



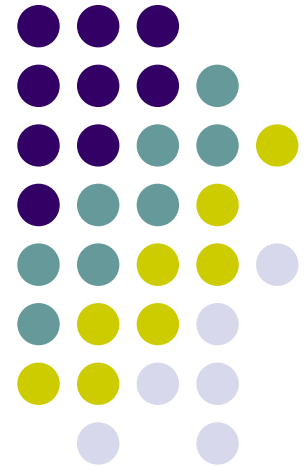
Investing in our future

# The Global Fund

To Fight AIDS, Tuberculosis and Malaria

## UNICEF SUPPLIER MEETING

Monday 20 October





# What is the Global Fund?



As a **partnership between governments, civil society, the private sector and affected communities**, the Global Fund represents **an innovative approach to international health financing**.

As a financing mechanism, The Global Fund's purpose is to attract, manage and disburse resources to fight AIDS, TB and malaria. **We do not implement programs directly**, relying instead on the knowledge of local experts.

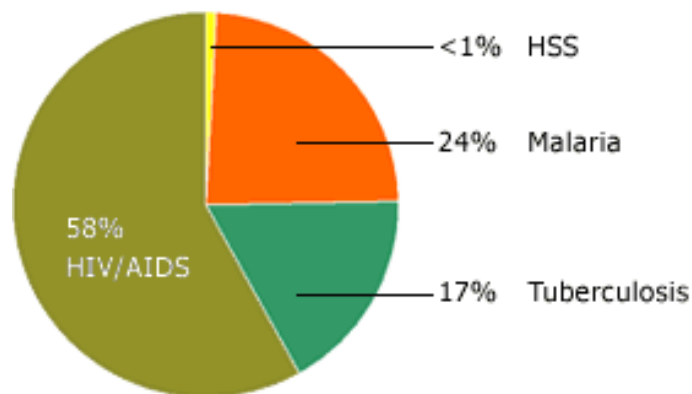
The Global Fund is **a financial institution**, about 30% of grant funds are for medicines and health products procurement.

The GF **does not conduct any procurement activities** for pharmaceutical products, PR are responsible for ensuring adherence to Global Fund QA/QC requirements

