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Challenges to Malaria MFT Implementation in Africa: Framework and Observations

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Background

- Evidence has been presented that if implemented properly, malaria MFTs will delay the emergence of drug resistance
- For decades, countries had implemented single monotherapy first-line treatment policies for malaria e.g. CQ or SP
- Due to the emergence of drug resistance, countries, in line with WHO recommendation successfully adopted and are currently implementing the use of ACTs largely as single first-line treatment policies for uncomplicated malaria

Purpose of a Malaria Treatment/Antimalarial Drug Policy

- To ensure availability of safe, effective, good quality and affordable antimalarial drugs to those that need them and at the same time promote rational drug use which will minimize the development of antimalarial drug resistance.[1]

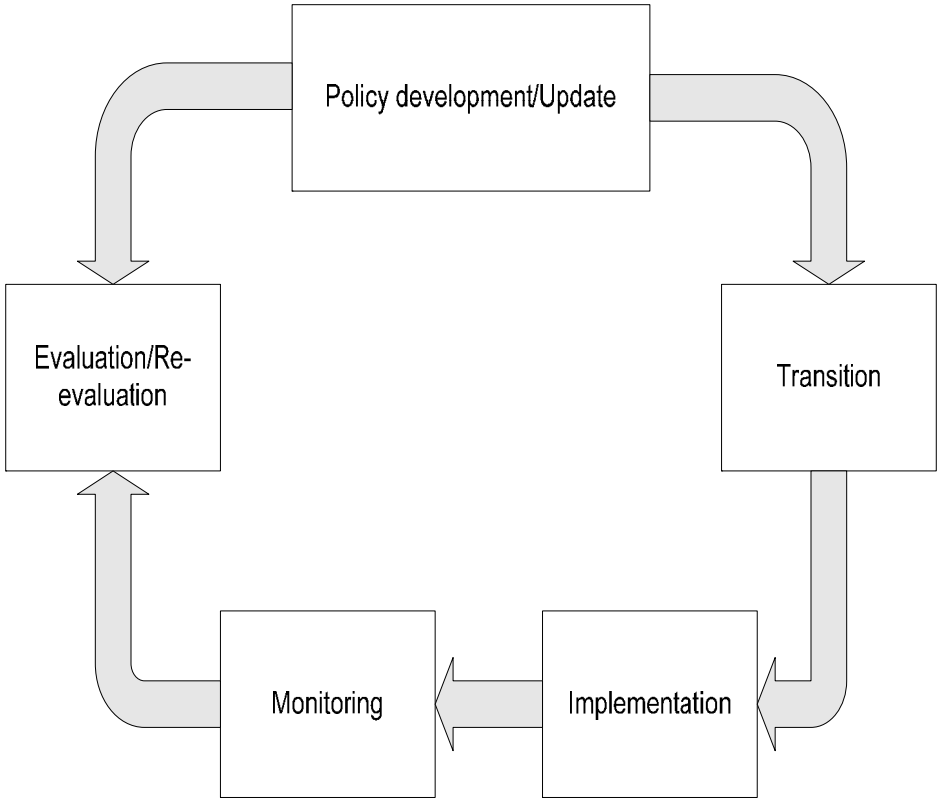
[1] WHO. 2001. Monitoring Antimalarial Drug Resistance. Report of a WHO Consultation, Geneva, Switzerland, 3–5 December 2001. WHO/CDS/RBM/2002.39. Geneva: WHO.

Process and Experiences of Recent Malaria Treatment Policy Change

- The change in treatment policy at country level may be said to have occured in four phases—
- The policy review and change process: the processes and procedures leading up to the selection of the new treatment policy, including discussions on financing
- The transition phase: the period when the decision on the new treatment policy had been made but the implementation of the policy has not yet occurred
- The full implementation of the new policy: national rollout of the new policy
- Monitoring and evaluation: during and after implementation

Process and Experiences of Recent Malaria Treatment Policy Change (2)

- Development of parasite resistance to antimalarial drugs is a dynamic process, hence countries have been constantly reminded that a malaria treatment policy must also be continually monitored, reevaluated, and updated to ensure its effectiveness.



