# Ensuring success: MMV Access

Curing Malaria Together www.mmv.org

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# Structure of the presentation

- Setting the stage
- MMV Access Strategy
- Illustrations of current activities
- Resources needed to ensure success

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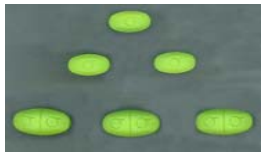
# Why did MMV get involved in Access?

- Five MMV-supported products likely to enter the market in next few years

iv artesunate?

- But the market often fails to deliver drugs to the poor

- MMV-supported products will only achieve health impact if available
  - Immediately when needed
  - At the **right** price
  - At the **right** place
  - With the **right** information

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# What is our mission?

- To increase speed and reach of MMV-supported product adoption and use to achieve health impact

## Our target population

# What are our operating principles?

- Follow MMV's partnership model:
  - Work closely with Pharma partners, International agencies, Health ministries, Global health community
- Build on existing initiatives and minimize duplication of effort
- Prioritize initiatives based on:
  - Unique MMV positioning
  - Magnitude of health impact

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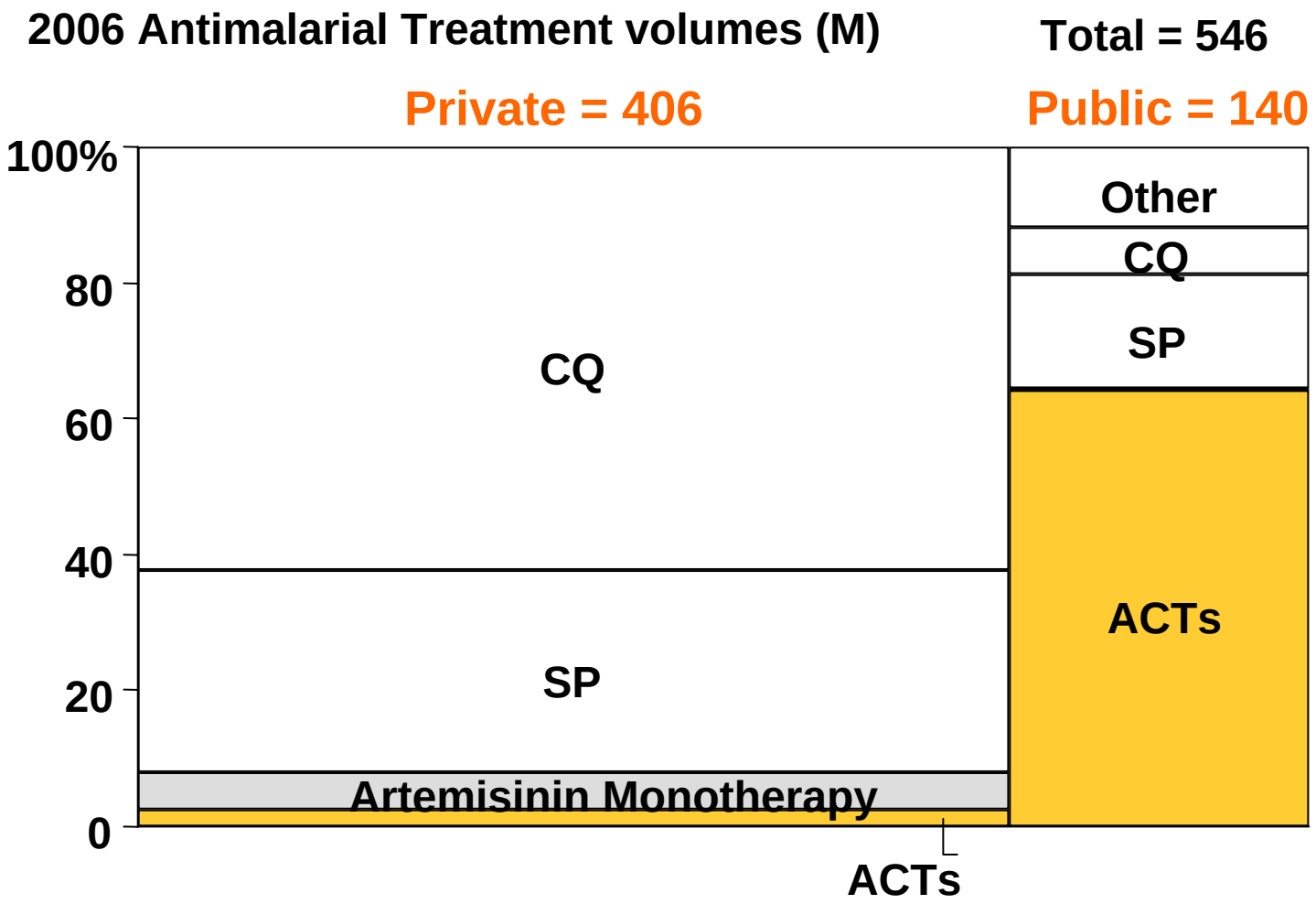
# ACTs still remain a small share of the total antimalarial market

