NEWSLETTER ISSUE 8 AUGUST, 2020

DRUGLENS

Message from the Chief Executive Officer

DELESE MIMI DARKO

I wish to welcome you to the 8th Edition of the Druglens; this Newsletter provides comprehensive safety information on drugs, vaccines and other medicinal products and also seeks to inform stakeholders about activities by the Food and Drugs Authority (FDA) to promote patient safety.

In 2019, the FDA undertook a number of activities including the successful launch of the Med Safety App. The app aims to facilitate reporting of safety issues and improve a two-way communication between the Authority and its stakeholders.

As at the end of April 2020, ten months after the launch, there have been 1,670 downloads and 75 safety reports received through the app. Of these 75 reports, 60 (80%) were submitted by healthcare professionals and the remaining 15 (20%) were from patients.

The FDA will first of all in 2020 focus on activities that will promote patient safety by introducing strategies to actively engage patients and healthcare professionals on the benefits of using technology to enhance pharmacovigilance. This will be achieved by collaboration with private and public institutions aimed at building public confidence with respect to information sharing on medicine safety issues.

Secondly, the FDA looks forward to extending safety monitoring activities to lower levels of the healthcare delivery system with the objective of widening the scope of pharmacovigilance activities, increasing reporting of safety issues and improving the possibility of signal detection of marketed products.

The third strategy is to continue to strengthen the pharmaceutical industry's involvement in pharmacovigilance in line with the Public Health Act 2012, Act 851 to promote safety of marketed products. To this end, the FDA will hold a seminar for Qualified Persons for Pharmacovigilance (QPPVs) to receive feedback on progress so far and chart the way forward for effective implementation of this requirement.

Finally, the FDA is committed to improving patient safety at all times and especially during the COVID-19 pandemic. The FDA will also continue to provide services needed during the pandemic and in particular safety monitoring of all products recommended by the Emergency National Medicines Selection Committee of Experts for the treatment of patients with COVID-19.

The FDA is also working around the clock to come up with new guidelines during this unprecedented times to ensure registration of new technologies and fast-track approval of health products to combat the pandemic including hand sanitizers, face masks and issuance of Emergency Use Authorization for drugs recommended by the Emergency National Medicine Selection Committee of Experts of the Ministry of Health so that physicians can prescribe these drugs for the treatment of patients with COVID-19.

I wish you all the best in 2020 as we continue to seek perfection in all we do.

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SPONTANEOUS REPORTING FOR 2019

The National Pharmacovigilance Centre received two thousand, two hundred and thirty-six (2,236) spontaneous reports in 2019. This represents a reporting rate of 75 reports per million population. Although Ghana has seen an increase in reporting rate more efforts needs to be made as the current rate is low compared to the WHO reporting rate of 200 safety reports per million population.

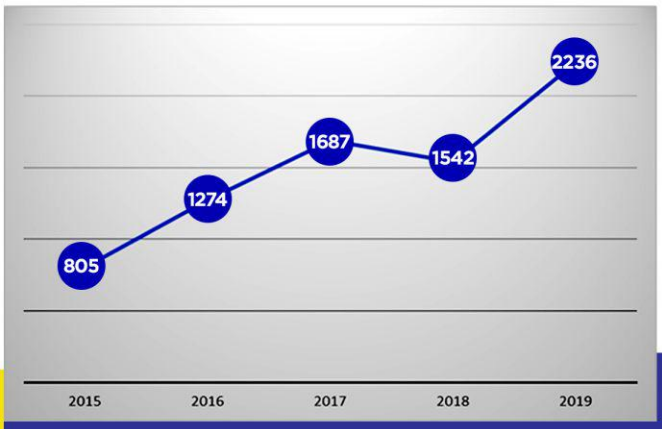


Figure 1: Number of Reports Received from 2015-2019

The 2,236 spontaneous reports received includes 66 product quality reports. The analysis below is for the 2,170 reports excluding those for product quality. Out of 2,170 reports, 1,317 (60.7%) were from females and 743 (34.2%) from males, the gender for the remaining 110 (5.1%) is unknown.

