Medicine Pricing and Universal Access to Treatment

Fact Sheet

Prayas & Jan Swasthya Abhiyan

प्रयास Prayas

www.prayaschittor.org

Jan Swasthya Abhiyan

People's Health Movement - India

Frequently Asked Questions

Introduction:

Healthcare expenditure is the second greatest cause of rural indebtedness in India today. As of 2008, 72% of total healthcare expenditure was privately funded, 89.5% of which was paid out of pocket by patients[i]. Between 1999-2000, 32.5 million patients fell below the poverty line after just a single hospitalization[ii]. 40% of those hospitalized are forced to borrow money or sell assets to meet costs[iii], and 23% of ill patients simply never seek treatment because of their inability to pay. WHO estimates that 65% of India's population lacks regular access to essential medicines[iv].

The cost of medicines is one of the largest factors contributing to this breach of human dignity. Medicines account for 70% of out-of-pocket expenditure[v]. Even if patients are able to receive a free check-up at a government clinic, they are often forced to pay out-of-pocket for the actual medicines prescribed for their illness. Medicines purchased by patients from the local chemist can be between 2 to 40 times more expensive than the bulk prices offered to retailers, private hospitals, nursing homes and government agencies. This fact sheet seeks to address some major determinants of medicine pricing, and suggests ways that India can provide truly free treatment to all its citizens.

What is meant by the terms "brand-name" and "generic" version of a medicine?

When a new medicine is first researched, the company or institution can apply for a patent, which gives it the legal right to "own" the chemical for a period of 20 years. The institution can then further develop the medicine until it is fit for use in humans, and be the sole producer and seller of the medicine for the remainder of the 20 year patent period. During this period, the company will market the medicine under its own "brand-name". When the patent period expires, other companies are allowed to produce their own "generic" version of the medicine. A generic is therefore a medicine out of patent. Generic medicines can be referred to as "generic generics" when marketed under an agreed international name – a name that is not 'owned' by anybody. Generics marketed under their own name can be called a "branded generic".

What is an INN name?

An **International Nonproprietary Name** (**INN**) is the official non-proprietary (not "owned" like a brand name) name given to

a pharmaceutical substance, as designated by the World Health Organization. The plethora of named proprietary preparations containing a given substance can lead to confusion about the identity of the active ingredient. INNs facilitate communication by providing a standard name for each substance. A similar role is played in chemistry by IUPAC names. However, these are less suited to common usage, being typically very long and unwieldy.

For example, the full chemical name of Paracetamol (or Acetaminophen) is *N*-**a**cetyl-**p**ara-**a**mino**p**henol. Paracetamol is the generic or International Nonproprietary Name (INN) name, while Crocin, Tylenol, etc. are some leading brand names, or proprietary trade names. As paracetamol is out of patent, different manufacturers make it and market paracetamol under different brand (that is, proprietary trade) names. Another example is of frusemide ($C_{12}H_{11}C_1N_2O_5S$), its chemical name is 4-chloro-N-furfuryl-S-sulphamoylanthranilic acid, its INN is furosemide, and a brand (or proprietary trade) name is Lasix.

Non-proprietary names are intended for use in pharmacopoeias, labeling, product information, advertising and other promotional material, drug regulation and scientific literature, and as a basis for product names, e.g. for generics (see definition of generics and discussion below).

Is there any therapeutic difference between a patented drug and its generic version? Is there any difference in a drug sold under its original brand name, under an INN name, or even under a chemical name? Are they different versions of the same medicine? Is either type superior to the other in treatment?

No, all versions of the medication, branded or generic, contain the same active ingredients. In fact, the first generic company to sell a medicine has to prove that its version is "bio-equivalent", or acts the same way in the human body. Therefore, no version of medicine is better than another for treatment.

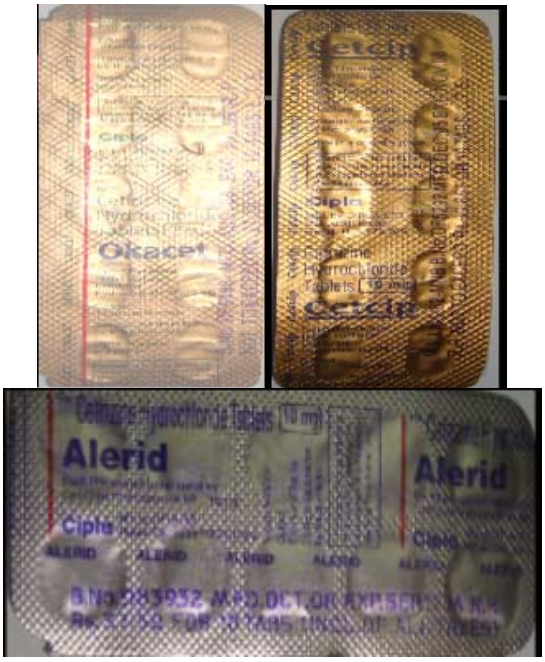
Why do different versions of the same medicine have different prices?

