RAKSHAK FOUNDATION

# Generic Drug Distribution Regulation and Policy Issues

JUNE 2013

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# Preface

Healthcare ought to be the fundamental right of every human being. Unfortunately in India, the high out of pocket expenditure has led many a family to poverty. Major contributors to this expenditure are drugs. Branded and branded-generics account for more than 70% of the total expenditure. The government has implemented schemes to popularize generic drugs but what has been the impact? This project looks at the problem facing the country in detail and identifies possible solutions to monitor/ regulate/ better the drug distribution scenario in India.

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## Acknowledgements

This internship could not have been fruitful without the guidance of the Almighty. His grace has been immense, since I received a project which I was very inclined to work on. My mentor, Dr. Jagdish Kaur has been very supportive. Always ready to help out and guide me, her encouraging e-mails and network have ensured that this project turns out well. The internship coordinators Nikita, Pritesh, Ishika and Siddhartha have been very enthusiastic in ensuring that we get ample time to work as well as relax. Their enthusiasm, no doubt is what is driving this program today. I would also like to thank Mr. Sachin Bansal who provided me this opportunity. My final year project guide Prof. Anju Chadha, Department of Biotechnology, IIT Madras has been instrumental in ensuring that I get to continue in this project. Her constant encouragement keeps me motivated to perform well. Dr. Meenakshi Krishnan of Apollo Hospitals, Chennai was my initiator into the field of Public Health, having set apart her valuable time to support my endeavour. My parents, DrReji Varghese and Dr. Anita Eapen, my sister Namita and my close friends Reneeta, Snehil, Neelesh, Vivek, Nikhil, Sumedha, Shruthy, Vishnu, Akand, Govind, Sohan, Tanuj, Mukesh, Anand have constantly encouraged me to pursue my dreams in the institute. However, this internship wouldn't at all have been as much fun and eye-opening had it not been for my friends at Rakshak, especially the Satpura residents and Nehru group members who have ensured that the time is well spent!

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# Contents



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# TABLE OF FIGURES



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# Executive Summary

The Healthcare spending in India consists majorly of Out-of-Pocket (OOP) expenses. Majority of this is spent on therapeutic drugs. The generic medicines are distributed through the public and private health sector which includes hospitals, clinics and health centres. Due to the unethical practice by pharmaceutical industry and nexus with doctors, many a times, costly branded drugs/medicines are prescribed. OOP expenses account for 78% of private health expenditure. Medicines contribute to 74% of this![1]

This project aims to look at the distribution patterns of generic drugs across private and public clinics, the mindset issues associated with them and possible promotion avenues for generic drugs and awareness regarding the same.

As of now, generic drug regulations in many countries all over the world have been studied. Field visits have been undertaken to Guru Gobind Singh Government Hospital, a model hospital of the Government of Delhi which uses the Hospital Management Information System (developed and managed by CDAC). Data regarding prescriptions have been obtained as well as stock inventory data collection for a week has been started. Valuable inputs regarding the project have been obtained from the senior doctors at GGSGH specialized in General Medicine, Pediatrics and Surgery.

Some of the major inputs received were:

1. To identify a cut-off based system (based on prior quality of supply) for identifying generic drugs suppliers rather than lowest bidder getting the contract
2. To study major reasons for interruption in supply of essential drugs, this could range from few days to months.
3. To study possibility of developinga feedback loop between policy makers and doctors with regard to quality of drugs supplied. This could strengthen *pt.* (1)
4. To provide recommendations to use Line 1 (basic) as first prescription drugs instead of Line 2/3 (advanced, stronger and more expensive drugs); focus primarily on confidence being instilled in doctors about generics

My 2 major recommendations would be the following

1. Establishment of a Healthcare Management Information System
2. Establishment of a Feedback mechanism to facilitate communication among health care providers and Administration to ensure that quality drugs are supplied at government pharmacies.

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# 1. Introduction

## 1.1 Background Information

### 1.1.1 Laws and Litigations:

The following are the sequence of laws which gradually led to the Patents Act on 1970.

1872- The Patent and Designs Protection Act

1883- The Protection of Inventions Act

1888- The Inventions and Designs Act

1911- Indian Patents and Designs Act[2]

1972- The Patents Act, 1970: This did not recognize patents in drugs (and food), leading to significant changes in the structure and growth of the pharmaceutical industry. Under the Patents act, the term of a process patent was restricted to 5 years from date of sealing or 7 years from date of filing, whichever was shorter.

The act gave companies decisive advantage that they could change the process by which a drug was manufactured and market them in India. It, thus, offered no protection for pharmaceutical patents. The onus was also on the patentee to prove that the drug could not have been manufactured by any other process. This was highly in favor of the Indian manufacturers. [3]

**1.1.2 Growth of the Generics Industry**: Thanks to the Patents Act of 1970, multinationals represent only 35% of the market, down from 70%, thirty years ago. The industry presently is third largest in the world in terms of volume and stands 14$^{th}$ in terms of value.[4] Global demand from developed nations resulted in the growth of Indian companies such as Ranbaxy Laboratories, Dr. Reddy's Laboratories, Cipla and Sun Pharmaceutical Industries. Ranbaxy, for example in 2012 reported 25% of its sales as domestic and 50% of its sales in the USA. The race to get approval for a drug, once it's patent expires in the USA is hectic, as the winner gets a 180-day Exclusive Marketing Rights (EMRs).[5]

Hon. Minister for Health, GhulamNabi Azad said that one in every five generic drug consumed in the world has been made in India. The export of pharmaceutical products in 2011-12 stood at over INR 40,000 Crore. (Fig 1.1.2)