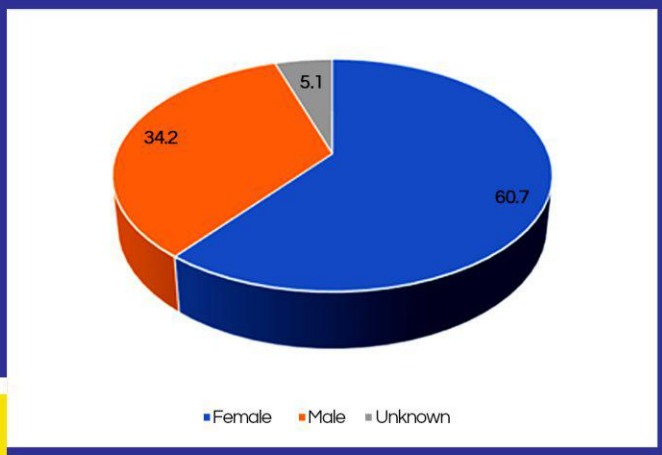


Figure 2: Gender distribution of patients who had adverse reactions

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

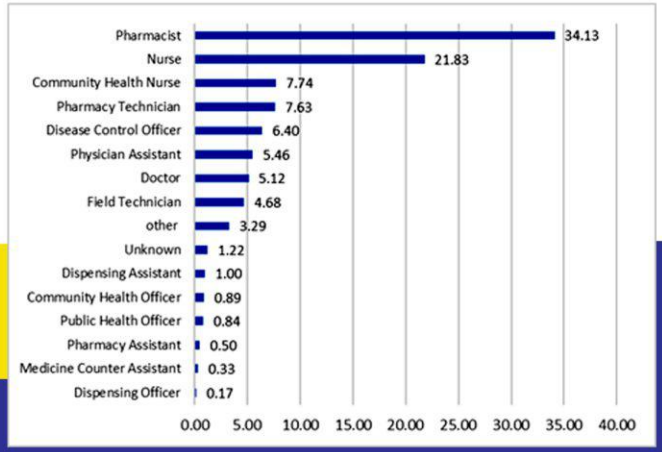


Figure 3: Percentage reporting by healthcare professionals

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

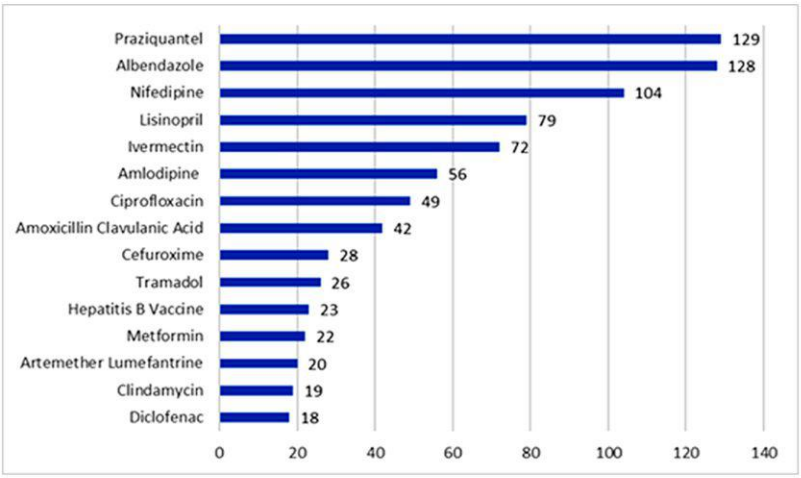


Figure 4: Top 15 medicines with the most commonly reported adverse reactions

Albendazole and Praziquantel combination is used in school-based mass deworming exercise to control schistosomiasis and hookworm infections.

The highest occurring ADRs to Nifedipine was headache. Although the exact frequency of occurrence cannot be established due to the challenges with spontaneous reporting, the reporting pattern observed in 2019 does not deviate from what is in literature.

THE OUTCOME OF THE REPORTED REACTIONS IS SHOWN IN FIGURE 5 BELOW

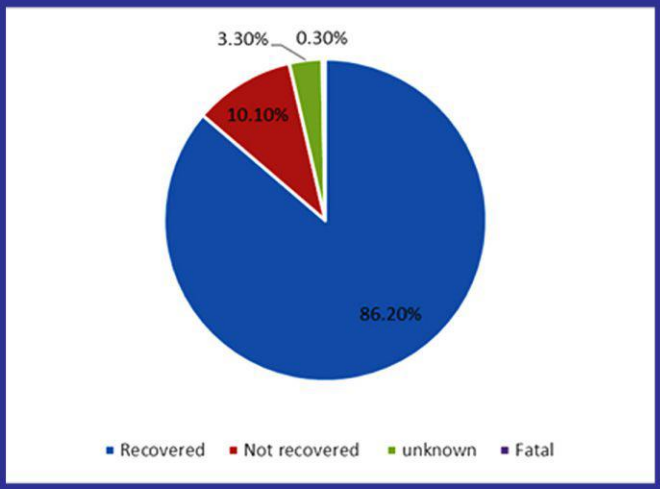


Figure 5: Outcome of the Reported adverse reactions

THE NUMBER OF REPORTS RECEIVED FROM THE REGIONS

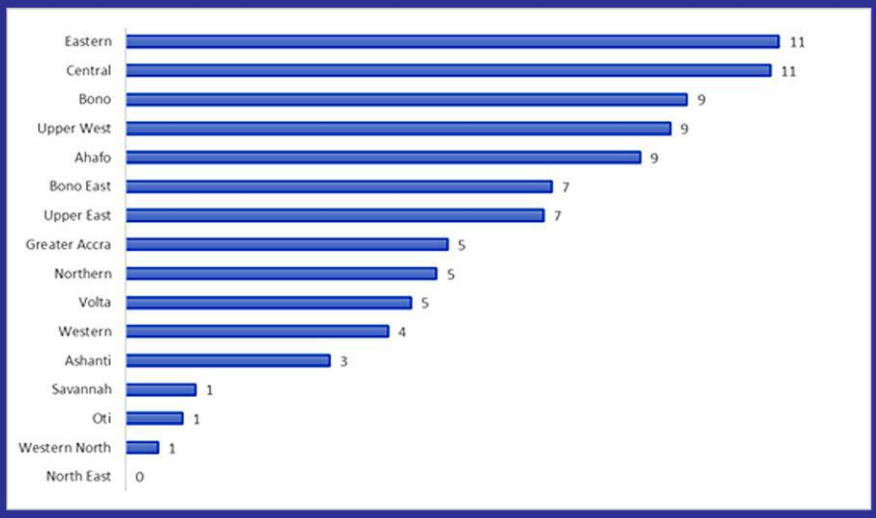


Figure 6: Number of spontaneous reports received per 10,000 inhabitants

TABLE 1: TOP 20 REPORTING HEALTHCARE FACILITIES IN 2019

FACILITY	REGION	NUMBER OF REPORTS
Kwahu Government Hospital	Eastern	51
Atua Government Hospital	Eastern	49
Nsuaem CHPS	Western	43
Peki Dzake Health Centre	Volta	42
Akuse Government Hospital	Eastern	41
St. Francis Xavier Hospital	Central	41
Komfo Anokye Teaching Hospital	Ashanti	38
Eastern Regional Hospital	Eastern	36
St. Gregory Catholic Hospital	Central	36
Bolgatanga Regional Hospital	Upper East	36
Greater Accra Regional Hospital	Greater Accra	27
University of Ghana Hospital	Greater Accra	27
Oda Government Hospital	Eastern	25
St. Joseph Hospital, Koforidua	Eastern	25
Tema Polyclinic	Greater Accra	22
Praso Health Centre	Central	20
Awisem CHPS	Central	19
Madina Polyclinic, Kekele	Greater Accra	18
Agona Swedru Municipal Hospital	Central Region	17
Gomoa Obuasi Health Centre	Central Region	15

UPDATE ON PATIENT SAFETY CENTRES

Patient Safety Centres are community pharmacies that have been so designated by the Food and Drugs Authority after training and resourcing with educational materials to promote direct patient/consumer reporting of safety issues including side effects, product quality issues and medication errors.

