

Review of results from the medicines quality monitoring program and discussions regarding enforcement actions with Food and Drug Board

**Accra, Ghana
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Trip Report

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About PQM

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID's response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical leadership to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States Government. It may be reproduced if credit is given to PQM and USP.

Abstract

Dr. Lukulay travelled to Accra, Ghana to review results of the recent round of medicine quality monitoring and to meet with Food and Drug Board (FDB) senior management to discuss possible enforcement actions based on results obtained. Three brands of counterfeit antimalarials were identified, as were several poor quality products produced by local manufacturers. The counterfeit products were mimics of Pfizer's Metakelfin, Guilin's artesunate tablet, and Biochemie's quinine sulfate tablets.

Dr. Lukulay also took the opportunity to meet with the architects involved with the design of the new FDB laboratory to discuss the lab design and its specifications regarding compliance with ISO 17025 requirements.

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Key Words

Ghana, Food and Drug Board, antimalarial, enforcement, medicine quality

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- Dr. Stephen Opuni, the FDB Chief Executive Officer, for making time to meet with me on several occasions during my visit.
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ACRONYMS

CCM	Country Coordinating Mechanism
CDC	U.S. Centers for Disease Control and Prevention
FDB	Food and Drug Board
GF	Global Fund
GMP	Good Manufacturing Practices
GPHF	Global Pharma Health Fund
PMI	President's Malaria Initiative
PQM	Promoting the Quality of Medicines Program
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Background

The Promoting the Quality of Medicines (PQM) Program first began supporting the Ghana Food and Drug Board (FDB) in 2005, and continued their support in 2008 with funding from the President's Malaria Initiative (PMI). PQM support focuses on providing technical assistance to the FDB to establish a functional post-marketing surveillance program throughout the country. This has involved training the central FDB staff, World Health Organization (WHO), and regional FDB office staff in medicine quality testing using Global Pharma Health Fund (GPHF) Minilabs[®]—portable, mini-laboratories contained in suitcases—and conducting confirmatory testing using pharmacopeial testing procedures.

Since 2008, PMI funds have been used to equip five sentinel sites with Minilabs[®], reagents and chemicals needed to conduct testing of antimalarials. The Minilabs[®] are housed at FDB regional offices and local staffs carry out sampling and conduct preliminary screening tests according to the protocol established by PQM. Confirmatory testing of failed or doubtful samples is done at the national laboratory in Accra. The sentinel sites have assisted the FDB carry out their regulatory functions in a timely manner, helping to promote medicine quality in Ghana. Due to a change from a centralized procurement system to a decentralized system, where hospitals handle their own procurement, there is increased risk of procuring poor quality products, as different institutions may follow different procurement guidelines.

The FDB laboratory has been conducting tests of medicines procured by Global Fund (GF). However, the new GF policy (July 2009) stipulates that testing must be done for all GF-procured products imported into a country and throughout the life cycle of the product, but only laboratories prequalified by WHO or ISO 17025 accredited can conduct testing. Because the FDB laboratory does not meet these conditions, it can no longer conduct testing of GF samples, and the medicines will be shipped abroad to a laboratory that is WHO prequalified or ISO 170025 accredited. The FDB has identified a laboratory in South Africa to conduct the testing. Testing GF samples abroad is lost revenue for the FDB laboratory.

Because the FDB lab stands not to benefit from funds that are earmarked for quality control tests, Dr. Lukulay urged the Malaria Control Program and GF Country Coordinating Mechanism (CCM) to make funds available to the FDB lab to sample and conduct screening tests of the samples collected in the field using Minilabs[®] prior to deciding which samples were to be shipped to an accredited laboratory for full confirmatory testing. This strategy has now allowed the FDB lab to receive some funds from GF while they work to get the laboratory accredited.

Purpose of Trip

- Review results of the medicine quality monitoring program
- Review blueprint of the new FDB laboratory and make final decisions about the structural, mechanical and electrical designs
- Meet with the FDB laboratory staff
- Review resumes for the PQM consultant position in Ghana
- Review workplan with CDC resident advisor

Source of Funding

These activities were funded by USAID/Ghana through PMI.

