

Quality Assurance of Medicines in Zambia: Inspectors training workshop organized by the Pharmaceutical Regulatory Authority in collaboration with the World Health Organization and European Community: Trip Report

Peter Risha

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Rational Pharmaceutical Management Plus
Center for Pharmaceutical Management
Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Phone: 703-524-6575
Fax: 703-524-7898
E-mail: rpmpplus@msh.org

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About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

Abstract

In effort to improve the quality of drugs on market through effective regulation, MSH/RPM plus with support from the USAID is working with the Zambia Pharmaceutical Regulatory Authority (PRA) to improve the inspection system and institute a Minilab based drug quality screening program. In July 2006, a team of two MSH/RPM plus visited the PRA to learn on the pharmaceutical environment and hold discussions and initial planning. As a follow up to the initial visit, Peter Risha traveled to Lusaka from 13th -19th August, 2006 to attend inspectors training workshop organized by the PRA in collaboration with the World Health Organization (WHO) and the European Commission (EC). During the workshop, Dr Risha presented a paper on the Overview of the Tanzanian MSH/SEAM/TFDA QA initiative. The visit was also provided opportunity to discuss with the PRA management on work-plan activity matrix developed by RPM Plus detailing the QA roll out plan and responsibility of each partners.

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Key Words

Quality assurance, Inspector Training Workshop Minilab, Zambia, PRA, TFDA

Rational Pharmaceutical Management Plus
Center for Pharmaceutical Management
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703-524-6575
Fax: 703-524-7898
E-mail: rpmplus@msh.org
Web: www.msh.org/rpmplus.org

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ACRONYMS

ADDO	Accredited Drug Dispensing Outlets
EC	European Commission
MOH	Ministry of Health -Zambia
MSH	Management Sciences for Health
PRA	Pharmaceutical Regulatory Authority (Zambia)
QA	Quality Assurance
RPM Plus	Rational Pharmaceutical Management Plus
SEAM	Strategy for Enhancing Availability of Medicines
TFDA	Tanzania Food and Drugs Authority
TLC	Thin Layer Chromatography
USAID	United States Agency for International Development
WHO	World Health Organization

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BACKGROUND

Lack of effective regulation is one of the major factors contributing to the high incidence of substandard and counterfeit medicines in developing countries. Such medicines pose a high risk to public health, as among other things their inadvertent use may contribute increase the risk of development of resistance to antimicrobial drugs which may results into treatment failure for infectious disease particularly so as the antibiotics is a class of medicines more commonly counterfeited.

RPM Plus/ Management Sciences for Health (MSH) has worked in partnership with developing countries in improving the quality pharmaceutical on market. For example from 2002 to 2005, the MSH's Strategy for Enhancing Access to Medicines (SEAM) funded by the Bill and Melinda Gates Foundation, collaborated with the Tanzanian Food and Drugs Authority (TFDA) to develop and implement a cost-effective QA system, based on product quality screening at ports of entry using Minilab^{®1}. In this approach, the inexpensive Thin Layer Chromatography (TLC) based screening methods were coupled to standardized and structured inspection to improve the regulatory capacity and reach of TFDA in addressing the problem of presence of substandard/counterfeit drugs on Tanzanian market

The effort in Tanzania has led to the improvement of quality control of medicines and could be a model to be adopted by other countries in the region. With support from USAID (RPM Plus core funds SO5/AMR), the MSH/RPM Plus -TFDA established contacts with the Pharmaceutical Regulatory Authority of Zambia (PRA) to roll out the successes and key lessons learned in Tanzania. Initially MSH/RPM Plus/TFDA shared a concept paper with the PRA, outlining the key details of program implementation in Tanzania and the outcomes. In response, PRA showed great interest and enthusiasm in working with MSH/RPM Plus. PRA commented that the situation of pharmaceutical market obtaining in Zambia at the moment could be similar or even worse that that found in Tanzania before the MSH/SEAM-TFDA QA initiative.

The PRA invited MSH/RPM Plus to visit Zambia to learn of the pharmaceutical environment of Zambia and discuss an implementation plan consistent with the physical and human resources of Zambia. Following the success visit to Zambia in the month of July², MSH/RPM Plus invited two PRA staff to visit Tanzania in July 2006 to acquaint with the TFDA QA system especially the use of Minilab as a QA tool. During the visit PRA informed that they would be conducting an Inspectors Training Workshop in August 2006 and shared the agenda with the partners for comments. This workshop was already in the PRA annual work plan at the time PRA was contacted by the partners (MS/RPM Plus/TFDA). It was important for MSH/RPM plus to send a participant to present an overview of the Tanzania QA initiative to the workshop participants who are key players in the country's pharmaceutical supply chain. The workshop provides an

¹ See www.gphf.org

² Tran, D. and P. Risha. 2006. *Quality Assurance of Medicines in Zambia – An Assessment Visit of the Zambia Pharmaceutical Regulatory Authority: Trip Report*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

opportunity for the MSH/RPM Plus participant on the PRA guidelines for inspection of retail and wholesale outlets as these drive the process of developing Standard Operating Procedures (SOPs) for structured inspection.

