

# World Bank Training Program on HIV/AIDS Drugs

## Training Module 6 Financing and Pricing

based on the World Bank document  
**Battling HIV/AIDS: A Decision Maker's  
Guide to the Procurement of Medicines and  
Related Supplies World Bank, 2004**

Dr Michel Grupper, MPH, Ph.D  
Ana Johnson-Masotti, PhD, Amanda Bradford, MSc  
Laura Wyman, MSc  
Beirut, June 2005

# *Learning/Training Objectives*

- To understand how the pharmaceutical supply chain works including comprehension of who the components and key players are
- To understand price discrimination and pricing differences both within and across countries
- To understand how international programs have sought to implement programs with the goal to allow countries with widespread access to antiretroviral medicines at the lowest possible prices

# *Learning/Training Objectives*

- To understand how compulsory licensing, domestic production, and pool procurement have contributed towards reduced drug prices
- To acquire an understanding on how to decode local pricing structures, where to find domestic drug pricing information, and on identifying important factors when conducting any international price comparisons
- To describe and understand how countries can contribute towards low drug prices

# Final/Ultimate Objectives

- To obtain the lowest possible prices with a standard quality for the HIV/AIDS related pharmaceuticals and medical products (i.e. 4 years ago a triple cocktail ART \$10'000 per year / patient in US, today \$200 per year / patient (sourced Indian generics))
- To ensure adequate financing of these products in order to improve the affordability and financial sustainability of the flow of products required by the HIV/AIDS programs

# What determine drug prices?

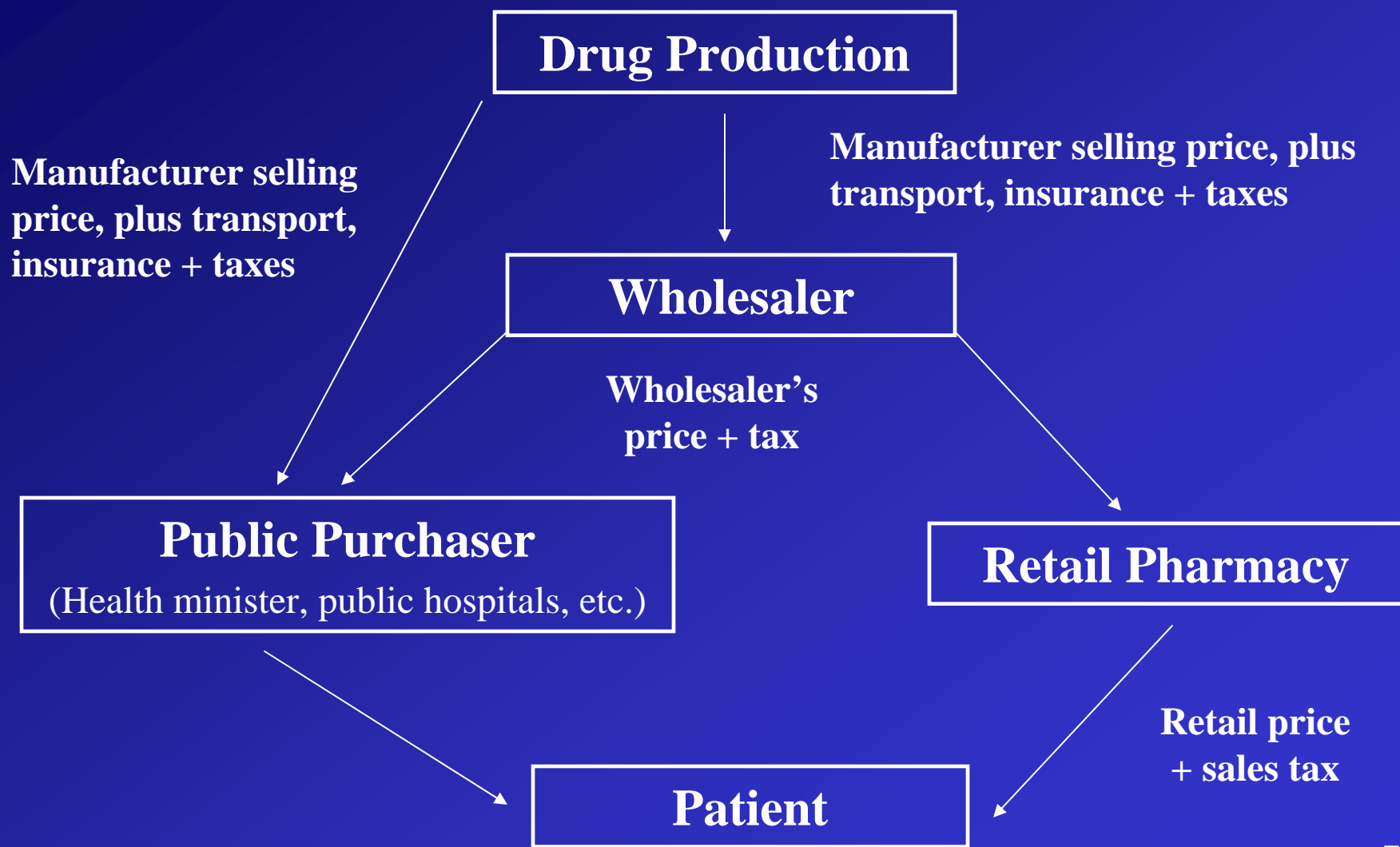
- The pharmaceutical supply chain
- Production costs
- Market structure and competition
- Resources needs
- Funding sources
- Pricing