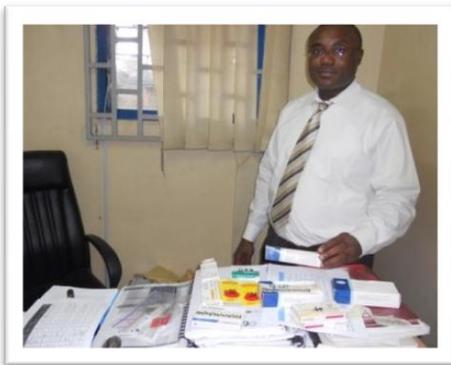
Overview of Activities

Review results of the medicines quality monitoring program

The main objective of the trip was to be in Ghana during the compilation of results of the medicines quality monitoring program in order to assist the FDB staff with interpretation of the results and to help present the data logically for easy comprehension. In reviewing the results the following decisions were made:

- In order to expedite enforcement actions, the lab staff was advised to first identify all products that were found to be counterfeit. Indications of which products were counterfeit were first seen in the results of the Minilab[®] testing where the identification tests show the absence of a spot on the TLC plates. Confirmatory testing subsequently revealed that there was no active ingredient and the inspection of the packaging material showed that the packaging was not genuine.
- Going forward, the lab will be advised to conduct confirmatory testing on products in order of severity of failure so that timely actions can be taken on counterfeits and products with very poor quality defects.

Results of the failed samples are shown in the Press Release attached as *Annex 1*.



Dr. Lukulay examines some of the counterfeit and substandard samples discovered by the medicine quality monitoring program

Meeting with the CEO of FDB

The Chief Executive Officer of FDB, Dr. Stephen Opuni, was notified of the results, and he asked for a summary of the products that had serious quality defects. The following actions were immediately taken:

- Representatives of manufacturers whose products were counterfeited were summoned to a meeting to inform them about the FDB findings
- Local manufacturers and importers whose products had serious quality defects were also summoned to a meeting and informed that their products will be recalled from the market
- A press release will be issued to warn the Ghanaian public about the counterfeits and poor quality products
- One of the manufacturers whose product was counterfeited (Pfizer) was also informed.

Meeting at the U.S. Embassy

Attendees: Dr. Paul Psychas, CDC resident advisor; Aaron Fishman, First Secretary, Regional Environment, Science & Technology Officer for West & Central Africa; Heather Byrnes, Senior

Commercial Officer, U.S. Embassy, Ghana; Gretchen Evans, Trade Specialist

Dr. Lukulay and Dr. Psychas met with staff from the U.S. embassy and briefed them about the findings from the recent round of post-marketing surveillance activities in Ghana. Dr. Lukulay showed samples of one of the fake antimalarials (Metakelfin) discovered during the surveillance. The product purported to be made by Pfizer and looked similar to the genuine product. Ms. Byrnes and her colleague discussed an important document that they have produced to educate U.S. businesses about intellectual property protection in Ghana to help them understand the business environment in the country. Dr. Lukulay indicated that PQM will continue to inform Ms. Byrnes's and Dr. Fishman's office about its findings in Ghana and will be open to collaboration. One potential area of collaboration is the inclusion of other types of medicines in the post-marketing surveillance program currently funded fully by PMI.

Dr. Psychas explained that the decentralized procurement system adopted in Ghana may have had an influence on the prevalence of counterfeit and substandard medicines and suggested a review of the system. He praised PQM's work and urged the rapid dissemination of the results to the malaria control program.

Meeting with the architects of the new FDB laboratory

Dr. Lukulay met with the local architects of the FDB lab and contacted Mr. Christian, a PQM lab design consultant, by telephone to discuss the final proposals for the lab. The architects discussed the modifications that they made in response to PQM's comments and will send the final drawings to Mr. Christian.



Dr. Lukulay and the lab staff in the current FDB laboratory

Conclusions

The post-marketing surveillance program has been effective in monitoring the quality of antimalarials in Ghana. Hundreds of samples have been collected and tested, which has resulted in regulatory enforcement action being taken by FDB management. This surveillance program has been the main mechanism by which the FDB assesses the quality of antimalarials on the Ghanaian market.