The Patient Safety Centre initiative has entered its fourth year since the launch in June 2016.

Community pharmacists have embrace this initiative because of the added benefit of being awarded two Continuing Professional Development (CPD) points to pharmacists who submit adverse reaction reports to the FDA.

Forty-seven (47) community pharmacists were awarded CPD credits for participating in the Patient Safety Centres programme in 2019.

The FDA appreciates all community pharmacists, who continue to put patient safety first by reporting side effects of medicines experienced by patients. The FDA says "Ayekoo" to all of you for adhering to Patient Safety, one of the core mandates of pharmacy practice. All of you have helped to empower patients on how to effectively use their medicines and also contribute to knowledge on the safety of medicines and other health products.

Management and staff of GinaPharma in the Northern Region displayed exceptional dedication to patient safety in 2019.

Management of GinaPharma (from left to right) **Pharm. Agyepong Kwame, Pharm. Fauzia Alhassan and Dr. Paul Benissah**

The staff believe that being a Patient Safety Centre has encouraged their clients to talk to them openly about safe use of medicines and other health products.

The FDA appreciates the work of all reporting Patient Safety Centres for their good work in promoting patient safety. Table 2 shows the top ten reporting Patient Safety Centres.

Table 2: Top 5 Patient Safety Centres in Ghana

FACILITY	REGION	NUMBER OF REPORTS
GinaPharma	Northern	16
Union Square Pharmacy	Central	12
Obrasi Pharmacy	Northern	10
Super Light Phamacy	Northern	6
Equity Pharmacy	Greater Accra	6
Trust Care Pharmacy	Northern	4
Smart Chemist	Northern	4
Open Arms Pharmacy	Northern	4
Mauplaus Pharmacy	Northern	4
Fabby Chemist	Greater Accra	4

PASSION FOR PATIENT SAFETY

DR. ADJOA POKUA OSAE AWUKU is an Optometrist currently practicing at Abesim Health Center/Eye Clinic in the Bono Region. She is the first eye specialist to have shown such great interest in patient safety. The eye is often described as the mirror of the soul. Eye conditions are very painful and disabling, thus to have an adverse drug reaction from treatment received for an eye condition is very unpleasant.

Dr. Osae Awuku is very passionate about her work and looks forward to seeing her patients happy on review due to quality service delivery as well as use of effective/efficacious drugs. However, whenever she suspects an adverse reaction, she ensures that these are promptly reported to the Food and Drugs Authority and the patient managed promptly

Dr. Osae Awuku admitted that the pharmacovigilance training she received as part of Medical and Dental Council accredited CPD programme in 2018 organized by the FDA has given her a better understanding of the risks associated with the use of medicines and other health products. She understands that spending some few minutes to know whether her patients have any safety issues with prescribed medicines has helped identify adverse drug reactions and also yielded better treatment outcomes.

In her words, she encourages all prescribers to spend time in knowing about any safety issues with medicines, manage these issues and most importantly report them to the FDA by completing the adverse reaction reporting form or through the Med Safety App".

The FDA truly appreciates efforts of prescribers like Dr. Adjoa Pokua Osae Awuku who take time off their busy schedule to contribute to patient safety.

VACCINE SAFETY UPDATES

Underreporting of adverse events following immunization (AEFI) is a major challenge for vaccine pharmacovigilance. The year 2019 saw an increase in the number of spontaneous AEFI reports received as compared to previous years. A total of 397 spontaneous AEFI reports were received with regional distribution shown in Figure 7.

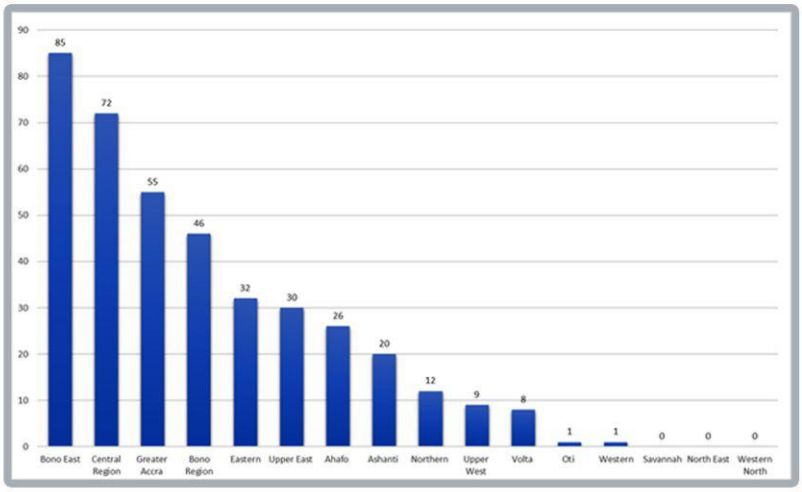


Figure 7: Regional distribution of AEFI reports received in 2019

Out of the 397 AEFI reports received, 7 (1.8%) were classified as serious and the results of the causality assessment 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 Table 1. (ref is https://apps.who.int/iris/bitstream/handle/10665/259959/9789241513654-eng.pdf;jsessionid=75C16A189D0D9FD8A93658196CFF66A9?sequence=1)