Purpose of Trip

During visit to Tanzania July 2006 for the purpose of acquainting with the TFDA –QA system, the PRA Acting Director General informed that her organization was planning to hold inspectors training workshop in August 2006 in collaboration with the World Health Organization (WHO) country office under European Community (EC) financial assistance. Since it was not possible to further postpone the workshop to coincide with our ZambiaQA roll out plans (due to the funding conditionality) and also due to the importance of the workshop agenda to our future work in the country, it was agreed that MSH/RPM Plus will send one participant to present an overview of the MSH-SEAM/TFDA QA initiative during the workshop.

The objectives of the workshop which were to raise the awareness of the participants on the legal framework and functions of the PRA and also strengthen the inspection skills of the Provincial Pharmacists played in the role of the QA rollout.

The event was also seen as an opportunity for MSH/RPM Plus to learn more on the PRA guidelines on inspection in which is key in driving the process of developing SOP's and check list for a structured inspection as is planned for in the QA initiative roll out. The visit would also be used as an opportunity to further push forward the roll out plan, discussing with the PRA on the work plan activity matrix.

Scope of Work

The scope of work for Dr. Risha on this trip was to:

- To attend the inspector training workshop organized by the PRA in collaboration with the WHO country office with EC financial assistance
- Meet with PRA Director General and other key staff, discuss QA roll out implementation activity matrix

Under this scope of work, the specific objectives included:

- To present a paper titled an Overview of the MSH-SEAM/TFDA QA initiative in Tanzania
- To learn about the PRA guidelines on Inspections and importation
- To get a first hand information from Provincial pharmacists in Zambia about their roles as PRA inspectors in the provinces and status of the pharmaceutical distribution chain
- To discuss with PRA management on the future plans for the roll out activities
 - Development of Inspection SOPS and PRA staff to be allotted for this function
 - Venue for training and who should be involved

ACTIVITIES

1. Attending the workshop and making presentation.

The three days workshop was held at the Cresta Golfview Hotel, Lusaka starting 16th August 2006. The agenda of the workshop is as shown in Appendix 1. The proceedings and presentations made during the workshop are summarized below.

(a) Attendance:

The workshop was well attended and participants of the workshop included Pharmacists/pharmaceutical technologist from all nine administrative provinces, a representative from Zambia Revenue Authority (ZRA), PRA management and PRA inspectors. Also in attendance during the opening ceremony were the WHO country representative Dr. S. Anyangwe and EU delegation head of Health and Social Service Sector, Mr. E. Rossete and the WHO country EDM Medicines Advisor, Ms. L. Lishimpi. The guest of honor was the Permanent Secretary Ministry of Health (Zambia) who was represented by the Director of Dr. Mutonga, the Director of Technical Support- MOH

(b) Workshop proceedings

Opening ceremony

During the opening ceremony the WHO representative Ms Anyangwe, lauded the PRA efforts in trying to address the problems of substandard and counterfeit medicines. She advocated for creative solutions to be applied to counter this problem especially in countries with poor resources. The EU representatives expressed satisfaction that PRA has been able to arrange this event in Zambia as it was long overdue. Further informed that EU usually support such initiatives at regional and global level

The guest of honour's speech acknowledged the support from WHO/EU in the support to PRA in its efforts toward establishing effective regulation. The guest of honour also acknowledged MSH presence in the meeting and hoped that the planned QA initiative would succeed towards improving market compliance. The Permanent Secretary reiterated the important function and role of inspectors of drugs and herbal medicines in reducing the incidence of counterfeit/substandard medicines in the country.

She outlined the challenges facing the PRA: need to increase inspections coverage in to whole country and presence of unauthorized drug outlets/dealers in the country citing the case of Lusaka where there are more than 100 such outlets. She called the involvement of provincial pharmacists to complement PRA efforts.

(c) Presentations.

(i) Overview of the MSH-SEAM/TFDA QA initiative

During the workshop, Dr. Risha made a 30 minute presentation on the MSH-SEAM/TFDA QA initiative outlining the situation in Tanzania prior to the MSH-SEAM/TFDA intervention, implementation of the QA initiative, observations and lessons learned (Annex 2). The presentation was well received by the provincial pharmacist and it was followed by about 30 min discussion/question session.

Some of the key discussion points during this presentation were-:

- resources applied for the successes achieved can TFDA sustain the process
- effectiveness on Minilab as drug quality control tool
- who were the stakeholders and their role in implementing the initiative, the importance of obtaining political support for the program.
- On the view of persistent shortage of qualified personnel in Zambia, how should the PRA proceed in implementing the initiative
- how to coordinate PRA with the Medical Stores Limited in the QA initiative even if the latter acquire its own Minilab kit
- Key lessons from the Tanzanian ADDO initiative as a way developing ideas on how best to control/regulate Part II dispensing outlets in Zambia. The participants elaborated that in the present Pharmaceuticals Act of 2004, these outlets are not legally recognized, yet they are the major distribution outlets in Zambia particularly in provinces where there are no pharmacies.

In general the presentation was well received and served as an advocacy tool in winning the support of key players (provincial pharmacists) to the proposed roll out initiative.

