DrugLens NEWSLETTER

DRUGLENS ISSUE 2 | JANUARY 2014

CEO's MESSAGE
Mr. Hudu Mogtari

I am pleased to introduce the second edition of the DrugLens and to wish our readers a Happy and Prosperous New Year.

As the Chief Executive of the Food and Drugs Authority, my vision for 2014 is to firstly focus on capacity building for pharmaceutical industry to comply with the new requirements in the Public Health Act and secondly, public education to promote adverse drug reaction reporting by patients in order to improve the reporting rate. These will further enhance the detection of substandard and counterfeit medicines thereby ensuring patient safety.

The Food and Drugs Authority will continue to protect and promote the health of every Ghanaian by capacity building to meet the new and expanding roles of the Authority to fully implement the Public Health Act, Act 851 2012.

Once again I wish you a Happy and Prosperous New Year.

In this issue...

Editor's Note...

Counterfeit Medicines:

The Role of Healthcare Professionals in Ensuring Patient Safety

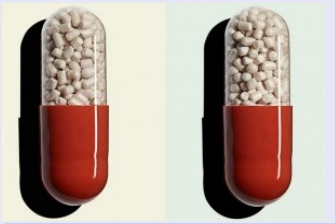
The increase in the incidence of Counterfeit medicines globally, now referred to as Substandard, Spurious, Falsely–labeled, Falsified, Counterfeit (SSFFC) medicinal products poses a danger to public health and may negatively affect the achievement of health-related Millennium Development Goals (MDGs). There is therefore the need for increased efforts from all stakeholders especially healthcare professionals in the identification of SSFFCs. The threat posed by importation and marketing of counterfeit and unregistered medicines has become a global challenge and regulatory authorities worldwide, including the Food and Drugs Authority are working to combat this menace. In order to ensure product quality issues identified at the hospital are reported, the FDA's **Blue Form** has been designed to capture information on suspected SSFFC medicinal products. Important information that must be provided when reporting on the FDA's Blue Form in addition to product name (brand and generic) are batch numbers, manufacturer's details and product source. The FDA continues to educate healthcare professionals on how they can use the **Blue Form** to report all drug related problems.

No country is isolated when it comes to drug counterfeiting and marketing of unregistered medicines. The press release by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) in June 2013 about record seizure of counterfeit and unregistered medicines in the United Kingdom worth £12.2 million attests to this fact[1].

Secondly, the press release by the US Food and Drugs Administration on September 16, 2013, prohibiting the sale of medicines manufactured by Ranbaxy from its Mohali facility in India which was **previously marketed** in the USA strengthens the need for continuous monitoring of registered products. The prohibition will be in place until the company complies with Good Manufacturing medicines regulation.

Finally, the findings of "Operation Biyela" organized by the World Customs Organization (WCO) and the Institute of Research Against Counterfeit Medicines (IRACM) revealed the incidence of counterfeit and dangerous medicines in African countries[3].

During the Operation, 550 million doses of illicit, potentially dangerous if not deadly medicines were intercepted including: antibiotics, analgesics, anti-inflammatory drugs, medicines for high blood pressure and diabetes and food supplements. The total value of the medicines collected was estimated at more than $275 million US Dollars[3].



Which of these is counterfeit?

The Democratic Republic of Congo and Togo were mentioned as countries where the most significant discoveries were made in terms of volume[3]; this finding is worrying because Ghana shares about 877km land borders with Togo and the illicit medicines could easily find their way into Ghana.

Many SSFFC medicinal products are identified through suspected lack of efficacy or therapeutic failure reports received from healthcare professionals and their role in the identification of SSFFCs cannot be overemphasized. The FDA is committed to ensuring that medicines on the Ghanaian market are safe, efficacious and of good quality. Let's all work together to ensure better drug safety in Ghana!