Table 1: Outcome of the causality assessment of the seven serious AEFI reports

NO	CASE NO.		CAUSALITY
1	0819AATNAR0002	Oral Polio vaccine, Pentavalent vaccine, Inactivated Polio vaccine, Pneumococcal conjugate vaccine	A1 (vaccine product related reaction) and C1 (coincidental)
2	0819AAFSBA0123	Pentavalent vaccine	A1 (vaccine product related reaction) and C1 (coincidental)
3	0819AAFSBA0124	Pneumococcal conjugate vaccine	A1 (vaccine product related reaction) and C1 (coincidental)
4	0919AAKNAR0013	Oral Polio vaccine, Pentavalent vaccine, Pneumococcal conjugate vaccine, Rotavirus vaccine	Ineligible for causality assessment due to insufficient information
5	0819AKUMAR0003	Oral Polio vaccine, Pentavalent vaccine, Pneumococcal conjugate vaccine, Rotavirus vaccine	Ineligible for causality assessment due to insufficient information
6	0719AMUNUW0001	Pentavalent vaccine, Pneumococcal conjugate vaccine	Ineligible for causality assessment due to insufficient information
7	0719AAFKAR0001	Oral Polio vaccine, Pentavalent vaccine, Pneumococcal conjugate vaccine, Rotavirus vaccine	Ineligible for causality assessment due to insufficient information

Four (57%) of the serious AEFI reports were classified as ineligible for causality assessment due to insufficient information because clinical investigations were not done, so the required information and documents to facilitate causality assessment (e.g. autopsy report, clinical notes, AEFI investigation form) were not available.

UPDATE ON THE SAFETY MONITORING OF THE MALARIA VACCINE

Background

On 30th April 2019, the Ministry of Health launched the first malaria vaccine (Mosquirix or RTS,S/ASO1E) to be given to young children in routine immunization programme in selected areas of Ghana and two other African countries, Kenya and Malawi. The pilot introduction of the vaccine followed rigorous testing in Africa; when given in 4 doses, the vaccine significantly reduced malaria among children.

The malaria vaccine is given to children up to 2 years of age.

The phased introduction is taking place in seven regions in Ghana, namely, Ahafo, Bono, Bono East, Central, Oti, Volta and Upper East Regions.

Additionally, 10 districts in the Upper East and Bono East regions are involved in phase 4 studies led by GlaxoSmithKline, the manufacturer of the vaccine. These studies are required and standard for a new vaccine introduction to gather additional information on the vaccine's effectiveness and any side effects associated with routine use.

The MVIP is specifically designed to assess the feasibility of administering the recommended 4 doses of the vaccine in children; the vaccine's potential role in reducing childhood deaths; and its safety in the context of routine use. Data and information derived from the pilot will inform a World Health Organization (WHO) policy recommendation on the broader use of the vaccine.

Outcome of Safety Monitoring

The FDA in collaboration with the Expanded Programme on Immunization (EPI), Ghana Health Service (GHS), has a robust safety monitoring system in place to ensure that any issues that may arise from the use of Mosquirix are promptly reported and adequately assessed to ensure safety of children receiving the vaccine.

A seven-member Safety Committee of independent experts, known as the Joint Malaria Vaccine Committee (JMVC), constituted by the FDA, is in place to review all adverse events following immunization (AEFI) reports received from the Malaria Vaccine Implementation Programme (MVIP) and make recommendations to the FDA regarding the continued implementation of the MVIP or otherwise. The JMVC has had five meetings between June and December 2019 and reviewed AEFI reports received.

The WHO defines an AEFI as any untoward medical occurrence which follows immunization and which does not necessarily have any causal relationship with the usage of the vaccine. Before the launch of the MVIP, healthcare workers were trained to report all AEFIs in children who receive Mosquirix to the FDA.

A total of 262,431 doses of Mosquirix had been given to children as at 31st March 2020, with 1,030 (one thousand and thirty) AEFI reports received within the same period.

Out of the 1,030 AEFI reports, 999 (97%) were received from the phase 4 study in the Upper East and Bono East regions where children who received the vaccine are actively followed up and all events after vaccination are documented.

Out of the 1,030 AEFI reports received, 96 (9%) were serious and the remaining 934 (91%) were non-serious. Causality assessment by the Joint Malaria Vaccine Committee of the 48 serious AEFI reports showed that there was no direct relationship between the vaccine and the events reported.

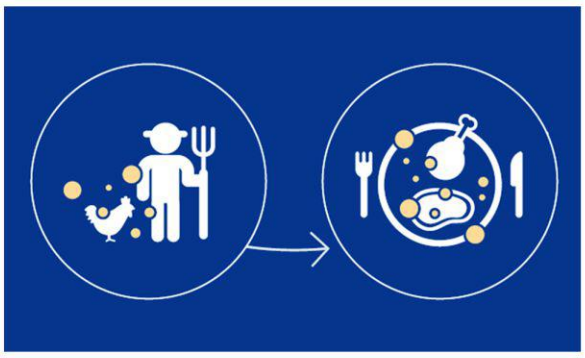
Impact of COVID-19 Pandemic on the MVIP
Vaccine uptake is closely being monitored to assess the impact of COVID-19 pandemic and containment measures on the MVIP.

"An AEFI is serious if it results: in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage."

ANTIMICROBIAL RESISTANCE- ARE THE HEYDAYS OF ANTIBIOTICS OVER?

By: Jennifer Bonnah

Antimicrobial Resistance (AMR) is the ability of disease-causing microorganisms to counteract the effects of antimicrobial agents administered so that they are not killed or their growth is not stopped. Infections in humans and animals caused by resistant microorganisms are difficult to treat and invariably become very costly to healthcare systems across the world.