Because the original brand-name company is allowed to be the only seller of the medicine for the 20-year patent period, it can sell at high prices, as patients will have no alternatives to choose. The introduction of secondary "generic" companies after 20 years gives patients more choices. These companies then have to compete to be chosen, and lower their prices to attract customers. While the original brand-name medicine may also reduce in price, it

usually does not reach the level of the "generic" prices, because the company can advertise the reputation and trust placed in its original version. Also, for medicine that is available only by prescription, the original supplier can continue to pressure doctors to prescribe the medicine they have been prescribing for years.

For example, there is a blood cancer medicine, imatinib besylate. The Swiss pharmaceuticals company Novartis was the original patent-holding developer of the medicine, and sells it under the brand-name *Glivec* at Rs. 1,14,000 for 120 capsules. Two companies, Natco and Cipla, produce generic versions of imatinib besylate at Rs. 10,800 and Rs. 10,200, respectively. These are branded generics, as they sell under the names *Veenat* and *Imatinib-alpha*, respectively. Interestingly, Cipla supplies to Indian railways in just Rs. 6500 only![vi]

Generic medicine prices are also sometimes "positioned" for different population groups or market segments, based on what these groups are perceived to be able to afford. If a certain group has higher purchasing power, or insurance, the company may "tap" this market by higher pricing for that group. They may also sell at an intermediate price to groups with moderate purchasing power. For example, Cipla makes three "branded generic" versions of 10 mg cetrizine: Okacet, Cetcip, and Alerid.



For 10 pills packaged in strips, Cipla sells these for Rs. 27.50, Rs. 33.65, and Rs. 37.50, respectively. Interestingly, the same drug is available in government supply at Rs. 1.20 for 10 tablets! This phenomenon is explored further below.[vii]

As these reasons for price differences have nothing to do with quality or therapeutic value, we promote the prescription and use of the most affordable options.

Is there any reason that doctors tend to favor prescribing brand-name or generic medicine? Can a patient influence the doctor's choice?

There is no scientific reason that doctors should prefer an expensive brand-name medicine to cheaper versions, as they act in the same exact way in the human body. However, because the factors behind pricing are complex and poorly understood, doctors tend to equate high price with higher quality, and prescribe the costlier versions. Doctors are also subject to advertising pressure from companies that produce the expensive versions, which influences their prescriptions. If a patient wants to save money, they should ask their doctor to prescribe the least expensive version of the needed medicine.

If a patient wants to buy a generic version of a medicine at the chemist, how can he or she tell the difference?

As mentioned before, choosing a "generic" medicine is complicated because many branded generics add their own names to their medicines. It is therefore advisable to choose based on price, and not be fooled by warnings that the more expensive medicines are more effective. As discussed above, the determinants of medicine pricing are many and have little to do with therapeutic value. All versions should work equally as well in treatment. Unfortunately, it is not guaranteed that a local chemist will always carry low-cost versions of medicine. They tend to stock only those medicines that doctors frequently prescribe, and these are often the costlier brands.

Are there differences in the prices sold to government, private retailers, and patients?

The bulk procurement prices sold to governments and retailers are very different than the Maximum Retail Price (MRP) sold to patients, even for generic medication. This table shows some of these differences for generic drugs purchased in Chittorgarh through open tender:

Frequently Asked Questions

Generic Name of Drug	Chittorgarh Tender Rate* (Rs.)	Unit	MRP Printed on pack / strip (Rs.)
Albendazole Tab IP 400 mg	11.00	10 tablets	250.00
Alprazolam Tab IP 0.5 mg	1.40	10 tablets	14.00
Arteether 2 ml Inj	9.39	1 Injection	99.00
Amlodipine Tab 5 mg	2.50	10 tablets	22.00
Cetrizine 10 mg	1.20	10 tablets	35.00
Ceftazidime 1000 mg	52.00	1 Injection	370.00
Atorvastatin Tab 20 mg	18.10	10 tablets	170.00
Diclofenac Tab IP 50mg	2.20	10 tablets	25.00
Diazepam Tab IP 5 mg	1.90	10 tablets	29.40
Amikacin 500 mg	6.95	1 Injection	70.00

Chittaurgarh Generic Medicine Cooperative Departments Shop

Thus the pharmaceutical company is able to sell these medications in bulk for 5-30 times less money than the Maximum Retail Price they print on their labels!