[1] www.mhra.gov.ukNewsCentre/Press releases/CON287024
[2] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm368445.htm
[3] http://online.wsj.com/article/PR-CO-20130613-908669.html

A Doctor's Commitment to Patient Safety

Dr. Natalya Brightson

In this edition of *DrugLens* we feature Dr. Natalya Brightson, a physician specialist at the Achimota Hospital. Dr. Brightson has the passion for pharmacovigilance and patient safety and has contributed more reports to the National Database than any other doctor in the country.

She encourages other doctors to contribute to the FDA's pharmacovigilance programme because this is the only way to identify safety problems with drugs and prevent other patients from suffering from negative consequences of drugs. Her experiences have so far been fulfilling though she admits that on some occasions it has been a challenge completing the "Blue Form" due to her busy schedule. In such instances, other professionals on her team are always ready to help.

Reports Received by the FDA through the Blue Form

The National Pharmacovigilance Centre received two hundred and sixty (260) reports of suspected Adverse Drug Reactions (ADRs) during the first 9 months of 2013 (January 2013-September 2013). Of the reports received, 179 (68.9%) were experienced by females whereas the rest (31.1%) were by males. The 15 drugs with most commonly reported Adverse Drug Reactions are shown in Figure 1.

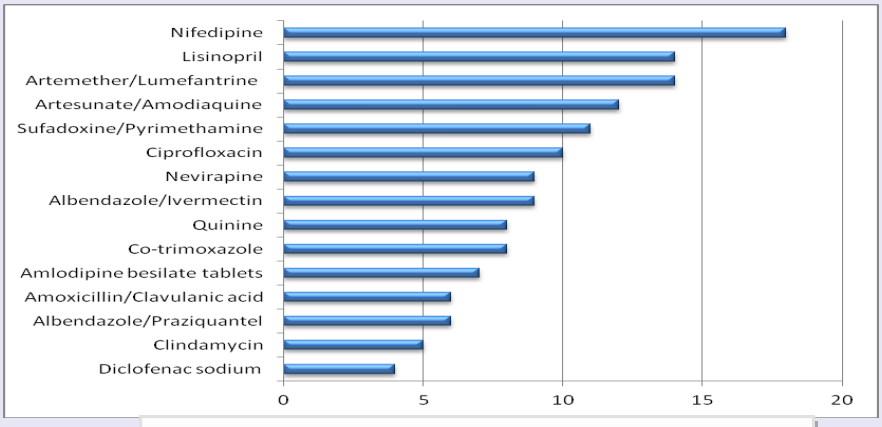


Figure 1: 15 Drugs with Most Commonly Reported ADRs

Figure 2 shows spontaneous reports received from different categories of healthcare professionals. Pharmacists, doctors and nurses contributed 56.9%, 16.9% and 8.8% of the reports received respectively. Physician assistants contributed 8.1% of the reports to the National database during the reporting period.

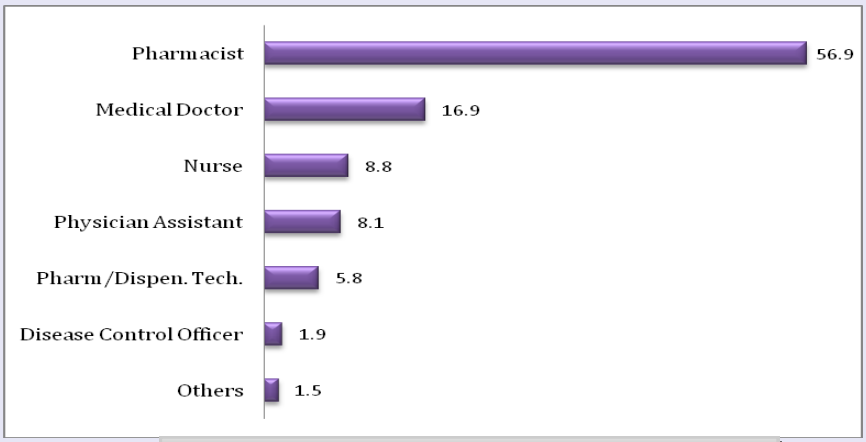


Figure 2: Percent Reporting by Healthcare Professionals

The reports were received from 78 different facilities from nine of the ten regions; no spontaneous report was received from the Northern Region from January-September 2013. Bolgatanga Regional Hospital contributed 44 (17.0%) of the reports and we are grateful to Pharm. Abdul Razak AL-Abdneger-Issifu and his team for ensuring that the safety of medicines given to patients at the Bolga Regional Hospital are monitored.

