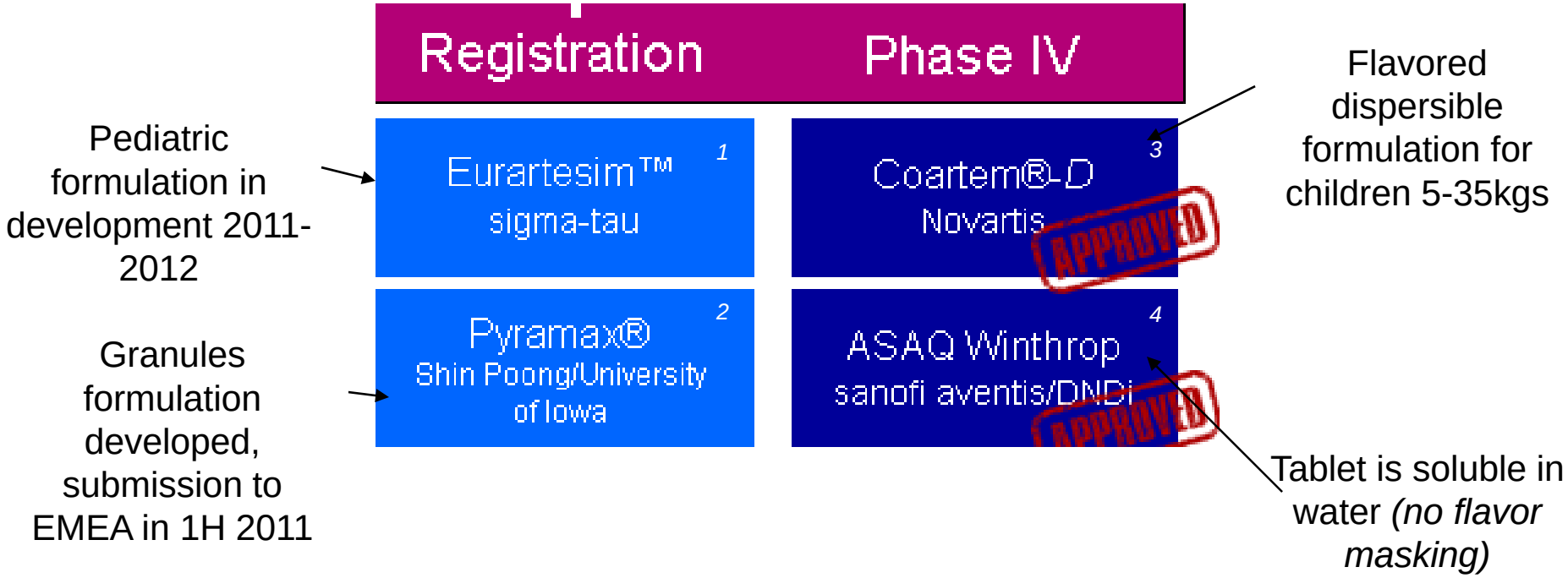
Barriers to Policy Change: Seeking insights from the introduction of paediatric Artemether-Lumefantrine in Sub Saharan Africa

ASTMH Symposium
Friday 5Th November, 2010, Atlanta
Hilton Hotel, Grand Salon E

Dr. Ambrose Talisuna
Director Global Access
Case Management Policy and Country Operations

MMV
Medicines for Malaria Venture

Where MMV Access & Delivery focuses their attention…and which products are ready to go with child-friendly treatment



[1] *Dihydroartemisinin piperaquine (DHA-PQP)*

[2] *Pyronaridine artesunate*

[3] *Artemether lumefantrine*

[4] *Artesunate amodiaquine*

MMV
Medicines for Malaria Venture

Why are we anxious for better post-launch effectiveness evidence?

Do paediatric drug formulations of artemisinin combination therapies improve the treatment of children with malaria? A systematic review and meta-analysis

www.thelancet.com/infection

February 2010

Florian Kurth, Sabine Bélard,* Ayola A Adegnika, Oumar Gaye, Peter G Kremsner, Michael Ramharter*

So far no adequately powered direct comparison of the effectiveness of paediatric versus tablet formulations has been published. It should be a research priority to establish whether children will ultimately benefit from paediatric ACTs that are easier to give and therefore improving their effectiveness and reducing the rate of hospital admissions.

