Generic drugs: Review and experiences from South India

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Abstract

The cost of pharmaceuticals, as a percentage of total healthcare spending, has been rising worldwide. This has resulted in strained national budgets and a high proportion of people without access to essential medications. Though India has become a global hub of generic drug manufacturing, the expected benefits of cheaper drugs are not translating into savings for ordinary people. This is in part due to the rise of branded generics, which are marketed at a price point close to the innovator brands. Unbranded generic medicines are not finding their way into prescriptions due to issues of confidence and perception, though they are proven to be much cheaper and comparable in efficacy to branded medicines. The drug inventory of unbranded generic manufacturers fares reasonably when reviewed using the World Health Organization-Health Action International (WHO-HAI) tool for analysing drug availability. Also, unbranded generic medicines are much cheaper when compared to the most selling brands and they can bring down the treatment costs in primary care and family practice. We share our experience in running a community pharmacy for an urban health center in the Pathanamthitta district of Kerala State, which is run solely on generic medicines. The drug availability at the community pharmacy was 73.3% when analyzed using WHO-HAI tool and the savings for the final consumers were up to 93.1%, when compared with most-selling brand of the same formulation.

Keywords: Drug availability, drug industry/legislation and jurisprudence, drugs, economic competition, essential medicines, generic*, generic medicines, global health, India, patents as topic/legislation and jurisprudence*, poverty, unbranded generics

Introduction

The World Health Organization (WHO) estimates that almost 30% of the world population lacks access to essential medicines and that the figure will rise to more than 50% in some countries of Africa and Asia.^[1] The cost of the pharmaceuticals is the main factor that hampers access to medicines and the governments in poor countries seem to be doing very little to counter this problem. The public sector availability of essential medicines was less than 50% in most of the countries of Africa and Asia.^[2] This is appalling in the face of increases in healthcare expenditure in most of the developing nations, mostly financed through secured loans by international development banks and consortia.

The situation in India is not very different than that of other developing nations. Healthcare expenditures have been growing in India, both in real terms and also when considered as a proportion of the Gross Domestic Product (GDP).^[3] However, even with this recent increase in healthcare spending, India's expenditure on health is nowhere near that of OECD (Organisation for

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Economic Cooperation and Development) nations.^[4] The total public spending on healthcare in India accounted for only around 1.2% of GDP in 2012, with the per-capita spending on health around USD 160. This is a miniscule amount when compared against the OECD per-capita healthcare spending of USD 3,484 in 2012.^[3,4] This shows that the healthcare spending in the country is set to rise further in the coming years and the healthcare industry is all set for a boom time.

The cost of medicines and pharmaceuticals as a percentage of total healthcare spending has also been rising worldwide.^[5] It is the fastest-growing item in the healthcare budgets worldwide and it varies between 20-60% in various healthcare budgets of countries.^[6] By 2020, the prescription drug market in United States of America is set to grow to USD 700 billion (B) and China will be USD 260 B.^[5] Though no credible predictions about the Indian pharmaceutical industry are available, it is quite safe to assume that Indian pharmaceutical industry will also grow manifold. The growth of the pharmaceutical market worldwide and its increased share in total healthcare spending will reignite the age-old debate on how to balance the cost of innovation in drug research and universal access to the fruits of that research.^[7]

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Rise of Generics

The role of generic medicines in reducing the healthcare expenditure has been recognised for a long time. Multiple studies have proven that saving through substitution of originator brands by cheaper generic medicines, savings in the range of 10-90% can be achieved.^[8] Most national governments have been encouraging the use of generic medicines worldwide and many healthcare systems have policies of substituting expensive branded original medications with generic medicines.^[9] In the United States, generic substitution (GS) is an accepted practice and at the end of 2012, almost 80% of all the prescriptions were of generic medications. This has resulted in a substantial moderation of expenditure growth in widely used drugs and significant savings to the economy.^[6] In the United Kingdom, GS is now a standard practice in hospitals operated by the National Health Service (NHS) and medical schools have included generic prescribing as a part of their medical training.[10]

