

Current & Emerging Options for Price Regulations

International Seminar on Pharmaceutical Pricing & Regulatory Framework for

Affordable Medicines” on 12th April,2008 in New Delhi and

-S.Srinivasan
LOCOST, Baroda, India
Email: locost@satyam.net.in

Impoverishing the Poor



**I did take the tonic, Sir !
But had to starve for days to buy it.**

**I did take the
tonic sir!
But had to
starve for
days to buy
it.**

India's public health crisis:

Poor health indicators:

- Infant mortality rate: 69 per 1000 live births. (compare with 17/1000 of Sri Lanka)
- Maternal mortality rate: 498 per lac births.
- Anemia: 74% of children 6-35 years of age, 49-56% of women.

Burden of diseases-1

Burden of diseases:

- **Tuberculosis: 1/3 of world's cases.15 million cases. Largest no. of Multi-drug resistant cases.**
- **HIV/AIDS. Second highest in the world.3.5 million.**
- **Acute respiratory diseases: 950,000 deaths per year.**
- **Acute diarrhea: 19 crore illness episodes.**

Burden of diseases-2

- Hypertension: 20-40% in urban areas, 12-17% in rural areas.
- Diabetes mellitus: largest no. in the world.
- Coronary artery disease:
- Cancer: 7 lac per year.
- Chronic respiratory diseases: 65 million cases.

(Ref:BMJ April 2004)

Some of the Context

- Average earning of an Indian - US\$ 440 per year or about (This is based on a GDP of US\$ 440 billion and 1 billion people): **Rs. 1,727**
- Minimum earning required, as per WORLD BANK, to live at above poverty line, for underdeveloped countries like India, China etc, about **US\$ 1.0 per day or US\$ 30 per month: Rs. 1,410**
- MINIMUM WAGES, as per Government of India, for all the States, about Rs. 40 to 60 per day per person, average about Rs. 50 per day. **For 25 days per monthRs. 1,250**
- POVERTY LINE definition, as per Government of India, at Rs. 10 per day, per person, approx.: Rs 300

Are India's "low-priced" drugs affordable in India?

- **Affordable for whom?**
- **Cost of drugs for multi-drug resistant TB (maintenance phase) is equivalent to 737 days of daily wage of a wage laborer in India**
- **Daily wages is Rs 60/- average (One Euro = Indian Rupees 50)**
- **Coronary heart disease: 209 days of wage labor**
- **Prevention of Hepatitis A: 30 days of wage labor**

Are India's "low-priced" drugs affordable in India?

- **An unskilled worker in US or UK needs to work for 10 minutes to buy 10 tablets of Paracetamol**
- **In India a daily wage worker will have to work at least one hour.**
- **And our Paracetamol is one of the cheapest in the world!**

Price of Glivec, anti-cancer drug

- Novartis: Rs 1,30,000 per month
- Price of Indian generic equivalents: Rs 10,000 per month
- **Still unaffordable**

Cost of Treatment with Biotechnology based Drugs -1

- Abciximab (antianginal, Eli Lilly): **Rs. 39,480** for a **60 kg man** per day
- Epoetin alfa (Wepox/*Wockhardt*, Treatment of anemia of chronic renal failure): **Rs. 10,200** for **8 weeks** for a 60 kg man **AND**
- **Rs. 1912 to 11475** per week for a **60 kg man** thereafter

Cost of Treatment with Biotechnology based Drugs -2

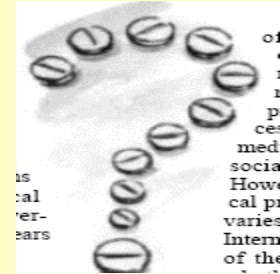
- Interferon alpha-2a (Roferan-A/Nicholas Piramal) used in types of leukemia: Initial therapy costs of Rs. 43,552- Rs 1,30,656 then maintenance therapy costs of Rs. 1,06,158- **Rs.3,18,474 (6-18 months tt cost)**
- Etanercept (Enbrel/Wyeth) –in severe arthritis: **Rs. 18,131 per week of therapy** which has to be taken long term.

Are these low priced....

Costs of treatment :

- Iron deficiency anemia (using Dexorange): Rs. 3,744 for 6 months.
- Coronary artery disease: Rs.12,541 per year (using the expensive brands)
- Diabetes using oral glimepiride 2 mg: Rs.3,660 per year.
- Multi-drug resistant TB: > Rs.100,000 for 2 years.

What is Wrong with India's Drug Situation? –1

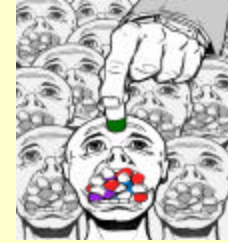


- **Problem of poverty amidst plenty**
- **Drug costs are about 40-80 percent of the health care costs**
- **Health care is the second most common reason for rural indebtedness.**

What is Wrong with India's Drug Situation? –2

- **No health insurance**
- **Decaying and in most rural areas non-functioning public health systems**
- **Increasing privatization of health services**

What is Wrong with India's Drug Situation? –3



- **Irrational, unscientific drugs**
- **62 percent of top-selling 300 drugs are not in the National List of Essential Medicines!**

Pricing Anomalies of India's Drugs

- **Overpricing**
- **Profit margins can be up to 4000 percent**
- **Different brands of same drug sell at vastly different prices**
- **Most drugs out of Govt price regulation**



Market Characteristics: Competition does not reduce prices!