# The pharmaceutical supply chain

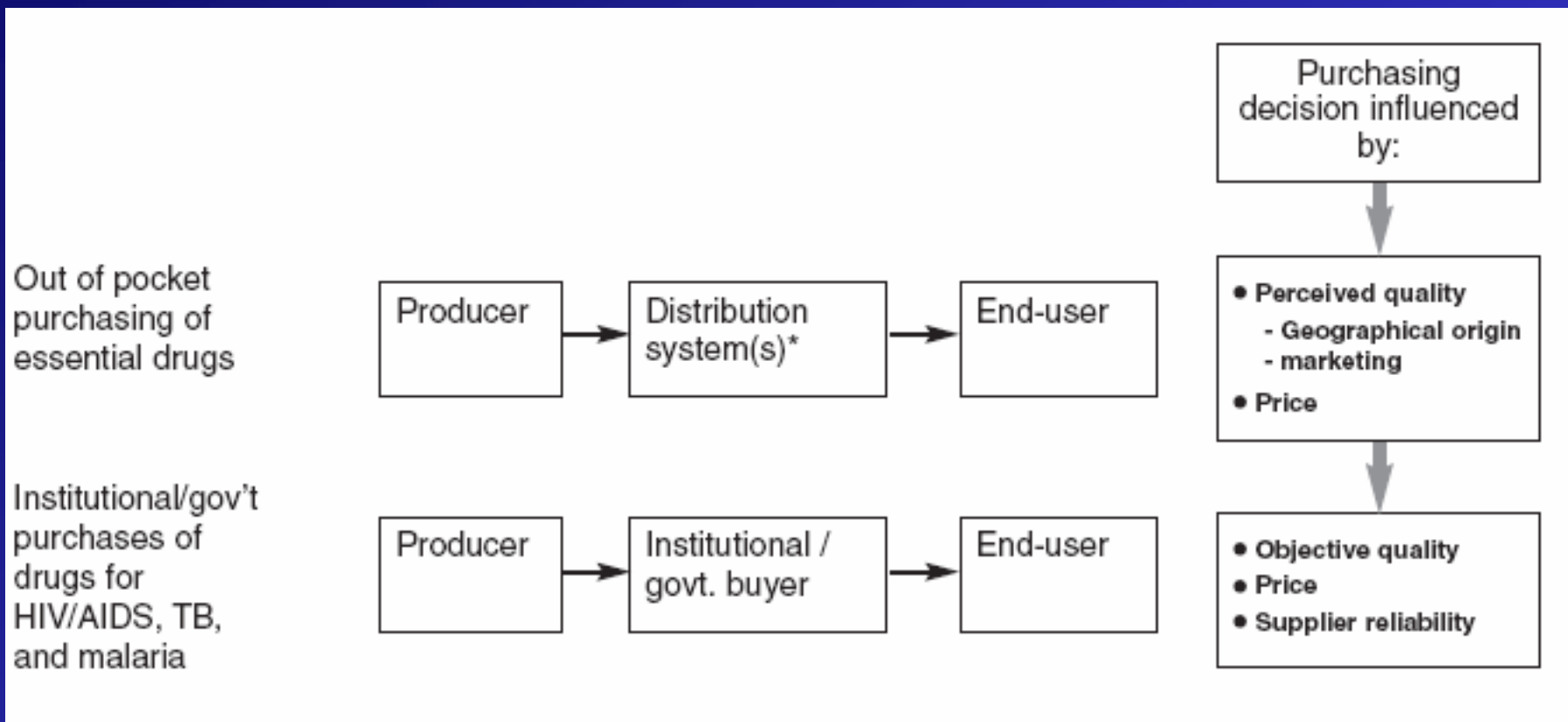
## Key Players

- *Manufactures*
  - *Innovative Pharmaceutical Firms*
  - *Generic Manufacturers*
- *Wholesalers/Distributors*
- *Retailer*
  - *Pharmacies*
  - *Doctors*
  - *Hospitals*
- *Governmental & Non-Profit Sellers*
  - *Public Pharmacies*
  - *HC*