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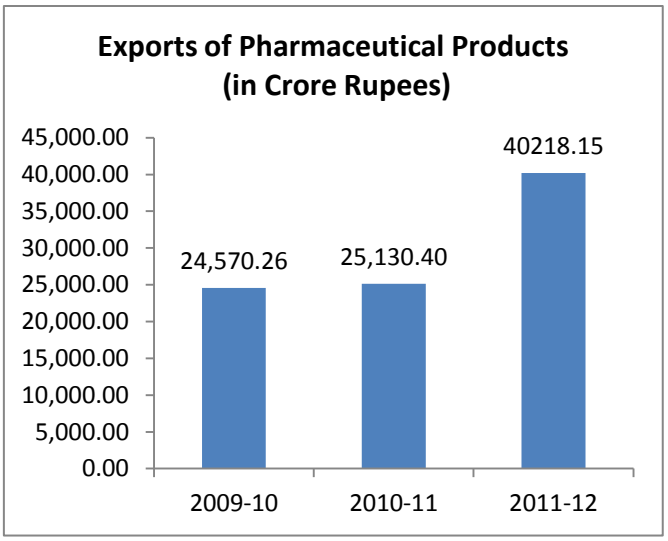


**Figure 1- Export of Pharmaceutical Products**

*(Source:* http://pharmabiz.com/NewsDetails.aspx?aid=73910&sid=1)

As of now, Indian generics have 15% share in the US market and accounting for 70% of the drugs supplied to poor nations as part of humanitarian efforts. With $250 billion worth of patents set to expire by 2015, India aims to boost it's share from $10 billion to at least $40 billion.[6] However, the recent scandal involving Ranbaxy could dampen the demand for Indian generics. [7]

**1.1.3 Trade Related Intellectual Property Rights (TRIPS)**: Having come into effect in 1995, TRIPS permitted India 10 years to implement the provisions of TRIPS as it was a member of the World Trade Organization (WTO). The 2001 Doha Declaration, which was in lieu of certain apprehensions put forward allowed member nations to take appropriate measures to protect public health.[8]

The granting of an EMR to Novartis for ImatinibMesylate in beta-crystalline form in November 2003 created a controversy. Novartis had received a patent (in 1993 for ImatinibMesylate) before TRIPS came into existence. The Patents Act of 2005 Sec 3 (d) "*bars patent protection for all incremental inventions of chemical and pharmaceutical substance".* [9]This resulted in thejudgment which is beneficial for generic manufacturers like Natco and Cipla.[10] According to Novartis, the judgment took away incentive to do R&D in India and invest in the country.TRIPS is not a permanent agreement and the Supreme Court ruling implies that a proper justification cum review of TRIPS be done. [11]

**1.1.4 Jan Aushadhi Scheme of the Department of Pharmaceuticals:**In November 2008, the Government of India opened the first ever Jan Aushadhi store at Amritsar with the aim of providing quality generic medicines at affordable prices. There are presently 3 Jan Aushadhi stores in New Delhi, 19 listed in Punjab, 53 in Rajasthan, 14 in Odisha, 2 in Andhra Pradesh, 3 in West Bengal, 2 in Haryana, 2 in Uttarakhand, 3 in Chandigarh, 1 in Jammu and Kashmir and 5 in Himachal

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Pradesh. A total of 107 stores running according to the website.[12] However, there have been many objections raised towards the sub-standard quality of generics which are delivered at these stores, with the Disease Management Association of India (DMAI) wanting to scrap the scheme in March 2011. The scheme was accused of being poorly planned and badly executed, with the bureaucracy keeping money only in mind. [13]

**1.1.5Aamir Khan and SatyamevJayate:** After Aamir Khan's iconic episode on 27th May 2012 screened on Star Plus[14]- "Every Life is Precious", Maharastra[15] and Karnataka (Janatha Bazaar Generic Stores at 50% less than MRP)[16]state governments planned to open generic drug stores. This is in line with the "Life Line Drug Stores" which are prevalent in Rajasthan. [17]

**1.1.6 National List of Essential Medicines 2011 and Drug Price Control Order 2013:** The Drug Price Control Order aims to make 348 drugs available at Generic Drug Stores. This is a revolutionary order which ensures that many of the medicines which come under the National List of Essential Medicines (NLEM) 2011 becomes available to the commoner for a reduced price. It helps reduce the cost by following a price ceiling which is the arithmetic average of the 3 most popular drugs which come under this order.[18]The order will enable the National Pharmaceutical Pricing Policy 2012 to regulate prices of 348 drugs covered under the National List of Essential Medicines (NLEM) 2011 and will bring 652 drugs under price control.[19]

**1.2 Main Problems, their scope and impact on the society**

**1.2.1 High Out-of-Pocket Expenditure:** According to the High Level Expert Group for Universal Health Coverage for India, Out of Pocket spending accounts for over 70% of all healthcare spending and drugs contribute to 74% of the same

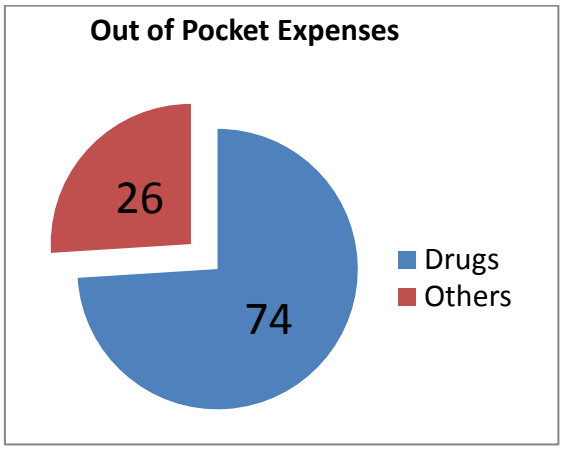


Figure 2- Out of Pocket Expenses

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If this menace is curbed, the number of families that go into poverty because of medical expenses will come down drastically.

