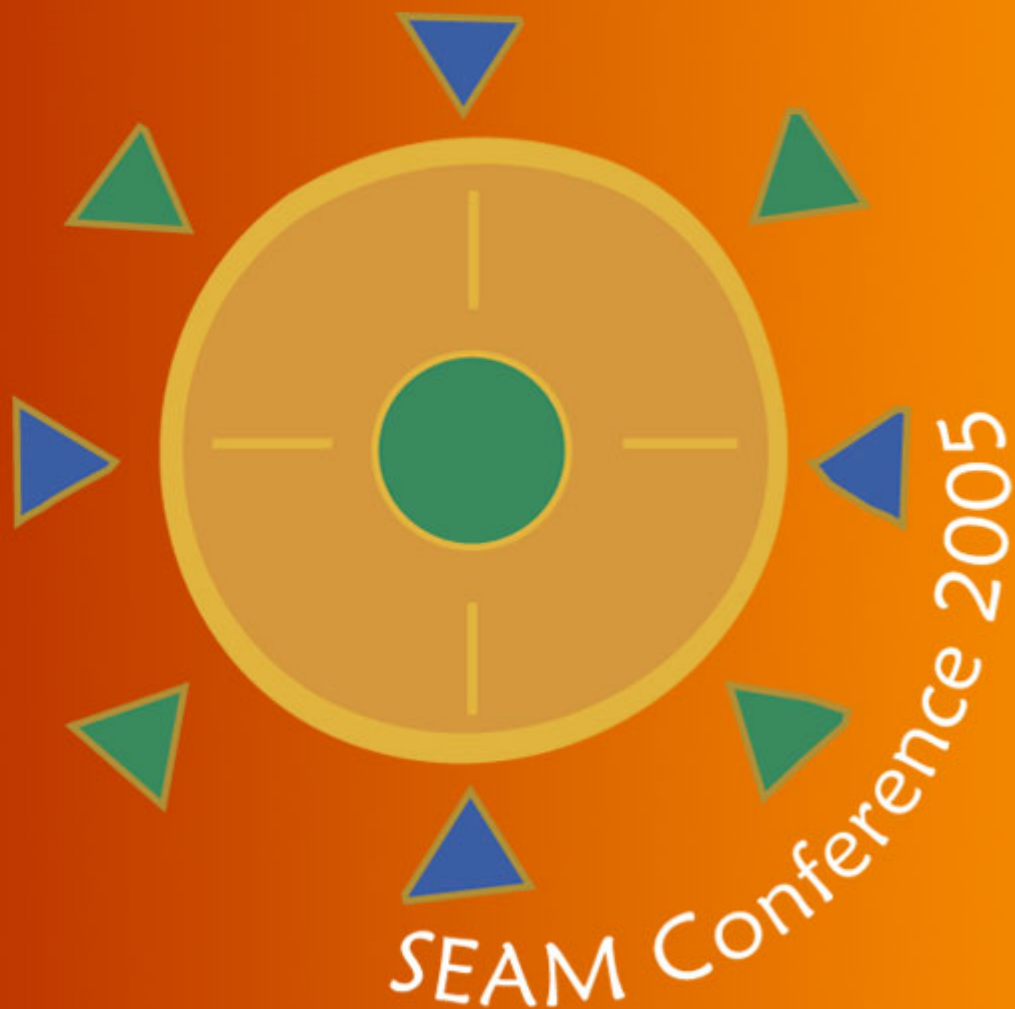




Accra, Ghana • June 20–22

Targeting Improved Access

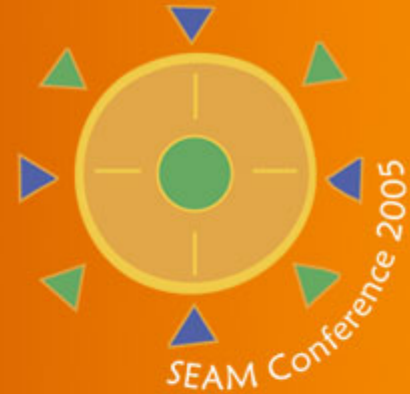


MANAGEMENT SCIENCES *for* **HEALTH**

SEAM | Strategies for Enhancing Access to Medicines

Funding for the SEAM Program is provided by the Bill & Melinda Gates Foundation.

