Issues in Availability, Affordability and Efficacy of Generic Drugs in India

Two Day Workshop on Innovative Practices
ATI, MP, Sep 24, 2014

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Acknowledgments

- Some slides and data are courtesy Dr Samit Sharma, IAS, Rajasthan and Dr Sakthivel Selvaraj, PHFI, New Delhi
Why Medicines are a unique commodity

- Purchase or non-purchase based on price may mean the choice between life and death.
- The need for medicines is immediate and involuntary.
- Decision as to purchase is made by doctors and pharma companies.
- Medicines therefore need to be available, affordable and accessible.
Why market cannot decide medicine prices in India?

• Pharma markets do not work generally – in favour of the consumer

• Because of asymmetry, no real decision making power of buyer, etc.

• 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
“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 (except in the initial stages of generic introduction).

- In fact more players seems to result in a range of prices.
India’s Pharma Industry

• Total Sale Rs 73,000 cr within India (Mar 2013 IMS)

• Out of which Rs 13000-14000 cr is under price control.

• Exports Rs 70,000 cr

• Unbranded generics : Rs 7000 cr

• 3rd largest by volume, 13th by value

• “Pharmacy of the developing world”
India: Poverty Amidst Plenty?

- Medicines are overpriced and unaffordable in India.
- Medicines constitute 50 to 80 percent of health care costs in India.
- Health care is the second-most leading cause of rural indebtedness, after dowry.
- No universal health insurance in India.
- Crumbling public health system,
- the first choice of patients is a private practitioner which means more out of pocket expenditures apart for loss of wages etc.
- In Tamil Nadu 70% of inpatients go to pvt sector.
FDCs and Irrational Medicines

• Nowhere in the world there are 100,000 brands (of generics)
• A study by LOCOST (2012) says 50% of the top-selling 300 medicines (IMS 2009) are not in the National List of Essential Medicines, 2011.
• Many unnecessary drugs including medicines of uncertain efficacy, safety, such as ginseng, liver extract, Vitamin E, and nimesulide; irrational combinations of antibiotics, which lack therapeutic justification;
• Many irrational FDCs - only 65% of the top selling 300 are rational (LOCOST 2012)
• Need for clear criteria for weeding out irrational and useless medicines
Some other 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
“MCI corrupt, clinical trials body a snake pit”: Harsh Vardhan
Indian Express | New Delhi | July 18, 2014

• “As a doctor and former health minister, I am more aware than anybody else of the corruption that is eating into the entrails of every aspect of governance, including the health system. Within days of assuming office I had remarked that the Medical Council of India is a corrupt organisation...

There is corruption in the approval of drugs. The Central Drugs Standard Controls Organisation, which is supposed to oversee clinical trials, is another snake pit of vested interests.”
“Corruption ruins the doctor-patient relationship in India”
David Berger in *BMJ* 2014; 348 (Published 08 May 2014)

- “Kickbacks and bribes oil every part of the country’s healthcare machinery, writes David Berger. If India’s authorities cannot make improvements, international agencies should act.”
- “Lack of trust in doctors, and the costs associated with going to see them, mean many patients rely on pharmacists, who seem to have a similar lack of ethics, selling inappropriate drugs over the counter at exorbitant prices to people who often have to borrow the money to pay for them.”
- “Many Indian doctors have huge expertise, and many are honourable and treat their patients well, but as a group, doctors have a poor reputation. Until the profession is prepared to tackle this head-on and acknowledge the corrosive effects of its corruption then the doctor-patient relationship will continue to lie in tatters.”
“Corruption: medicine’s dirty open secret”
BMJ 2014; 348 (Published 25 June 2014)
Anita Jain, India editor, Samiran Nundy, dean, Kamran Abbasi, international editor

• “The United States ... lost between $82bn and $272bn in 2011 to medical embezzlement, mostly related to its health insurance system.”

• “Patients everywhere are harmed when money is diverted to doctors’ pockets and away from priority services. “

• “Yet this complex challenge is one that medical professionals have failed to deal with, either by choosing to enrich themselves, turning a blind eye, or considering it too difficult.
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
India’s Pharma Industry

• Total Sale Rs 80,000 cr within India (June 2014, Pharma Trac)
• Out of which Rs 13000-14000 cr is under price control (15 %)
• Exports Rs 80,000 cr
• Unbranded generics : Rs 7000 cr
• 3rd in (10% in global sales) terms of volume and 14th (1.5%) in terms of value.
• “Pharmacy of the developing world”
• It is among the top Five producers of bulk drugs in the world
• After USA (169), India has the highest number of ANDA approved (132) plants in US in the year 2007
Indian pharmaceutical market

• Nominal rate of growth in 2012: 11%.

