DrugLens

DRUGLENS ISSUE 3 | MARCH 2015

NEWSLETTER

The BlueForm being introduced to a patient

PATIENTS AND CONSUMERS CONTRIBUTING TO THE SAFETY OF MEDICINES

Anytime adverse drug reaction reporting by patients is mentioned, what comes to mind is the song by Bob Marley & the Wailers titled "He Who Feels It, Knows It"; thus the contribution of patients' towards ensuring the safety of marketed drugs and vaccines cannot be underestimated, because patients can tell about their experiences with medicines better than anyone else.

Since Ghana joined the WHO Program for International Drug Monitoring in 2001 adverse drug reactions reports from patients have been received mainly through their healthcare professionals. Patient reporting directly has been discussed but has not been fully implemented. Starting in 2015, the FDA will fully implement patient reporting and it is hoped this will increase the adverse drug reaction reporting rate and contribute to the generation of signals and early detection of safety problems with medicines on the Ghanaian market.

The National Pharmacovigilance Centre has received fifteen reports directly from patients since 2005.

The Centre receives on the average 12 adverse drug reaction reports per 1,000,000 Ghanaians per year, which is less than the WHO recommendation that a fully functional pharmacovigilance system should receive 200-250 reports per million population per year. Based on this recommendation and the 2013 population of 25,900,000 population, it is therefore expected that approximately 5,000 reports should be received by the National Centre per year.

Due to the high level of underreporting it is possible that safety problems with medicines used in Ghana will go undetected. In view of this the National Centre is being supported by the UK Department for International Development (DFID) and the UK Medicines and Health Products Regulatory Agency (MHRA) to introduce patient/consumer reporting in an attempt to boost ADR reporting and increase the chances of signal generation.

There are also several other benefits of patients' reporting of which some are:

- Patient reports are direct, detailed and unambiguous because these reports describe exactly how the patient feels. Reports from patients will usually provide information on concomitant medicines, including herbal medicines and over-the-counter medicines due to high level of self-medication.

- Spontaneous reporting by patients has important benefits beyond pharmacovigilance because the patient becomes an active participant instead of a largely passive recipient of treatment.

- In the process of actively reporting any adverse reactions to their medicines, the patient/consumer learns how to manage his/her medicines and to communicate more effectively with and better provide critical information to their health professionals

The National Pharmacovigilance Centre is working with the Pharmaceutical Society of Ghana through the Community Pharmacy Practice Association (CPPA) to promote Patient Reporting by using and designating Community Pharmacies as "Patient Safety Centres". The FDA would therefore like to appeal to all healthcare professionals to support this initiative to improve on the safety of marketed drugs, herbal products and vaccines.

> ***Starting in 2015, the FDA will fully implement patient reporting and it is hoped this will increase the adverse drug reaction reporting rate and contribute to the generation of signals and early detection of safety problems with medicines on the Ghanaian market.***

IN THIS ISSUE

References

1. Bhuvan K.C. et. al, (2013), Do community pharmacists in Nepal have a role in adverse drug reaction reporting systems? Australasian Medical Journal, 6, 2, 100-103

2. Roberto L. et. al, (2013), Effect of Pharmacist Involvement on Patient Reporting of Adverse Drug Reactions: First Italian Study, Drug Safety, 36:267–276

REPORTS RECEIVED BY THE FDA THROUGH THE BLUEFORM

The National Pharmacovigilance Centre received a total of four hundred and thirty six (436) spontaneous reports in 2014. Of the ADR and AEFI reports received 277 (67.7%) were experienced by females whereas 135 (31.6%) were experienced by males. The 15 most commonly reported drugs that led to ADRs are shown in Figure 1.