ESTIMATES




Note: Estimates of actual malaria treatments (vs. fever) are between 25%(BCG) and 40%(WHO). Other category includes MQ, AQ, etc.. P. Vivax treatment included (90M CQ treatments). ACT numbers updated after manuf. Interviews from 82M (WHO) to 90M public sector, and from 8M to 10M in private sector.
Source: Biosynthetic Artemisinin Roll-Out Strategy, BCG/Institute for One World Health, Dalberg

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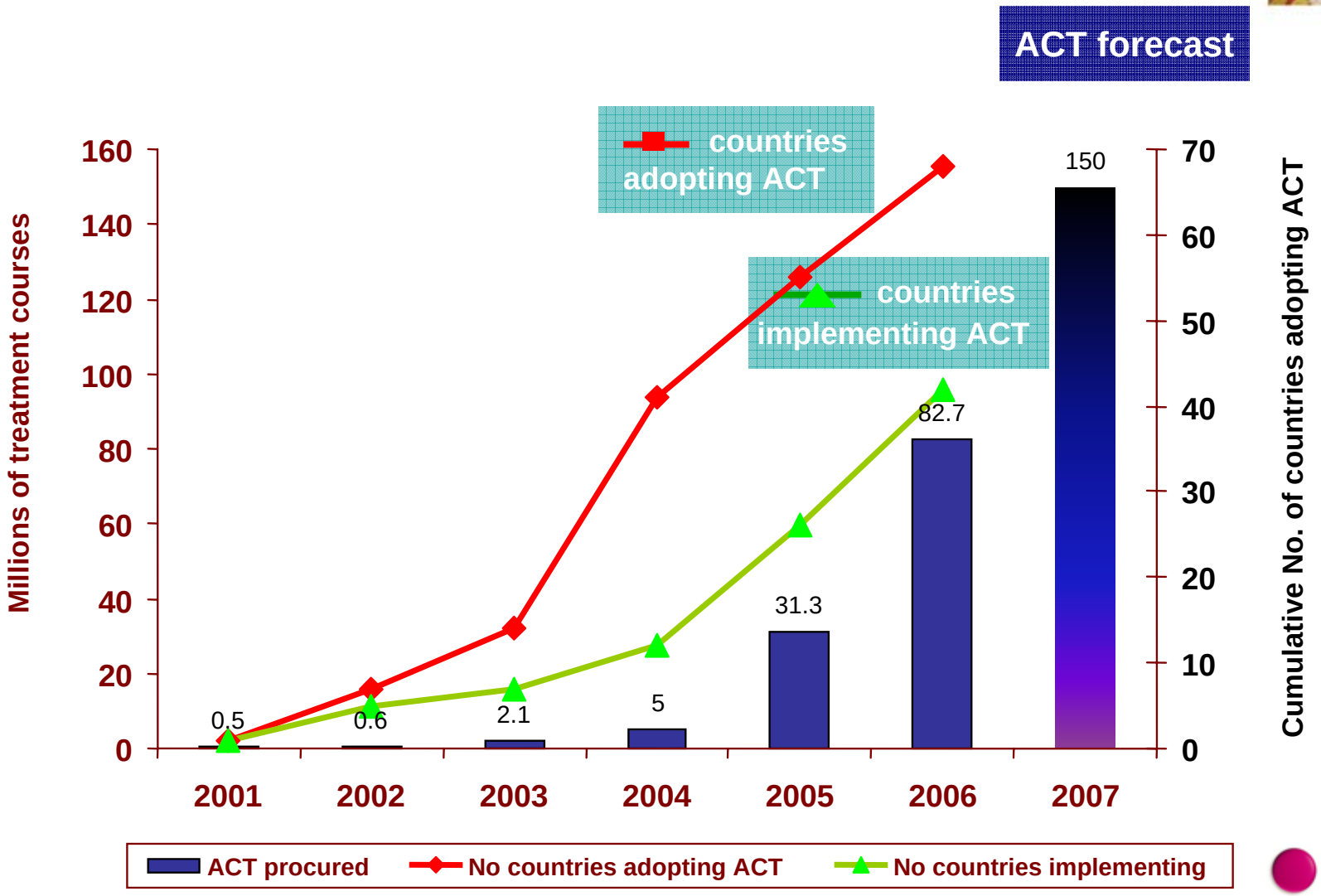
# There has been a dramatic increase in public sector procurement of ACTs