• If we take out inflation real growth rate was 7%.

• The total number of brands in the pharma market in India in 2012 was 62345.

• The brands launched after 2005, had a combined market share of 30% in 2012.
Breakup by brands, patented etc

• India’s domestic drug market: Rs 75 000 cr

• Branded generics dominate, representing 70 to 80% of the generic drug market.

• Generic Generics: Rs 7000 cr

• Patented drugs make up approximately 8% of total market sales in India: Rs 6000 cr

• 90 percent of Indian drugs mkt is out of patent
DPCO 2013

- All 348 drugs in NLEM 2011 under price control
- Ceiling price: simple avg price of prices of brands with more than 1 % mkt share
- Touches 18 % of the mkt of Rs 72000 crores.
- Leaves most FDCS and other formulations untouched
- Escape hatches: combinations, non-standard dosages
- Most ceiling prices are still in the range of 200 to 4700 % margin
## Breakup of Sales: Combinations vs Plain

<table>
<thead>
<tr>
<th>Total Sales</th>
<th>Combinations</th>
<th>Plain</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covered under NLEM 2011/DPCO 2013</td>
<td>Rs 1,900 cr</td>
<td>Rs 11,197 cr</td>
<td>Rs 13,097 cr (18 %)</td>
</tr>
<tr>
<td>Not covered under NLEM 2011/DPCO 2013</td>
<td>Rs 31,866 cr</td>
<td>Rs 26,283 cr</td>
<td>Rs 58,149 cr (82 %)</td>
</tr>
<tr>
<td>Total</td>
<td>Rs 33,766 cr (47 %)</td>
<td>Rs 37,480 cr (53 %)</td>
<td>Rs 71,246 cr</td>
</tr>
</tbody>
</table>

Source: IMS TSA Dec 12 MAT, as per affidavit filed by DOP in SC, Nov 2013
Ceiling Price Mechanism: Mkt Based Pricing (MBP)

- Simple average of the brands with one percent market share
- Applies to specified 348 drugs and their 600+ dosages in the NLEM 2011.
- Drugs outside the NLEM are not in price control.
## Illusion of Price Control

*Prices in Rupees per 10 tabs*

Source: LOCOST, NPPA and DOP

<table>
<thead>
<tr>
<th>Name of Drug</th>
<th>LOCOST Generic Price July 2014</th>
<th>Ceiling Price After April 2014</th>
<th>Use of Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Albendazole 400 mg tabs</td>
<td>14.50</td>
<td>Rs 97</td>
<td>Against worms</td>
</tr>
<tr>
<td>2. Cetrizine 10 mg tabs</td>
<td>2.15</td>
<td>19.20</td>
<td>Anti Allergic</td>
</tr>
<tr>
<td>3. Atorvastatin 10 mg tabs</td>
<td>9.25</td>
<td>62.80</td>
<td>Cholesterol lowering agent</td>
</tr>
<tr>
<td>4. Flucanozole 150 mg caps</td>
<td>29</td>
<td>251</td>
<td>Antifungal</td>
</tr>
<tr>
<td>5. Fluoxetine 20 mg caps</td>
<td>9</td>
<td>36.90</td>
<td>Anti depressant</td>
</tr>
<tr>
<td>6. Enalapril maleate 5 mg tabs</td>
<td>4.25</td>
<td>31.50</td>
<td>Anti hypertensive</td>
</tr>
</tbody>
</table>
## Paracetamol Market

<table>
<thead>
<tr>
<th></th>
<th>MAT Oct 12</th>
<th>%</th>
<th>No. of Formulations</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Single Ingredient</td>
<td>527.73 cr</td>
<td>20.52%</td>
<td>358</td>
<td>11.65%</td>
</tr>
<tr>
<td>Paracetamol 500 mg</td>
<td>128 cr</td>
<td>4.9%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combinations</td>
<td>2043.49 cr</td>
<td>79.48%</td>
<td>2714</td>
<td>88.35%</td>
</tr>
<tr>
<td>Total</td>
<td>2571.22 cr</td>
<td></td>
<td>3072</td>
<td></td>
</tr>
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</table>
Percent of Sales of Drug Categories not Covered by DPCO 2013

