

# The RBM Partnership

Day 3

Eighteenth Meeting of the Board

Geneva, 14 May 2010



## 18<sup>th</sup> RBM Partnership Board meeting agenda

### Day 3

08.00	Welcome Coffee
09.00	Session V (Special Ministerial Session)
10.15	Break
10.45	Containing the spread of drug resistance
13.00	Lunch
14.00	Session VI (RBM strategic response to challenges)
15.00	Proposed resolution pre-qualification
15.30	Break
16.00	RBM Board Vice Chair Election
16.30	19 <sup>th</sup> RBM Board Meeting – Venue & Date
17.00	AOB



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## Health Systems Strengthening Through Malaria Funding: Zambia's Experience

*Presented by Honorable Kapembwa Simbao, MP  
Minister of Health  
Zambia  
18<sup>th</sup> RBM Board Meeting  
Geneva , 14<sup>th</sup> May 2010*

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## Presentation Overview

- Background-NMCP goals, targets**
- Program impact, coverage**
- Factors facilitating achievements**
- Health Systems Challenges**
- Health systems strengthening**
  - Specific Health systems challenges
- Conclusions**

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 **background** 

Malaria;

- Is no longer the leading cause of morbidity in Zambia although:
  - *about 3 million cases and 3,000 deaths annually at HF's (HMIS)*
- A key priority outlined in the Zambia National Health Strategic Plan 2006-2010
- *A malaria 'free' Zambia*
- *Scaling up for impact. Focus on:*
  - *Prevention*
  - *Improving diagnosis and care*
  - *Effective program management*
  - *Empowering individuals and communities*
  - *Commitment to M&E*

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 **Malaria Interventions** 



**Prevention**

- ITNs, now exclusively LLINs
- Indoor Residual Spraying (IRS) in 36 districts, expanding to 54 in 2010
- Prevention of Malaria in Pregnancy- IPT(SP) and ITNs

**Case management**

- ACTs (Coartem©) first line treatment
- Improvements in diagnosis using microscopy and RDTs

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## National Goals

**National Strategic Plan 2006-2010**



**Reduction of malaria *incidence* by 75% and deaths due to malaria will be significantly reduced by the end of 2011**

**Reduction of all cause mortality by 20% in children under five**

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## Our Malaria Control Partners


Line Ministries  
WHO  
UNICEF  
Global Fund  
World Bank  
PMI - USAID / CDC

NGOs

- Health Systems Strengthening Program (HSSP)
- Society for Family Health (SFH)
- Reaching HIV/AIDS Affected People with Integrated Development and Support (RAPIDS)
- Health Communication Partnership (HCP)
- MACEPA

- Churches Health Association of Zambia (CHAZ)
- Japan International Cooperation Agency (JICA)
- More NGOs and groups
  - Malaria Consortium
  - Zambia Malaria Foundation
  - NHCs, CBOs
- Research Institutions - UNZA, TDRC, MIAM, Boston, Johns Hopkins, Liverpool, Kwazulu Natal, Tulane, Harvard
- Private Sector
  - Banks
  - Oil companies
  - Agro chemical companies
  - Copper Mining Companies
  - Agriculture companies
- And many more!!

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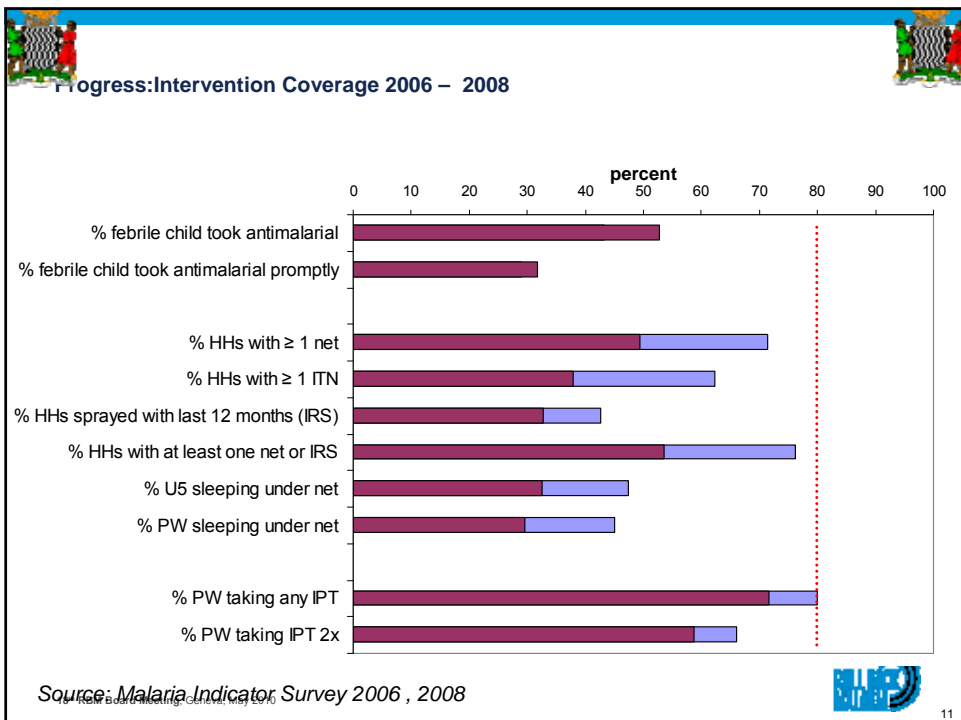
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**Progress-Impact**

**Attained 2010 RBM target of more than 50% reduction in malaria mortality.**

- Malaria deaths declined by 66% in H/F(2002-2008, WHO 2009)
- Parasite prevalence in U5 children declined by 53% 2006-2008 (MIS 2006, 2008)
- Severe Anemia in U5 children declined by 68% 2006-2008 (MIS 2006, 2008)
- All cause mortality for children under age 5 (U5MR) **decreased by 29%** comparing the periods ~1998-2002 to 2002-2007


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### Progress in Malaria Control-Zambia DHS 2007

Indicators from Zambia Demographic and Health Survey	2001-2002	2007
Under-five mortality	168/1000	119/1000
Percent of under five children who slept under an ITN the previous night	9.8%	28.6%
Percent of pregnant women who under an ITN the previous night	7.9%	32.7%
Percent of pregnant women who took an antimalarial drug during pregnancy	35.8%	86.5%



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### Progress: Intervention Coverage


Over 6,700 ITNs distributed since 2005

IRS protected 4 million people in 2009 compared to 1 million population in 2005.