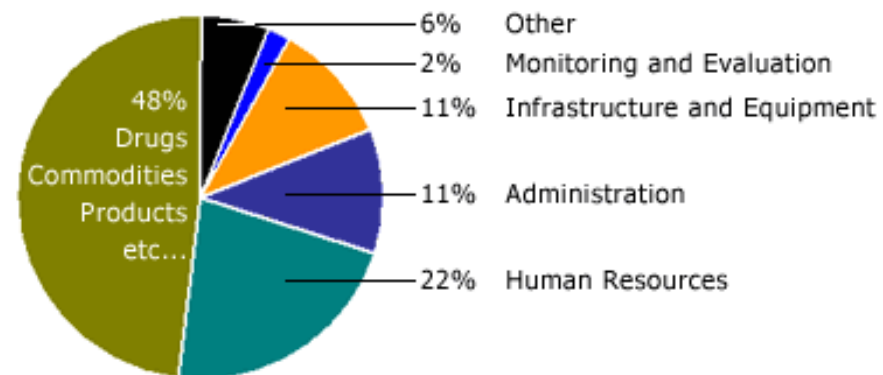


# Distribution of funding?

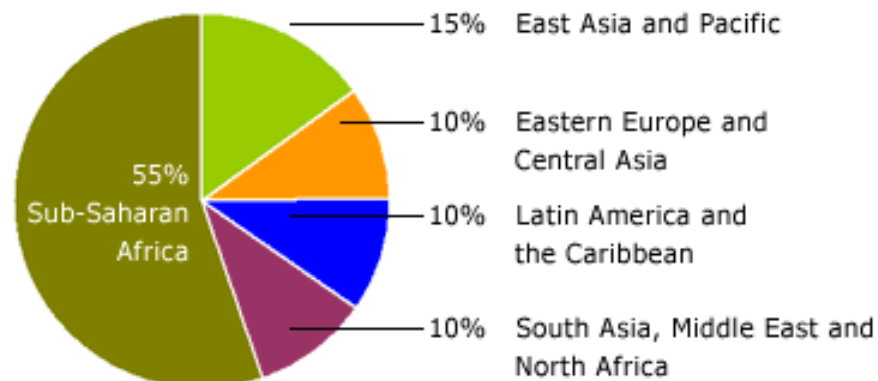
**Disease**



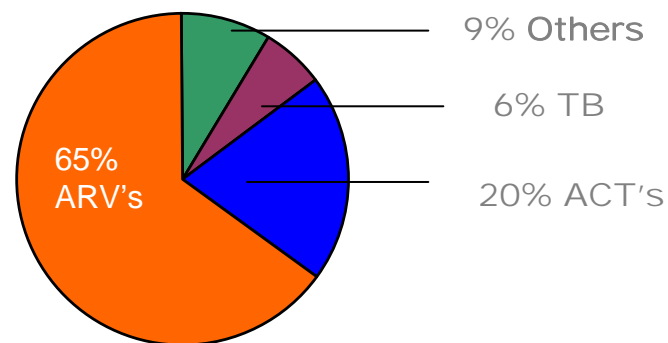
**Expenditure Target**



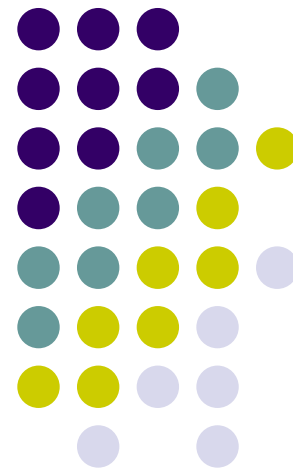
**Geographic Region**



**Pharmaceuticals**



# Global Fund policy on Quality Assurance for Pharmaceutical Products



# Current Global Fund Quality Assurance

**Policy** (10th Board Meeting, April 2005 and 16th Board Meeting, November 2007)



## Multi-Source pharmaceutical products

Products generally off-patent and product standards are available in the public domain (e.g.: Int.P, BP and USP before October 2002)

**Must comply with quality standards and requirements of Drug Regulatory Authority in the recipient country.**

## Single and Limited-Source Pharmaceutical Products

**Must procure single or limited source pharmaceutical product that meets the criteria approved by the Global Fund Board**

and

**Must comply with quality standards and requirements of Drug Regulatory Authority in the recipient country.**

# Current QA Policy for single- and limited-source products : selection of products



**Option A:** Products pre-qualified by WHO ( UN procurement quality and sourcing project)

**Option B:** Products registered by a stringent regulatory authority

**Option Ci:** The manufacturer has submitted an application for pre-qualification to the WHO or approval from a stringent regulatory authority and the manufacturing site is GMP compliant as certified by WHO or a stringent regulatory authority.

**Option Cii:** The product is manufactured at a GMP compliant manufacturing site as certified by WHO or a stringent regulatory authority