MMV
Medicines for Malaria Venture

The overarching concern…

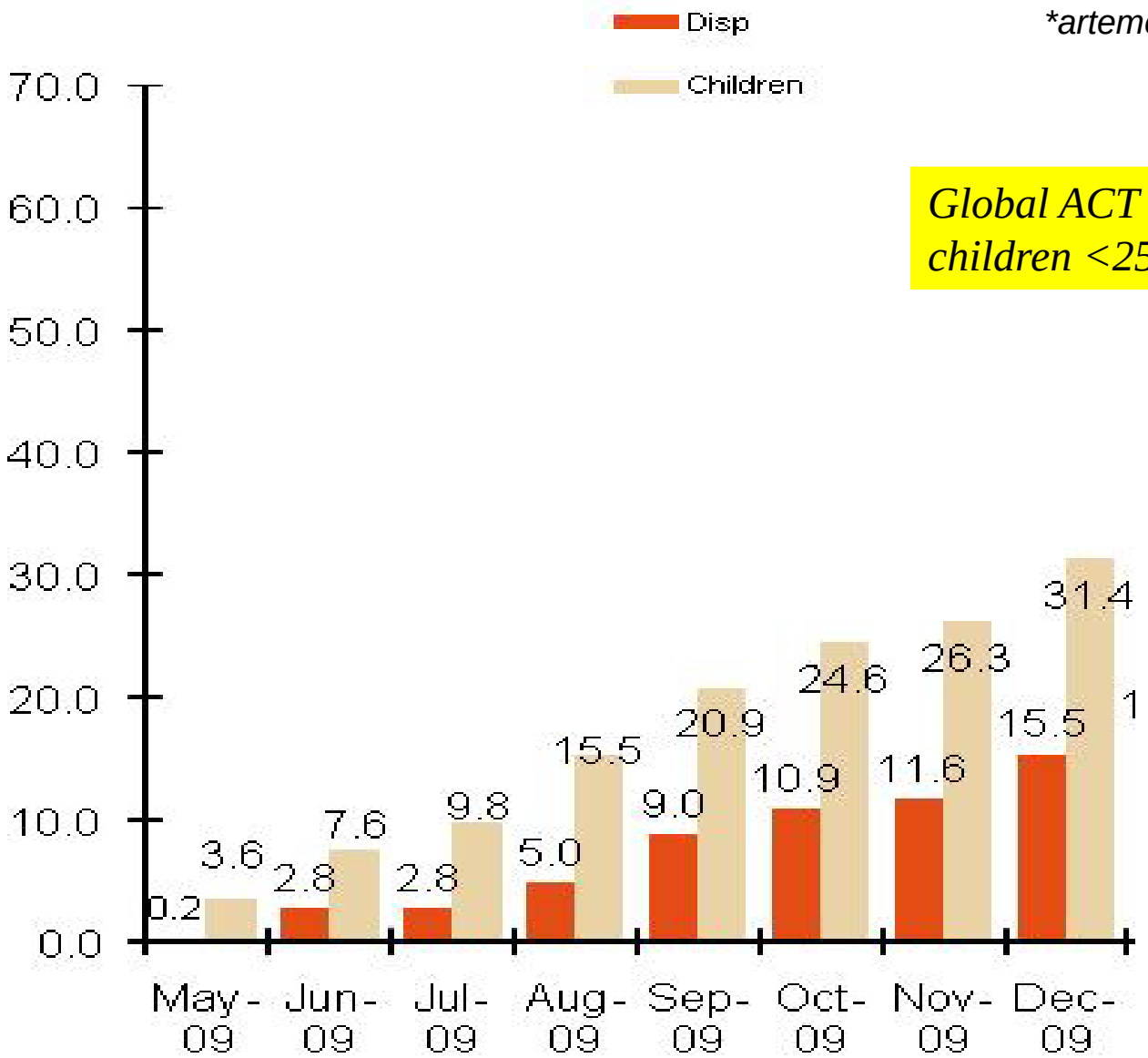
What if MMV and partners and other PDPs develop better medicines for children…. And no one:

- Notices!
- Cares!
- Thinks it makes a difference!