IRS was scaled up to 36 districts in 2009 from 15 in 2005

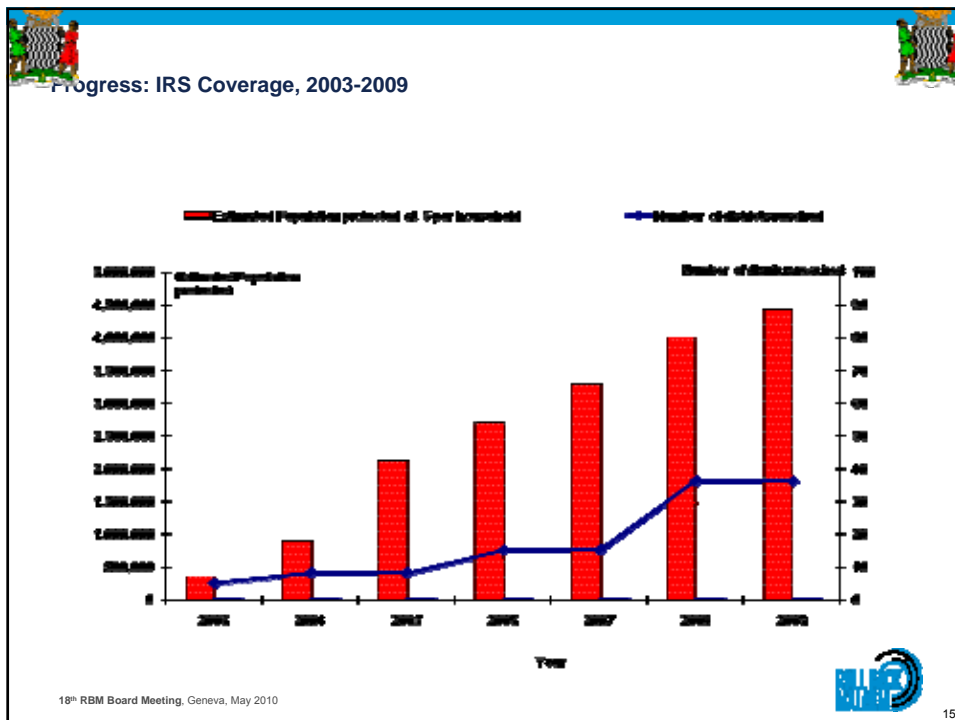
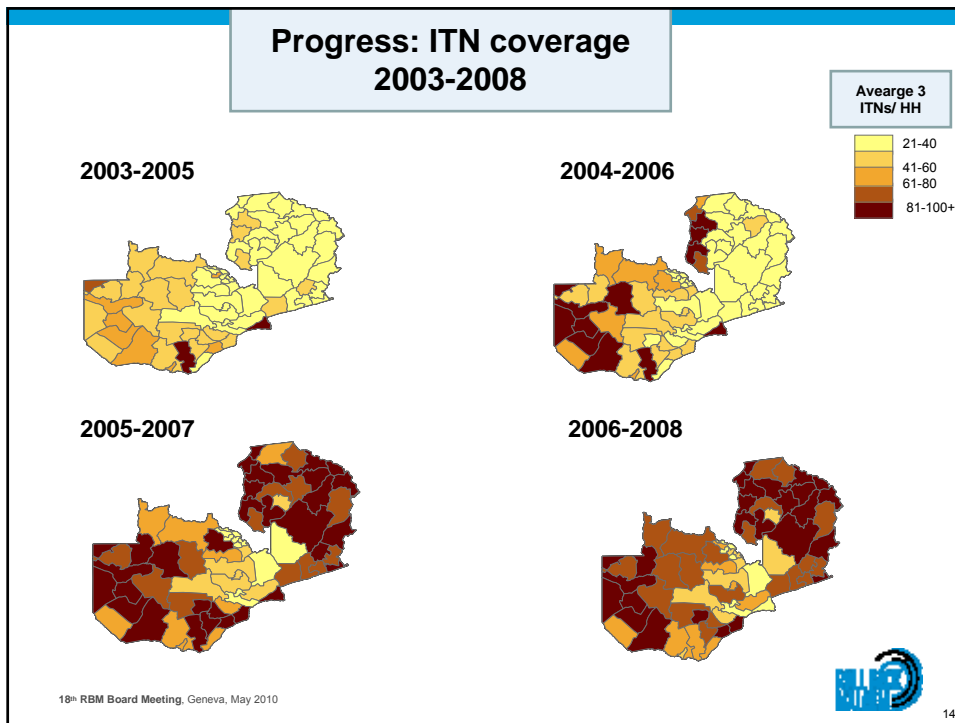
IRS to be scaled up to 54 out of 72 districts in 2010.



Fully digitized household enumeration of targeted spray areas in 11 districts



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## Progress-Malaria Case Management


**ACTs and RDTs rolled out nationwide**

- Diagnosis and treatment guidelines in place
- Microscopy 'gold standard'
- Quality Control / assurance in place



**Home management of malaria initiated**

- CHW training conducted in 21 districts; 600 trained
- Job aids developed and translated into 7 major languages
- Operations Research, IEC, M&E are guiding implementation

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## Government stewardship in malaria control

Increased funding for malaria control  
 Improved disbursement of the GRZ grant  
 Increased financing from bilateral, multilateral and private sector



Strengthening and coordination of partners under the stewardship and leadership of Government  
 Implementation of Sector Wide Approach (SWAp)/pooling of resources into the district basket funding leading to regular, predictable and sustained flow of resources  
 Implementation of the three –ones: one coordinating mechanism; one implementation and one monitoring plan

Shared Vision and strategies  
 National Development Plan  
 National Health Strategic Plan  
 National Malaria Control Strategic Plan

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## Government Action Underlying Success



Ensuring equitable access to cost effective malaria control interventions.

- **Taxes and Tariffs:**
  - Removal of taxes and tariffs on ITNs and all insecticides used in the prevention and control of malaria
- **Malaria Treatment:**
  - Artemisinin-Combined Therapy (ACTs) as FREE first line treatment for malaria countrywide
- **Removal of user fees**
  - User fees removed in all public health facilities in rural (56/72) districts
- **FREE ITNs & IRS**
  - Mass distribution free for 3/HH
  - MIP nets through ANCs and under five clinics also free
  - IRS at no cost to the household

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## Government Action Underlying Success



High level programme support:

- H.E The President
- Vice-President
- Minister of Health and other Ministers in line ministries
- Faith Based Organization
- Civil society
- uniformed forces

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## Health Systems Strengthening

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## Health Systems Challenges

- Human resources- numbers, skills, motivation
- Integration as service delivery mode
- Procurement and supply chain management
- Transport/infrastructure
- Communication for access and uptake of interventions

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## Strengthening Health Systems

**Sector Wide Approach:**



**Shared Vision and strategies**

- National Development Plan, 2006-2010
- National Health Strategic Plan, 2006-2010
- National Malaria Control Strategic Plan, 2006-2010
- Implementation of Three Ones  
*(Coordinating mechanism; implementation and monitoring plan)*

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## Human Resources-Capacity Building

**Systematic capacity building for H/Ws;**


**Improved case management**

- Through improved diagnostic capacity at all levels (RDTs, Microscopy).
- This improvement has trickled to assure diagnosis and proper management for other disease conditions



**Improved M & E capacity**

- A pool of expertise in M&E at all levels in:
  - malaria surveys (since 2004) and special skills e.g. In use of Personal Digital Assistant (PDA)
  - HMIS to validate, analyze data and use it for action.

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## Retention of Human Resources



**Provision of non-monetary incentive has helped MOH to retain staff in hard-to-reach health centres**

- Provision of solar panels to health facilities and staff houses
- Provision of transport (vehicles, motorbikes and bicycles) for H/W to implement programs
- Radio equipment for communication

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## Human Resources- Delivery Platform

**Home Management of Malaria program(HMM) has trained 600 CHWs to diagnose and treat malaria in the community**

**The same CHW provide other disease program interventions including mobilization for participation in health**

- Increased community access to health services
- Decongested H/F to allow H/W to treat severe cases
- Increased community participation in health

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### **Improved Transport System/Supply Chain**

Different types of transport procured at all levels:

Central level

District level

Rural Health Centres

Transport used for:

Moving malaria and other disease commodities

Outreach programs for all disease programs

Disease program implementation/monitoring



### **Infrastructure**

Solar panels procured and installed in 564 health centres in hard to reach areas

The benefits have improved health service delivery in the rural health centres;

- Permits attendance to clients in the night
- Facilitates improved storage for medicines and other medical supplies at health centres



## Improved Communication



### Radio communication in 66 health facilities

- A good and effective referral system not only for malaria patients but for all patients especially expectant mothers.



## Conclusion



As malaria control programs move towards sustained control and eventually Elimination;  
solid leadership,  
Community engagement and participation  
timely implementation and evaluation  
sustained adequate investments,  
are critical.

The sustained and adequate investments in the Malaria programs will continue to contribute to overall health systems strengthening in the context of integration



## Zambia's Victoria Falls



**THANK YOU**

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**“SMS for Life”**  
Improving medicine access through innovation

A Roll Back Malaria Partnership Initiative

## Tanzania Pilot Results

Prof. David Mwakyusa



The United Republic of Tanzania  
Ministry of Health and Social Welfare

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1 | “SMS for Life” | Geneva, May 2010



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## SMS for Life

### Project Purpose

- Bring visibility to medicine stock at the health facility level
- Eliminate stock-outs of life-saving anti-malarials
- Ensure patients have access to the medicines they need, when and where they need them.
- Demonstrate the effectiveness of a public-private partnership model.

