

# Analysis of the Global TB Drug Market and Country-Specific Case Studies of TB Drug Distribution Channels

## Overview of 1<sup>st</sup> and 2<sup>nd</sup> line TB Markets



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# 1st Line Drug Procurement: The Global Drug Facility

# Many of the countries/organizations involved in DOTS source their drugs from the Global Drug Facility (GDF)

## The GDF is . . .

- Organization that helps to facilitate the procurement of 1<sup>st</sup> line TB meds for DOTS expansion
- Started in 2001 by the Global Partnership to Stop TB
- Housed within the WHO and managed by the Stop TB Partnership Secretariat

## GDF offers the following . . .

- In-kind grants of TB drugs for DOTS expansion
- Direct procurement of TB drugs
- List of pre-qualified manufacturers who produce high-quality, low cost TB drugs
- Technical support
- Standardized packaging and labeling

The customers of the GDF fall into one of two categories: direct purchasers and grantees

1

### Direct purchasers

- In most cases, this purchaser is the national level Ministry of Health
- In countries in which the national level of government is not playing a strong role in governance, state ministries of health or other agencies (e.g., PIH, MSF) may serve as the primary purchaser in the country

2

### Grantees

- Not technically purchasers per se but approach the GDF for in-kind grants of TB drugs

# Before a direct purchaser can procure drugs through the GDF, it must demonstrate that it is committed to implementing and expanding DOTS

## Criteria for GDF Direct Purchase Pre-approval

Countries implementing the DOTS strategy in 90% or more of the population & NGOs supporting DOTS in these countries.

Countries or NGOs approved by the Global Drug Facility for a grant of free TB drugs.

Countries or NGOs approved for a grant for tuberculosis control by the Global Fund to fight AIDS, Tuberculosis & Malaria.

Organizations, donors and technical agencies supporting the above categories of countries or NGOs.

*Example: Indonesia, India*

## Alternative approval process for GDF direct purchase

GDF also accepts applications from countries/organizations that may not be pre-approved for DP

As long as these parties conform to DOTS and support the Stop TB Strategy, they may still be eligible for DP through the GDF

GDF reviews these applicants on a case by case basis

*Example: Albania, Georgia*



GDF's major value proposition to customers are its prices, assurance of quality, and logistical support

### Value Proposition of the GDF

- **Reduced Prices:** For countries that do not have local manufacturers and/or purchase low volumes of TB drugs, the GDF catalogue prices are often better than what they could negotiate independently in the global market
- **Assurance of quality:** GDF sets clear specifications around products, packaging, and labeling; screens suppliers; and batch tests orders
- **Logistical support:** GDF facilitates access to reliable procurement agents for countries who do not have the experience in or capacity to procure drugs on their own

Some of the highest TB-burden, high-volume purchasers are not working through the GDF

## High TB Burden Countries

*These 22 countries account for approximately 80% of global prevalence and incidence of TB*

- |                |                         |
|----------------|-------------------------|
| 1. India       | 12. Russian Federation* |
| 2. China*      | 13. Vietnam             |
| 3. Indonesia   | 14. Tanzania            |
| 4. Nigeria     | 15. Brazil*             |
| 5. Bangladesh  | 16. Uganda              |
| 6. Pakistan    | 17. Thailand            |
| 7. Ethiopia**  | 18. Mozambique          |
| 8. S Africa*   | 19. Zimbabwe            |
| 9. Philippines | 20. Myanmar             |
| 10. Kenya      | 21. Afghanistan         |
| 11. DR Congo   | 22. Cambodiaa           |

*\*Do not purchase TB drugs through the GDF*

*\*\*GDF only supplies isoniazid*

Source: WHO, IMS analysis

### Alternative forms of TB drug procurement:

- Local procurement—leveraging in-country manufacturers for TB drugs (India, Indonesia, China, Brazil, South Africa)
- International bids run independently from the GDF (South Africa, Gulf States, Caribbean)



While the GDF is the chief gatekeeper/conduit of this procurement mechanism, it does not directly perform the procurement function per se

- GDF is a virtual organization that helps to link up key parties in the TB drug procurement process
- Serves as a screener and broker:
  - Identifies and brokers relationships with the agencies/organizations best suited to performing the TB drug procurement and distribution function
  - Introduces eligible countries to its contractual partners and the global drug procurement mechanism
  - Facilitates programs' access to an uninterrupted supply of specially-priced, high-quality TB drugs
- According to its original prospectus, the GDF was meant to be **a temporary organization** that helps to initiate the global TB drug procurement mechanism and then ultimately exits when it is self-sustaining--it is not clear if this is still true

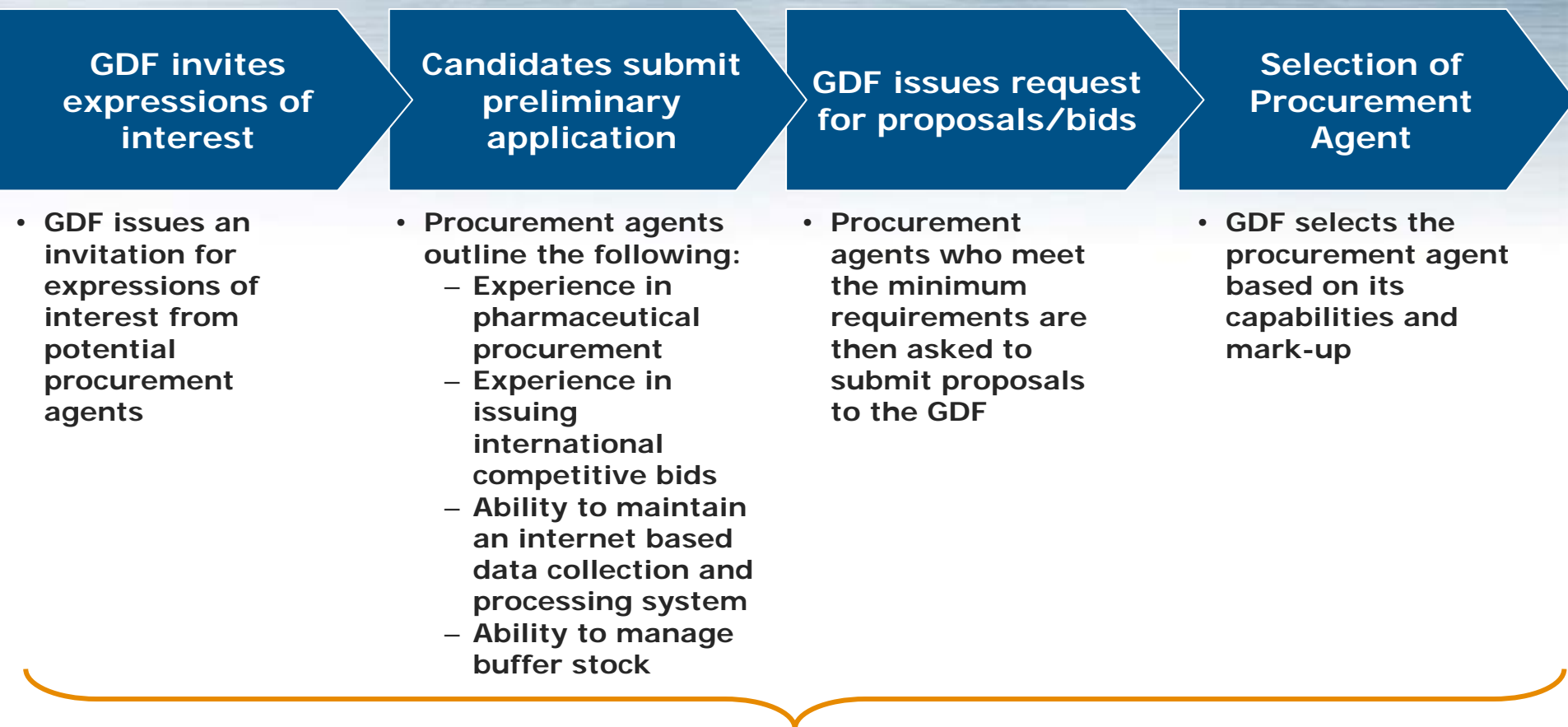
Instead, it selects contractual partners on a competitive basis to perform the actual procurement and distribution

	Who selects?	Who currently plays this role?
Procurement Services Agency	Selected by the GDF	UNDP-IAPSO*
Quality Control	Selected by the Procurement Agent	Societe Generale de Surveillance (SGS) and Intertek
Suppliers	Pre-qualified by the GDF/WHO but selected by the Procurement Agent	Cadila, Lupin, Svizera Europe, Strides-Sandoz
Freight Forwarder	Preferably sub-contracted by the Procurement Agent	Kuehne-Nagel and Mahe Freight AS (subcontracted by UNDP-IAPSO)

Source: IMS Interviews.