Process and Experiences of Recent Malaria Treatment Policy Change (3)

- While the change process can be described in these phases, in reality the policy change and implementation process can be highly political, lengthy, and iterative
- The policy change process generally takes between 12 and 18 months however, unless appropriate mechanisms have been put in place early in the process, it has taken as long as 10 years in some countries.
- It is essential to begin the collection of data, consensus building, and the development of action plans early in the process to ensure timely decision making and implementation

New policy uptake takes a long time- requires lead planning…….

	Uganda June 2004	Zambia (Dec 2003)	Kenya (Apr, 2004)
Policy change discussion	6	6	6
Policy announcement	0	0	0
Approval of GFATM proposal	8	4	2
Treatment guidelines revised	8	6	14
GFATM Funds remitted to country	12	7	15
Drug ordered (Through WHO)	4	8	16
TOT, sub national training and TG distribution	5	7	24
Drug arrives at National medical stores	6	9	19
Drug distributed	13 +	12	26
Total time	62+ Months	59+ Months	122+ Months

Decision to change/update drug policy

- Triggered by a number of factors, including:
  - Increased mortality and morbidity due to malaria
  - Consumer and/or provider dissatisfaction with the current first line therapy
  - Evidence of poor efficacy of antimalarials currently in use
  - Evidence of good efficacy of new drugs, strategies and approaches

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Framework for mapping the process of adopting, introducing and implementing multiple first-line treatments (MFTs) for malaria

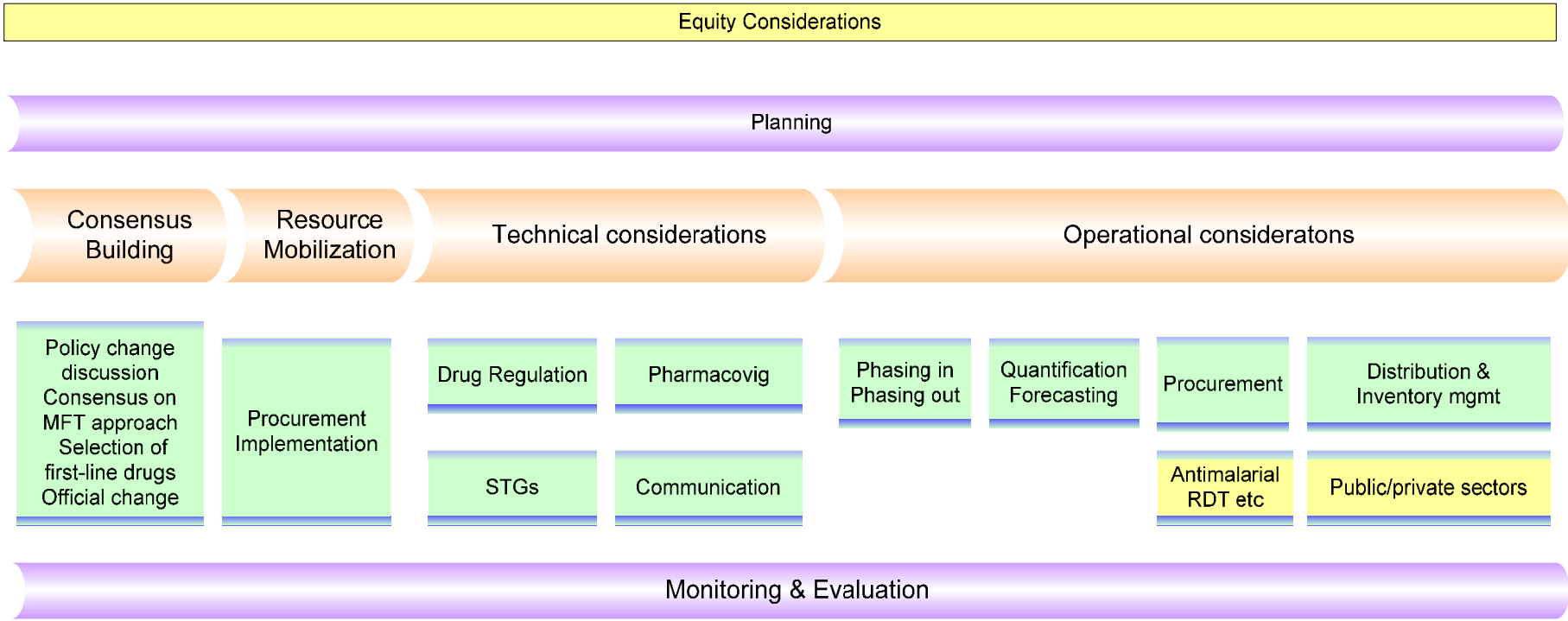
Approaches to MFT policy development

- Levels:
  - Regional / Country Level MFT policies
- Variations in Approach:
  - One first-line treatment in the public sector and a different one in the private sector
  - Different first-line drugs for children and adults
  - "Cycling" drugs over a selected period, preferable a period short enough to forestall resistance