In India, the procurement price of essential medicines is generally lower than the mean International Reference Pricing (IRP) but availability of these drugs in the public sector has always been a problem. The exorbitant cost of some of the commonly used medications in private pharmacies makes it inaccessible to majority of the poor.^[11] Also, the difference between procurement prices and retail prices in case of some of the generic medicines, were as high as 28 times, which shows a very high margin of profit-taking in view of limited price control mechanisms.^[11] It is in this light, that the government revised the National Pharmaceutical Pricing Policy in 2012. It gave methods to calculate ceiling prices for drugs which are under the National List of Essential Medicines (NLEM) which was modified in 2011. It gave a formula for deciding the ceiling prices for drugs under NLEM, using a market-based pricing (MBP) method, taking into account the prices of all manufacturers having a market share of more than 1% nationally.^[12] The Drug Price Control Order of 2013 was a follow-up to the National Pharmaceutical Pricing Policy and gave the price ceiling for 348 drugs and over 600 formulations. However, the action was considered inadequate by many activists lobbying for cheaper drugs and they termed it as a sell-out to international pharmaceutical companies.^[13]

Indian Pharmaceutical Industry

The multiplicity of brands and manufacturers makes it difficult to decipher the actual market dynamics and the structural issues in the Indian pharmaceutical industry. The complexity of the market and the intensity of the competition between companies in India have made the country a hub for manufacture of generic medicines, earning a sobriquet "pharmacy of the developing world."^[14] This, along with a favorable governmental stance has made India a powerhouse in this field, bringing it into direct confrontation with certain developed nations where most of the big multinational pharmaceutical companies are located^[14] There have been many instances when the Indian Patents Office and the Supreme Court of India effectively used certain flexibilities of the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement of the World Trade Organization and also the safeguards embedded in the Indian Patents Act. The compulsory licensing of Sorafenib, a drug used in treatment of advanced liver and renal cancer and the rejection of patent application for Imatinib, a drug used in the treatment of leukaemia, were considered as landmark decisions by many state and non-state organizations involved in pharmaceutical sector.^[15,16]

Considering the Indian scenario, we can divide the brands into innovator brands (IB), most-selling generics (MSG), and least-priced generics (LPG).^[17] The IBs will be at the highest price point, followed by MSGs and LPGs. A new category of generic drugs known as unbranded generics (UB) are also coming into the market now. These drugs are usually manufactured by not-for-profit organizations or are subsidised by certain non-governmental organizations (NGO).^[18] Though the price points of these different categories of drugs are different, their efficacies are comparable. This fact has been proved by multiple studies all over the world and it belittles the reasoning which goes behind differential pricing of the same drug.^[19,20] Even though it has been proved that there is not much difference in efficacy between the above categories of drugs, physicians tend to prescribe drugs manufactured by highly-reputed companies. Their trust is often misplaced as most of these leading companies market drugs manufactured by less-known manufacturers.^[18]

A Model Community Pharmacy: Experiences from South India

Pushpagiri Medical College, which is a teaching hospital in Kerala state of India partnered with a social organization, Bodhana Social Service Society, involved in poverty alleviation and income generation programmes, to start an urban health center with an objective to improve patient accessibility to cost-effective medical care. The urban health center serves a population of 10,000, spread over 5 municipal wards of Tiruvalla municipality and was intended as a model for cost-effective primary care. A comprehensive population survey was carried out before the start of the project and the health center started functioning in September 2014. As a part of the initiative, a community pharmacy was opened to stock unbranded generic drugs manufactured by two non-governmental organizations. Low-Cost Standard Therapeutics (LOCOST), Baroda and Comprehensive Medical Supplies India (CMSI), Chennai were the two NGOs providing us with the drugs which were needed at the community pharmacy.^[21,22] The drugs were provided to us at a nominal cost, after we provided an undertaking that the Pushpagiri Medical College is a charitable institution with no intention of making profits. Also, the physicians working at the health center made a collective decision to prescribe all the drugs generically and the pharmacist was advised to dispense the cheapest generic brand.