(ii) Provincial Pharmacist experiences

- Nine provincial pharmacists attended the workshop and presented their experiences as regards to the situation of the pharmaceutical supply chain in their respective provinces and the regulatory function they play.
- The majority of registered outlets are situated in Lusaka, Copperbelt and Central provinces.
- Some of the provinces for example Eastern and Luapula do not have a single registered pharmacy.
- Although provincial pharmacists are not employees of the PRA, they do perform inspection activities in their provinces as MOH employees. All provincial pharmacists who participated in the workshop reported to have been involved in inspections of the dispensing located outlets in their respective provinces at least once in a year (especially prior to mandatory annual license renewal).
- In some provinces the pharmacists are conducting follow up inspections incase of reported/suspected malpractice in the dispensing outlets. In some instances, the provincial

pharmacists joins the PRA inspectors in conducting inspections carried out in their provinces.

- Presence of Drug stores as dispensing outlets in all the provinces. In some provinces these are the majority of such outlets although they are considered illegal as per the Pharmaceutical Act 2004. Control of these illegal dispensing outlets is posing as serious challenges to the PRA and Provincial pharmacists.
- Provincial pharmacist expressed problems with expired medicines from donated consignments especially to missionary hospitals
- The major problems reported by the Provincial pharmacist for these illegal drug stores is
 - Dispensers not trained
 - Stocking of unauthorized medicines especially antibiotics
 - Malpractices such as administering injections

In general the picture depicted by the provincial pharmacists is similar to that obtained in Tanzania during the SEAM pharmaceutical sector assessment³

(iii) PRA presentations: guidelines and roles of inspectors

The PRA presented guidelines and procedures for handling drug donations and for inspection of import/export and wholesale premises also retail and hospital pharmacy premises. In addition the roles of inspector in medicines regulation and in conducting post marketing surveillance were also outlined. PRA has done a great job in developing guidelines defining the inspection activity. For the purpose of developing the structured inspection there are some deficiencies noted. For example

- Guidelines for import/export does not outline what should the importer do when intending to import a consignment of medicines
- The inspection of retail outlets do not require inspector to examine products stocked in the shelf and perform a physical exam on some batches
- No decision trees are outlined in case the inspector encounters a non compliance

After addressing these minor outcomes the MSH/RPM Plus-TFDA will assist PRA to develop SOPs as outlining what inspector's activity during the inspection

(iv) WHO presentations.

The WHO EDM country medicines advisor made two presentations: Role of the WHO in Quality Assurance and Substandard and Counterfeit Drugs and their detection.

- The provides standards which may be adopted by other countries

³ Center for Pharmaceutical Management. 2003. *Access to Essential Medicines: Tanzania, 2001*. Prepared for the Strategies for Enhancing Access to Medicines Program. Arlington, VA:Management Sciences for Health

- The WHO is concerned on the incidence of counterfeit particularly in developing countries and encourages these countries to take measures to combat substandard drugs
- Outlined the contents of the Rome declaration on counterfeit drugs and its importance in Zambian context

(v) Activity plans:

In the view of the Permanent Secretary remarks that Provincial Pharmacists should play a role in addressing the problem of substandard /counterfeit drugs and presence of illegal drug dispensing outlets in their provinces, the pharmacist were encouraged to chart out activity plan outlining strategies to be adopted and setting out targets.

(2) Discussions with PRA/ Partners

(a) Discussion with WHO EDM office

During the meeting I had an opportunity to discuss with WHO EDM country national professional officer (medicines advisor)Ms. L. Lishimpi on MSH/RPM Plus-TFDA QA roll out plans and also informed her that the WHO played a very important role in the Tanzanian initiative as they supported acquisition of Minilabs by the TFDA. She was impressed with the MSH/RPM Plus-TFDA initiative and was happy that the roll out is planed for Zambia. She proposed that the PRA acting Director General to highlight this information on the workshops report to be submitted to the WHO and also keep her informed on the progress.

(b) Discussion with MSH Zambia Office

I had an opportunity to visit the MSH office in Lusaka and brief with Mr. Oliver Hazemaba (Regional Technical Advisor) on the QA roll out and future plans. Specifically we discussed on the purchase of one Minilab for the PRA and the best possible to proceed. It would be possible for the QA team to contact with Technologie Transfer Marburg –Germany the suppliers of the kit and ask for possibility of delivering the Minilab to MSH offices in Lusaka who will then handle it to the PRA and effect payment.

(c) Discussion with PRA

At the end of the workshop, we had a discussion with the PRA management: Ms E. Mwape, Ms. B. Mwale and Mr. F. Chizu on the way forward. They were happy that it was possible for MSH/RPM Plus to send participants to the workshop, and that the Provincial pharmacists were impressed of the work done in Tanzania.

On the general the work plan submitted looked ok. However, since they were intensely involved in running the workshop, they had not had time to read the roll out work plan activity matrix, they asked for some time and would activity work plan. We agreed that we

MSH will take a lead in developing the SOPs for inspection based on the PRA guidelines. In addition it was agreed that there is need to look on closely on facilities available for the for coming Minilab training. PRA proposed that National Council for Scientific and Industrial Research Institute (NCSIR) as a training venue, and also as the site for placement of the Minilab that would be catering for the Lusaka International Airport port of entry due to its proximity to the airport.