Targeting
Improved
Access



Accra, Ghana • June 20–22

THE TANZANIA DRUGS QUALITY ASSURANCE/TLC INITIATIVE

By. Zera Msuya (B.Parm, MSc)

TFDA .United Republic of Tanzania

Funding for the SEAM Program is provided by the Bill & Melinda Gates Foundation.



MANAGEMENT SCIENCES *for* HEALTH

SEAM | *Strategies for Enhancing Access to Medicines*

Introduction

❖ **Objective:**

To establish an appropriate and comprehensive National Drug Quality Assurance System to ensure availability of quality medicine to consumers

❖ **Major components:**

QA program was established with two major components: -

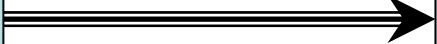
- 👉 A well-structured drug inspection system
- 👉 Drugs screening using the GPHF Minilab kits.

Key players & category of activities

Key Players

CATEGORY OF ACTIVITIES

TFDA



MSH



WHO



1. Establishing level one drug inspection program
2. Establishing a tier one Minilab based drug screening program
3. To implement drugs inspection program
4. Establishing Personal Digital Assistance (PDA) Inspection data logging system

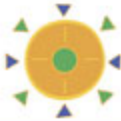
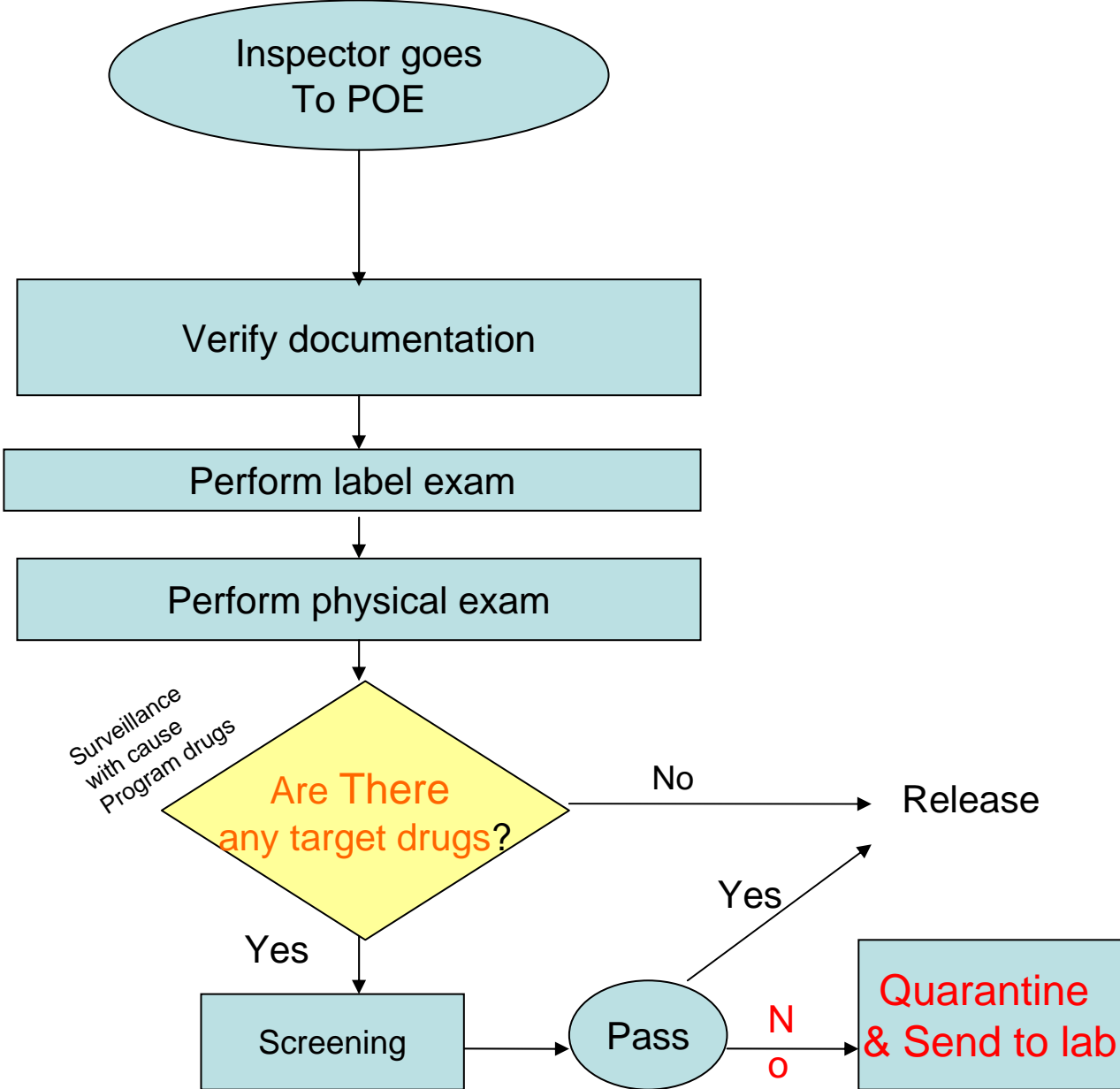
Program activities