The drug inventory available with these not-for-profit manufacturers were fairly comprehensive when reviewed using the World Health Organization-Health Action International (WHO-HAI) tool for quantifying availability of essential medicines.^[23] The WHO-HAI tool is a validated method for measuring availability of drugs in a health system and includes 30 core medicines: 14 essential medicines for global burden of disease and 16 medicines specific to the WHO region [Table 1].^[24]

The WHO-HAI tool showed a drug availability of 73.3% for LOCOST, Baroda and 43.3% for CMSI, Chennai. This is much better when compared to drug inventory in public hospitals in other parts of India, assessed using the same methodology.^[11] There are a multitude of companies and NGOs manufacturing UB medicines and the drug inventory of a health system can be made comprehensive through a mixed purchase model where procurement is done from multiple vendors.^[23]

Similarly, unbranded generic drugs offered significant savings to the health system in terms of costs involved for procurement. When reviewed against the MSBs, UB medicines were costing only a fraction of the maximum retail price (MRP) of MSPs [Table 2].

The community pharmacy has been in operation since September 2014, and stocks over 120 formulations manufactured by unbranded generic manufacturers. In addition, it also supplies LSG to augment the drug inventory of the pharmacy. There is a family physician and a general practitioner who run the center, apart from regular specialist visits from Pushpagiri Medical College Hospital. The urban health center has an outpatient load of 20-25 patients a day within 6 months of starting operations. The staff from the center is providing services to 3 old-age homes and a few surrounding schools and the drugs from the community pharmacy is being used for free supply during the medical camps conducted by the department of community medicine.

The patients and the physicians have responded positively to this novel initiative and the general acceptability has been found to be high, though objective studies to assess the same are yet to be done. Some physicians have suggested replicating this model in other similar health initiatives also. The financial sustainability of the model is still unproven, and the urban health center along with the community pharmacy is being sustained with large subsidies provided by Pushpagiri Medical College and Bodhana Social Service Society. The cost of setting-up such a facility was around INR 500,000, which includes the furniture, basic medical equipment, basic lab accessories, and first round of procurement for the community pharmacy and is exclusive of the capital expenditure on the building. The average monthly expenditure in running the health center, has been around INR 150,000 a month, including salaries, cost of consumables and medicines and exclusive of building rent and depreciation. The income earned by the center is around INR 40,000, and there is an excess of expenditure over income to the range of more than INR 100,000 a month, which is subsidised by Pushpagiri Medical College and Bodhana Social Service Society. Both the organizations are charitable societies run by a prominent religious group and the subsidies are meant to further their commitment to social causes.

Table 1: Drug inventory of LOCOST, Baroda and CMSI,
Chennai: Review using WHO-HAI tool for WHO
South East Asian Region

Name of the drug	Strength	LOCOST,	CMSI,
		Baroda	Chennai
Amitriptyline	25 mg	-	-
Amlodipine	5 mg	Yes	-
Amoxicillin	500 mg	Yes	Yes
Amoxicillin susp	25 mg/ml	-	-
Atenelol	50 mg	Yes	Yes
Atorvastatin	10 mg	Yes	-
Beclomethasone inhaler	200 mcg/dose	-	-
Captopril	25 mg	-	-
Ceftriaxone inj	1 g/vial	Yes	-
Ciprofloxacin	500 mg	Yes	Yes
Clotrimazole cream	1%	-	-
Co-trimoxazole susp	8+40 mg/ml	Yes	Yes
Diazepam	5 mg	Yes	-
Diclofenac	50 mg	Yes	-
Diethylcarbamazine	50 mg	Yes	Yes
Doxycycline	100 mg	Yes	Yes
Enalapril	5 mg	Yes	-
Fluoxetine	20 mg	Yes	-
Gentamycin drops	0.30%	Yes	-
Glibenclamide	5 mg	Yes	Yes
Glicalzide	80 mg	-	-
Ibuprofen	400 mg	Yes	Yes
Metformin	500 mg	Yes	Yes
Metronidazole	400 mg	Yes	-
Omeprazole	20 mg	Yes	Yes
Paracetamol susp	25 mg/ml	Yes	Yes
Phenytoin	100 mg	Yes	Yes
Ranitidine	150 mg	Yes	Yes
Salbutamol inhaler	100 mcg/dose	-	-
Simvastatin	20 mg	-	-