- Over all: 82%
- antidiabetics (86%);
- antimalarial (88%);
- anti-infectives (63%);
- anti-TB (81%);
- blood related (99%);
- cardiac (71%);
- derma (90%);
- gastrointestinal (85%);
- gynaec (86%);
- hepatoprotecives (100%);
- HIV related (73%);
- hormones (56%);
- neuro/CNS (82%);
- opthal/otologicals (94%);
- sex stimulants/rejuvenators (99%);
- pain/analgesics (90%);
- respiratory (94%);
- stomatologicals (100%);
- vitamins/minerals/nutrients (99%);
- vaccines (68%)
Market “Shrinkage” due to DPCO 2013

• Sales of 2073 brands, of some 250 NLEM drugs in 370 dosages: Rs 11234 cr sales
• No of brands that would actually have their sales shrunk – at constant volumes: 978 brands (with sales of Rs 6492 cr)
• Actual Shrinkage: Rs 1281 cr.
• Actual loss to companies: a fraction of that
Price Control of More Drugs on July 10, 2014 by Govt and Sep 15, 2014

- This puts the important antidiabetics and some cardiovasculars under price control
- A bold move by govt using Para 19 of the DPCO 2013
- Industry has protested
- But govt will probably put left out medicines of more therapeutic categories under price control
Para 19 of DPCO 2013

• Gives Powers to Govt to impose price control on any drug if the situation so demands

• “Fixation of ceiling price of a drug under certain circumstances.- Notwithstanding anything contained in this order, the Government may, in case of extra-ordinary circumstances, if it considers necessary so to do in public interest, fix the ceiling price or retail price of any Drug for such period ......:
Generic = Brand?
Clinical Equivalence of Generic and Brand-Name Drugs Used in Cardiovascular Disease: A Systematic Review and Meta-analysis

Aaron S. Kesselheim, MD, JD, MPH, Alexander S. Misono, BA, Joy L. Lee, BA, Margaret R. Stedman, MPH, M. Alan Brookhart, PhD, Niteesh K. Choudhry, MD, PhD, and William H. Shrank, MD, MSHS
Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women’s Hospital, Harvard Medical School, Boston, Massachusetts.

Abstract

Context—Use of generic drugs, which are bioequivalent to brand-name drugs, can help contain prescription drug spending. However, there is concern among patients and physicians that brand-name drugs may be clinically superior to generic drugs.

Objectives—To summarize clinical evidence comparing generic and brand-name drugs used in cardiovascular disease and to assess the perspectives of editorialists on this issue.

Data Sources—Systematic searches of peer-reviewed publications in MEDLINE, EMBASE, and International Pharmaceutical Abstracts from January 1984 to August 2008.

Study Selection—Studies compared generic and brand-name cardiovascular drugs using clinical efficacy and safety end points. We separately identified editorials addressing generic substitution.

Data Extraction—We extracted variables related to the study design, setting, participants, clinical end points, and funding. Methodological quality of the trials was assessed by Jadad and Newcastle-Ottawa scores, and a meta-analysis was performed to determine an aggregate effect size. For editorials, we categorized authors’ positions on generic substitution as negative, positive, or neutral.

Results—We identified 47 articles covering 9 subclasses of cardiovascular medications, of which 38 (81%) were randomized controlled trials (RCTs). Clinical equivalence was noted in 7 of 7 RCTs (100%) of β-blockers, 10 of 11 RCTs (91%) of diuretics, 5 of 7 RCTs (71%) of calcium channel
Equivalence of Generic Drugs and Brand Name Drugs

• The study evaluated the results of 38 published clinical trials that compared cardiovascular generic drugs to their brand name counterparts

• and no evidence was found that branded cardiac drugs worked any better than generic heart drugs

Source: Kesselheim et al. Clinical equivalence of generic and brand name drugs used in cardiovascular disease: a systematic review and meta-analysis. JAMA. 2008;300(21)2514-2526
Generic and Innovator Drugs

Comparing generic and innovator drugs: a review of 12 years of bioequivalence data from the United States Food and Drug Administration.