*\*While UNDP-IAPSO has been the procurement agent, the GDF is currently in the process of reviewing bids for a new procurement agent*

# The pricing and procurement of TB drugs is executed by the GDF's procurement agent, which is selected through a competitive bid process



*While UNDP-IAPSO has been the procurement agent, the GDF is currently in the process of reviewing bids for a new procurement agent*

That procurement agent runs an international competitive bid (ICB) among suppliers whose manufacturing sites and products are pre-qualified

### Two step pre-qualified of GDF suppliers/products

**In order to qualify to participate in the GDF bids, manufacturers must meet a stringent set of criteria...**

Manufacturing sites must, at a minimum, comply with Good Manufacturing Practices as assessed by WHO/PSM under the TB Prequalification Project

**... In addition, the products that these manufacturers supply to the GDF must meet one of two conditions**

Products manufactured must fall on one of the following

- Option 1: Fall on the List of Pre-qualified TB Drugs
- Option 2: Are assessed and approved via a product dossier by an expert WHO Procurement and Supply Management (PSM) committee

# Suppliers whose products are on the GDF's List of Pre-qualified TB Drugs are usually given preference

International Non-proprietary Name (INN)	Strength	Dosage form	Supplier	Manufacturing site	
Ethambutol	400mg	Tablet	Cadila Pharmaceuticals Ltd. Ahmedabad	Cadila Pharmaceuticals Ltd. Dholka, Ahmedabad	India
Pyrazinamide	400mg	Tablet	Cadila Pharmaceuticals Ltd. Ahmedabad	Cadila Pharmaceuticals Ltd. Dholka, Ahmedabad	India
Rifampicin/ Isoniazid/ Pyrazinamide/ Ethambutol	150/ 75/ 400/ 275mg	Tablet	Wyeth Pakistan Limited, Karachi	Wyeth Pakistan Ltd, Karachi	Pakistan
Rifampicin/ Isoniazid	150/ 75mg	Tablet	Lupin Ltd, Mumbai	Lupin Ltd, Aurangabad	India
Rifampicin/ Isoniazid/ Pyrazinamide/ Ethambutol	150/ 75/ 400/ 275mg	Tablet	Lupin Ltd, Mumbai	Lupin Ltd, Aurangabad	India
Rifampicin/ Isoniazid	300/ 150mg	Tablet	Sandoz Pty Ltd, Isando	Novartis SA (Pty) Ltd, Kempton Park	South Africa
Rifampicin/ Isoniazid	150/ 75mg	Tablet	Sandoz Pty Ltd	Novartis SA (Pty) Ltd Kempton Park Strides Arcolab Ltd, Bangalore	South Africa India
Rifampicin/ Isoniazid/ Pyrazinamide/ Ethambutol	150/ 75/ 400/ 275mg	Tablet	Sandoz Pty Ltd	Novartis SA (Pty) Ltd, Kempton Park Strides Arcolab Ltd Bangalore	South Africa India

Source: GDF website



When selecting the bid winners, the procurement agent then denotes a primary and secondary supplier for each product

TB Product	Unit	Supplier	Product Prequalification Status: Option I or II	Compliance with WHO GMP (as assessed under TB Prequalification Project): Yes/No
Rifampicin 150 mg / Isoniazid 75 mg / Pyrazinamide 400 mg / Ethambutol 275 mg film coated tablets	box of 672 tablets in 24 blister sheets	PRIMARY: <b>Svizera Europe BV</b>	Option II	YES. Site: Svizera Private Labs Limited, Plot No D16/6, TTC Industrial Area, MIDC, Turbhe, Navi, Mumbai - 400 703, India
		SECONDARY: <b>Sandoz Pty Ltd., Sector of Novartis</b>	Option I	YES. Site: KRS Gardens, Suragajakanahalli, Indhawadi Cross, Annekal, Taluk, Bangalore 562, India



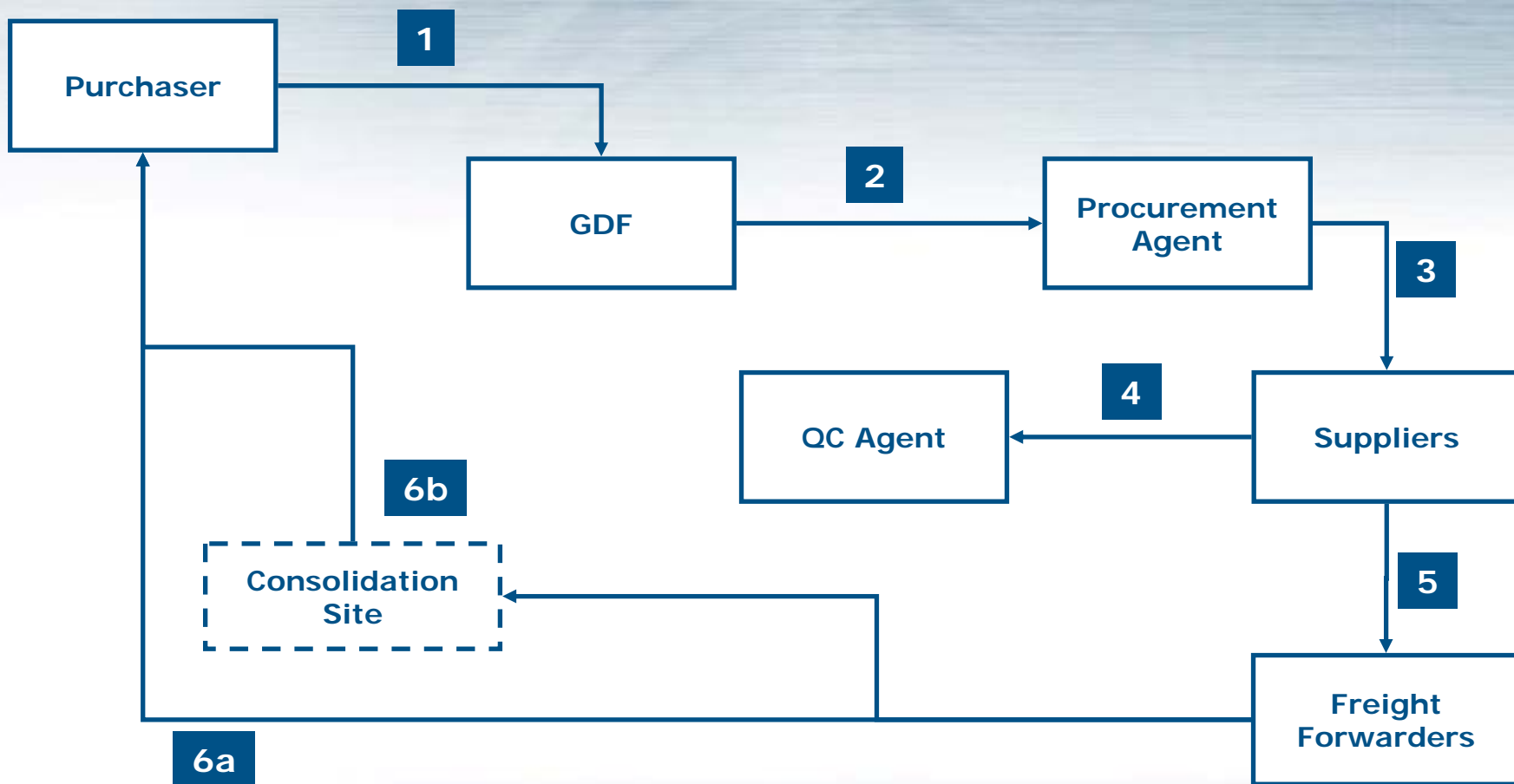
- **The Award period for each product is specified in the Long Term Agreement (LTA)—the most recent LTA was awarded for April 2005-2006**
- **PRIMARY denotes approximately 65% of the annual supply award**
- **SECONDARY denotes approximately 35% of the annual supply award**

Source: GDF website

## Prices of GDF products usually remain stable but may fluctuate depending on the results of the bid and tender process

- Since its inception, the cost of GDF-sourced treatment per patient has risen from \$12 to \$18
- The prices that the GDF lists in its catalogue are not guaranteed
- The fluctuation of prices offered by the GDF is due to:
  - Inherently changing outcomes of the competitive bidding process
  - Changes in the cost of goods for suppliers
  - Unexpected reliance on secondary suppliers due to shortages or inability of primary supplier to meet direct procurement needs

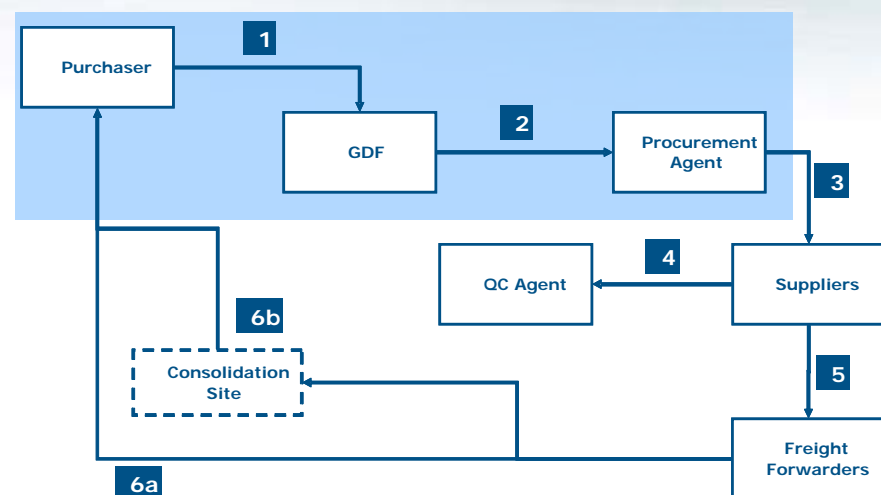
# Ordering through the GDF Direct Procurement (DP) Mechanism is a multi-step process



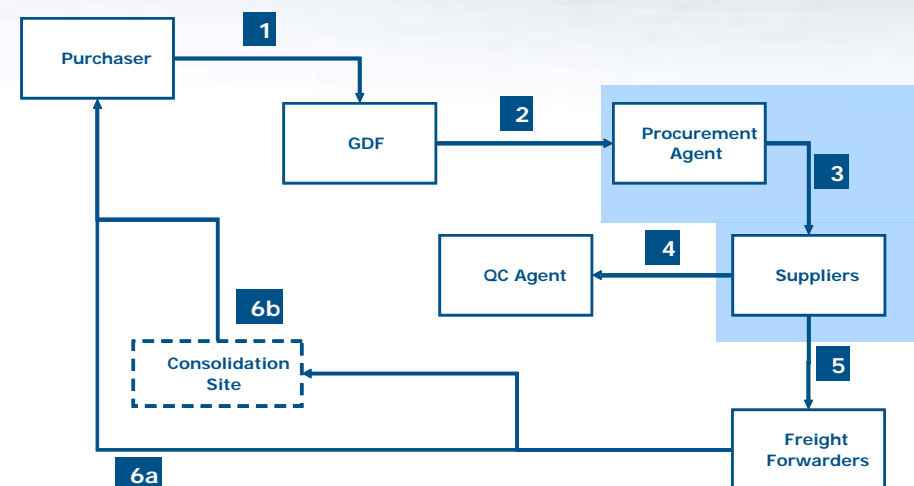
The first step of this process is the confirmation of eligibility of countries for direct procurement

