



## The FDA Bids Farewell to Two Advisory Committees

The Food and Drugs Authority (FDA) on Tuesday, December 22, 2015 bid farewell to a total of 24 (twenty-four) scientific experts of the Technical Advisory Committees on Safety and Clinical Trials. This was in line with the Terms of Reference of the Committees, which provides the maximum tenure of office for members.

These two Committees are independent Scientific Advisory Committees of the FDA tasked to provide the Authority with medical and scientific advice on issues related to clinical trials and safety of medicines (including herbal), vaccines, cosmetics and medical devices.

*(read more on page 6...)*



Technical Advisory Committee Members with Board Chairman & CEO of FDA and Staff Members

## FDA Collaborates with the Nursing and Midwifery Council of Ghana (NMCG) to Introduce Pharmacovigilance into the

The FDA has worked with the NMCG since 2013 to introduce a course in Pharmacovigilance, Vaccine Vigilance and Patient Safety into the revised curriculum for training nurses and midwives dated October 2015. It is hoped that this will help improve the knowledge of the nurses in medicine safety and improve the reporting rate of adverse drug reactions and adverse events following immunization (AEFI) in Ghana leading to better patient safety. *(read more on page 6...)*

## FDA Hosts Global Vaccine Safety Experts

The Food and Drugs Authority, Ghana has hosted the 8<sup>th</sup> meeting of global experts on vaccine safety in Ghana as they conclude the development of a Universal Guide for Vaccines Safety from March 22-23, 2016.

The Council for International Organizations of Medical Sciences /World Health Organization (CIOMS/WHO) working Group on Vaccine Safety was established in 2013 to provide a forum for Information exchange and interaction between Public Health Agencies, Regulatory Authorities, Industry and other stakeholders on vaccine safety.

*(read more on page 5...)*

## Ghana leads in Pharmaceutical Industry's Involvement in Pharmacovigilance

The Food and Drugs Authority (FDA) in collaboration with the World Health Organization Collaborating Centre for Advocacy and Training in Pharmacovigilance (WHO-CC) has trained the first batch of Qualified Persons for Pharmacovigilance (QPPVs) in May – June 2015; the first ever to be held in Africa. The training programme is in line with the new requirements in Part 7, Section 125 of the Public Health Act, 2012, Act 851 and the Food and Drugs Authority (FDA) Guidelines for Selection of Qualified Persons for Pharmacovigilance. This makes it mandatory for Marketing Authorization Holders (MAHs) of pharmaceutical products to have a qualified person responsible for pharmacovigilance resident in Ghana to oversee the safety monitoring of marketed products.

*(read more on page 6...)*

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## Promoting Patient Safety in the Ashanti Region



Pharm. Douglas Kumah

**P**harm. Douglas Kumah is a clinical pharmacist at the Komfo Anokye Teaching Hospital Polyclinic with over 10 years working experience. He developed a passion for Pharmacovigilance when he became aware that patients were rejecting prescribed medicine due to their past undesirable experiences.

He began to promote patients' trust in the healthcare system by making following up on patients who were dispensed with medicines that are expected to cause some level of discomfort to patients due to known adverse reactions by encouraging them to report these.

Pharm. Douglas Kumah and his colleagues under the leadership of Pharm. Akwasi Appiah (Institutional Contact Person (ICP) from the Komfo Anokye Teaching Hospital (KATH) have trained a lot of pharmacy staff working at KATH Polyclinic on pharmacovigilance which has resulted in their institution submitting the highest number of adverse drug reaction reports to the FDA in 2015.

The National Pharmacovigilance Centre appreciates all healthcare professionals who have contributed to patient safety in Ghana.

### REPORTING FOR 2015

The National Pharmacovigilance Centre received eight hundred and nine (809) reports for the year 2015 from healthcare professionals, the pharmaceutical industry, and patients/consumers across the country. A total of 697 came from healthcare professionals, 112 of the reports were received from the pharmaceutical industry and 3 reports from patients/consumers. Of these 545 were spontaneous reports and 152 received during the Seasonal Malaria Chemoprevention (SMC) in the Upper West region, 112 of the reports were received from the pharmaceutical industry and 3 reports from patients/consumers. Reports received from patients/consumers in 2015 was less than in 2014 where the Centre received 34 due to the piloting of the patient engage-

ment in safety monitoring of medicines. We look forward to receiving more reports from patients in 2016 from Patient Safety Centres. It is hoped that reporting from industry will continue to increase due to the legal obligations on industry to submit adverse drug reaction reports to the FDA.

