POLICY BRIEF

# Monitoring Medicine Quality at a Ghanaian network of Health Facilities: TruScan as simple point-of-care methodology

**Purpose of this brief**

- Highlight key research findings of a study conducted on TruScan as a methodology for monitoring the quality of medicines at selected CHAG facilities in Ghana
- Make the study's findings accessible to relevant stakeholders such as government and policy officials, healthcare providers, patients, and the global health community.
- Discuss lessons learned and policy implications for improving quality of medicines on the Med4All supply chain platform

## EXECUTIVE SUMMARY


Medicines quality assurance is a key aspect in pharmaceutical supply systems to verify that medicines reaching patients are safe, effective, and of acceptable quality. In Ghana, the Food and Drugs Authority (FDA) is the body mandated to ensure the quality, safety, and efficacy of all pharmaceutical products marketed in Ghana. However due to financial constraints and overstretched capacity, the expected periodic post market surveillance of subsequent batches of products that receive initial market authorization is severely curtailed. The PharmAccess Group has been collaborating with the Christian Health Association of Ghana (CHAG) and the FDA to establish a digital pharmaceutical supply chain management system (Med4All) to increase the quality, availability and accessibility of essential medicines to patients who access healthcare at CHAG health facilities. This policy brief presents the outcome of a post market surveillance study that assessed the quality of selected frequently used medicines in a sample of CHAG facilities.

Sixty (60) CHAG facilities participated in the study and the quality of 639 representative samples of 14 generic products were digitally tested for presence of active pharmaceutical ingredients (APIs) using a handheld portable spectroscopic TruScan™ Raman analyzer. Products that failed the TruScan test were further screened at the FDA Drugs Laboratory to determine the presence of APIs using GPHF MiniLab analysis.

The majority of drug samples collected (429/639) passed the TruScan test. Results from the FDA MiniLab indicated that the samples submitted for secondary screening contained the APIs as indicated on their respective labels. The study showed that from a regulatory perspective the TruScan/MiniLab combination is an efficient post market surveillance tool although both tests are unable to conclude whether therapeutic concentrations were adequate.

## Introduction: Problem of falsified and substandard medicines

Falsified and substandard drugs are a serious problem in Africa as in many other parts of the world, leading to unnecessary deaths and severe public health and economic challenges. Various studies have revealed that middlemen, illegal trade, counterfeits and low-quality products depict the medicines supply chain for healthcare providers in Africa. Economic exploitations promote the production of falsified medicines, and inadequate storage or poor distribution practices could result in substandard medicines (Bekoe et al., 2020; Roth et al., 2019). The WHO estimates that 1 in 10 medical products in low- and middle-income countries (LMICs) is substandard or falsified with antibiotics and anti-malarials particularly susceptible (WHO, 2017). Taking counterfeit medicines can potentially cause more harm to patients than if they had not sought any medical treatment at all.

## Context of falsified and substandard medicines problem in Ghana

In Ghana, antimalarials are among the most faked medicines on the market. For example, 13 out of 14 (93%) Artemisinin-based medicines obtained from the Ghanaian market, had too low or too high API (El-Duah & Ofori-Kwakye, 2012). Another study found that about 9% of antimalarials for public consumption in Ghana had gone beyond their expiry date and 35% were substandard (Tivura et al., 2016). The FDA in Ghana is mandated by law, (PNDC Law 305B) to ensure the quality, safety, and efficacy of all pharmaceutical products marketed in Ghana in addition to packaged food, cosmetics, chemical devices and household chemicals. Once a product has been granted marketing authorization by FDA, the quality of subsequent batches of the product either locally manufactured or imported is to be assessed regularly through a post-market surveillance system. However, due to financial constraints, coupled with the overstretched capacity of the FDA's quality control laboratory services, only few categories of medicines are selected for testing one at a time.

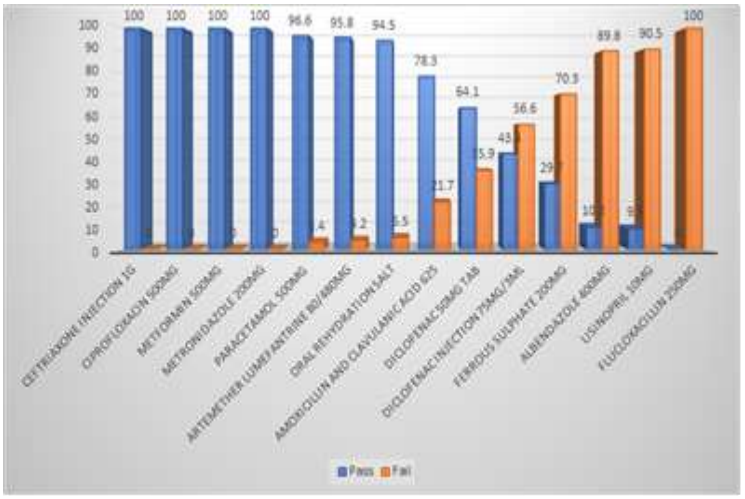
## The need for real time post market medicines surveillance in Ghana

Given that healthcare facilities in Ghana do not have any reliable measures in place to check the quality of medicines currently in use, the combination of TruScan at point-of-care and GPHF Minilab at a central location is an attractive option for affordable medicine quality monitoring.