Collaborators and Partners

The key collaborators and partners on this visit were:

- Ms. Esnat Mwape, Acting Director General, PRA
- Mr. Felix Chizu, Senior Pharmacist, PRA and project liaison
- Mr. Oliver Hazemba, Regional Technical Advisor, MSH PRM+

NEXT STEPS

Immediate Follow-up Activities

- MSH/RPM Plus and PRA start working on the SOPS and training materials based on the current PRA guidelines from September 2006. Mr. Chizu will be the lead for PRA in this activity while Dr. Risha would do so from MSH/RPM Plus side.
- MSH and PRA initiate the process of acquiring Minilab from Technologie Transfer Marburg (TTM). For the PRA this activity would include looking acquiring funds from the Ministry of Health. For the purpose of planed training, A Minilab need to be acquired by November 2006
- PRA to start looking on appropriate venues for Minilab training considering availability of necessary facilities such as running water sufficient for the number of trainees.

ANNEX 1. AGENDA FOR THE WORKSHOP

WORKSHOP ON INSPECTORS OF MEDICINES AND HERBAL MEDICINES FOR DISTRIBUTION CHANNELS 16th -18th AUGUST 2006, CRESTA GOLF VIEW HOTEL, LUSAKA, ZAMBIA

PROGRAMME

Time	Topic	Responsible
Wednesday 16th August, 2006		
08:00- 08:30	REGISTRATION	PRA Secretariat
	Welcome Remarks	Ms E. Mwape, A/Director-General, PRA
	Welcome Remarks	PS, MoH & Chairperson of PRA Board
	Opening Remarks	WHO Representative Zambia
	Self-introductions	All
10:30- 11:00	TEA BREAK	
11:00- 13:00	Introducing Workshop Programme	Ms E. Mwape, A/Director-General, PRA
	An Overview of Medicines Regulation in Zambia(Regulatory Functions/Legislation)	Ms E. Mwape, A/Director-General, PRA
	An Overview of Drug registration system	Mrs Bernice C. Mwale, Pharmacist, PRA
	An Overview of PRA Inspectorate system	Mr Felix Peter Chizu, Pharmacist, PRA
13:00- 14:00	LUNCH BREAK	
14:00- 17:00	An Overview of WHO's Role in Quality Assurance of Pharmaceuticals	WHO technical Expert
	An Overview of Tanzania Quality Assurance Initiative	Dr. P. Risha, MSH
	Provincial experience presentations	All Provinces
	Discussions	All
Thursday 17th August, 2006		
08:00- 10:30	Guidelines and Procedures on inspection of import/export and wholesale premises	Mrs Bernice C. Mwale, Pharmacist, PRA
	Guidelines and Procedures on labeling, Drug Promotion and Advertising	Mr Felix Peter Chizu, Pharmacist, PRA
10:30- 11:00	TEA BREAK	
11:00- 13:00	Substandard and Counterfeit Drugs and their detection	WHO technical Expert
	Guidelines and Procedures on monitoring quality	Mr Pelekelo Mangisha, Pharmacist,

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	and safety of products, including taking of samples (PMS)	PRA
13:00-14:00	LUNCH BREAK	
14:00-17:00	Guidelines and Procedures on inspection of Retail and Hospital Pharmacy Premises	Ms E. Mwape, A/Director-General, PRA
	Guidelines and Procedures on handling of Drug donations, product recalls and expired drugs	Mr Pelekelo Mangisha, Pharmacist, PRA
	Presentation of format for Activity plans	Mr Felix Peter Chizu, Pharmacist, PRA
	Friday 18th August, 2006	
08:00-13:00	Attributes of an inspector, Code of conduct/ethics and conflict of interest in medicines regulation	Mr Felix Peter Chizu, Pharmacist, PRA OR WHO technical Expert
	Visit to Retail Pharmacy outlet	Group A
	Visit to Hospital Pharmacy Storage Premises	Group B
	Visit to Import & Wholesale outlet	Group C
13:00-14:00	LUNCH BREAK	
14:00-17:00	Plenary presentations on the visits- Group Reports	All Groups
	Discussions	All
	Presentation of Activity Plans	All
	Summary of the Workshop Outcome	Mrs Bernice C. Mwale, Pharmacist, PRA
	Closing Remarks	Ms E. Mwape, A/Director-General, PRA

**ANNEX 2. TANZANIA QA INITIATIVE: PRESENTATION AT THE PRA/WHO
INSPECTORS TRAINING WORKSHOP**



Overview of
the Quality
Assurance
Initiative in
Tanzania

Peter Risha, Ph.D.
Senior Program Associate
Management Sciences for Health

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 **US**
FROM THE AMERICAN PEOPLE

Presentation Outline

- Overview
- Drug Quality Assurance (DQA): Challenges in developing countries and what can be done
- Implementation of quality assurance (QA) program in Tanzania and achievements
- Minilab[®] as a tool in a QA system: SWOT
- Lessons learned