Similarly, the following table lists the difference between the stockist's prices and MRPs for the 2.0 ml vial of antibiotic injection Amikacin, as well as the names used by various companies:

Drug manufacturing company	Name given by company (Brand Name)	Ingredient name of medicine (Generic Name)	Rate at which drug is purchased by the chemist (Stockiest price) ONE INJECTION	Rate at which drug is sold to the customer (Printed MRP)
Cadila	Amistar 500	Amikacin 500 mg	8.00/-	70/-
German Remedies	Amee 500	Amikacin 500 mg	8.00/-	70/-
Wockhardt	Zekacin 500	Amikacin 500 mg	9.90/-	70/-
Alembic	Amikanex 500	Amikacin 500 mg	8.22/-	64.25/-
Intas	Kami 500	Amikacin 500 mg	8.13/-	60/-
Unichem	Unimika 500	Amikacin 500 mg	7.80/-	72/-
Ranbaxy	Alfakim 500	Amikacin 500 mg	8.50/-	70/-
Cipla	Amicip 500	Amikacin 500 mg	7.42/-	72/-

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These price mark-ups are very high and consistent across eight different producers! The ill patient suffers the repercussions, with little individual power to understand the system and find reasonable prices. For this reason, we seek to promote more transparency, regulation, and rationality in medicinal pricing. We advocate the procurement of medicines at bulk prices by third parties interested in patient welfare, and the delivery of the medicines to the patients at reasonable prices. In fact, as we argue below, they can be free of cost. Specifically, we believe the Government of India should act as this third party, and provide free treatment to all its citizens.

What about the pharmaceutical industry's argument that drug prices need to be high to fund research and development for new medicines?

The price mark-ups and profits of pharmaceutical companies often far exceed the amount of money they spend on research and development. Also, a great deal of new medicinal research is funded by public institutions such as governments: in a study of 21 drugs introduced between 1965 and 1992 that were considered by experts to have had the highest therapeutic impact on society, public funding was instrumental in the discovery of 15 of these drugs (71 %)[viii]. With respect to Indian companies in particular, not one successful new molecule marketed internationally has come out of India in the last four decades[ix].

Can the Government of India control the price of medicines? Are there any medicines currently under price control?

Price controls are a legal option for the Government of India under the Drugs Price Control Order. However, the government has been increasingly reluctant to using this power. Currently there are only 74 medicines under price control, down from 347 in 1979. The government has argued that competition between generic companies should be adequate to lower prices.[x] However, as the table above shows, prices can remain quite high even for "generic medicines", with companies still able to skim enormous mark-ups from bulk to individual retail price.

What changes has India recently undergone in its patenting and intellectual property laws?

As mentioned above, a patent allows the first company to develop a medicine to be the only supplier for 20 years. The high prices they are allowed to charge in this system are meant to reimburse them for developing the new medicine. For several decades, starting from 1970, India did not allow product patents. The Government allowed drug companies in India to immediately produce newly researched medicines, through "reverse engineering", thus keeping the price lower than it would have been under a brand-name only system. However, India joined the World Trade Organization in 1995, and was required to acknowledge product patents by 2005. Since 1995, Indian and foreign companies can apply for patent protection on newly researched medicines. In 2005, patents began to be granted on these applications. It is likely that this will result in higher prices for these newly patented medicines.

What is meant by the term "evergreening"? Have there been examples of this in India?

When a company's 20-year patent monopoly is about to expire, it may try to slightly modify a medicine in a way that adds minimal therapeutic value. It will then try to apply for a patent on the new chemical, allowing it another 20 years to sell at high prices. This process is called "evergreening." It is a dangerous practice because it forces patients to continue to pay high prices for many more years.

India's modified Patents Law of 2005 contains a clause, called section 3(d), which requires patents to represent significant therapeutic advances over previous versions of a medicine. In 1998, the Swiss pharmaceuticals company Novartis attempted to evergreen their blood cancer treatment capsule imatinib. The Chennai Patent Office eventually rejected Novartis' patent request for imatinib mesylate because it did not represent a significant therapeutic advance over the previous form of the medicine. Novartis filed a case with the Madras High Court to not only overturn this decision, but to overturn the constitutional validity of section 3(d) in the first place. Fortunately, the Madras High Court did not rule in their favor.

What proportion of healthcare spending is paid privately, or out-of-pocket?

As noted in the introduction, private spending accounts for 72% of total health expenditure, 89.5% of which is paid out-of-pocket by patients. As a result, health costs are the second largest cause of rural indebtedness in the country. Because of the cost of a single hospitalization, 32.5 million people fall below the poverty line, and more than 40% of those hospitalized are forced to borrow money or sell their assets to pay for treatment. And gravest of all, over 23% of the ill never seek treatment due to their inability to pay.

