Drug Pricing Case of AIDAN et al, Pharma Pricing Policy 2011

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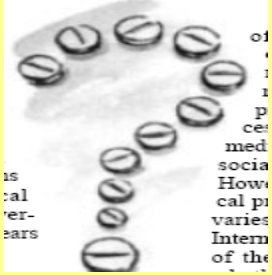

What is Wrong with India's Drug Situation? -1

- India: "Pharmacy of the World" (msf document)
- 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

- There are more than 20,000 drug formulations available in the Indian market.
- A great many are irrational and unscientific.
- Too many combination drugs
- 62 percent of top-selling 300 drugs are not in the National List of Essential Medicines!
- Poor regulation by drug authorities; corruption and inefficiency

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

- 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

What is Wrong with India's Drug Situation? –4

- Many players
- But prices of drugs have not come down
- Same drug is sold at different prices by different companies

“Competition” does not reduce prices!

- Same drug is sold at different prices by the SAME company too!
- 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

Dates

- 1975 Hathi Committee releases its report with a list of 116 essential drugs.
- 1977 WHO releases its Model List of Essential Drugs
- 1978 Alma-Ata Charter on Comprehensive Primary Health Care of which access to Essential Drugs was one of the eight components of Primary Health Care –declaration signed by 134 Governments including India.

Decreasing List of Drugs under Price Control in India

- 1979 The Drug Price Control Order (DPCO) list of drugs under price control contains 347 drugs.
- 1987 The DPCO list is pruned to 142 drugs by the Ministry of Chemicals and Fertilisers.
- 1995 The DPCO list is further pruned to 74 drugs.
- 1996 The U.O.I releases the first National Essential Drugs List.

Pharma Policy 2002 and its Discontents

- 2002 The Ministry of Chemicals and Fertilisers releases the Pharmaceutical Policy 2002 document.

- 12.11.02 Karnataka High Court makes an order in W.P. 21618 of 2002 staying the pharmaceutical policy 2002

  [on the grounds that from the list of 74 drugs found in the 1995 price control order some are likely to be omitted when the fresh list is prepared in accordance with the PP 2002.]

Pharma Policy 2002 and after

- 2003 WHO releases its " WHO Model List of Essential Medicines 2003"
- 2003 U.O.I. releases its "National List of Essential Medicines 2003". About 350 drugs in the list
- 10.3.03 SLP(C) 3668/2003 is filed by U.O.I. impugning the order of the Karnataka High Court dated 12.11.02. Notice is issued.

Our Writ Petition filed

- 1.8.03 SLPs 6652/2003 and 6638/2003 are filed by the Indian Drug Manufacturers Association and the Organisation of Pharmaceutical Producers of India respectively. Permission is granted to file SLPs. Notice is issued.

- 1.9.03 Our writ petition

- 10.3.2003: "Meanwhile, we suspend the operation of the order to the extent it directs that the Policy dated: 15.2.2002 *shall* not be implemented. However, we' direct that the petitioner *shall* consider and formulate appropriate criteria for *ensuring essential and life* saving drugs not to fall out of price, control and further directed to review drugs which are essential and life saving in nature till 2nd May, 2003."

- March 2011: Govt withdraws PP 2002 case saying new policy is coming by Oct 2011

Our Critique of Pharma Policy 2002: 1

- Most essential and useful drugs are kept out of price control.

- Non-essential and harmful drugs like analgin, phenylbutazone, Vitamin E, sulphadimidine, mebhydrolin, diosmine panthonate and panthenols, bacampicilin, etc is under price control.

- Drugs for HIV /AIDS, cancer, hypertension, coronary artery disease, multidrug resistant tuberculosis, diabetes, iron deficiency anemia, ORS, tetanus, filariasis, vaccines (new) for rabies, hepatitis B, sera for use in tetanus, diphtheria, Rh isoimmunisation, anticonvulsants and antiepileptics, diptheria, snake bite, suspected rabid dog bite/rabies, etc. fall outside price control (See boxes below).

Our Critique of Pharma Policy 2002: 2

- Price control, since it is based on market share criteria, produces only partial regulation.
- Chloroquine for malaria would be under price control but not equally important other anti-malarials
- True also for leprosy drugs and analgesics.
- Of the 300 top selling brands (as per ORG list), only 36 (that is only 12 percent) were price controlled
- The rest that is 88 percent were not

Post Petition (2003) Developments

- National List of Essential Medicines 2003 by Govt of India
- Attempts by Minister Paswan to reduce price by holding ‘talks’ with drug companies
- Sandhu Committee Report
- Pronab Sen Task Force Report – recommends all drugs be put under price control 2005
- 2005: UPA-1 Govt/Paswan comes out with new policy: recommends all drugs be put under price control. Opposed by some prominent cabinet Ministers
- PM sets GOM
- GOM holds a lot of consultations with stake holders
- UPA 2: Still no new policy
- New List of Essential Medicines 2011

SC order of Oct 11, 2011

- File reply within four weeks indicating therein as to within what time the revised list of National List of Essential Medicines (NLEM 2011) will be added in Schedule-I of the Drugs (Price Control) order, 1995.
- A comprehensive revised list of National List of Essential Medicines (NLEM) be also produced along with affidavit to be filed on behalf of the Ministry of Family & Welfare.