Global Level Actions

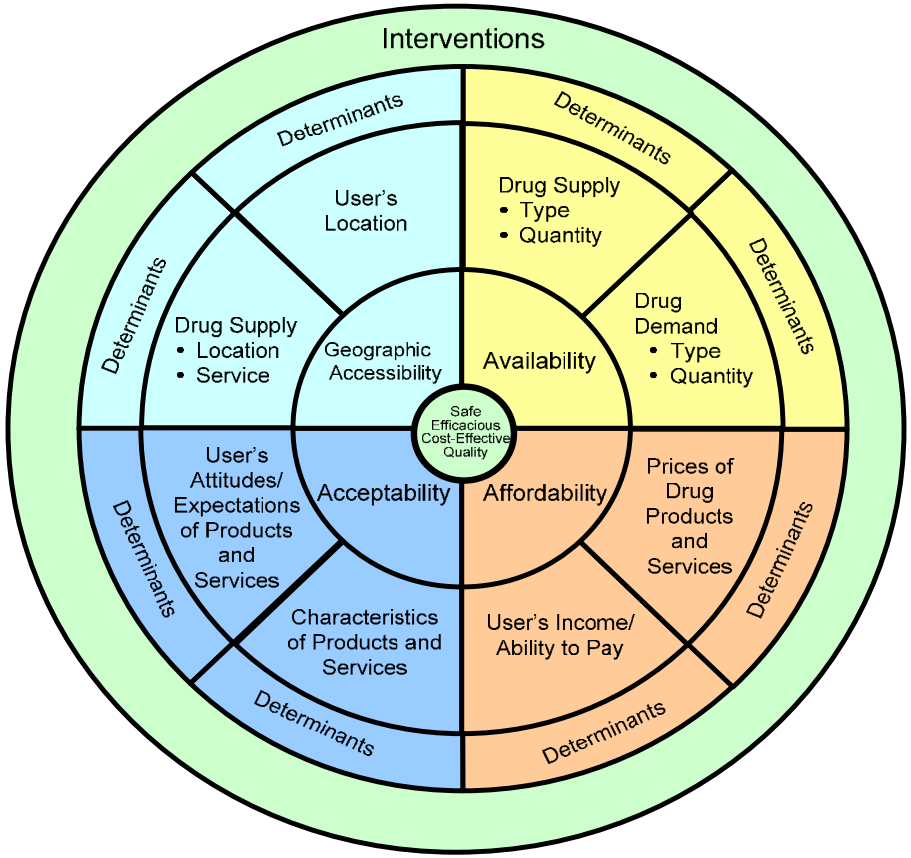
- Dissemination of available evidence at global level
- WHO endorsement of MFT policy adoption as a global/regional/country strategy for delaying resistance emergency
- Global level stakeholder buy-in and pledge for support (RBM Secretariat, UNICEF, World Bank, Global Fund, USAID, Gates Foundation, UNITAID, PMI etc)
- Development at global level and dissemination to regional/country level of a technical update on MFT policies by WHO