1. To establish Level One drugs inspection program

- ❖ From existing policy, laws and regulations:
- 👉 Develop flow charts, SOPs and Checklists for structured inspection activity at POE and PMS
- 👉 Develop training materials
- 👉 Train Inspectors in structured inspection

Results: SOPs in place, Inspectors Handbook, Facilitation guide, Flow charts, Decision tree

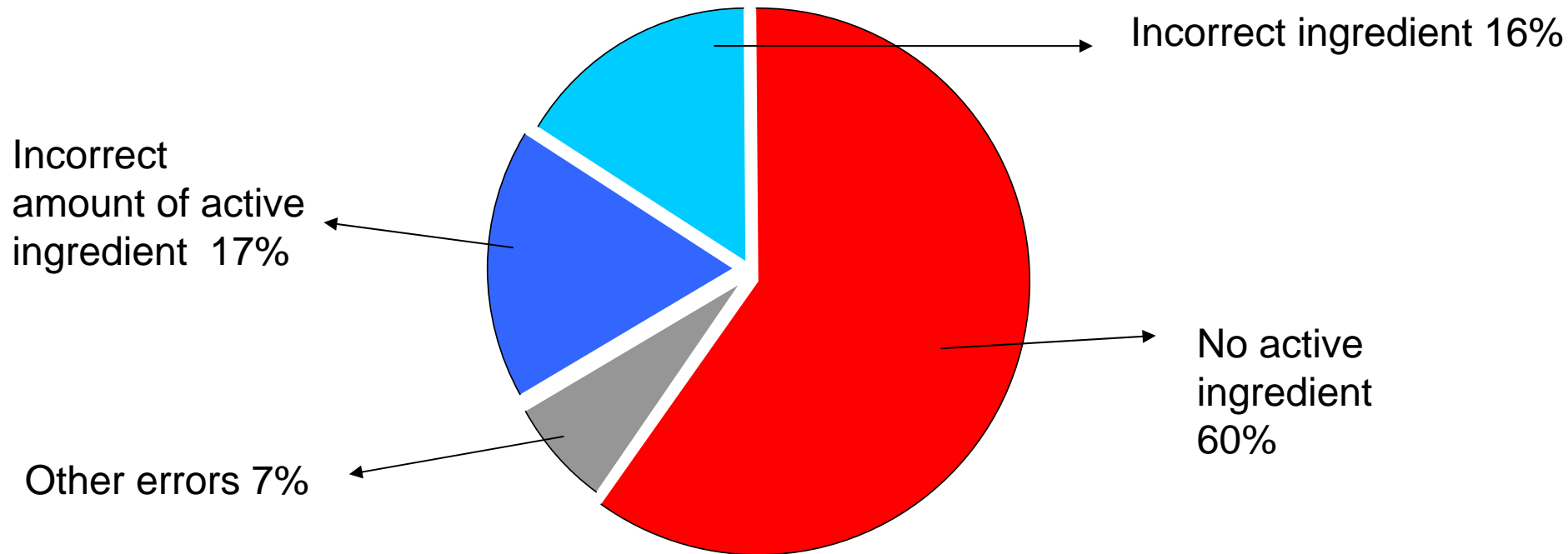
Inspection Process at POE



Program activities.....