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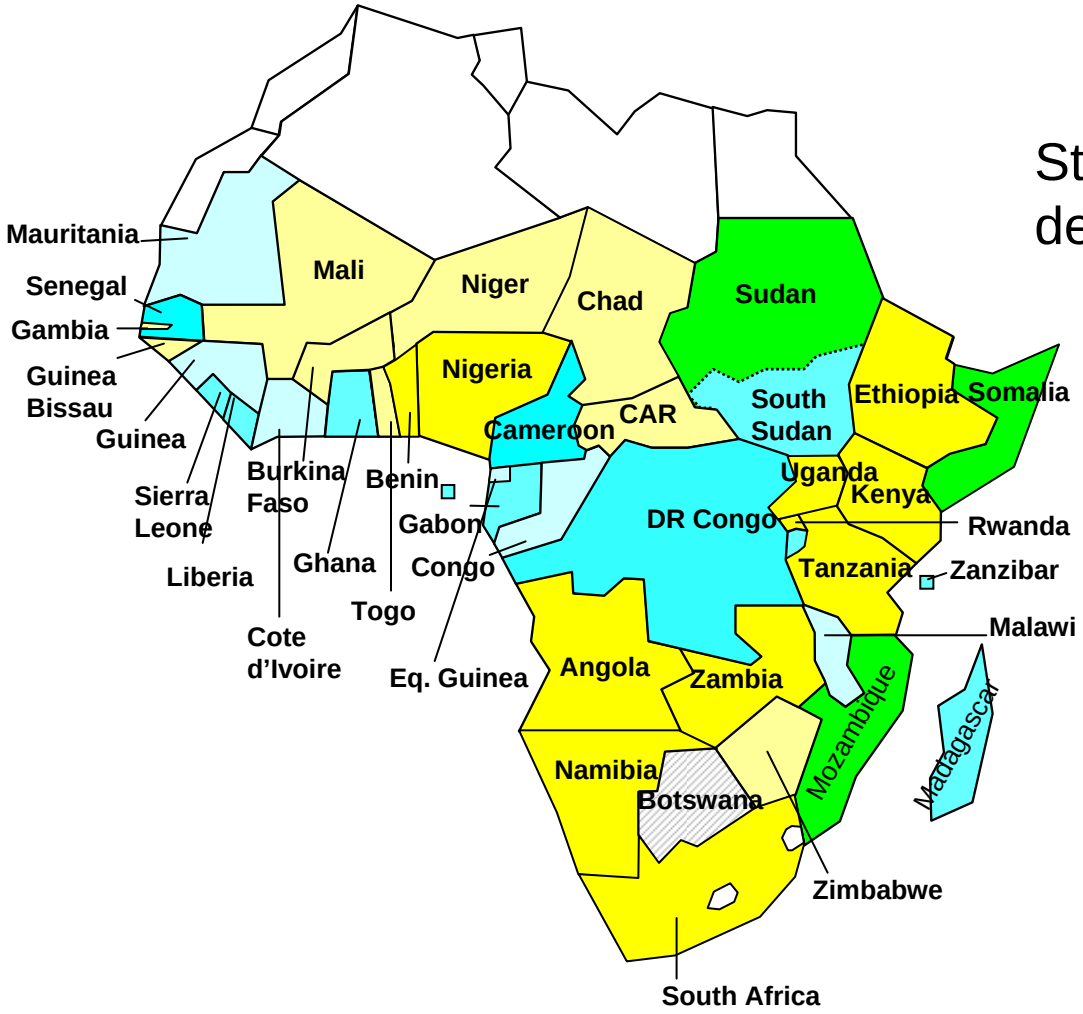
Source: WHO GMP