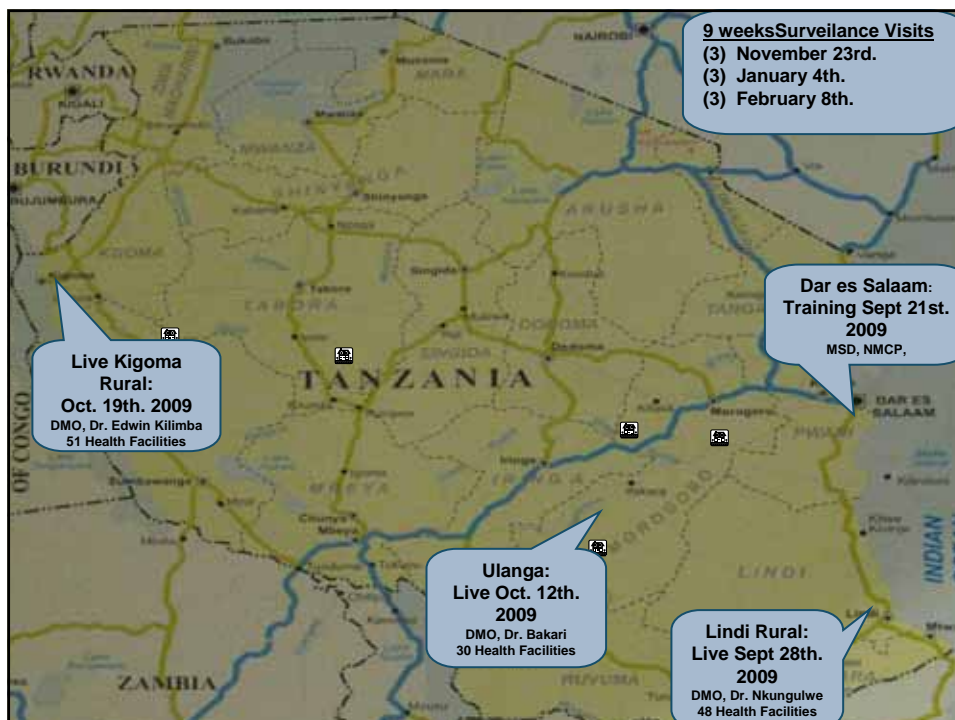


The United Republic of Tanzania  
Ministry of Health and Social Welfare



11th NMCP Board Meeting, Geneva, January 2010

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# “SMS for Life”

Improving medicine access through innovation

## A Roll Back Malaria Partnership Initiative

**1** Pokea SMS unaoitisha habari za Akiba ya madawa

**2** Hesabu Akiba ya Madawa

**3** Andika matokeo na tuma SMS kwenya nambari: 15000

**4** Pokea muda wa maongezi wa bure

1 | "SMS for Life" Board | May 2010

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Stock Levels

This report shows the level of stock available for each of the drug types, across each district.

- Red figures represent a stock subject the line stock has been zero.
- represents no stock report provided.
- Click on a Health Facility for detailed analysis.

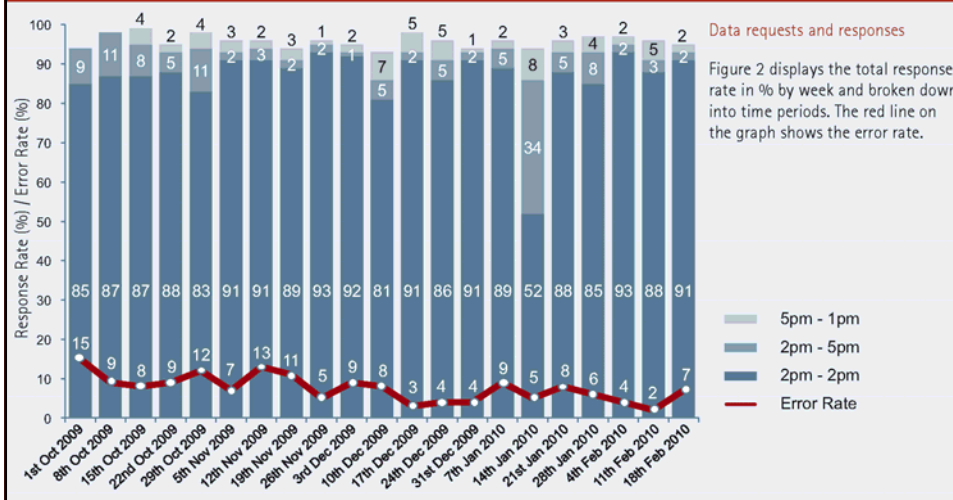
Search

Choose:

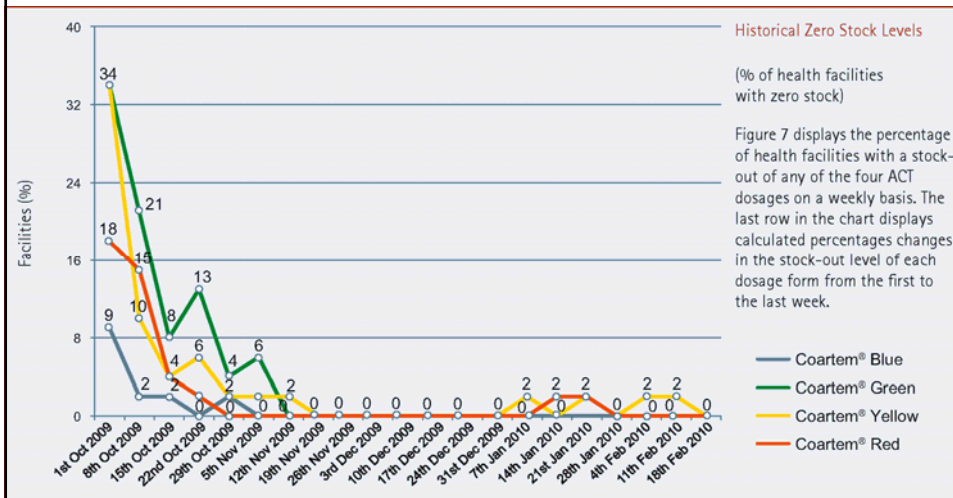
1 Small Rural District	Coartem Blue	Coartem Green	Coartem Yellow	Coartem Red	Outlines
020101 PITOMANJA	21	3	9	12	116
020102 NYANGAMARA	7	5	6	21	170
020103 RANGABO	3	8	10	10	111
020108 RUTAMBA	17	2	9	10	147
020120 CHINDA	19	5	27	10	120
020180 IDHUTA	6	4	5	5	129
020181 DABA	16	5	9	7	41
020142 PRIGAPALE	20	14	11	4	150
020143 KUMENI	10	7	11	9	162
020188 NYANGALA	15	5	8	9	440



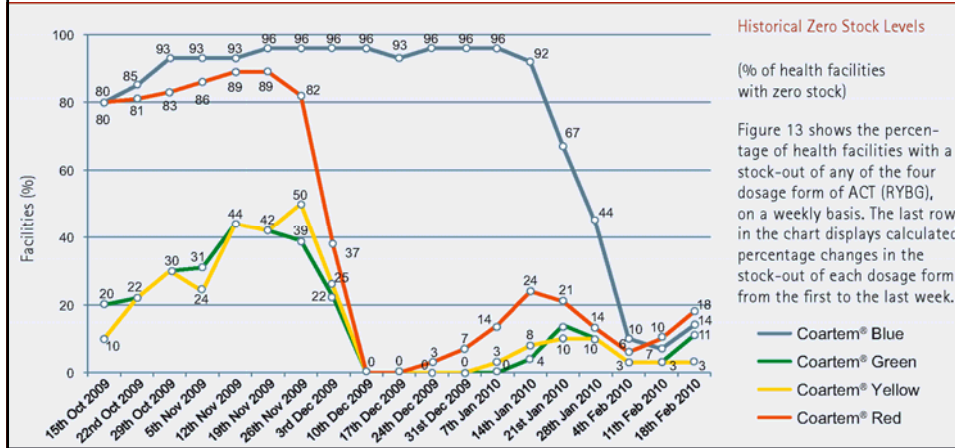
Average response rate of 95%  
 Data accuracy rate of 94% (physical count)  
 Data accessed on a daily basis (system log)