MMV
Medicines for Malaria Venture

Uptake curve – 1st year A-L* dispersible

*artemether lumefantrine



Global ACT use ~160MN tx in 2009. children <25kg= 60% of demand

MMV Medicines for Malaria Venture

The overarching concern…(continued)

In the first six months after launch of artemether-lumefantrine dispersible, we perceived that:

- Some country level technical working groups were slow to respond
- Procurement rules slow to change
- Policy-making “machinery” moving on its own timeline, independent of new breakthroughs

MMV, with a research partner (Dalberg) and using conceptual guidance from WHO-EMP, decided to examine the levers of policy change using this new child-friendly medicine as a probe

MMV
Medicines for Malaria Venture

Research Summary

We wanted:

1. to gather country perspectives and information about the process of policy adoption for new malaria medicines with a specific focus on paediatric formulations

2. to review required steps for policy adoption at national and higher level

3. to identify bottlenecks in the policy adoption process, and make recommendations on ways to address them

4. to draw comparisons between countries, share lessons learned as well as share transferable best practices

5. To develop recommendations for strategic interventions

MMV
Medicines for Malaria Venture

Methodology and Approach- Country selection Criteria

Country short list

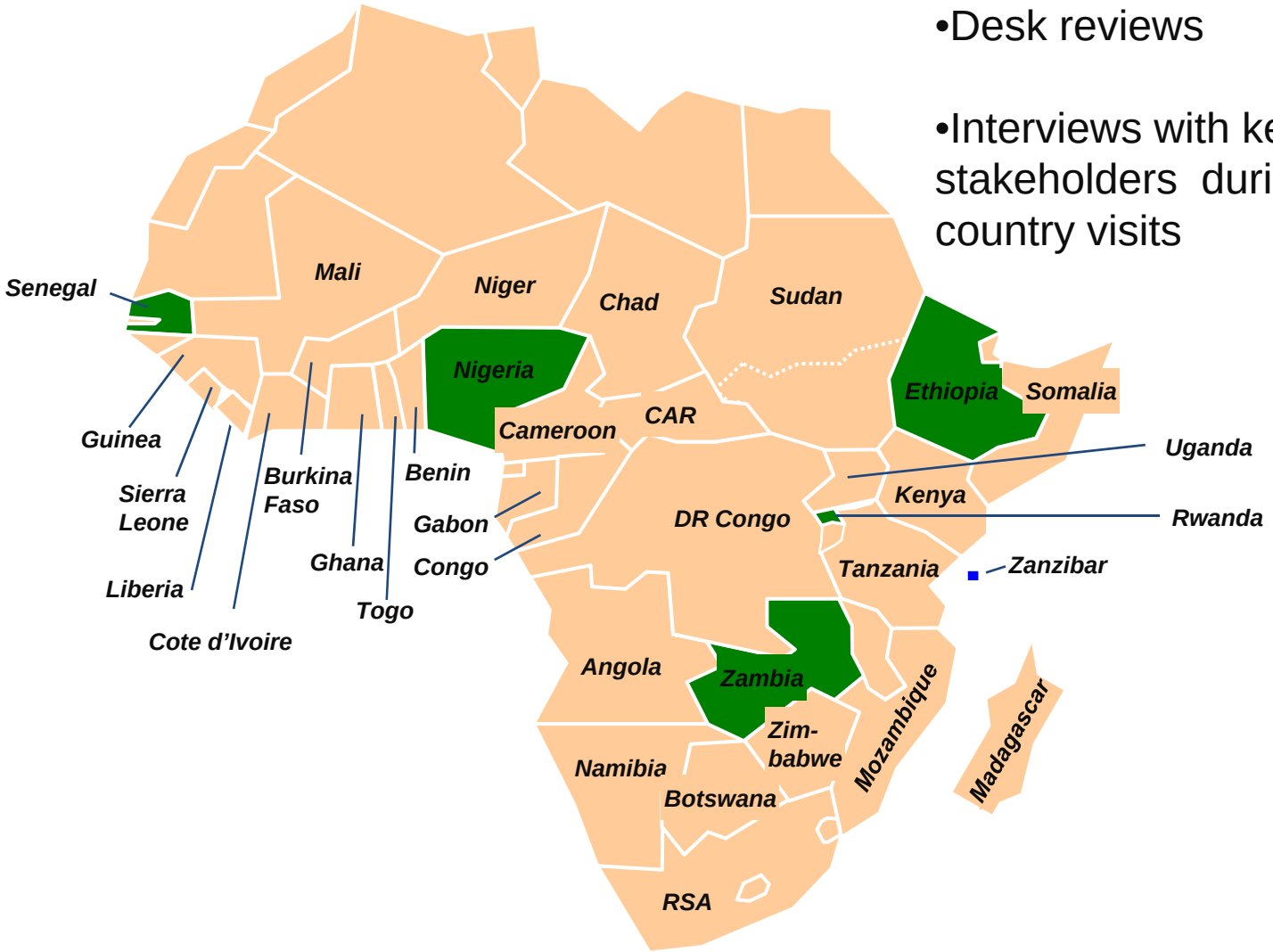
Country	Malaria Burden	Population	AL recommended 1st line treatment	Coartem D adopted	Local Industry	ACT availability	Relative malaria funding	Language	Region	Market*
Ethiopia	○	●	✓	✓	✓	◑	◑	English	East	Private
Nigeria	●	●	✓	✓	✓	○	○	English	West	Private
Senegal**	○	○	✗	✓	✗	●	◑	French	West	Public
Rwanda**	●	○	✓	✗	✗	○	Tbd.	English	East	Private
Zambia**	◑	○	✓	✓	✗	◑	●	English	Southern	Public
Alternative countries										
Ghana	●	○	✓	✗	✓	●	●	English	West	Public
Malawi	●	○	✓	✗	✗	○	●	English	Southern	Public