The SMC is a new WHO recommended intervention using intermittent administration of full treatment courses of an anti-malarial medicine in children between the ages of 3-59 months during the malaria season in areas of highly seasonal transmission.

The objective of the SMC is to prevent malarial illness by maintaining therapeutic antimalarial drug concentrations in the blood throughout the period of greatest malarial risk. The antimalarial medicine used during the programme was sulfadoxine-pyrimethamine and amodiaquine. The exercise was carried out in the Upper West Region in four rounds from July 2015 to November 2015. Seventeen (17) serious adverse drug reactions were received out of the 152 and none was found to be related to the medicines used during the programme<sup>1</sup>. Of the adverse reaction reports received, 222 (33.3%) were experienced by males, 409 (61.4%) by females and for 35 (5.3%) the gender was unknown as this information was missing and could not be followed up. This finding is not surprising because studies have revealed that females report adverse drug reactions more frequently compared to males.<sup>2, 3</sup>

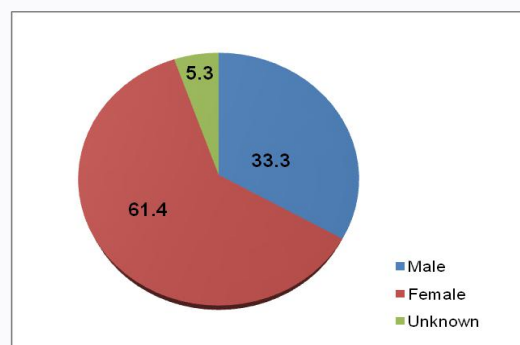
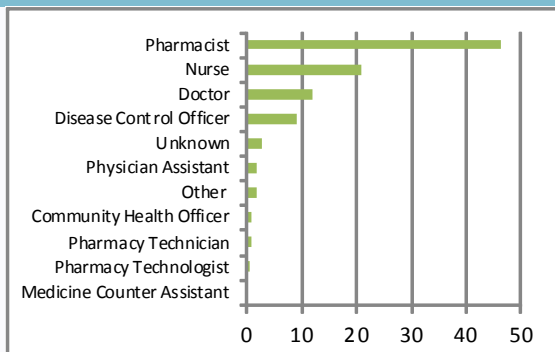


Figure 1: Gender Distribution of Patients

Figure 2 shows spontaneous reports received from different categories of Healthcare Professionals (HCPs). Of the spontaneous reports received from Healthcare professionals 20 (2.87%) did not indicate the profession (unknown). The National Pharmacovigilance Centre would like to encourage HCPs to fully complete reports in the future.

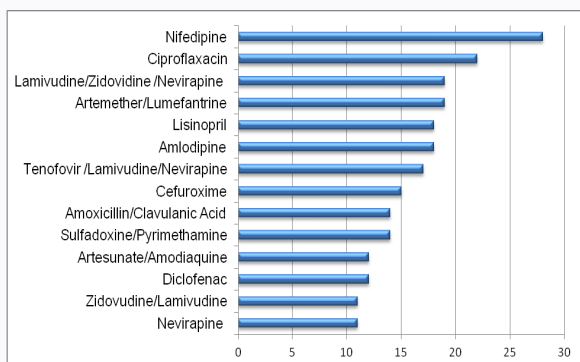
#### References:

- [http://www.who.int/malaria/areas/preventive\\_therapies/children/en/](http://www.who.int/malaria/areas/preventive_therapies/children/en/)  
 Tharpe N Adverse drug reactions in women's health care, J Midwifery Women's Health (2011), 56(3):205-13  
 Montastruc JL, Lapeyre-Mestre M, Bagheri H, Fooladi A., Gender differences in adverse drug reactions: analysis of spontaneous reports to a Regional Pharmacovigilance Centre in France, Fundam Clin Pharmacol. (2002), 16(5):343-6.



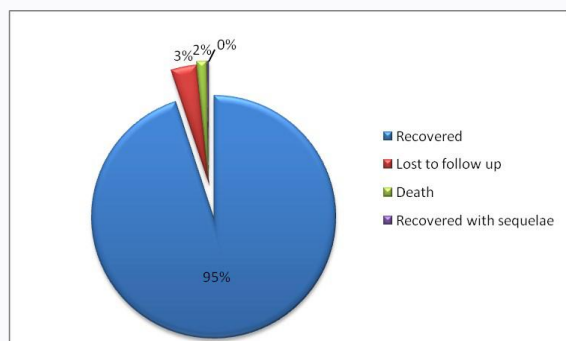
**Figure 2: Percent Reporting by Healthcare Professionals**

The top 15 drugs with most commonly reported ADRs is almost similar to what was obtained in 2014.