Table 1 represents the top twenty facilities that submitted reports to the National Pharmacovigilance Centre in 2013. It is worth noting the commitment of some private facilities including St. Martins Catholic Hospital, Agroyesum; Sape Agbo Memorial Hospital, Aflao and Samartex Hospital, Samreboi for ensuring medicine safety. The Food and Drugs Authority is grateful to all these facilities and others not mentioned here for contributing their knowledge to patient safety. Reports were classified into the System Organ Class (SOC) using the Medical Dictionary for Regulatory Activities (MedDRA). Skin and subcutaneous tissue disorders were the most commonly reported adverse reactions, with blood and lymphatic system disorders being the least.

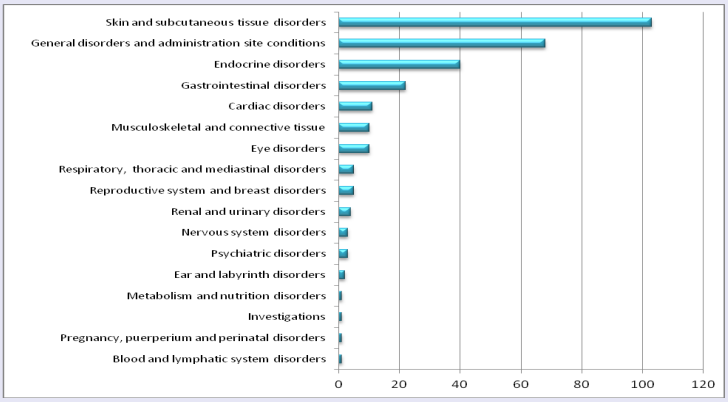


Figure 3: SOC classification of the ADRs using MedDRA

As shown in Figure 4, 1% of the suspected reactions had fatal outcomes and 88% of those who had reactions fully recovered

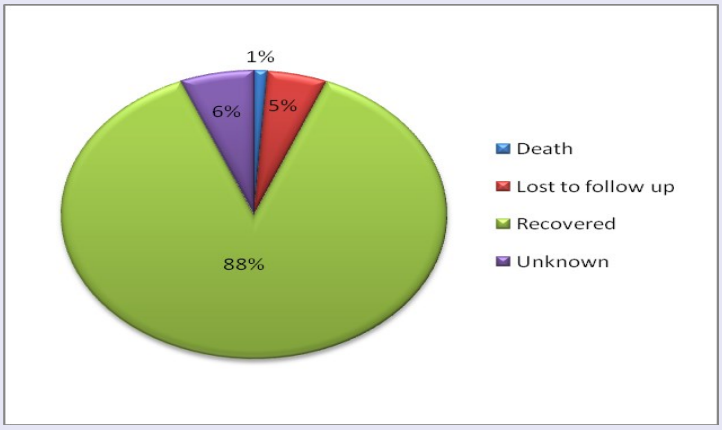


Figure 4: Outcome of the Reported ADRs

[2]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm368445.htm
[3]http://online.wsj.com/article/PR-CO-20130613-908669.html
[4]The Lancet, (May 2013), http://dx.doi.org/10.1016/S0140-6736(13)60900-9
[5]http://www.bbc.co.uk/news/health-22694858