- Countries in short list vary along segmentation variables
- Alternative countries suggested for potential fine-tuning of list

*First hypotheses, further research required
** Good contacts either through MMV or Dalberg
Source: World Development Indicators, Kenyan Export Processing Zones Authority, ACTwatch, World Malaria Report 2008 and 2009

MMV
Medicines for Malaria Venture

Paediatric policy decision making process review conducted in 5 countries

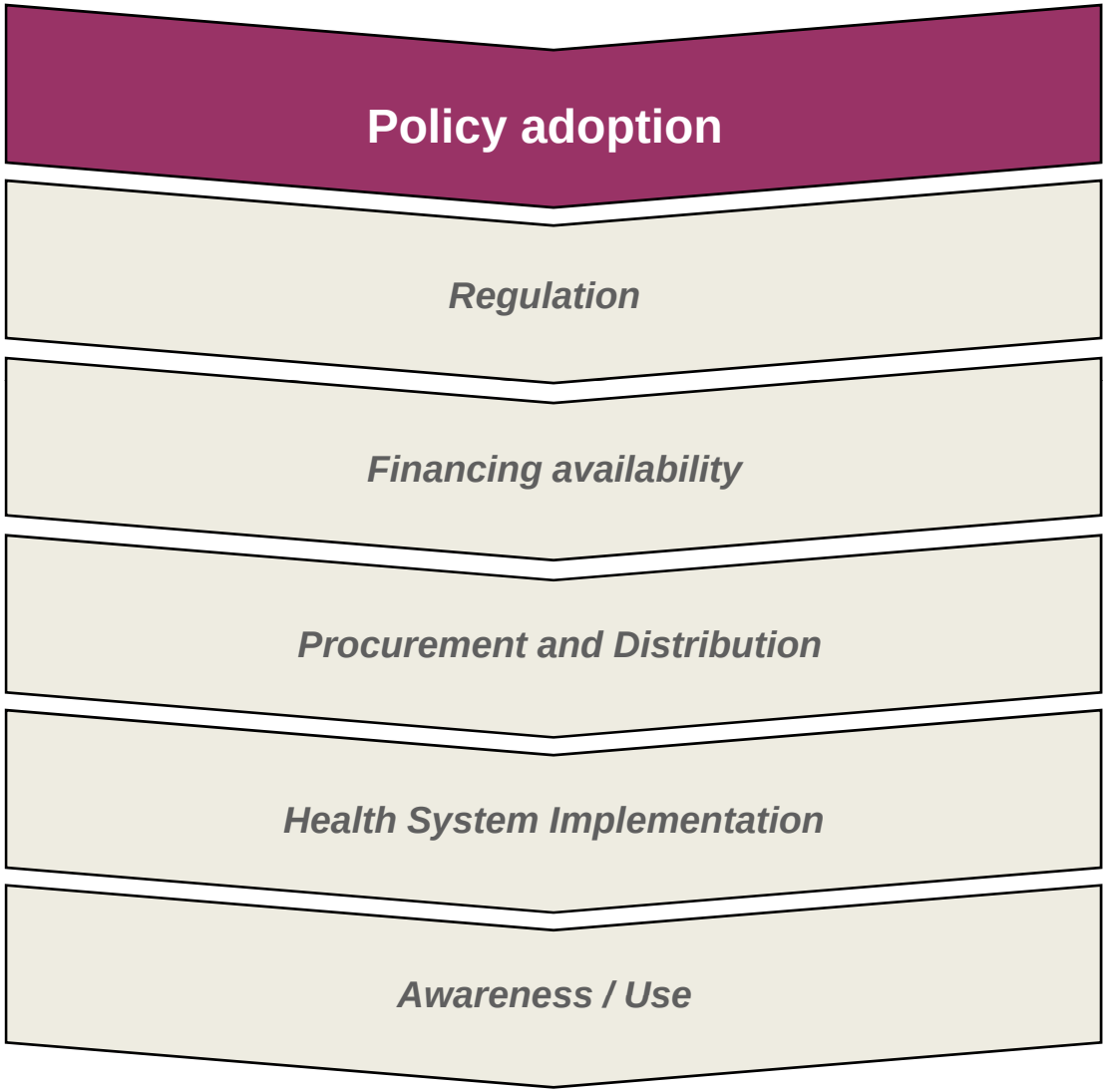


- Desk reviews
- Interviews with key stakeholders during country visits

MMV
Medicines for Malaria Venture

Six-step framework developed with WHO to guide country level analysis to identify bottlenecks

Focus of our study



What were the key findings and bottlenecks?

MMV
Medicines for Malaria Venture

On paper, policy adoption processes follow similar steps

1. Technical Working Group (TWG) with broad membership provides technical inputs to policy deliberations

2. Recommendation are made to the responsible government institution-Usually the Ministry of Health (MOH)

3. Different processes for ‘minor’ and ‘major’ changes
   - Minor - Ministry reviews and adopt policy directly through a ministerial instruction
   - Major - Process vetted at cabinet level or through an equivalent process in country

4. After policy change decision, Essential Medicine List (EML) and Standard Treatment Guidelines (STG) are updated as required (depending on nature of the change)

MMV
Medicines for Malaria Venture

But the implementation looks different ….

1. Stakeholders informed about existence of alternative medicines?
2. Appropriate efficacy and resistance data available for current and alternative medicines?
3. Policy process clear?
4. Financial resources for medicines available?
5. Health system implementation secured?

MMV
Medicines for Malaria Venture

Stakeholders informed about the existence of alternative medicines?