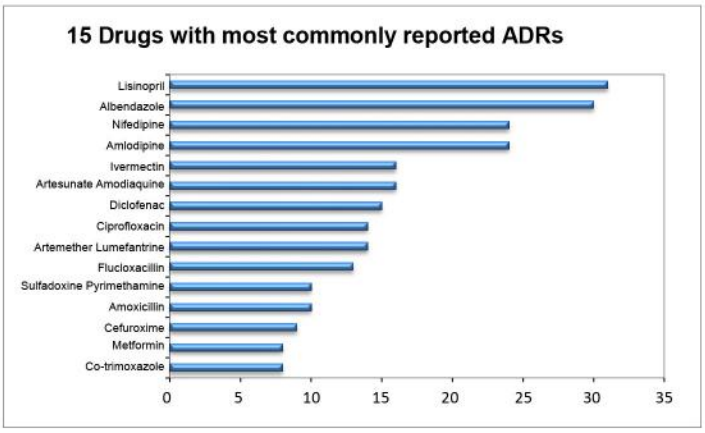


Figure 1: 15 Drugs with Most Commonly Reported ADRs

Figure 2 shows spontaneous reports received from different categories of healthcare professionals, pharmacists, doctors and nurses contributed 64.4%, 18.6% and 8.9% respectively.

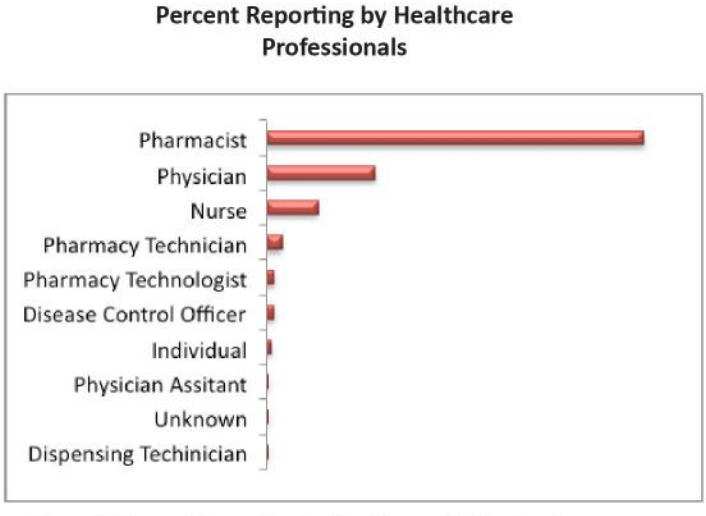


Figure 2: Percent Reporting by Healthcare Professionals

The reports were received from 87 different facilities from all 10 regions and Komfo Anokye Teaching Hospital contributed (81) 18.6% of the reports received. Table 1 represents the top fifteen facilities that submitted reports to the National Pharmacovigilance Centre in 2014.