**Figure 3: 15 Drugs with Most Commonly Reported ADRs**

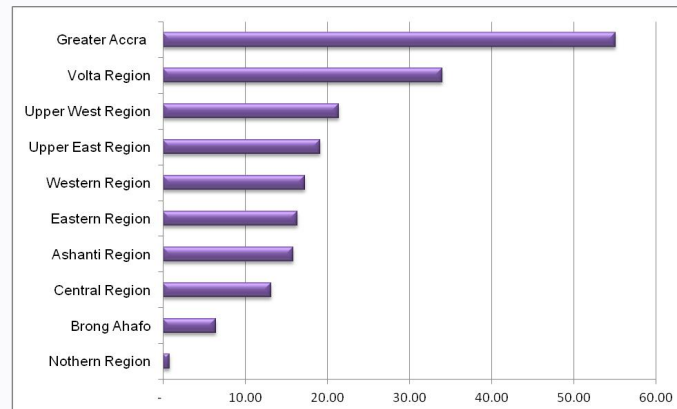
Fig. 4 revealed that 2% of the patients who reported adverse drug reactions had fatal outcome, 95% fully recovered from the reported reactions with 3% lost to follow up. The percent recovery and the lost follow up obtained in the preceding year were 8.0% and 88.4% respectively. We can therefore conclude that there is better management of suspected adverse drug reaction cases with better follow up of patients who reported adverse drug reactions. There was also 1.4% fatal cases reported compared to 2.5% in 2014.



**Figure 4: Outcome of the Reported ADRs**

The top twenty healthcare facilities that submitted reports to the National Pharmacovigilance Centre in 2015 is shown in Fig 1. The Food and Drugs Authority appreciates the leader-

ship and members of staff of the Komfo Anokye Teaching Hospital for paying particular attention to patient safety issues thereby submitting the maximum number of reports in 2014 and 2015. We also appreciate Lambussie Polyclinic, Hamile Health Centre and Piina Health Centre all from the Upper West region who are new list of entrants to the list of the top 20 reporting facilities.



**Figure 5: Number of Spontaneous Reports Received from the Regions per 1,000,000 Inhabitants**

**Table 1: The Top 20 Reporting Healthcare Facilities**

| Facility                       | Region         | Number Of Reports |
|--------------------------------|----------------|-------------------|
| Komfo Anokye Teaching Hospital | Ashanti Region | 72                |
| Korle-bu Teaching Hospital     | Greater Accra  | 19                |
| Nadowli District Hospital      | Upper West     | 18                |
| Ga West Municipal Hospital     | Greater Accra  | 18                |
| Koforidua Regional Hospital    | Eastern Region | 15                |
| Ridge Regional Hospital        | Greater Accra  | 15                |
| Shai Osudoku Dist. Hospital    | Greater Accra  | 14                |
| Achimota Hospital              | Greater Accra  | 13                |
| Effia Nkwanta Hospital         | Western Region | 13                |
| Ga South Municipal Hospital    | Greater Accra  | 12                |
| Jasikan District Hospital      | Volta Region   | 12                |
| Lapaz Community Hospital       | Greater Accra  | 12                |
| Nandom Health Centre           | Upper West     | 12                |
| Hamile Health Centre           | Upper West     | 11                |
| Korle-bu Polyclinic            | Greater Accra  | 11                |
| Piina Health Centre            | Upper West     | 11                |
| Hohoe Municipal Hospital       | Volta Region   | 10                |
| Bolga Regional Hospital        | Upper East     | 10                |
| Ridge Hospital OPD             | Greater Accra  | 10                |
| Lambussie Polyclinic           | Upper West     | 9                 |

Ghana Statistical Service. Population and Housing Census, Population by Region and Sex, 2010 [cited 2016 Jan 20]. Available from: [http://www.statsghana.gov.gh/docfiles/2010phc/20%2010\\_population\\_and\\_housing\\_census%28view\\_pop%20ulation\\_by\\_sex\\_regional\\_and\\_district%29.pdf](http://www.statsghana.gov.gh/docfiles/2010phc/20%2010_population_and_housing_census%28view_pop%20ulation_by_sex_regional_and_district%29.pdf)

Table 1 represents the top twenty healthcare facilities which submitted reports to the National Pharmacovigilance Centre in 2015. The Food and Drugs Authority appreciates the leadership and members of staff from these facilities and all other facilities who continue to contribute to patient safety.