2 Establish a Tier One Minilab-based drugs screening program:

Rationale: 325 cases of substandard drugs reported by WHO

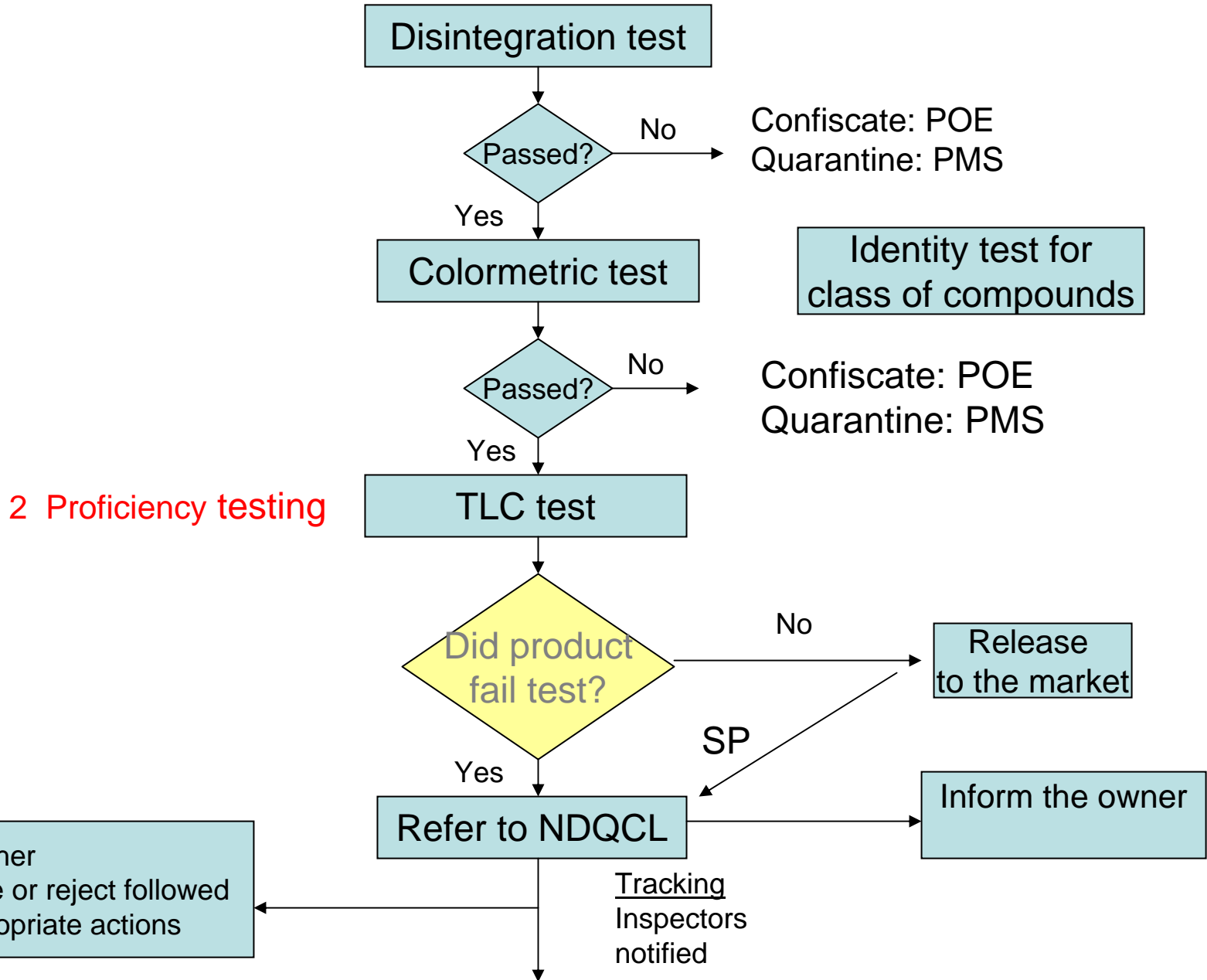


Program activities...

Establish a Tier One Minilab-based drugs screening program...