• CONCLUSIONS

• The criteria used to evaluate generic drug bioequivalence studies support the FDA's objective of approving generic drug formulations that are therapeutically equivalent to their innovator counterparts.

• The average difference in pharmacodynamics between generic and brand-name products was about 4%; in nearly 98% of the studies reviewed, the properties of generic products differed from those of the brand-name product by less than 10%.”
Generic Drugs: Problems

• Quality
• Bioequivalence/bioavailability issues
• At present Bioequivalence of generics is only a problem of some 40 medicines like warfarin, digoxin, carbamezipine.
• In general in vitro BA tests (like dissolution) plus compliance with IP parameters is considered good enough.
Bioequivalence Curves

- **150 mg bupropion** (x-release, Impax Labs, "Budeprion XL")
- **150 mg bupropion** (x-release, Biovail, "Wellbutrin XL")

Graph showing mean plasma concentration (ng/mL) over time (hours) for two different formulations of 150 mg bupropion.
When Bioequivalence Study is Required

• Drug indicated for Serious disease requiring assured therapeutic response
• Drug having narrow therapeutic index
• Drug with Non-Linear Pharmacokinetics.
• Documented Evidence of BA problems
• Unfavorable Physicochemical Properties
  – BCS (Biopharmaceutics Classification System) Classification
    BCS-1:- High Solubility and high permeability
    BCS-2:- Low Solubility and high permeability
    BCS-3:- High Solubility and low Permeability
    BCS-4:- Low Solubility and Low Permeability

Bioequivalence study not required for drug falling under BCS-1, 3
Unbranded Generic Name Drugs are Cheaper than Branded Drugs

• Cheaper does not mean lower quality.

• Generic manufacturers are able to sell their products for lower prices because they are not required to pay for costly advertising, marketing, and promotion.

• In addition, multiple generic generic companies are often approved to market a single product; this creates competition in the market place, often resulting in lower prices.
Case Studies

• Public Health System:
  – Govts of Tamil Nadu, Kerala, Rajasthan, Gujarat
  – Jan Aushadhi, Jeevandhara Scheme

• Not for profit sector:
  – LOCOST, Vadodara
  – CMSI, Chennai
Some features of TNMSC
Tamil Nadu Medical Services Corporation

• 260 drugs in its EDL (2011-12)
• Surgicals 75 items, sutures 113 items
• 21 fast moving drugs account for 80 % of procurement budget
• ‘Speciality” drugs 292 (2010-11) - 10 drugs account for 85.6 %
• One drug – Temozolamide caps - 52 %
• CAT scan and X Ray centres
• 21 % of popln utilization in 2001-02 (currently 40 %)
• Services top to bottom level of care
• Drugs are free

(Source partly: Maulin R.Chokshi. TN Drug Procurement Model, Nov 2008, WHO-SEARO)
TNMSC: Scan Centers

- At present 45 nos. of single slice CT scan centers in the Government Hospitals all over the State (min. 1 CT scanner in each dist.) and 4 slice CT scanners one each at Govt. General Hospital, Chennai, ICH & Govt. Hospital for Children, Chennai are in operation.

- **45 scan centers**

<table>
<thead>
<tr>
<th>Category</th>
<th>Plain</th>
<th>With Contrast</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatients</td>
<td>Rs. 350/-</td>
<td>Rs. 550/-</td>
</tr>
<tr>
<td>Outpatients</td>
<td>Rs. 500/-</td>
<td>Rs. 700/-</td>
</tr>
</tbody>
</table>
TNMSC: Other Supportive Services

- MRI scan centers in 9 govt hospitals: Rs 2500 (plain); Contrast: Rs 1500 extra
- Lithotripsy
- Regional diagnostic centers
- Lab Services
25 warehouses
Inside Warehouse at Sivagangai
STORAGE

34 District Drug Warehouses for proper storage.
QUALITY ASSURANCE

• All drugs received are stored in quarantine area.
• Sample are sent to QC cell at RMSC head office.
• Samples are coded & sent to empanelled labs.
• Examination of samples is carried out as per pharmacopeias.
• If sample is found “as of standard quality” then only drugs are issued to hospitals.
A positive side effect!
Generics advertised by pvt pharmacists!
Manufacturer is Cipla for all the three brands. One branded & Two generic.