**1.2.2 Low Prescription of Generic Drugs:** In a sample study conducted at DeenDayalUpadhyay Hospital, New Delhi, it was found out that only 34.8% of drugs prescribed are by their generic name. This is despite the government ruling that all prescriptions are to be by the salt name. This can be due to a variety of factors such as poor quality of generics available, lack of trust in the efficacy of the generic varieties and pharma-doctor nexus.

The trust deficit existing between the various parties involved leads to the benefactor (the patient) being over-burdened. A clear mechanism needs to be in place which will ensure that a patient has a set of informed alternatives.

### 1.3 Goals and Objectives

The project tasks could be classified on the basis of 3 objectives.

**1.3.1 Regulatory Provisions regarding prescription and distribution:** Regulatory mechanisms for ensuring quality of drugs available at the pharmacy counters are to be studied. Also, the different regulations in place to establish a pharmacy would also be studied. According to Dr. Samid Sharma, MD, IAS[20] "The hospital management or the local self-government or NGO or any other private entity should discuss the issue, evolve a consensus, take doctors and staff into confidence and adopt a resolution to provide low-cost drugs to the citizens." The ease of setting up a generic drug store will also be studied.

**1.3.2 Analysis of Prescriptions and Prices:** Prescriptions retrieved from Guru Gobind Singh Government Hospital, New Delhi and in future, DDU Hospital & CGHS Wellness Centers would be studied. The percentage of prescriptions which are generic and branded would be studied and a price comparison would be done.

Also, data regarding the consumption of 20 essential drugs at Guru Gobind Singh Government Hospital, New Delhi is being analysed.

**1.3.3 Methods of Promotion:** A false notion regarding generic drugs exist not only amongst the consumers (patients) but also amongst pharmacists and doctors. Suitable mechanisms for promotion need to be identified which will ensure that maximum people are aware of the good quality generic drugs which can substitute for their expensive branded counterparts

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# 2. Methodology

## 2.1 Literature Search

The literature used could be broadly divided into

**2.1.1 Research Papers:** These were chiefly looked at for specific topics such as TRIPS, Prescription Analysis and regulations in other countries. The important points were summarized.

As a model for Prescription Analysis, I studied the paper by Dr. Uma Tekur and DrBhupinderKalraon "Monitoring an interventional programme of drug utilization in a health facility of Delhi". It spoke about the salt name prescription by doctors in a tertiary care health facility of Delhi. Apart from this, an important paper I studied was "Pharmaceutical Industry in India after TRIPS" by Prof Sudip Chaudhuri.

**2.1.2 Government Reports:** These were looked at for understanding the government machinery in place and possible recommendations which could have been implemented. Major reports which were looked at were the CDSCO recommendations by the BrajeshPathak, M.P Panel [21] and HLEG 2012 Report. Also, these were used to collect data on various government schemes such as Jan Aushadhi and NLEM 2011[22].

**2.1.3 Newspaper and Blog articles:** To study popular opinions and to track the progress of the various issues such as Novartis Patent Case, Jan Aushadhi Stores, Drug Price Control Order 2013, Comparative studies across countries, new drug developments etc

## 2.2 Field Visits

Field Visits have been undertaken to Guru Gobind Singh Government Hospital and DeenDayalUpadhyay Hospital, both located in Delhi NCR. The Medical Superintendents were met and further course of action was planned in both hospitals.

The visits to GGSGH were hugely successful with multiple interviews being conducted and a large amount of useful data being provided with the help of HIMS at the hospital. The visit to DDU's Jan Aushadhi store helped understand the patient satisfaction. The findings have been given in detail in Section 4.

## 2.3 Meetings and Interviews

The telephonic meetings with my mentor Dr Jagdish Kaur were instrumental in defining a path for the project. Through her efforts, I was able to get in touch with a lot of personnel in the medical sector who were helpful in formulating the present structure of the project.

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| Date | Name | Designation | Institution | Topic of Discussion |
|---|---|---|---|---|
| 29th May 2013 | Dr. Ashok Kumar | Medical Superintendent | Guru Gobind Singh Government Hospital | Data Collection Procedure, Opinion on generic drugs |
| | DrManojGami | General Medicine specialist | -do- | Opinion on generic drugs, HIMS |
| | Dr. Vineet Gupta | Surgeon | -do- | Opinion on generic drugs |
| 8th June 2013 | Dr. Sangeetha Rani | Head of Department, Pediatrics | -do- | Opinion on generic drugs |
| | Dr. Vivek Bhatia | Senior Resident, Pediatrics | -do- | Opinion on generic drugs |

**Please refer Appendix A for details of Mentor Meetings***

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# 3. Current NGO and Government Efforts

## 3.1 Non-Governmental Organization Involvement

NGO involvement in the generic drug scene first came to light majorly during the Kenyan HIV crisis. The Kenyan Coalition on Access to Essential Medicines (NCAEM) in 2001 challenged pharmaceutical companies to match the offer of Cipla for anti-retroviral drugs.[23]Cipla in turn, brought the cost down from ~$15,000 per year to under $100 per year. The Kenya Coalition of NGOs on Access to Medicines includes: Action Aid, The Association of People living with AIDS in Kenya (TAPWAK), Network for people living with HIV/AIDS (NEPHAK),Women Fighting AIDS in Kenya (WOFAK), Society for Women and AIDS in Kenya (SWAK), Health Action International (HAI Africa),Nyumbani, International Federation of Women Lawyers - Kenya (FIDA), Médecins sans Frontières (MSF), DACASA, Pharmaciens sans Frontieres (PSF), Kenyan Medical Association (KMA), Consumers Information Network.[24]

**3.1.1 Novartis Case:** The Cancer Patients' Aid Association (CPAA) was instrumental in fighting the Novartis (Gleevec). [25] The Drug Action Forum in Karnataka instituted an online petition in 2007 to put public pressure on Novartis. [26] In 2009, Berne Declaration, a Swiss NGO had come out against the Swiss company urging them to drop the case.[27]. More details were discussed previously in Sec 1.1.3.