The greater number of spontaneous reports was from the Greater Accra, Ashanti and Volta regions with 221, 76 and 72 reports respectively. The number of spontaneous reports received was normalized per 1,000,000 inhabitants in a region based on the results of the 2010 population and housing census<sup>1</sup> as shown in Figure 5.

## FDA and Pharmaceutical Society of Ghana (PSGH) work to ensure Patient Engagement in Promoting Safety of Medicines

The FDA in collaboration with the PSGH organized a one-day training workshop on December 3, 2015 for a total of 247 community pharmacists in the Northern Sector. The workshop took place at the Miklin hotel in Kumasi. A similar workshop was organized for the Southern Sector at the Miklin hotel in Accra on December 8 and 9, 2015. The workshops were in preparation towards the launch of Patients' Engagement in Medicines Safety Project with the objective to equip the pharmacists with the knowledge and skills for optimum patient engagement. It is expected that implementation of Patients' Engagement in Medicines Safety will increase the number of adverse reaction reports and improve on the early detection medicine safety problems.



CEO and section of participants at the training workshop for Community Pharmacists on Patients' Engagement in Medicines Safety in Accra



Southern Sector Participants at the training workshop for Patients' Engagement in Medicines Safety held in Accra

As part of the project, Community Pharmacies will be designated as Patient Safety Centres to promote adverse drug reaction (ADR) reporting by patients and hence the need to train all Community Pharmacists to ensure the success of the project.



Northern Sector participants at the training workshop for Patients' Engagement in Medicines Safety held in Kumasi

## FDA Collaborates With Ghana Health Service (GHS) to Improve Medicine Safety

The FDA is working with the GHS to introduce an innovative programme sponsored by the UK Department for International Development (DFID) to improve medicine safety and the culture of adverse event reporting by healthcare professionals. The overarching objective of the project is to integrate pharmacovigilance in the healthcare delivery system by introducing what is called the Pharmacovigilance Assessment Tool (PAT). PAT is a two-paged evaluation checklist developed with guidance from the Indicator-Based Pharmacovigilance Assessment Tool (IBPAT)<sup>1</sup>. The checklist has five set of indicators, namely,



Participants use the PAT to access Pharmacovigilance activities at the SDA Hospital

Staff and Infrastructure, Tools for Pharmacovigilance, Systems and Structures, Training and Skills, and Knowledge on the Safety Issues to be Reported. Training was provided for staff from healthcare facilities in Greater Accra Region in September 2014 where the tool was piloted. In preparation for the roll-out in the other Regions, a two day Training-of-Trainers Workshop was organized for Regional Pharmacovigilance Officers from the FDA and the underlisted Senior Staff from the Ghana Health Service.

1. Deputy Director of Public Health or Representative
2. Deputy Director of Pharmacy or Representative
3. Deputy Director of Clinical Care or Representative
4. Deputy Director of Nursing or Representative

The roll out of the project in the regions will be preceded by baseline data collection using the PAT in order to evaluate the impact of this intervention and also training programmes for healthcare professionals in all the regions.

## FDA HOSTS GLOBAL VACCINES SAFETY EXPERTS

*(continued from page 1)*

Mrs. Delese Darko, the Ag. Deputy Chief Executive in charge of Safety Monitoring and Clinical Trials represents the interest of Ghana, Africa and low and middle income regulators in shaping the global landscape for vaccine safety.

In his welcome address, the Chief Executive of the Food and Drugs Authority, Mr. Hudu Mogtari, expressed his pleasure at hosting the Working Group (WG) in Ghana. Present at the meeting are the Vaccine Safety Experts from the USA, European Union, WHO - Switzerland and the leading Vaccine manufacturers from both Developed and Developing Countries.



