

Improving Antimalarial Drug Quality in Africa

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President's Malaria initiative



President's Malaria Initiative

President's Malaria Initiative – an interagency USG initiative led by USAID with HHS/CDC as key partner



Goal: Reduce malaria-related mortality by 50% in 15 focus countries

Targets: 85% coverage of vulnerable groups with 4 proven and effective interventions:

- ITNs
- IRS
- IPTp
- ACTs

PMI Focus Countries

- **FY06: Angola, Tanzania, Uganda**
- **FY07: Rwanda, Senegal, Mozambique, and Malawi**
- **FY08: Benin, Ghana, Mali, Kenya, Liberia, Madagascar, Zambia, Ethiopia (Oromiya Region)**

Year 3 Progress: Jan 1-Dec 31, 2008

PMI invests heavily in ACTs and other pharmaceutical procurements

- **Treatment:**
 - 15.6 million ACT treatments procured ←
 - Over 35,397 HWs trained
 - Over 2 million RDTs procured ←
- **Prevention**
 - IRS: >24 million people covered
 - ITNs: > 6 million LLINs procured
- **Malaria in pregnancy:**
 - 1 million IPTp treatments procured ←
 - over 14,000 HWs trained

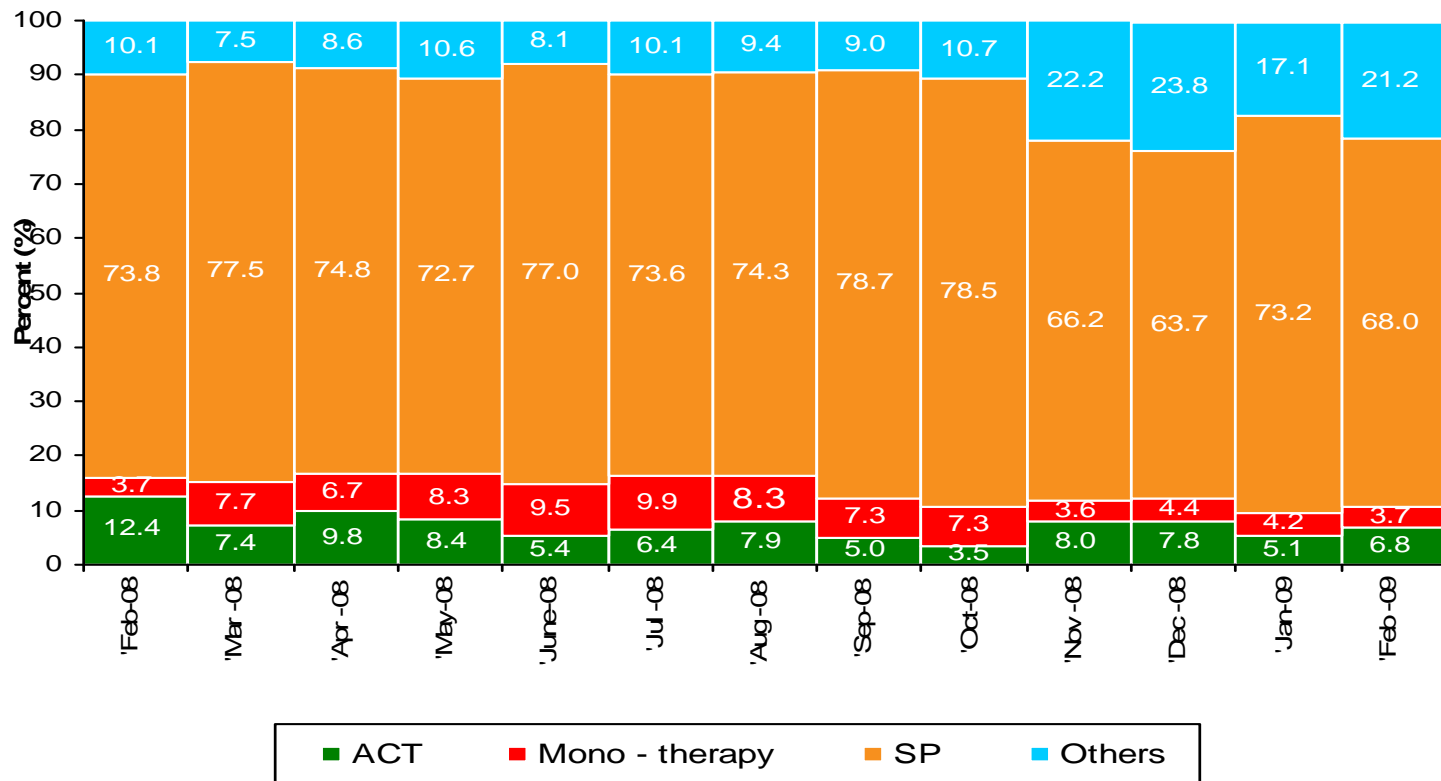


Quality of ACTs and Antimalarial Drugs

- Growing evidence that substandard and counterfeit antimalarial medicines pose a growing threat to treatment goals in Africa, particularly in private sector
 - “Antimalarial Drug Quality in the Most Severely Malarious Parts of Africa—A Six Country Study”; Bate et. al.
 - “Manslaughter by Fake Artesunate in Asia—Will Africa Be Next?”; Newton et.al.