Framework for Regional/Country Level Actions



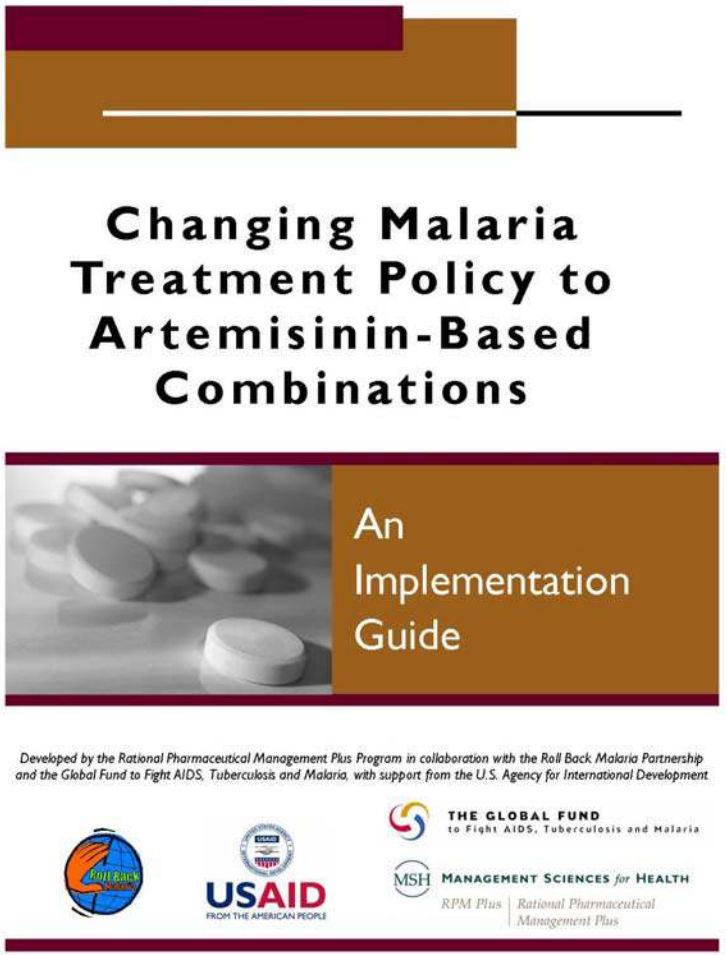
Potential Challenges at Policy and Implementation Level