The community pharmacy concept faced the following key challenges:

- Absence of intermediaries for drug procurement results in inordinate delays in transit, mainly on account of the tardy services rendered by private logistics companies
- Advance payment in full has to be remitted to the bank • accounts of these NGOs for supply of drugs, which goes against the standard practice of procurement followed in hospitals. This has been an issue with the internal audit department
- The difference between procurement price and the MRP is minimal and this is causing worries of long-term financial sustainability of the community pharmacy model
- Packaging of the drugs is unattractive in some cases, resulting in difficulty to convince patients about the efficacy of the drug
- We have faced difficulty in convincing some of the specialist doctors on the quality of the drug, despite providing ample literature proving the efficacy of unbranded generic drugs.

Drug and strength	Most selling brand Most selling		Lowest MRP among	Savings on prescribing the generic
0 0	(manufacturer)	brand (MRP)	available generics	instead of most selling brand (%)
Amitriptyline 25 mg	Tryptomer (Wockhardt)	Rs 33.4/10 tabs	-	-
Amlodipine 5 mg	Amlokind (Mankind)	Rs 5.9/10 tabs	Rs 3.75/10 tabs#	36.5
Amoxicillin 500 mg	Mox-500 (Ranbaxy)	Rs 144.75/15 caps	Rs 34.5/15 tabs#	76.2
Amoxicillin susp 25 mg/ml	Mox-D (Ranbaxy)	Rs 35.2/60 ml	-	-
Atenelol 50 mg	Aten-50 (Zydus Cadilla)	Rs 38.9/14 tabs	Rs 4.48/14 tabs#	88.5
Atorvastatin 10 mg	Storvas (Ranbaxy)	Rs 93.35/10 tabs	Rs 9.25/10 tabs#	90.1
Beclomethasone inhaler 200 mcg/dose	Beclate (Cipla)	Rs 307 per inhaler	-	-
Captopril 25 mg	Capotril (Lupin)	Rs 32.83/10 tabs	-	-
Ceftriaxone inj 1 g/vial	Gramocef (Micro labs)	Rs 78.5/vial	Rs 24/vial#	69.6
Ciprofloxacin 500 mg	Cifran (Ranbaxy)	Rs 98.6/10 tabs	Rs 19.0/10 tabs#	80.8
Clotrimazole cream 1%	Candid (Glenmark)	33.2/15 g	-	-
Co-trimoxazole susp 8+40 mg/ml	Septran (GSK)	Rs 11.9/50 ml	Rs 11/50 ml#	7.6
Diazepam 5 mg	Calmpose (Ranbaxy)	Rs 24.31/10 tabs	-	-
Diclofenac 50 mg	Voveran (Novartis)	Rs 47.6/15 tabs	Rs 4.50/15 tabs#	90.6
Diethylcarbamazine 50 mg	Banocide (GSK)	Rs 4.8/10 tabs	Rs 3.0/10 tabs#	37.5
Doxycycline 100 mg	Microdox (Microlabs)	Rs 33.5/10 tabs	Rs 10.75/10 tabs#	32.1
Enalapril 5 mg	Envas (Cadilla)	Rs 46.07/15 tabs	Rs 3.25/15 tabs*	93.1
Fluoxetine 20 mg	Fludep (East West)	Rs 41/10 Caps	Rs 9.0/10 caps [#]	78.1
Gentamycin drops 0.3%	Bactigen (FDC Spectra)	Rs 6.99/5 ml	Rs 7.50/10 ml [#]	-7.2
Glibenclamide 5 mg	Daonil (Sanofi Aventis)	Rs 9.15/10 tabs	Rs 2.66/10 tabs*	70.9
Glicalzide 80 mg	Glyloc (Cadilla)	Rs 43.36/10 tabs	-	-
Ibuprofen 400 mg	Brufen (Abbot)	Rs 9.51/15 tabs	Rs 9.45/15 tabs#	0.7
Metformin 500 mg	Glyciphage (Franco-Indian)	Rs 22.6/20 tabs	Rs 8.50/20 tabs#	62.4
Metronidazole 400 mg	Flagyl (AHPL)	Rs 10.3/15 tabs	Rs 5.1/15 tabs#	50.5
Omeprazole 20 mg	Omez (Dr Reddy's)	Rs 81.6/15 Caps	Rs 7.5/15 Caps#	90.9
Paracetamol susp 25 mg/ml	Calpol (GSK)	Rs 25.8/60 ml	Rs 11.25/60 ml [#]	56.4
Phenytoin 100 mg	Eptoin (Abbot)	Rs 185/100 tabs	Rs 16.5/100 tabs*	91.1
Ranitidine 150 mg	Zinetac (GSK)	Rs 14.76/10 tabs	Rs 4.0/10 tabs#	72.9
Salbutamol inhaler 100 mcg/dose	Asthalin (Cipla)	Rs 95 per inhaler	-	-
Simvastatin 20 mg	Simcard (Cipla)	Rs 150.34/10 tabs	-	-