### Steps 1 and 2: Application and confirmation of eligibility

- Purchasers (e.g., NGOs, national TB control programs) approach the GDF with requests for TB drugs
- GDF confirms the eligibility of purchasers and then forwards the order on its selected procurement agent



Next, the procurement agent places orders with the suppliers who have won the international competitive bid

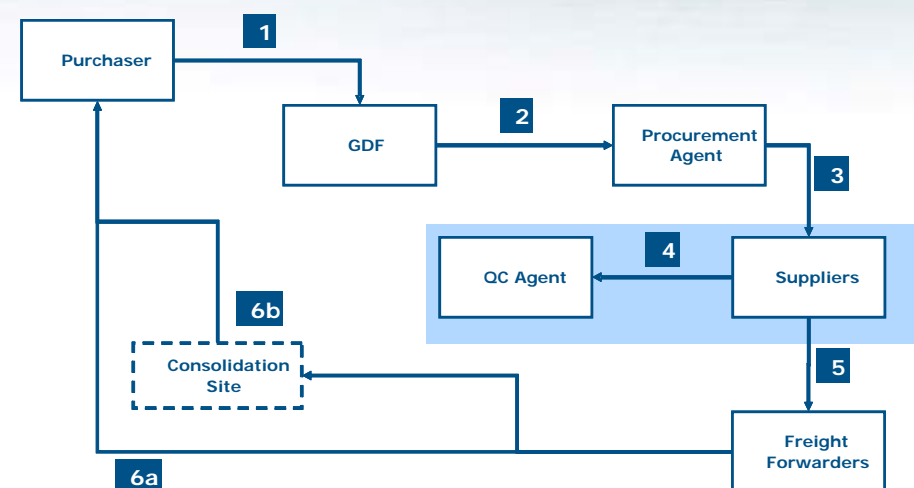


### Step 3: Order placed with suppliers

- Majority of orders are forwarded to primary supplier named in the international competitive bid, which is run each year
- If necessary, the secondary supplier is used to provide additional volumes



Before products are picked up for shipment, suppliers are required to submit a sample of the product to GDF for quality control testing



### Step 4: Quality Control and Assurance

- QC agent ensures that the product packaging and labeling meet the GDF standards
- QC lab tests the product itself
- All product orders must clear this step before being released for shipment

# Quality assurance and control are coordinated by the quality assurance agent

## GDF sets guidelines around products

- GDF formulates its guidelines/specifications around products, packaging, and labeling

## QC agent initiates quality control process

- Supplier notifies QC agent that an order is ready for assessment
- Agent sends a local agent to the supplier facility to check product packaging and labeling
- Local agent reports results back to QC agent

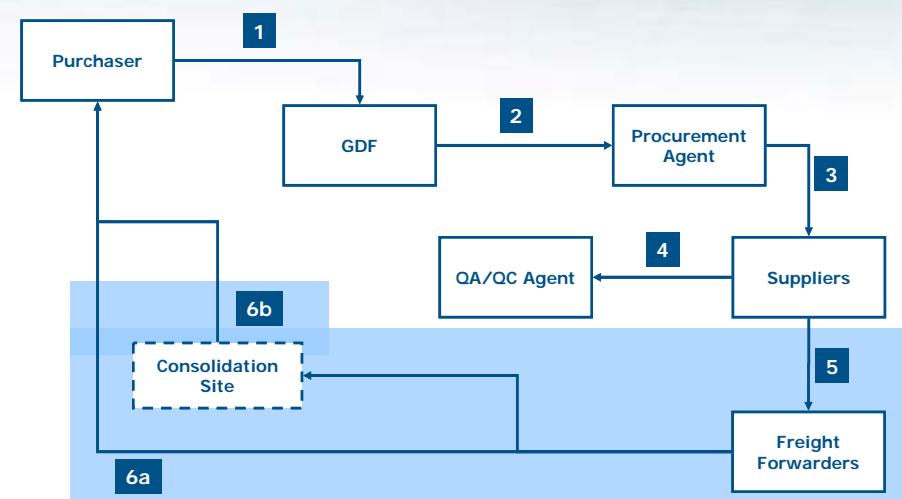
## QC lab conducts testing of product

- Next, a sample of each product batch is sent to QC lab for testing

## QC agent releases or continues to hold the order

- Once it is confirmed that an order meets all of GDF specifications, QA agent then notifies Procurement Agent to release the shipment to the freight forwarder

Once an order has been released, the freight forwarders contracted by the procurement agent pick up the product and transport it to its final destination



### Steps 5 and 6: Shipment to the purchasing geography

- The procurement agent's freight forwarders pick up orders from the supplier facility and ship to one of the following to the purchaser
- Once the order has been shipped to a pre-specified destination, the distribution of drugs becomes the responsibility of the purchaser

After orders are picked up from the manufacturer facility, they are shipped via one of two routes



In addition to conducting direct procurement, the GDF issues in-kind grants of TB drugs to certain countries' TB control programs

### Eligibility requirements for GDF Grants

- Meets all eligibility requirements for direct procurement
- Annual per capita GNP under US\$ 3000
- National plan and budget for DOTS expansion to meet global targets
- Technical guidelines demonstrating commitment to meet global targets
- Annual report on DOTS performance (WHO TB collection form)
- Recent external national TB program review

- Countries that are approved for grants receive them for:
- A 3 year period if a regular grant
- A 1 year period if an emergency grant
- Countries and patient numbers approved in the most recent round of applications:
  - Afghanistan 37,580
  - Democratic People's Republic of Korea 106,600
  - Djibouti 6,500
  - Kyrgyzstan 15,700
  - Lesotho 26,146

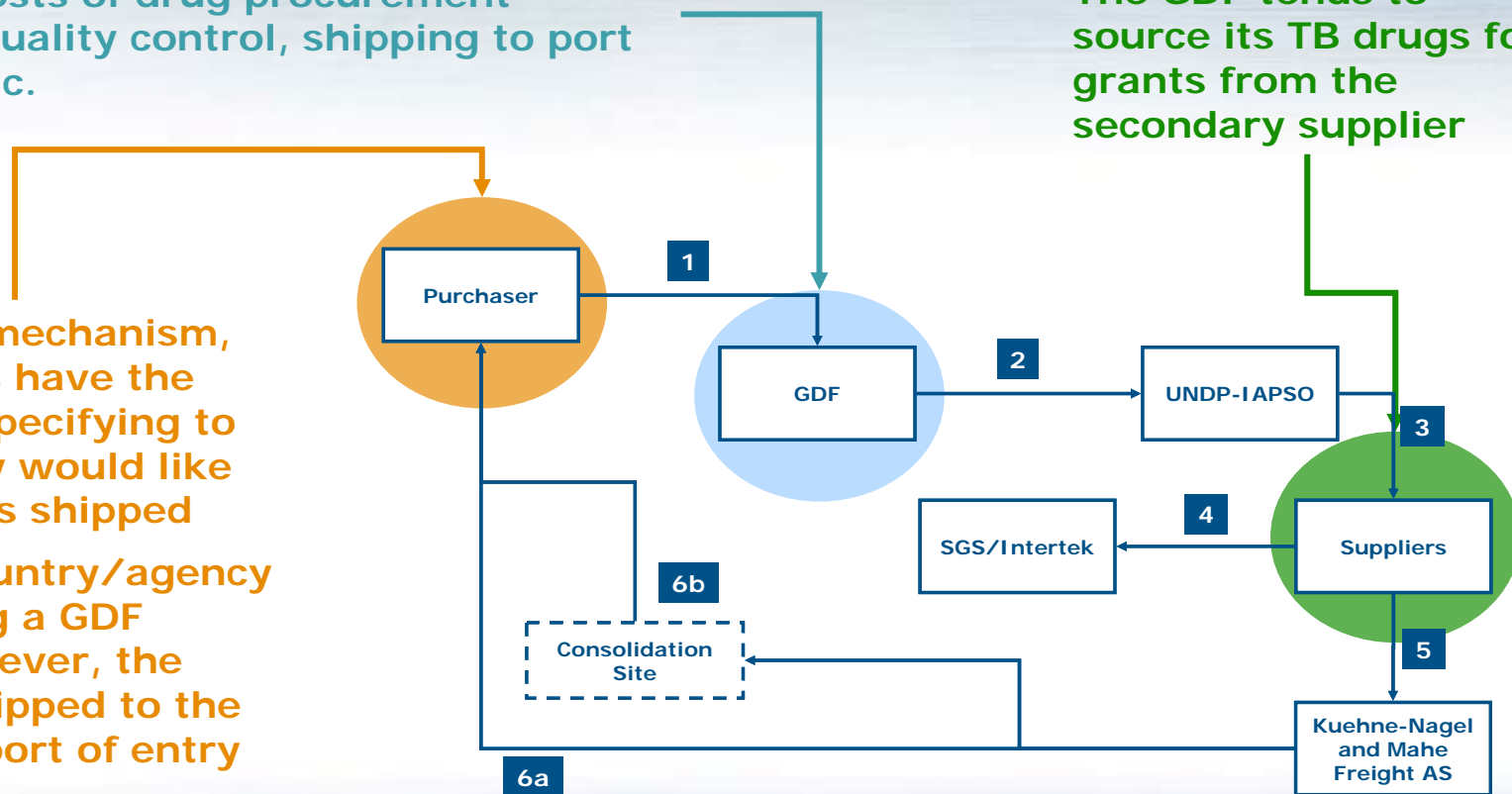


# The procurement mechanism for GDF grants differs from the direct purchase mechanism in three ways

- When the GDF issues a grant, it agrees to cover all costs of drug procurement including quality control, shipping to port of entry, etc.

