Investing in our future
The Global Fund
To Fight AIDS, Tuberculosis and Malaria

Global Fund Experience:
access to patent information and impact on procurement of medicines

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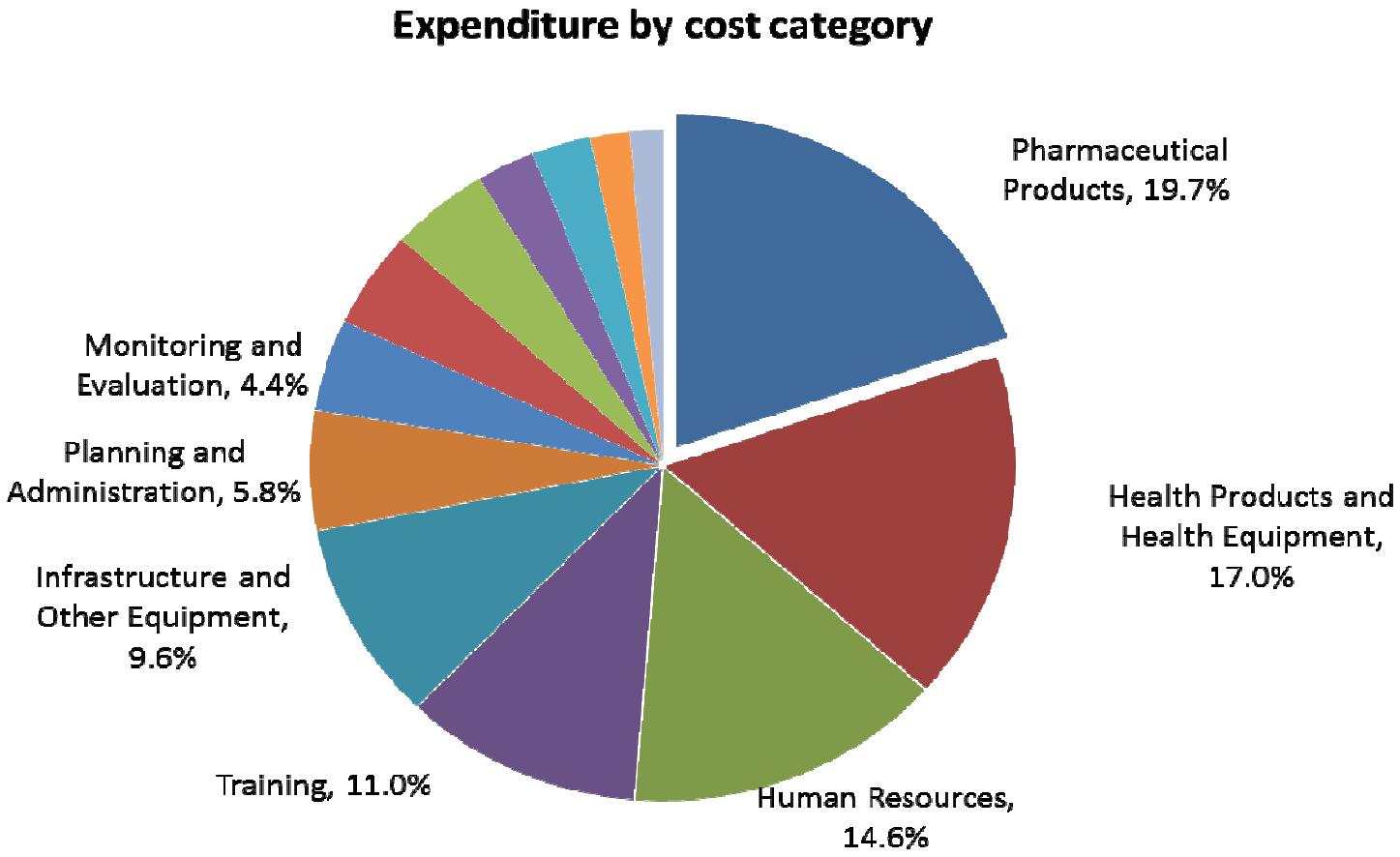
  - Procurement and Supply Management Policies
  - Price differences among grantees
- General information from experience:
  - Management of patent issues in procurement cycle
  - Availability and quality of information
- Searching for solutions to facilitate procurement:
  - What information could be useful
  - Sustainable and simplified approaches