**3.1.2 Generic Drug Distribution:** In Rajasthan, the Life Line Drug Stores are operated by Rajasthan Medicare Relief Societies with a 10% profit margin on sales to make it sustainable.TheJeevandhara stores in Andhra Pradesh, set up by the AP Medical Services and Infrastructure Development Corporation (APMS&IDC) are run in coordination with NGOs like AP Senior Citizens' Confederation and Red Cross.

## 3.2 Government Efforts

**3.2.1 Drug Price Control Order (DPCO):** 348 drugs under the NLEM are being brought under price control through DPCO. With the notification of the order, the National Pharmaceutical Pricing Policy (NPPP) 2012 comes into effect and all drugs under NLEM, which account for 60 per cent of total domestic pharmaceuticals market amounting to nearly INR 29,000 crore, would come under price control. As per the new drugs policy, all strengths and dosages specified in the National List of Essential Medicines (NLEM) 2011 will be under price control. According to the approved policy, prices of medicines will now be capped by taking simple average of all brands which have more than one per cent market share instead of input costs. The DPCO 2013, issued under the Essential Commodities Act, 1955, will lay the framework of the drug policy and mechanism of regulating prices. According to it, the National Pharmaceuticals Pricing Authority (NPPA) will be the implementation authority for the new policy and the new DPCO.[28]

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**3.2.2 Central Drug Standards Control Organization (CDSCO):** In order to check the quality of pharmaceuticals available in the country, the Central Drugs Standards Control Organization was instituted under the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India. [29]

**3.2.3 Jan Aushadhi stores:** In order to provide cheap and good quality generic drugs to all, the Department of Pharmaceuticals started these generic drug distribution stores in many parts of the country. Presently 107 Jan Aushadhi stores are active across India and I got a chance to visit the one at DDU Hospital. Patients are satisfied with the service at these stores.

**3.2.4 Regulation on Prescription of drugs:** The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 states, "Every physician should, as far as possible, prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and use of drugs."[30]The Medical Council of India (MCI) also issued a notice to all Deans of medical colleges across the country that they ought to prescribe generic drugs in May 2013.[31]

The Ministry of Health and Family Welfare in October 2012 directed all state Health Secretaries to instruct their drug license issuing authority to issue licenses only on the basis of their generic names and not on their brand or trade names.[32]A decision taken at SSKM Hospital in Kolkata mandated doctors to write the prescriptions using a carbon paper. The copies are to be then submitted to the HoD. This is a very basic, but effective way of ensuring accountability of doctors in prescribing generic drugs.[33]

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# 4. Results and Discussions

## 4.1 Findings from the literature

**4.1.1 Patents and Evergreening:** Amy Kazmin talks about the drug "Sprycel" and it's generic variety ( 1.6 lac and 9 k). Patent case for the same is ongoing (BMS of USA vsNatco of India). Western drugmakers, according to the article, feel that India will inspire other emerging nations to challenge their patents. Indian generic lobbyists feel that India is trying to balance IPR nuances of western manufacturers with the need for affordable drugs for 1.2 billion people. Senior officials comment that victories of the pharmaceutical companies never get reported. In other countries, the government only can issue licenses for manufacturing generic drugs. India has a system wherein the manufacturers can get the license from the Independent Patent controller. Indian patent laws also prevent "Ever Greening" of patents- extension of patent by slightly modifying the drug. Free trade laws might work against Indian manufacturers though as they give the western drug-makers greater power to subdue their Indian counterparts. Western manufacturers content that India's major problem is not unaffordability but an unstable healthcare system/ spending instituted by the government.[34]

**4.1.2 Stocking Issues:** Pritha Chatterjee talks about the fact that the Yellow Fever vaccine which is essential to all who travel to South America and Africa has to be imported. The manufacturers sell the vaccines directly to doctors and these are not available to the common man. Last stock sent to government offices were in 2011. Authorities at Kasauli's Central Research Institute (CRI) said there was delay in trying to identify a company that could repair the imported machine purchased in 1994-95. Cost of vaccine in private sector is INR 2,500 to 3000, while in government centers it is available for INR 150.[35]

**4.1.3 Accused patent infringement overruled**:Gemzar- a drug used for cancer treatment. Eli Lily complained that Sun infringed on its patent on Gemzar for manufacturing an abbreviated new drug application (ANDA). In the Michigan lawsuit, Eli Lilly had contended that Sun Pharma's ANDA infringed certain claims from the 826 patent and US Patent No. 4,808,614 (614 patent) that described gemcitabine and its uses -- the active ingredient in Gemzar.[36]

**4.1.4 Price Regulation of pharmaceuticals in India:** It is deemed possible end to arbitrary pricing and bring down medicine prices due to market based pricing model. [37]Drug firms will be given just 45 days to comply with making essential drugs cheaper based on the new DPCO. Manufacturers are also not free to sell previous batches at earlier prices.[38] Companies may soon **have to** share details of essential drugs. This was one of criterion mentioned by inter-ministerial panel working on DPCO. NPPP (National Pharmaceutical Pricing Policy) 2011 to decide max prices at which drugs can be sold (MRP) and also decide the span of control. [39]

3 types of pharmaceutical innovations can claim immunity from the price-control regime

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1. Indigenously developed product. Shouldn't be manufactured anywhere else in the world
2. If a pharmaceutical company develops a new process to make an existing drug and gets a patent according to Indian laws
3. A finished drug which uses a different delivery system from indigenous development ( 5 year count from date it gets market approval and not from date it starts manufacturing drug)[40]

**4.1.5 Quality Regulation of pharmaceuticals in India:** Estimates are that 75-90% of drugs are unregistered trademarks. The 68,000 Cr pharma market consist of branded generics, which doctors directly prescribe rather than the generic name of the drug.