# The pharmaceutical supply chain

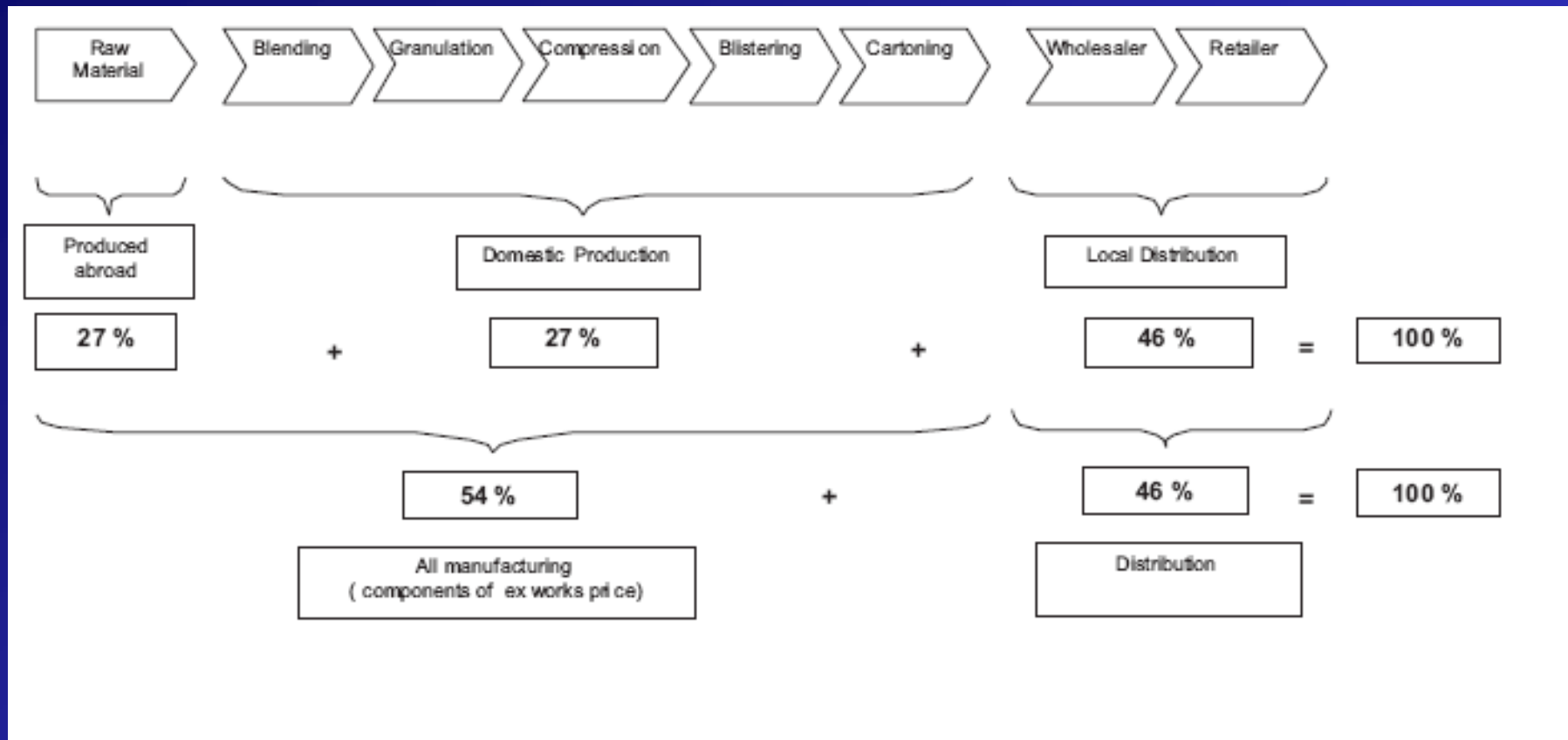


# Relationship of end-user to drug manufacturer



Source: Guimier, Lee, Grupper, DFID 2004

# Value chain flowchart of pharmaceutical production cost



Notes: Based on a drug in which API represents 50% of the ex works price. For the drugs used in this study, with the exception of the ethical drugs, the median and mean costs of API in the ex works price are 47% and 51%, respectively.

# Market structure and competition

## Perfect Competition

- Multiple small buyers and sellers in the market - no one buyer or seller is large enough – no market influence
