DrugLens NEWSLETTER

DRUGLENS ISSUE 7 | JULY 2019

MESSAGE FROM THE CHIEF EXECUTIVE

The FDA's strategies to improve patient safety are the use of technology, active engagement of stakeholders to reduce abuse of prescription medicines and improve information sharing.

The rebranded Food and Drugs Authority has positioned itself as an evolving and dynamic entity, with capacity to move and change with the times, whiles remaining relevant in an ever - changing business environment.

Welcome to the 7th Edition of the DrugLens, 2018 was a successful year for monitoring the safety of medical products and as the FDA continues in its efforts to ensure optimal patient safety, we will focus on the three main strategic areas this year to ensure utmost public health and safety

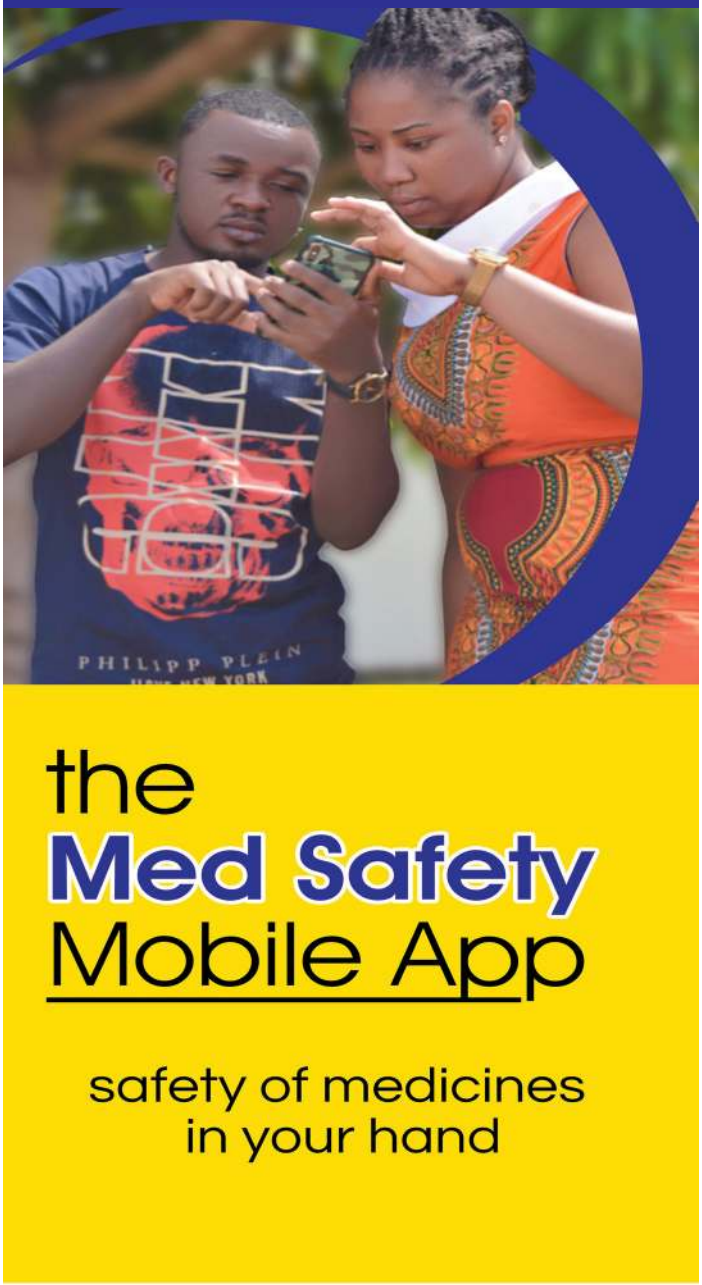
The first strategy is the use of technology to promote patient safety and reporting adverse reactions to regulated products. Never before has the use of technology transformed lives and made the way we live much safer; this includes timely delivery of urgently needed medical products by drones, as well as monitoring and reporting the safety of these products using mobile devices.

For this reason, the FDA's National Pharmacovigilance (PV) Centre seeks to improve the communication of safety issues with its stakeholders including healthcare professionals, patients and the general public. The Authority has introduced the Med Safety App to promote a two-way communication between the National PV Centre and stakeholders. The introduction of the Mobile App to report adverse reactions is expected to reduce the incidence of underreporting of safety issues by patients and healthcare professionals in Ghana.

As collaboration with stakeholders is fundamental in a robust Patient Safety System, the National PV Centre will also focus on improving timely information sharing with all stakeholders including patients, healthcare professionals, pharmaceutical industry, media, academia and international partners to better promote patient safety.

Secondly, improved stakeholder collaboration has been found most effective, as the recent opioid epidemic - abuse of codeine, tramadol and other prescription medicines continues to be one of the major challenges facing the youth in our country. To help address this, the Honorable Minister for Health, after receiving

THE MED SAFETY APP FOR REPORTING SAFETY ISSUES



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expert advice from the Technical Advisory Committee on Safety of Medicines of the FDA, in 2018 passed Executive Instruments E. I. 167 and E. I. 168 to prohibit the importation and sale of codeine–containing cough syrups and control the importation, manufacture and sale of tramadol respectively. Strategies put in place include increased public education and awareness creation on the dangers of these products, withdrawal of the marketing authorization and ban on the importation of codeine-containing cough syrups, reclassification of tramadol as a controlled narcotic medicine, intensification of market surveillance particularly at the ports of entry and collaboration with relevant stakeholders like Pharmacy Council, Mental Health Authority, the security agencies and the media to execute measures aimed at reducing the incidence of abuse. The FDA continues to monitor the situation in collaboration with all stakeholders and to take additional regulatory action when needed to protect public health and safety.