State controllers give licenses to companies on brand names without verifying whether it is a registered trademark or whether a similar brand exists. In the courts, the smaller company might furnish the drug manufacturing license sporting the brand name to argue that its brand is legitimate. It is this sort of embarrassment the government is trying to avert by omitting brand name from licences. "On the pattern of the RNI (Registrar of Newspapers for India) website, we should have a website for all drug brands used in country — registered or unregistered — which pharma manufacturers can check to avoid duplication of brands," said CM Gulhati, a drug regulatory expert. [41]

**4.1.6 Generic Medicine promotion initiatives internationally:** The Government of Canada instituted an 18% upper cap on 6 majorly prescribed drugs such as Omeprazole and Atorvastatin. This would lead to them saving about 100 million CAD. Under this initiative, all manufacturers willing to supply the market at the 18% price point enter into agreement with Blue Cross in Alberta, the organizationthat was administering the plan. Their products were then to be listed on provincial/territorial drug benefit plan formularies. [42]

The situation in Italy is very similar to India's. The doctors were "advised" to write "Do Not Substitute" on the prescriptions (if they were not confident of the generic variety) by the Italian Federation of General Practitioners to ensure fairness to the patient. As of now in Italy, just 40% of the drugs prescribed are generic and the situation is expected to worsen as there has been a 5% increase in "Do Not Substitute" prescriptions. Currently, as in India there are no incentives for the doctors to prescribe generics while there is a strong Big Pharma- Doctor nexus already in place.[43]

Russia changed some of its drug regulation policies. They identified the fact that it was important to clarify the terminology used. Acceptance of clinical trials for drugs done outside the country is another positive steps, especially considering the fact that there were not enough patients available for tests of rare disease drugs. The government in Russia also ensures that the price increase is regulated, unlike Brazil which experienced on an average a 9% increase in prices of 94% drugs.[44]

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## 4.2 Field Findings and Impact on Theoretical Basis of Project

**4.2.1 Documentation of Prescriptions and Medicines disbursed:** Learned about the e-documentation protocol used by Guru Gobind Singh Government Hospital (Healthcare Information Management System) for prescriptions. However, there is no method in place to check which doctor disburses which medicine in real time. Also, the prescriptions are scanned, which ensures they are stored for future reference, but they are not digitalized which does not allow scope for easy data analysis.

The project has evolved to focus on an ideal E-Documentation system for drugs and prescriptions, tallying it with doctors.

**4.2.2 Doubtful quality of generics supplied at pharmacies:** Since the pharmaceutical companies are unregulated, one can never be sure of the quality of drugs supplied. Every batch of drugs supplied is accompanied by a Quality Test Report. But the efficacy of the drugs bothers many doctors. Due to this, many doctors out of concern for the patients prescribe expensive generics from outside the hospital.

The project has evolved to focus on Quality Testing of popular varieties of drugs available at stores and generic variety available at Jan Aushadhi stores/ government pharmacies supported by CPA.

**4.2.3 Trust deficit and Lack of a Feedback Loop:** The doctors are skeptical about the quality of drugs and prescribe expensive drugs to patients. While many doctors in the private sector may deny the pharma-doctor nexus, the public sector doctors I had the opportunity to meet, admit to the existence of black sheep in the medical fraternity.

Also, the drugs procured by the Central Procurement Authority (CPA) for patients of GGSGH, are through Tenders which allow any vendor to bid. This practice may result in sub-standard manufacturers supplying drugs. Doctors should be given a say, according to the specialists at GGSGH, in selecting which suppliers ought to be allowed.

Through the field visits, the 2 major reasons that contribute to this trust deficit were identified. These two reasons have been the crux of all recommendations offered via this report.

1. Lack of awareness of doctors on the quality of drugs available in the market
2. Lack of awareness of patients on the alternates available and where they are available

Let us look at this problem in detail.

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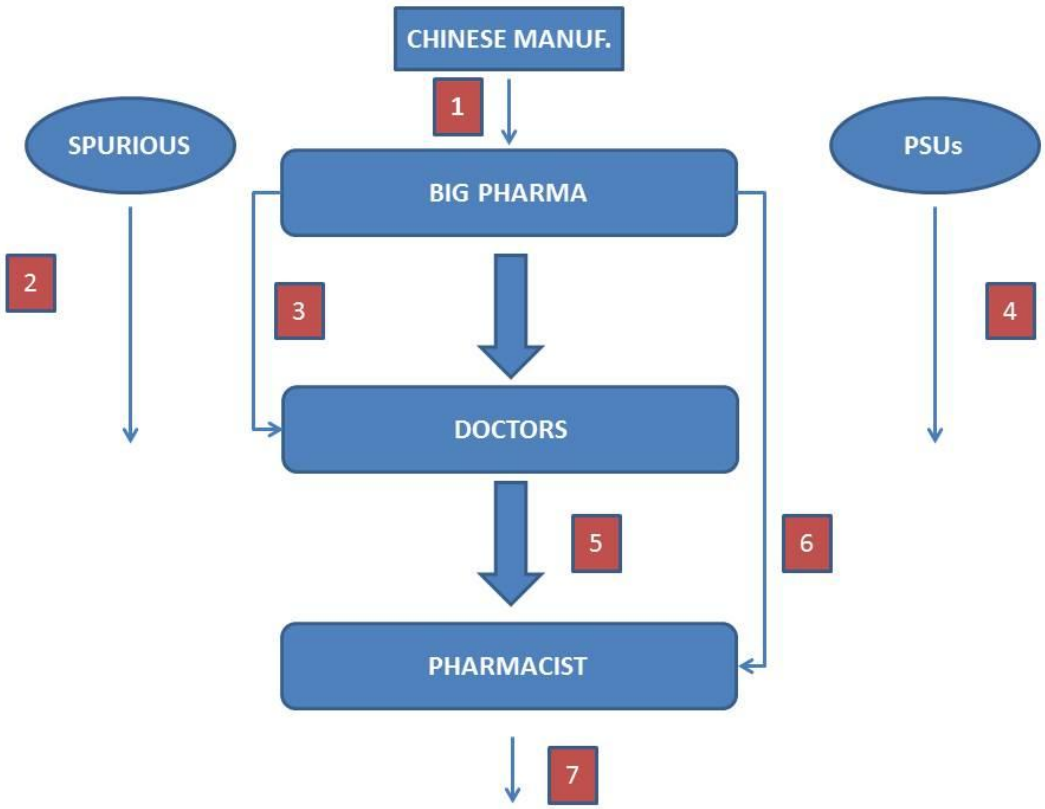