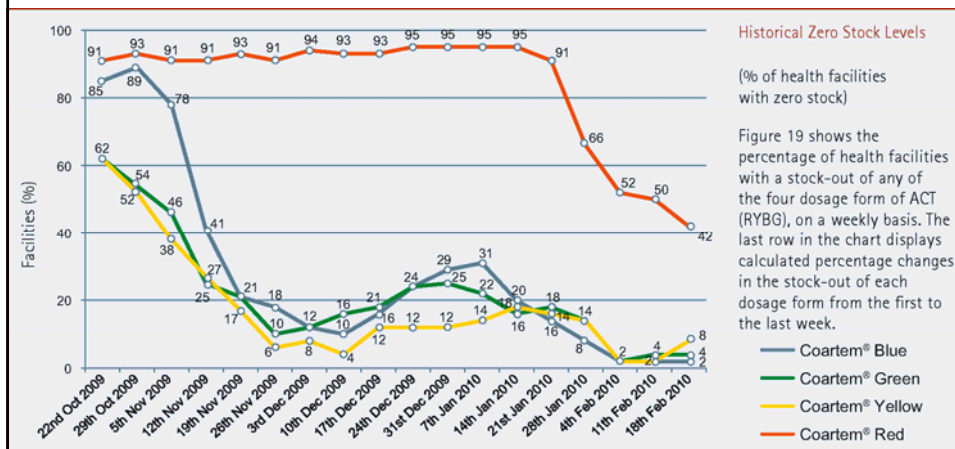
Lindi Rural – % of the 48 facilities with a stock-out by ACT dosage form.  
 (57% stock-out to 0% stock-out)



**Ulanga – % of the 30 facilities with a stock-out by ACT dosage form  
(87% stock-out to 22% stock-out)**



**Kigoma Rural – % of the 51 facilities with a stock-out by ACT dosage form  
(93% stock-out to 47% stock-out)**



## Results – all 5 Medicines

At the start of the Pilot only 29 of the 129 facilities had all 5 medicines in stock (*77% stock-out*)

At the end of the pilot 96 of the 129 had all 5 medicines in stock (*26% stock-out*)

A threefold or 300% improvement.



## Results ACTs

At the start of the Pilot 26% of facilities had no ACT of any dosage form in stock.

At the end of the Pilot 99% of facilities had at least one dose form of ACT in stock.



### **Pilot project team recommendations:**

**Implement the SMS for Life solution in all districts of Tanzania**

**Encourage the use the SMS for Life solution to track other medicines of priority in your national environment.**

**Apply the SMS for Life solution to disease surveillance.**

**Implement SMS for Life in other African and non- African countries that have a need to eliminate stock-outs at health facility level.**



### **Costs to Implement**

**Implementation and First Year costs are approx. \$5000 per District. i.e. \$650,000 for 131 Districts in Tanzania.**

**Operational costs in the following years, is approx. \$5000 per District per Year.**



Thank You



**for your time and attention**

11 "SMS for Life" | Geneva, May 2010  
18th RBM Board Meeting, Geneva, May 2010



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## 18th RBM Partnership Board meeting agenda

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- 08.00 Welcome Coffee
  - 09.00 Introductory Remarks & Special Session Objectives
  - 09.15 Country example on progress towards 2010 targets with focus on:
    - Health Systems Strengthening through malaria funding - Zambia
    - Improving malaria control through innovative technologies - Tanzania UR
    - Discussions
  - 10.15 Coffee/Tea Break
  - 10.45 Containing the spread of drug resistance:
    - Eliminating oral artemisinin-based monotherapies and substandard ACTs - WHO/GMP
  - 13.00 Lunch

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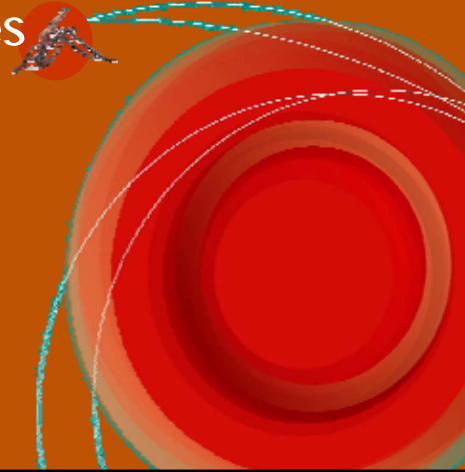
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# Withdrawal of oral artemisinin-based monotherapies to prolong the useful therapeutic life of artemisinin derivatives

Dr. Robert D. Newman  
Director  
WHO Global Malaria Programme  
3 May 2010, Geneva



## Outline

- Artemisinin resistance – nature of the problem
- Why monitoring of artemisinin resistance is a critical part of responding to the threat
- The primary role of oral artemisinin-based monotherapies in promoting the spread of resistance
- How countries can act to halt the marketing and use of oral artemisinin-based monotherapies



## The spread of drug resistance

Person A: Malaria parasites – sensitive and resistant



Oral artemisinin monotherapy

Person A: Resistant malaria parasites



Mosquito



Person B: Resistant malaria parasites

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## Rapid development of resistance to monotherapies

Antimalarial drug	Year of introduction	1st case of resistance	
● Quinine	1632	1910	
● Chloroquine	1945	1957	12 years
● Proguanil	1948	1949	1 year
● Sulfadoxine-pyrimethamine	1967	1967	<1 year
● Mefloquine	1977	1982	5 years
● Atovaquone	1996	1996	<1 year
● Artemisinin derivatives	1990	2009	20 years?

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ORIGINAL ARTICLE

## Artemisinin Resistance in *Plasmodium falciparum* Malaria

Arjen M. Dondorp, M.D., François Nosten, M.D., Poravuth Yi, M.D.,  
Debashish Das, M.D., Aung Phae Phyo, M.D., Joel Tarning, Ph.D.,  
Khin Maung Lwin, M.D., Frederic Ariey, M.D., Warunee Hanpithakpong, Ph.D.,  
Sue J. Lee, Ph.D., Pascal Ringwald, M.D., Kamolrat Silamut, Ph.D.,  
Mallika Imwong, Ph.D., Kesinee Chotivanich, Ph.D., Pharath Lim, M.D.,  
Trent Herdman, Ph.D., Sen Sam An, Shunmay Yeung, Ph.D.,  
Pratap Singhasivanon, M.D., Nicholas P.J. Day, D.M., Niklas Lindegardh, Ph.D.,  
Duong Socheat, M.D., and Nicholas J. White, F.R.S.

N ENGL J MED 361:5 NEJM.ORG JULY 30, 2009



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## Artemisinin resistance

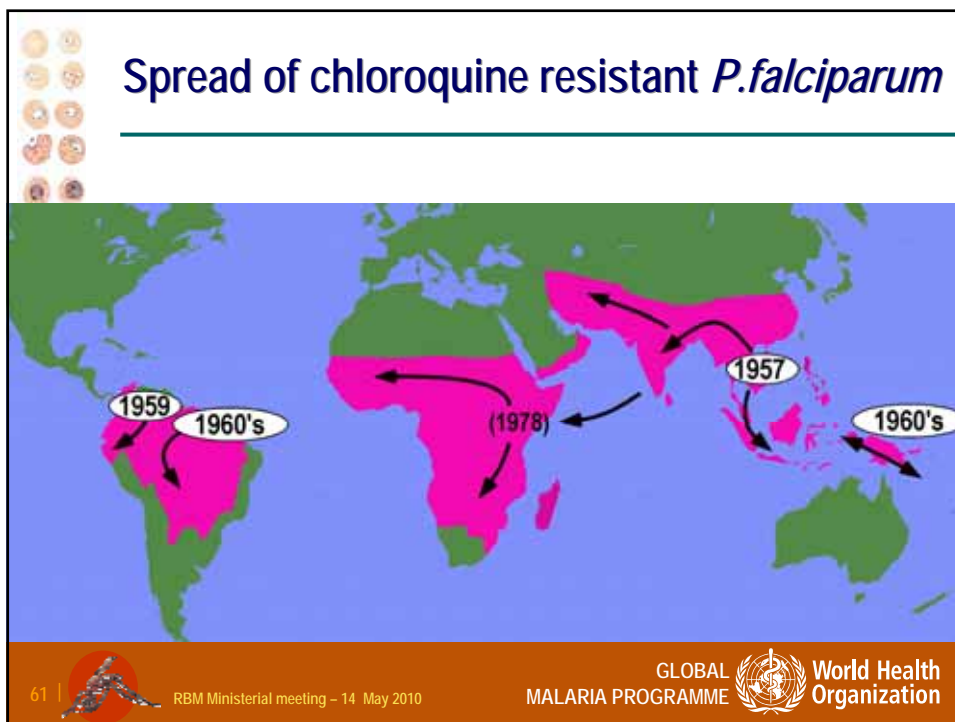


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## What is the mechanism or artemisinin resistance?