CEO of the FDA with working group of the Global Vaccines Safety Experts

## Ghana leads in Pharmaceutical Industry's Involvement in Pharmacovigilance

*(continued from page 1)*

The requirement further states that the QPPV should receive a formal training in pharmacovigilance recognized by the FDA. Since this training is at the moment not being offered by any providers around the globe, the FDA partnered with the WHO-CC who together with the FDA have recently been designated as Regional Centre of Regulatory Excellence in Pharmacovigilance by the Africa Union to run the course. The course has a minimum of 60 hours contact time and was developed to meet the busy schedules of the senior pharmaceutical company executives who participated in the course. The course has 9 modules includes the following:

### References:

Indicator-Based Pharmacovigilance Assessment Tool: Manual for Conducting Assessments in Developing Countries, December 2009 [Cited 2015 Aug 23]. Available from [http://pdf.usaid.gov/pdf\\_docs/PNADS167.pdf](http://pdf.usaid.gov/pdf_docs/PNADS167.pdf)

1. Introduction to Pharmacovigilance;
2. The QPPV: Legal framework, Roles and Responsibilities;
3. Pharmacovigilance Quality System;
4. Individual Case Safety Reports, Data Management, Coding and Case Causality Assessment;
5. Pharmacovigilance Methods;
6. Periodic Safety Update Reports (ICH E2C) and Periodic Benefit Risk Evaluation Reports (ICH E2 R1);
7. Signals and Signal Management;
8. Pharmacovigilance Audits and Inspections;
9. Communication and Crises Management in Pharmacovigilance.

## FDA Collaborates with the Nursing and Midwifery

Students who undertake the course are expected to know the following:

1. Define key terms and concepts in Pharmacovigilance and safety monitoring of drugs and vaccines.
2. Understand importance of Pharmacovigilance and spontaneous reporting in ensuring patient safety.
3. Describe the Pharmacovigilance system in Ghana emphasizing the role of healthcare professionals.
4. Appreciate the role of Pharmacovigilance in public health programmes with particular focus on Immunization Programme.
5. Understand issues regarding prevention, diagnosis, management and reporting of adverse events
6. Understand principles of causality assessment and signal generation

The FDA is grateful to the Registrar of the NMCG, Mr. Felix Nyante, for the visionary leadership in making this possible.

The FDA is also working with other tertiary institutions and healthcare professional regulatory bodies to help in incorporating pharmacovigilance into the pre-service training curriculum for all healthcare professionals in Ghana.

## The FDA Bids Farewell to Two Advisory Committees

*(continued from page 1)*

Present at the farewell ceremony were the Chairman of the Governing Board of the FDA, Mr. Kofi Totobi Quakyi, the CEO of the FDA, Mr. Hudu Mogtari and the Acting Deputy Chief Executive of the Safety Monitoring and Clinical Trials Division, Mrs. Delese Darko, the secretary to the committees.

The CEO commended the Committee members for their faithfulness, distinction and selflessness in serving the FDA in particular and Ghanaians in general. The CEO asked that members pledge their continued support to the FDA in terms of knowledge, experience and expertise as the Authority continues its quest to deliver safe and effective health products and technologies to Ghanaians and also in protecting public health and safety.



Mr. Hudu Mogtari, CEO of the FDA presents a certificate to a participant after the QPPV training programme. Looking on are Prof. Alex Dodoo and Dr. Sarah Daniels

Participants for the first phase of the QPPV training represented multinational companies such as Astra-Zeneca, Bayer, Roche, Pfizer, MSD, Novartis, Novo Nordisk, Eli Lilly, Servier, Janssen, Sanofi, Merck and GlaxoSmithKline. The second phase of training is scheduled for the first/second quarter of 2016 and is expected to host regulators and MAH representatives from other African countries. This programme has been published in the Uppsala Reports<sup>1</sup> and the results of the implementation presented during the 38<sup>th</sup> National Centers meeting held in New Delhi, India on November 2015 during the Problems of Current Interest session.

**Reference:** Uppsala Reports, 70, page14, <http://www.who-umc.org/graphics/29603.pdf>

## Major Achievements

Some of the achievements of the FDA with the support of the Committees during their tenure are highlighted below:

- Designation of the FDA as a Regional Centre of Regulatory Excellence (RCORE) in Clinical Trials and Pharmacovigilance by the NEPAD under the African Medicines Regulatory Harmonization (AMRH) programme.
- Commencement of pharmaceutical industry's involvement in pharmacovigilance following the enactment of Act 851, 2012, Sec 125.
- Introduction of the patients' engagement initiative in post approval safety monitoring of medicines.
- Increase in spontaneous reporting rate of adverse drug reactions from less than 200 reports in 2009 to 700 reports in 2015.
- Provision of support in the development of robust software for both pre-approval and post approval safety data entry.
- Develop the content of the annual Good Clinical Practice training programme for principal investigator and study staff.