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Overview

- Presence of substandard medicines in the marketplace, especially antimicrobials, is a major public health concern in all countries
- Based on studies done in 10 countries, the WHO reported that up to 20 percent of medicines failed quality control tests—either substandard or counterfeit
- Use of poor quality medicines contributes to resistance



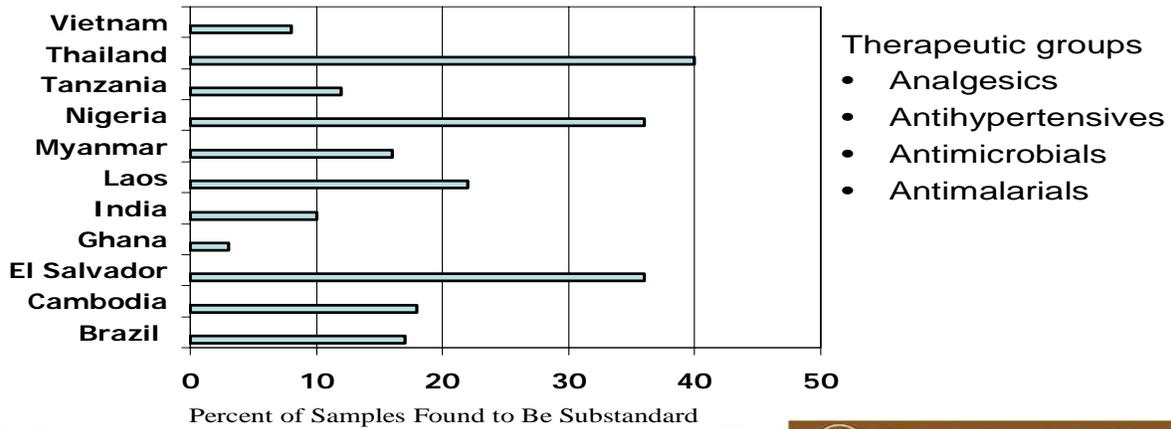
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Scope of the Problem

Substandard Medicines in Some Developing Countries

Unstructured Sampling—Not Necessarily Indicative of the Marketplace



Substandard Medicines: What Needs to Be Done

- It is essential that the pharmaceutical market is effectively regulated to ensure that each and every product used by consumers meets legal standards.
- Even industrialized countries with strong regulatory systems do not attain this ideal situation.
- **Developing countries should strive to have a QA system in place to minimize the incidence of poor quality medicines in the marketplace.**

Challenges in Developing Countries (1)

- Establishing a functional laboratory for medicine quality control is resource intensive.

For example—

- About 150,000 U.S. dollars (USD) are required for a medium-level medicine quality control laboratory and even more is necessary for complex analysis (WHO).
- Daily running cost (personnel and reagents) is high. For example, about USD 5,000 per sample (FDA).
- Need highly trained manpower.

Yet, quality testing alone is not enough to ensure the quality of medicines in the marketplace.



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Challenge in Developing Countries (2)

- Prioritize resources to address the highest risk
- Use cost-effective technologies whenever possible
- Consider interventions at each level of regulatory universe, for example—
 - Registration
 - Inspection
 - Laboratory testing

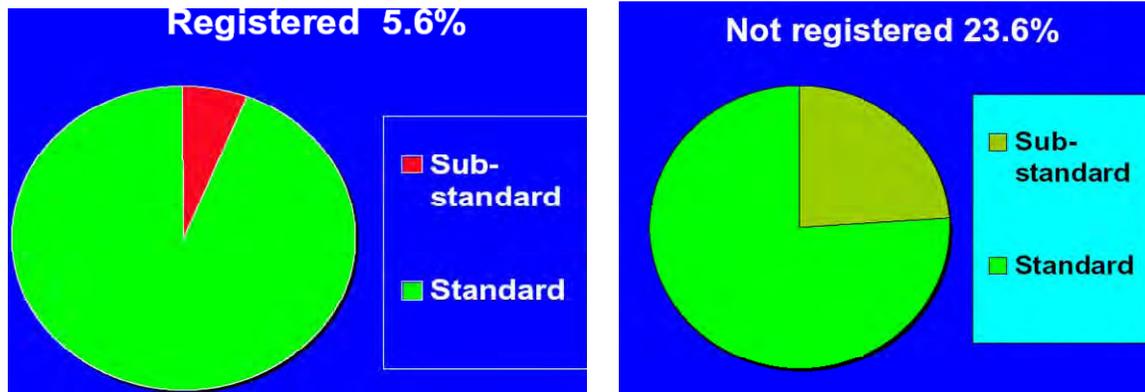


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Registration

Defines what comes on the market. Simply applying registration improves the market. Example from Myanmar and Vietnam—



* Study in Myanmar and Vietnam 1996-1997 WHO Data



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Inspection

Ensures what comes into the market has been authorized.