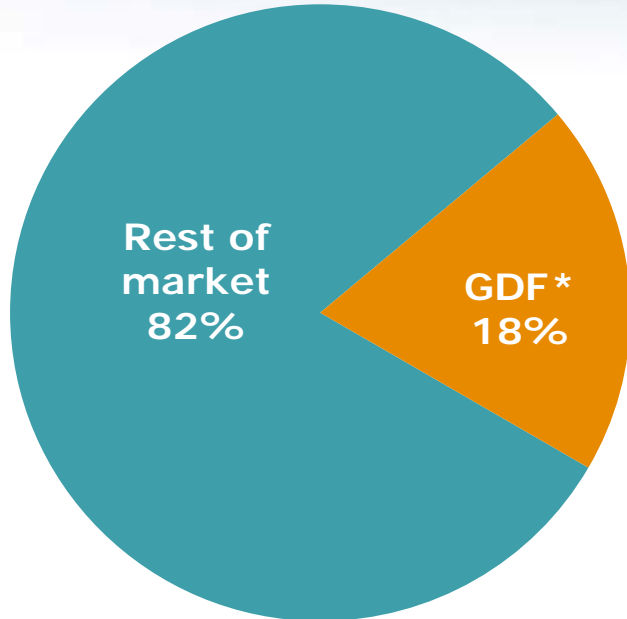
- In the DP mechanism, purchasers have the option of specifying to where they would like their orders shipped
- When a country/agency is receiving a GDF grant, however, the order is shipped to the country's port of entry

- The GDF tends to source its TB drugs for grants from the secondary supplier

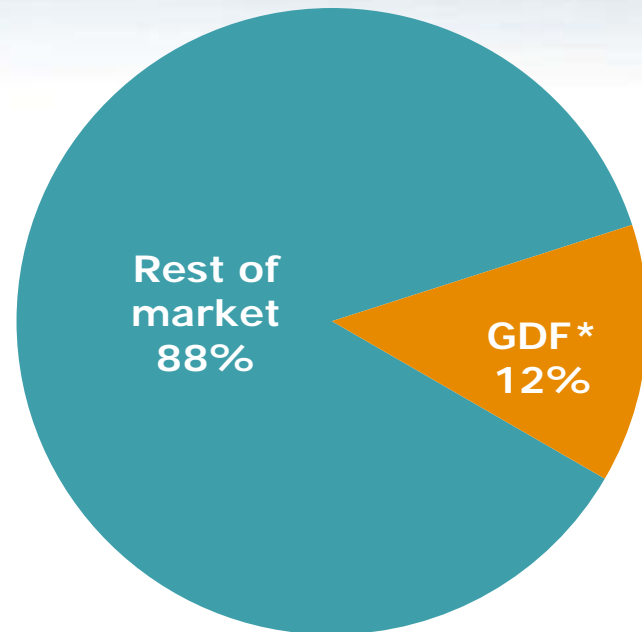


Given what we know about the global TB market and GDF's estimated value of TB drugs, the GDF supplies around 10- 15% of the global market for 1st line medicines

**Worldwide 1<sup>st</sup> line TB Market:  
Market:  
Low End (268M USD)**



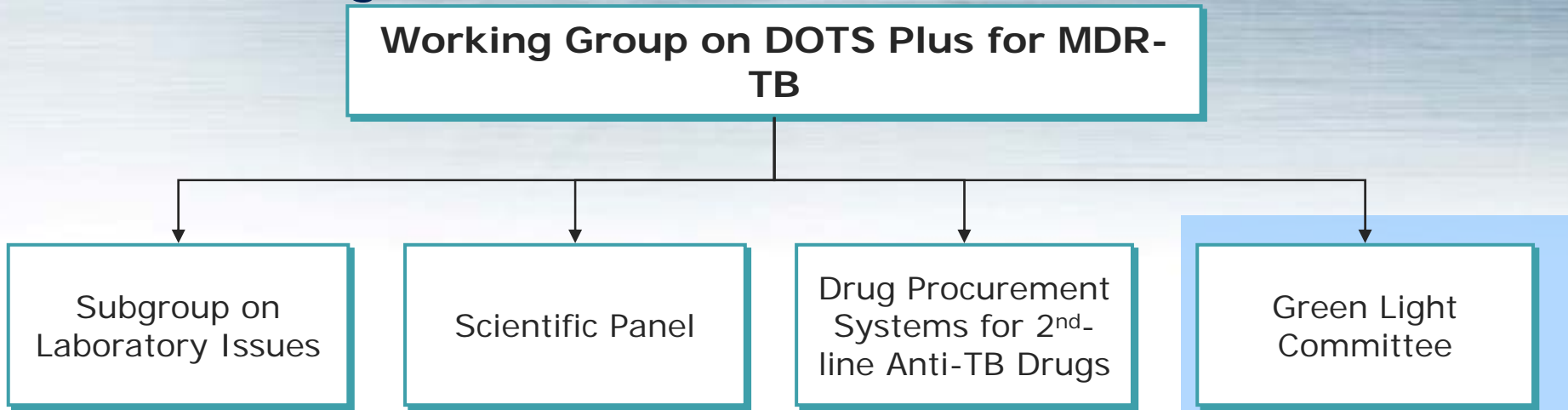
**Worldwide 1<sup>st</sup> line TB Market:  
High End (424M USD)**



**\*The value of drugs supplied through the GDF (direct procurement and grants) was ~\$49.17M USD in 2005**

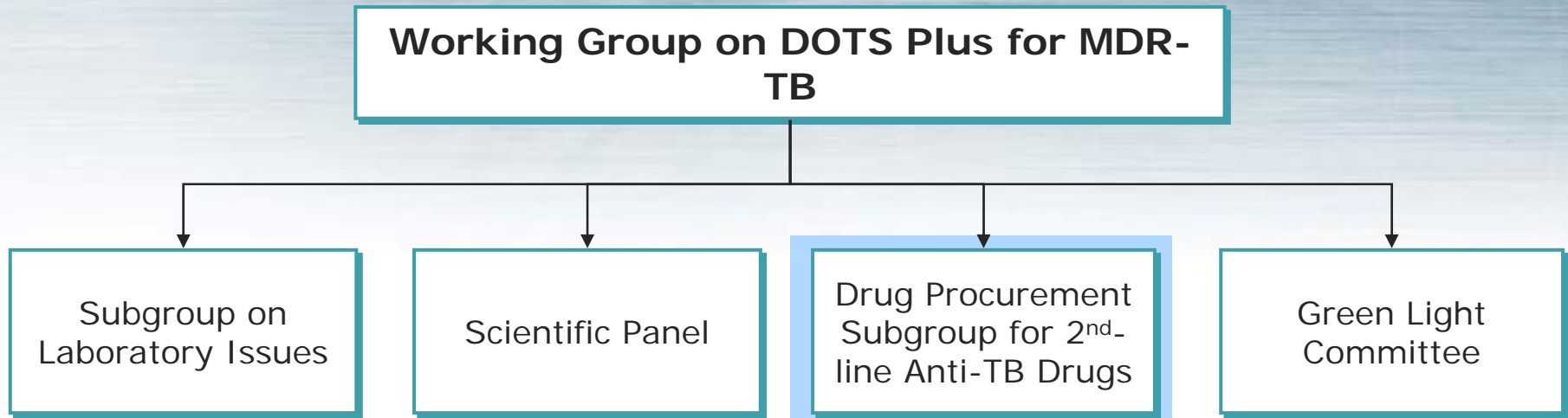
## 2nd Line Drug Procurement: The Green Light Committee

# The Green Light Committee (GLC), part of the Working Group on DOTS Plus, serves the global marketplace for MDR-TB drugs



- Meets 6 times/year to assess applications from DOTS-Plus pilot programs
- Determines whether or not the program is in compliance with the Guidelines for Establishing DOTS-Plus Pilot Projects for the Management of MDR-TB
- Provides access to GLC-negotiated prices for 2nd line anti-TB drugs to approved programs

Initially, the Drug Procurement Subgroup was responsible for the initial agreement with 2<sup>nd</sup> line TB drug manufacturers



- Party that negotiated the initial access to reduced-price 2<sup>nd</sup> line TB drugs
- MSF, acting on behalf of the Subgroup, sought out and initiated informal agreements with manufacturers of 2<sup>nd</sup> line TB drugs
- Subsequent agreements were formed by IDA, which was the procurement agent selected for 2<sup>nd</sup> line TB drugs



The GLC accepts applicants from any program, agency or organization that has the endorsement of its country's national TB program

- **Pre-application steps**

- Ensure that the DOTS strategy is in place and is functioning well
- Secure government commitment and adequate funding
- Develop a coordinated project management plan
- Provide adequate laboratory resources
- Devise a rational treatment strategy
- Develop an adequate information (data) management system
- Confirm that the drugs requested are registered in the country of the project
- Develop a drug management plan including transportation, registration, custom procedures, storage, distribution, monitoring and reporting

In 2005, programs representing ~9,000 patients were approved by the GLC, with more than half in Peru

		Patients
Abkhazia	MSF	30
Costa Rica	NTP	24
Dominican Republic	GF	125
Estonia	NTP	200
Egypt	GF	75
Honduras	GF	50
Haiti	PIH	60
Jordan	NTP	45
Kyrgyzstan	GF	50
Lebanon	NTP	15
Moldova	GF	100

MSF – Medecins Sans Frontieres

NTP – National TB Program

GF – Global Fund for AIDS, TB and Malaria

PIH – Partners in Health

		Patients	
	Nicaragua	GF	21
1	Peru	PIH	800
		GF	5000
2	Philippines	GF	750
	Romania	GF	200
	Orel	CDC	200
3	Tomsk	GF	600
		PIH	400
	Syria	NTP	161
	Uzbekistan	MSF	232

**Total number = 9,138**

Applicants to the GLC must specify how many patients they plan to treat and the anticipated volume of 2<sup>nd</sup> line TB drugs they expect to purchase

**Application must include:**

- Location
- Size of patient cohort
- Anticipated start date and duration
- Time schedule for inclusion of patients during the pilot project
- List of all organizations involved
- Justification of the need for a DOTS plus pilot project
- Must also facilitate a site visit, if requested

*Projects are approved for a specific number of patients – if patient numbers are increased, the program must apply for expansion*

GLC requires that products are pre-qualified, a process that limits the number of eligible manufacturers