# Gaps in ACT deployment

**43 countries have adopted ACTs - 26 are deploying them**




Status of ACT adoption / deployment as first-line treatment

- Artesunate + amodiaquine (deployed)
- Artesunate + amodiaquine (adopted)
- Artemether/lumefantrine (deployed)
- Artemether/lumefantrine (adopted)
- Artesunate + SP

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Source: WHO Global Malaria Programme, Status 1.2.2007

# Procurement looks good but stock-outs high in public sector

Stock-outs recorded in Zambia, 2006

| | Health facility with stock out | Mean No of stock out days | % time out of stock |
|---|---|---|---|
| AL 6 pack | 95% | 113 | 31% |
| AL 12 pack | 89% | 108 | 30% |
| AL 18 pack | 91% | 123 | 34% |
| AL 24 pack | 81% | 123 | 34% |

**People have nowhere else to turn but the private sector**

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# The private sector poses a different set of challenges

- >200 products on market
  - Variable quality, provenance, price
  - Counterfeits


- ACTs distribution restricted by prescription-only status
- Price is key driver for choice
  - SP / chloroquine remain best sellers

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# MMV Access strategy is designed to address key challenges

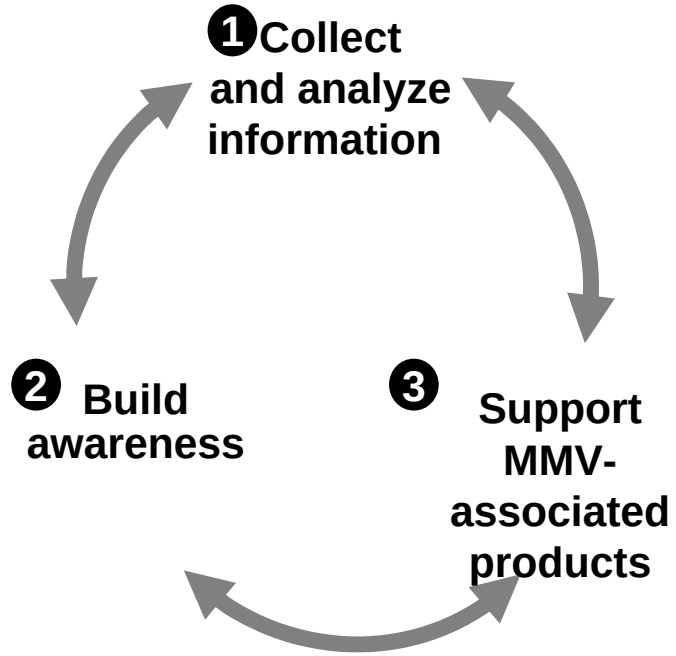

## Objectives

1. **Support adoption** of MMV-supported products at international and national levels

2. **Help expand the reach** of MMV products beyond existing ACT delivery channels in a responsible manner

3. **Help shape MMV product development** based on market insights

## Key activities

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# MMV Access and Partners will focus on selected activities

**Objectives**

**Activities**

| Activities | A Support adoption | B Help expand product reach | C Shape product development |
|---|---|---|---|
| 1 Collect and analyze information | • Map regulatory and policy processes<br>• Identify barriers to rapid uptake<br>• Advocate harmonization of regulatory processes<br>• Highlight need for early | • Focused market research<br>• Supply and pricing surveys in informal sector<br>• Studies of treatment<br>• Demand forecasting | • Gather market data to feedback to target product profiles and packaging<br>• Assess impact of OTC rescheduling |
| 2 Build awareness and advocate | • POM to OTC switch<br>• Information meetings with policy makers<br>• Advocate for policy changes to remove uptake barriers | • Advocate for improved market information and sustainable financing<br>• Disseminate information (website, conferences, etc) | • Advocate for norms and branding to protect ACT |
| 3 Support MMV products | • Support inclusion of registered products into guidelines / prequalification<br>• Work with decision makers to support product launch<br>• Phase IV studies to compare treatment options | • Product access plans beyond traditional Pharma remit<br>• Supply chain support | • Participate in product teams<br>• Identify opportunities for label extension studies<br>• Improve packaging and<br>• Conduct pharmaco-vigilance studies<br>• Monitor drug resistance |