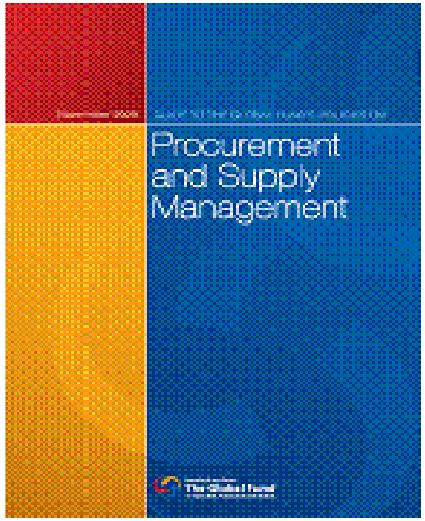
Use of the Global Fund Grant Funding



37% percent of funds are used for medicines and health products procurement

The Global Fund PSM Policy and Principles

- Procurement activities are the responsibility of the Recipient
- Global Fund policies aim to ensure that the Recipient is able to select :
  - among quality assured products (monthly list),
  - at the lowest possible price,
  - in the most adequate formulation (FDCs, children,..)
- Transparent, fair and competitive procurement
- Value for money
- Review of PSM plan and Price & Quality Reporting system



National and International Laws

Recipients must procure their products in accordance with national and international laws. The Global Fund encourages recipients to apply the flexibilities provided within national laws and in the World Trade Organization's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), as interpreted in the Declaration on the TRIPS Agreement and Public Health (Doha Declaration), to achieve the lowest possible price for products of assured quality.

In the event that a Principal Recipient does not have the requisite capacity to assess the national and international intellectual property rights issues that apply to the desired products in their country, it may contract the necessary expertise using funds budgeted for this purpose in the Global Fund grant.

Global Fund HIV Financing

140 countries

US$ 10.8 billion (Approved Grant Amount)

US$ 17.4 billion (Total Lifetime Budget)