	<u>Units</u>	<u>Price (USD)</u>	<u>Supplier</u>
Capreomycin, 1 gram powder for injection	1 vial	\$3.21	Eli Lilly
Cycloserine, 250 mg	100 cap	\$14.12	Eli Lilly
Cycloserine, 250 mg	100 cap bl	\$50.96	Macleods Daman Plant
Ethionamide, 250 mg	100 tab	\$10.21	Macleods Daman Plant
Amikacin 500 mg/2mL injection	100 amp	\$23.15	Gland Pharma Ltd. Pally Factory
Kanamycin, 1 gram powder for injection	50 vls	\$18.58	Panpharma
Ciprofloxacin, 250 mg	100 tab bl	\$2.12	Micro Labs Ltd. (Brown & Burke)
Ciprofloxacin, 500 mg	100 tab	\$3.81	Micro Labs Ltd. (Brown & Burke)
Ciprofloxacin, 500 mg	100 tab bl	\$3.80	Micro Labs Ltd. (Brown & Burke)
Ofloxacin, 200 mg	100 tab	\$3.49	Micro Labs Ltd. (Brown & Burke)
PAS acid sachet eq. to 4 gram aminosalicylic acid	30 sac	\$48.18	Jacobus Pharma Company Inc.
Prothionamide, 250 mg	100 tab	\$13.03	Fatol Arzneimittel
PAS sodium granules 60% (p- aminosalicylate sodium)	100 g	\$9.74	Macleods Daman Plant
Ofloxacin, 200 mg	60 tab	\$2.74	Macleods Daman Plant

As a result, the GLC does not use bids to procure its drugs today; instead, it forms agreements with suppliers to fill the demand for 2<sup>nd</sup> line drugs

**IDA initiates an agreement with a manufacturer**

- IDA pre-qualifies manufacturers
- IDA approaches manufacturers who produce 2<sup>nd</sup> line TB drugs
- Forms agreement for reduced price 2<sup>nd</sup> line drugs
- Manufacturer may or may not specify a maximum volume of reduced price drugs that it will provide to the GLC

**IDA submits orders to manufacturer**

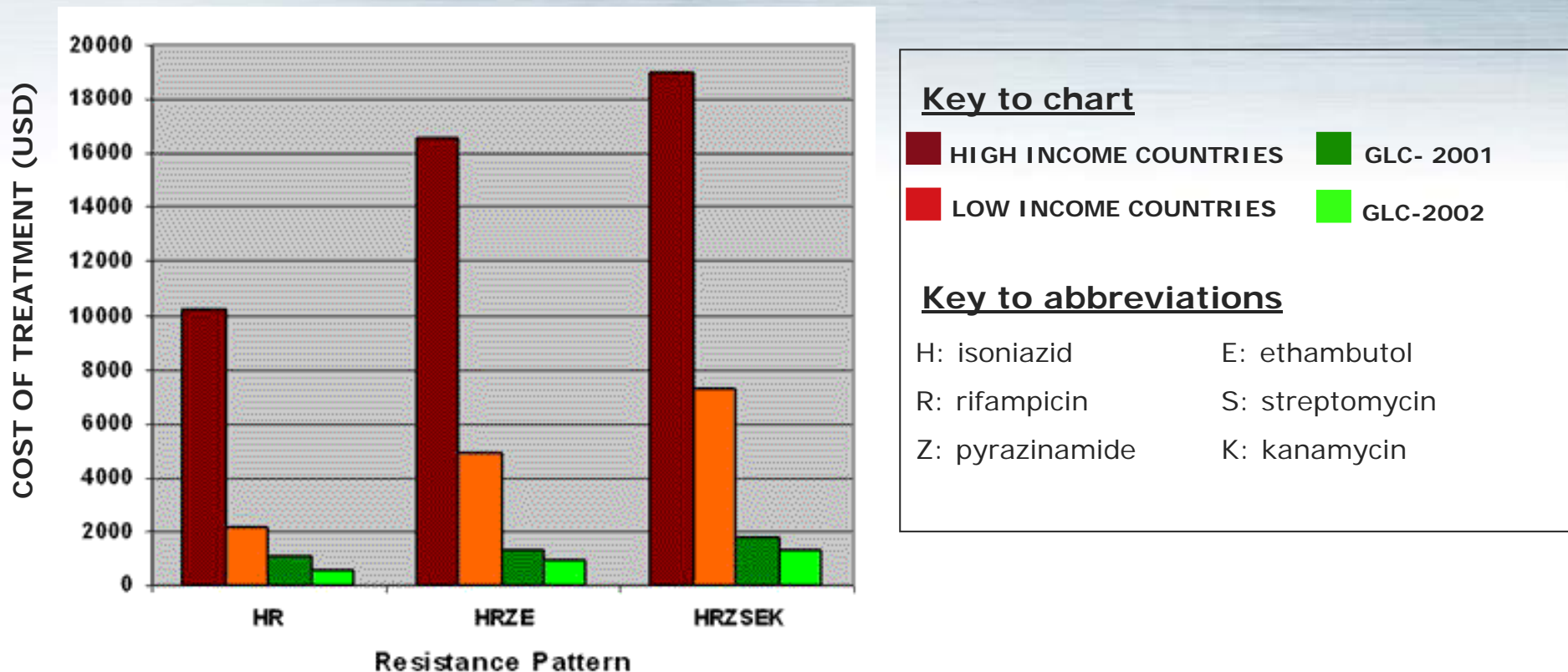
- When orders are submitted by GLC-approved pilot projects, the IDA submits to the manufacturers with whom it has relationships

**IDA performs QC**

- When an order is ready and sent to IDA by the manufacturer, the IDA checks the product packaging and labeling and tests batches of the product



Still, prices of 2nd line drugs procured through the GLC are significantly lower than those procured separately by countries/agencies



# The IDA Foundation (IDA) is currently the procurement agent for the GLC\*



Source: IMS interviews; GDF web-site; IDA web-site

\* At the time of writing of this report, the IDA was the procurement agent for the GLC. A tender is currently open for procurement agents.

Under its current contract, the IDA plays an integral role throughout the process

1

### Supply

- Starts with WHO eligible list of manufacturers and drugs
- Pre-screens and identifies manufacturers based upon internal QA
- Negotiates prices with manufacturers producing drugs

2

### Quality control and assurance

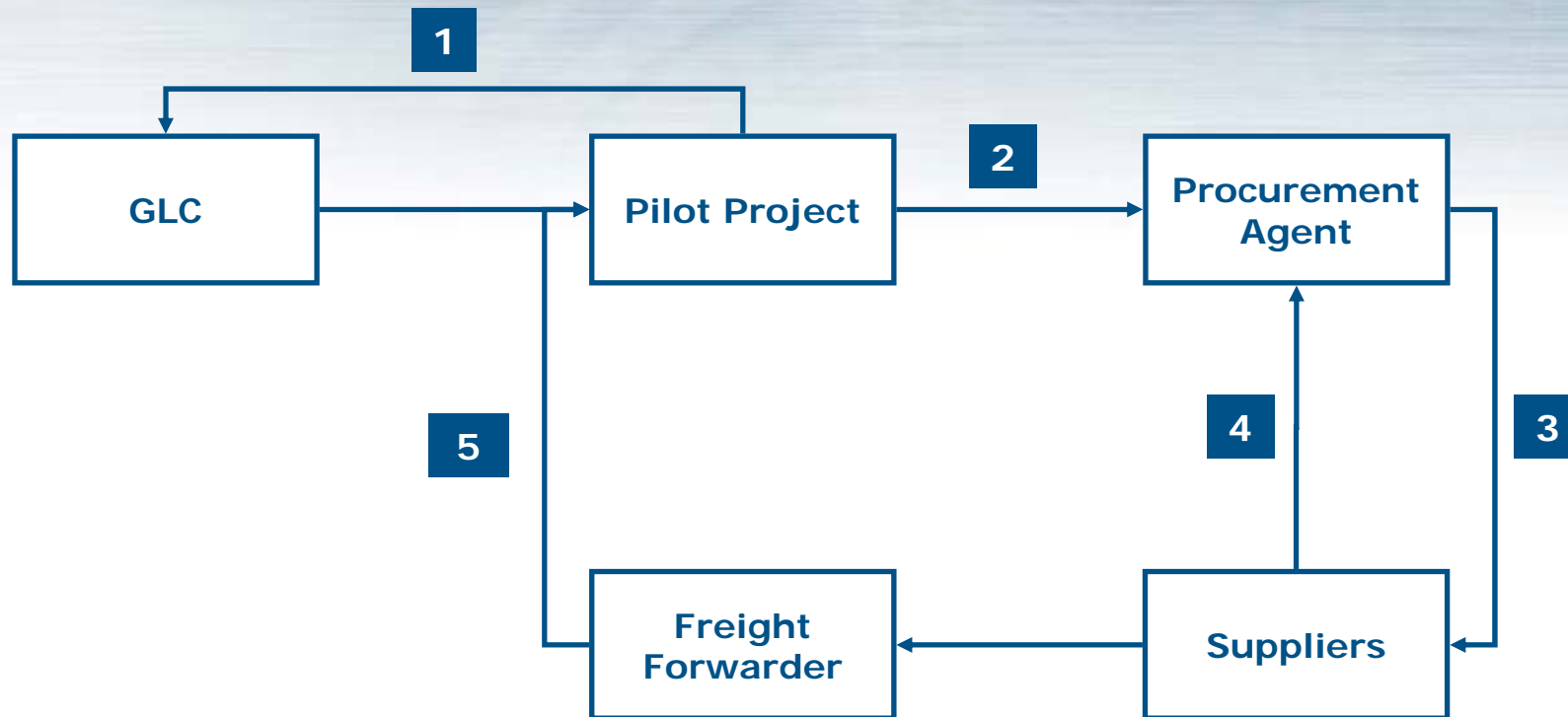
- Pre-screens potential manufacturers and approves manufacturing sites
- Approves products and conducts quality assurance and quality control of procured drugs
- Standardizes packing, labeling, and product information specifications for generics