- Not yet clear despite much research
- There is not yet an identified genetic marker in the parasite
  - Cannot currently screen populations for resistant parasites
- As a result, the only way to monitor for artemisinin resistance is through in vivo drug efficacy studies

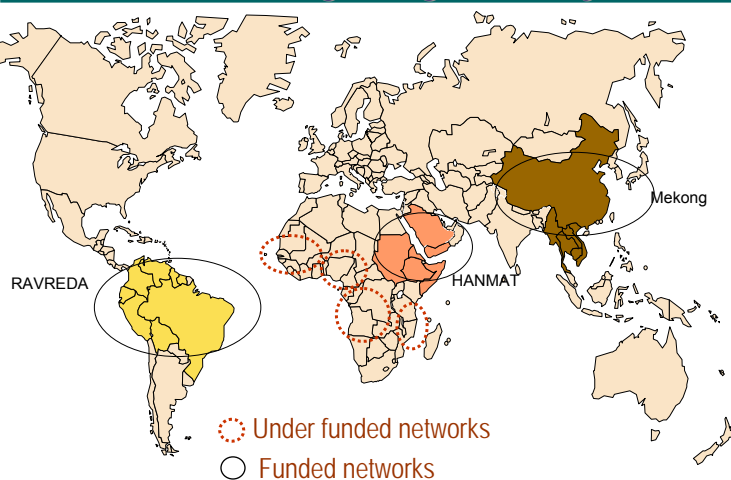


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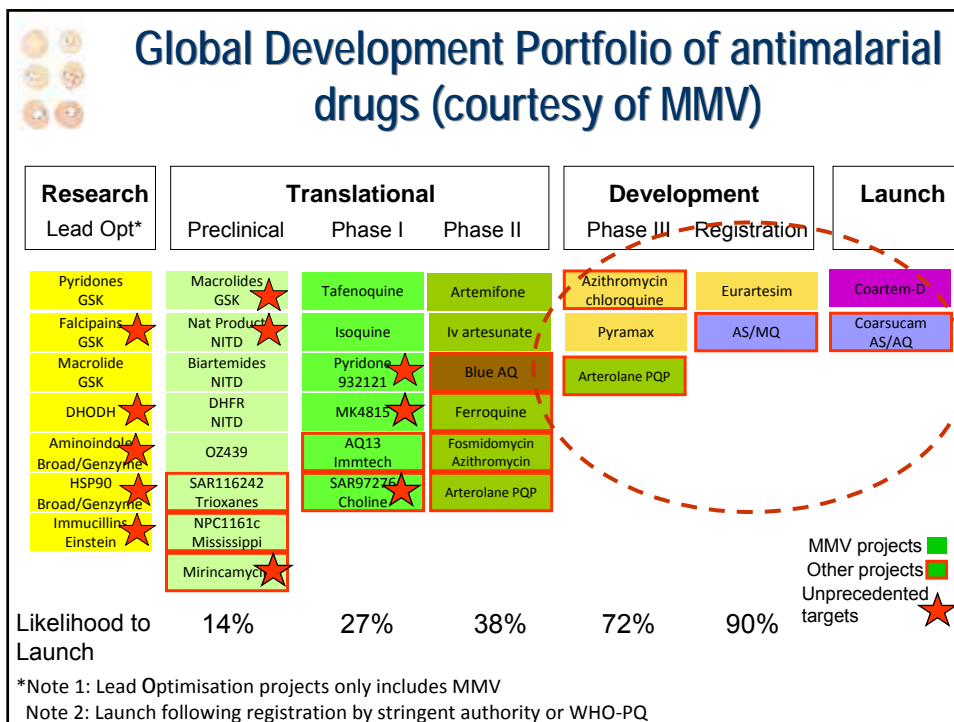


## Regional and sub-regional networks on monitoring drug efficacy



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## Strategies to contain antimalarial drug resistance

- Increase vector control efforts to reduce transmission
- Promote access to effective ACTs with laboratory confirmation of malaria (microscopy and rapid diagnostic tests)
- Remove oral monotherapies and sub-standard medicines from the market
- Remove drug pressure against the resistant medicines
- Monitor the therapeutic efficacy of antimalarial medicines
  - to replace ineffective ACTs in national malaria treatment policies
- Ensure a robust pipeline of new antimalarial combination medicines

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WHO calls for...

"It is critical that artemisinins be used correctly," said Dr LEE Jong-wook, WHO's Director-General. "We request pharmaceutical companies to immediately stop marketing single-drug artemisinin tablets and instead market artemisinin combination therapies only. The new treatment guidelines we are releasing today provide countries with clear and evidence-based direction on the best treatment options for malaria."

According to the new WHO malaria treatment guidelines, uncomplicated falciparum malaria must be treated with ACTs and not by artemisinin alone or any other monotherapy.

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Clinical trials of artemisinin and its derivatives in the treatment of malaria in China

Guo-Qiao Li, Xing-Bo Guo, Lin-Chun Fu, Hua-Xiang Jian and Xin-Hua Wang *Sanya Tropical Medicine Institute, Guangzhou College of Traditional Chinese Medicine, Guangzhou, People's Republic of China*

**Introduction**  
Since 1979, several different formulations of artemisinin

Table. The relation between course of treatment and recrudescence of malaria

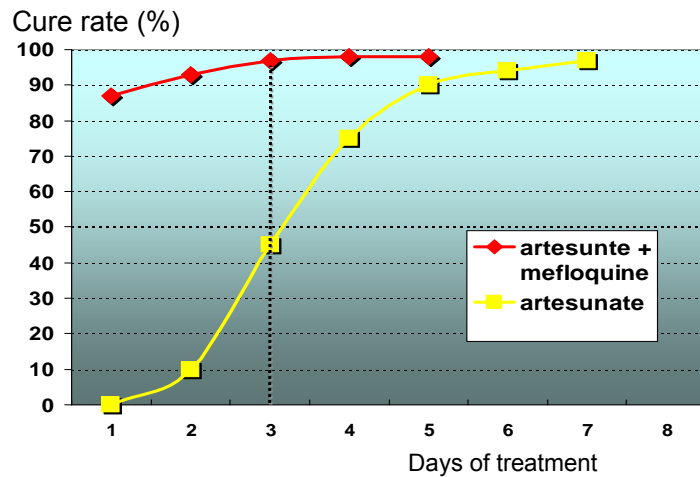
Drug	Treatment course <sup>a</sup>					
	3 d		5 d		7 d	
Artemisinin suppositories	50/113 (44%)					
Artesunate						
Tablets	30/56 (54%)		7/144 (5%)			
Intramuscular	13/25 (52%)		9/82 (10%)		1/40 (2.5%)	
Intravenous	44/89 (49%)				2/36 (6%)	
Artemether tablets	14/30 (47%)		5/97 (5%)		2/41 (5%)	
Dihydroartemisinin tablets	12/25 (48%)		3/50 (6%)		4/205 (2%)	
Total	163/338 (48%)		24/373 (6%)		9/322 (3%)	

<sup>a</sup>Recrudescence rates are shown as no. of recrudescences/no. treated (with percentages in parentheses).