- 👉 Selection of target drugs
- 👉 Develop SOPs, decision trees for sampling and screening of targeted antimalaria drugs
- 👉 Train inspectors on GPHF Minilab screening for the antimalarial drugs
- 👉 Sensitize and involve stakeholders
- 👉 Establish Minilab screening centers
- 👉 Launch the program

FLOW CHART MINILAB SCREENING



Launching of QA in 2002 by Minister of Health Hon. Anna Abdallah (MP)



Launching of QA in 2002 by Minister of Health Hon. Anna Abdallah (MP)...



Program activities

3. To implement drug inspection program at POE and PMS

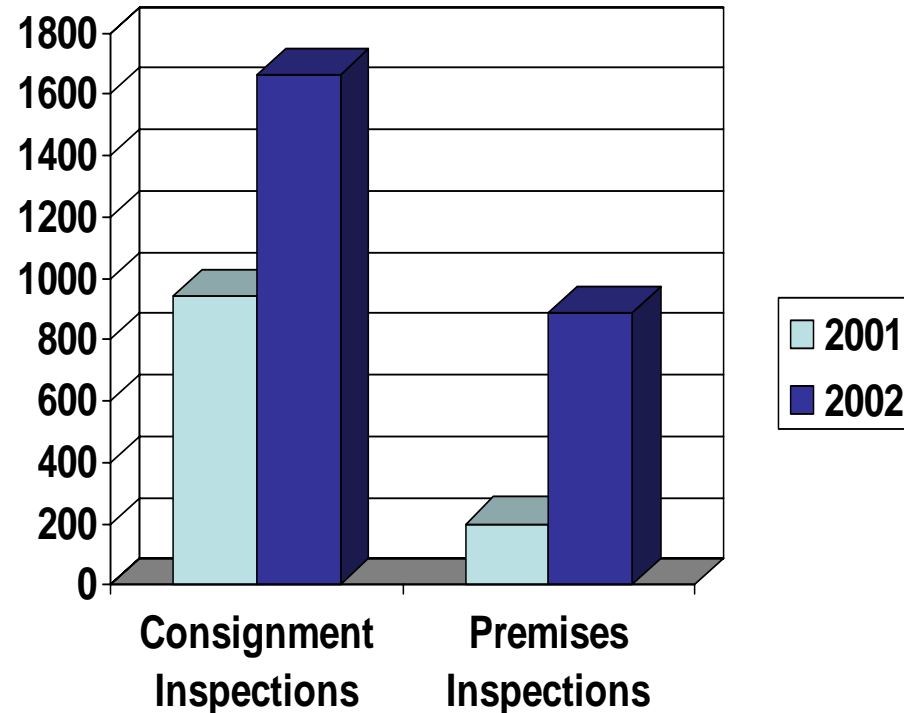
- 👉 To perform POE & PMS using established system
- 👉 To conduct screening of targeted products
- 👉 To develop sample tracking SOPs and register log book to ensure smooth flow of samples from field inspectors to Lab and results back to inspectors
- 👉 To conduct regular monitoring and evaluation to ensure smooth running of the program

Program Activities...