= MMV lead  = MMV supportive

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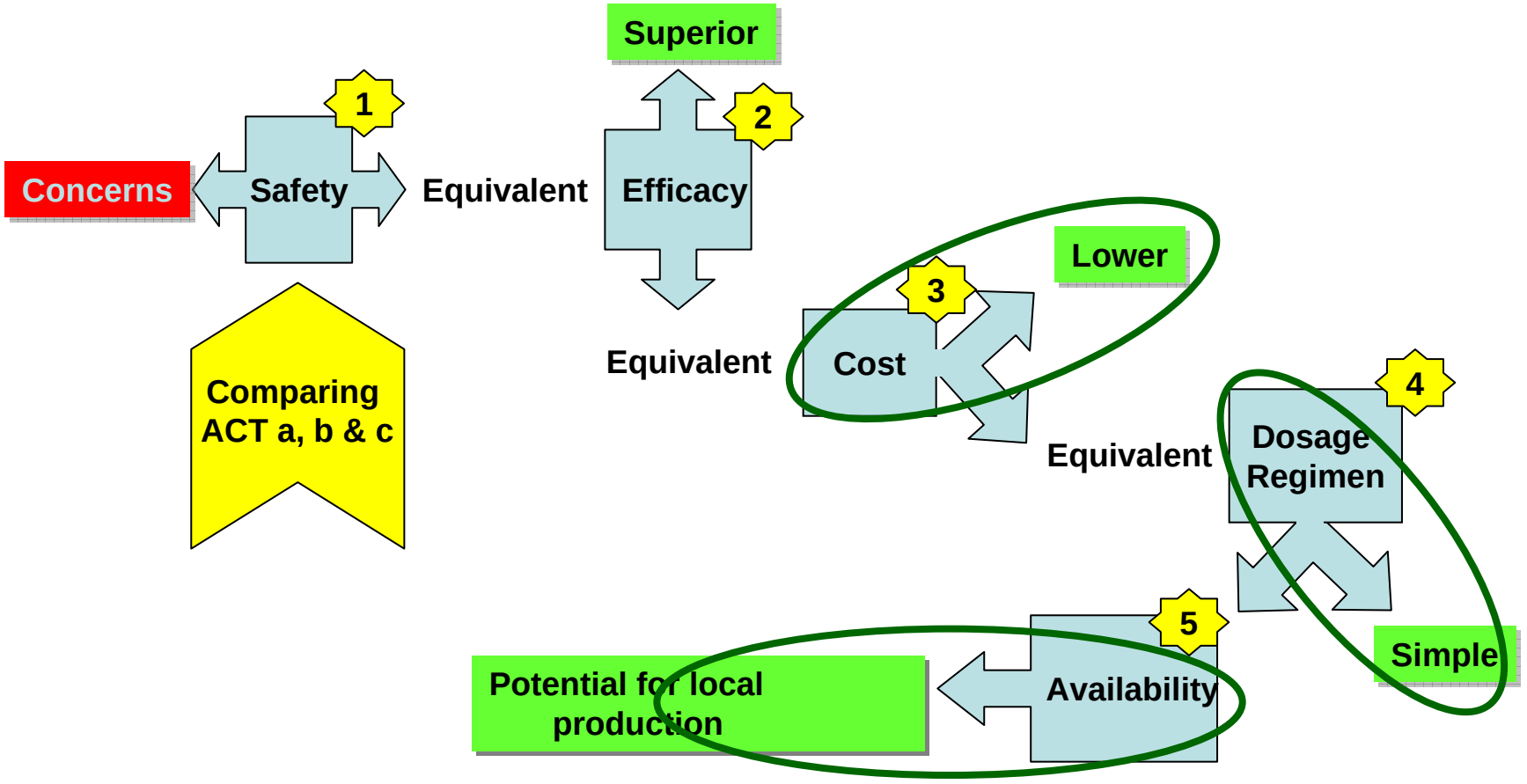
# Where do MMV products feature on the current WHO treatment guidelines?