Finally, I want to use this opportunity to introduce readers to the new FDA. The new FDA is one with an improved corporate identity, heralded by a new logo, which was officially unveiled and launched by Her Excellency, The First Lady of the Republic of Ghana, Mrs. Rebeca Akufo-Addo on 16th April 2019.

The new FDA is one that has positioned itself as an evolving and dynamic entity, with capacity to move and change with the times, whiles remaining relevant in an ever - changing business environment. The new logo realigns the FDA to fully embrace and achieve its objectives.

The new logo has two interlocking arcs forming a circle, which signifies the willingness of the Authority to engage stakeholders and the 360° required checks the FDA conducts on products to ensure safety and wellbeing of the public. The new FDA tagline, "Your Wellbeing, Our Priority" is empathetic and compelling and points to a commitment from the Authority to learn and use new approaches to regulation that improve the lives of our clients every day. The rebranded FDA portrays an organization that places the needs of its clients at the centre of its service provision

Our clients and stakeholders should therefore expect committed, improved consumer-centered service provision and greater commitment towards patient safety.

Sincerely,
Delese Mimi Darko
CEO

FDA LAUNCHES THE MED SAFETY APP

The FDA launched the Med Safety App on 25th June 2019 to enable patients / consumers and healthcare professionals to report adverse reactions to drugs, herbal medicine, vaccines and other health products.

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 (Recognising 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 underlisted 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 watchlist 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 medi cine(s) taken in addition, if any.
- **Reason(s) for taking the Medicine:** What the medi cine 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.

The CEO of the FDA, Mrs Delese A. A. Darko delivering the welcome address at the launch.

Mrs Martha Gyansa-Lutterodt delivering the Keynote address on behalf of the Honourable Minister of Health.

A Cross Section of the participants

The Abibigromma drama group demonstrating how to use the Med Saftey App.

PASSION FOR PATIENT SAFTEY

Juliet is a Senior Physician Assistant at Peki Dzake Health Center in the South Dayi District of the Volta Region and believes that timely reporting of adverse reactions to health products is vital for early identification of medicine safety issues to prevent patients and potential users of these products from preventable harm.

Madam Juliet Ama Anaglo is a **Senior Physician Assistant** with over 15 years working experience with the Ghana Health Service. She is currently working at Peki Dzake Health Center in the South Dayi District of the Volta Region, where she has been the Institutional Contact Person for the past three years.

Her first exposure to patient safety was in 2013 during a pharmacovigilance training programme at St. Anthony's Catholic Hospital, Dzodze in the Volta Region.

Juliet believes that timely reporting of adverse reactions to health products is vital for early identification of medicine safety issues to protect patients and potential users of such products from preventable adverse reactions. She had to travel on a number of occasions from Peki to the FDA Regional Office in Ho to pick up adverse reaction reporting forms when none was available in her institution.

The message she has for the readers is to be actively involved in the detection, management and reporting of adverse reactions to health products to promote early signal generation and protection of public health and safety.

SPONTANEOUS REPORTING FOR 2018

The National Pharmacovigilance Centre received **3,729** reports in 2018. Two thousand five hundred and ninety-seven (2,597) were spontaneous reports received from healthcare professionals, pharmaceutical industries and patients/consumers. The remaining 1,132 were AEFI reports from stimulated spontaneous reporting during the nationwide yellow fever and measles rubella campaigns. Of the 3,729 reports received, 1,820 were adverse events following immunization (AEFIs). Adverse drug reactions (ADRs) from medicines and other products were 1,909.

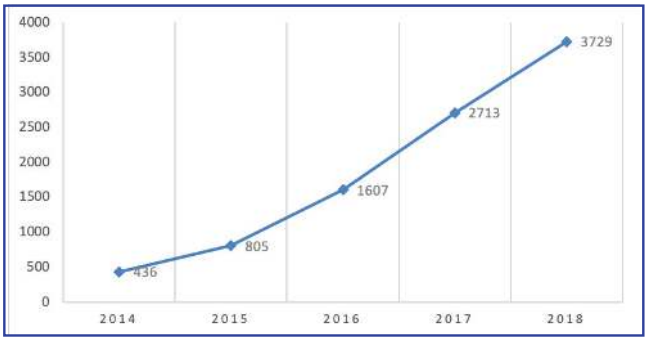

Figure 1: Number of Reports Received from 2014-2018

Out of 3,729 reports received 2,074 (56.6%) were from females and 1,508 (41.1%) from males, the gender for the remaining 147(3.9%) is unknown.

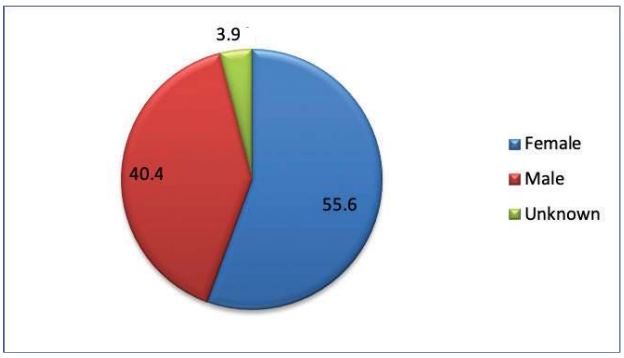

Figure 2: Gender distribution of the ADRs received

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

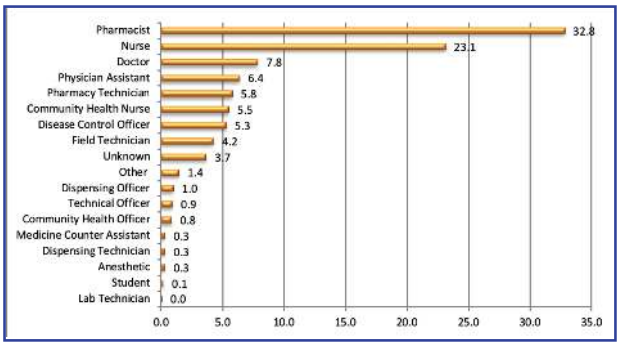

Figure 3: Percentage reporting by healthcare professionals

The top 10 medicines with the most commonly reported adverse reactions are shown in Figure 4.