4. Establishing Personal Digital Assistance (PDA)
Inspections data logging system

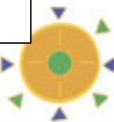
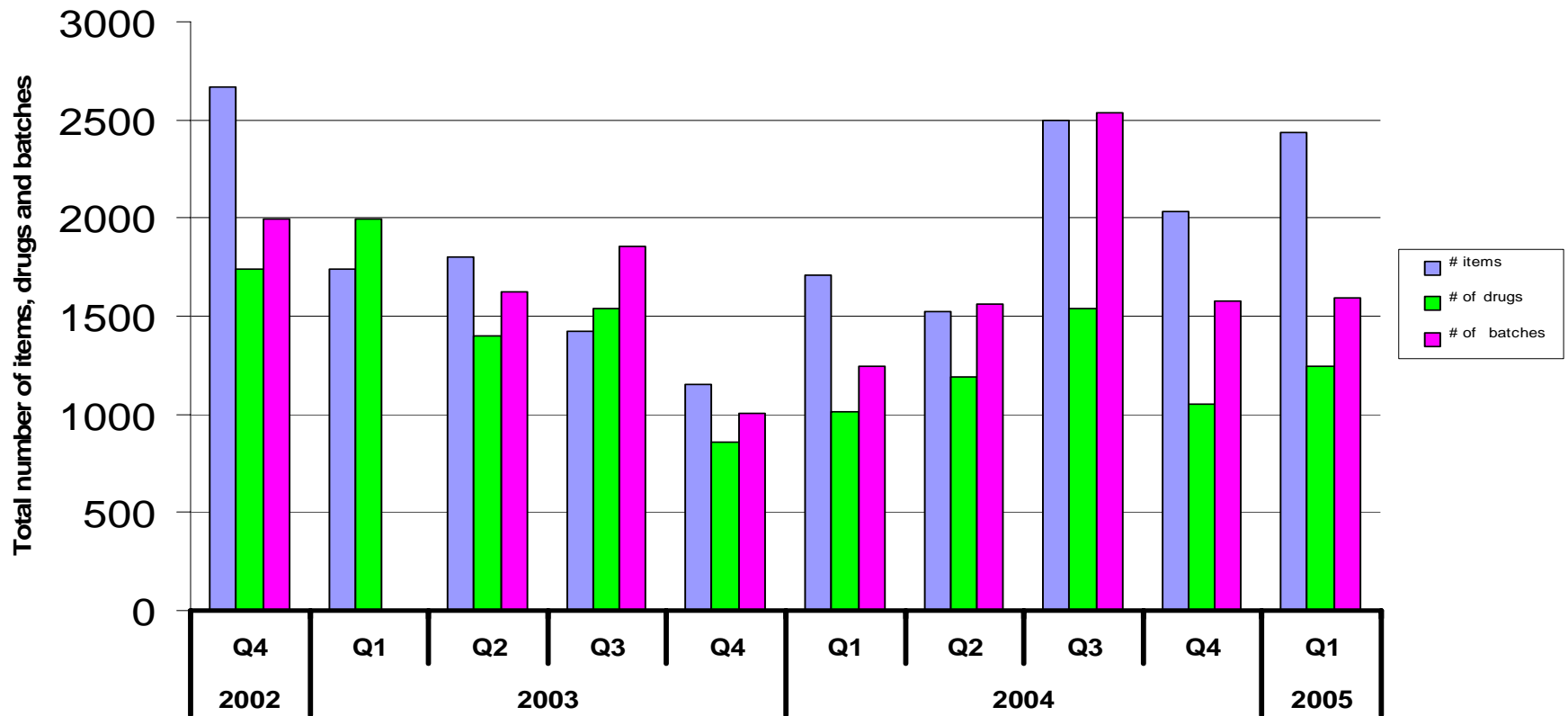
Results

- ↑ Port of entry inspections increased from **942** consignments in 2001 to **1,665** in 2002,
- ↑ Premises inspections from **201** premises in 2001 to **887** in 2002.
- ↑ Trend maintained since then
- ↑ 1,257 samples were screened with failure rate 3.7% including 5 counterfeit drugs.