- **Coartem Dispersible:**
  - Coartem already on WHO treatment guidelines and prequalified
- **DHA-PQP:**
  - shown to be safe and effective in large trials in Asia (not GCP)
  - not included 2006 recommendations
    - not yet available as a formulation manufactured under GMP
    - not yet been evaluated sufficiently in Africa and South America.
- **CDA:**
  - Phase 3 data not yet available and not yet registered
- **i.v. artesunate**
  - recommended for severe malaria in low transmission areas
  - recommended along with quinine and artemether in high transmission areas
- **Pyronaridine Artesunate**:
  - not yet registered so not mentioned

Source: WHO Guidelines for the Treatment of Malaria, 2006
7.3.1 Rationale for the exclusion of certain antimalarials

# What will drive future ACT selection?

## Learning from the past: Country selection criteria, 2002-2006




Source: WHO GMP

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# Phase IV: Evidence-base needed to inform choice

- Why do we need Phase IV?
  - Phase III studies are not under real-world conditions
    - strict inclusion / exclusion criteria, hospital environment, run by global and national experts, etc.
    - Small numbers (1000-2000 patients)
  - Need objective comparator data against all available products
    - Should be non-sponsor led
    - Large patient numbers under real life conditions
  - Required for decision makers to make policy choices

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# OTC status is crucial for improved access

- Prescription only status restricts ACT distribution to public and premium private sector
  - Legal sale through non-premium private and inclusion in community based kits requires switch to OTC
- Switch to OTC is usually late event in product life cycle
  - Requires extensive pharmacovigilance data to ensure risk-benefit is favourable
  - With existing OTC antimalarials failing (CQ, SP), the risk-benefit for ACTs is likely to justify early switch
  - Switch is decided by the National Drug Regulatory Authorities, typically at the request of manufacturers
- Urgent need for WHO initiated consultative meeting to reach consensus with key stakeholders
  - National drug authorities, pharma companies, national control programme managers, experts

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# Outreach to endemic countries and decision makers

**Increasing awareness of MMV and products**

**Understanding critical path to adoption**

**Accelerated product adoption**

- Meetings with MoH: Tanzania, Kenya, Mozambique (May 07)
- Information meeting with Francophone African authorities (Senegal: Nov 07)
- Participate in key meetings (RBM, EARN, etc.)

- Survey of regulatory processes with partners
- Regular engagement with WHO (GMP, EDL, PQ, etc.)
- Sharing information with financing and procurement agencies (GFATM, UNICEF, PMI, JSI etc.)

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Objectives

Activities

| | A Support adoption | B Help expand product reach | C Shape product development |
|---|---|---|---|
| 1 Collect and analyze information | • Map regulatory and policy processes<br>• Identify barriers to rapid uptake | • Focused market research<br>• Supply and pricing surveys in informal sector<br>• Studies of treatment behavior | • Gather market data to inform target product profiles and packaging |
| 2 Build awareness and advocate | • Road shows in countries<br>• Information meetings with policy makers<br>• Advocate for policy changes to remove uptake barriers | • Advocate for improved market information and sustainable financing<br>• Disseminate information (website, conferences, etc) | • Advocate for norms and branding to protect ACT |
| 3 Support MMV products | • Support inclusion of registered products into guidelines / prequalification<br>• Work with decision makers to support product launch | • Product access/launch plans for target segments | • Participate in product teams<br>• Support label extension studies<br>• Improve packaging and user instructions |

= MMV lead  = MMV supportive

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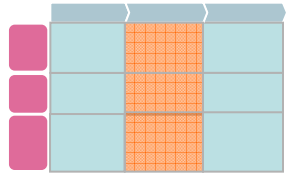
# Learning through engagement to inform product launch in informal sector*

**B** **Expand reach**



**Understanding the market**

- Pricing Study (WHO, HAI, MoH)
- Supply chain survey (WHO, HAI, MoH Uganda)
- Market demand survey (PSI)

**Responsibly providing a low priced ACT through the informal sector**

- Limited early OTC status (MoH / NDA)
- Training
- Adapted packaging
- Social marketing
- Monitor Impact