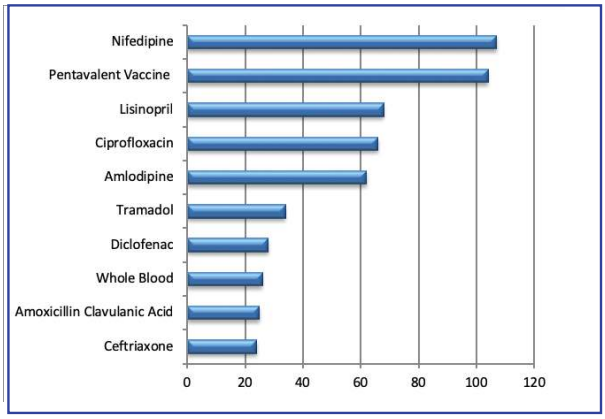

Figure 4: Top 10 medicines with the most commonly reported ADRs

The highest number of adverse reactions was for Nifedipine tablets, with the most commonly reported reactions being sleepless nights, general body discomfort, cough, dizziness, headache and palpitation. These reactions were reported with a minimum frequency of three and all these reactions are listed for Nifedipine.

The outcome of the reported reactions is shown in Figure 5 below

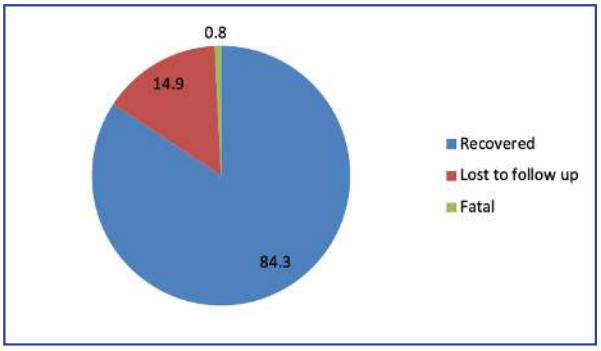

Figure 5: Outcome of the Reported ADRs

Figure 6 is the regional distribution per 10,000 of the spontanous reports per 10,000 population.

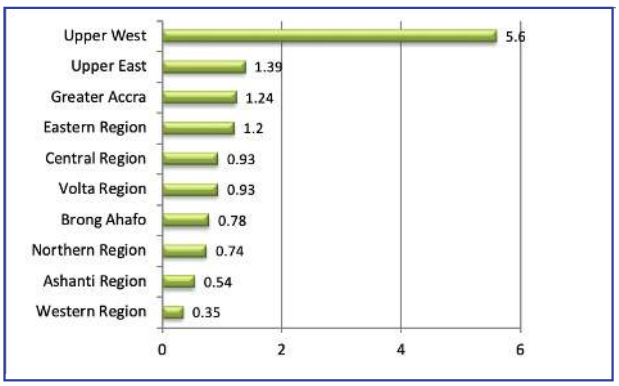

Figure 6: Regional distribution of thre reports per 10,000 population

Table 1 represents the top 20 healthcare facilities who were committed towards patient safety in Ghana for the year 2018

Table 1. Top 20 reporting healthcare facilities in 2018

Institution	Number of Reports	Position	Region
Atua Government Hospital	48	1st	Eastern Region
Koforidua Regional Hospital	48	1st	Eastern Region
Komfo Anokye Teaching Hospital	47	2nd	Ashanti Region
Peki Dzake Health Centre	46	3rd	Volta Region
St. Francis Xavier Hospital, Assin Fosu	32	4th	Central Region
St. Martins Hospital, Agroyesum	31	5th	Ashanti Region
Goaso Municipal Hospital	29	6th	Ahafo Region
SDA Hosiptal, Sunyani	29	6th	Bono East Region
Volta Aluminium Company Ltd Hospital	28	7th	Greater Accra Region
Akuse Government Hospital	27	8th	Eastern Region
St. Dominic Hospital, Akwatia	27	8th	Eastern Region
Tamale Central Hospital	27	8th	Northern Region
Hamile Health Centre	26	9th	Upper West Region
Achimota Hospital	25	10th	Greater Accra Region
Kwahu Government Hospital	25	10th	Eastern Region
Eggu Health Centre	24	11th	Upper West Region
Holy Family Hospital, Nkawkaw	24	11th	Eastern Region
Gengenkpe Health Centre	22	12th	Upper West Region
Ga South Municipal Hospital	21	13th	Greater Accra Region
Agona Government Hospital	19	14th	Ashanti Region
Bagli CHPS	18	15th	Northern Region
Korle Bu Teaching Hospital	18	15th	Greater Accra Region
Daffiama Health Centre	17	16th	Upper West Region
Lambussie Polyclinic	16	17th	Upper West Region
Lekma Hospital	16	17th	Greater Accra Region
University of Ghana Hospital	16	17th	Greater Accra Region
Wa Adolescent Health Centre	16	17th	Upper West Region
St. Joseph's Hospital Koforidua	15	18th	Eastern Region
Bussie Health Centre	14	19th	Upper West Region
Adibo Health Centre	13	20th	Northern Region
Cocoa Clinic	13	20th	Greater Accra Region
Ussher Polyclinic	13	20th	Greater Accra Region