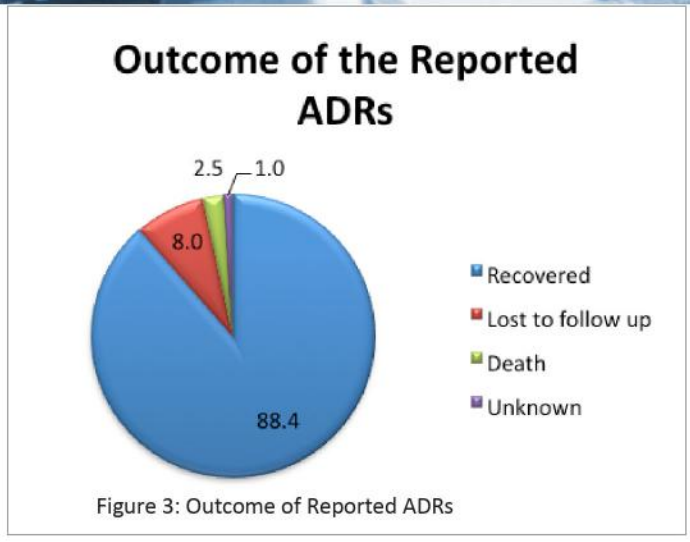


Figure 3: Outcome of Reported ADRs

Health Facility	Frequency	Percent
Komfo Anokye Teaching Hospital	81	18.6
Bolga Regional Hospital	33	7.6
Achimota Hospital	32	7.3
Nadowli District Hospital	23	5.3
Maamobi General Hospital	21	4.8
Ridge Regional Hospital	16	3.7
Sunyani Regional Hospital	14	3.2
St. Dominic Hospital	12	2.8
Volta Regional Hospital	11	2.5
Sunyani Municipal Hospital	10	2.3
Ga South Municipal Hospital	9	2.1
Korle Bu Teaching Hospital	8	1.8
Police Hospital	7	1.6
Nsawam Gov't Hospital	6	1.4
Maple Leaf Pharmacy	6	1.4
Tema General Hospital	5	1.1
Asesewa Gov't Hospital	5	1.1
Lekma Polyclinic	5	1.1

Table 1: The top 15 Reporting Health Facilities

GHANA FDA DESIGNATED REGIONAL CENTRE OF REGULATORY EXCELLENCE (RCORE)

The Food and Drugs Authority has been designated by the New Partnership for African Development (NEPAD) and the African Regulatory Harmonization (AMRH) as a Regional Centre of Regulatory Excellence (RCORE) in two areas - Clinical Trials and Drug Registration.

The FDA is also a Regional Centre of Regulatory Excellence (RCORE) in Pharmacovigilance as part of a consortium with the World Health Organisation Collaborating Centre (WHO-CC) for Advocacy and Training in Pharmacovigilance.

This designation means that the FDA with its collaborators, the faculty of Pharmacy and Pharmaceutical Sciences, Kwame Nkrumah University of Science and Technology (KNUST) and the School of Public Health, University of Ghana Medical School (SPH UGMS) will be earmarked to provide formal training and capacity building courses and offer fellowship programmes to other regulatory authorities in Africa.

AIFA—UNICRI—FDA TRAINING COURSE ON GOOD CLINICAL PRACTICE INSPECTIONS

To promote the vision of the Food and Drugs Authority Clinical Trials conducted should be in compliance with international standards by ensuring compliance to Good Clinical Practice standards, the Authority in collaboration with United Nations Interregional Crime and Justice Research Institute (UNICRI) and the Italian Medicines Agency (AIFA) delivered a capacity building training course for 28 Regulatory Officers of the Food and Drugs Authority to undertake activities relating to Good Clinical Practice (GCP) Inspections in July, 2014 in Accra .

The training was facilitated by the following persons from the collaborating institutions, namely, Angela Del Vecchio, Umberto Filibeck, Fabrizio Gallicia and Anna Maria Lepore.

The training was aimed at enhancing appropriate application of international standards in the evaluation and monitoring of clinical trials in Ghana and also equip Regulatory Officers of the FDA with the necessary knowledge and skills required to ensure the application of ethical principles and good clinical practices in biomedical research conducted locally.

Ag. DCE, Safety Monitoring & Clinical Trials Division (middle) and Staff of Clinical Trials with Facilitators

A section of participants

ENSURING PATIENT SAFETY IN THE UPPER EAST REGION

Mr. Abdul Razak Issifu

Mr. Abdul Razak Al-Abdneger-Issifu, Head of Pharmacy Department at the Bolgatanga Regional Hospital and holds an MSc in Clinical Trials from the School of Public Health, University of Ghana. He has special interest in pharmacovigilance and patient safety and has worked tirelessly to promote this cause at his hospital.

Mr. Al-Abdneger-Issifu led the team of health workers at the Bolgatanga Regional Hospital to contribute the maximum number of adverse drug reaction reports to the National Database in 2013. He also took other initiatives at the Bolgatanga Hospital including Heamovigilance (follow up and reporting unexpected or undesirable effects resulting from therapeutic use of blood products), medication errors and developing G6PD notification forms for clients.