Our Prayers

- All essential drugs shld be under price control
- All irrational medicines should be removed
- Only rational drugs shld be marketed in India
- Free medicines for all in public sector
- Govt use CL on essential drugs under patent

Pricing Policy 2011 of Govt of India

- Draft policy released in Oct 2011 in anticipation of court directives
- Policy says all 348 drugs in NLEM 2011 will be under price control
- Delinks price of formulation from price of API (or bulk drug)
- Gives a procedure for calculating ceiling prices of drugs under price regulation using market based prices
- Attempts to control drugs outside NLEM, and combinations with NLEM under the same formula

Method of Arriving at Ceiling Price in 2011 Policy

- Ceiling Price would be fixed on the basis of Weighted Average Price (WAP) of the top three brands [para 4.7 of the draft policy]

- Dosages of essential drugs not mentioned in the NLEM 2011 to be discouraged by lowering the pro-rata (proportional) ceiling price.
- Therefore market prices of leading brands will determine ceiling prices

Some features of market based pricing

- The same drug is sold at a range of prices
- Higher priced equivalents are sold more largely because they are marketed aggressively to doctors and pharmaceutical traders by often unethical means.
- Doctors also believe higher priced drugs are of better quality
- Profits tend to be very high if you compare the cost of raw material used and the MRP (see Table 1)
- Lower priced equivalents are not easily available at retail pharmacies because of lower margins
- Market based prices have no relation to raw material used and as a result manufacturers end up making high profits

Problems with Calculating Ceiling Price using WAP for most commonly used drugs

- Brand leader is price leader in medicines that is most selling drugs tend to be the high priced ones
- WAP ceiling price will end up justifying high pricing
- As lower prices will move towards the high ceiling price
- Even now it is difficult to get cheaper equivalents of high priced drugs at retail pharmacies: in future it will be impossible
- Will also justify super-profits and the idea that higher priced drugs are of better quality
- Will lead to further impoverishment in the absence of guaranteed free quality health care by the State
- If bulk drug prices shoot up (like during Beijing Olympics), or for other genuine reasons, formulation ceiling prices will be unviable and therefore some formulations will go out of the market.

Table 1: A Comparison of Medicine Prices

Generic Name of Drug (1)	Unit (2)	Chittorgarh Tender Rate (3)	MRP Printed on pack/strip (4)	TNMSC Prices (5)	(Column 4/ Column 5) (6)
Albendazole Tab 400 mg	10 tablets	11.00	250.00	4.55	54.94
Alprazolam Tab IP 0.5 mg	10 tablets	1.40	14.00	0.51	27.45
Amlodipine Tab 2.5 mg	10 tablets	2.30	23.00	0.41	56.01
Atorvastatin Tab 10 mg	10 tablets	9.90	65.00	2.10	30.95
Cetrizine 10 mg	10 tablets	1.20	35.00	0.49	71.42
Diazepam Tab 5 mg	10 tablets	1.40	18.00	0.55	32.72

Table 2: Data on Relationship to Bulk Drug Price in relation to Price of formulations of Market Leaders

Name/Strength/Use	1. Bulk Drug Price per Kg	2. Cost of Active ingredients per 1000 Tabs	3.Total RM Cost per 1000 Tabs	4. Mfg Cost	5. Total Cost per unit	6. Price of Market Leaders per unit	7. Market Leader's Price/ Total Cost per Unit (as percent)
Albendazole Tabs 400 mg Anti-hookworm	1260	504	564.17	282.38	0.85	17 (Glaxo)	2000
Amlodipine Tabs 5mg Anti-hypertensive, anti-anginal	2982	21	34.98	58.27	0.10	2.45 (Cipla)	2450
Amoxy 500 Caps Antibiotic	1583	931	1017.71	272.23	1.30	8.00 (Ranbaxy)	615
Atenolol Tabs 50 mg Anti-hypertensive, anti-anginal	1173	59	67.64	79.59	0.15	2.85 (Nicholas Piramal)	1900
Cephalexin Caps 250 mg Antibiotic	2791	698	841.53	361.71	1.20	7.00 (GSK)	583
Cephalexin Caps 500 mg Antibiotic	2791	1396	1612.83	370.12	1.99	13.00 (GSK)	653
Cetrizine Tablets 10 mg Antiallergic	3510	35	44.65	68.45	0.12	3.10 (Cipla)	2583
Diazepam Tabs 5 mg Sedative	2850	14	20.69	85.89	0.11	2.20 (Ranbaxy)	2000
Enalapril Maleate Tabs 5 mg Congestive Cardac Failure, hypertension	5954	30	48.69	66.89	0.12	3.00 (Cadilla)	2500
Fluconazole Caps 150mg Candidasis, opportunistic infections in AIDS	5836	884	978.33	265.55	1.25	34.51 (Cipla)	2760
Fluoxetine capsules 20 mg Depression, psychiatric problems	2496	57	180.59	280.38	0.47	4.00 (Cadilla)	851
Glibenclamide Tabs 5mg Anti-diabetic	2341	12	19.10	73.25	0.10	0.90 (Aventis)	900
Metformin HCl Tabs 500mg Anti-diabetic	218	109	125.83	142.92	0.27	1.00	370
Paracetamol Tabs Pain, fever	227	113	123.96	152.98	0.28	1.80 (Crocin)	642
Pyrazinamide Tabs. 750 mg TB	966	743	752.28	248.38	1.00	6.30 (Lupin)	630