# QA policy for single and limited source pharmaceutical products



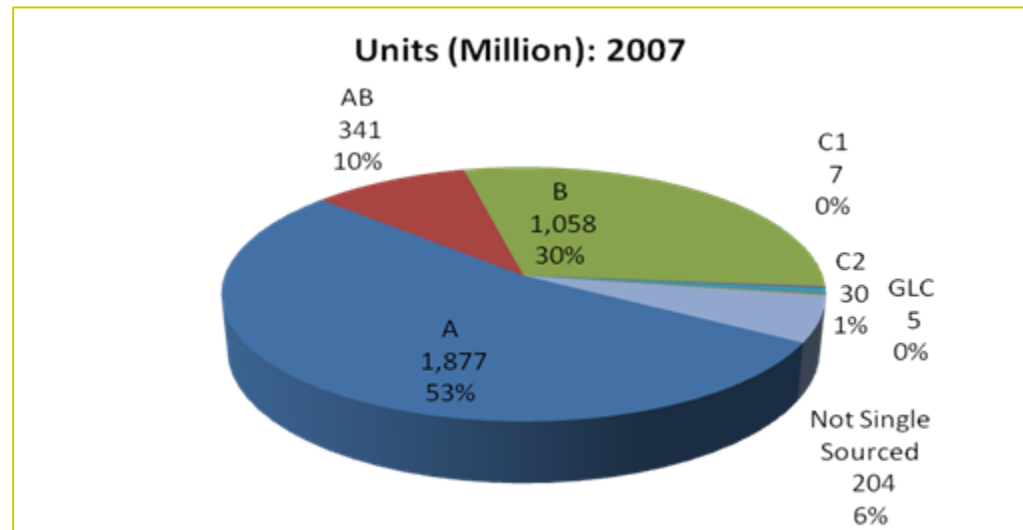
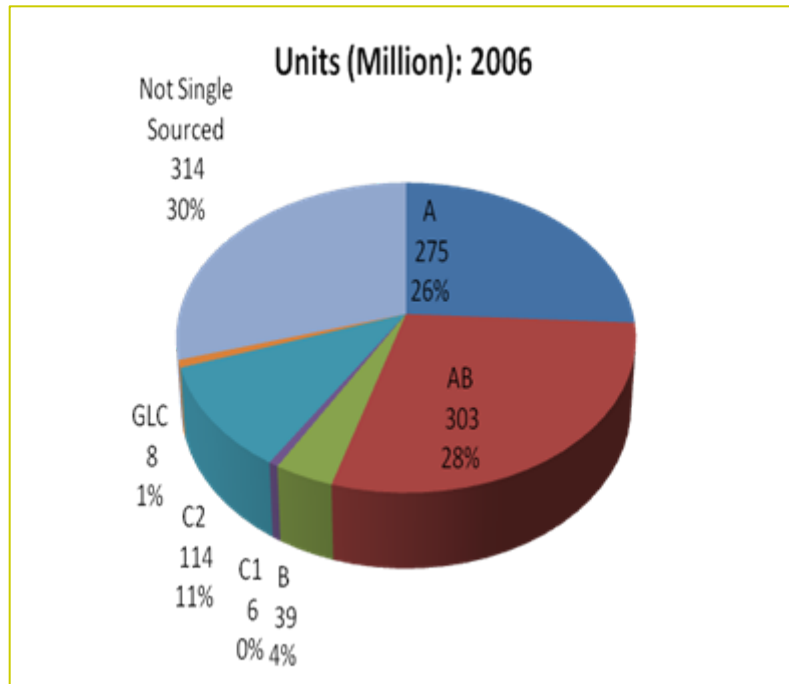
- Procurement under Option Ci/Cii
  - ✓ Time-limited
  - ✓ Approved by GF Secretariat:
    - review of the notification sent by PR
    - quality control of the lots before shipment to the country
  
- PRs are required to report purchases in the PRM

# ARVs, ACTs, Anti-TB drugs Purchases in 2006 and 2007



Proportion in unit of products classified Ci and Cii out of total FPPs purchased

2006: 12% of Ci & Cii  
2007: 1% of Ci & Cii



# Quality Control applicable to Ci and Cii products: GF Secretariat responsibilities



- ❑ Sampling at manufacturing sites by SGS
- ❑ Testing of products in qualified laboratories: SGS Belgium
- ❑ Test methods: Pharmacopoeia methods when available  
Or Manufacturer's validated methods and specifications
- ❑ Interpretation : a lot is acceptable if the results of the testing are within the pharmacopoeia or manufacturer's specifications  
batch Pass, to be supplied, batch Fail, should not be supplied,
- ❑ As of September 2008, Quality Control of 162 batches
  - ✓ QC 113 lots (ARV-57 batches; ACT-56 batches) completed: green light for the shipment of these products have been sent accordingly to manufacturers.
  - ✓ QC of 49 lots in QC process
  - ✓ 100 % of lot tested passed the QC criteria

# Testing Activities



## Important Manufacturer 's role

- ❑ To send in due time all the information requested by SGS: documentation, SOPS, list of lots to be shipped to the specific country
- ❑ To immediately inform PR, GF Secretariat, SGS Procurement Agent, on any problem occurring during the production of the medicine and on possible delay in the delivery of the medicines



# The Global Fund List

- A procurement tool for Principal Recipient
- Concerns only Limited and single source Pharmaceutical Products
- The products listed “ are not Approved by the Global Fund”
- An overview of classified products and manufacturers according to the Global Fund Quality Assurance Policy criteria

## A classified product:

- ✓ WHO prequalification letter

## B classified product:

- ✓ Stringent NDRA letter

## Ci classified product:

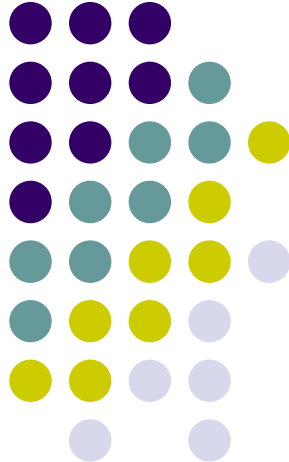
- ✓ GMP certificate issued by a stringent NRA or WHO Prequalification letter
- ✓ Proof of dossier submission and accepted for review from WHO prequalification program **OR** from NDRA for registration