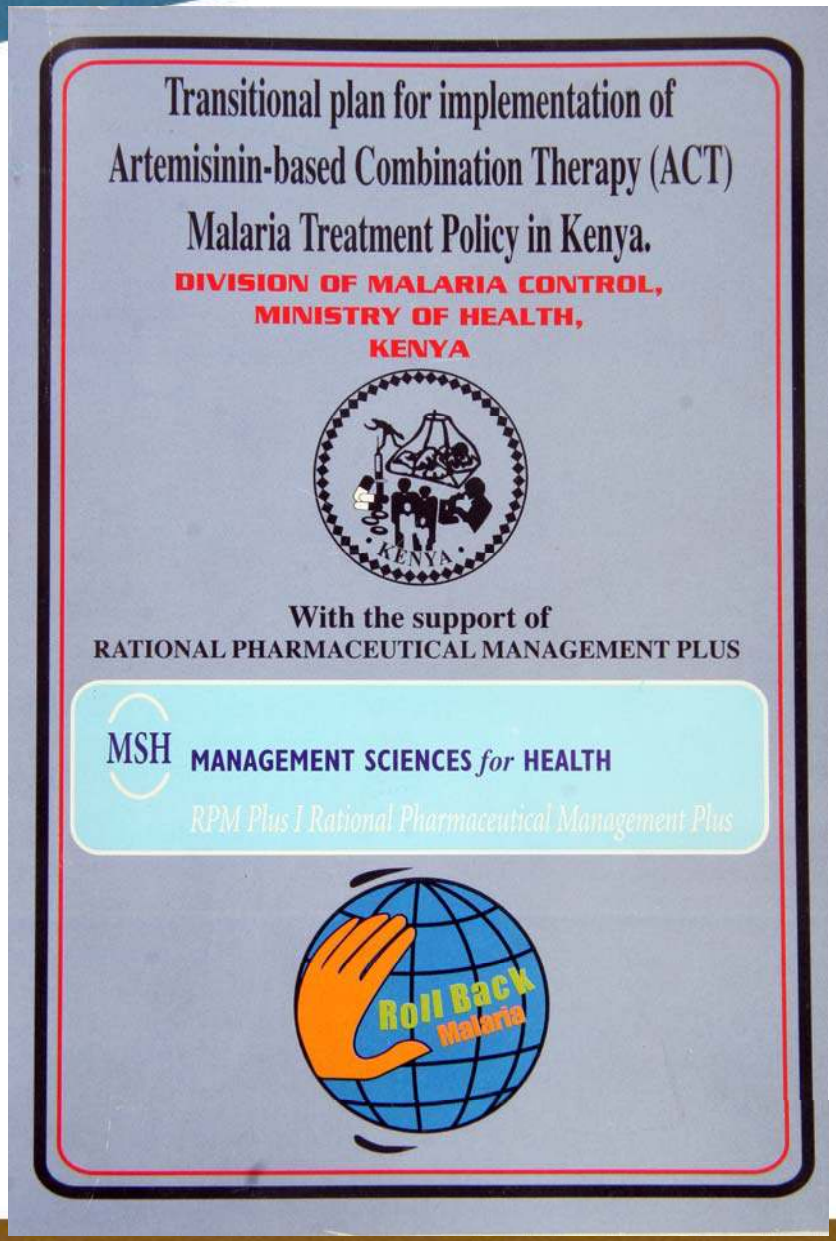
Equity Considerations



Implementation

- ACT Implementation Guide developed to provide guidance to countries on actions to take when rolling out a new treatment policy for national level implementation
- Key actions for each framework area detailing Tech/Op lead, Estimated timeline, Resource Requirements, Performance indicators




Transitional plan for implementation of
Artemisinin-based Combination Therapy (ACT)
Malaria Treatment Policy in Kenya.
DIVISION OF MALARIA CONTROL,
MINISTRY OF HEALTH,
KENYA
KENYA
With the support of
RATIONAL PHARMACEUTICAL MANAGEMENT PLUS
MSH MANAGEMENT SCIENCES for HEALTH
RPM Plus I Rational Pharmaceutical Management Plus
Roll Back Malaria

Key actions - Policy Change

- Analyze and present the evidence for change
- Analyze and appraise the MFT options available and select
- Develop appropriate bodies/committees to oversee the process of the development and implementation of the new policy
- Analyze the health systems capacity for implementing the policy
- Analyze regulatory environment
- Build consensus and advocate change amongst appropriate stakeholders
- Announcement and publication of policy change

Key actions - Planning and Coordination

- Identify stakeholders
- Determine their importance at the various stages, their roles and responsibilities, and how they should be engaged (stakeholder analysis)
- Identify composition of transition committee or, if using an existing mechanism, determine which existing committee or group should carry out this process
- Establish working groups or task forces and their respective membership within the committee
- Establish terms of reference for working groups/task forces
- Develop/review mode of work and frequency of meetings

Key actions - Resource Mobilization

- Develop/review budget for transition and implementation
- Identify potential national-level resources—e.g., Heavily Indebted Poor Country (HIPC) Trust Fund
- Evaluate current spending profile and redirect funds if necessary
- Develop a strategy for accessing funds
- Develop/review proposals for GFATM or other funding agency
- Identify commitments from departments within MOH and from donors
- Evaluate cost-sharing and exemption mechanisms and develop methods for improving equity
- Develop/review financial accountability mechanisms

Key Actions – Revision of Drug Regulation

- Register new drugs
- Establish fast-track registration system as needed
- Evaluate whether regulatory requirements may have a negative impact on implementation and establish mechanisms to alleviate this
- Evaluate and strengthen regulatory enforcement capacity if needed
- Promulgate regulations for appropriate importation, distribution, prescribing and dispensing of ACTs and ensure that they are consistent with the MFT policy

Key actions – Review, Harmonization, Dissemination of Guidelines, Medicines Lists

- Determine which guidelines need to be revised and where harmonization should occur (with STGs, EML, IMCI, Ins lists)
- Determine the process for revision and the groups involved
- Determine whether new guidelines needs to be published or an addendum made to the existing guidelines
- Publish revised guidelines/EML and/or addendum
- Disseminate new guidelines and EML

Key actions - Review and dissemination of BCC materials + Targeted IEC

- Develop/review behavior change communication strategies, and coordinate with IEC strategy
- Develop/review BCC and IEC materials (Job Aids, Posters, Content of TV, Radio spots, documentaries, Interpersonal Communication)
- Develop/review plan for implementing the BCC strategies

Key actions - Update of training curriculum, training, supervision of HWs

- Revise pre-service and in-service training curricula to incorporate MFTs
- Develop/review plan for training of health workers (public and private sectors) and develop training materials
- Convene training workshops soon after procurement of the new MFTs and carry out a cascade training (Major challenge area – provider training and their ability to practice appropriate diagnosis, prescribing and dispensing practices)

Phasing in "new" and phasing out "old"

