

Aid for Early Decision about a Malaria Vaccine:

The Draft Regional Decision-Making Framework

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**MALARIA
VACCINE**
DECISION-MAKING
FRAMEWORK

The logo for the Malaria Vaccine Decision-Making Framework. It features the words "MALARIA VACCINE" in a large, bold, blue sans-serif font. Below this, the words "DECISION-MAKING" and "FRAMEWORK" are stacked in a smaller, blue sans-serif font. To the left of the word "FRAMEWORK" are three small, stylized arrows pointing to the right, colored purple, green, and blue.

A malaria vaccine is needed

- Malaria claims the lives of thousands of African children each year, in spite of improvements in treatment and prevention measures
- Mosquitoes and parasites may become resistant to drugs and chemicals currently used for treatment



A malaria vaccine is near

- The international malaria community has established 2015 as the goal for development of a licensed, first-generation malaria vaccine
 - Must offer at least 50% efficacy for 1 yr. or more
- However, a promising vaccine candidate could be licensed as early as **2012**
 - RTS,S, the most advanced vaccine candidate, is entering a pivotal phase 3 trial in 11 sites across 7 African countries. If these go well, licensure could occur by 2012.



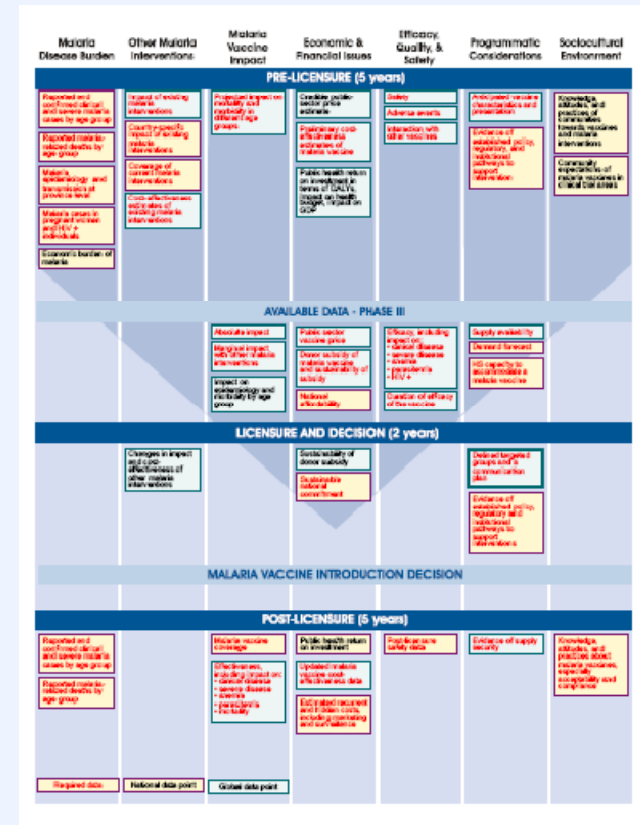
Deciding on vaccine use—a complex process

- When a malaria vaccine becomes available, deciding whether to use it in national health programs is not straightforward:
 - Policymakers must take into account many interwoven financial, programmatic, and regulatory factors
- What will guide the decision to introduce or not a new tool in the arsenal of malaria control measures ?



A new tool can aid preparation

- The Decision-Making Framework (DMF) is a new tool to help countries plan now to make a timely, informed decision when a licensed malaria vaccine becomes available
 - The DMF identifies information to gather, processes to establish, and timeline for preparation



Malaria vaccine decision-making framework

Process started in 2006:

- Priority area identified in the Malaria Vaccine Technology Road map
- Coordinated by PATH MVI and WHO AFRO
- Sponsored by USAID and the Bill & Melinda Gates Foundation
- Guided by a steering committee made up of malaria and immunization experts