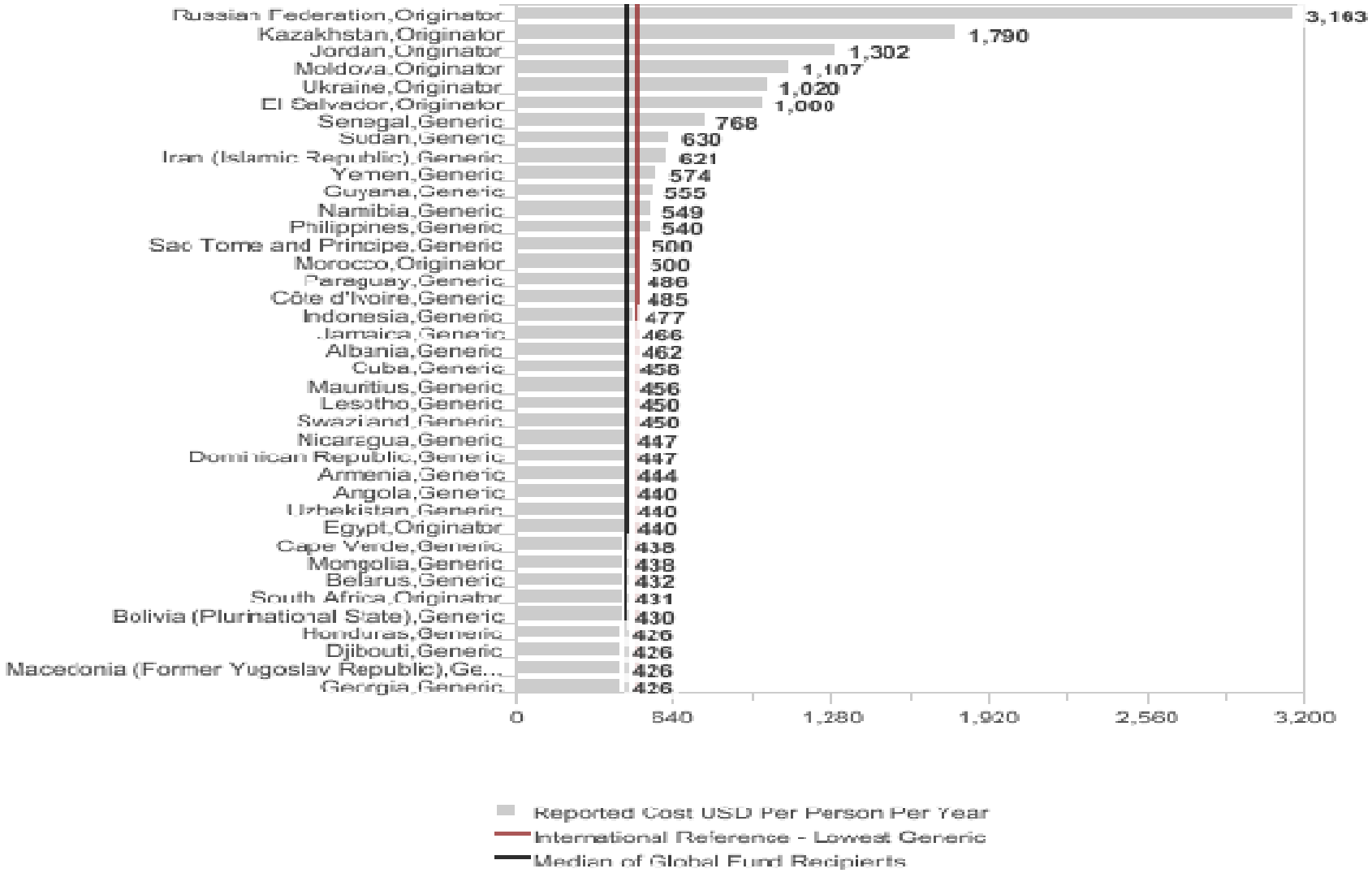
Global Fund Financing

Wide spectrum of countries among grantees:

- Unequal access to differential price programs of pharmaceutical companies;
- Different level of patent protection and TRIPS implementation;
- Bilateral and regional trade agreements;
- Unequal level of knowledge in IP.

Price differences across grantees: examples

Lopinavir (LPV)/Ritonavir (RTV), 200/50mg
Prices paid per year/patient in middle-income countries- since July 2009

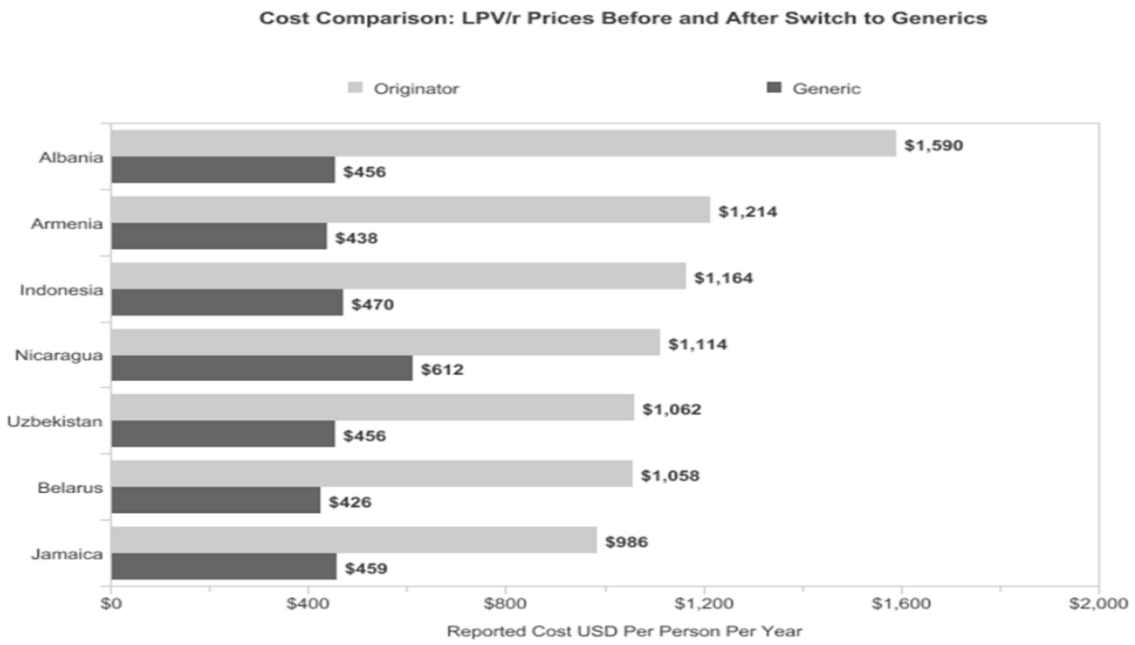


Price differences across grantees/2

- Patent barriers affect some countries' capacity to :
  - Procure lower priced versions of ARVs
  - Procure improved formulations (FDCs or children solid formulations) when they only exist as generics
    - eg.3TC in China
- Among Global Fund grants, affected countries are middle-income countries outside Sub-saharan Africa
  - Where patents for pharmaceutical products exist for key products
  - Excluded from discounts from patent holders or eligible only to second level of discount