To search low cost branded drugs, please visit: www.rmsc.nic.in, www.rmsc.co.in or www.tnmsc.com
# ILLUSION OF PRICE CONTROL

The profit margins, even post May 2013 price control under the new DPCO are anywhere between 100 to 4000 percent.

<table>
<thead>
<tr>
<th>Disease</th>
<th>Drug &amp; Pack form</th>
<th>Ceiling price (as per DPCO 2013) (Rs.)</th>
<th>Ceiling price (as per DPCO 1995) (Rs.)</th>
<th>RMSC Tender price. (Rs.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antihypertensive</td>
<td>Atenolol 50 mg (14 tabs)</td>
<td>30.80</td>
<td>3.5</td>
<td>1.75</td>
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<tr>
<td></td>
<td>Amlodipine 5 mg (10 tabs)</td>
<td>30.10</td>
<td>1.77</td>
<td>0.82</td>
</tr>
<tr>
<td></td>
<td>Enalapril Maleate 5 mg (10 tabs)</td>
<td>31.50</td>
<td>2.4</td>
<td>1.27</td>
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<tr>
<td>Antiemetic</td>
<td>Domperidone 10 mg (10 tabs)</td>
<td>24</td>
<td>2.5</td>
<td>1.21</td>
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<tr>
<td>Antidiabetic</td>
<td>Glibenclamide 5 mg (10 tabs)</td>
<td>10.2</td>
<td>1.42</td>
<td>0.84</td>
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<tr>
<td>Antiallergic</td>
<td>Cetirizine 10 mg (10 tabs)</td>
<td>19.2</td>
<td>2</td>
<td>0.77</td>
</tr>
<tr>
<td>Cholesterol lowering drug</td>
<td>Atorvastatin 10 mg (10 tabs)</td>
<td>62.8</td>
<td>5.6</td>
<td>2.61</td>
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<tr>
<td>S.No.</td>
<td>Name of manufacturer participated in tender</td>
<td>Price quoted (Rs)</td>
<td></td>
<td></td>
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<tr>
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<td>------------------------------------------------------------------</td>
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<tr>
<td>1</td>
<td>Preet Remedies</td>
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<td>Biogenetic Drugs Pvt Ltd</td>
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<td>3</td>
<td>Samson Laboratories Private Limited</td>
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<td>4</td>
<td>Arion healthcare</td>
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<td>Zee Laboratories</td>
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<td>WINGS PHARMAcEUTICALS PVT. LTD.</td>
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<td>8</td>
<td>Lark Laboratories (India) Ltd.</td>
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<td>ARBRO PHARMACEUTICALS LTD</td>
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<td>Zim Laboratories Ltd</td>
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<td>11</td>
<td>Medicamen Biotech Limited</td>
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<td>12</td>
<td>Innova Captab</td>
<td>12.18</td>
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<td>13</td>
<td>Next Wave (India)</td>
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<td>14</td>
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<td>15</td>
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<td>17</td>
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<td>18</td>
<td>MORACEAE PHARMAcEUTICALS (P) LTD</td>
<td>15.56</td>
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<tr>
<td>19</td>
<td>MAXTAR BIO-GENICS</td>
<td>15.73</td>
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<td>20</td>
<td>Stallion Laboratories P. Ltd.</td>
<td>16.25</td>
<td></td>
<td></td>
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<tr>
<td>21</td>
<td>MICRON PHARMAcEUTICALS</td>
<td>27.54</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RMSC Price Rs 7.7  
DPCO Ceiling Price: Rs 192 (for 10x10 Tab)  
Prices (MRP) of Brands available in the Market:  
Cetzine Rs 201.6, Alerid 190.1, Zyncet 190.1, Zyrtec Rs 190
Necessities For

MAKING MEDICINES AFFORDABLE

• Generic prescribing
• Adoption of essential drugs list
• Standard Treatment Guidelines
• Centralized drug procurement: open tender system
• Distribution of Low cost drugs through Govt. drug counters
• Public awareness and demand generation
How much does medicines for all cost?

• Rs 300 crores TNMSC medicine budget per year approx

• Under assumptions of about 30 percent of those ill using public health services

• It costs around Rs 1000 cr max for free medicines for all – pvt and public sector in TN

• For all of India’s 128 cr population this will be Rs 18000 cr for free medicines for all

• Assumption is that these are at TNMSC prices which are very low: 3 to 40 times cheaper than market prices
What can make a free medicine scheme fail?