The emergence of antimicrobial resistance poses a serious threat to human life across the globe resulting in life-threatening infections leading to morbidity and mortality. In low-middle income countries, AMR puts additional burden on scarce healthcare resources with resultant increase in mortality.

The mechanisms used by these microbes to counteract antibiotics and cause resistance include production of enzymes to inactivate the medicines, modification of the target which the antibiotics bind with to effect action and alteration of the biological environment of the organism which makes it difficult or impossible for the medicine to penetrate the bacterial cell walls.

It is indeed possible for one or more of these mechanisms to work together to confer resistance to a single antimicrobial agent by microorganisms.

According to research by Lawn et al, 2010, of the 3.6 million neonatal deaths recorded annually, 33.3% were due to infections. Fifteen percent (15%) of maternal deaths that occurred annually worldwide was due to infections. Additionally, it has been estimated that 15% of patients in low income countries develop infection during their hospital stay.

Poor quality antibiotics, including substandard and falsified antibiotics pose a serious threat in the treatment of infections and is a major contributor to the development of resistance of microorganisms to antibiotics. It is in this vein that the FDA has taken the bull by the horn to rid the Ghanaian market of medicines including antibiotics that do not meet the required standard.

The FDA through consistent training of staff, investment in modern equipment and sampling and testing of antibiotics has made significant gains in ensuring that regulated products including antibiotics on the Ghanaian market meet specifications as prescribed by national and international standards.

The FDA is involved in the rolling out of preventive strategies such as the following:

- Collaboration with WHO, USAID, FAO, Expanded Program for Immunisation (EPI) and other stakeholders to vaccinate children and adults against infections.

- HAND WASH campaigns that place emphasis on frequently washing hands with soap and water to prevent diseases.

- Extensive media campaigns to educate the public on the repercussions of antibiotic abuse and misuse.

Coordinated effort is needed from all and sundry to ensure infection prevention and appropriate use of antibiotics to curtail the menace of AMR to ensure continuity of the human race.

NOTICE OF MARKET AUTHORIZATION WITHDRAWALS FOR COMMERCIAL REASONS

The marketing authorization of the underlisted medicine has been withdrawn by the Marketing Authorization Holders (MAHs).

The decision to discontinue marketing these medicines was based on commercial reasons and not safety or efficacy.

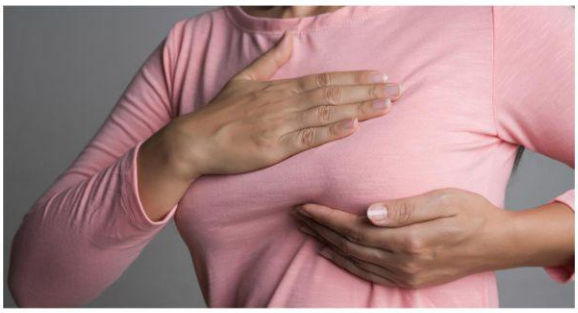
No	MAH	Name of Drug	Active Ingredient	Indication
1	Sanofi	Zeben 100mg/5ml Suspension	Albendazole	It is indicated in the treatment of single or mixed intestinal parasites, effective in the treatment of Ascaris lumbricoides (roundworm), Trichuris trichiura (whipworm), Enterobius vermicularis (pinworm/threadworm), Ancylostoma duodenale and Necator americanus (hookworm), Taenia spp. (tapeworm) and Strongyloides stercoralis. It has also been shown to be effective in the treatment of Giardia (duodenalis or intestinalis or lamblia) infections in children.

SAFETY COMMUNICATION PUBLISHED IN 2019

Severe but Rare Lung Inflammation with Palbociclib

Ibrance (Palbociclib) is a prescription only medicine belonging to a class of drugs known as cyclin-dependent kinase 4/6 inhibitors (CDK4/6). It is used in the treatment of hormone receptor positive, human epidermal growth factor receptor 2 (HER2)- negative advanced or metastatic breast cancer in combination with other drugs and has been registered by the FDA since 2017.

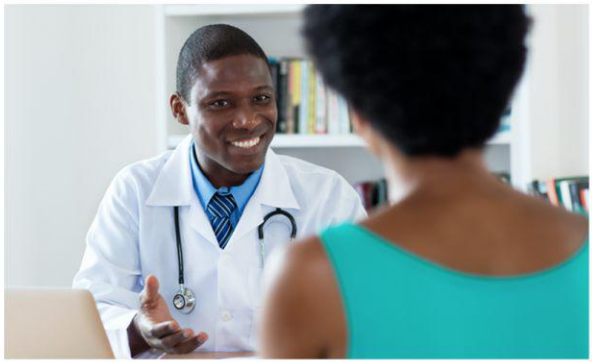
The new safety information was related to rare but severe lung inflammation with Ibrance.



Advice to Patients:

Patients should notify their healthcare providers immediately if they have difficulty or discomfort with breathing and shortness of breath while at rest or with low activity.

Healthcare Professionals:



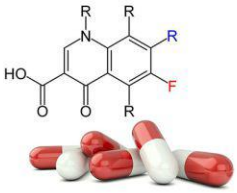
• Patients should be monitored regularly for pulmonary signs or symptoms indicative of inflammatory lung disease (ILD) or pneumonitis, some of which include hypoxia, cough, dyspnea or interstitial infiltrates on radiologic exams in patients who have had other causes excluded.

• Ibrance treatment should be interrupted immediately in patients who have new or worsening respiratory symptoms or are suspected to have developed pneumonitis. Such patients should be evaluated immediately.

• Discontinue Ibrance in all patients with severe ILD or pneumonitis.

• During counseling, patients should be advised to immediately report new or worsening respiratory symptoms.

• Healthcare providers should be encouraged to read the patient package insert they receive with their Ibrance prescriptions which provides important information and explains the safety risks associated with the medicine.