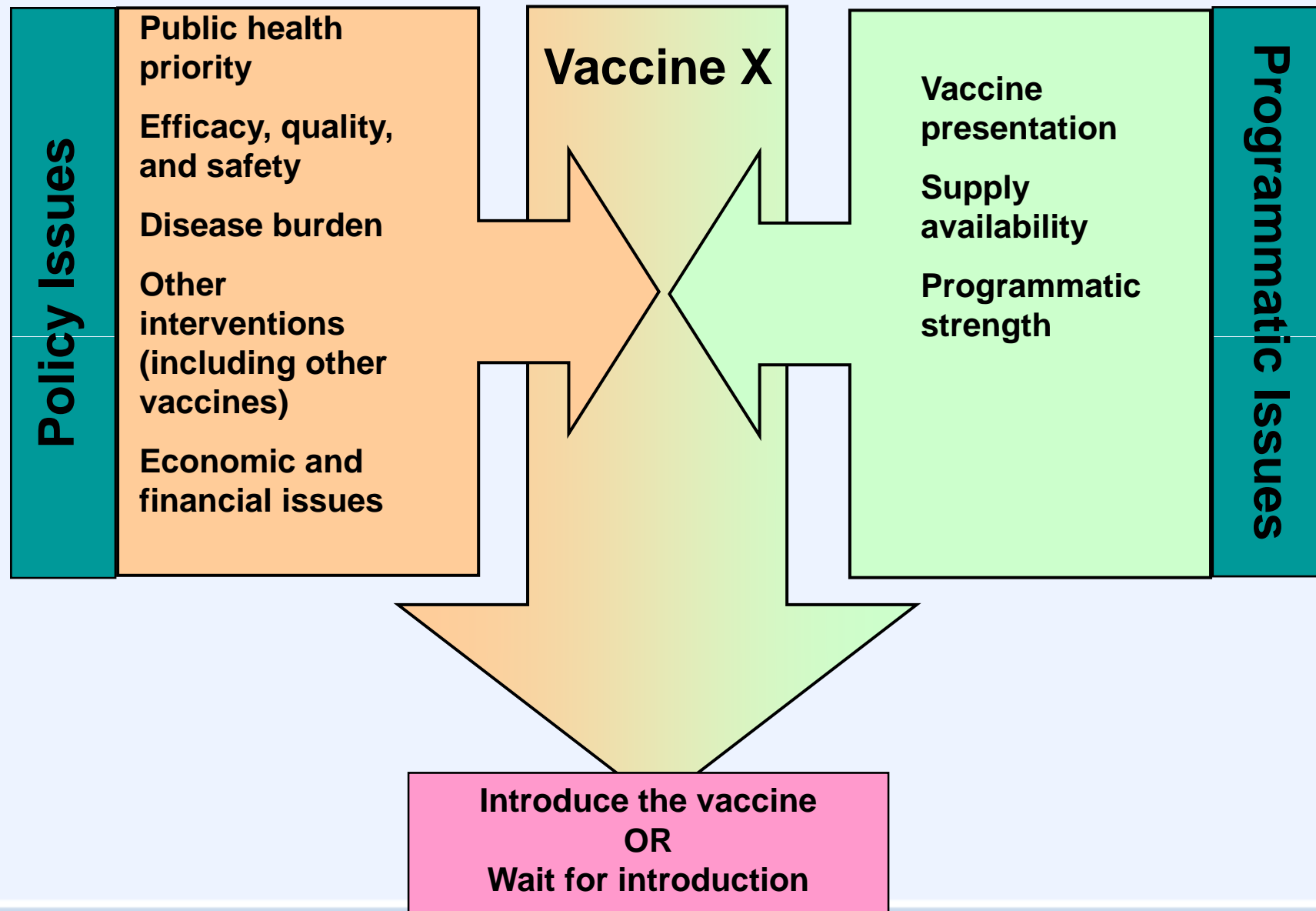
DMF Process -1

✓ Regional meeting with 13 countries in January 2006;
Background information - briefing papers:

- *Malaria control policies;*
- *Moving from development to policy to implementation of new products malaria endemic countries;*
- *Status of malaria vaccines;*
- *Landscape of other vaccines and malaria control options on the horizon over the next decade;*
- *Analysis of the demand for a malaria vaccine:*
- *The return on investment for malaria vaccines: preliminary estimates of public health impact in Africa*

Vaccine introduction guidelines from WHO

WHO guidelines for introducing new vaccines



DMF Process -2

- ✓ Development of a generic Decision-Making Framework
- ✓ Consultations in 6 countries Country-specific DMF: (Gabon, Ghana, Kenya, Mali, Mozambique and Tanzania)
- ✓ Synthesis into a Draft Regional Framework