He has the passion to work with other healthcare workers to impart knowledge and skills at all levels in the detection, management and reporting of adverse drug events.

The National Pharmacovigilance Centre is grateful for the passion and the initiatives Razak and all hardworking staff from the Bolgatanga Regional Hospital bring to patient safety issues.

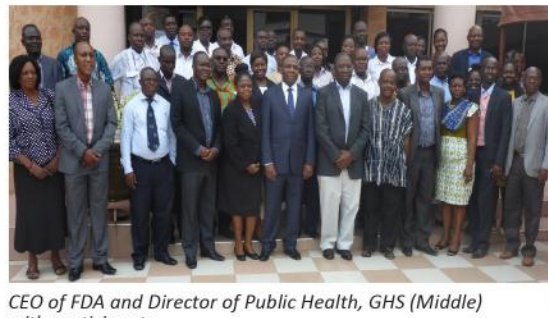
Ayeekoo!

VACCINE SAFETY TRAINING OF TRAINERS WORKSHOP

A three-day Vaccine Safety Training of Trainers Workshop was organized by the Food and Drugs Authority (FDA) in collaboration with the Expanded Program on Immunization (EPI) as a residential course for four Focal Persons from each of the 10 regions November 18-20, 2014 at the Forest Hotel, Dodowa. The four representatives from the regions included, the FDA Pharmacovigilance Officers, Regional EPI Focal Persons, Director of Public Health and Regional Clinicians. Participants at the training are expected to provide Vaccine Safety Training Programs for health staff involved in the Immunization Program at the lower levels (District and Sub-District) in their respective regions.

Upon completion of the training programs at the lower levels, staff involved in the immunization program should gain the necessary knowledge and skill to respond to and effectively manage vaccine-related safety issues and also ensure that Adverse Events Following Immunization (AEFI) that occur during immunization programs are detected, managed and reported in a timely manner to ensure public safety and continuous confidence in the immunization program.

The training workshop was sponsored by the UK Department for International Development (DFID) as part of the support for pharmacovigilance in Ghana.



CEO of FDA and Director of Public Health, GHS (Middle) with participants

COSMETIC PRODUCTS AND THE HAZARDS OF SKIN BLEACHING

(continued from issue 2)

Prolonged use of skin lightening products containing hydroquinone and steroids can result in any of the following:- hyperpigmentation (ochronosis) i.e. blue-black irreversible pigmentation, reversible brown discolouration, skin thinning (enabling skin cancer), corneal opacities upon contact with the eyes, stretch marks, poor wound healing, over-sweating and brittle bones.

Continuous application of hydroquinone and steroid-containing creams over a period of time also results in cutaneous complications on light-exposed skin of ochronosis (black pigmentation), nodules and milia (subepidermal keratin cyst) formation on the skin.

Bleaching agents commonly used are soaps and/or creams and lotions. There is a habit by individuals of either mixing one or more of the steroid products alone or in combination with skin lightening creams with the aim of enhancing a desired effect.

It is imperative that all stakeholders including government, manufacturers, importers, healthcare professionals, media and advertising agencies promulgate the regulation and enforcement of such products to ensure their appropriate use.

In addition consumers, importers and the general public are also reminded to report any adverse reactions experienced as a result of using skincare and skin lightening/bleaching products to healthcare institutions and the Food and Drugs Authority for appropriate regulatory measures to be taken to ensure public health and safety.

Continuous application of hydroquinone and steroid-containing creams over a period of time also results in cutaneous complications on light-exposed skin of ochronosis (black pigmentation), nodules and milia (subepidermal keratin cyst) formation on the Skin

CLINICAL TRIALS - Opportunities in Ghana

(continued from issue 2)

Owing to the many health challenges across the African continent, drug companies have made a commitment to improve healthcare across the continent. The clinical development strategies of these companies are intertwined with the improvement of healthcare. In the years ahead, it is expected that the drug market and medical device industries will greatly expand their clinical development presence in Africa.