Low

Country 1
Country 2

Medium

High

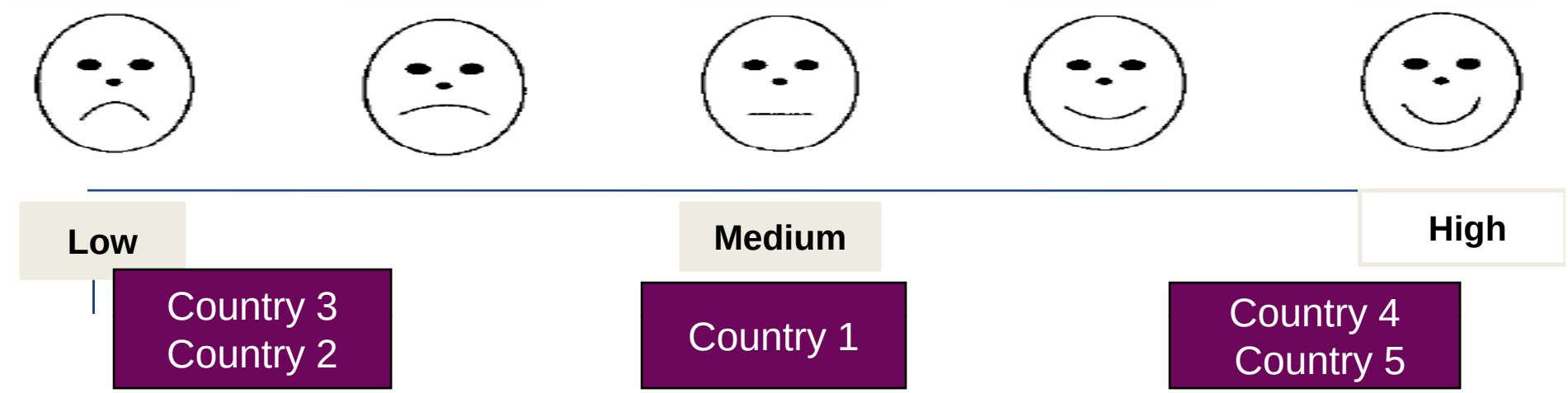
Country 3
Country 4
Country 5

- Information rarely moves beyond the key recipient
- Strength of national level partnership critical to facilitate information sharing

- **Communications plans for product introduction must:**
  - reach national and international stakeholders and involve them in further disseminating messages

MMV
Medicines for Malaria Venture

Appropriate efficacy and resistance data available for current and alternative medicines?

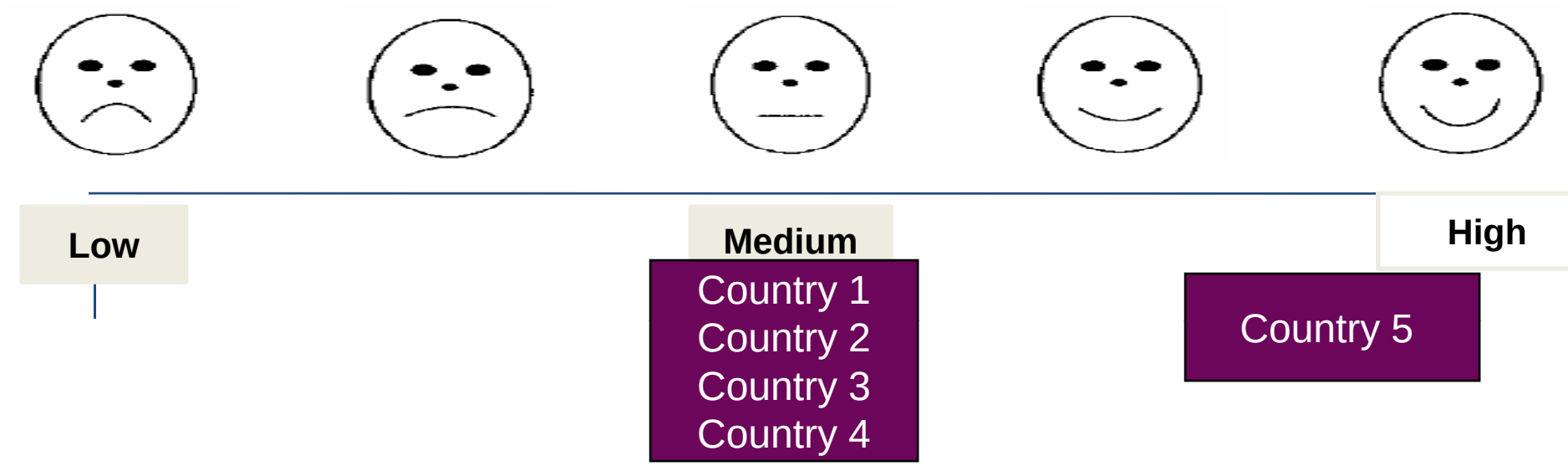


- No systematic resistance monitoring
- Lack of effectiveness data to trigger policy change

- **Need for regular efficacy monitoring and testing potential alternatives**
- **Need for effectiveness studies to justify switch from one ACT to another**

MMV
Medicines for Malaria Venture

Process for policy change established?