UPDATES FROM THE PATIENT SAFETY CENTRES

Increasingly more patients through the Community Pharmacies are becoming active participants in the Patient Engagement in Medicine Safety initiative since it was launched in June 2016. The Patient Engagement in Medicine Safety initiative helps to improve the quality of pharmaceutical care clients receive from Community Pharmacies in line with the Pharmacy Council's objectives. The Council has accredited the Patient Engagement in Medicine Safety initiative and awarded two (2) CPD credit points to community pharmacists who promote patient reporting in their pharmacies.

In 2018, forty (40) pharmacists were awarded CPD points for taking the online course and reporting medicine safety issues to the FDA; the two prerequisites to earning the CPD points.

The Pharmacy Council has accredited the Patient Safety initiative for 2 CDP points. Just submit a completed adverse reaction report and take a 5 minute online test at https://www.az-engage.com/login/ to obtain your 2 points

The FDA appreciates all Community Pharmacists, especially the 2018 top 5 patient safety centered reporting community pharmacies (Table 2) for contributing to the early identification of medicine safety issues in order to enable the necessary regulatory action to be taken to promote public health and safety.

Table 2: Top ten reporting community pharmacies in 2018

Name of Facility	Number of Reports	Position	Region
Royal Avenue Pharmacy	11	1st	Ashanti Region
Open Arms Pharmacy	8	2nd	Northern Region
Obrasi Pharmacy	7	3rd	Northern Region
Fabby Chemist	7	3rd	Greater Accra Region
Barzila Pharmacy	4	4th	Brong Ahafo
G and E Health Service	4	4th	Volta Region
Gina Pharma	4	4th	Northern Region
Honsal Pharmacy	4	4th	Central Region
Smart Chemist	3	5th	Northern Region
City Care Pharmacy Ltd	3	5th	Greater Accra Region

The Patient Engagement in Medicine Safety initiative was introduced to help patients and consumers actively participate in the pharmacovigilance system by having easy access to reporting tools through the community pharmacies.

VACCINE SAFETY UPDATES

Five hundred and seventy-six (576) adverse events following immunization reports were received through the passive reporting system in 2018. The Food and Drugs Authority in collaboration with the Expanded Programme on Immunization (EPI) also employed enhanced (stimulated) passive surveillance for adverse events following immunization (AEFI) during the 2018 sub-national yellow fever and nationwide measles-rubella vaccination campaigns.

Figure 7: A man ready to receive yellow fever (YF) vaccine in the Akatsi South District in the Volta Region

The measles-rubella (MR) vaccination campaign was conducted from 17th -22nd October 2018 with the rationale to boost population immunity levels towards measles elimination in Ghana. The campaign took place in all the 10 regions, and a total of 4,737,841 children from 9 to 59 months were targeted for vaccination. Out of the total number of 4,639,797 were vaccinated, representing 98% coverage.

A total of 695 non-serious and 11 serious AEFI reports were received during the campaign which gave an AEFI reporting rate of 15.2 per 100,000 persons vaccinated.

The number and rates of AEFIs reported by region during the campaign is shown in Table 3 and the distribution of AEFI by type in Figure 8.

Table 3: Number and Rates of AEFI reported by Region, MR vaccination campaign AEFI surveillance, 17th Oct – 19th Dec 2018

REGION	TARGET (9 - 59 MONTHS)	NUMBER VACCINATED WITH MR VACCINE	NUMBER OF AEFI REPORTED	AEFI RATE/100,000 VACCINATED
Ashanti	905,876	877,638	64	7.3
Brong-Ahafo	445,824	446,301	107	24.0
Central	402,979	390,950	107	27.4
Eastern	507,479	477,428	107	22.4
Greater Accra	773,074	770,877	59	7.7
Northern	478,969	566,645	75	13.2
Upper East	199,197	181,493	29	16.0
Upper West	132,797	104,831	18	17.2
Volta	407,881	359,596	76	21.1
Western	483,765	464,038	64	13.8
National	4,737,840	4,639,797	706	15.2