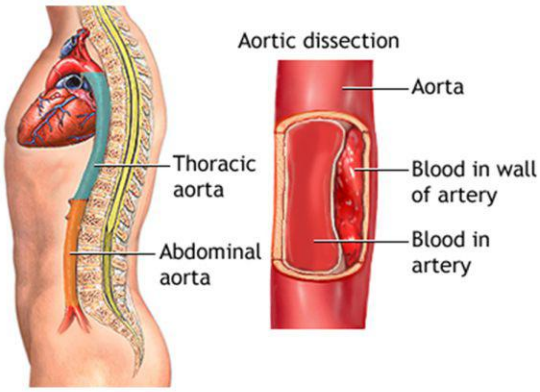


Restriction of use of Fluoroquinolones due to an increased risk of ruptures or tears in the aorta blood vessel in certain patients

This safety communication was to provide update on rare but serious adverse events of increased rupture or tears in aorta blood vessel (aortic dissections) in certain patients due to systemic use of fluroquinolone-based anti–bacterials given by mouth or injection. The aortic dissections could lead to dangerous bleeding or even death.

Persons at risk of developing aortic dissections include those with a history of blockages or aneurysms (abnormal bulges) of the aorta or other blood vessels, high blood pressure, certain genetic disorders that involve blood vessel changes and the elderly.

Fluoroquinolones are gram positive and gram negative anti-bacterials that are indicated for the treatment of bacterial infections, they work by killing or stopping the growth of bacteria. Fluoroquinolone anti-bacterials registered by the FDA include Ciprofloxacin, Levofloxacin, Moxifloxacin, Norfloxacin and Ofloxacin. A list of these medicines can be accessed on the FDA website at https://fdaghana.gov.gh/records/



Advice to Patients:

• Seek medical attention immediately by going to the hospital if you experience sudden, severe and constant pain in the stomach, chest or back during treatment with fluroquinolones.

• Report any unusual side effects from taking fluoroquinolones to your healthcare provider immediately since the symptoms of an aortic aneurysm often do not show up until the aneurysm becomes large or bursts.

• If you have a history of aneurysms, blockages or hardening of the arteries, high blood pressure or genetic conditions such as Marfan syndrome or Ehlers-Danlos syndrome, inform your healthcare provider before you start taking an antibiotic prescription.

• Do not stop taking antibiotics without consulting your healthcare provider first, if you have been prescribed one.

Advice to Healthcare Professionals:

• Avoid prescribing fluoroquinolone antibiotics to patients with aortic aneurysm or those who are at risk of developing it. This includes patients with peripheral artherosclerotic vascular diseases, hypertension, elderly patients and those with genetic conditions such as Marfan syndrome or Ehlers-Danlos syndrome.

• Only prescribe fluoroquinolones to patients at risk only when there are no other treatments available.

• Stop fluoroquinolone treatment immediately if a patient reports side effects suggestive of aortic aneurysms or dissection.

• Advice all patients to seek immediate medical treatment for any symptoms associated with aortic aneurysm.

PRODUCTS WITH ADDITIONAL RISK MINIMIZATION ACTIVITIES OR RISK MINIMIZATION MEASURES

Risk Minimization Measures are interventions intended to prevent or reduce the probability of the occurrence of an adverse reaction associated with the exposure to a medicine, or to reduce its severity should it occur. These activities may be routine risk minimization (e.g. product information) or additional risk minimization activities (e.g. healthcare professional or patient communications/ educational materials).

RESTRICTIONS TO PREVENT THE USE OF VALPROATE-CONTAINING MEDICINES IN WOMEN AND GIRLS OF CHILDBEARING POTENTIAL:

Risk minimization measure to prevent valproate exposure during pregnancy due to a high risk of serious developmental disorders (in up to 30-40% of cases) and/or congenital malformations (in approximately 10% of cases) in babies exposed in utero were submitted by the MAH.

Valproate is registered for use in Ghana for the treatment of generalized, partial or other epileptic seizures. Those registered by the FDA are Epilim Tablets and Epilim Syrup.

SUMMARY OF THE RESTRICTIONS:

• Valproate should not be used in female children and women of childbearing potential unless other treatments are ineffective or not tolerated.

• In pregnancy and in women of childbearing potential who have epilepsy valproate is contraindicated unless the conditions of the pregnancy prevention programme are fulfilled (see below).

• For women of childbearing potential currently using valproate the treatment may need to be re-evaluated to decide if the conditions of the pregnancy prevention programme are fulfilled.

KEY ELEMENTS OF THE PREGNANCY PREVENTION PROGRAMME:

The prescriber must ensure that:

• patients are evaluated individually and involved in the discussion, to guarantee their engagement, discuss therapeutic options and ensure their understanding of the risks and the measures needed to minimize the risks.

• the potential for pregnancy is assessed for all female patients and the patient understands the need to undergo pregnancy testing prior to initiation of treatment and during treatment, as needed. The patient also has to be counseled regarding contraception, and must be capable of complying with the need to use effective contraception, without interruption during the entire duration of treatment with valproate.

• the patient has clearly understood and acknowledged the risks of congenital malformations and neurodevelopmental disorders, including the magnitude of these risks for children exposed to valproate in utero and should urgently consult her physician in case of pregnancy.

• the patient understands the need for regular (at least annual) review of treatment by a specialist experienced in the management of epilepsy and understands the need to consult her physician as soon as she is planning a pregnancy to ensure timely discussion and switching to alternative treatment prior to conception, and before contraception is discontinued.

• the patient has acknowledged that she has understood the hazards and necessary precautions associated with valproate use. These conditions also concern women who are not sexually active unless the prescriber considers that there are compelling reasons to indicate that there is no risk of pregnancy.

PRODUCT WITH ACTIVE DRUG SAFETY MONITORING (aDSM)

Background

In Ghana TB prevalence is estimated at 290 per 100,000 population (2013 prevalence survey report) and TB incidence rate is estimated to be 152/100,000 (Global TB report 2018).