Health Facility	Frequency	Percent
Bolga Regional Hospital, Bolga	44	17.0
Komfo Anokye Teaching Hospital	24	9.3
Achimota Hospital, Achimota	21	8.1
Volta River Authority Hospital, Akosombo	16	6.2
Ridge Hospital, Accra	10	3.9
Korle Bu Teaching Hospital, Accra	8	3.1
Comboni Hospital, Sogakope	7	2.7
Effia Nkwanta Regional Hospital, Sekondi	5	1.9
University Hospital, Cape Coast	5	1.9
Kwahu Gov't Hospital, Atibie	5	1.9
Sunyani Regional Hospital, Sunyani	5	1.9
37 Military Hospital, Accra	4	1.5
Kadjebi Health Centre, Kadjebi	4	1.5
Mamprobi Polyclinic, Accra	4	1.5
Sogakope District Hospital, Sogakope	4	1.5
Old Ningo Health Centre, Old Ningo	4	1.5
Aninwah Medical Centre,	3	1.2
District Hospital, Begoro	3	1.2
GPHA Clinic, Tema	3	1.2
Holy Family Hospital	3	1.2
Kintampo Municipal Hospital, Kintampo	3	1.2
Nadowli District Hospital, Nadowli	3	1.2
Tema General Hospital, Tema	3	1.2
Bekwai Municipal Hospital, Bekwai	2	0.8
Bolga Municipal Health Directorate, Bolga	2	0.8
Central Aflao Hospital, Aflao	2	0.8
Ho Municipal Hospital, Ho	2	0.8
Keta Municipal Hospital, Keta	2	0.8
Mary Theresa Hospital, Dode Papase	2	0.8
Obuasi Gov't Hospital, Obuasi	2	0.8
Osudoku Health Centre, Osudoku	2	0.8
Sherigu Health Centre, Sherigu	2	0.8
St. Anthony Hospital, Dzodze	2	0.8
Tepa District Hospital, Tepa	2	0.8
University Hospital, Legon	2	0.8
Ussher Polyclinic, Accra	2	0.8
Volta Regional Hospital, Ho	2	0.8
War Memorial Hospital, Navrongo	2	0.8
Others	38	14.7

Table 1: The Top 20 Reporting Healthcare Facilities

Safety Issues of Current Interest

NSAIDs and Cardiovascular Events

'The research showed that for every 1,000 people taking the drugs there would be three additional heart attacks, four more cases of heart failure and one death as well as cases of stomach bleeding every year as a result of taking the drugs.'

Non-steroidal anti-inflammatory drugs (NSAIDs) are among the most widely used drugs in the world. They are chiefly used to treat pain, but their long-term use is limited by serious gastrointestinal and cardiovascular adverse effects. Some of these effects are well known, however, in May 30, 2013, the Lancet[4] published an article titled :

"Vascular and upper gastrointestinal effects of non-steroidal anti-inflammatory drugs: meta-analyses of individual participant data from randomised trials[2]".

The main outcomes of this study were major vascular events (non-fatal myocardial infarction, non-fatal stroke, or vascular death); major coronary events (non-fatal myocardial infarction or coronary death); stroke; mortality; heart failure; and upper gastrointestinal complications (perforation, obstruction, or bleed)[2]. The researchers from the University of Oxford investigated more than 353,000 patient records from 639 separate clinical trials to assess the impact of non-steroidal anti-inflammatory drugs[5]. They looked at high-dose prescriptions levels of Diclofenac and Ibuprofen, rather than over-the-counter pain relief, of 150mg Diclofenac or 2,400mg Ibuprofen each day.

The research showed that for every 1,000 people taking the drugs there would be three additional heart attacks, four more cases of heart failure and one death as well as cases of stomach bleeding every year as a result of taking the drugs[4].'The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) has concluded that the effects of the painkiller diclofenac on the heart and circulation when given systemically (by means such as capsules, tablets or injections) are similar to those of selective COX-2 inhibitors, another group of painkillers. The PRAC therefore recommended the same cardiovascular precautions for diclofenac as for selective COX-2 inhibitors[6].