3

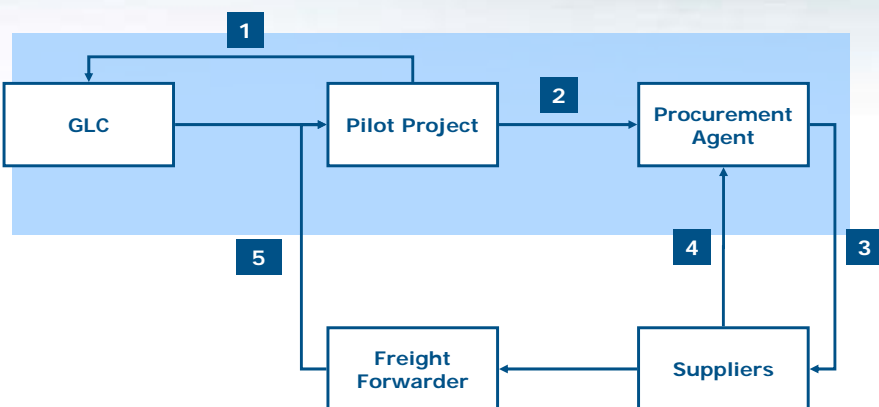
### Distribution

- Responsible for distributing to purchasers' port of entry or airport

The GLC ordering process is also a multi-step process involving several key stakeholders



The first step of GLC procurement is the application process, which all potential purchasers must go through

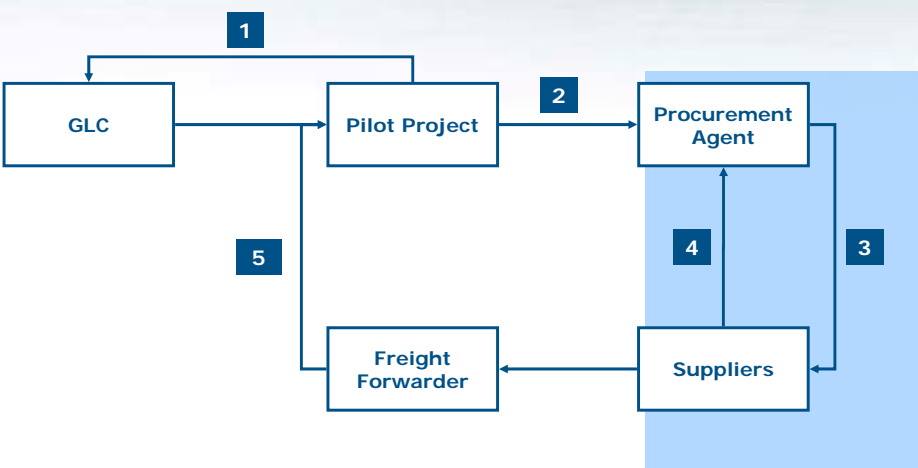


### Steps 1 and 2: Application and Approval Process

- DOTS+ pilot projects submit applications to the GLC
- GLC reviews applications and decides whether or not to grant access to 2<sup>nd</sup> line TB drugs priced through GLC-negotiations
- If approved, the GLC issues a letter of approval to the applicant which outlines how many patients have been approved



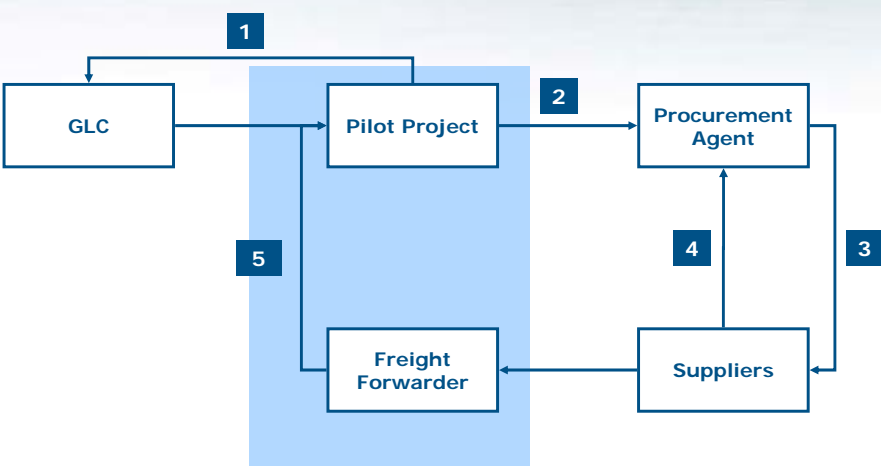
Once GLC approval has been obtained, pilot projects are then allowed to place orders for drugs through the GLC's selected procurement agent



### Steps 3 and 4: Drug Procurement and Quality Assurance/Control

- Pilot Projects then submit orders to the IDA for their projects
- IDA works with its network of suppliers to fill orders
- Once a supplier has filled an order, drugs are sent to the IDA warehouse
- IDA conducts a QA/QC assessment to ensure the product meets quality standards

After the quality of an order has been confirmed, a freight forwarder—contracted by the IDA—picks it up for transportation



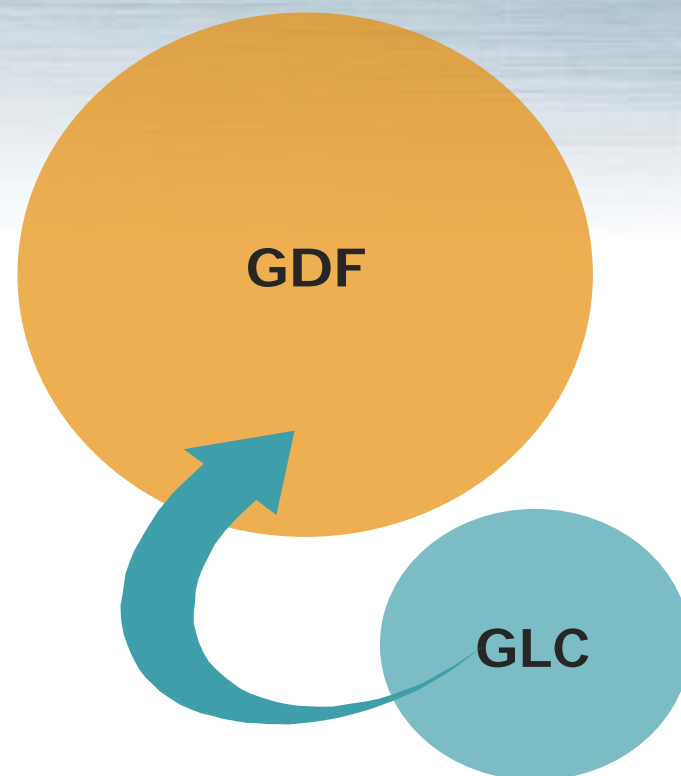
### Step 5: Shipment of Drugs to Pilot Project

- Once an order has cleared QA/QC assessment, it is shipped out from the IDA warehouse
- Orders are sent directly to the countries to a pre-specified location
- Once the order reaches that location, the distribution of the drugs becomes the responsibility of the pilot project

A number of changes will be taking effect in the GLC this year, one of which is the recently announced merger of the GLC and GDF

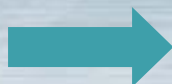
### Details on the merger

- Initiated in part because the GLC had reached capacity to review applications and manage the procurement process
- GLC will be folded under the GDF
- GDF will select the 2<sup>nd</sup> line TB drug procurement agent
- GLC will continue to review applications and grant access to the 2<sup>nd</sup> line TB drugs
- Currently the IDA remains the procurement agent for the GLC – a tender is currently open for a procurement services agent and is expected to be finalized by end of year



# The GLC currently supplies a portion of the 2nd line TB drugs utilized globally

The GLC approved  
9,138 patients for  
treatment in 2005



## Using current estimates on the prevalence...

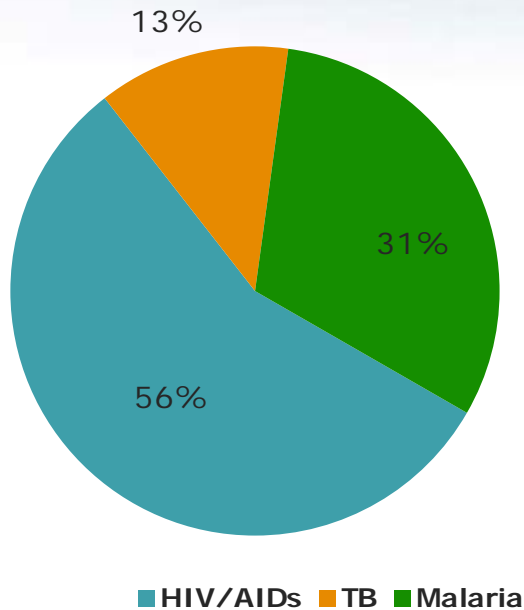
- New cases of MDR TB in 2000 was estimated at 273,000 (3.2% new cases)
- This only accounts for new cases – prevalence could be much higher
- If we use this estimate and compare to the number of patients approved for treatment through the GLC in 2005 (9,138) it would represent **3.4% of total patients**
- To place this in context, there is some uncertainty around this number:
  - Epidemiology and case reporting for MDR-TB is less reliable
  - Prevalence figures include both treated and untreated patients
  - Some programs approved by GLC for a specific number of patients never purchased drugs

# Funding

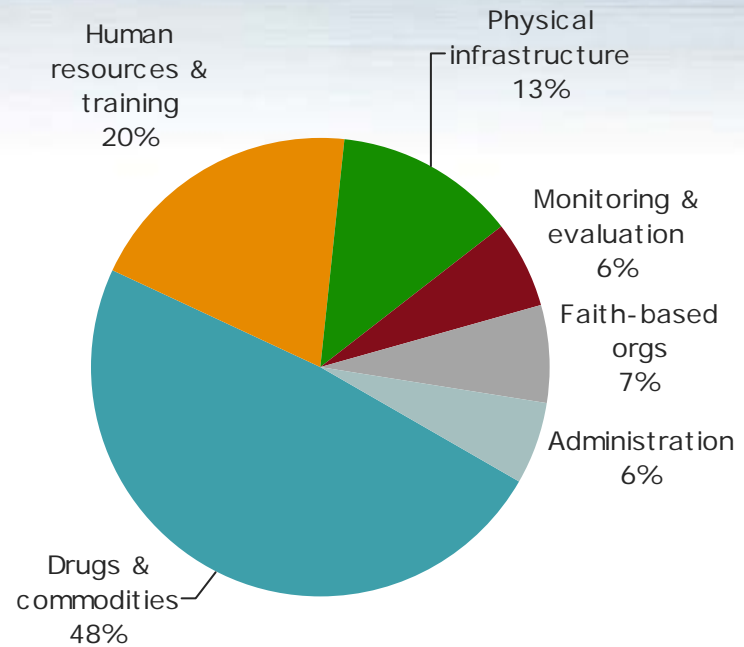


# The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) estimates that 13% of total funding is for TB, and about ½ of that amount is for drugs and commodities