Many major pharmaceutical manufacturers frequently overlook the African countries when sponsoring clinical studies. This may be due to the fact that in the past, political instability, cultural barriers, and poor infrastructure were stumbling blocks when companies considered sites for clinical studies. However with the recent advancements made by the various countries in the past decade, Africa particularly Ghana has become attractive once again. A wide range of expertise is now on offer to companies looking for cost-effective study sites and appropriate patient populations. Ghana now offers good regulation, ethics committees and suitable sites for the conduction of clinical trials.

The Food and Drugs Authority is the national agency mandated by Part 8; Sections 150-166 of the Public Health Act, of 2012, Act 851, to regulate clinical trials in Ghana. The Clinical Trials Department is the department responsible for carrying out this mandate and does this through authorisation and monitoring of the trials conducted. The law also establishes a Technical Advisory Committee for Clinical Trials, to provide the Authority with on-going and timely medical and scientific advice on current and emerging issues related to clinical trials. The FDA's activities have made the country a more desirable destination for clinical trials with over 40 protocols evaluated fully since November 2004 about 10 active trials

DFID-SPONSORS WORKSHOP FOR STAFF OF FDA

The FDA hosted a team of experts from the Vigilance and Risk Management of Medicines Division of the UK Medicines and Healthcare Products Regulatory Agency (MHRA) for a four-day Pharmacovigilance training workshop from July 28, 2014 to July 31, 2014 as part of the UK Department for International Development assistance to support drug safety in Ghana. Twenty-eight members of staff including Regional Pharmacovigilance Officers benefitted from this program.

The objectives of the workshop were to equip FDA staff with the skills to:

- *Evaluate Risk Management Plans submitted by Marketing Authorization Holders (MAHs) and propose additional risk minimization activities when necessary to protect public health and safety.*
- *Initiate Good Pharmacovigilance Inspection of MAHs sites or third parties*
- *Implement Patient/Consumer reporting to improve adverse drug reaction reporting rate. Participants expressed appreciation for the upgrade in knowledge and skills in areas of risk management plans, patient reporting and pharmacovigilance inspections.*

CEO of FDA showing appreciation to training facilitators from MHRA

FDA staff in training

References
1. Tsang, A.K.L (2010), Teething, teething pain and teething remedies, International Dentistry - Australasian Edition Vol. 5, No. 4
2. http://www.fda.gov/Drugs/DrugSafety/ucm402240.htm
3.http://www.fda.gov/ForConsumers/ConsumerUpdates /ucm385817.htm

ORAL ANAESTHETIC GELS FOR TEETHING PAIN MAY CAUSE HARM TO BABIES

Teething pain, sometimes referred to as "dentitio difficilis" is the commonest symptom associated with the eruption of the primary dentition. There are pharmacological and non-pharmacological strategies for managing teething pain in babies.

The US Food and Drug Administration (FDA) has warned that prescription drugs such as viscous 2% Lidocaine gel is not safe for treating teething pain in infants or young children, and may be harmful to some children who used these products.

The US FDA also advised that topical pain relievers and medications that are rubbed on the gums are not necessary or even useful because they wash out of the baby's mouth within minutes.

When too much viscous lidocaine is given to infants and young children or they accidentally swallow too much, it can result in seizures, severe brain injury, and problems with the heart.

The US FDA has therefore recommended the following for parents/care givers for treating teething pains:

- *Use a teething ring chilled in the refrigerator (not frozen).*
- *Gently rub or massage the child's gums with your finger to relieve the symptoms.*

Local Situation

The FDA's Technical Advisory Committee for Safety however recommended that this product has been used in Ghana for a number of years without any identified safety concerns. The Committee also noted that the strength of Lidocaine (2%) contained in the products referred to by the US FDA is almost ten times what is registered for use in Ghana (0.33%). The Committee, therefore, advised that healthcare professionals should advise parents and caregivers to use non-pharmacological remedies recommended by the US FDA in managing teething pain in infants and children.