- Freedom of entry and exit into the market
- Buyers and sellers have perfect knowledge about market prices and output
- Prices close to production costs

# Market structure and competition

## Monopolistic Competition

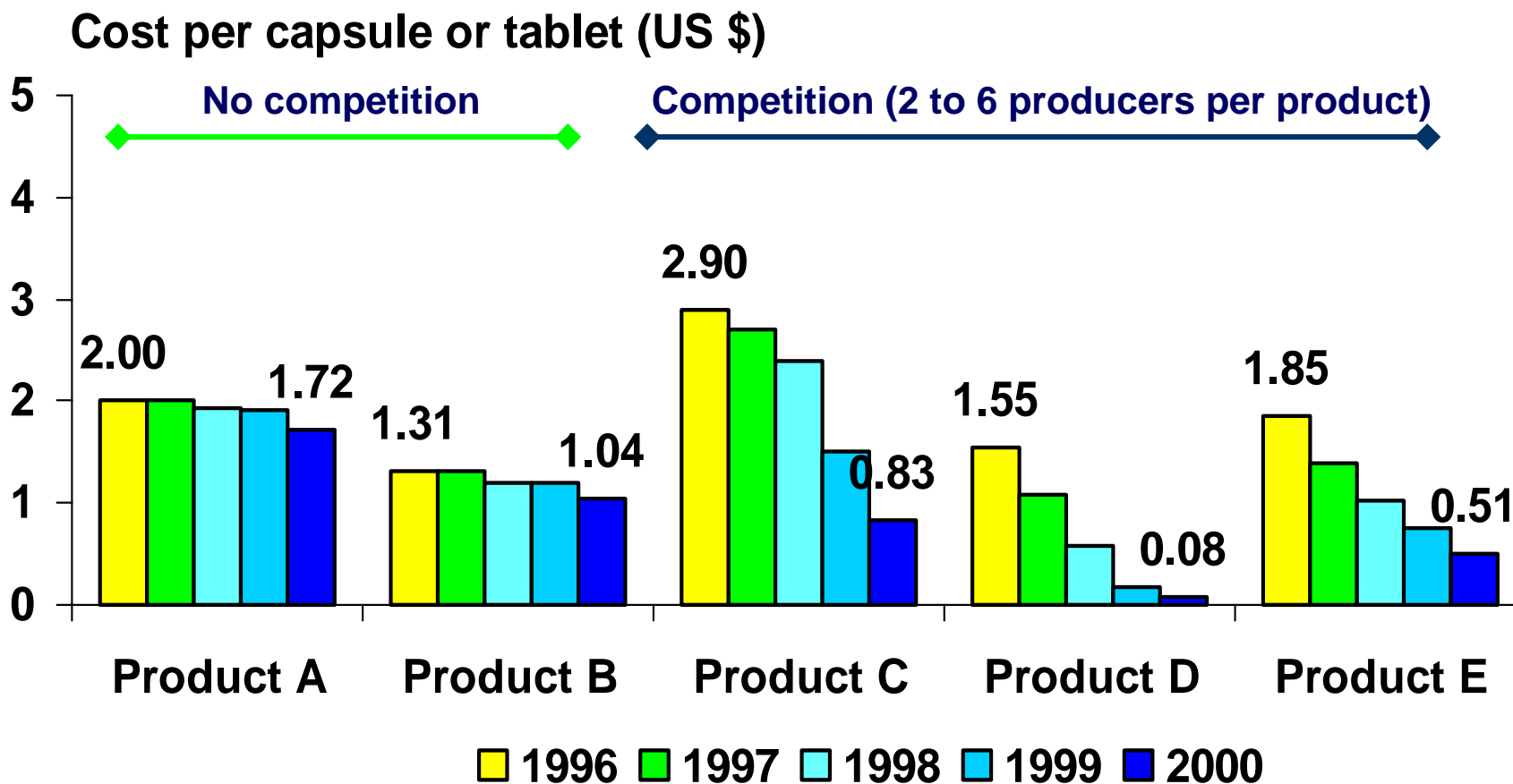
- Same conditions hold as for perfect competition except that firms produce differentiated products with close substitutes
- Firms have a certain degree of market power as they can raise prices without losing all of their customers