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## Therapeutic efficacy of artesunate monotherapy versus ACT



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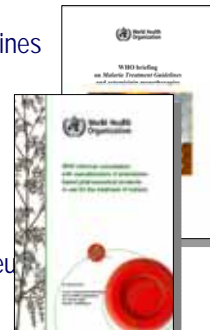


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## Steps to implement WHO recommendations

1. 19 January 2006 – WHO Press Release
2. Monitoring marketing practices and position of NDRA on <http://malaria.who.int>
3. Dissemination of WHO position via WHO Offices, WHO staff briefings, inter-country and regional meetings with MOH officials
4. 19 April 2006 – WHO technical briefing on malaria guidelines and artemisinin monotherapies
5. Alignment of funding and procurement agencies
6. 23 May 2007 - WHA Resolution 60.18
7. 24 August 2007 – WHO informal consultation with manufacturers of artemisinin-based antimalarials
8. WHO country meetings with NDRA, NMCP and pharmaceutical companies (India, China, Pakistan, Viet Nam)



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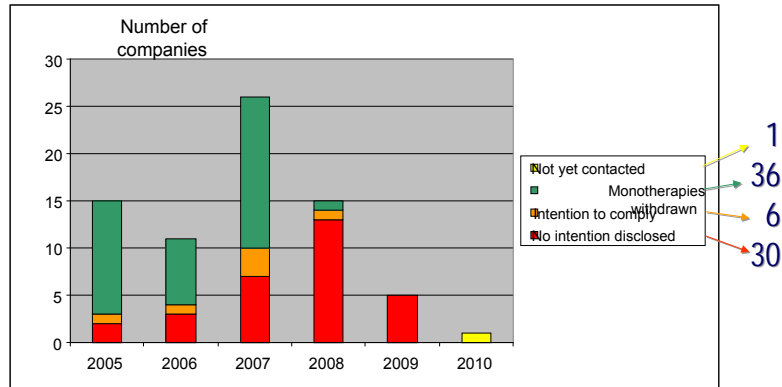
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## Response to WHO appeal of 73 manufacturers of oral artemisinin-based monotherapies

by year of identification by WHO  
(last update on 9.4.2010)



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## Main challenges

- A number of companies do not respond to WHO appeal
- Most of "non-responders" market oral artemisinin monotherapies
- Poorly regulated pharmaceutical market in endemic countries
- Limited access to ACT: i) slow roll-out of ACTs in the public sector and ii) limited penetration of ACTs in the private sector
- Manufacturing of sub-standard products exploiting "niche market" left open by companies complying to WHO recommendations
- Need of multiple sources of information for monitoring

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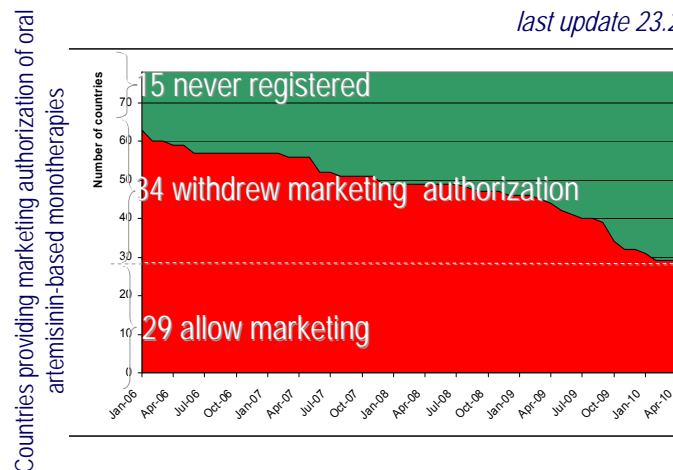


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## 29 countries provide marketing authorization of oral artemisinin-based monotherapies

last update 23.2.2010



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## Phasing out of oral artemisinin-based monotherapies: Examples of country success stories

- **Benin:** Consensus meeting in March 2006 – Agreement on transitional period – Critical step: large-scale availability of ACTs
- **China:** Meeting in October 2006 – Areas of collaboration – 2007: only ACTs used for drug donation programmes - 2008: **De-listing** of monotherapies from the national treatment guidelines
- **Pakistan:** May 2007: Consensus meeting – November 2007: Importation stop – March 2008: **Withdrawal** of marketing authorizations
- **Viet Nam:** Since December 2007 dialogues with the country to phase out monotherapies - 2008: **De-listing** of monotherapies from national treatment guidelines
- **India:** Major role in exporting antimalarials – October 2008: Timelines for withdrawals were defined – December 2008: Decision of DCGI to **Withdraw** marketing authorizations over 6 months

## Phasing out chloroquine and SP in Burundi

- 2001 - efficacy studies comparing AS+AQ vs AL to evaluate potential alternatives to CQ (1<sup>st</sup>-line) and SP (2<sup>nd</sup>-line) for malaria treatment
- July 2003 – adoption of AS + AQ as 1<sup>st</sup>-line treatment based on study results
- November 2003 - introduction of the new medicine and MOH regulation (ordonnance) to remove CQ and SP from the market. Measures included:
  - stopping importation of CQ and SP,
  - active recall of CQ and SP from all public health facilities and Provincial warehouses
  - immediate stop of in-country distribution of CQ and SP stocks available at central level by the Centrale d'Achat des Médicaments Essentiels du Burundi (CAMEBU) and donation of these stocks to neighbouring countries still deploying these medicines, and
  - sales ban of CQ and SP products in the private sector.
- In 2008 the DNDi survey on ACT implementation in Burundi confirmed the complete absence of CQ and SP in both public and private sector health facilities, warehouses and pharmacies across the country.

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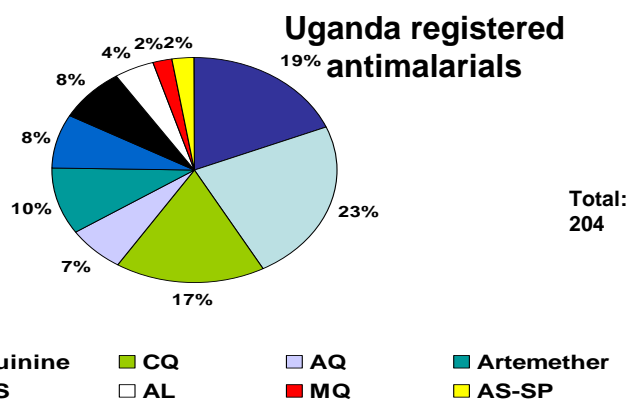
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## Monotherapy remains widely available

**ACTs account for only 14 %!**

- AL -4 %
- AS/AQ -8 %
- AS/SP -2 %




THE REPUBLIC OF UGANDA

Source: MoH-MMV supply side survey, 2007




## Decision of Cameroon: in May 2006




- 01 Alaxin 60mg comprimé (dihydroartémisinine) B/6 GVS Labs
- 02 Alaxin Suspension Buvable (dihydroartémisinine) F/60ml GVS Labs
- 03 Amodiaquine 200mg comprimé B/1000 CIPLA
- 04 Amodiaquine 200mg comprimé B/1000 MANNESH
- 05 Ainate 100 mg comprimé (artésunate) B/6 DAFRA PHARMA
- 06 Ainate 50 mg comprimé (artésunate) B/6 DAFRA PHARMA
- 07 Arsumax 50 mg comprimé (artésunate) B/12 SANOFI - AVENTIS
- 08 Artemax 60 mg comprimé (dihydroartémisinine) B/6 G.A. HARMACEUTICALS
- 09 Artémédine 40 mg gélule (artéméthér) B/12 KUNMUNG
- 10 Artémédine 50 mg comprimé (artéméthér) B/12 KUNMUNG
- 11 Atenam 50 mg comprimé (artéméthér) B/14 QUALIFAR
- 12 Atenam 60 mg comprimé (artéméthér) B/6 QUALIFAR
- 13 Artésiane 300 mg Enfant poudre pour suspension F/38g DAFRA PHARMA orale (artéméthér)
- 14 Artésunate 100 mg comprimé B/120 DAFRA PHARMA
- 15 Artésunate 50 mg comprimé B/120 DAFRA PHARMA
- 16 Artexin 60 mg comprimé (dihydroartémisinine) B/6 BDH Industries
- 17 Camoquin 200 mg comprimé (amodiaquine) B/9 PFIZER
- 18 Camoquin 200 mg comprimé (amodiaquine) B/25 blisters/3 PFIZER
- 19 Camoquin 200 mg comprimé (amodiaquine) B/25 blisters/3 PFIZER
- 20 Camoquin 200 mg comprimé (amodiaquine) B/24 PFIZER
- 21 Camoquin 600 mg comprimé (amodiaquine) B/3 PFIZER
- 22 Camoquin suspension buvable 50mg/5ml F/60ml PFIZER (amodiaquine)
- 23 Côtectin Suspension buvable (dihydroartémisinine) F/60ml COTEC
- 24 Côtectin 60 mg Comprimé (dihydroartémisinine) B/6 COTEC
- 25 Daraprim comprimé (pyriméthamine) B/30 GLAXOSMITHKLINE
- 26 Falcinil 50mg comprimé (artésunate) B/12 CIPLA
- 27 Flavoquine suspension buvable 50mg/5ml F/90ml SANOFI-AVENTIS (amodiaquine)
- 28 Flavoquine 200 mg comprimé (amodiaquine) B/16 SANOFI-AVENTIS
- 29 Flavoquine 200 mg comprimé (amodiaquine) B/240 SANOFI-AVENTIS
- 30 Gsunate forte comprimé (artésunate) B/6 GVS Labs
- 31 Gvitter Poudre pour suspension buvable (artéméthér) F/100ml GVS Labs
- 32 Halfan 250mg comprimé (halofantrine) B/6 GLAXOSMITHKLINE
- 33 Halfan 250mg comprimé (halofantrine) B/120 GLAXOSMITHKLINE
- 34 Halfan suspension buvable 5mg/5ml (halofantrine) F/45ml GLAXOSMITHKLINE
- 35 Malartin 200 mg comprimé (artésunate) B/6 TRI-HEALTH
- 36 Malartin 60 mg comprimé (artésunate) B/12 TRI-HEALTH
- 37 MMH-Malarex 450 mg Gélule (Peschiera Fuchsiaefolia) B/20 ROPACK
- 38 Paludrine 100 mg Comprimé (proguanil) B/56 ASTRA ZENECA
- 39 Plasmotrim 200 mg comprimé (artésunate) B/25 Blisters /6 MEPHA
- 40 Plasmotrim 200 mg comprimé (artésunate) B/6 MEPHA
- 41 Plasmotrim 50 mg Lactab (artésunate) B/12 MEPHA
- 42 Plasmotrim 50 mg Lactab (artésunate) B/25 Blisters /6 MEPHA