> ***When too much viscous lidocaine is given to infants and young children or they accidentally swallow too much, it can result in seizures, severe brain injury, and problems with the heart.***

References
*1 .http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Domperi done_31/Recommendation_provided_by_Pharmacovigilance_Risk_*

2. http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON418518

DOMPERIDONE AND THE RISK OF CARDIAC SIDE EFFECTS

The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) has concluded that domperidone is associated with a small increased risk of serious cardiac side effects. The indication is now restricted to the relief of nausea and vomiting and the dosage and duration of use have been reduced. It is also no longer recommended for the treatment of bloating and heartburn.

Domperidone is a dopamine antagonist taken orally or as rectal suppository for the short term treatment of nausea and vomiting.

The Pharmacovigilance Risk Assessment Committee (PRAC) therefore recommended the following:

• Domperidone should only be used for the management of symptoms of nausea and vomiting for not more than one week. It is no longer recommended for the treatment of other conditions such as bloating or heartburn.

• The recommended dose is now 10 mg up to three times daily by mouth or as suppositories at a dose of 30 mg twice daily in adolescents and adults weighing 35 kg or more.

• The dosage for children and adolescents weighing less than 35 kg is 0.25 mg per kg bodyweight up to three times daily given by mouth. Graduated measuring devices should be included in liquid formulations to allow accurate dosing by bodyweight.

• It is contraindicated in patients:
  - o With conditions where cardiac conduction is, or could be, impaired
  - o With underlying cardiac diseases such as congestive heart failure
  - o Receiving other medications known to prolong QT interval or potent CYP3A4 inhibitors
  - o With severe hepatic impairment

• Patients with these conditions should have their treatment reviewed at their routine appointment and be switched to an alternative treatment if required

• Products supplied at a dose of 20 mg by mouth, and 10 or 60mg suppositories are no longer recommended for use and should be withdrawn.

Brands of domperidone registered in Ghana are Motilium (tablets 10mg and syrup 1mg/ml) and Emex (tablets 10mg.)

Local Situation

The information from EMA and other safety literature available was presented to the Technical Advisory Committee for Safety. The Committee agreed that recommendations made by PRAC, should be implemented in Ghana and also recommended that since domperidone is currently registered in Ghana as a prescription-only-medicine, this should be strictly adhered to by all healthcare professionals.

3. https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102155

GHANA'S NATIONAL CENTRE FOR PHARMACOVIGILANCE WINS A PRIZE

The National Centre for Pharmacovigilance has won the Third Poster Prize for a poster presentation titled "The Value of Patient Reporting in Signal Generation." The poster was presented as a joint effort between the FDA and EPI during the 14th International Society of Pharmacovigilance (ISoP) Meeting held in Tiajin, China from October, 19-22, 2014 on the theme of "New Ideas in Ancient Cultures: Advancing Pharmacovigilance in Asia". The prize includes a certificate, a plaque and an unlimited access to one Addis Journal of choice. This achievement is the second to be awarded by ISoP to the National Centre, the first was in November 6, 2010 when a poster presented titled "The Role of Spontaneous Reporting in the Identification of Substandard Medicines; The Case with Diazepam Injection" also won the Third Poster Prize.

The Abstract published in Drug Saf (2014) 37:831-891 is reproduced below;

THE VALUE OF PATIENT REPORTING IN SIGNAL GENERATION

BACKGROUND: Although available literature highlights the usefulness of patient reporting, there is limited information on specific signals generated from spontaneous reports received from patients[1,2]. In 2013, Ghana conducted a mass Measles-Rubella (MR) vaccination exercise, targeting 9 months to 14 year old children, as part of strategies to eliminate measles and Congenital Rubella Syndrome (CRS)[3]. All 11,062,605 vaccinees were placed under vaccinovigilance. Vaccinees and caregivers were encouraged to report Adverse Events Following Immunization (AEFI) directly to the National Pharmacovigilance Centre via phone.