1. **Chinese Supply of therapeutic salts:** There are opinions among doctors that many small manufacturers who do not have their own manufacturing facility rely on Chinese suppliers for drug salts. These are of doubtful quality but since there has been little reporting done on this front, one does not know the magnitude of the same.

2. **Spurious Drugs in Market:** Due to the existence of spurious drugs in the market, the doctors are in a fix. They do not know the quality of the various suppliers in the market and hence, tend to prescribe branded generics from known/ reputed companies (more expensive)

3. **Big Pharma- Doctor Nexus:** The doctors are lured to prescribe the drugs of a particular company by the medical representatives of these companies. This is the only way by which many doctors come to know of the developments in the sector as the Continuing Medical Education (CME) program is not taken seriously by many practitioners. The doctors, mostly the junior doctors, are lured by kind and cash. One could attribute this to the low pay of the medical professional as compared to the other professions.

   Doctors sometimes prescribe drugs (as has been observed at a CGHS Wellness Center in NCR) in large quantities and numbers as against the WHO guidelines. Drugs are often prescribed more than 6/7 at a time.

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4. **PSUs and lack of marketing:** The PSUs are not able to convince the doctors that the drugs they manufacture are of same quality as the big-pharma. This results in the patients spending much more than necessary on drugs. One could attribute it to the fact that there is a wide spread notion among doctors that it is easy to get a quality certificate attributing adherence by the company

5. **Doctor-Pharmacist Nexus:** This results in a doctor recommending a particular pharmacy to patients who come to him/her for consultation.

6. **Big Pharma- Pharmacist Nexus:** Doctors, who adhere to the Code of Conduct, are afraid that if they prescribe the salt name, pharmacists will give drugs which offer them maximum commission. This will result in patients unnecessarily spending money on drugs of same quality. One could say that this stems from the lack of awareness of patients on the lack of options available to them. This motivates doctors to prescribe good quality branded generics.

7. **Pharmacist Dispensing:** Pharmacists sometimes give away spurious drugs unknowingly because they are unaware of the quality of these drugs. Computerization has helped prevent a major problem of expiry of drugs.

**4.2.4 Interrupted Supply of Drugs**: Predictive analysis could be employed to find out by when the new stock should be received and new tenders should be floated. The problem of new tenders usually results in supply interruption from CPA ranging from a few days to months at a secondary care government hospital in Delhi

The project has evolved to focus on the possible predictive analysis of government drug inventory and how to ensure there is never a short supply of drugs.

**4.2.5 Indenting of Drugs prevalent in Central Government Health Scheme Wellness Centers:** Due to the nexus operating between the hospital administrators and the pharmacists, many of the drugs are not available at a CGHS Pharmacy. These then have to be purchased from outside. The figures from the prescription analysis are below.

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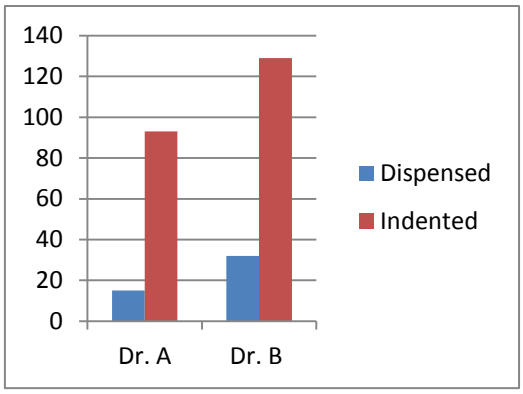