Price differences among grantees/3

- Some of these countries are making substantial savings in grant budget by shifting to generic products (2009/2010)
  - In some cases after implementation of TRIPS flexibilities (governmental use-type licenses)



Management of patent issues in procurement cycle/1

- Procurement bottlenecks are common among grantees
  - weakness in forecasting, lack of capacity in PSM, problems on storage and distribution, etc

- Management of intellectual property issues is also a **procurement bottleneck**, further delaying the process
  - PSM plans (including estimated prices) are usually prepared without taking into account patent issues
  - Problems arise only late in the cycle, when procurement should actually start
  - Searching information, clarifications, etc. creates long delays
  - This leads to emergency procurement to avoid treatment disruption/stocks outs

Management of patent issues in procurement cycle/2

- Information about patents (and patent law) is not readily available.
- Delays on clarifying situation and potential options for the countries due to:
  - Disconnection between Ministry of Health and other authorities (trade, industry..)
  - Confusion with registration of medicines
  - Lack expertise of Procurement offices in countries

- Technical assistance possible with Global Fund grants but not very often requested

Management of patent issues in procurement cycle/3

- **Procurement agents** used by grantees:
  - In some cases, responsibility placed at country level for compliance with national law
    - acceptance of governmental use licenses
  - Or, request for patent status for all products in the order
  - Generally, limited patent search:
    - difficulties faced on doing patent search and very resource demanding
    - responsibility for verifying information placed at country level

In any case, time limit assessment to avoid stocks outs

Availability and quality of information

- Information about patent status often available only from the originator company (*letters*)
- If no information, or when information available from originator and other available information are not coincident ➔ *Chilling* effect
    - procurement agent unwilling to take risks (e.g. China lamivudine)
    - generic companies refusal to quote (e.g. Guatemala)
    - Pressure of time
    - And eventually procurement of higher priced products