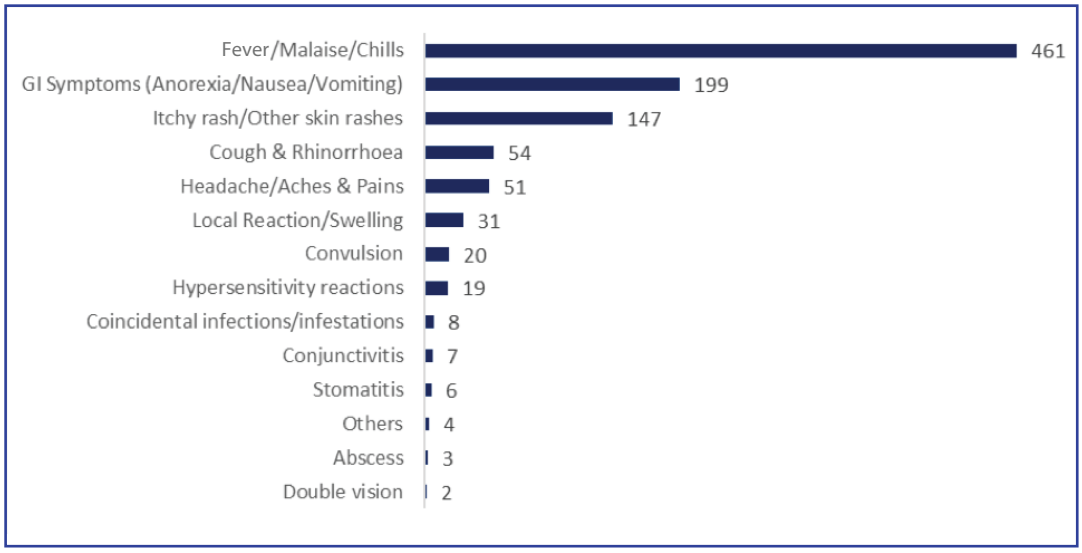

Figure 8: Distribution of the AEFI by type, MR vaccination campaign AEFI surveillance, 17th Oct – 19th Dec 2018

All AEFIs were expected and causality assessment by the FDA's independent Technical Advisory Committee on Safety of Vaccines and Biological Products (TAC-VBP) for the eleven serious AEFI cases using the World Health Organization (WHO) revised classification of AEFI is shown in Table 4.

Of the 4,639,797 children vaccinated during the MR campaign, a total of 695 non-serious and 11 serious AEFI reports were received. The AEFI reporting rate is therefore 15.2 reports per 100,000 persons vaccinated. Causality assessment by the TAC-VBP classified nine of the eleven serious AEFI cases as coincidental and the remaining two as unclassifiable.

None of the AEFIs was assessed to be related to the MR vaccine.

Table 4: Causality assessment of serious AEFI, MR vaccination campaign AEFI surveillance, 17th Oct – 19th Dec 2018

No.	EPI Code	FDA Code	Causality
1	ASH-SEK-18-001	1218AEFIAR0013	Coincidental
2	ASH-SKC-18-001	1218AEFIAR0012	Coincidental
3	BAR-SUW-18-009	1218AEFIBA0047	Coincidental
4	BAR-TAS-18-002	1218AEFIBA0046	Coincidental
5	BAR-TAS-18-003	1218AEFIBA0045	Coincidental
6	CEN KEA-18-006	1218AEFICR0088	Coincidental
7	EAS-AKS-18-003	1218AEFIER0010	Unclassifiable
8	EAS-EAK-18-006	1218AEFIER0011	Coincidental
9	EAS-EAK-18-008	1218AEFIER0013	Coincidental
10	EAS-KAP-18-002	1218AEFIER0012	Coincidental
11	VOL-HOH-18-001	1218AEFIVR0020	Unclassifiable

The EPI also carried out a sub-national yellow fever (YF) preventive mass vaccination campaign from 28th November to 4th December 2018 in nine regions excluding the Upper West Region. The objective was to boost population immunity levels as part of the global strategy to eliminate YF epidemics.

AEFI surveillance was conducted as part of the campaign from 28th November 2018 to 1st January 2019. About 5.2 million (5,204,147) children and adults between the ages of 10 to 60 years were targeted for vaccination. At the end of the campaign, 5,581,540 were vaccinated, which represents 107% coverage. Out of the total number of 5,581,540 persons vaccinated, 534 non-serious AEFI reports and 4 serious AEFI reports were received. The AEFI rate of 9.6 per 100,000 vaccinated.

The number and rates of AEFIs reported by region during the campaign is shown in Table 5 and the distribution of AEFI by type is as shown in Figure 9 .

Table 5: Number and Rates of AEFI by region, YF sub-national preventive mass vaccination campaign AEFI surveillance, 28th Nov 2018 – 1st Jan 2019

Regions	Target Population (10 -60 years -Excluding pregnant women)	Total No. vaccinated	Total AEFIs Reported	AEFI Rate/100,000 vaccinated
Ashanti	797,853	878,466	48	5.5
Brong-Ahafo	381,098	401,019	69	17.2
Central	475,172	534,123	150	28.1
Eastern	504,061	528,645	42	7.9
Greater Accra	1,204,653	1,313,965	77	5.9
Northern	173,031	183,630	15	8.2
Upper East	294,273	303,144	43	14.2
Volta	1,079,201	1,129,262	73	6.5
Western	294,806	309,286	21	6.8
National	**5,204,147**	**5,581,540**	**538**	**9.6**

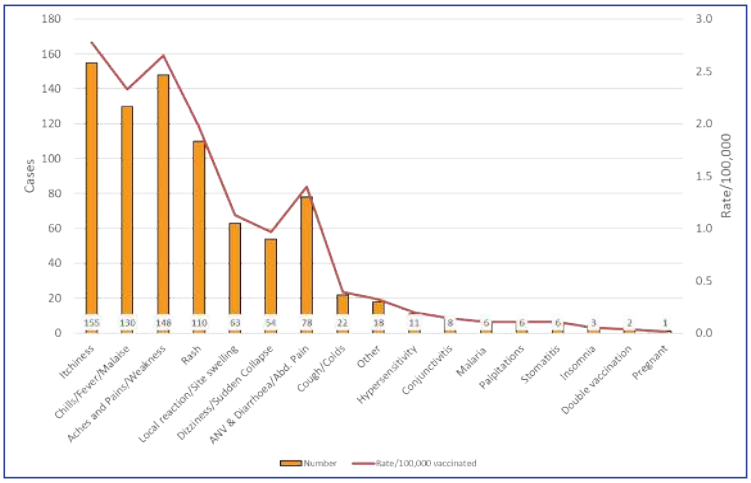

Figure 9: Distribution of AEFIs by type, YF sub-national preventive mass vaccination campaign AEFI surveillance, 28th Nov 2018 – 1 Jan 2019

The outcome of the causality assessment by the TAC-VBP is shown in Table 6.