[1]This report did not include those for vaccines; 16 AEFI reports were received through the spontaneous system in 2012
[2]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm368445.htm
[3]http://online.wsj.com/article/PR-CO-20130613-908669.html
[4]The Lancet, (May 2013), http://dx.doi.org/10.1016/S0140-6736(13)60900-9
[5]http://www.bbc.co.uk/news/health-22694858
[6]http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2013/06/WC500144451.pdf
[7]http://www.fda.gov/Drugs/DrugSafety/ucm362415.htm
[8]http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Ketoconazole-containing_medicines/WC500146616.pdf

The Local Situation

The National Pharmacovigilance Centre has not received any reports of cardiovascular events associated with the use of Diclofenac. The publication and decisions by other regulatory agencies were presented to the Technical Advisory Committee for Safety; the Committee recommended that a Dear Healthcare Professional letter should be distributed to communicate this information to health workers in Ghana as below to;

- Give the lowest effective dose and for the shortest period of time to minimize the risks of arterial thromboembolic events (blood clots in the arteries).
- Carefully consider patients with underlying medical conditions that will increase the risk of these events (hypertension, hyperlipidaemia, diabetes, ischaemic heart disease and smoking)
- Avoid Diclofenac in patients with serious underlying heart or circulatory conditions, such as heart failure, heart disease, circulatory problems or a previous heart attack or stroke.

Oral Ketoconazole

and the Risk of Severe Liver Injury, Adrenal Gland Problems and Harmful Drug Interactions

The European Medicines Agency (EMA) and the US FDA carried out a review of the use of oral Ketoconazole in July 2013 [7,8] due to the risk of severe liver injury, adrenal gland problems and harmful drug interactions. Whereas, the EMA has recommended suspension of marketing authorization for oral-ketoconazole containing products except for off label use in cushion's syndrome the US FDA has limited the use of the product.

In Ghana the Technical Advisory Committee on Safety recommended the following for healthcare professionals regarding this issue;

1. Oral Ketoconazole should be prescribed at the lowest recommended dose and for the shortest possible period of time.

2. Monitor patients on oral Ketoconazole for signs of liver injuries.

3. Report any suspected adverse drug reactions associated with the use of oral Ketoconazole to the Food and Drugs Authority using the "blue form"

4. Oral Ketoconazole is registered by the FDA as Prescription-Only-Medicine and this should be taken into account when dispensing this drug.

Codeine:
Restricted Use as an Analgesic in Children and Adolescents

The use of codeine as an analgesia in children and adolescents under 18 years has been restricted after review by the US Food and Drugs Administration (US FDA)[9] and European Medicine Agency (EMA)[10]. This is as a result of reported deaths which occurred in children with obstructive sleep apnea who were given codeine for pain relief after tonsillectomy and/or adenoidectomy.

Ghana's Technical Advisory Committee on Safety recommends the following with respect to the use of Codeine in children and adolescents;

- Use of Codeine is contraindicated in patients younger than 18 years of age for pain relief following tonsillectomy and/or adenoidectomy for Obstructive Sleep Apnoea Syndrome (OSAS) and in those known to be CYP2D6 ultra-rapid metabolisers.
- Codeine –containing medicines should only be used to treat acute moderate pain in children above 12 years of age, and only if it cannot be relieved by other pain killers such as paracetamol and ibuprofen.
- Cough medications containing codeine are no longer recommended for use in children less than 12 years of age.

Paracetamol Containing Products:
Technical Advisory Committee for Safety Requests for New Labeling Information

The Technical Advisory Committee for Safety has recommended a new product labeling for paracetamol-containing products.

The Committee's recommendation followed a similar review by the US FDA of its adverse event reporting system database and the medical literature to evaluate cases of serious skin reactions (Stevens - Johnson syndrome, toxic epidermal necrolysis and acute generalized exanthematous pustulosis) associated with paracetamol[11]. Four of such cases have been reported to the National Pharmacovigilance Centre and were taken into account by the committee in arriving at the recommendation.

In view of this the Food and Drugs Authority has informed manufacturers and Marketing Authorization Holders of paracetamol-containing products to include the likelihood of this serious adverse reactions in the product labels.