	<u>Myanmar</u>	<u>Vietnam</u>
Substandard drugs	16%	8%
# of inspectors	2	61
QCL: # samples/yr	32	31,000

*Study in Myanmar and Vietnam 1996-1997-WHO Data

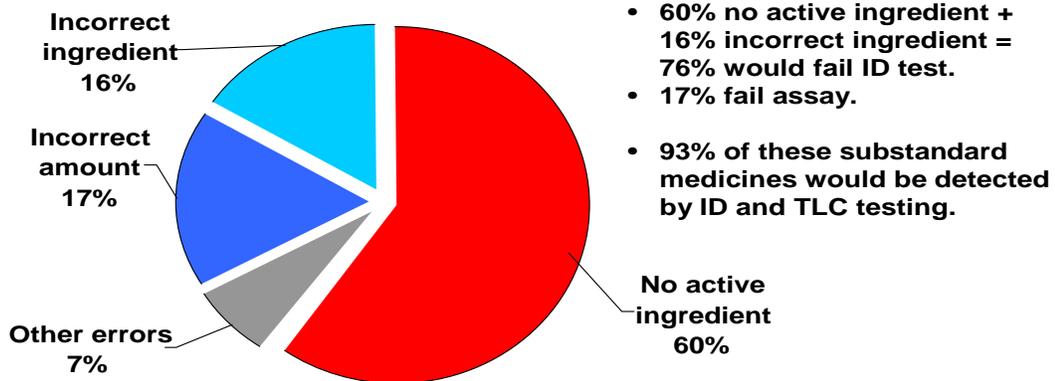


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Use of Appropriate Technology

325 Cases of Substandard Medicines—Including Antibiotics, Antimalarials, and Antituberculosis Medicines Reported to WHO



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Tanzania Situation In 2002

MSH Strategies for Enhancing Access to Medicines (SEAM) Program

- Tanzania Food and Drugs Authority (TFDA) evaluated pharmaceutical market—
 - Significant proportion (46 percent) of medicines on the market was of questionable quality because they were from sources not approved by the TFDA
 - Ten percent of medicines sampled from the market at the time of 2002 survey failed assay tests
 - Limited capacity for quality control of medicines because TFDA relied on the central laboratory, which had limited resources



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MSH/SEAM–TFDA QA Initiative

- Ministry of Health, through the TFDA and the MSH/SEAM Program, has developed a model QA program in a resource-limited setting
- SEAM Program involved—
 - Two-tier drug testing
 - Standardized inspection of pharmaceuticals at both point of entry (POE) and post-marketing surveillance



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Implementation of the Program (1)

- Develop structured and standardized inspection procedures and train TFDA inspectors on level 1 inspection techniques
- Train inspectors on basic thin-layer chromatography (TLC) techniques (1–2 weeks)
- Implement structured inspection coupled with Minilab screening of targeted surveillance medicines from both POE and dispensing outlets



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Implementation of the Program (2)

- Provide continuous monitoring and supportive supervision including proficiency testing
- Develop pharmaceutical quality data/information reporting system
- Expand geographically and increase number of target medicines included in the screening program as the implementation becomes more established



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Observations

Evaluation of the program after 2.5 years of implementation showed significant improvement in the focus areas—

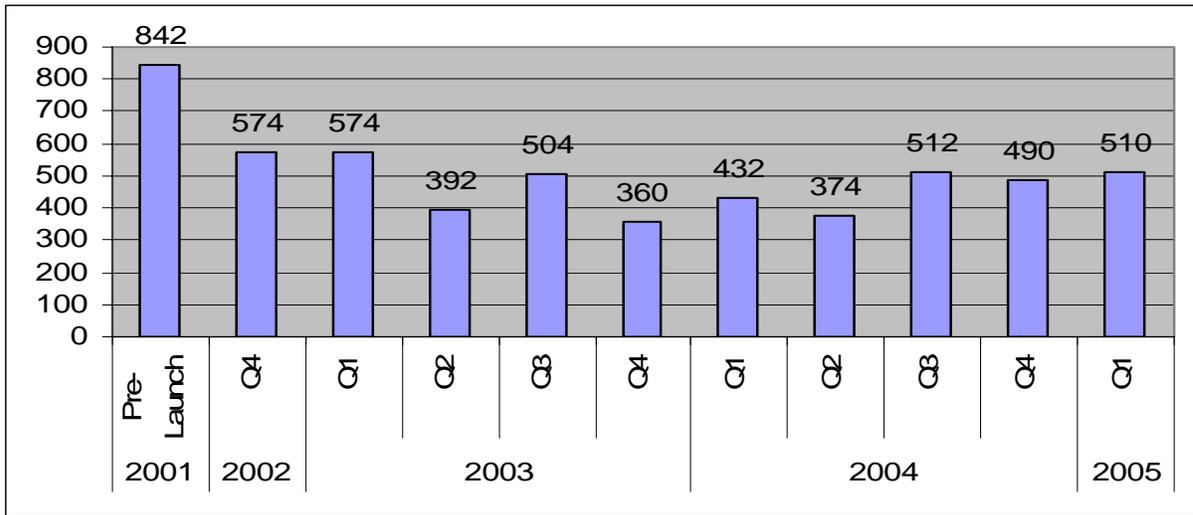
- Inspection
- Minilab screening of target medicines