In view of the significance of this program, PQM has started discussions with FDB about sustainability. One proposal is for FDB to task importers and manufacturers with the responsibility to monitor the market place to assure that the quality of their products are not compromised. They could do this by periodically submitting samples for testing to externally accredited laboratories, or alternatively, they could provide funds to the FDB lab to conduct the testing. FDB would have the overall responsibility to do verification tests at random intervals.

The exposure of the Ghanaian population to substandard medicines is a threat to the efficacy of antimalarials. The poor Good Manufacturing Practices (GMP) compliance of local manufacturers and inadequate training in formulation development is leading to the local manufacture of substandard medicines. Providing technical assistance to FDB to build their capacity to conduct GMP training for manufacturers is needed in the near future. This assistance will help to improve the quality of antimalarials manufactured locally and hence avert the possible development of resistance to the key antimalarials in circulation.

Next Steps

PQM will:

- Work with FDB to disseminate the results of the post-market surveillance program to the Ministry of Health and the Malaria Control Program.
- Discuss with FDB ways to raise awareness of counterfeit and substandard medicines in Ghana
- Complete the hiring of the local consultant to follow up on PQM activities in Ghana

DR. STEPHEN K. OPUNI

FDB/ MIS.23/VOL. 1/10

4TH NOVEMBER, 2010

**THE NEWS EDITOR,
ACCRA.**

Dear Sir,

PRESS RELEASE – COUNTERFEIT & SUBSTANDARD ANTIMALARIAL MEDICINES

The Food and Drugs Board (FDB) wishes to bring to the attention of the general public the circulation of some counterfeit and substandard anti-malarial drugs on the Ghanaian Market.

The Food and Drugs Board (FDB) in its quest to safeguard the health of the consuming public, conducts periodic market surveillance on select samples of medicinal products on the Ghanaian market for quality monitoring.

Recently, samples of antimalarial drugs were picked from both public and private hospitals, retail pharmacies, licensed chemical shops and wholesale facilities across the country by officers in respective zonal offices of the Food and Drugs Board to determine their quality status.

Laboratory analyses conducted by the Food and Drugs Board with the support of United States Pharmacopoeia and USAID revealed that samples of the anti-malarial medicines tested were either counterfeits or substandard, therefore compromising their quality, safety and efficacy.

According to the WHO definition, “a counterfeit medicine is a medicine which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, without active ingredients, with insufficient active ingredients or with fake packaging”, whereas a substandard product is one found to be short of the required quality standards. Both counterfeits and substandard medicine are unfit for use.

The counterfeited antimalarial drugs with their respective batch numbers are provided below:

#	PRODUCT NAME	BATCH NUMBER	RETAIL SHOP SELLING PRODUCT
1.	METAKELFIN TABLETS	C827A	NAT & SONS PHARMACY, TARKWA
2.	METAKELFIN TABLETS	E378A	C. CRENTSIL PHARMACY, KUMASI
3.	METAKELFIN TABLETS	E378A	SUPERLITE PHARMACY, BOLGA

4.	METAKELFIN TABLETS	E378A	JODAMUS PHARMACY, KONONGO
5.	ARTESUNATE TABLETS	080504	KEKULE PHARMACY, TARKWA
6.	QUININE SULFATE	30551Q	SAPE AGBO MEMORIAL HOSPITAL, HO

The original manufacturers of Artesunate Tablets and Metakelfin Tablets are Guilin Pharmaceutical Company Limited, China, and Pharmacia & Upjohn under authority of Pfizer Inc., New York respectively.

Some unscrupulous people however managed to package these counterfeit anti-malarial medicines to look similar to the original ones.

Each of these two (2) counterfeited products was found to be without some essential identifying features characteristic of the true/authentic products, therefore confirming the laboratory findings.

However, the Food and Drugs Board has directed the Zonal Offices of the Food and Drugs Board to ensure the immediate removal of these counterfeit products from the retail shops involved and also from circulation.