Example of Weighted Average Ceiling Price Calculation

- Eg: Paracetamol 3 top brands sell at (per strip of 10 tablets):
  - Rs 20 (60 % market share)
  - Rs 18 (25 % market share)
  - Rs 15 (15 % market share)
- Ceiling price (weighted for market share) will be
  - Rs 20 x 0.60 + 18 x 0.25 + 15 x 0.15 = Rs 18.75
  - The actual price of generic generic is Rs 2 per 10

In effect

- This is not price control
- But effectively decontrol by allowing high prices to remain
- With slight decrease of the price of the top brand
- Therefore a sleight of hand and a bit of fraud on ordinary people
- **Question: if the govt was serious, why not take the weighted average price of the 3 cheapest brands?**

Draft Policy's Exemptions from Price Regulation: Unjustified

- For drugs which are part of Hospital Supply as maintained by M/o Health and Family Welfare;
- For drugs which are part of Public Health Products as maintained by M/o Health and Family Welfare
- *This will encourage the corruption which is at present rampant in drug procurement. (Legitimises not going for lowest tender when that shld be the logical option).*
- Exemption for Drugs having weighted average price less than or equal to Rs3/-
- *Many low-priced drugs will move towards the Rs 3/- level – and it gives leeway to drugs that cost much less to produce [for example cetrizine (0.15) or iron folic acid (0.06)]*

Other major reasons for poor access to the right medicine at affordable prices

- Aggressive Drug Promotion by drug companies
- Inducements to doctors
- Over/under prescribing by doctors
- Cut Practice

Why formulation ceiling prices should not be delinked from bulk drug prices?

- Gives no idea of how much profits are being made
- MRP to raw material ratio is about 2000 % to 3000 % for many formulations (see Tables)
- In the absence of such knowledge, high prices become the normative state of affairs.
- Patient is the one who suffers in the process.
- Contradiction is clearly exposed when you compare prices of efficient government procurement agencies and market based prices. (See Table 1)

Why bulk drug prices should not be left to the market completely?

- Likelihood of cartelization
- In some vital drugs (like anti-TB Rifampicin) only 2-3 major manufacturers are present
- Government has no recourse if bulk drug prices shoot up without reason (or with reason).
- Only deterrent to very high pricing is availability of cheaper imports from China
- But that option is not available to smaller manufacturers for all drugs
- So they will have to rely on higher priced local manufacturers of bulk drugs
- This will render smaller manufacturers of formulations uncompetitive
- Eventual shakeout of the market will leave only bigger players
- This is not good for the country and endangers ability of government to procure drugs efficiently and at the lowest prices
- Also fewer players means production technology gets mystified and government itself has less ability to "call the bluff" when it needs to of bigger players. This is already happening to some extent in vaccines and biotech drugs.

So what is a better pricing policy?

- That will be one that brings down the prices of overpriced drugs and not increase it
- That has some linkage to the actual cost of production
- And therefore to the cost of the raw material, and
- Does not legitimize overpricing of drugs.
- Does not nominally reduce the price of the top-selling brands and expects prices to fall.

Our Suggestions for a Pricing Policy that brings down Prices

- Take as reference price the prices of well-run public procurement systems. The government says it is difficult to get cost data. Let us assume then that the selling price to the TNMSC is the cost price.
- Take a multiple, say 5, of the reference price as the ceiling price.
- Or follow the successful example of Bangladesh – operational since 1982: ceiling price would be 100-125% more than the cost of the bulk drug content in the formulation. In India's case it could be 5-6 times the cost of the bulk drug content.
- Bulk drug price monitoring is simpler – lesser number than formulations per se.