Table 6: Classification of AEFI cases by cause, YF sub-national preventive mass vaccination campaign AEFI surveillance, 17th Oct – 19th Dec 2018

NO	EPI CODE	FDA CODE	CAUSALITY
1	BAR-NKS-18-001	1218AEFIBA0044	Coincidental
2	GAR-NIP-18-005	1218AEFIGR0021	Vaccine product related reaction
3	CEN-CAC-18-012	1218AEFICR0087	Unclassifiable
4	ASH-ATN-18-001	1218AEFIAR0011	Coincidental

Of the 5,581,540 children and adults vaccinated during the YF campaign, 534 non-serious AEFI reports and 4 serious AEFI reports were received. The AEFI reporting rate was 9.6 reports per 100,000 persons vaccinated. After causality assessment, one AEFI was assessed to be related to the vaccine product, two were coincidental and the causality of one case could not be assessed due to insufficient information.

SAFTEY COMMUNICATION PUBLISHED IN 2018

Below is the summary of Safety Communication sent to healthcare professionals in 2018, detailed information on this can be accessed on the FDA's website. https://fdaghana.gov-.gh/index.php/dear-healthcare-professional-letters/

1

Restrictions to Prevent the Use of Valproate Medicines in Women and Girls of Childbearing Potential

This is to inform healthcare professionals about the Valproate Pregnancy Prevention Programme and the additional risk minimization measures to prevent exposure of girls and women of child bearing potential to valproate containing medicines. This is because babies exposed in utero to valproate are at high risk of serious developmental disorders (in up to 30-40% of cases) and/or congenital malformations (in approximately 10% of cases).

Valproate has been registered for use in Ghana for the treatment of generalized, partial or other epileptic seizures.

The following precautionary measures are recommended:

- 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 contra indicated unless the conditions of the pregnancy prevention programme are fulfilled.
- 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.

Healthcare professionals are advised to read key elements and the Guide on the Valproate Pregnancy Prevention Programme on the FDA website on the link below:

https://fdaghana.gov.gh/images/stories/pdfs/Dear%20Helt - care%20Prof/FDA_GH%20Valproate%20guide%20for%20%20healthcare%20professionals.pdf

2

Hydrochlorothiazide and the Risk of Skin Cancer

Outcome of two epidemiological studies suggested an increased risk of non-melanoma skin cancer (basal cell carcinoma [BCC], squamous cell carcinoma [SCC]) with exposure to increasing cumulative doses of hydrochlorothiazide.

Results of the two studies suggested an increased in the risk of 7.7-fold for SCC and 1.5-fold for BCC based on a length of usage of hydrochlorothiazide 12.5mg daily for 44 years or 25 mg daily for 22 years.

Non-melanoma skin cancer is a rare event and the incidence rate for BCC in Africa is less than 1/100, 000 person-years.

Hydrochlorothiazide-containing medicines are used to treat hypertension, as well as cardiac and hepatic oedema, or chronic heart insufficiency.

The FDA therefore advised healthcare professionals that:

- Patients taking Hydrochlorothiazide-containing products should be informed about the risk of NMSC, particularly in long term use and advise to regularly check for (and report) any new or changed skin lesions or moles.
- Suspicious moles or skin lesions should be examined, potentially including histological examination of biopsies.
- Patients should be advised to limit exposure to sunlight and UV rays and use adequate protection when exposed to sunlight and UV rays to minimize the risk of skin cancer.
- The use of Hydrochlorothiazide should be carefully reconsidered in patients who have had previous skin cancer.

3

Safety Information on Medicines Containing Valsartan from Zhejiang Huahai Following Detection of an Impurity

Some medicines containing valsartan manufactured with active ingredient from Zhejiang Huahai Pharmaceuticals in Linhai, China with an impurity, N-nitrosodimethylamine (NDMA), an organic chemical that is in a family of potent cancer-causing agents.

The FDA in collaboration with the importers made a recall of the affected products from the Ghanaian market.

4 Study Suggests Risk of Birth Defects in Babies Born to Women on HIV Medicine Dolutegravir (Tivicay)

Preliminary results from an observational study in Botswana found that women who received dolutegravir at the time of becoming pregnant or early in the first trimester were at a higher risk of neural tube defect (NTD) with an incidence of 0.9% compared with an expected background rate of 0.1%.

Dolutegravir is an antiretroviral medicine approved by the FDA under the brand name Tivicay for use in combination with other antiretroviral medicines to treat HIV, the virus that can cause acquired immunodeficiency syndrome (AIDS). Dolutegravir works by blocking integrase, an HIV enzyme, to prevent the virus from multiplying and can reduce the amount of HIV in the body.

The following precautionary measures are recommended for healthcare professionals involved in the management of HIV patients:

- Do not prescribe Dolutegravir HIV medicines to women seeking to become pregnant.
- Exclude pregnancy in women of child bearing potential before starting dolutegravir.
- Women who can become pregnant should use effective contraception while taking dolutegravir medicines.
- If pregnancy is confirmed in the first trimester while a woman is taking dolutegravir, treatment should be switched to an alternative treatment unless there is no suitable alternative.

5 Hyoscine Butylbromide Injection: Risk of Serious Adverse Effects in Patients with Underlying Cardiac Disease

This publication sought to update healthcare professionals on a publication in the 2017 edition of the Druglens on the safety information relating to reports published by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) of acute myocardial infarction or cardiac arrest with fatal outcomes associated with the use of hyoscine butylbromide injection.