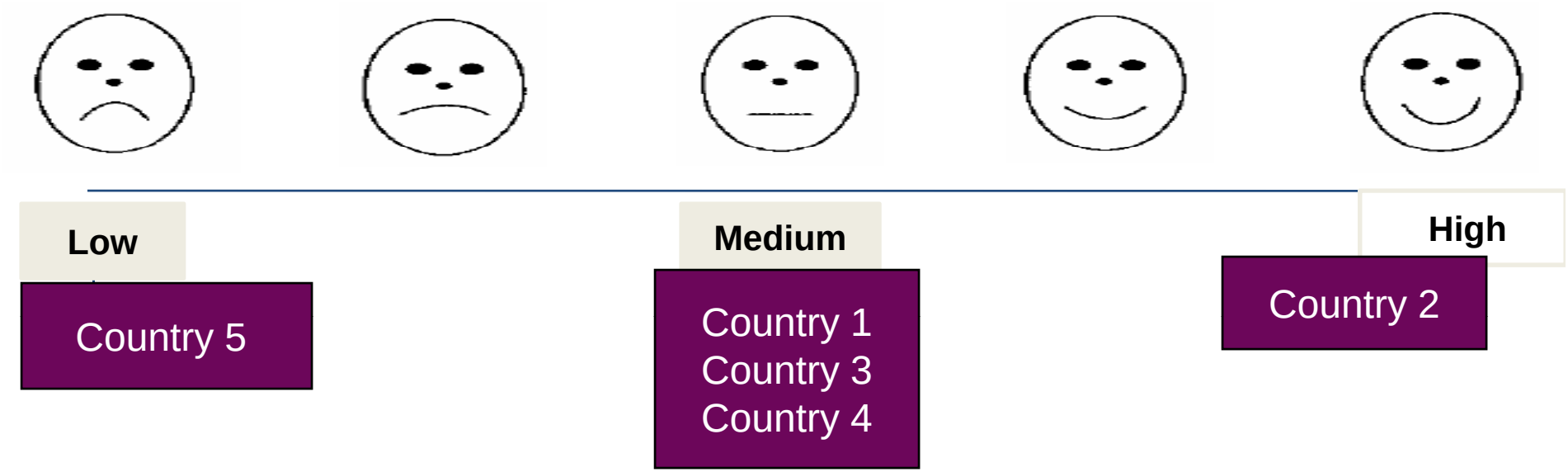


- For some countries inadequately institutionalized (processes and SOPs); for others very slow process

- **Ensure strong technical support to establish processes**

MMV
Medicines for Malaria Venture

Financial resources for medicines?



- Depends on Global Fund (grant performance and proposals)

- **Ensure strong technical support for proposal development / implementation process**

MMV
Medicines for Malaria Venture

Level of health systems organization?

Low | **Medium** | **High**

Country 1
Country 3

Country 2
Country 4
Country 5

- Complicating factors:
  - A high level of decentralization
  - Business process re-engineering
  - Predominance of the private sector

- **Need to strengthen linkages between federal, state and local authorities**
- **Prioritize strengthening technical capacity in the Ministries of Health**
- **Engage the private sector in IEC/BCC to develop relevant and participatory campaigns for consumers**

MMV
Medicines for Malaria Venture

Conclusions

- Timely Policy Revisions in response to availability of better medicines for children is a multi-pronged challenge
- One-size-fit-all approaches to engaging country policy making processes **will not work**
- Despite country-level differences, there are recurring themes common to all countries we studied:
  - Communicate early with policy makers and implementers about the need for paediatric medicines and new options to meet this need
    - *Challenge is finding the right voice-pieces to engage the necessary stakeholders*
  - Comparative Effectiveness Data should anchor this policy dialogue
  - More timely policy review processes are needed in most countries.
    - *Need to distinguish between printing a policy or guideline vs. getting TWGs activated to work more routinely and systematically*
  - Exogenous factors, e.g. donor financing and HSS activities, can impinge on the ability to revise policies on a timely basis.