The substandard medicines with their respective batch number are as follows:

#	PRODUCT NAME	BATCH NUMBER	SOURCE
1.	ARTILUM-140 TABLETS	RT923	IMPORTED
2.	RENOVATE TABLETS	MH932	IMPORTED
3.	MALMED TABLETS	M080218	IMPORTED
4.	MALMED TABLETS	M090034	IMPORTED
5.	CO-ARTESUN TABLETS	FS090301	IMPORTED
6.	ACUMAL JUNIOR POWDER FOR RECONSTITUTION	RA8001	IMPORTED
7.	TRAFAN TABLETS	0108J	LOCALLY MANUFACTURED
8.	TRAFAN TABLETS	03	LOCALLY MANUFACTURED
9.	TRAFAN TABLETS	26	LOCALLY MANUFACTURED
10.	TRAFAN TABLETS	24	LOCALLY MANUFACTURED
11.	TRAFAN TABLETS	02	LOCALLY MANUFACTURED

Additionally, the following substandard Chloroquine Injections, which have not been registered by the Food and Drugs Board, were also found on the market despite the fact that the use of Chloroquine as anti-malarial has been discontinued in Ghana since January 2005:

No.	PRODUCT NAME	BATCH NUMBER	SOURCE/ MANUFACTURER	RETAIL SHOP SELLING DRUG
12	CHLOROQUINE PHOSPHATE INJECTION	70901	NOT STATED	EXPERIENCE LICENSED CHEMICAL SHOP, BOLGA
13.	CHLOROQUIN INJECTION	70805	SINOPHARM, CHINA	PUBLIC SECTOR
14.	CHLOROQUIN INJECTION	O004125	YANZHOU XERKMJTAI PHARMA, CHINA	AGYENKWA LICENSED CHEMICAL SHOP, SECONDI
15.	CHLOROQUIN INJECTION	O71124	BEROVA	FRANCIS K. OCLOO LICENCED CHEMICAL SHOP, MANKESSIM
16.	CHLOROQUIN INJECTION B.P	70901	SINOPHARM & DEVAG GUILIN PHARMACEUTICALS LTD, CHINA	2F PHARMACY, KUMASI
17.	CHLOROQUIN INJECTION	80414	NOT STATED	RIJAY PHARMACY, KUMASI
18.	BEROVA CHLOROQUIN	071124	SISHUI XIERKANG PHARMACUETICAL CO LTD, CHINA	ST PETERS CLINIC, RTC, HO
19.	INJECTION CHLOROQUIN	O70905	SINNOCHEM NINGBO, CHINA	OBRA YE BONA LICENCED CHEMICAL SHOP, TARKWA
20.	ZOQUIT	O070913	JINLING PHARMA, CHINA	BRAKATU PHARMACY, TARKWA
21.	CHLOROQUIN INJECTION	O80412	BEROVA	GOODBRAND PHARMACY, TAKORADI
22.	BEROVA INJECTION	80412	SISHUI PHO XIERKANG PHARCUETICAL COMPANY LTD. CHINA	JODAMUS PHARMACY, KONONGO

The Food and Drugs Board has directed the recall of these substandard antimalarial medicines from circulation by the respective manufacturers and importers and submit a complete **product recall report** to the Food and Drugs Board ten (10) days from the day of this publication.

This practice of selling counterfeit or substandard medicines is in contravention of section 12 of the Food and Drugs Law, PNDC Law 305B and its subsequent amendment Act 523, 1996, which states that:

“Where a standard has been prescribed for any drug..., any person who labels, packages, sells or advertises any substance in such a manner that it is likely to be mistaken for that drug... Commits an offence....”

Additionally, section 18 of the Food and Drugs Law states categorically that;

“No person shall manufacture, prepare, sell, supply, export or import into Ghana any drug, cosmetic, medical device or household chemical unless the article has been registered with the Food and Drugs Board...”

The general public is therefore advised not to patronize the specified batches of the above mentioned products and to report anyone found offering them for sale to the nearest FDB office.

Furthermore, any Wholesaler, Pharmacy or Licensed Chemical Shop that has in stock these medicines (with the specified batch numbers) should immediately return them to the importer, distributor, manufacturer or to the Food and Drugs Board.

The Food and Drugs Board has authorized the respective companies to immediately withdraw the products from the market in order not to endanger public health and safety.

Meanwhile, the FDB is taking the necessary regulatory actions against the manufacturers/importers of these medicines.

Information from the general public on persons suspected to be in any practice possible of endangering public health and safety to FDB’s mandate is most welcomed through any of the following contact numbers; 0244337235, 0244337245 or 0244385086.

DR. STEPHEN K. OPUNI
CHIEF EXECUTIVE