Safety Monitoring Activities

We promised to provide you with feedback regarding monitoring activities to ensure safety of medicines and vaccines used in Ghana.

Below are summaries of AEFI monitoring for Yellow Fever Phases I and II and MenAfriVac vaccination campaigns which were carried out in collaboration with the Expanded Programme on Immunization.

Yellow Fever

Yellow fever is an acute viral hemorrhagic disease transmitted by infected mosquitoes; up to 50% of severely affected persons without treatment will die from yellow fever. The virus is endemic in Africa and Latin America with 900 million people at risk. There is no treatment for yellow fever and vaccination is the most important preventive measure against the disease [12].

Ghana organized its yellow fever preventive campaign for a total of 7,021,342 persons above 10 years of age excluding pregnant women in November 2011 and September 2012 covering 58 districts involving all the regions in Ghana except Upper West Region.

Adverse Events Following Immunization (AEFI) monitoring was by the FDA in collaboration with the Expanded Programme on Immunization (EPI) to identify and manage any AEFI that may result from the vaccination campaign.

Of the 7,021,432 people vaccinated during the two phases a total of 1,067 AEFIs were reported giving the AEFI attack rate of 15.20 per 100,000 vaccinated. 47 cases were classified as serious by the reporters, of these 30 were reclassified by the NEC as non-serious. Causality Assessment was done for the 17 cases using the WHO Revised Classification for Causality Assessment[13]. This indicated a serious AEFI attack rate of 0.07 per 100,000 vaccinated; this rate is lower than serious AEFI attack rate of 0.1 – 0.3 per 100,000 doses or the average reported rate in other countries of <0.5 cases per 100,000 vaccine doses.

Only, 5 of the 17 serious cases were classified as vaccine product-related reaction.

[9] http://www.fda.gov/Drugs/DrugSafety/ucm339112.htm
[10] ttp://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2013/06/WC500144851.pdf
[11] http://www.fda.gov/Drugs/DrugSafety/ucm363041.htm
[12] WHO, Fact Sheet No. 100, May 2013
[13] http://www.who.int/vaccine_safety/publications/aevi_manual.pdf

MenAfriVac

The three northern regions of Ghana with 50 Districts lie within the "meningitis belt", with 4,500,000 people at risk of epidemics. The largest epidemics in 1996/1997 recorded 18,551 cases with a Case Fatality Rate (CFR) of 8 per cent[14]. The most recent outbreak occurred in February, 2012 with 36 cases and 6 deaths[15].

Meningitis is an inflammation of the meninges caused by *Neisseria meningitides.* There are 12 serogroups of this bacteria and serogroup A is responsible for about 80% -85% of all cases in Africa.

MenAfriVac is a new conjugate vaccine manufactured by Serum Institute of India Ltd in partnership with Meningitis Vaccine Project (MVP).

The vaccination campaign was for 10 days and AEFI monitoring was carried out during the campaign and 42 days after, between 9th October to 30th November, 2012. A total of 3,038,393 persons between 1-29 years were vaccinated with 621 AEFI cases reported (20.44 cases per 100,000 vaccinated). There were 52 serious cases with 3 reclassified by the National Expert Committee as non-serious. 32 of the serious cases were classified by NEC using the WHO Revised Classification for Causality Assessment[8] with 20 (62.5%) as Coincidental, 7 were unclassifiable, 4 were Indeterminate and 1 was classified as immunization error related. 17 of the cases from Tamale Central Metropolis were not classified because the cases were not accompanied by clinical documentation as requested by the Guidelines and Standard Operating Procedures.

Five most commonly reported AEFIs occurred within 7 days of vaccination and were fever/chills, gastro intestinal disorders, headache, injection site reactions and loss of appetite. The AEFI reporting rate was consistent with what was obtained during immunization campaigns carried out in other countries in Africa[16,17].