MMV
Medicines for Malaria Venture

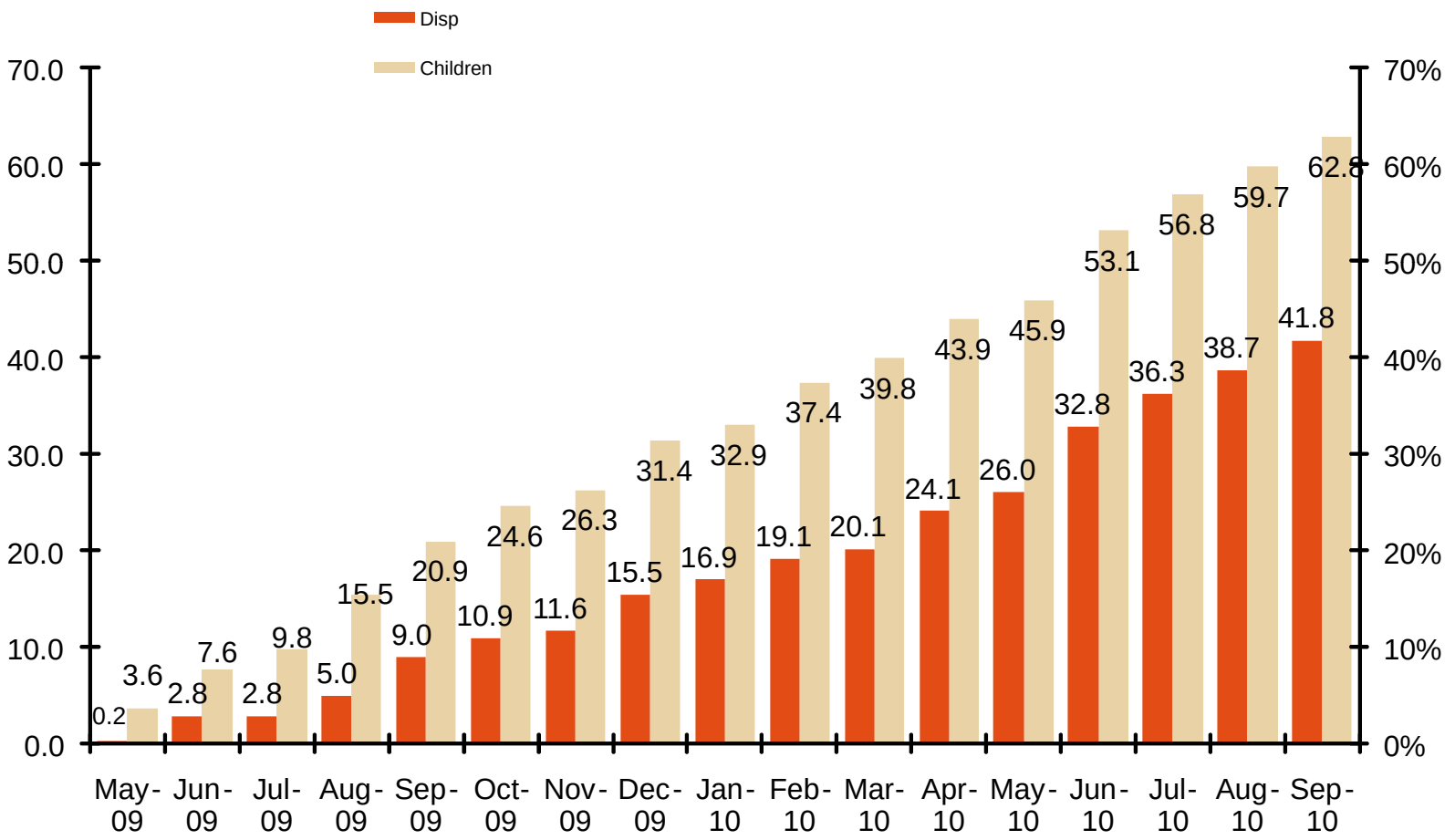
Perspectives for the future

- Product development partnerships can help by “shining a light” on current processes and engaging in “process improvement” around policy change and adoption of new medicines?
- Are there good avenues to work these issues (e.g. RBM SRNs in the case of malaria, or Global fund procurement guidelines?)
- How can we maximize meaningful dissemination of information ?
- Are we coordinated enough in generating requisite evidence to drive policy change for the right reasons?
  - Country level stakeholders need more evidence beyond proof of equivalence (POE)
  - Real life effectiveness and proof of value (POV) studies are needed….BUT do we have standards /guidance for doing these type of studies?

Thank You

MMV
Medicines for Malaria Venture

Epilogue: A-L Dispersible to date: 41.8 million treatments



MMV
Medicines for Malaria Venture