# Market structure and competition

## Monopoly

- There is only one firm in the industry (the monopolist)
- Patented drugs
- No price substitutes
- Creating brand loyalties
- Monopolist maximizes profits in the short-run

# Competition is Highly Effective in Reducing Prices - The Example of Antiretrovirals



Source = Samb, B., 2000 UNAIDS, in Levison, L., Boston University School of Public Health, 2003

# Market structure and competition

Multinational companies: brand name drugs

- Conduct their own R&D and own many patent portfolios: however, also typically spend more money on marketing and administration than research and development
- Bayer, Boehringer Ingleheim, Bristol-Myers Squibb, GlaxoSmithKine, Merck, Pfizer and Schering-Plough

# Market structure and competition

## Generic Manufacturers

- Generic manufacturers that compete in the production of off-patent drugs
- Produce drugs that are marketed under approved non-proprietary and proprietary names
- Major generic producing nations include Brazil, China, India and Thailand

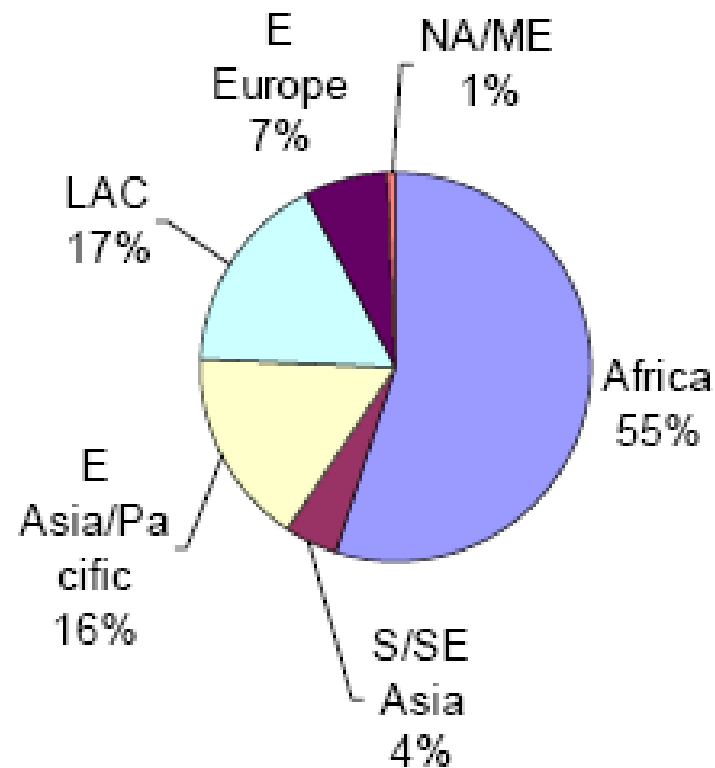
# Resources needs

**Table 5. Total treatment and care resource needs and ART coverage**

<i>US\$ million</i>	<b>Coverage ART</b>	<b>Million People</b>	<b>Total Resources</b>
2006	55%	3.0	2 986
2007	67%	4.8	4 029
2008	75%	6.6	5 250
2009	79%	8.3	-
2010	80%	9.8	-