Figure 3- Indented vs Dispensed for CGHS Wellness Center in Delhi NCR

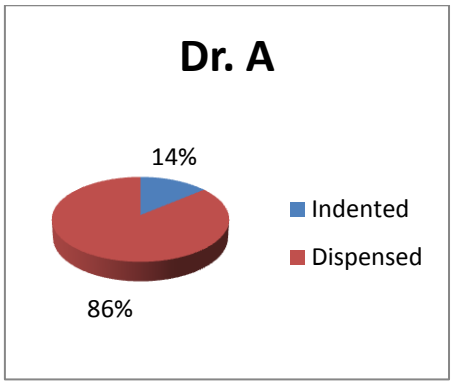


Figure 4- Prescription Analysis of Dr. A

## Dr. A: Total Prescriptions- 34; Average- 3.176

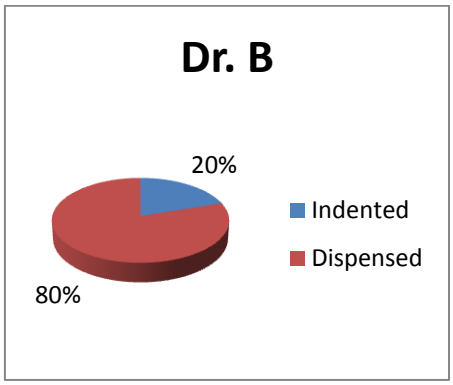


Figure 5-Prescription Analysis of Dr. B

## Dr. B: Total Prescriptions- 44; Average- 3.659

| | Total Amount | Number of Patients | Per capita expenditure |
|---|---|---|---|
| **Serving** | Rs 40437.49 | 61 | Rs 662.909 |
| **Retired** | Rs 7439.53 | 18 | Rs 413.307 |
| **Net** | Rs 47877.02 | 79 | Rs 606.038 |

Table 1- Cost Analysis of Indented Prescriptions for a day

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**4.2.6 Prescription Analysis**: Prescription Analysis was carried out to determine Generic vs Branded for prescriptions obtained for a state-run government hospital in New Delhi. It was carried out for 3 departments- General Medicine, Pediatrics and Surgery. Below are the findings.

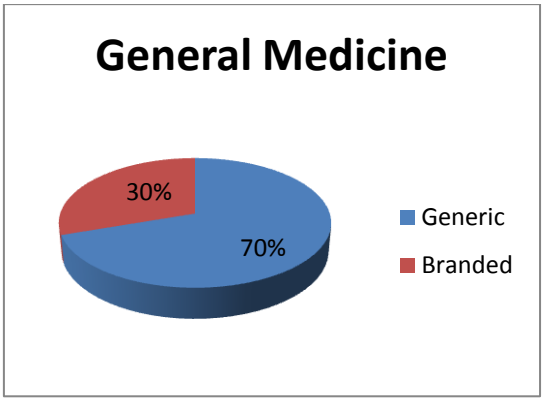


Figure 6- Prescription Analysis for General Medicine

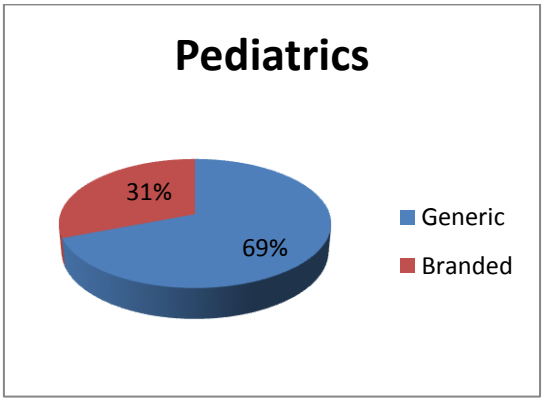


Figure 7- Prescription Analysis for Pediatrics

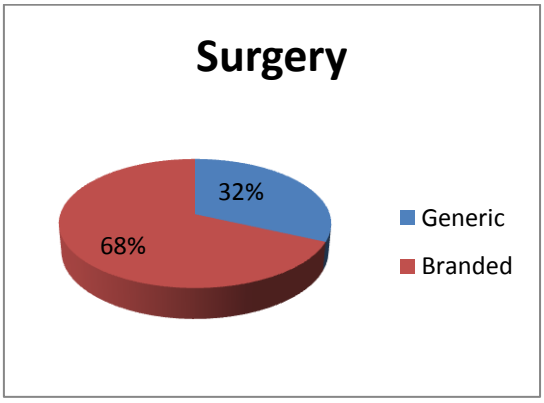


Figure 8- Prescription Analysis for Surgery

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### 4.3 Gap analysis

**4.3.1 Lack of Manpower and Equipment for Quality Monitoring:** CDSCO is substantially understaffed. Of the 327 sanctioned posts, only 124 are occupied. 1,045 additional posts that have been proposed but with the slow uptake of employees, these are not expected to be filled fast. If the manpower requirement of the CDSCO does not correspond with their volume of work, naturally, such shortage of staff strains the ability of the CDSCO to discharge its assigned functions efficiently. This shortcoming needs to be addressed quickly. Consideration can also be given to employ medically qualified persons as Consultants/Advisers (on the pattern of Planning Commission) at suitable rank.

There are presently 6 Central Drug Testing Laboratories at Hyderabad, Kolkata, Mumbai, Chennai, Guwahati and Chandigarh. These are not fully equipped "for testing/analyzing complex formulations and detect spurious, misbranded, sub-standard and adulterated drugs."The present drug testing capacity of the six laboratories is 8,000 samples per annum, which is targeted to be increased to 24,000 samples per annum

**4.3.2 Drug Quality at Jan Aushadhi Stores and other government stores:** Gujarat Medical Service Corporation (GMSC), Tamil Nadu Medical Service Corporation (TNMSC) and Rajasthan Medical Service Corporation (RMSC) follow strict quality standards in the supply of drugs and medicines being issued to the common public through various government hospitals.[45]The state of inferior quality medicines at Jan Aushadhi stores have been already discussed in Sections 1.1.4 and 3.2.3

Patients need to be made aware of asking doctors if a generic variety for the brand prescribed is available as many a time, doctors prescribe the branded drug fearing for the patient being provided drugs of inferior quality by the pharmacist.

**4.3.3 Prescription patterns of Doctors:** Doctors increasingly prescribe Line 2 or Line 3 drugs fearing for lack of effect of Line 1 drugs on patients. Apart from a lack of confidence that comes only through trying, there is an increased effort from the side of the pharma industry to build a rapport with the doctors through foreign trips, goodies and sometimes even, hefty amounts of cash.