## Research Methods

The study digitally checked the quality of 639 representative samples of 14 generic products in 60 CHAG facilities just participating or earmarked to participate in the digital procurement platform (Med4All) programme. A multistage sampling procedure was applied to select geographic areas comprising of administrative regions and CHAG health facilities. After visual inspection, the sampled products were tested on site using a handheld portable spectroscopic TruScan™ Raman (RM) analyzer. Some products which failed the TruScan test were submitted to further screening by the Ghanaian FDA to determine the presence or otherwise of the active pharmaceutical ingredients (APIs) using GPHF MiniLab analysis.

## Summary of all TruScan results for fourteen generic products tested




## Checking Medicines Quality with the TruScan

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## KEY FINDINGS

- The majority of the drug samples collected (429/639) passed the TruScan test, with high passes from all generic samples obtained for products such as ceftriaxone injection 1g, ciprofloxacin 500mg, metronidazole 200mg, metformin, paracetamol, artemether/lumefantrine 80/480mg, and oral rehydration salt.)
- The observed results thus confirm these samples contain the API's stated in the manufacturers specifications although the results were not able to provide the quantitative therapeutic concentration.
- A third of the samples obtained, failed the TruScan test. These included all samples obtained for flucloxacillin 250 mg generic while lisinopril 10 mg, albendazole 400 mg, and ferrous sulphate 200 mg generics also recorded high failures. This was similar to other studies conducted where products with high florescence, low dose of APIs, and fixed-dose combinations of active ingredients recorded false negatives (Hajjou, et al, 2013; Ricci et al., 2008).
- Some of the products failed as a result of batch problems where the batches programmed in the TruScan devise or system differed from the batches obtained in the field.
- Results from the FDA MiniLab indicated that all samples submitted for secondary screening contained their respective APIs as indicated on their respective labels. However, it will require HPLC analysis to determine therapeutic concentrations because both TruScan and minilab analysis are qualitative methods.

## POLICY IMPLICATIONS AND TAKE-AWAYS

From a regulatory perspective the TruScan/Minilab combination is an efficient post market medicine quality surveillance tool, provided standard spectra are available in its library for comparison. The regulator needs to ensure that suppliers provide a sample each time a new batch of a licensed product is issued to update the TruScan library for a seamless post market surveillance performance.

The correct choice of tracer drugs must be considered for this algorithm. The panel of medicines used for TruScan monitoring should be selected carefully to exclude drugs with high levels of fluorescence, low levels of active ingredients or those that contain multiple generics to avoid false negative TruScan results.

The TruScan/Minilab combination is practical and affordable, but only qualitative conclusions can be drawn about medicine quality. Quantitative analyses will however require expensive central laboratory-based HPLC technology.

## RECOMMENDATIONS

The selection of tracer drugs for Truscan testing requires careful consideration; apart from frequency of use and clinical importance, the technical aspects like low background fluorescence and high levels of active ingredients are essential.

From a regulatory perspective the Truscan is an efficient post market surveillance tool provided standard spectra are available in its library for comparison. Product suppliers should therefore be required to provide a sample to the regulator when a new batch number of issues after the tender evaluation and licensing to update the library sample.

Truscan test results should ideally be validated by retesting failure results with a confirmatory method such as the GPHF MINILAB to confirm the true and false negatives.

The Truscan is as good as it provides results for the right active pharmaceutical ingredient, but it will require a HPLC analysis to determine the actual API quantities.

The TruScan / Minilab combination can be safely recommended as a viable and affordable algorithm for on-site/central quality assessment of drugs in Ghana.

We recommend follow-up research on alternative tracer set(s), the impact of Med4All and the quality of drugs at the supplier level.

## CONCLUSION

The TruScan/Minilab analysis demonstrated presence of APIs in all 14 selected medicines of all 60 CHAG facilities. From a regulatory perspective the TruScan/MiniLab combination can be an efficient post market surveillance tool.

However, the selection of tracer drugs for TruScan requires careful consideration; apart from frequency of use and clinical importance, the technical aspects like background fluorescence and levels of active ingredients are essential.

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