OBJECTIVE: To identify specific signals generated from spontaneous adverse events reports from patients.

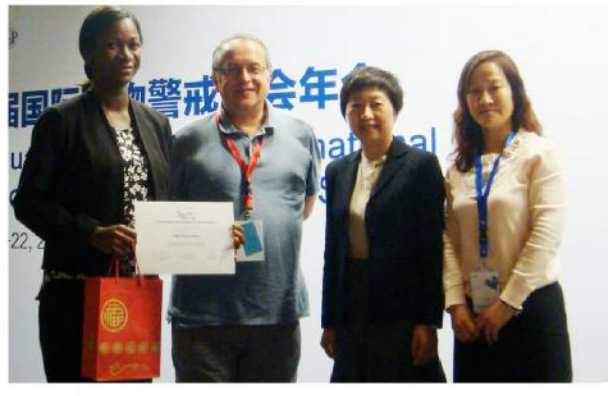
METHODS: The routine spontaneous AEFI reporting system in Ghana was used to report AEFI during and 28 days after the campaign covering the period from September 11 to October 18, 2013. Healthcare professionals and vaccinees or their care givers were encouraged to report any AEFI using a standard form or through telephone calls to the National Centre.

Potential vaccinees were educated on AEFI reporting through media campaigns.and were provided with appropriate phone numbers on their vaccination cards.

RESULTS: A total of 2,677 AEFI reports were received during the 36 day-reporting period. Of these, 1,972 (91.8%) were received from healthcare professionals and the remaining 705 (8.2%) originated from vaccinees. The topmost reported AEFI by vaccinees was "double vaccination", (219) at a rate of 19.8 (95% CI 17.0, 22.3) per 1,000,000 vaccinated compared to 12 reports of "double vaccination" by healthcare professionals at a rate of 1.10 (95% CI 0.6, 1.9) per 1,000,000 vaccinated. On the contrary, healthcare professionals reported local reactions as the topmost events (785 cases) at a rate of 71.0 (95% CI 66.1, 76.1) per 1,000,000 vaccinated.

To protect vaccinees from further programmatic errors, The National Pharmacovigilance Centre in collaboration with the Expanded Programme on Immunization sent an alert via telephone and e-mail messages to vaccinators through designated district and regional health officers. This resulted in over 90% decrease in the incidence of "double vaccination" reports received from patients.

CONCLUSIONS: Patient reporting can contribute significantly to signals for events that may not be reported by healthcare professionals, especially, medication and programme-related errors.



A Staff of Safety Monitoring Department proudly displaying Ghana's prize

References
1. Avery AJ, et, al. (2011), Evaluation of patient reporting of adverse drug reactions to the UK 'Yellow Card Scheme': literature review, descriptive and qualitative analyses, and questionnaire survey, Health Technology Assess Journal, 15 (20):1-234.

2. Durrieu G, et, al. (2012), First French Experience of ADR Reporting by Patients After a Mass Immunization Campaign with Influenza A (H1N1) Pandemic Vaccines: A Comparison of Reports Submitted by Patients and Healthcare Professionals, Drug Safety, 35 (10): 845-854
http://www.ghanahealthservice.org/includes/upload/publications/GHS%202011%20Annual%20Report%20Final%2014-8-12.pdfm, Assessed on May 20, 2014

3. Weekly Epidemiological Record, No. 29, 2011, 86, 301–31

GHANA SHARES BEST PRACTICES WITH THEIR COUNTERPARTS FROM OTHER NATIONAL REGULATORY AUTHORITIES

As part of the Pharmacovigilance Fellowship Program organized by the WHO Collaboration Centre for Advocacy and Training in Pharmacovigilance, a 15 member team paid a one-day working visit to the National Pharmacovigilance Centre on September 25, 2014 to learn first-hand what works well in Ghana's pharmacovigilance system. The visiting team was taken through the safety monitoring system in Ghana, processing of Individual Case Safety Reports (ICSRs), systems for signal generation and intervention by the National Centre to improve reporting rate for adverse drug reactions.