# Resources needs

**Figure 5. Treatment and care per region**



# Resources needs

**Table 13. Annual costs for AIDS treatment and care**

Annual cost per person per year (constant prices)	Low-income countries	Middle-income countries
Provider-initiated HIV testing	8	8
Palliative care	267	580
OI treatment	618	1 300
OI prophylaxis	103	312
Average drugs costs ART	519	2 389
Average costs ART Tuberculosis	883	2 753
Average cost second line ART	2 245	4 115
Laboratory monitoring for ART	3	117
Nutritional support ART	113	225

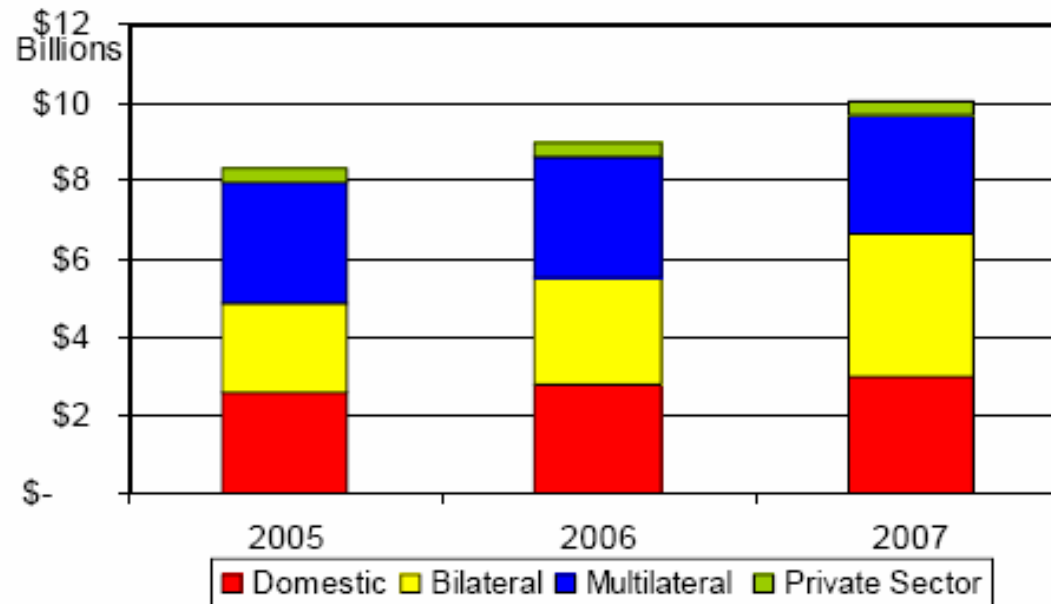
**Table 6. Treatment and care components**

<i>US\$ million</i>	2006	2007	2008
Palliative care	308	302	295
Provider initiated testing <sup>28</sup>	66	79	109
OI Treatment	686	703	707
OI Prophylaxis	287	403	510
ART, including nutritional support	1 642	2 482	3 624
Laboratory testing	54	79	104
<b>Total</b>	<b>3 043</b>	<b>4 048</b>	<b>5 349</b>

Source: RESOURCE NEEDS FOR AN EXPANDED RESPONSE TO AIDS IN LOW AND MIDDLE INCOME COUNTRIES, UNAIDS, 27-29 June 2005

# Funding sources

**Figure 4. Projection of available resources for AIDS from all sources between 2005 and 2007**



Source: RESOURCE NEEDS FOR AN EXPANDED RESPONSE TO AIDS IN LOW AND MIDDLE INCOME COUNTRIES, UNAIDS, 27-29 June 2005

# Funding sources

## International Programs

### The Global Fund to Fight AIDS, Tuberculosis, and Malaria

- Investment in battle against AIDS, tuberculosis, and malaria
- Contributions made to fund from countries and independent individuals
- Independent governing body
- Conduit for mobilizing, managing, and disbursing new and additional resources
- \$402 million disbursed in 2004 for all interventions
- \$1.7 billion committed over two years for HIV/AIDS
- Projecting \$1.6 million to receive antiretroviral treatment by 2007

