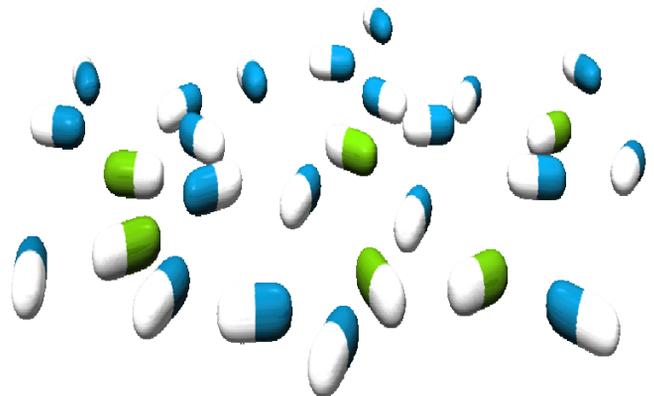


Improving Medicines Quality in Ghana through Routine GPHF-Minilab®



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Executive Summary



- Counterfeit and substandard drugs have been serious problems across the globe but capacity to deal with them is limited.
- In Ghana, the Food and Drugs Board (FDB) uses routine medicine quality testing approach of the GPHF-Minilab® confirmed with full monograph analysis to improve monitoring.
- The main **objective** is to obtain scientific data on the quality profiles of targeted products on the Ghanaian market.
- MeTA funding has been a welcome support for the minilab monitoring initiative and to date, two MeTA supported rapid quality medicine testing have been conducted by the FDB.
- Study 1 looked at the extent of counterfeit and substandard Amoxicillin, Co-Amoxyclov and Ciprofloxacin while study 2 assessed quality profiles of Glibenclamide (antidiabetic) and Mebendazole (anthelmintic) on the Ghanaian market.
- **Sampling** was based on protocol developed by the WHO in the QAMSA Project. Samples were first screened using minilab technique followed by confirmatory tests.
- In both studies, all products tested passed for presence of active pharmaceutical ingredients and did not involve counterfeiting. Products failures were however reported in specific reference to test of potency (assay of indicated active ingredient) and dissolution in both studies.
- Necessary regulatory interventions to address the problems identified were taken. The findings underscore the need to maintain collaboration to build Ghana's national medicines quality assurance infrastructure in the interest of public health and safety.

Introduction /Background

- Counterfeit and substandard drugs have been a serious problem across the globe but capacity to deal with them is limited.
- Ghana's medicine regulatory mechanisms incorporate quality assurance during registration and post market surveillance but counterfeiters and grey importers of sub-standard medicines to Ghana use unofficial channels to outwit the existing system.
- The Food and Drugs Board (FDB) is using rapid routine medicine quality testing approach of the GPHF-Minilab® to improve monitoring.
- MeTA funding has been a welcome support for the minilab monitoring initiative.



Informal medicines retail in Africa

Credit: <http://www.securingspharma.com/15/articles/144.php>

Objectives

- **Main Objective**

- To obtain scientific data on the quality profiles of targeted products on the Ghanaian market

- **Specific Objectives**

- Identify targeted formulations sampled nationwide meeting specific quality standards.
- Identify possible causes of the proportions not meeting the required quality specifications
- Propose possible strategies and implementation plans to address the problems identified by the study.
- Establish the proportion of the sampled medicines that have/have not been granted marketing authorization by the Board.
- Verify the appropriateness and accuracy of the product package insert and labeling.

Medicines Tested

- Due to financial constraints and limited capacity of the Food and Drug's Board Quality Control Laboratory, few categories of medicines are selected for testing at a time based on:
 - Prime importance to public health programmes
 - Narrow margin of safety
 - Products instability
 - Potential to be counterfeited.
- To date two MeTA supported rapid quality medicine testing have been conducted by the FDB
- Study 1 looked at the extent of counterfeit and substandard Amoxicillin, Co-Amoxyclov and Ciprofloxacin; 345 products were analyzed
- Study 2 assessed quality profiles of Glibenclamide (antidiabetic) and Mebendazole (anthelmintic) on the Ghanaian market; 90 products (45 each) were analyzed

Sampling

- **Sampling** in each study was based on protocol developed by the WHO in the QAMSA Project. Products were sampled from different distribution channels, hospitals and clinics across the ten regions of the country.
- Samples were first screened using minilab technique followed by confirmatory tests.



Scientists carrying out routine medicines testing using GPHF-Minilab®

Antibiotics Study Findings

- All products tested passed the tests for identification of active ingredients indicating that the worst case of counterfeiting involving wrong active ingredients were not found
- Out of the 345 products analyzed, 291 products representing 84.3% passed all the tests performed whilst 54 products representing 15.7% failed.
- With specific reference to the test of potency (assay of indicated active ingredients), 301 products representing 87.2% passed as against 41 products representing 11.9% failed.
- 39.7% of the antibiotics on the market during the time of the survey did not have officially marketing authorization.
- Ideal storage conditions for most of the products as indicated on the label were not adhered to.
- Prescription-Only antibiotics were purchased without prescription.

Outcome of Antibiotic Study

- **Regulatory interventions were taken to address the problems as follows:**
- All sub-standard products and importers and manufacturers associated with them were identified.
- A formal written directive to the manufacturers and distributors to withdraw from the market of all sub-standard batches of products;
- Communication to prescribers, pharmacists and the public at large about products which pose safety risks to consumers because of poor quality.
- Withdrawal of all unregistered products from the market.
- Post Market Surveillance, including regular sampling and testing of products across the country were intensified.

Antibiotic Study Regulatory Decision Caption



Results of Glibenclamide & Mebendazole

- Thirteen (13) products each representing 28.9% of both Glibenclamide and Mebendazole samples failed minilab analysis.
- Fifty-five percent of all products had valid registration while 18.8% had expired registration and 17.8% had no official marketing authorization and 7.8% were pending registration
- All products tested passed the tests for presence of active pharmaceutical ingredients and therefore did not involve counterfeiting
- Products were found to be adequately packaged.

Outcome of Glibenclamide & Mebendazole Study



- Awaiting additional confirmatory results for necessary regulatory measures to be applied.
- MeTA Ghana held initial meeting with FDB to discuss dissemination plans

Recommendations

- The regulatory capacity of the FDB in the area of post market surveillance needs to be strengthened by training more field inspectors and boosting the testing capacity (equipment and logistics) of the Quality Control Laboratory.
- The collaboration between MeTA, FDB, the WHO and their funding partners such as DfID and World Bank needs to be strengthened to improve Ghana's national medicines quality assurance infrastructure in the interest of public health and safety

Lessons learned

- Regular sampling and analysis of medicines on the Ghanaian market would help reduce the number of sub-standard and counterfeit products on the market.
- A simple analytical technique as offered by the MiniLab concept has tremendous impact on monitoring of quality of medicines on the Ghanaian market.

Conclusions

- The quality testing study outcomes suggest the need to enhance the quality of medicines on the market
- MeTA's support in facilitating the quality testing has been immensely helpful and ways should be sought to sustain it.
- There is need to seek ways to support local industry through capacity building to enable them meet expected quality standards.