**42 médicaments du paludisme interdits**  
Depuis quelques années, de nombreux médicaments sont déclarés inopins à la guérison du paludisme.

Including rectal artesunate, recommended by WHO for pre-referral treatment of severe malaria in children

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## Decision of Cambodia: in March 2009






Withdrawal of Marketing Authorization of oral artemisinin-based antimalarial medicines

- widespread dissemination of new regulation (posters + leaflets)
- empowerment of drug inspections (confiscation, fines, prosecution)
- letters of appreciation + logos for approved outlets

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REPUBLIQUE DU BENIN  
MINISTRE DE LA SANTE  
DIRECTION DES PHARMACIES  
ET DU MEDICAMENT  
TELE FAX 21 11 88 82  
ET BP 2044  
COTONOU

20 MAI 2009

LE MINISTRE DE LA SANTE

**DECISION :**

Vo le texte du communiqué de presse OMS/02 du 19 Janvier 2006 relatif à l'arrêt immédiat de commercialisation des produits antipaludiques par voie orale notamment uniquement des dérivés d'Artemisine :

Considérant les nouvelles lignes directrices de l'Organisation Mondiale de la Santé (OMS) pour le traitement du paludisme ;

Considérant la mise en place des Combinaisons Thérapeutiques à base d'Artemisine (CTA) sur toute l'étendue du territoire béninois ;

**DECIDE :**

**Article 1<sup>er</sup> :** Les Autorisations de Mise sur le Marché (AMM) des quarante six (46) Médicaments antipaludiques dont la liste est annexée à la présente décision sont retirées.

**Article 2 :** L'importation, la commercialisation, la prescription et l'usage des antipaludiques dont les AMM font l'objet de la présente décision de retrait sont interdits.

**Article 3 :** Les Directeurs des Sociétés de Gestion – Répartiteurs, les Pharmaciens d'offices et les Responsables des Formateurs Sanitaires sont chargés de veiller à l'application stricte de la présente décision.

Fait à Cotonou, le 20 MAI 2009


Alfred DANSOU

## Decision of Benin: in May 2009


Withdrawal of  
Marketing Authorization of  
46 antimalarial medicines

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NUMERO	NOM DU PRODUIT	DCI	LABORATOIRE	N° VISA	DATE SOUS
1	Chloroquine 100mg comp B/10x2	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
2	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	14/12/2004
3	Chloroquine Progen 100mg comp B/10	CHLOROQUINE	INDUSTRIE CHIMIQUE	533309	13/02/2005
4	Chloroquine Progen 200mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	533309	13/02/2005
5	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	26/08/2004
6	Chloroquine 100mg comp B/10x20	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
7	Chloroquine 100mg comp B/10x100	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
8	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
9	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
10	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
11	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
12	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
13	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
14	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
15	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
16	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
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18	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
19	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
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27	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
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32	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
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36	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
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43	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
44	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
45	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004
46	Chloroquine 100mg comp B/10x10	CHLOROQUINE	INDUSTRIE CHIMIQUE	488306	21/08/2004

## Decision of Benin:


Withdrawal of  
Marketing Authorization  
of 22 brands  
of chloroquine

and of  
24 brands of oral  
artemisinin-based  
monotherapies

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ANNEXE RELATIVE A L'ARRETE N° 1173/09 06 AOU 2009  
 SUSPENSION DES VISES D'ENREGISTREMENT DE MOLECULES ET COMBINAISSONS DE MOLECULES  
 ANTIPALUDIQUES EN COTE D'IVOIRE


**Decision of Côte d'Ivoire in August 2009:**

**withdrawal of certain ACTs from the market to align the private sector with the public sector**

LISTE DES MOLECULES ET COMBINAISSONS DE MOLECULES ANTIPALUDIQUES NON RECOMMANDEES PAR LE NOUVEAU SCHEMA THERAPEUTIQUE

- ARTESUNATE 200 mg (forme suppositoire, Adulte) = PLASMOTRIM
- ARTESUNATE/MEFLOQUINE = ARTEQUIN
- ARTESUNATE/NAPHTOQUINE = ARCO
- ARTESUNATE/SULFAMETHOXYPYRAZINE/PYRIMETHAMINE = CO-ARINATE
- ARTESUNATE/SULFADOXINE/PYRIMETHAMINE = ARTEJAR 50 et 100mg
- DIHYDROARTEMISININE/PIPERAQUINE = DUO-COCTEXIN, MALACUR, DARTE-Q
- DIHYDROARTEMISININE/PIPERAQUINE/TRIMETHOPRIME = ARTECOM
- AMODIAQUINE/SULFAMETHOXYPYRAZINE = DUALKIN

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**Decision of Mozambique in November 2009:**


**withdrawal of artemisinin-based monotherapies for oral administration**

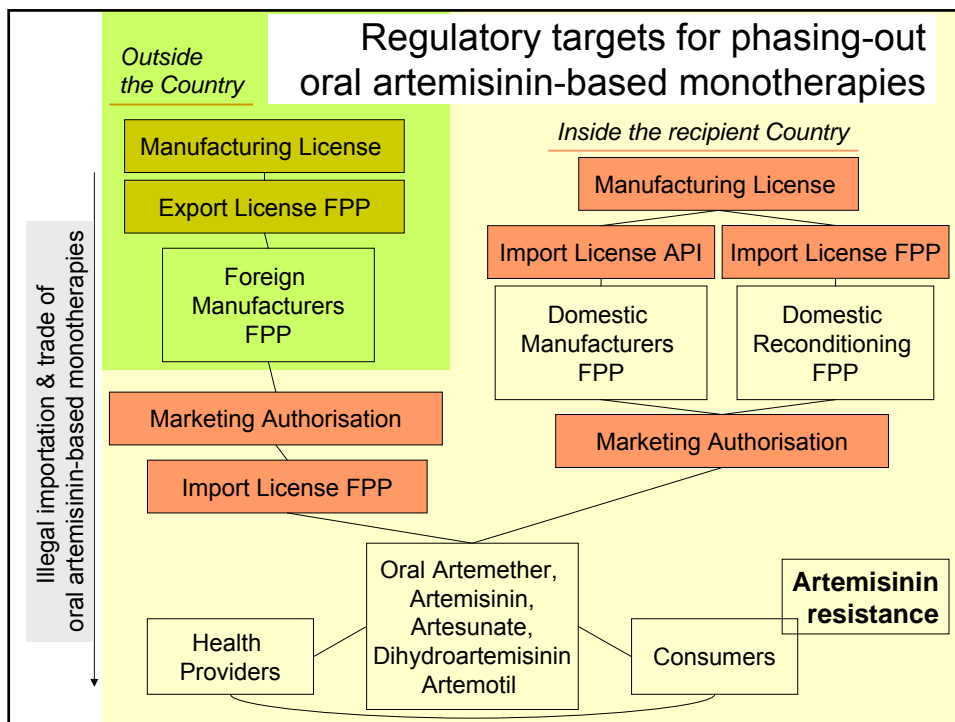
REPÚBLICA DE MOÇAMBIQUE  
 MINISTÉRIO DA SAÚDE  
 GABINETE DO MINISTRO  
 DESPACHO N.º 21/2009

Artigo 1. É proibida a circulação no mercado nacional de todos os medicamentos antimaláricos derivados da artemisinina cuja composição se destine ao uso em monoterapia e por via de administração oral.