## Cii classified product:

- ✓ GMP certificate issued by a stringent NRA or WHO Prequalification letter

- ✓ <http://www.theglobalfund.org/en/about/procurement/quality/>

# Voluntary Pooled Procurement



# Introduction: Voluntary Pool Procurement Services (VPP)



## Why the VPP?

- **Influence the market dynamics**
  - Approach the market in a coordinated manner, as one buyer
  - Consistent access to quality-assured products, lower prices and enhanced long-term sustainability of the market
- **Address the key procurement “Bottlenecks”**
  - Reduce lead time in procurement process, reduce episodes of stock-outs due to delays in procurement
- **Improve the grant management and performance**

# VPP model



## Price Negotiation Agent:

- A partner is engaged to support GF in negotiating prices and determining approach to markets
- Objective is to negotiate prices, where none exists and facilitate access to other globally negotiated / competitive prices
- Set price ceilings and negotiate terms and conditions

## Procurement Services Agent:

- A Lead Procurement Service Agent or Consortium is engaged to manage the operational process of the VPP
- Contracting of suppliers on the basis of negotiation conducted by the negotiating agent
- Establishing the VPP Order Platform (aggregate demands, process orders, organise deliveries, facilitate tracking of orders)
- Effecting payments to suppliers through the direct payment mechanism
- Providing reports and data

# VPP Products- Core group



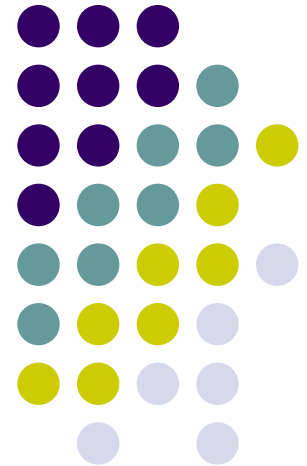
## Core Products:

- 1st and 2nd Line ARVs, ACTs, LLINs
- Standard list of core products to cover therapeutic requirements in line with GFQuality Assurance principles
- Ceiling prices only for these 4 categories

## Additional product categories

- Others product categories e.g. Drugs for Opportunistic Infection, Laboratory supplies etc
- For PRs that might be interested to conduct all purchasing from one agent
- To meet the procurement needs of 'mandatory' PRs that are required to make all GF purchases through a Procurement Agent

# Affordable Medicines Facility - Malaria



# Introduction: Affordable Medicines Facility - malaria



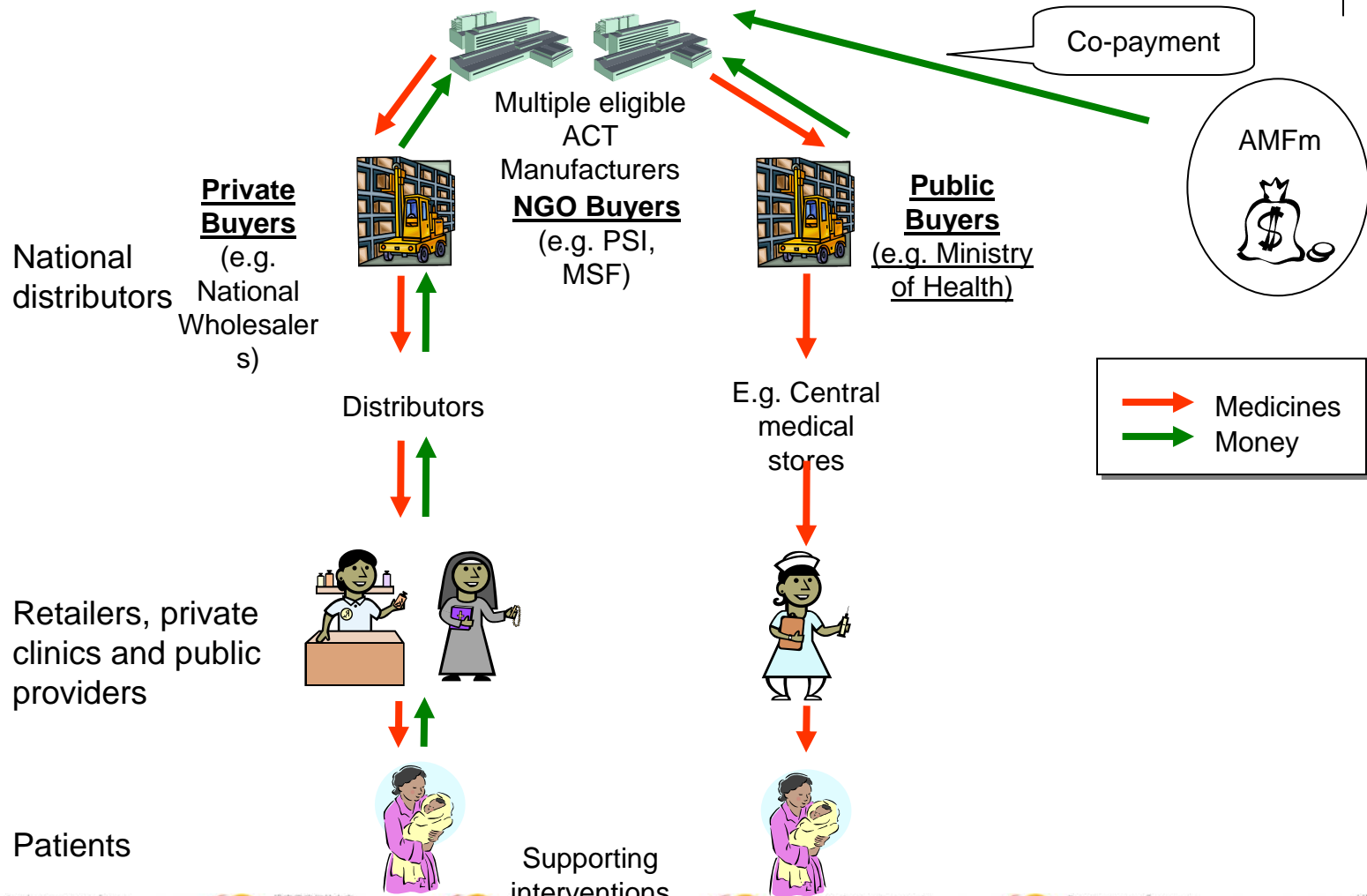
## What is the AMFm?