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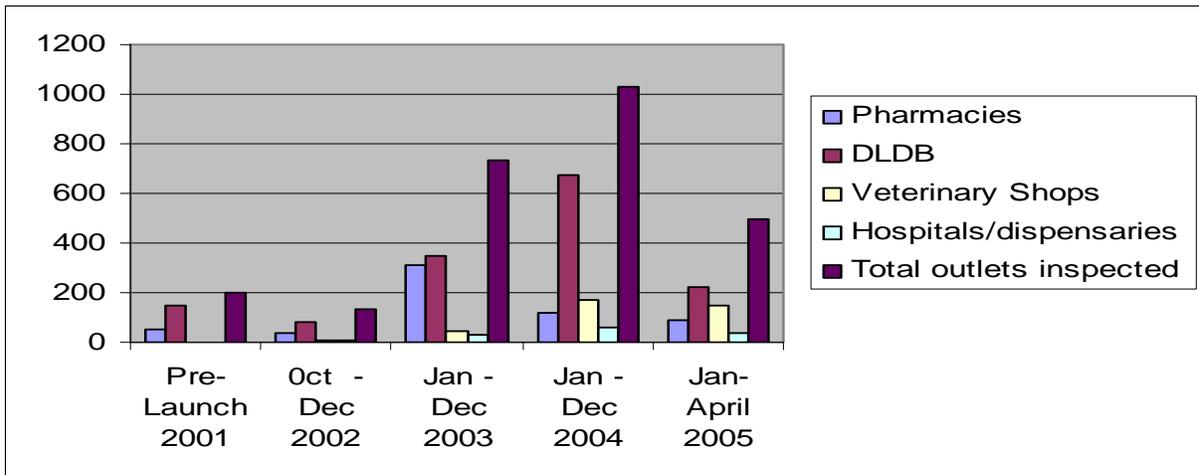
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POE Inspections



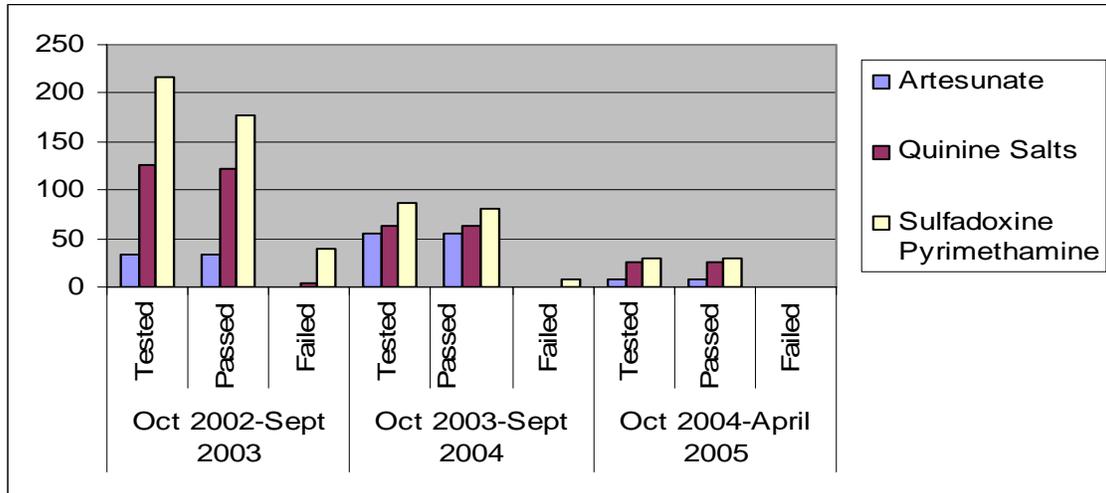
Total of 7,800 consignments, approximately 3,200 consignments per year, containing 28,185 batches of pharmaceutical products

Outlets Inspections

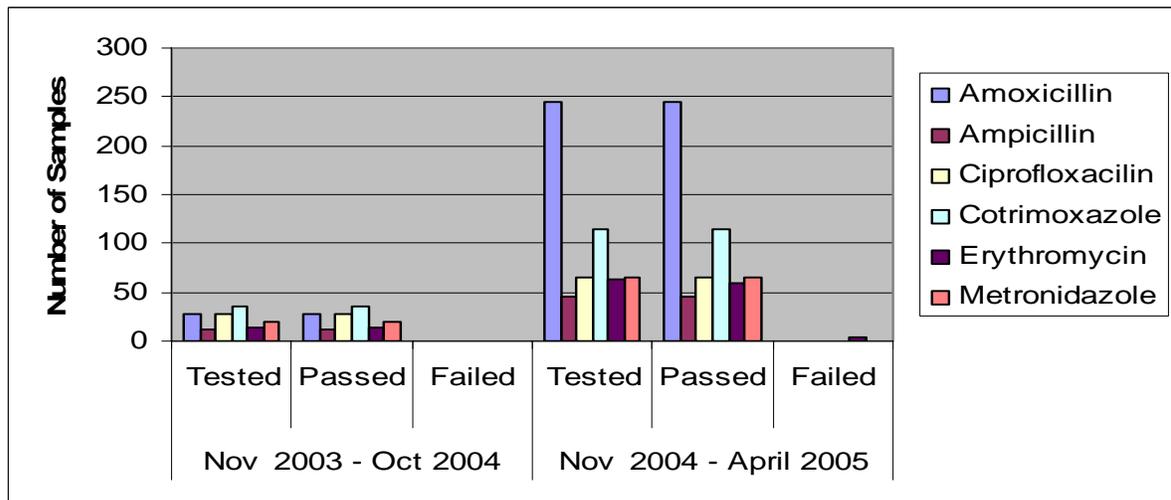


- Number of facilities inspected one year postlaunch increased four times
- Trend maintained