Tanzania—Proliferation of Monotherapy, ACTs of Unknown Quality, and Inefficacious Medicines (SP, AQ) in Private Sector

Private Sector Sales of Malaria Treatments--Tanzania (five regions)



**T Marc Social Marketing Project; AED--Retail audit data Feb 08-Feb 09

The Private Market for Antimalarials



Challenges to Scaling Up Access to High Quality Antimalarial Drugs

Complex Regulatory Landscape for Antimalarial Drugs

- Lack of incentives for manufacturers to seek FDA or SRA approval
 - ➔ malaria is not endemic in developed countries
 - so, there is no market
- Only one ACT (artemether-lumefantrine) has been approved by an SRA (Swiss Medic and FDA)
- Four brands of artesunate-amodiaquine (including 1 FDC) have been approved by WHO Pre-qualification project
- Several other lifesaving drugs lack any regulatory approval status
 - pre-referral severe malaria drugs
 - other ACT combinations
- Local pharmaceutical industry influences local drug regulatory authorities

Challenges to Scaling Up Access to High Quality Antimalarial Drugs

Ensuring Access to High Quality Antimalarial Treatment at the Country Level



- **Public Sector**

- Quality of antimalarial drugs can be controlled to a certain extent through the procurement selection and drug quality testing process
- Weak supply chains and distribution systems, e.g. poor storage, exposure to humidity and heat, and transport issues

- **Private Sector**

- Very difficult to regulate drugs in the private sector
- Most countries do not allow OTC purchase of ACTs in private shops

PMI Approach to Scaling Up Access to High Quality Antimalarials— Principles

- Quality Control and Chain of Custody for PMI procurements
- Close partnership and capacity building with host government
 - national malaria control programs
 - national drug regulatory authorities
- Partnership and coordination with international partners
 - Global Fund
 - World Bank
 - WHO
 - UNICEF

PMI Approach to Scaling Up Access to High Quality Antimalarials—

Procurement and Selection of Drugs

- All PMI drug procurements comply with applicable statutes and regulations
- Drugs with FDA or SRA approval status are preferred, if recommended and available
- But most antimalarial drugs do not meet this criteria
 - So, PMI reviews each drug procurement request on a case by case basis to assess the evidence for quality



PMI Approach to Scaling Up Access to High Quality Antimalarials—

Procurement and Selection of Drugs

- In addition, PMI requires
 - Confirmation of SRA approval, WHO Prequalification status, or prequalified wholesalers (for generic multi-source drugs)
 - Consistency with WHO treatment recommendations
 - Consistency with national treatment guidelines
 - Confirmation of satisfactory GMP inspection by WHO, US FDA, or SRA
 - Quality testing of drugs procured with PMI funds prior to shipment to countries
 - Documentation on chain of custody until consignment through shipping documents with batch numbers, bills of lading, and proof of delivery

PMI Approach to Scaling Up Access to High Quality Antimalarials—

In-Country Support

- Strengthening all aspects of the pharmaceutical supply chain, including
 - storage
 - transportation
 - inventory
 - logistics information systems.
- Support to national regulatory authorities to improve drug quality through (9 out of 15 PMI countries have dedicated FY09 funding)
 - post-market surveillance
 - regulation
 - enforcement
 - in-country drug testing (Mini-labs)
- Working with host governments to develop and implement strategies for increasing access to high quality ACTs through the private sector (Tanzania, Rwanda)



PMI Approach to Scaling Up Access to High Quality Antimalarials—

Other Key Success Factors

- Local media involvement is helpful in generating political will and action
 - “Kenya-16% of Malaria Drugs Fake”, reported in the Daily Nation, May 29, 2008.
- Political will and capacity of local food and drug regulatory authority is critical
 - Tanzania-“Fake Drugs Abound—TFDA bans importation of Metakelfin as fake drugs are found”, reported in the Citizen, April 2, 2009.

Conclusion

- Urgent attention to drug quality issues is critical to saving lives and successfully achieving global treatment targets
- A comprehensive, holistic, systematic approach is required to support access to effective malaria treatment
- Donors and host governments need to collaborate on an ongoing basis to develop a coordinated, harmonized approach
- Strengthening national drug regulatory authority capacity and advocacy for appropriate regulation, quality assurance testing, and enforcement is critical