- Determine phase-in plan for MFT policy
- Determine pipeline for the "old" drugs (if existent)
- Adjust future procurements of MFTs based on available viable old treatments and ensure that large pipelines of outgoing drugs do not accumulate when the new drugs are procured
- Develop/review a plan for the phase-out of old unrequired drugs (especially monotherapies) from the health system (public and private sectors) as the new MFTs becomes available

Key actions - Forecasting of demand and quantification

- Include MFTs in overall quantification and select appropriate quantification method for each first-line treatment based on data available (include RDTs if appropriate)
- Using treatment guidelines, develop appropriate assumptions for frequency and duration of treatment use
- Adjustments for inventory position, lead time, safety stock, growth and losses
- Ensure that forecasts for parallel procurement efforts of the MOH and grants (including GF) are harmonized
- Support private sector quantification (pub/priv approach)
- Establish consumption tracking through LMIS to guide future quantification

Key actions - Procurement

- Depending on source of funding for treatment, follow procurement requirements
- Ensure incorporation of MFTs in national procurement plan for antimalarials and diagnostic commodities
- Facilitate private sector procurement (if pub/priv approach)
- Process procurement through selected procurement agent
- If need to repackage product, identify supplier/ manufacturer that can repackage
- Develop packaging and labels for prepackaged product if needed and pretest these
- Develop tender documents, initiate and manage procurement
- Supplier performance monitoring

Key actions - Distribution

- Develop/review distribution plan (public/priv or essential kits for children)
- Review/develop distribution systems to allow for coordination between the public and private sectors
- Develop/review strategies to avoid leakage to between the sectors
- Develop/review storage capacity and conditions in both sectors
- Develop/review human capacity for efficient implementation of distribution plan and supervision
- Develop/review transportation systems in both sectors
- Develop/review redistribution systems and systems to remove expired or excess stocks from one system to another
- Develop/review systems to monitor efficiency of distribution system and redistribution mechanisms

Key actions - Inventory management

- Review/develop inventory management systems to improve the management of the drugs in the public health facilities and in private clinics, drug outlets etc
- Develop/review security measures to prevent theft or stored products
- Develop/review systems to ensure management of the shelf life of products (including capacity building and supervision)
- Develop/review systems for dealing with expired products

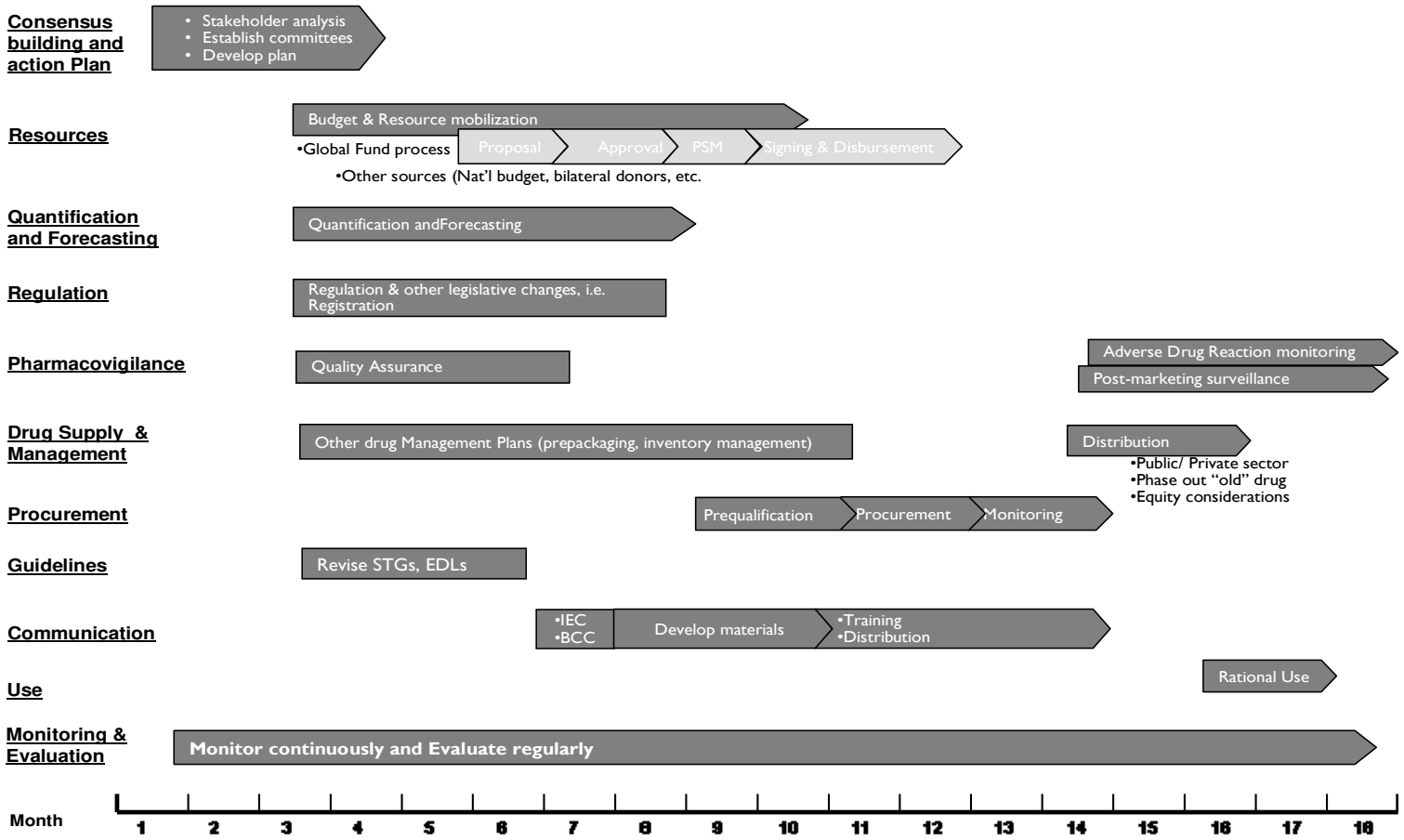
Key actions – Revision of QA mechanisms (PV and product quality surveillance)