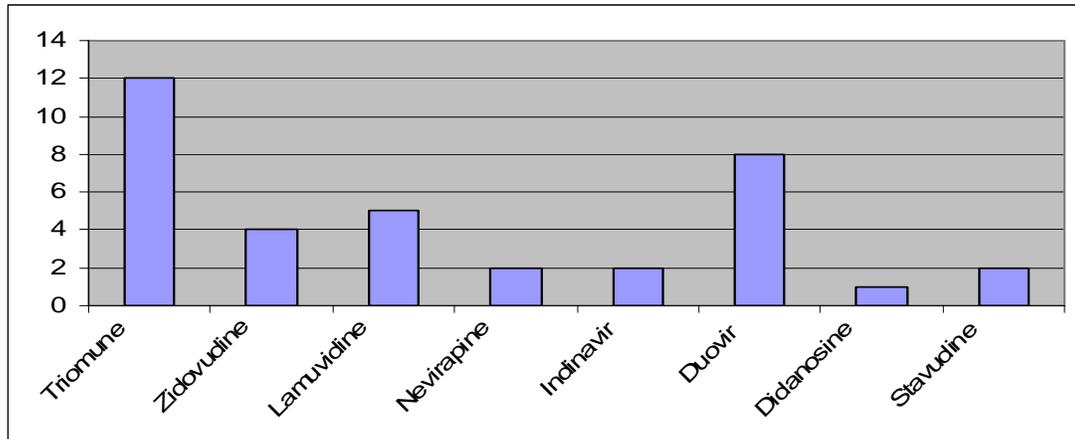
Antimalarials Screened



Antibiotics Screened



ARV Samples Screened



At the end of the SEAM Program—
1,257 batches of the targeted medicines screened
1,211 passed and 46 (3.7%) failed

Regulatory Impact: Compliance Actions

- Facility inspections—
 - Number of unregistered products dramatically reduced
- POE inspections
At POEs, confiscations/detention of 25 consignment/products:
 - Failed physical examination (5)
 - Failed documentation (4)
 - Have expired medicines (5)
 - Have unregistered medicines (3)
 - Failed labeling requirements (3)
 - Unauthorized products (2)
 - Banned cosmetics (3)

Minilab in a QA System (1)

Strengths

1. Initial costs are within reach (about USD 5,000 per kit).
2. Nontoxic solvents are used—minimal installation costs. Only requires a single well-ventilated room with a table and running water (no fume cupboards).
3. Do not require highly trained manpower (Tanzania has trained pharmaceutical assistants).
4. Running costs minimal—only need to replace supplies and reagents. No maintenance costs.



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Minilab in a QA System (2)

Weaknesses

1. Can only give a rough estimate of the medicine content.
2. Limited number of analytes. Generally only two or three at one time.
3. Reliability of detection depends on operator training and visual acuity.
4. Methods available with those solvents for about 80 medicines (40 in Minilab).



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Minilab in a QA System (3)

Opportunities

- Offers possibility for a Drug Regulatory Authority (DRA) in a developing country to expand regulatory capacity and reach
- Placing the Minilab at POEs enables a DRA to make an intervention at a very critical point in the pharmaceutical distribution chain that has a potential for a huge impact on improving medicine quality

Threats

- None—there is no competing analytical system using the same modalities



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Lesson Learned (1)

- Entire program is conducted with a relatively modest amount of TFDA resources while posing a significant deterrent effect
- Structured inspection complements the Minilab screening program and makes the regulatory actions comprehensive
- Necessary to institute supportive supervision and monitoring, including proficiency of the inspectors on adherence to standard operating procedures and screening techniques



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Lessons Learned (2)

- Important to ensure political support during planning and implementation and also involve stakeholders
- QA program needs to be supported by other regulatory measures to augment clean up of the marketplace
 - For example, pharmaceutical registration process and approval of manufacturing facilities introduced prior to the DQA launch may have greatly contributed to the low incidence of substandard medicines in the country



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Lesson Learned (3)

- Minilab is useful in detecting **No drug or Wrong drug**, and the model provides cost-effective and high output testing—
 - It is inexpensive (cost per sample about USD 1.50)
 - Field screening requires an average of 1.5 hours per sample, which for the approximately 1,200 samples screened over the 2.5 year period required a total of about one person-year of activity.
- Need to be complemented with a full service quality control lab for verification of results and support regulatory action



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Conclusion

- QA program can be effectively implemented using resources that are within reach of regulatory authorities in resource-limited settings
- QA improves regulatory reach and capability, providing deterrent against introduction of substandard medicines into the marketplace



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