UK and Ghana Collaborate to Build Excellent Pharmacovigilance Systems

A three-member team from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) was on a three day official visit to the Safety Monitoring Department in June 2013 to help the Department finalize processes to develop an online E2B compliant data management system in Ghana. The system known as ***Safety-Watch*** will ensure that healthcare professionals and patients report adverse events directly to the FDA. The new system will improve data management, increase the reporting rate and ensure real-time reporting which will enable the Authority receive the reports in good time to take decisions that will help protect public health and safety.

Cosmetic Products and the Hazards of Skin Bleaching

Emmanuel Nkrumah

Cosmetic products have been one of the most adored companions of man from ancient civilization to date and have been used to enhance looks, promote attractiveness and confidence, alter and improve upon the condition of the body.

There is a perception in some societies that having a fair complexion imply beauty; and this has resulted in the ever-increasing patronage for skin lightening/bleaching products. Skin lightening/ bleaching products however are used to suppress pigmentation in order to lighten dark areas of the skin and treat pigmented spots such as melasma and freckles. A clinical study carried out at the Dermatology Outpatient Clinic of Korle-Bu Teaching Hospital, Accra suggested that the use of bleaching agents among Ghanaian men and women with dark skin was purely for aesthetics.[19] Skin bleaching has been reported in various parts of the world such as USA, Great Britain, Saudi Arabia, Kenya, South Africa, Zimbabwe etc.[18], and its has become a menace currently in most parts of Asia and Africa.

[14]Hodgson, A. et. al. (2001), Survival and sequelae of meningoccocal meningitis in Ghana, Int. Journal of Epidemiol. 30 (6)
[15]WHO_AFRO, Epidemic & Pandemic alert and Response (EPR), February, 2012.
[16]Ouaadaogo, et. al.,/Vaccine 30S (2012) B46-B51
[17]Chaibou, et. al., Vaccine 30 (2012) 5229-5234
[18]Addo H.A., A clinical study of hydroquinone reaction in skin bleaching in Ghana, Ghana Med J 1992; 26: 448
[19]Findlay G.H., Morrison J.G.L., Simson I.W. Exogenous ochronosis and pigmented colloid milium from hydroquinone bleaching creams. British J Dermatol 1975; 613

The use of bleaching face creams by blacks concurrently depends on a strange allurement of tradition, aesthetics, advertising, money and power.[18] Skin lightening/ bleaching agents particularly hydroquinone, kojic acid, arbutin, azelaic acid etc are effective inhibitors of melanogenesis in vitro and in vivo. The mechanism of the depigmenting action is the tyrosinase catalysed conversion of tyrosine to melanin. Continuous skin bleaching with hydroquinone and steroids leads to the loss of melanin thus a reduction in the natural photo-protection of the skin resulting in a cumulative effect of direct exposure of ultra violet radiation on the skin. Hence the high incidence of squamous cell carcinoma and other sun-related skin carcinomata in some individuals especially in the tropics[20].

Continuous skin bleaching with hydroquinone and steroids leads to the loss of melanin

Hydroquinone content of 2% is safer and has produced results equal to higher concentrations for a limited period. However there is an optimal point beyond which continued use of skin lightening products (2% or less hydroquinone) do not produce any resultant effect in melanin reduction.

Individuals with the urge to look fairer however use skin creams and lotions with hydroquinone content higher than 2%, and in some cases add other steroid creams (e.g. Clobetasol propionate based creams) to enhance the effect of these products. In some instances, toothpastes and perming creams have been used as skin bleaching products by people in countries where hydroquinone base creams as well as medicated steroids have been banned.