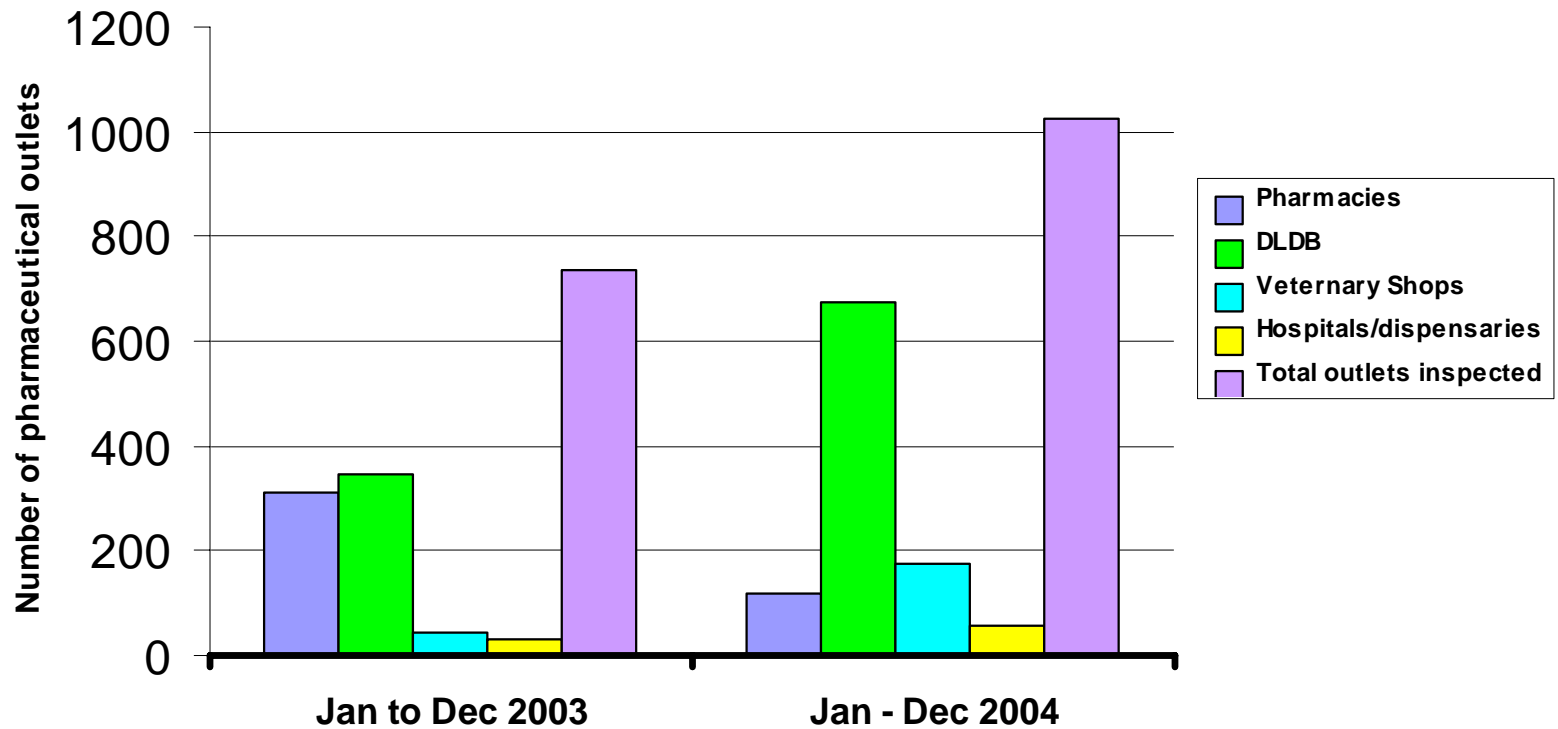
POE Inspection

Graph showing number of imported pharmaceuticals inspected at ports of entry from October 2002 to April 2005