**Product access plans developed with Pharma partners**

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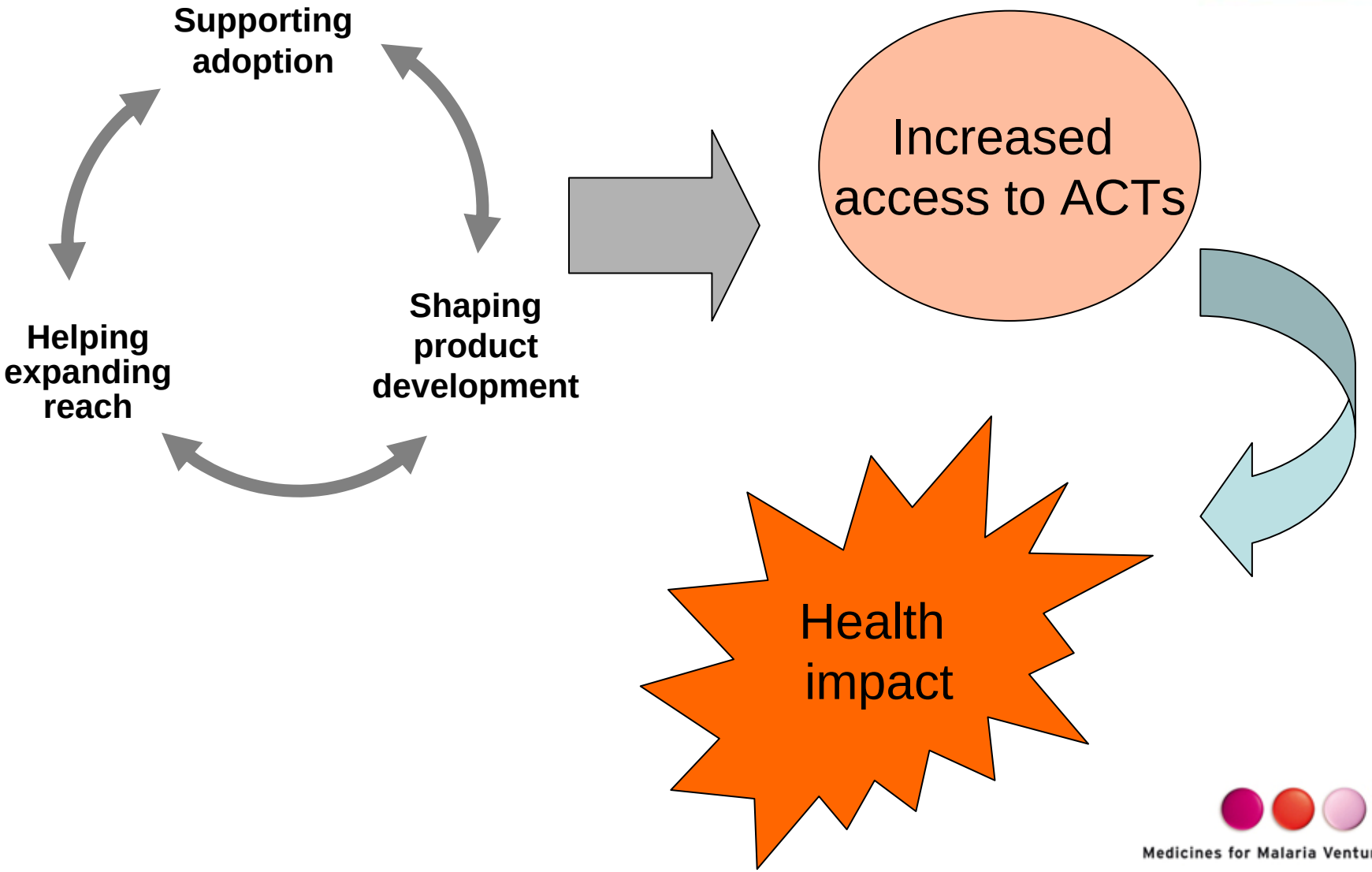
***with Ministry of Health and other partners in Uganda**

# Our activities are starting a virtuous cycle of increased access to ACTs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# MMV Access will help ensure our drugs will save lives

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