The recently conducted National TB Drug Resistance Survey estimates multi drug resistance (MDR) TB among new cases at 1.5% and 7% among retreatment cases. Since the initiation of Programmatic Management of Drug Resistant TB (PMDT), over 350 cases have been enrolled on the second line TB regimen.

The latest treatment success rate for MDR TB (2015 cohort) is 55%. To improve treatment adherence and outcome, NTP introduced shorter MDR TB regime in the second quarter of 2018.

A large number of MDR-TB patients initiated onto treatment in Ghana experienced ototoxicity and renal impairment in course of the treatment with the standard shorter treatment regimen (sSTR). The standard shorter MDR/RR-TB treatment has many severe Adverse Drug Reactions (ADRs) like deafness, renal insufficiency, and psychosis which are often difficult to manage, may be irreversible or life threatening, and may require halting treatment.

Those ADRs are mainly due to the use of injectable Kanamycin, Amikacin or Capreomycin. For those on the longer RR/MDRTB treatment, the lost to follow-up rate is high with impact negatively on the treatment outcomes.

In 2019 WHO recommended new treatment guidelines which included priority ranking for medicines available for treatment. The National TB Control Programme has introduced new injectable free regimen and modified shorter regimen (bedaquiline-based shorter regimen) for treatment of tuberculosis (TB) in Ghana based on the WHO regimen.

Conditions for the implementation of bedaquilline includes having an active Drug-safety monitoring and Management (aDSM) in place. TB aDSM describes a new TB programme component to provide for the active and systematic clinical and laboratory assessment of patients on treatment with bedaquilline to detect, manage and report suspected or confirmed drug toxicities. TB aDSM targets serious adverse events.

The National TB Control Programme has organised training for healthcare providers involved in TB management on the active monitoring of bedaquilline to equip them with knowledge and skills in the effective monitoring of the safety of bedaquilline.

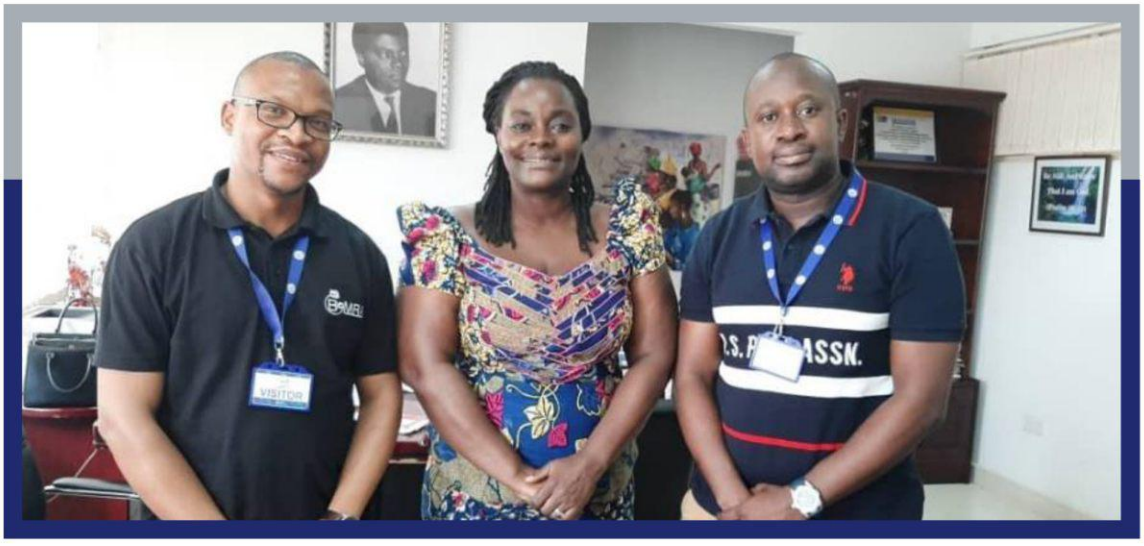
The Food and Drugs Authority will collaborate with the National TB Control Programme to assess the causality for all the adverse drug reactions reports received.

PHARMACOVIGILANCE BENCHMARKING MISSION BY BOTSWANA MEDICINES REGULATORY AUTHORITY TO FDA

Two members of staff from the Botswana Medicines Regulatory Authority (BoMRA), Dr. Thabang Phetlhe and Mr. Wapapha Nthomiwa paid a five-day pharmacovigilance benchmarking visit to Ghana from the 22nd to 26th July 2019 to learn first-hand best practices from the Ghanaian counterparts including effective integration of pharmacovigilance into public health programmes.

The team participated in all routine pharmacovigilance activities including the 21st Meeting of the Technical Advisory Committee on safety of Vaccines and Biological Products at the FDA and also interacted with Programme Managers of some public health programmes.

The visiting team appreciated the experience in Ghana and looked forward to building a robust pharmacovigilance system in their country.



Dr. Thabang Phetlhe and **Mr. Wapapha Nthomiwa** with **Mrs. Akua Amartey**, Deputy Chief Executive in-charge of Medical Devices, Cosmetics and Household Chemicals Substances Division

APPROVAL AND SAFETY MONITORING OF PRODUCTS IN PANDEMICS

The World Health Organization defines Emergency Use Authorization (EUA) or Emergency Use Listing (EUL) as a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostics for use primarily during public health emergencies of international concern (PHEIC) but also in other public health emergencies if appropriate.[1]

The approval of any medicine(s) or diagnostics for EUA is not intended to interfere with ongoing clinical trials. This means that clinical development should proceed as planned after the initial submission and subsequent updates.