Allocation of funding across disease (2001-2005)



Allocation of funding (2001-2005)



Most GFATM funding (61%) goes to Sub-Saharan Africa

Recipients vary and include governments (51%), NGOs (24%) and other organizations

In 2005, GFATM contributed \$144 M total to the 22 high-burden countries, comprising 17% of funding for NTPs\*

High Burden Country	GFATM Funding	Percentage of total funding
India	12	21
China	19	14
Indonesia	25	43
Nigeria	8	47
South Africa	--	--
Bangladesh	8	50
Pakistan	0.6	4
Ethiopia	5	70
Philippines	2	15
Kenya	3	21
DR Congo	8	40

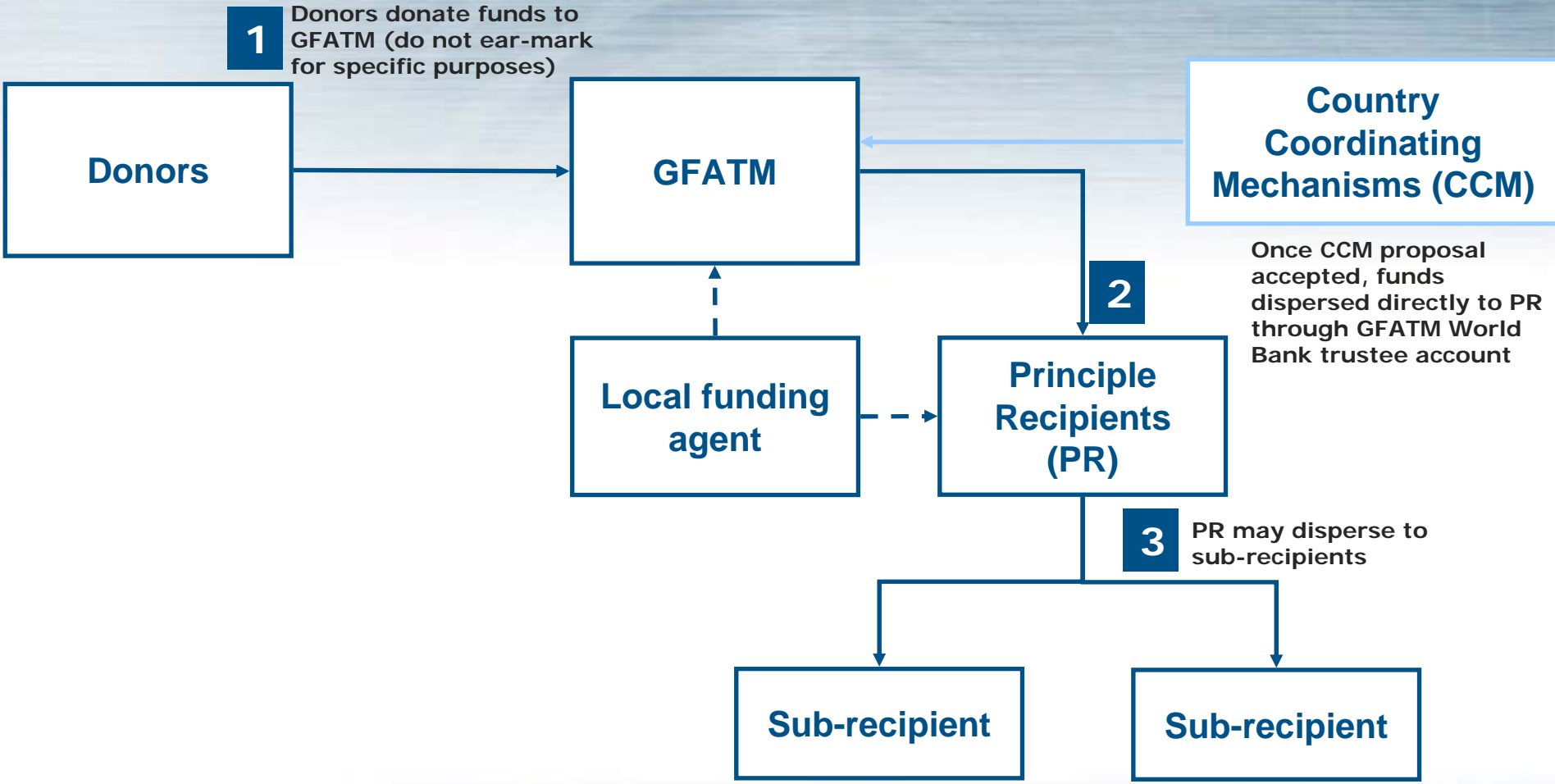
High Burden Country	GFATM Funding	Percentage of total funding
Russian Federation	29	8
Viet Nam	2	18
UR Tanzania	0.2	3
Uganda	0.3	12
Brazil	5	16
Afghanistan	--	--
Thailand	2	40
Mozambique	6	67
Zimbabwe	7	44
Myanmar	2	59
Cambodia	1	21

**Total funding provided by GFATM to HBC's = \$144 M**

\*Total funding = \$831 M and does not include funding gap of \$141 M

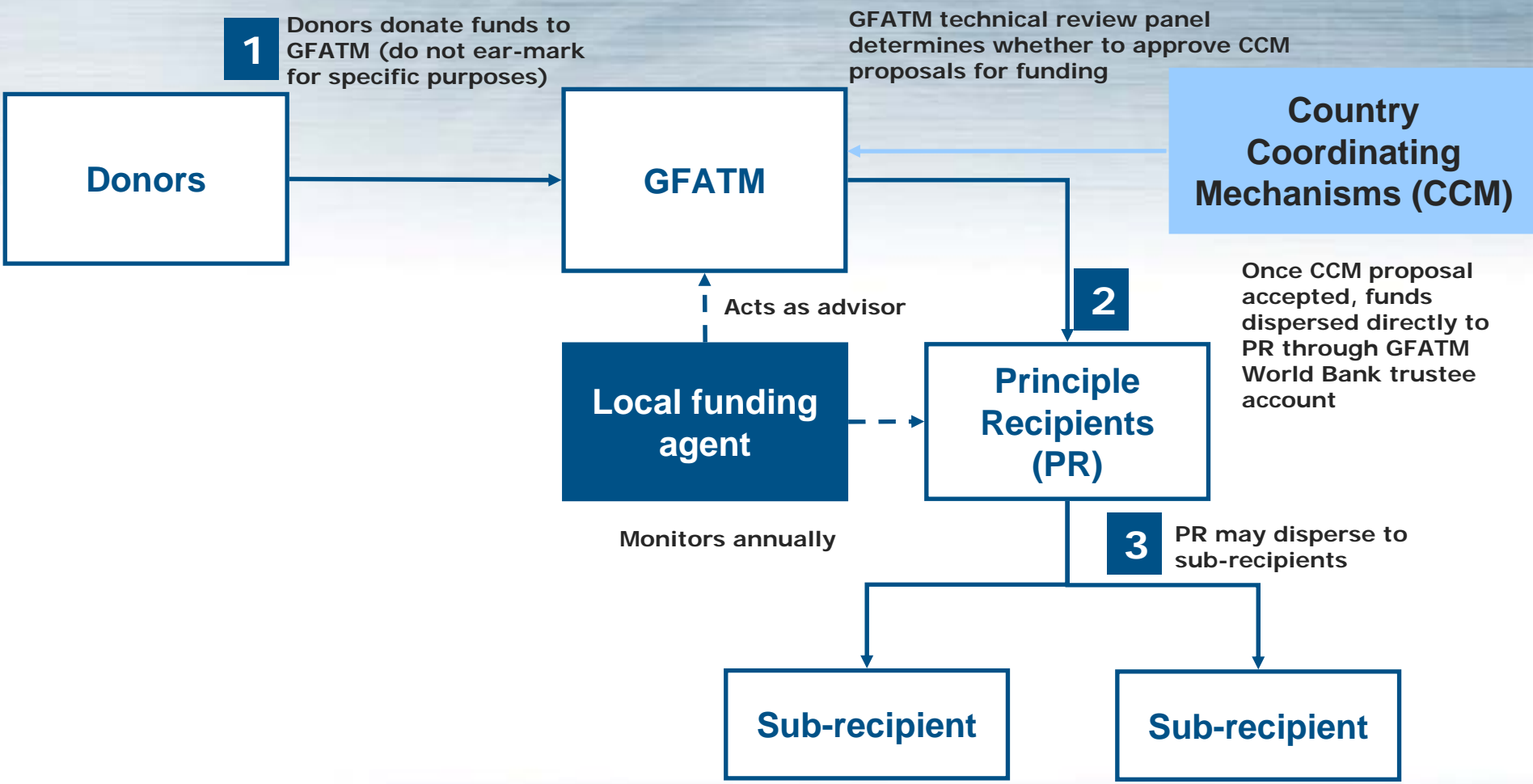
Source: WHO Global Tuberculosis Control: surveillance, planning, financing (2006)