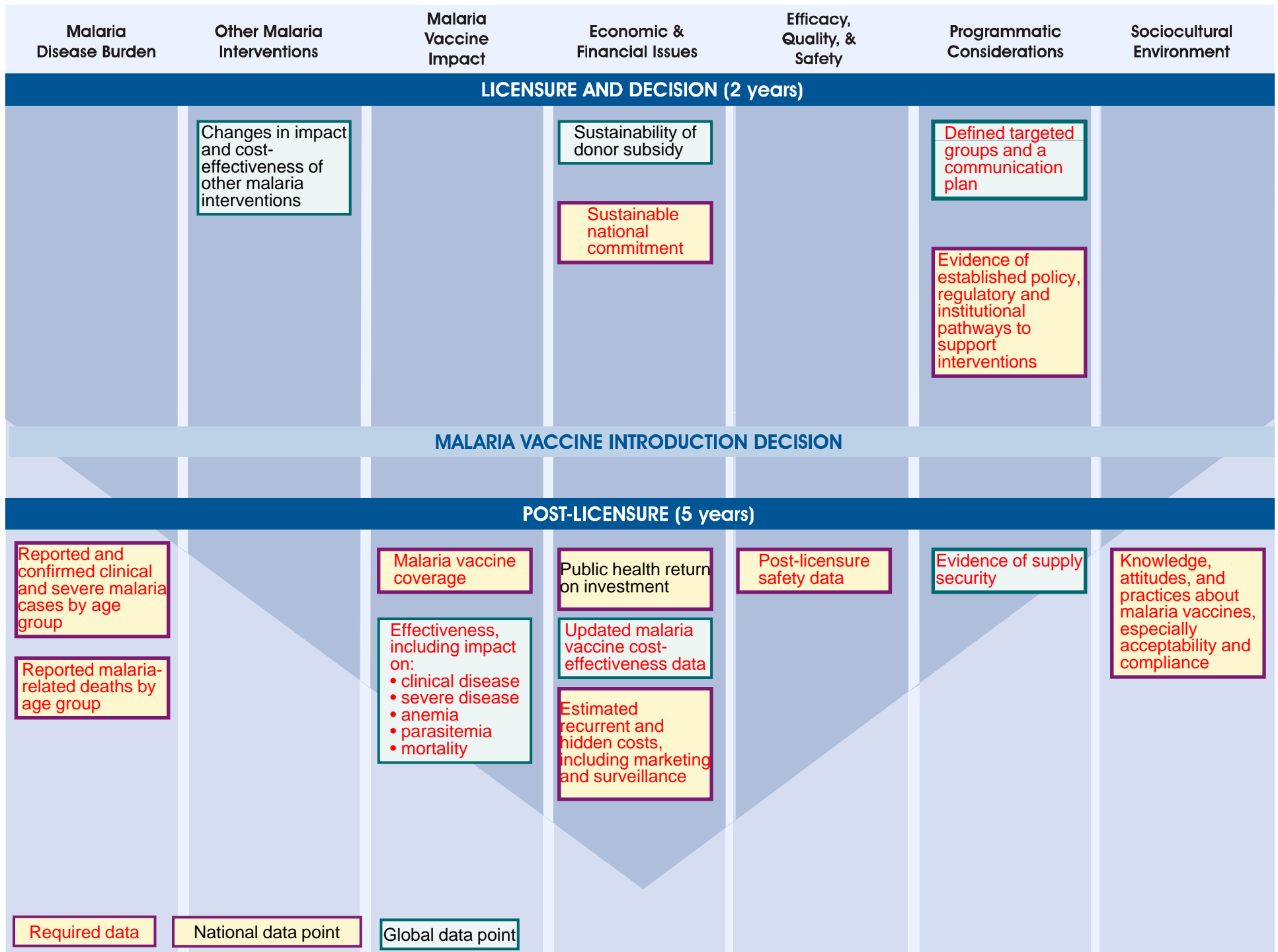
Where are we?

- Review of the draft regional DMF by additional countries in 2007-2008:
 - Consultations in Ethiopia, Malawi and Burkina Faso
- Validation of the DMF as a common tool for decision making on malaria vaccines in Africa
 - Central Africa in January 08
 - East and South Africa in August 08
 - **West Africa in November 08**

Draft Regional Malaria Vaccine Decision-Making Framework

- The first part of framework features **data**, both global and regional, that stakeholders will require to make a decision about the appropriate use of a malaria vaccine within national health systems.