- A proposed solution to a specific challenge in treating malaria: effective treatment is too expensive or simply unavailable to the 60% of patients who access antimalarial medicines through the private sector
- A financing intervention that seeks to increase availability of ACTs by making them as cheap or cheaper than CQ and SP for all first line buyers in the **public, private and non-profit sectors**

## What is the objective of the AMFm?

- To ensure that people suffering from malaria have access to inexpensive, effective antimalarial treatment in the form of ACTs.
- Promote the use of effective antimalarials and drive ineffective medicines from the market by:
  1. Reducing consumer prices to an affordable level
  2. Introducing in-country supporting interventions to ensure that those suffering from malaria benefit from the reduced price

# AMFm - Structure



# Contact details



- For more information, please contact:

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***THANK YOU***

# Annex: Quality Control applicable to Ci and Cii products: GF Secretariat responsibilities



- Sampling at manufacturing sites by SGS
- Testing of products in qualified laboratories: SGS Belgium
- Test methods:
  - Pharmacopoeia (International, British or US) methods when available
  - Manufacturer's validated methods and specifications
- Items to be tested and reported:
  - Appearance, Identification, Assay, and Impurity control
  - Dissolution or disintegration for tablets and capsules
  - Content uniformity or weight variation for Tablets and capsules
  - pH and microbial limits for the solutions ( if in the spec.)
  - Sterility and Bacterial endotoxin test (for injectables)

# Testing process



## Step A - Implementation of manufacturer's methods at SGS lab

- documentation reviewed by SGS : manufacturer' SOPs and validation data, certificate of analysis of each batch tested.  
**5 working days**
- tests to be performed to evaluate the feasibility of the methods and to implement them ( at least on 2 lots). **16 working days**
- Implementation satisfactory if methods feasible and appropriate and results within the specifications

## Step B - Routine quality control tests of batches

- After satisfactory implementation of the methods
- SGS to select at random, at the manufacturing site, batches for testing after notification accepted by GF. **5 working days**
- quality control testing on the selected batches. **11 working days**

# Quality Control applicable to Ci and Cii products: GF Secretariat responsibilities (2)



## Communication of the results

Interpretation : a lot is found acceptable if the results of the testing are within the pharmacopoeia or manufacturer's specifications

- The GF to review SGS reports /recommendations
- The GF to prepare final conclusion:
  - ✓batch Pass, to be supplied
  - ✓**batch Fail, should not be supplied,**
- The GF to send CoA and conclusion to PR and to Supplier