These achievements, the CEO admitted did not come easy. There were a few challenges; the most recent one being the controversy surrounding the clinical trial for a vaccine against Ebola Virus Disease. Also, due to the increasing number of individual case safety reports, the Committee on Safety had to work additional hours to review Individual Case Safety Reports (ICSRs) sometimes exceeding one hundred reports per meeting.

## Visitors to the National Pharmacovigilance Centre in 2015

### • Participants of the Vaccine Fellowship Training Programme

Sixteen (16) participants from nine (9) African countries paid a one-day visit to the National Pharmacovigilance Centre on September 17, 2015 to have a firsthand knowledge about Pharmacovigilance in Ghana with specific focus on Vaccine Safety.

Participants were impressed with the Pharmacovigilance (PV) system in Ghana and established that the visit was worthwhile.

### • Director of the Uppsala Monitoring Centre, Sweden

On November 23, 2015 the Director of the WHO Collaborating Centre for International Drug Monitoring (the Uppsala Monitoring Centre), Dr. Marie Linqvist and WHO Programme Expert, Mr. Sten Olssen together with two members of staff visited the FDA offices in Accra and held a meeting with the CEO and staff of the Safety Monitoring Department.

The objectives of the visit were:

1. Introduce the FDA PV staff to the new version of Vigilyze, version 2.0 which was launched on December 1, 2015
2. To learn about the FDA's new Individual Case Safety Report (ICSR) management system, the SafetyWatch System (SWS) and how it helps improve daily workflow at the National PV Centre.
3. FDA to seek areas of assistance on how to improve on the SWS and integration of other safety reports received from patients and clinical trials and also legacy data (ICSRs) in Vigiflow.
4. Other possible areas of collaboration in PV to improve patient safety in Ghana.



CEO of the FDA, team from WHO Collaborating Centre for International Drug Monitoring and Staff of FDA

The FDA was represented at this meeting by the Chief Executive Officer, Acting Deputy Chief Executive of the Safety Monitoring and Clinical Trials Division and staff of the Safety

Monitoring Department.

The team from the WHO Programme was impressed with innovative ways the FDA is adopting to promote patient safety including, introduction of patient engagement in medicine safety, pharmaceutical industry's pharmacovigilance, incorporation of medicine safety into the curriculum for training nurses and midwives and integration of pharmacovigilance into the healthcare delivery system.

## Drugs of Current Interest

### Rosiglitazone-containing Diabetes Medicines: Elimination of Risk Evaluation and Mitigation Strategy (REMS) by US Food and Drugs Administration

In 2010, the European Medicines Agency (EMA) suspended the marketing authorization for Rosiglitazone-containing medicines (Avandia and Avandamet) due to evidence of increased cardiovascular risk for products containing Rosiglitazone<sup>1</sup>. The US Food and Drugs Administration, however recommended Risk Evaluation and Mitigation Strategy (REMS) for products containing Rosiglitazone.<sup>2,3</sup> Other regulatory authorities like Health Canada and the Therapeutic Goods Administration of Australia also took decisions which mirror that of the US FDA.<sup>4,5</sup>

The REMS introduced restricted access and distribution programme which required physicians to be specially trained and registered to prescribe the medicines; pharmacies to be registered to dispense the medicines and that access be limited to patients already taking the medicines and benefitting from it or new patients whose conditions could not be managed with diabetes medicines.<sup>6</sup>

#### References

- [http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2010/09/news\\_detail\\_001119.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2010/09/news_detail_001119.jsp&mid=WC0b01ac058004d5c1)  
<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm226956.htm>  
<http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM255624.pdf>  
<https://www.tga.gov.au/alert/rosiglitazone-avandiaavandamet>  
<http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2010/16117a-eng.php>  
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm477601.htm>  
<http://www.fda.gov/Drugs/DrugSafety/ucm376389.htm>

Meanwhile, in December 2015, the US Food and Drugs Administration announced the elimination of Avandia-Rosiglitazone Medicines Access Programme because it was no longer necessary to ensure that the benefits of rosiglitazone medicines outweigh their risks.

The US FDA had earlier informed healthcare professionals that data did not demonstrate an increased risk of heart attack with Rosiglitazone-containing medicines compared to the standard type 2 diabetes medicines metformin and sulfonylurea.<sup>7</sup>

#### Local Situation

The Ghana FDA on 29<sup>th</sup> November, 2010 suspended the marketing authorization for Rosiglitazone-containing medicines (Avandia and Avandamet) following the decision by the EMA. This decision has not been reviewed by the Ghana FDA since EMA's position has not changed after the suspension of the marketing authorization in 2010.<sup>1</sup> Meanwhile, the FDA is reviewing the situation and any decision will be communicated to healthcare professionals and other stakeholders.