- Develop/review system and tools for monitoring of adverse events
- Develop/review systems for quality assurance during drug registration and procurement
- Develop/review system for dealing with violations of drug quality standards
- Establish mechanism to coordinate the various surveillance systems—ADR, product quality, effectiveness etc
- Develop/review plan for post- marketing product quality surveillance. Ensure that samples will be regularly sampled, tested by a qualified laboratory and interventions instituted on the basis of findings

Key actions - Monitoring & Evaluation

- Define policy change milestones
- Include outcome and impact targets within overall country targets (indicators)
- Identify data needs and sources (priority areas – routine data recording & collection; planning, budgeting, monitoring for donor funded activities; survey based data; LMIS; sentinel sites; training data)
- Ensure the collection of data through existing information systems and collate appropriately
- Strengthen M & E capacity at NMCP
- Facilitating linkages and partnerships for M & E
- Develop schedule for MFT implementation M&E activities with roles and responsibilities

Illustrative timeline



Conclusion (1)

- The decision to change antimalarial treatment policy and the subsequent implementation of the policy brings with it challenges and complexities at every level, involving a variety of stakeholders, ranging from departments within the Ministry of Health (MOH) to manufacturers and private providers
- At country level, the adoption of MFT will be a multi-sector process leading to an explicit policy decision. The policy decision will follow an analysis of its benefits, risks, and costs and the health system's capacity to finance, manage, and ensure its sustainable and effective implementation.

Conclusion (2)

- Introducing MFT requires countries to carry out *coordinated activities* to prepare for effective implementation (done before with lessons learned)

- The implementation process encompasses the steps needed to operationalize the policy, including a system to monitor and evaluate the progress of these activities and their impact on malaria control

Drug policy change breakout session

- How would an MFT policy differ from a new policy of just one drug (or combination drug)?
- What are the steps involved in adopting and introducing multiple first-line therapies for malaria (MFT)?
- What are the key operational challenges and potential economic costs that may be encountered?
- What are the practical questions of how deploying more than one co-formulated malaria drug as first-line might be accomplished at the national level adoption and implementation at national and lower levels of the health care system?

Drug policy change breakout session

- What are the potential obstacles at the policy and implementation levels?
- In what way will the global subsidy now being planned through the Affordable Medicines Facility for malaria (AMFm) potentially influence national malaria drug policies, particularly the choice of specific drugs and implementing MFT policies?
- Are there any known examples of similar policy changes that could provide a useful context for MFT?

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Thank You!