What proportion of total healthcare costs are spent on medicines in India?

This issue is very important because medicines make up an enormous share of total healthcare costs. As mentioned in the introduction, 70% of out-of-pocket health expenditures are spent on medicines. Unfortunately, this is made worse by the fact that doctors frequently prescribe additional medicines that add no real therapeutic value to treatment of a disease. For instance, the Moving Annual Total for the year ending Dec 2006 for the irrational multivitamin preparation Neurobion forte was an astonishing Rs. 48 crores. For the same period, the irrational Dexorange amassed Rs. 77 crores, the irrational Corex

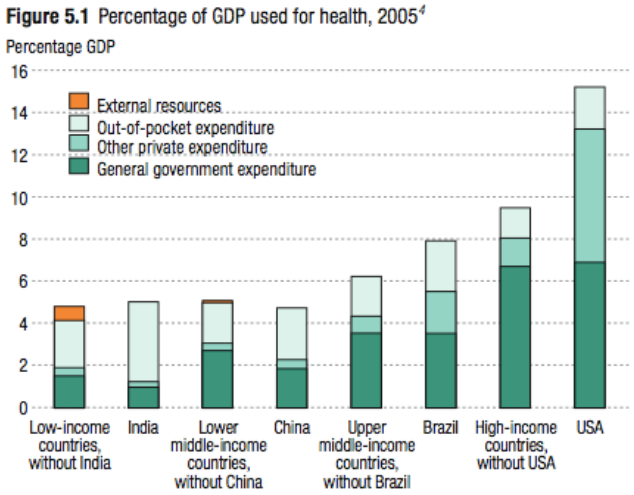
Rs. 135 crores, and the absolutely unwarranted Liv 52 sells Rs 95.8 crores!

If the Government of India were to supply free medicines to treat its entire annual burden of disease, how much would this cost if procured at the government prices listed above?

Prayas has studied the data from National Commission on Macroeconomics and Health, as well as the amount of medicine needed to fully treat all diseases through government institutions. If medicines are acquired at the bulk prices mentioned above, it should only require around Rs. 6000 crores to provide free treatment for all diseases not requiring hospitalization. Not only will this allow universal access to medicines for India's citizens, but it will place significantly less burden on the healthcare system, as medicine costs will be reduced to the bulk prices paid by the government. On the other hand, if each patient continues to buy individually, the total cost for the same amount of medication would be Rs. 25000 crores.

Can the Government of India afford to provide free treatment to all citizens?

The sum of Rs. 6000 crores is only one-tenth the annual budget of the National Rural Employment Guarantee Scheme. As of 2008, the Indian government spent 1.12% of the country's GDP on healthcare[xi], which is extremely low compared to most countries of the world, including several poorer countries in Sub-Saharan Africa.



(WHO, World Health Report 2008)

When the UPA government came to power in 2004, it promised to increase the health budget from 0.9% to 2-3% of GDP annually. The additional sum of Rs. 6000 crores would not push the health budget to even 2% of GDP. It is therefore affordable, and the right thing to do.

If more disease was treated now at this extra expense, could this actually save the Government of India money in the long term?

When a patient delays treatment for a serious disease, this adds more cost to the healthcare system in the end, because treatment costs will be higher as the

disease progresses and becomes more severe. If free treatment is assured, then more patients will seek treatment early on in out-patient facilities, avoiding "catastrophic" illnesses which lead to hospitalization and extremely high costs. Additionally, a healthy population is far more likely to contribute to the economic activity of the country, further fueling the growth of the Indian economy.

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[i] *National Health Accounts*. Geneva, World Health Organization. (http://www.who.int/nha/country/ind/en/, accessed April 2010).

[ii] Garg CC, Karan AK. "Reducing out-of-pocket expenditures to reduce poverty: a disaggregated analysis at rural-urban and state level in India." *Health Policy and Planning*, 2009, 24(2): 116-128.

[iii] Narayan, Jayaprakash. "Towards a National Health Service" Presentation to Planning Commission on Behalf of National Advisory Council, 9 December 2004.

[iv] "Ch. 7: Access to Essential Medicines." The World Medicines Situation. *World Health Organization*. Geneva, 2004. (http://apps.who.int/medicinedocs/fr/d/Js6160e/9.html, accessed April 2010).

[v] Garg 2009.

[vi] Chittaurgarh Generic Medicine Cooperative Departments Shop.

[vii] Ibid.

[viii] United States Senate - Joint Economic Commission. "The Benefits of Medical Research and the Role of NIH." May 2000.

[ix] Gulhati, Chandra M. "Drug Price Regulation: Principles, Problems and Prospects." Editor, Monthly Index of Medical Specialties.

[x] Ibid.

[xi] *National Health Accounts*. WHO.