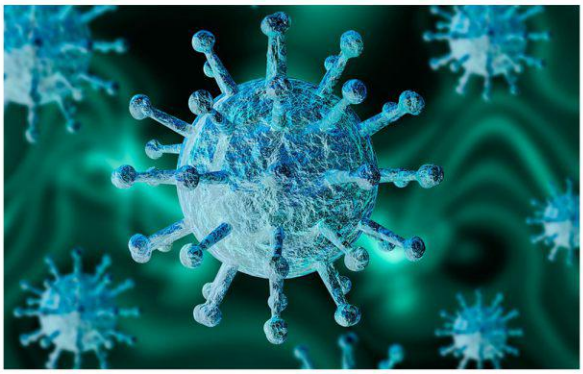
During a Public Health Emergency declared by the Minister of Health under Sections 169 – 173, the Food and Drugs Authority could grant an EUA to potentially life-saving medicinal products when there are no adequate and available alternative(s) to the candidate product for the diagnosis, prevention or treatment of the disease or the condition.

A product may be considered for an EUA if the FDA determines in consultation with the Ministry of Health and/or the FDA's Technical Advisory Committees based on the circumstances of the emergency. [2] In taking this decision the FDA has to be convinced that the known and potential benefits of the product, when used to diagnose, prevent or treat the identified disease or condition, outweigh the known and potential risks.

EUA of products is done in line with the FDA's Guidelines for Emergency Use Authorization of Medical Products.

Products approved through EUA procedure do not require informed consent prior to administration to patients.

However, patients or his/her representatives must be provided clear information on the product including the fact that the product was issued with EUA by the FDA based on the available information which may change as more data become available. Information to be provided to patients should also include the expected benefits and potential risks including possible adverse reactions of the product.



The FDA has therefore issued EUA to drugs recommended by the Emergency National Medicine Selection Committee of Experts of the Ministry of Health so that physicians can prescribe these drugs for the treatment of patients with COVID-19.

The selection of the medicines for use in COVID-19 was based on in-vitro activity against the virus and promising results in small studies in countries most affected by the pandemic, particularly China and France. There are also a number of ongoing clinical trials to find safe and effective treatment for COVID-19.

SAFETY MONITORING OF PRODUCTS DURING THE COVID-19 PANDEMIC

SAFETY MONITORING OF PRODUCTS ISSUED WITH EUA

The FDA has set up safety monitoring system for the medicines issued with EUA to promote patient safety and the continued use or otherwise of these products during the pandemic. Healthcare professionals are expected to follow up on patients administered with any of the therapies and report any adverse reactions to the FDA

The pharmacovigilance system in place involves active monitoring of patients administered the recommended drugs, collection and analysis of information on the safety and effectiveness of these drugs and feedback to inform decision on continuous use of these products.

The objective of the safety monitoring is to ensure that healthcare professionals report all suspected adverse reactions associated with medicines issued with Emergency Use Authorization to facilitate early detection of safety signals to promote patient safety.

What to report?

All adverse drug reactions including therapeutic failures for drugs being used in the treatment of patients with COVID-19 should be reported within 24 hours.

In addition, information on patients treated with any of the medicines during pregnancy should also be reported with follow up on the outcome of the pregnancy.

To assist the FDA in the assessment of suspected adverse reaction reports, as much information as possible should be provided in the initial report, particularly the underlisted information if available:

- suspected drug
- the age and gender of the patient
- description of the adverse reaction (including indication of seriousness)

- any concomitant medications, whether supportive or already prescribed
- outcome of the reaction (resolved, revolving, death)
- state whether medicine was discontinued as a result of the adverse reaction

For product issued with EUA in accordance with the Guidelines for Emergency Use Authorization of Medical Products, the Marketing Authorization Holder shall comply with the FDA's safety monitoring requirements.

References

[1] WHO, "Emergency Use Listing Procedure," 2020.
[2] FDA, "food and drugs authority guidelines for emergency use authorization of medical products."
[3] FDA, "food and drugs authority guidelines for conduct of clinical trials during emergencies."
[4] FDA, "food and drugs authority guidelines for authorization of clinical trials of medicines, food supplements, vaccines and medical devices in Ghana."

SAFETY OF MEDICINES IN YOUR HAND

The Med Safety App is an additional electronic platform which has been added to the existing reporting tools to enable consumers, patients and healthcare professionals to report safety issues concerning their medicines and other health products to the FDA in real time.

The Med Safety App is developed with support from the Access and Delivery Partnership (ADP), the WEB-RADR (Recognizing Adverse Drug Reactions) Project and the UK Medicines and Healthcare Products Regulatory Agency (MHRA).

The Med Safety App is downloadable from App Store or Google Play Store and it is a convenient alternative to paper or online reporting tools.

The App Offers the Under listed Benefits to Users:

- Submit reports of adverse reactions whiles offline.
- View and submit updates to previously submitted reports.
- View previous ADR reports submitted through the App.
- Receive immediate acknowledgement of their reports.
- Create a watch list of medications on which to receive personalized news and alerts

You will need the following information to submit a report using the Med Safety App:

•Your Personal Details: Name and email address; this will help us acknowledge receipt of the report submitted.

•Patient Details: Gender, date of birth or age, initials, weight or height.

•The Name(s) of the Suspected Medicine(s) or Product(s): the name of the suspected medicine(s) and other medicine(s) taken in addition, if any.

•Reason(s) for taking the Medicine: What the medicine is being used for and the dosage.

•The Reaction: Details of the adverse reaction, when it started, when it ended and the outcome. Choose from the list of reactions and also describe in detail what happens to you (or the patient).

•Medical History: Add a short medical history, if known.

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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 views on any edition of the newsletter you receive.

Name (optional):.....

Organization(optional): .....

E-mail (optional): .....

1.Has the newsletter been beneficial to you: .....

2.Do you plan to share the newsletter with others? Colleagues, friends? Yes ☐ No ☐

3.Any other comments: .....

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What to report?

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

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

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 for 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** 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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