(to be *continued in next issue…*)

Clinical Trials In Ghana

Yvonne Adu -Boahen

More often than not, health research studies we hear about observe people or do not involve them at all. Clinical trials, however, are different in that, in this type of research, people volunteer to test new drugs, products or medical devices. A clinical trial is a scientific study of how a new medicine or treatment works in people. They are conducted in order to gain knowledge on the safety and efficacy of a new health intervention, mostly medications and devices. It normally compares one kind of treatment with another and may involve patients or healthy individuals or both. It is an effective way of determining what works and what does not. Clinical Trials are conducted in order to gain knowledge on the safety and efficacy of a new health intervention, mostly medications and devices. It normally compares one kind of treatment with another and may involve patients or healthy individuals or both. New medicines and treatments are tested on animals or in the laboratory and are found to be safe and effective but they must also be proven safe and effective in humans before they can be licensed and prescribed by doctors and even sold to the general public. Because clinical trials are conducted on humans, testing is only permitted if the person volunteers for participation and understands the risks and/or benefits associated with taking part in the study. This is referred to as informed consenting and the participant is at liberty to leave the study at any time.

Phase I trials aim to test the safety of a new medicine. There is an unavoidable element of risk in this phase because this will usually be the first time the drug has been tested on humans. Usually 20-80 people, who may be healthy volunteers, are given the medicine and researchers test for side effects and calculate what the right dose might be to use in treatment (known as dose-ranging studies). In order to minimise the risk, small doses are used initially and this is only increased if the participants do not experience any adverse events or experience only minor ones.

Phase II trials are conducted in a slightly larger number (100-300) people who suffer from the condition for which the medicine is intended to treat. This is to get an idea of the effectiveness of the drug.

"Clinical Trials are conducted in order to gain knowledge on the safety and efficacy of a new health intervention, mostly medications and devices. It normally compares one kind of treatment with another and may involve patients or healthy individuals or both".

Phase III trials are only conducted once the medicine has successfully passed the first two phases of the trial and may last for at least a year. In this phase, the test is conducted in a larger population (usually thousands) who suffer from the respective disease to see if the test medicine works better and has minimal safety issues as compared to current treatment options. After successful Phase III trials, a medicine maybe given approval for use in routine clinical practice i.e. registered or granted marketing authorization.

Phase IV trials take place after the drug has been given marketing authorisation. This is to continue studying the effectiveness and safety of the medicine. (*to be continued in next issue…)*

[20] Addo H.A., Squamous cell carcinoma associated with prolonged bleaching, Ghana Med J 2000; 34: 144

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 : drugsafety@fdaghana.gov.gh

In our attempt to improve on our information sharing on safety issues relating to medicines through our newsletter, *DrugLens*, we wish to collect your views on any edition of *DrugLens* you receive.

Name (optional): .....

Organization (optional): .....

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

1. Please, give details of how you intended to use the *DrugLens:*

.....

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

3. Any other comments: .....

.....

.....

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,
Tel: 03520 28791
Fax: 03520 28790
Location: Sam Bennet Building
Central Market Area

Bolgatanga
P.O. Box 612, Bolgatanga
Tel/Fax: 03820 23727
Location: Regional Administration Building, Bolgatanga

Cape Coast
P.O. Box CC1373
Cape– Coast
Tel: 03221 32300/0322 090110
Location: Within the premises of the Regional Administration, Cape Coast

Koforidua
P.O Box KF 2431, Koforidua
Tel: 03420 20580/1
Fax: 03420 205802
Location: Hospital Road, Opposite Assemblies of God Church

Tamale
P.O Box TL1763, Tamale
Tel/Fax: 03720 24889
Location: Regional Administration Building, Tamale

Ho
Private Mail Bag, Ho
Tel: 0362026659
Fax: 03620 28411
Location: GNA Building, Ho

Takoradi
P.O.Box MC2129, Takoradi
Tel/Fax: 03120 27558
Location: SSNIT Building Room 309, Near Central Police Station

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

Chief Editor
Mimi Delese Darko

Editor
George Sabblah

Contributors

Dr. Kwame Achiano
Adela Gwira
Abena A-Amoakohene
Nartekuor N-Amooh
Richard Osei Buabeng
Amma Antwi-Boasiako

Iverta Addo
Abena Yawson
Irene Frempong
Mr. James Lartey
Dinah Gogo

Design: Iverta Addo