Hyoscine butylbromide given intravenously or intramuscularly is indicated in acute muscular spasm, as in renal or biliary colic; in radiology for differential diagnosis of obstruction and to reduce spasm and pain in pyelography; and in other diagnostic procedures where spasm may be a problem (eg, gastroduodenal endoscopy).Hyoscine butylbromide injection can cause adverse effects including tachycardia, hypotension, and anaphylaxis. These effects can be more serious in patients with underlying cardiac disease (eg, heart failure, coronary heart disease, cardiac arrhythmia, or hypertension). Studies have suggested that anaphylaxis is more likely to be fatal in patients with underlying coronary heart disease compared with those without.

Healthcare professionals are therefore advised to take note of the underlisted:

1. Hyoscine butylbromide injection can cause serious adverse effects including tachycardia, hypotension, and anaphylaxis.
2. These adverse effects can result in a fatal outcome in patients with underlying cardiac disease, such as those with heart failure, coronary heart disease, cardiac arrhythmia or hypertension.
3. Hyoscine butylbromide injection should be used with caution in patients with cardiac disease.
4. Monitor these patients, and ensure that resuscit ation equipment, and personnel who are trained on how to use this equipment, are readily available.
5. Hyoscine butylbromide injection remains contraindi cated in patients with tachycardia.

6 Increased Risk of Leg and Foot Amputations with Canagliflozin (Invokana, Vokanamet) Tablets

There are increased cases of lower limb amputation (mostly affecting the toes) observed in patients taking the Type 2 diabetes medicine **Canagliflozin** compared with those taking placebo in two clinical trials, CANVAS (Canagliflozin Cardiovascular Assessment Study) and CANVAS-R (A Study of the Effects of Canagliflozin on Renal Endpoints in Adult Participants with Type 2 Diabetes Mellitus) studies.

Results from two clinical trials, the CANVAS and CANVAS-R, showed that leg and foot amputations occurred about twice as often in patients treated with canagliflozin compared to patients treated with placebo.

Canagliflozin is a prescription medicine used with diet and exercise to lower blood sugar in adults with type 2 diabetes. It belongs to a class of drugs called sodium-glucose cotransporter-2 (SGLT2) inhibitors. Canagliflozin lowers blood sugar by causing the kidneys to remove sugar from the body through the urine.

Advice to healthcare professionals

- Consider factors which may predispose patients to the need for amputations including history of prior amputation, peripheral vascular disease, neuropathy and diabetic foot ulcers before starting canagliflozin.
- Monitor for the development of new pain or tender ness, sores or ulcers, or infections in the legs or feet of patients on canagliflozin.

7

Rare Occurrences of a Serious Infection of the Genital Area with Sodium-Glucose Cotransporter -2 (SGLT2) Inhibitors for Diabetes

There is rare but serious infection of the genitals and area around the genitals reported with the class of type 2 diabetes medicines called sodium glucose cotransporter-2 (SGL T2) inhibitors.

The serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene. Fournier's gangrene is an extremely rare but life-threatening bacterial infection of the tissue under the skin that surrounds muscles, nerves, fat, and blood vessels of the perineum. The bacteria usually get into the body through a cut or break in the skin, where they quickly spread and destroy the tissue they infect. Having diabetes is a risk factor for developing Fournier's gangrene; however, this condition is still rare among diabetic patients.

SGLT2 inhibitors are approved by the Food and Drugs Authority for use with diet and exercise to lower blood sugar in adults with type 2 diabetes. SGLT2 inhibitors lower blood sugar by causing the kidneys to remove sugar from the body through the urine.

Advice to patients and healthcare professionals:

Patients

- **Seek medical attention immediately** if you experience any symptoms of tenderness, redness, or swellng of the genitals or the area from the genitals back to therectum, and have a fever above 38oC or a general feeling of being unwell.

Health care professionals

- Assess patients who present with the symptoms listed above for Fournier's gangrene. Treatment should start immediately with broad-spectrum antibiotics and surgical debridement as necessary if Fournier's gangrene is suspected, SGLT2 inhibitors should be discontinued. The blood glucose levels should be closely monitored and appropriate alternative therapy given for glycemic control. SGLT2 containing-medicines registered for use in Ghana are Forxiga (Dapagliflozin) tablets, Invokana (Canagli flozin) tablets and Vokanamet (Canagliflozin and Metformin hydrochloride) tablets.

MARKET WITHDRAWALS
FOR SAFETY REASONS

The marketing authorization of the underlisted medicines have been withdrawn by the Food and Drugs Authority based on safety issues.

NO	NAME OF DRUG	REASON FOR THE WITHDRAWAL
1	Codeine Containing Cough Syrups (CCS)	This decision was arrived at following reports of widespread abuse of CCS. The Technical Advisory Committee of the FDA arrived at this decision based on the following reasons: • Codeine has no greater antitussive (cough suppres sant) activity compared with dextromethorphan. • Dextromethorphan, the alternative ingredient listed in the Standard Treatment Guidelines of Ghana (7th Edition, 2017), exhibits similar antitussive (cough suppressant) activity compared with codeine but has a lower addictive potential. • Codeine has a much greater side effect profile compared to dextromethorphan. • There are a number of products both locally manu factured and imported containing dextrometho rphan registered by the FDA which could be used in place of CCS.
2	Oral Keto-conazole products	This was as a result of the risk of severe liver injury, adrenal gland problems and harmful drug interactions associated with the use of oral ketoconazole and also because the additional risk minimization measures proposed in August 2013 were not effective in preventing the risk of hepatic related adverse drug reactions associated with the use of oral ketoconazole. This suspension of marketing authoriza-tion does not affect topical preparations containing ketoconazole.

