred Term.

Results: Information was received from 40 COVID-19 Treatment Centres across the country with 9 centres submitting a total of 53 ICSRs containing 101 ADRs; approximately two ADRs per ICSR. Females accounted for 29(54.7%) of the ICSRs and males 24(45.3%). Newly reported ADRs of interest were one report each of tremor for doxycycline; scrotal pain, dyspnoea, gait disturbances and dysgeusia for chloroquine; and dry throat, hyperhidrosis, restlessness and micturition frequency increased for hydroxychloroquine. A strong spontaneous system with availability of focal persons at the Treatment Centres played a key role in reporting ADRs during the pandemic.

Conclusion: This is the first experience with spontaneous reporting during COVID-19 pandemic. The profile of most of the ADRs reported appears consistent with what is expected from the summary of product characteristics. Larger sample size with well-defined denominator in future studies is paramount in determining the relative risk of these medications in SARS-CoV-2 positive patients.

Pharmacovigilance Benchmarking Mission by Regulators from Three West African Countires

Nine regulators from three West African countries, namely, Gambia, Liberia and Sierra Leone were in Ghana for three weeks to understudy Ghana's system for regulation of clinical trials and pharmacovigilance. The benchmarking mission afforded the Team the opportunity to learn the underlisted from their Ghanaian colleagues.

- Establishment and maintenance of a national pharmacovigilance system.
- Implementation of regulatory requirements for pharmaceutical industry.
- Patient engagement in pharmacovigilance.
- Clinical Trials Oversight and Authorization.
- Good Clinical Practice (GCP) Inspection and Report Writing.
- The use of other Compliance Tools in Clinical Trials.

The visiting team appreciated their learning experiences from the FDA and looked foward to building a robust clinical trials and pharmacovigilance systems in their countries.

Some members of the FDA Pharmacovigilance Team with the Regulators from the Gambia, Liberia and Sierra Leone with Mr. Alex Amoyaw (middle), representing Society of Pharmacovigilance Ghana

The CEO of the FDA, Mrs. Delese Darko, presented a certificate of participation to one of the participants (Mr. Essa Marenah) from the Gambia

Take Back of Unused or Expired Medicine (TBUM)

The Take Back of Unused or Expired Medicines (TBUM) initiative by the Food and Drugs Authority was launched in October 2020 as a programme for individual consumers to safely dispose off unwanted medicines by disposing them in FDA specified receptacles made available at strategic places (mostly community pharmcies) designated as TBUM Centres.

The goal of the TBUM initiative is to ensure safe disposal of a variety of unwanted medicines including prescrition drugs and over-the-counter drugs and supplements by consumers as per FDA's mandate stipulated in Section 132, Sub section 2 and 3 of the Public Health Act 2012, Act 851 and 3rd Edition of the National Drug Policy.

The TBUM initiative is being undertaken in collaboration with Community Pharmacists Practice Assocoation (CPPA) with support from corporate organizations who donate the receptables for collecting the unwanted medicines.

The initiative was started as a pilot with fifty (50) community pharmacies in the Greater Accra Region. This was extended to Western and Ashanti regions in May 2021 with plans of nationwide expansion to both community pharmacies and over-the-counter medicine sellers. Participating pharmacies are provided with branded receptacles for collecting the unwanted medicines to be placed in their community pharmacies and trained on the intiative and its importance.

As at August 2021, one hundred and seventy one (171) different medicines of various quantities had been collected at the various TBUM centres.

The TBUM initiative ensures that medicines including antiobiotics are not disposed off in a manner that will harm the environment and pose danger to Ghanaians and prevents accidental ingestion of medicines by toddlers or teenagers leading to poisoning or drug abuse.

The FDA greatly appreciates the collaboration of the community pharmacies who have supported the programme this far and Polytank Ghana Ltd for donating the first 50 receptacles.

The FDA is calling on all healthcare professionals to educate their clients on safe disposal of unwanted medicines and the TBUM initiative.

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Shiashie
GPS: GA-237-7316
Tel: 03022 35100
Call Centre: +233 30 825 0070

Upper West Regional Office
P. O. Box 291
Wa
Controller Block Ministries
GPS: XW-0021-9492
Tel: +233-3920-20111
Mobile: +233-244 470 413

Northern Regional Office
P. O. Box TL 1763
Tamale
Regional Administration Building
GPS: NT-0066-3381
Tel: 0372024935
Mobile: 0208 120 901

Western Regional Office
P. O. Box MC2129
Takoradi
Harbour Post Office
Adjacent Fidelity Bank
GPS: WS-406-1927
Tel: 0312027558
0544 338 829

Upper East Regional Office
P. O. Box 612
Bolgatanga
Regional Administration Building
GPS: UB-0034-4017
Tel: 0247 717 744, 0500 233 377

Eastern Regional Office
P. O. Box KF 2431
Koforidua
Hospital Road Opposite
Assemblies of God Church
Tel: 03420 21250
Mobile: 0277 705 752, 0244206302
GPS: EN-011-2579

Volta Regional Office
Private Mail Bag
Ho
Opposite GWCL Building
(Same Building with Cool FM)
GPS: VH-0016-3748
Tel: +233-3620-26659
Mobile: 0244339632, 0247 978 956

Central Regional Office
P. O. Box CC 1373
Cape Coast
UCC Credit Union Building Adjacent
CEDECOM Building Pedu Junction
GPS: CC-097-0402
Tel: +233-33-090110, 0245839521
0504422905

Ashanti Regional Office
P. O. Box ST 402
Kumasi
Regional Coordinating Council (RCC)
next to Electoral Commission's Office
Tel: +233-302-203-6027/70
Mobile: +233-507-187-420/1/2
GPS: AK-133-7324

Bono Regional Office
Postal address PMB, Sunyani
House No. 61A, Nkwabeng Extension
Sunyani. Near St. Mary's School.
Opposite Goode Goode Spot
Tel: +233-3520-28791
Mobile: +233-265-062697
GPS: BS-0054-2542

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 views on any edition of the newsletter you receive.

Name (optional):.....

Organization (optional):.....

Name (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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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 ADRs whether known or not which causes concern in the caregiver/the patient
- Lack of efficacy/therapeutic failure
- Suspected pharmaceutical defect
- Counterfeit pharmaceuticals
- Mediation errors

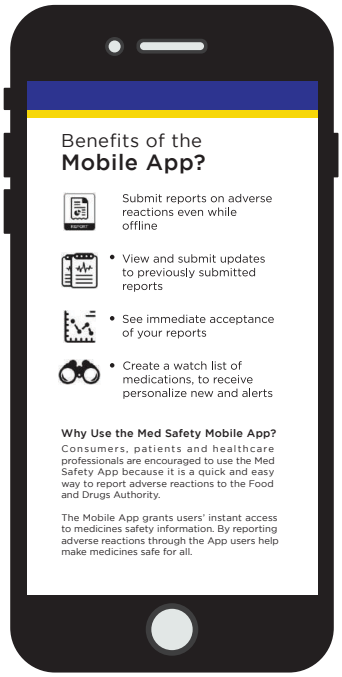
You don't need to be certain, just be suspicious!

Report may be submitted by using the FDA "Blue Form" available at hospitals and pharmacies and also available at the FDA website https://fdaghana.gov.gh/ or the Med Safety app available from Google play store or android or App store for IOS. You may also contact the National Pharmacovigilance Centre on Mobile No: 0244310279 or Email: drug.safesty@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 hand

- 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 receive personalize new and alerts



Why **USE** the **Med Safety Mobile App?**

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

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

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