• If govt/bureaucrats/doctors don’t prescribe or don’t support it
• Quality problems
• Procurement and stock problems
• Logistics
• Storage
• If people do not get the right medicine they need at the right time and the right dosage.
बिना जांच किए बांट दी 28 करोड़ की दवाइयां

प्रदेश के सरकारी अधिकारी ने गोलीयों की आपसी बात को मल्टीप्ले से निर्लक्षित किया है।

दवाइयों के अनुसार सूची की बात तरीका तरीका नहीं गई थी।

दिल्ली के नर्मदा ब्रांडर बने केबीसी के पहले ‘महाकरोड़ीपति’
सीएचएमओ ने अस्पतालों में बांट दीं 29 करोड़ की अमानक दवाएं

अधिकारी कॉलेक्टर रामपुर कार्यालय की मुखिया संभाल के प्रेरणे में
Health dept asked to explain use of drugs without tests in hospitals

Principal accountant general says provisions of policy not followed in medicine purchase

**LETTER**

Nirmal Bansal

The Principal Accountant General (PAG), in a recent report, has expressed concern over the non-compliance of provisions of the drug policy at Bhopal Medical Service Corporation (BMSC), which has resulted in financial losses to the institution. The PAG has directed the BMSC to ensure that the policy is followed strictly to avoid such losses in future.

**WHAT THE HEALTH DEPARTMENT SAYS**

The health department has issued a notification that no drug should be purchased without prior approval from the department. The drugs must be tested before being supplied to hospitals. The notification also mentions that irregularities in the supply of drugs have caused financial losses to the department.

**REGULARITIES RESULTED IN FINANCIAL BENEFITS TO FIRMS AS NEITHER THE COST OF MEDICINE WAS RECOVERED NOR THEY WERE BLACKLISTED**

The PAG has highlighted the need for strict adherence to the drug policy to avoid financial losses. The BMSC has been directed to ensure that all drugs are tested before being supplied to hospitals.

Medical Service Corporation (BMSC) and other government hospitals have been directed to ensure that all drugs are tested before supply to avoid financial losses.
विभाग में हो रही न्यायालय के आदेश की अवमानना
रक्षितार कर आपातको किया पदोन्नत

हेली की जा रही अवमानना
इस दौरान हो सकता है न्यायालय द्वारा लिखित अवमाननाओं की पर आवश्यकता होने के बावजूद इसकी ऑफिस द्वारा पहले किया गया है। न्यायालय द्वारा इस दौरान हो सकता है अवमानना का अनुरोध किया गया है।

सत्संग पर सर्कोड़ा
टेरेक्स सॉग सिर्प टूज़
What are the Barriers to Access to Medicines in Public Health Systems

• None except in the mind

• Failure of imagination

• In this case it does not even take much imagination

• As the homework has already been done in 2-3 states of India

• Resistance from pharma and medical lobbies need to be negotiated
Emerging trends

• Takeover of Indian companies
• Tying up of major India pharma companies with big pharma through medicines patent pool, voluntary licensing, contract manufacturing or part ownership thru brownfield route.
• Cipla’s marketing arrangement with Merck
• There will not be any Indian co.s to implement the CLs if awarded.
• Reluctance in GOI to use CL provisions
Systemic Changes Required in the Run Up to Medicines for all (say by 2020)

• Right to medicine and health needs to be legislated as a fundamental human right.

• All essential drugs shld be under price control

• All irrational medicines should be removed

• Only rational drugs shld be marketed/approved in India

• Govt use CL on essential drugs under patent

• Easy takeover of Indian Pharma companies should be stopped
A Strategy for the Future

• Increase seeding of new entrepreneurs in pharma as the old ones are getting co-opted by big pharma

• Govt capability of manufacture/working the CLs as in Thailand

• Strengthening of MSMEs so as to supply to the govt sector for medicines for all

  *estimated at Rs 18000 cr at TNMSC prices

• Battling US/USITC pressures at the WTO Dispute Settlement Body

• No TRIPS Plus measures in bilateral FTA clauses

• No arbitration clauses in agreements with private companies

• No treatment of markets and IP as “investment”
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