NOTICE OF MARKET AUTHORIZATION WITHDRAWALS FOR COMMERCIAL REASONS

The marketing authorization of the underlisted medicines have 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	Sandoz	Airflusal 50/250 Inhaler	Salmeterol xinafoate 50mcg/Fluticasone Propionate 250mcg	Symptomatic treatment of adults with COPD, with a forced expiratory volume in one second (FEV1) <60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations and who have significant symptoms despite regular bronchodilator therapy.
2	Sandoz	Airflusal 50/500 Inhaler	Salmeterol xinafoate 50mcg/Fluticasone Propionate 500mcg	Symptomatic treatment of adults with COPD, with a forced expiratory volume in one second (FEV1) <60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations and who have significant symptoms despite regular bronchodilator therapy.
3	Torrent Pharmaceutical Limited	Dopcor 80mg and 160mg tablets	Valsartan 80mg and 160mg	Treatment of high blood pressure (hypertension) in adults and children who are at least 6 years old. Valsartan is also used in adults to treat heart failure, and to lower the risk of death after a heart attack.
4	Astra Zeneca	Losec Mumps 20mg tablets	Omeprazole 20mg	Treatment of symptoms of gastroesophageal reflux disease (GERD) and other conditions caused by excess stomach acid. It is also used to promote healing of erosive esophagitis. Omeprazole may also be given together with antibiotics to treat gastric ulcer caused by infection with Helicobacter pylori (H. pylori)
5	Astra Zeneca	Nolvadex 20mg tablets	Tamoxifen 20mg	Treatment of some types of breast cancer in men and women. It is also used to lower a woman's chance of developing breast cancer if she has a high risk (such as a family history of breast cancer).

NO	MAH	NAME OF DRUG	ACTIVE INGREDIENT	INDICATION
6	GSK	Nepine SR 20mg tablets	Nifedipine SR 20mg	Treatment of hypertension (high blood pressure) and angina (chest pain).
7	GSK	Ventolin Rotacaps 200mcg	Ventolin Rotacaps 200mcg	Treatment or prevention of bronchospasm in people with reversible obstructive airway disease.
8	GSK	Ventolin Rotacaps 200mcg	Salbutamol Sulphate 200mcg	Treatment or prevention of bronchospasm in people with reversible obstructive airway disease.
9	Actavis Limited	Valsotens 80mg and 160mg tablets	Valsartan 80mg and 160mg	Treatment of high blood pressure (hypertension) in adults and children who are at least 6 years old. Valsartan is also used in adults to treat heart failure, and to lower the risk of death after a heart attack.
10	Bayer	Andorcur 50mg Tablets	Cyproterone acetate	Androcur is used to control sexual desire in men who have an increased sex drive (hypersexuality) and/or sexual deviation.
11	GSK	Augmentin ES 642.9mg/5ml suspension	Amoxicillin trihydrate /potassium clavunate	Used in adults and children to treat middle ear and sinus, respiratory tract, urinary tract, skin and soft tissue, including dental, bone and joint infections.

NO	MAH	NAME OF DRUG	ACTIVE INGREDIENT	INDICATION
12	GSK	Clavulin 457mg/5ml suspension	Amoxicillin trihydrate/ potassium clavunate	Used in adults and children to treat middle ear and sinus, respiratory tract, urinary tract, skin and soft tissue, including dental, bone and joint infections.
13	GSK	Duodart 0.5mg/0.4mg Tablets	Dutasteride/ Tamsulosin	Treatment and prevention of progression of benign prostatic hyperplasia (BPH) through alleviating symptoms, reducing prostate size (volume), improving urinary flow rate and reducing the risk of acute urinary retention (AUR) and the need for BPH-related surgery.
14	GSK	Flixonase Nasal Spray 0.05% w/w	Fluticasone propionate/ Salmeterol	Treatment and prevention of Inflammation in the lining of the nose (rhinitis) due to seasonal allergies, such as Hayfever and to year round (perennial) allergies, such as animal allergies.
15	Bayer	Magnevist Injection	Gadopentetic acid	Used with magnetic resonance imaging (MRI) in adults and pediatric patients (2 years of age and older) to visualize lesions with abnormal vascularity in the brain (intracranial lesions), spine and associated tissues.
16	GSK	Protedex 1000mg, 2000mg and 5000mg Injection	Ceftriaxone	Treatment of chest and sexually transmitted infections,Lyme disease, bacterial infection in patients with neutropenia and prevention of infections during surgery.
17	GSK	Seretide Diskuss 50/500mcg Inhaler	Fluticasone propionate/ Salmeterol	Treatment of asthma where use of a combination product (long- acting β2 agonist and inhaled corticosteroid) is appropriate and for the symptomatic treatment of patients with COPD, with a FEV1 <60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy.

NO	MAH	NAME OF DRUG	ACTIVE INGREDIENT	INDICATION
18	GSK	Seretide Evohaler 25/125mcg and 25/50mcg Inhaler	Fluticasone propionate/ Salmeterol	Treatment of asthma where use of a combination product (long- acting β2 agonist and inhaled corticosteroid) is appropriate and for the symptomatic treatment of patients with COPD, with a FEV1 <60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy
19	GSK	Xylal 5mg Tablets	Levocetirizine Hydrochloride	Symptomatic treatment of allergic rhinitis (including persistent allergic rhinitis) and urticaria in adults and children aged 6 years and above

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EDITORIAL TEAM

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