### Who Reads the Dear Healthcare Professional Letters?

In 2014, the Safety Monitoring Department conducted a nationwide survey amongst selected healthcare professionals, including doctors, pharmacists, nurses and physician assistants, on the effectiveness of Dear Healthcare Professional Letters (DHCPs) as a means of communicating safety information and measuring its impact.

Respondents provided important information on the effectiveness of the Food and Drugs Authority's current method of communicating product risk to healthcare professionals. The survey results will help in implementing more efficient ways of communicating safety information to healthcare professionals. The feedback received from healthcare professionals revealed that the FDA needs to initiate more efficient ways of communicating safety information including short messaging to mobile phones and email to ensure these letters are received in good time to protect patients from possible harm.



Of the 913 respondents only 350(38.34%) were aware of at least one of the letters distributed in 2013 and 314(89.71%) admitted that these letters have influenced their way of prescribing, dispensing and administering the medicines involved.

192(54.82%) of the respondents rated the level of understanding of the language used as good and there was no significant difference between the healthcare professionals rating of the language used in the letters (  $p=0.40$ ). Fifty-nine (59.25%) said the content was relevance to them.

Healthcare professionals suggested electronic methods such as short messaging service (SMS) to mobile phones 56.81%,email 85.86% and posting the letters on the FDA website 26.85%.

In conclusion, although DHCPLs from the FDA are largely effective in changing the attitude of healthcare professionals in terms of prescribing, dispensing and administering the medicines involved, only a few received these letters in good time. The department wish to gratefully acknowledge Institutional Contact Persons in all health facilities where the data for this survey was collected and FDA Regional PV officers.

## Safety Concerns with Tobacco Products and Controlled Substances

The Public Health Act, 2012, Act 851 mandates the Food and Drugs Authority to regulate Tobacco and Tobacco products by banning tobacco use in public places, advertising, promotion and sale of these products to persons below the age of eighteen (18) years. Tobacco is any of the several green leafy plants belonging to the group of plants called *Nicotiana*, especially the type called *Nicotiana tabacum* that yields nicotine rich. Two main types of processed tobacco leaves (dried, milled) are the smoked tobacco, e.g cigars, cigarettes, pipes, shisha. and then the smokeless tobacco e.g. chewing tobacco (placed in the mouth and chewed or sucked), snuff (sniffed through the nose).

Tobacco is a leading cause of death, illness and impoverishment which kill nearly six million people a year.

More than five million (5,000,000) of those deaths are the result of direct tobacco use while six hundred thousand (600,000) are the result of non-smokers, also known as passive smokers,



being exposed to second hand smoke. Second-hand smoke is the smoke that fills restaurants, pubs, nightclubs, offices or other enclosed spaces when people burn tobacco products such as cigarettes, bidis and water pipes.

There are more than seven thousand (7000) chemicals in tobacco smoke, of which at least two hundred and fifty (250) are known to be harmful and more than seventy (70) are known to cause cancer. There is no safe level of exposure to second-hand tobacco smoke.

Nearly eighty percent (80%) of the more than one billion (1,000,000,000) smokers worldwide live in low and middle income countries like Ghana where the burden of tobacco related illness and death is heaviest. Current trends in tobacco smoking are the water pipe cigarette (shisha) and electronic cigarettes. The shisha is usually a glass-jar-bottomed water-pipe (Hookah) in which fruit-flavoured tobacco is covered with foil and roasted with charcoal. The tobacco smoke passes through a water chamber and is inhaled deeply and slowly via a hose pipe attachment. Enthusiasts say the fruit-flavoured tobacco tastes smooth and smells sweet, making it an enjoyable and unrushed experience.

The volume of smoke inhaled in an hour-long shisha session is estimated to be the equivalent of smoking about a hundred (100) to two hundred (200) sticks of cigarettes.

The misconception that shisha is not as harmful as cigarettes because the tobacco is flavoured and passes through water first is untrue. The carcinogens and nicotine are still in there.



A regular shisha smoker should expect to be at risk of the similar health problems that cigarette smokers suffer, whether respiratory, cardiovascular, oral cavity and teeth,

according to WHO experts.