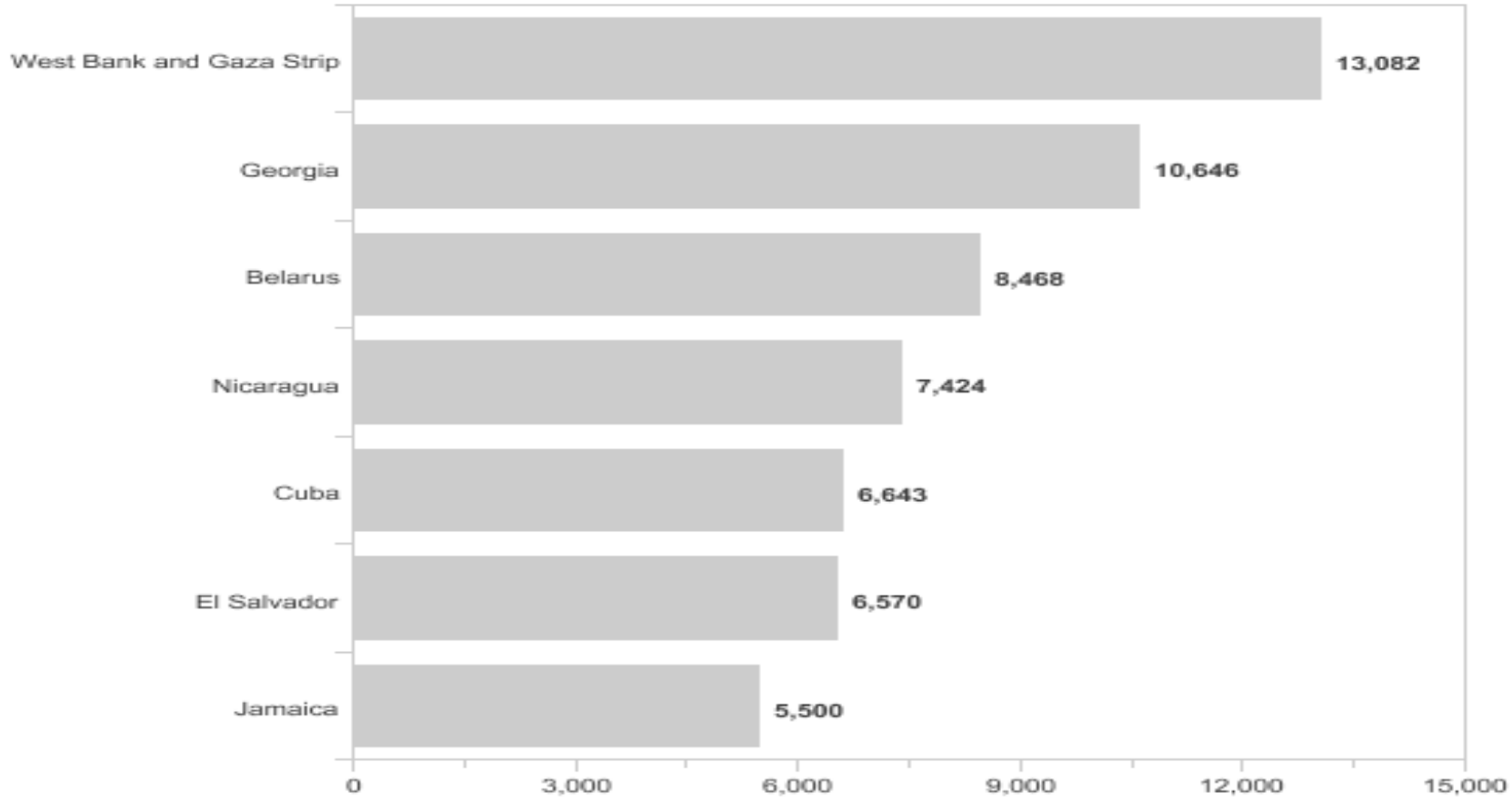
Availability and quality of information

- Validity of searches conducted at country level?
  - In many cases, search in local patent office done only using product name (INN) and formulation details.

    E.g. Key search word: Atazanavir 300 mg tablets.
  - With secondary patents, on new forms, combinations, .. How to ensure all possible patents are covered in search? (e.g. syrups)
  - Need for further guidance to patent offices on moving forward (new ARVs, increase in secondary patent applications)

More recent ARVs

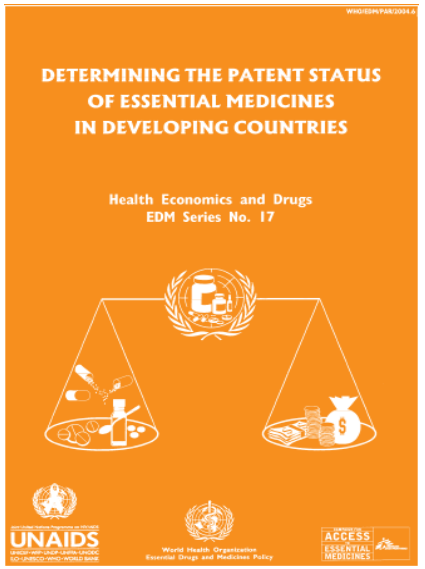
Darunavir prices paid per year/patient by all Recipients

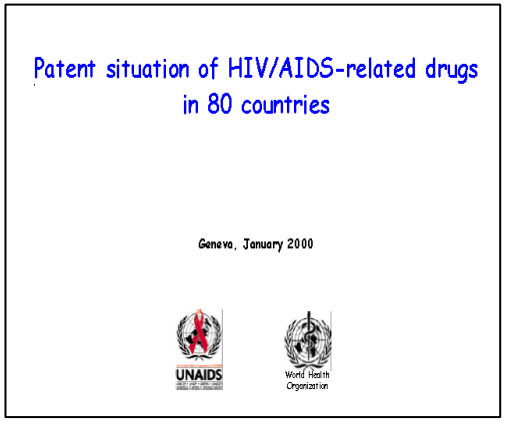


1,095$ offered by patent holder to Sub-Saharan Africa and LDCs

What patent information could be useful for facilitating procurement process?

- Public list of basic and secondary patents of key products and formulations
  - date and numbers
  - E.g. UNAIDS/MSF/WHO 2004
- On-line data-base or consultation service
  - Specifically important now for middle income countries
  - E.g. WIPO





Guidance and simplified tools

- Guidance for developing capacity at country level:
  E.g. WHO 2010, UNDP

- Once patent status known, in some cases ➔ will need Technical Assistance to determine options for procurement of lower-priced generics

- Need for simplified solutions for managing IP rights upfront ➔ Medicines Patent Pool