- **Many “players”**
- **But prices of drugs have not come down**

“Competition” does not reduce prices!

- **Same drug is sold at different prices by the SAME company too! Under different brands**
- **Brand Leader often also the Price Leader (costliest drug is most sold).**
- **Therefore competition does not automatically bring down the prices.**
- **In fact more players seems to result in a range of prices.**

“Free” Market?

- **Drug prices are fixed as to what the perceived target market for the brand can take.**
- **Markets are distorted by unfair and unethical marketing practices of drug companies**

Price Regulation by Govt.

- **Price control basket has come down over the years:**
- **350 in 1978 to less than 74 now.**
- **Prices of inessential drugs controlled – essentials are mostly left to the market**

Tender Prices a Fraction of Retail Prices!

- Govt tender prices fraction of retail prices
- For example: Albendazole 1.89 percent of market price!
- Amylodipine: 6.13 percent of market price!
- See www.tnmsc.com for tender prices of a good, transparent govt procurement agency

[See also: *Srinivasan, S. "How Many Aspirins to the Rupee? Runaway Drug Prices", Economic and Political Weekly, February 27-March 5, 1999*]

Prices of other commodities are not controlled?

- **Telephone rates, Insurance premia, Electricity tariff, Bank Interest rates**
- **Are Medicines less important?**
- **In addition, food for export, cooking gas, urban transport (rail and road), electricity, IITs and IIMs and AIIMS all enjoy heavy subsidy from the government.**

Price Control in Other Countries

- **U.K : Pharmaceutical Price Regulation Scheme (PPRS)**
<http://www.doh.gov.uk/pprs/index.htm>
- **Canada: Patented Medicines Prices Review Board**
- **France: Transparency Commission and Economic Committee on Medicines**
- **Egypt: All drugs under price control**
- **Italy: Restricted wholesale margins**
- **Germany: Reference pricing system**
- **And some system of price monitoring and price regulation prevails in Japan, Netherlands, China, Indonesia, Colombia and so on. In some of these countries drug pricing is tied with national health system reimbursements and or insurance schemes.**

Why market cannot decide medicine prices?

- Free Market/Invisible hand not possible
- Because buyers and sellers have different bargaining strengths (info asymmetry)
- Sellers and doctors decide
- Buyers (patients) have little or no choice
- Buyers have to make decision usually under distress

Is WTO Against Price Control?

- **TRIPS is silent on Price Control**
- **Doha Declaration and Art 7 (Objectives) and Art 8 (Principles) of TRIPS assert members right to protect public health.**
- **“Each member has the right to grant CL and freedom to determine grounds upon which such licenses are granted.” (Doha Declaration)**
- **Trade cannot be given primacy in comparison to health and human rights.**

Price Regulation in India: For/Against ?

- For: Ordinary citizens, Consumer groups, public health activist groups, judiciary (sometimes)
- Against: Pharma companies, most politicians of the right, National/MNCs, Corporate Hospitals, Private Sector, Insurance Companies

Financial Options

- **There is no alternative but to curb high drug prices**
- **Ceiling on profitability, prices, etc**
- **Tax and fiscal incentives to those who make generic generics as per WHO list and/or NLEM**
- **Tax and fiscal incentives to those who sell under the ceiling prices**
- **Tax and fiscal incentives to those who make diseases for drugs of national importance**
- **Plugging loopholes of how drug companies avoid price**

Some drugs that need special monitoring/price regulation

- Antibiotics, newer antibiotics, vaccines
- Drugs for national disease programmes as also ARVs, ARI, anticancer, diabetes, asthma, etc.
- Newer type of medical technologies like MRIs, CAT scans, operations for cataracts (IOLs), total knee replacement, etc
- Drugs in the top selling 300 drugs AC Nielsen
- Ayurvedic drugs, nutritional supplements, AMWAY products, etc

Therapeutic Options

- Remove irrationalities in the market like irrational FDCs
- Weeding out irrational, harmful and useless drugs
- Restricted list of drugs
- More careful introduction of new drugs especially antibiotics
- Control over promotional activities of drug cos.
- Prescription guidelines of antibiotics to be strictly enforced through professional associations
- Standard treatment guidelines ought to be constantly advocated and made available in all languages
- Running PHCs effectively in national mission mode
- Change in medical/nursing/pharmacy curriculum
- Control over promotional activities of drug cos.



Drug Price Regulation is simply necessary

because

we have promised in the Constitution

Right to Life to the People of India.

Right to Health is part of Right to Life.