Table 2: Comparison of drug prices of most-selling brands and their generic counterparts: drugs identified by WHO-HAI tool for WHO South East Asian Region^[17,25]

*LOCOST: Low Cost standard therapeutics; CMSI: Comprehensive Medical Services India; WHO-HAI: World Health Organisation-Health Action International Project; MRP: Maximum retail price; FDC: Fixed-dose combination; GSK: GlaxoSmithKline; AHPL: Abbott Healthcare Pvt Ltd

The Way Forward

Many studies have revealed apprehensions among physicians in prescribing UB medicines to their patients. Most of these apprehensions are related to quality of the product and the fear of losing patients.^[26] Along with these unfounded concerns, poor patient acceptability due to various issues like poor packaging, lack of brand promotion initiatives, etc., are affecting the extend of penetration of UB drugs in the country, even though India is becoming a lifeline for all developing countries in the supply of generic medicines.^[27] The government and the policy makers in India and other similar developing countries should focus on building the confidence of physicians and the patients regarding unbranded generic medications. The demand side management should include a multifaceted approach in which issues of different stakeholders are addressed and affirmative actions taken in favour of unbranded generic medicine manufacturers.^[27] Another important issue is concerning the inherent deficiencies and implementation status of the Drug Price Control Order of 2013. The said order has been criticised extensively for being myopic in its approach, as the number of formulations included is less than 20% of the whole pharmaceutical market. Also, it gave ample space for pharmaceutical companies to tweak their marketing strategies by focussing on formulations and dosages not covered by the Drug Price Control Order. It also leaves out the important area of fixed-dose combinations (FDCs), a potential loop-hole for the pharmaceutical companies to exploit fully. It is indeed distressing to note that more than 90% of the diabetic drug market is out of the purview of this order.^[13] The policy makers in the country needs to get a realisation that the share of drugs in out-of-pocket expenditure (OPP) is around 80% in India and a tighter regulatory framework is needed to protect the consumers against exploitation.^[28]

In the future, we intend to do a study on the perception about generic drugs, among the treating physicians and the patients who form the clientele of the community pharmacy. This can help us to understand the issues which affect the actual stakeholders and find means to improve the acceptability and penetration of generic medicines. Also, after the yearly financial audit, we plan to do a cost-benefit analysis to objectively analyse the efficacy of the model in monetary terms.

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