# GFATM funds flow directly to the principle recipients (PR) in the country, who may disburse to sub-recipients



Source: Global Fund Web-site; Interviews

# There are several entities involved in the Global Fund process



Source: Global Fund Web-site; Interviews

# Country coordinating mechanisms (CCMs) are the parties responsible for securing funding from the GFATM

## Country Coordinating Mechanism

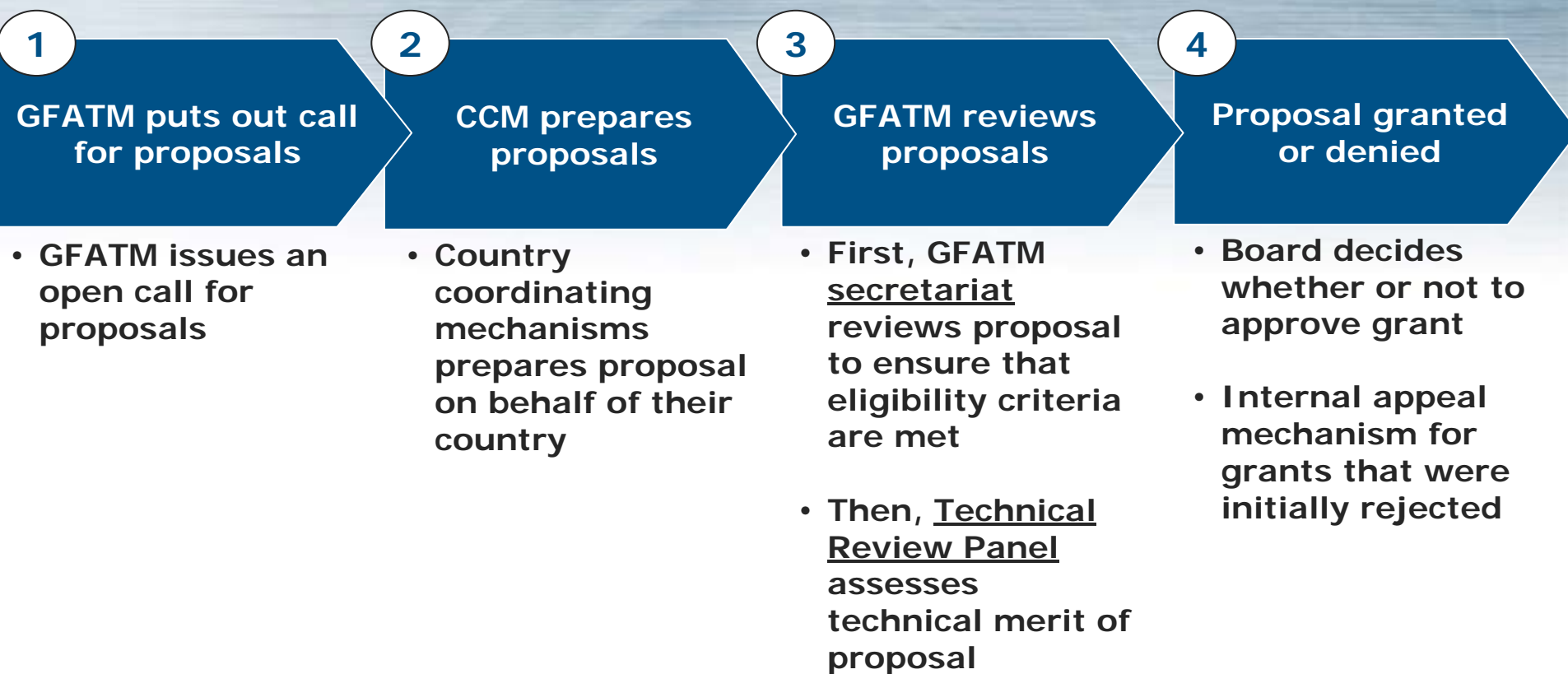
- **What does the CCM do?**
- Prepares and submits proposals to GFATM
- Identifies principle recipients in proposal
- Oversees implementation
- Requests continued funding for 3-5 years

### Who is on the CCM?

- Representatives from both the public and private sectors including
  - Governments
  - Multilateral/bilateral agencies
  - NGOs
  - Businesses
  - Academic institutions
  - People living with the diseases



# The process for a CCM to gain approval of funds from the GFATM involves 4 steps



*The initial proposal submitted by the CCM does not allocate or provide a detailed procurement plan. It only provides high-level estimates include the needed budget and the patients to be treated.*

After CCM proposal is approved, local funding agents (LFAs) monitor principle recipients before funds are disbursed

### Local funding agent

- **What does the LFA do?**
- Advises GFATM secretariat before funds are initially disbursed to principle recipient
- Continues to monitor principle recipient on annual basis

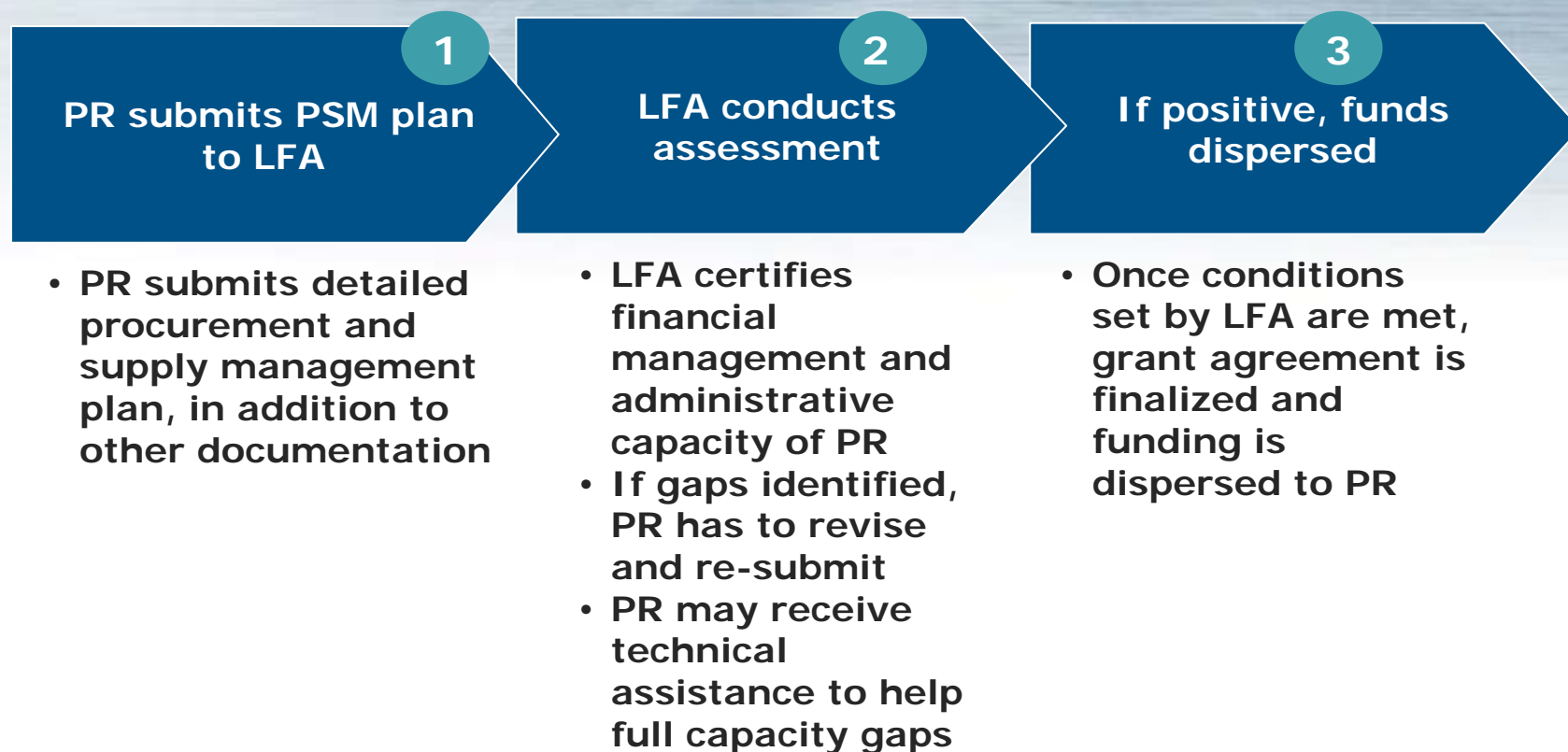
### Who are the LFA's?

- PriceWaterhouseCoopers
- KMPG
- Emerging Markets Group
- Swiss Tropical Institute
- UN Office for Project Services (UNOPS)
- Crown Agents
- The World Bank

## The GFATM has established supply and procurement policies that each principle recipient must adhere to

- A key objective of Global Fund procurement policies “is to procure quality assured products at the lowest possible price and in accordance with national and international law” and ensure that “procurement is conducted in a transparent fashion”
- To achieve this the GFATM has in place a procurement and supply management plan (PSM) to serve as a guideline for principle recipients
  - The PSM:
    - Supports the procurement of quality assured medicines and other health products in sufficient quantities
    - Reduces cost inefficiencies
    - Ensures the reliability and security of the distribution system
    - Encourages appropriate use of health products
    - Continuously monitors and evaluate the procurement process

# The principle recipient submits a detailed procurement and supply management plan to the LFA



***It is the responsibility of the local funding agent to review the procurement plan and send report to the Global Fund.***

# The procurement and supply management plan (PSM) includes several components

- Within the PSM, principle recipients must:
  - Indicate which entity or entities will implement relevant procurement and supply management activities
  - Describe how the PR will ensure adherence to each of the Global Fund's procurement policies
  - Include a list of key health products with their respective estimated quantities, cost, registration status and patent status
  - Include details about technical assistance requested
  - Encompass two years of implementation



## Specific guidelines to ensure “high-quality” drugs vary for 1st and 2nd line medicines

### For 1<sup>st</sup> line procurement, some guidelines are set . . .

- Drug must be “competitively priced” and meet quality standards
- Manufacturing sources must be:
  - WHO pre-certified for TB supply
  - GMP certified
- Drugs must be approved by relevant regulatory authority
- No specific procurement mechanisms required

### . . . For 2<sup>nd</sup> line, recipients must go through the GLC

- For 2<sup>nd</sup> line medicines, guidelines are more stringent as principle recipients must go through the GLC for procurement
- GFATM prefers that applicants have already submitted or received approval by the GLC, but this is not required

The GFATM does allow flexibility in manufacturing sources, but is preparing to become more involved in quality control in the future

### Category A and B

Principle recipients can purchase 1<sup>st</sup> line drugs from one of 2 categories:

Category A = WHO approved

Category B = approved by stringent regulatory body (EU EMEA or USA FDA)

If none or only 1 supplier is available from categories A and B, then principle recipients can purchase from Category C products.

### Category C

- Category C = approved by relevant nation's regulatory body
- Countries are required to notify their local funding agent or GFATM fund portfolio Manager when purchasing Category C drugs
- Product will be subject to quality control testing which will be outsourced by the GFATM to identified partners
- Quality control agents are currently being finalized through a tender process