# Funding sources

## International Programs

World Bank: **\$2.5 billion in total worldwide so far**

## President's Emergency Plan for AIDS Relief (PEPFAR)

- Five year plan, \$10 billion in new funding
- 15 focus countries in Africa, Caribbean and S.E. Asia
- Aims to treat 2 million people

# Funding sources

## International Programs

### The European Commission Council Regulation

- Voluntary global tiered pricing system
- 75% off “ex-factory” price or cost plus 15%
- Confidential pricing with independent audit
- Re-importation issues covered by differences in product size, colour, logo and shape

# Pricing

## Definition

Prices - There is only one price for which planned market demand is equal to planned market supply, which is known as equilibrium price or market clearing price

- Shifts in demand and supply can cause this equilibrium condition or price level to shift

# Pricing

## Equity Pricing

Definition: Can be viewed as 'The poor pay less than the rich'

An equitable price structure may take the following form:

- 'Market' pricing by manufacturers in different markets, according to the ability to pay
- Control illegal parallel trade
- Subsidization of drugs by international programs or donors
- Compulsory licensing and generic competition

# Pricing

## Price Discrimination

- *First degree* – charging whatever the market will bear – willingness to pay – maximum profit
- *Second degree price based on:*
  - Number of unit sold
  - Version of the drug
- *Third degree* – separate markets and customer groups each market is defined by its demand characteristics – i.e. Public / Private

# Pricing

## Pricing Differences within countries

- Patent protecting drug
  - Once patent expires, generic manufacturers can enter market
- Some companies produce only "Copy" molecules already developed (no R&D costs): Prices 35% cheaper
- Amount of state intervention
  - Originator antiretroviral drugs and generic locally manufactured drugs coexisting – competitive procurement
- Marketing, sales, and volume
  - Companies can sell high volume of drugs at discounted prices (brand name generics, generics)

# Pricing

## Pricing Differences across countries

- Differences in purchasing power
  - Comparison – Purchasing Power Parity based on Gross Domestic Product and Health Purchasing Power Parity
- Regulatory systems and tax levels
  - Positive list not the same across countries
  - Over the counter price differences due to regulation in pharmacy markets – Tax levels

# Domestic Pricing

## Decoding the Current Pricing Structure in your Country

- *Looking at information that compares domestic prices with prices in other countries – international price comparison*

## Where to Look

- *International conferences, fact sheets, workshop proceedings, journal articles, newspapers, news magazines and the world wide web*

## Important Factors to Identify

- *Price comparisons should be made at similar points in the supply chain*

# Reducing Drug Prices

*“Prices are an important factor, especially in developing countries, since while in developed countries pharmaceuticals are largely publicly funded through reimbursement and insurance schemes, in developing countries, typically 50%-95% of drugs are paid by the patients themselves. Thus in developing countries, prices of medicines have direct implications for access”*

# Reducing Drug Prices

- Compulsory Licensing
- Pool procurement
- Case study Brazil

# Reducing Drug Prices

## Compulsory Licensing

- Country may request patent holder permission to begin domestic manufacturing
- Local government could ask domestic firm to manufacture generic version of drug in domestic country
- Exporting firm could agree to manufacture drug in domestic country
- Decrease in drug prices

# Reducing Drug Prices

## Examples of Voluntary Licensing

- Boehringer Ingelheim licensed Aspen Pharmacare to produce nevirapine and GlaxoSmithKline agreed to license three antiretroviral drugs to Aspen Pharmacare
- Pharmacia, in partnership with International Dispensary Association (IDA), will grant non-exclusive license for delavirdine to genetic manufacturers

# Reducing Drug Prices

## Pool procurement

- lower drug prices by increasing the purchase volume
- National or regional
- Suppliers make economies of scale and lower their operational cost
- Reduced market and distribution costs
- Improved production planning from better demand forecasting

# Illustrative Case Study: Brazil

## Strategies Used

- Brazil is the first developing country to have implemented a large-scale universal antiretroviral therapy distribution program
- The public health system provides free antiretroviral therapy to approximately 125,000 patients
- The savings from out-patient and hospital costs outweigh the costs of implementation by more than US \$200 million

# Illustrative Case Study: Brazil

## Factors that Contribute to Success

- 1971 Law suspending intellectual property rights
- Large scale experimentation without legal restrictions
- Domestic national labs with the capacity to manufacture large quantities of antiretroviral drugs