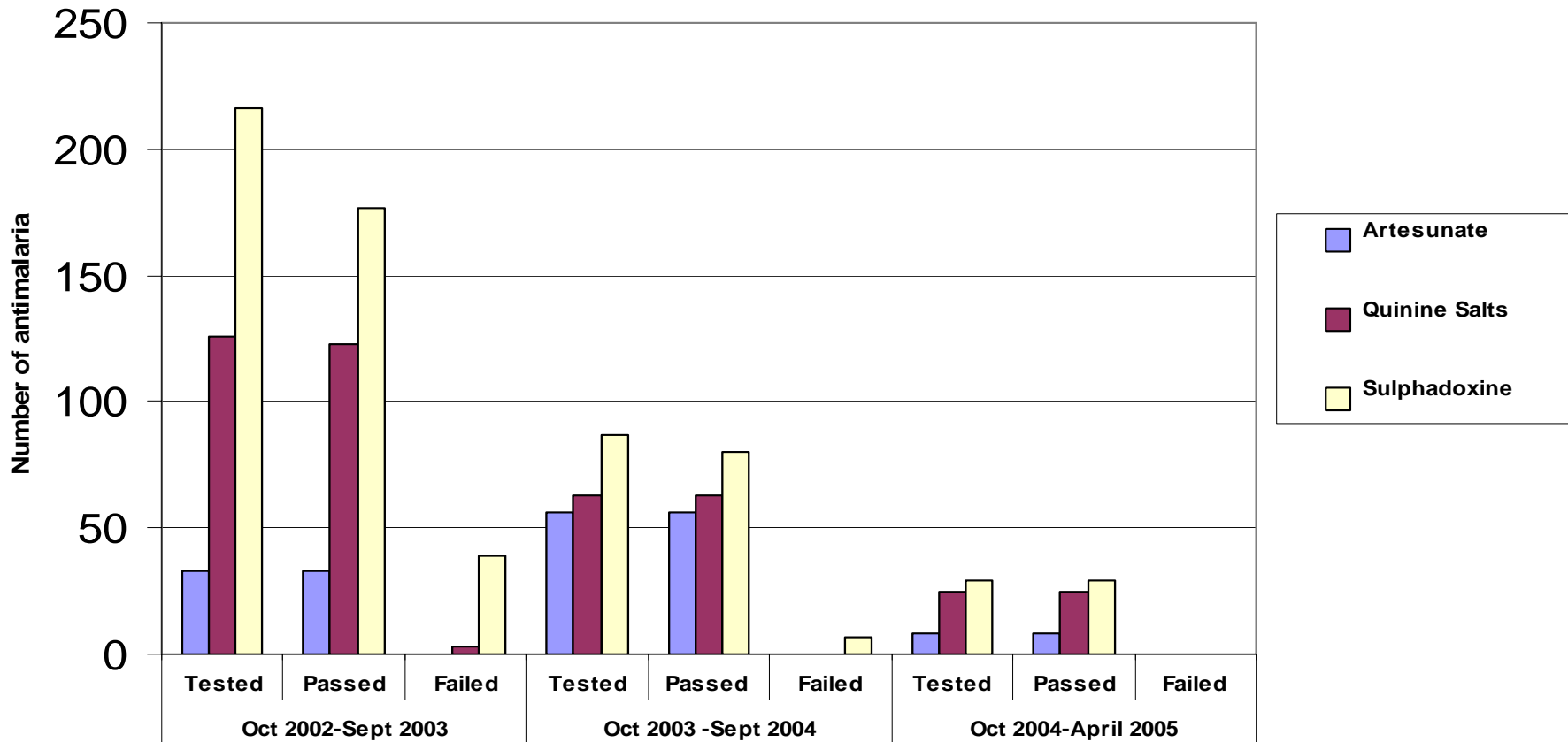
PMS activities

Graph showing total number of Pharmaceutical outlets inspected for the year 2003 and 2004



Screening activities

Graph showing the results of antimalaria drugs screened/tested from October 2002 to April 2005



Compliance actions

- ❖ At POEs, confiscations/detention of 22 consignments
 - 👉 failing physical examination (5)
 - 👉 failing documentation (4)
 - 👉 having expired drugs (5)
 - 👉 having unregistered drugs (3)
 - 👉 failing labeling requirements (3)
 - 👉 unauthorized products (2)

To expand the program by including more target drugs

- 👉 Include 6 mostly used antibiotic for screening
- 👉 Train inspectors on selected antibiotics screening
- 👉 Train inspectors on six ARV drug screening
- 👉 Include six antiretroviral done at POE and during PMS

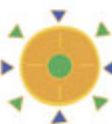
To expand the program by training structured inspection system to health workers in all zones

Zone	Number of trained health workers
Central	52
Eastren	43
Lake zone	78
Southern Highlands	66
Southern	32
Northern	58

–Expand the program geographically- More screening centers



- Lake Zone
- Central Zone
- Southern Highlands Zone
- Eastern Zone
- Souther Zone
- Northern Zone
- Minilab Centers





EXPERIENCE

- ❖ Despite high volumes and pressure at port of entries there is no unnecessary delay caused by the introduction of Minilab® in terms of clearance of legitimate products entering the market.
- ❖ The use of PDA facilitate data collection and shorten time required to fill the forms. Reduced cost versus use of paper forms
- ❖ The Minilab® testing cannot be used as a sole decisive tool to determine quality of SP tablets due to dissolution problem of these formulations as experienced by TFDA Laboratory.

Experience...

- ❖ Sensitisations of stakeholders to quality requirement facilitated the implementation of the program.
- ❖ Almost all samples that failed screening testing also failed full monograph testing at the National Drugs Quality Control Laboratory (5 counterfeit products encountered).

CONCLUSION

- ❖ The large number of samples screened since the launch of this program shows that the use of Minilab® is cost effective tool in drugs quality assurance, 1.5 hours per sample
- ❖ When coupled with a structured POE and PMS inspections the Minilab can greatly contribute towards improving quality of drugs in the market.

THE END

Thank you for listening!