Art. 2. O presente Despacho entra imediatamente em vigor.

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### Timelines for implementation of regulatory actions

ACTION	TASK	TIMELINE
Step 1	Agreement on time frame for phasing out oral artemisinin-based monotherapies and deployment of artemisinin-based combination therapies (ACTs)	Immediate
Step 2	Halting new marketing authorisations for oral artemisinin-based monotherapies	Immediate
Step 3	Suspension of import licence for artemisinin-based APIs and FPP to companies that are exclusively manufacturing oral artemisinin-based monotherapies	3-4 months
Step 4	Large scale deployment of ACTs in the public sector and communication campaigns to move prescribers and consumers	Time X
Step 5	Promotion of wide access to ACTs in the private sector	Time Z*
Step 6	Withdrawal of manufacturing licences for oral artemisinin-based monotherapies as finished pharmaceutical products (FPP)	6 months after Time X
Step 7	Suspension of export license to companies manufacturing oral artemisinin-based monotherapies as FPP for export market	6 months after Time X
Step 8	Complete elimination of oral artemisinin-based monotherapies from the market	10-12 months after Time X

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## 29 countries allow the marketing of oral artemisinin-based monotherapies: 16 in Africa



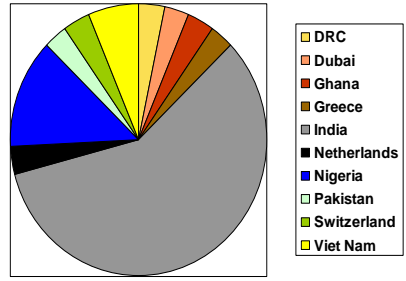
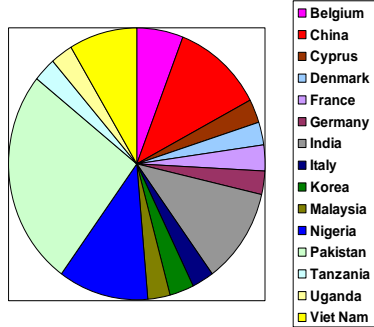
Algeria, Angola, Bangladesh, Bhutan, Bolivia, Botswana, Cape Verde, Central African Republic, Chad, Colombia, Congo, Equatorial Guinea, Gambia, Indonesia, Malawi, Myanmar, Namibia, Nepal, Papua New Guinea, Sao Tome & Principe, Solomon Islands, Somalia, Swaziland, Timor Leste, Togo, Vanuatu, Zambia, Zimbabwe and Yemen

## Country where companies have manufacturing site or are registered



36 companies withdrew oral artemisinin-based monotherapies

36 companies marketing oral artemisinin-based monotherapies



Last updated: 9 April 2010

## the example of NYD Pharma

- Consultation with Swissmedic (30.3.10)
- The company NYD has an authorisation from Swissmedic for the "Trade of medicinal products in foreign countries". Since these products are not manufactured in Switzerland and do not transit Swiss territory, they don't need a market authorisation from Swissmedic
- Article 21 al. 1 of the LPT stipulates that the export of medicinal products and their foreign trade from Switzerland shall be prohibited if:
  - a. they are prohibited in the destination country;
  - b. circumstances suggest that they could be intended for an illegal purpose.
- Since neither a) or b) apply, the Swiss law does not allow any intervention

WHO recommended medicines for the treatment of falciparum malaria			
Active pharmaceutical ingredient(s) in available formulation(s)	Uncomplicated malaria	Treatment failure	Severe malaria
Artemether/lumefantrine oral	✓	✓*	
Artesunate +/- amodiaquine oral °	✓		
Artesunate +/- mefloquine oral	✓	✓*	
Artesunate + sulfadoxine/pyrimethamine oral °	✓		
Dihydroartemisinin/piperaquine oral	✓	✓*	
Artesunate (or quinine) combined with tetracycline or doxycycline or clindamycin, oral		✓	
Artesunate, intravenous or intramuscular			✓
Artemether, intramuscular			✓
Quinine, intravenous or intramuscular			✓
Artemotil, intramuscular			✓**
Artesunate, rectal			✓***
Artemisinin, rectal			✓***

+, co-packaged products; /, co-formulated products; +/-, co-packaged FPPs also available as co-formulated tablets;  
 ° not recommended in areas where cure rates of amodiaquine or sulfadoxine/pyrimethamine is  $\leq$  80%  
 \*, not if used as first-line treatment; \*\*, only if no alternative is available (few clinical trials conducted); \*\*\*, for patients with severe malaria before referral to a facility to complete parenteral treatment with artesunate, artemether or quinine

## Next steps

1. Follow-up of recommendation from 2<sup>nd</sup> African Medicines Regulators Conference (24-26 November 2009, Maputo, Mozambique)
  1. Meeting with African NRAs (Francophone - Douala, 28-30 June 2010)
  2. Meeting with African NRAs (Anglophone - Dar Es Salaam, ?)
2. Follow-up of WHO/AFRO Regional Committee (RC 59) Resolutions on Acceleration of Malaria Control towards elimination and on Monitoring of Drug resistance related to Malaria, Tuberculosis and HIV
3. Presentation to Ministerial Session at RBM Board, 14 May 2010
4. Presentation African Leaders Malaria Alliance (ALMA) – July 2010
5. Meeting with manufacturers (Artemisinin Forum 2010 – Oct 2010)
6. Country presentation + Stand at International Conference of Drug Regulatory Authorities (ICDRA) in Singapore (30 Nov - 3 Dec 2010)

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## Conclusions

- Artemisinin resistance is a real threat to global malaria control efforts; its spread could reverse the tremendous gains we have made not only in fighting malaria, but in improving child survival
- The problem remains focal; it is not too late to act
- Regular monitoring of antimalarial drug resistance should be a part of every National Malaria Control Program
- Oral artemisinin based monotherapies remain the greatest threat to the spread of artemisinin resistance. The removal of these drugs from the market is the single most important action needed today.

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Thank you

## 18<sup>th</sup> RBM Partnership Board meeting agenda

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08.00	Welcome Coffee
09.00	Introductory Remarks & Special Session Objectives
09.15	Country example on progress towards 2010 targets with focus on:
•	Health Systems Strengthening through malaria funding - Zambia
•	Improving malaria control through innovative technologies - Tanzania UR
•	Discussions
11.00	Coffee/Tea Break
11.30	Containing the spread of drug resistance:
•	Eliminating oral artemisinin-based monotherapies and substandard ACTs - WHO/GMP
13.00	Lunch



## 18<sup>th</sup> RBM Partnership Board meeting agenda

### Day 3

---

08.00	Welcome Coffee
09.00	Session V (Special Ministerial Session)
10.15	Break
10.45	Containing the spread of drug resistance
13.00	Lunch
14.00	Session VI (RBM strategic response to challenges)
15.00	Proposed resolution pre-qualification
15.30	Break
16.00	RBM Board Vice Chair Election
16.30	19 <sup>th</sup> RBM Board Meeting – Venue & Date
17.00	AOB



## 18<sup>th</sup> RBM Partnership Board meeting agenda

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## 18<sup>th</sup> RBM Partnership Board meeting agenda

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## 18<sup>th</sup> RBM Partnership Board meeting agenda

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