# Illustrative Case Study: Brazil

## Factors that Contribute to Success (Cont..)

- Negotiation of drug prices with pharmaceutical companies that are exclusive producers
- Deals were made with Abbott, Merck and Roche cutting prices of four drugs by more than 50%

# Illustrative Case Study: Brazil

## Factors that Prevent Success

- Most developing countries lack manufacturing capacity building to produce local drugs under compulsory licensing
- Strengthening and capacity building require much funding
- Reduction of customs and tariffs over time – fierce competition
- High prices constitute necessary incentive for efficient R&D
- Still not perfectly universal system

# Illustrative Case Study: Brazil

## Take-Away Lessons

- Gather financial resources
- Confront cultural, religious, and legal barriers
- Compulsory licensing
- Local production by local laboratories
- Increased advantage in negotiating drug prices with patent holder pharmaceutical firms

# Illustrative Case Study: Brazil

## Mistakes Made: How and Why?

- Capacity for production of drugs does not entail entire production process
- Emphasis has been on strengthening capabilities of local laboratories
- Focus has been on production of raw materials and intermediates
- Trade liberalization – marketing and price competitiveness

# Illustrative Case Study: Brazil

## Mistakes Made: How and Why? (Cont.)

- Disincentives for investment of manufacturing capabilities by private firms
- 90% production costs accounted for by active principles produced by private firms
- Cheap principles from China and India
  - Quality control
  - Dependency

# Summary and Conclusions

## What determine drug prices?

- The pharmaceutical supply chain
- Production costs
- Market structure and competition
- Resources needs
- Funding sources
- Pricing

# Summary and Conclusions

## Reducing drug prices

- Compulsory Licensing
- Pool procurement
- Case study Brazil
- National drug policy

# Group exercise #1

1. Divide yourself into groups of five (Egypt + Botswana, Jordan + Iran, Lebanon, Morocco, Yemen).
2. Answer the following questions regarding your country:
  - Market structure and competition of ARV market / local production
  - Resources needs for ARV (prevalence, cost per patient..)
  - Funding sources for ARV (list all sources and amount) and how will secure your funding for the next 5 years
  - What is the margin for wholesaler and retailer on ARV in your country?
  - What do you think of your ARV supply chain in your country?
  - List and explain the 3 best policies that would reduce the price of ARV in your country
  - List and explain the 3 worse policies that would not reduce the price of ARV in your country
3. Please remember to apply what you have learnt from the presentations and background readings.
4. Be prepared to present your findings to the whole group for general discussion.

## Exercise #2

WHO has just issued an Expanded Programme on Antiretroviral Drugs (EPAD), seeking to provide the world with access to affordable antiretroviral drugs. As a result, EPAD will be issuing a new tender for the drugs it estimates it may need, awarding bids primarily on basis of price and potentially choosing many suppliers for each drug. Manufacturers may offer EPAD: 1) a low quality version of the drug; 2) a drug that has been on the industrialized market for a while; or 3) pool procurement in an effort to meet the low drug price that EPAD is willing to accept.

### Questions

1. Why is high volume manufacturing cost-efficient?
2. What effect does pool procurement have on drug prices?
3. Why offer a non-prequalified version of a drug or one that has already been on the industrialized market for a while?

# Exercise #2: Solution

## ***1. Why is high volume manufacturing cost-efficient?***

- Price per dose decreases with larger volume
- Volume production allows manufacturers to improve their processes more quickly allowing them to increase product yields

## ***2. What effect does pool procurement have on drug prices?***

- lower drug prices by increasing the purchase volume
- National or regional
- Suppliers make economies of scale and lower their operational cost
- Reduced market and distribution costs
- Improved production planning from better demand forecasting

## Exercise #2: Solution (Cont.)

### 3. *Why offer a non-prequalified version of a drug or one that has already been on the industrialized market for a while?*

- A non-prequalified version of a drug can be a way of reducing cost to the consumer
- Consumers can self-select the price point they can afford to pay for the drug
- Increase the profit of the manufacturer beyond what could be earned with a single price
- Manufacturers could provide EPAD the option of a less expensive drug that has already been released into the industrialized market
- Quality issues