| Malaria Disease Burden | Other Malaria Interventions | Malaria Vaccine Impact | Economic & Financial Issues | Efficacy, Quality, & Safety | Programmatic Considerations | Sociocultural Environment |
|--|--|--|---|---|---|--|
| PRE-LICENSURE (5 years) | | | | | | |
| <p>Reported and confirmed clinical and severe malaria cases by age group</p> <p>Reported malaria-related deaths by age group</p> <p>Malaria epidemiology and transmission at province level</p> <p>Malaria cases in pregnant women and HIV + individuals</p> <p>Economic burden of malaria</p> | <p>Impact of malaria interventions</p> <p>Country-specific impact of malaria interventions</p> <p>Coverage of current malaria interventions</p> <p>Cost-effectiveness estimates of malaria interventions</p> | <p>Projected impact on mortality and morbidity in different age groups</p> | <p>Credible public-sector price estimate</p> <p>Preliminary cost-effectiveness estimates of malaria vaccine</p> <p>Public health return on investment in terms of DALYs, impact on health budget, impact on GDP</p> | <p>Safety</p> <p>Adverse events</p> <p>Interaction with other vaccines</p> | <p>Anticipated vaccine characteristics and presentation</p> <p>Evidence of established policy, regulatory, and institutional pathways to support intervention</p> | <p>Knowledge, attitudes, and practices of communities towards vaccines and malaria interventions</p> <p>Community expectations of malaria vaccines in clinical trial areas</p> |
| AVAILABLE DATA - PHASE III | | | | | | |
| <p>Required data</p> | <p>National data point</p> | <p>Absolute impact</p> <p>Marginal impact with other malaria interventions</p> <p>Impact on epidemiology and morbidity by age group</p> <p>Global data point</p> | <p>National affordability</p> <p>Public sector vaccine price</p> <p>Donor subsidy of malaria vaccine and sustainability of subsidy</p> | <p>Efficacy, including impact on:</p> <ul style="list-style-type: none"> clinical disease severe disease anemia parasitemia HIV + <p>Duration of efficacy of the vaccine</p> | <p>Supply availability</p> <p>Demand forecast</p> <p>HS capacity to accommodate a malaria vaccine</p> | |



Regional Malaria Vaccine Decision-Making Framework

- The second framework features **processes**, both global and regional, that should take place in order to facilitate decision-making about malaria vaccines.

Global Level Processes

National Level Processes

PRE-LICENSURE (5 years)

Integrate country requirements into product development plans (5 years before)

Establishment of Technical Working Group

Assess and strengthen regulatory, ethics and data management processes in-country

Integrate the malaria vaccine in the multiyear strategic plan (4-5 years before)

Signal vaccine demand (1-3 years before)

AVAILABLE DATA - PHASE III

Share information on vaccine research

Conduct global advocacy to leverage funding

Engage local private-sector partners and pharmaceutical companies

Develop communication plan on the malaria vaccine (1 year before)

LICENSURE AND DECISION (2 years)

Donors provide funding to support vaccine

WHO issues policy recommending use of vaccine

WHO publishes vaccine management and introduction guidelines (licensure)

National expert group/technical working group issues recommendation regarding vaccine introduction

National regulatory authority reviews vaccine (within 1 year of licensure)

Advocacy with national decision makers

MOH makes a decision about integration of vaccine into EPI

Incorporate malaria vaccine into national budgeting processes

Develop plan for procurement and resource mobilization for financial sustainability

Global Level Processes

National Level Processes

MALARIA VACCINE INTRODUCTION DECISION

WHO pre-qualification (within 1 year of licensure)

International agencies plan for procurement (within 1 year of licensure)

Issue programmatic guidelines for implementation of a malaria vaccine (within 1 year of licensure)

Examine sustainability of existing funding and how to encourage in-country financing

Update the communication plan for implementation (one year after introduction)

POST-LICENSE (5 years)

Monitoring of vaccine performance, including evaluation of vaccine impact and pharmacovigilance

Monitor vaccine performance and safety

Monitor implementation of the vaccine and evaluate impact on health system infrastructure

ToR for Group Discussions on the DMF: Data Needs

- *Objective: Determine the data necessary to reach a decision on the potential introduction of a malaria vaccine*
- Review the data outlined in the DMF and discuss if:
 - They are relevant for decision making in the sub-region?
 - There is any which is not and why?
 - They are sufficient?
 - If not what are the most critical data for decision in the sub-region which are missing

ToR for Group Discussions on the DMF: Process Needs

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Group Structure

- Group A
 - Algeria, Benin, Burkina Faso, Cap Vert, Cote D'Ivoire, Guinea
- Group B
 - The Gambia, Ghana, Liberia, Nigeria, Sierra Leone
- Group C
 - Guinea Bissau, Mali, Mauritania, Niger, Senegal, Togo