Apart from the nicotine content, laboratory analysis of waterpipe smoke reveals measurable levels of carcinogens (including tobacco-specific nitrosamines, polycyclic aromatic hydrocarbons (PAH), volatile aldehydes like formaldehydes, and benzene), and toxicants such as nitric oxide and heavy metals. The burning charcoal generates high levels of carbon monoxide (CO) and carcinogenic PAH. These toxic substances have been linked to addiction, heart and lung diseases and cancer in cigarette smokers and can cause same diseases in Shisha users if these toxicants are absorbed into the body in appreciable amounts.

Electronic nicotine delivery systems (ENDS), of which electronic cigarettes are the most common prototype, are devices that do not burn or use tobacco leaves but instead vaporise a solution that the user then inhales. The main constituents of the solution, in addition to nicotine are propylene glycol, with or without glycerol and flavouring agents.

With regard to narcotics, psychotropic substances and precursor chemicals, there have been current reports of abuse of coughs and colds formulations containing codeine or pseudoephedrine. These formulations are purchased in quantities above treatment levels and consumed in large doses either with or without other substances. The addicts, who abuse the codeine formulations recreationally, claim they achieve an induced feeling of excitement (euphoria). However depression, anxiety and irritability may set in over time.

## Adverse Drug Reaction Reporting Made Easier

**Hurry!** Do not let that suspected adverse drug reaction (ADR) goes without reporting to the Food and Drugs Authority (FDA).

In order to reduce underreporting and improve spontaneous reporting the FDA now has an online portal for reporting all ADRs, known as the SafetyWatch System (SWS).

Just go online and log in to SWS at

<http://adr.fdaghana.gov.gh/> to submit your report.

SWS is a web based ICH-E2B compliance data management system for submitting all ADRs directly to the FDA.

Some of the benefits of SWS are:

- Real-time data entry by all stakeholders including, health workers, pharmaceutical Industries and public health programmes.

- Real-time data processing by the FDA to help in the early identification of serious issues

- particularly therapeutic failures, substandard and counterfeit medicines for earlier patient/consumer protection

- Enhance data sharing and data mining

Please, let us know about your experiences using the SWS; send email to the FDA at [drug.safety@fdaghana.gov.gh](mailto:drug.safety@fdaghana.gov.gh)

# SIDE EFFECTS OF YOUR MEDICINES CAN BE HARMFUL TO YOUR HEALTH



**REPORT SIDE EFFECTS TO YOUR HEALTH WORKERS  
BE A LIFE SAVER!**

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Tel: 0244-310297 / 0302-233200 / 235100



E-mail: [drug\\_safety@fda.gov.gh](mailto:drug_safety@fda.gov.gh)  
Website: [www.fda.gov.gh](http://www.fda.gov.gh)  
Short code to all Networks: 4015

**ARE YOU  
REACTING  
TO ANY  
MEDICINE?**



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## Patient Engagement in Safety Monitoring of Medicines Begins

The contribution of patients towards ensuring the safety of marketed drugs and vaccines cannot be underestimated. Patients can communicate their adverse experiences with medicines better than healthcare professionals and will therefore record with precision their medicines and other health products.

### *The Strategy in Ghana*

The FDA is working with the Pharmaceutical Society of Ghana through the Community Pharmacy Practice Association (CPPA) to promote Patient Reporting by designating participating Community Pharmacies as "Patient Safety Centres".

Community Pharmacies have been chosen to introduce this concept because of easy accessibility to patients within the community.

The patient reporting concept is also being promoted through the print and electronic media using posters, billboards, advertisement in newspapers, television and radio, text messaging, social media and other internet platforms.

### *The Role of Healthcare Professionals*

The FDA wishes to appeal to all healthcare professionals to educate patients on the new concept and advise them to visit the nearest community pharmacy labelled "Patient Safety Centre" to report any problems they may have with their medication by using the **BlueForm**.

Patients can also report directly to the FDA through the short code **4015**.

### *Expected Outcome*

The FDA hopes that Patient Engagement in Safety Monitoring of Medicines will improve adverse reaction reporting rate and contribute to the generation of signals and early detection of safety problems with drugs, vaccines and other health products marketed in Ghana.

## What to Report?

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

The FDA encourages the reporting of all suspected adverse reactions to medicines, including vaccines, over-the-counter medicines, 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

Reports may be submitted using the FDA "blue form" available at all hospitals and some pharmacies and also available at the FDA website at <http://www.fdaghana.gov.gh>.

Contact the National Pharmacovigilance Centre: Tel: 024 431 0297  
Email: [drug.safety@fdaghana.gov.gh](mailto:drug.safety@fdaghana.gov.gh)



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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.

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