The visitors were impressed with medicine monitoring system in Ghana - Dominique from Mozambique could not have said it better than "Ghana FDA is good experience for any country"

Safety Monitoring Team with counterparts from other African National Regulatory Authorities

SAFETY ISSUES OF CURRENT INTEREST

Aceclofenac: updated cardiovascular advice in line with Diclofenac and COX-2 inhibitors [1]

The UK Medicines and Healthcare Products Regulatory Agency (MHRA) has advised in its January 2015 edition of Drug Safety Update (DSU) that Aceclofenac is now contraindicated in patients with established cardiovascular diseases (CVDs) in line with other Non-steroidal Anti-inflammatory Drugs (NSAIDs) like diclofenac and COX-2 inhibitors.

Aceclofenac is therefore contraindicated in patients with ischaemic heart disease, peripheral vascular disease, cerebrovascular disease or NYHA class II-IV congestive heart failure. These patients should therefore be switched to another drug by their prescribers.

Also patients with diabetes mellitus, hyperlipidaemia or hypertension, or who are smokers, should only be considered for aceclofenac therapy after careful consideration of risk factors for CVDs.

Aceclofenac exhibits its pharmacological activity through its active metabolites diclofenac and 4-hydroxy diclofenac and structurally similar to diclofenac which is associated with arterial thrombotic events (myocardial infarction; stroke).[2]

Medicines related to valproate: risk of abnormal pregnancy outcomes[3]

The British medicines regulator, the MHRA has recommended that Valproate should not be prescribed to female patients unless other treatments are ineffective or not tolerated. It has advised that valproate should be used in women who can become pregnant unless other treatments are ineffective or not tolerated. Women of child-bearing potential for which valproate is prescribed should use effective contraception and treatment should be started and supervised by a doctor experienced in treating these conditions.

An updated guidance has been issued on the use of valproate in women with epilepsy or bipolar disorder, after a Europe-wide review found that children exposed to the drug in the womb are at high risk of serious developmental disorders including autism (in up to 30–40% of cases) and/or congenital malformations (in approximately 10% of cases).[4,5]

The review also showed that children exposed to valproate in the womb may be more likely to develop symptoms of attention deficit hyperactivity disorder (ADHD).[5]

References

1. https://www.gov.uk/drug-safety-update/aceclofenac-preservex-updated-cardiovascular-advice-in-line-with-diclofenac-and-cox-2-inhibitors

2. http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2013/06/WC500144451.pdf

3. https://www.gov.uk/drug-safety-update/medicines-related-to-valproate-risk-of-abnormal-pregnancy-outcomes

4. http://www.nice.org.uk/guidance/cg192/resources/guidance-ante-natal-and-postnatal-mental-health-clinical-management-and-service-guidance-pdf

5. http://www.ema.europa.eu/docs/en_GB/document_library/Press_rel

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

Report may be submitted by 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

FDA Regional Offices:

Kumasi
P. O. Box ST 402, Kumasi
Tel: 03220 36070
Fax: 03220 36027
Location: Regional Coordinating Council (RCC)
Danyame, Kumasi

Sunyani
Private Mail Bag,
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Fax: 03520 28790
Location: Sam Bennet Building
Central Market Area

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Tel/Fax: 0312027558
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Room 309, near Central Police Station

Wa
P. O. Box 291, Upper West Region
Tel: 0392020111
Tel/Fax: 0392020001
Location: Controller Block, Ministries

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Name (optional): .....

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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

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