A step to curb this would be to document the prescriptions in a way that it can be mapped to patients, doctors and which pharmacy the drug is disbursed from. A good Healthcare Information Management System for the entire country would be the key to regulation. This will help us in tracking which doctor is prescribing which branded drug in large quantities.

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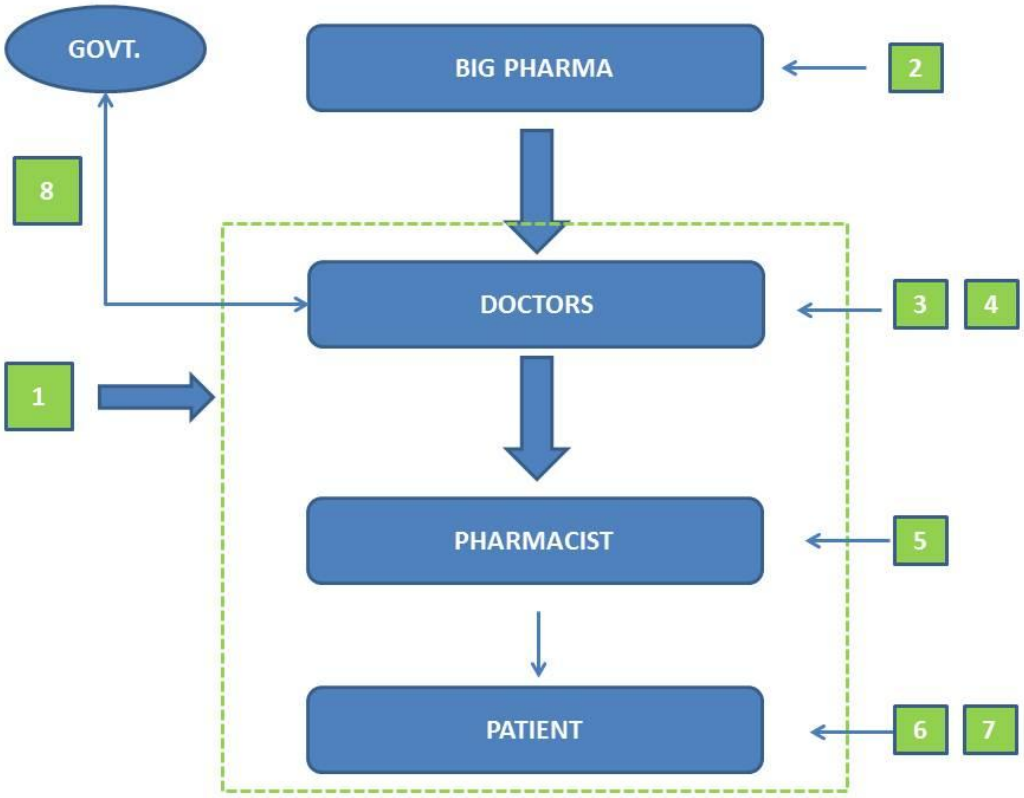
# 5. Recommendations, Scope and Strategy for Implementation




**5.1 Healthcare Management Information System:** A centralized system (preferably outsourced to TCS/ Infosys or HIMS specialists) is to be built, modeled along the lines of the HIMS of UK, where every doctor needs to sign in, enter the patient code (unique for each patient), prescribe drug and follow up. The drug disbursement is also to be mapped with a pharmacist logging in and updating the drugs supplied.

Issue: Will take time to implement in India due to the lack of training in IT, access to internet and the slower than required uptake of IT by the rural population

Use: This can help in ensuring greater transparency in drug prescriptions. One will be able to track the drugs prescribed by the doctor. The doctor thus can be monitored on which drugs he/she prescribes and we will be able to spot a possible nexus between a doctor and a pharmaceutical company.

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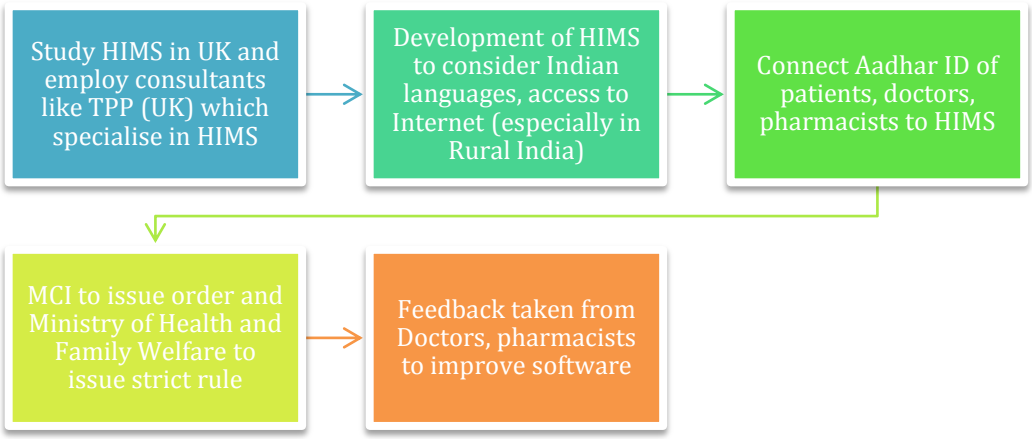


**Figure 9- Healthcare Information Management System- Process Flow**

A tentative layout of the HIMS has been arrived at. It has been divided into 3 major dashboards:

1. Doctor Dashboard
2. Patient Dashboard
3. Pharmacist Dashboard

The various issues pertaining to these dashboards have been discussed below and possible solutions are also provided.

**5.1.1 Doctor Dashboard**: The below diagram is a tentative outlay of the Doctor's Dashboard.

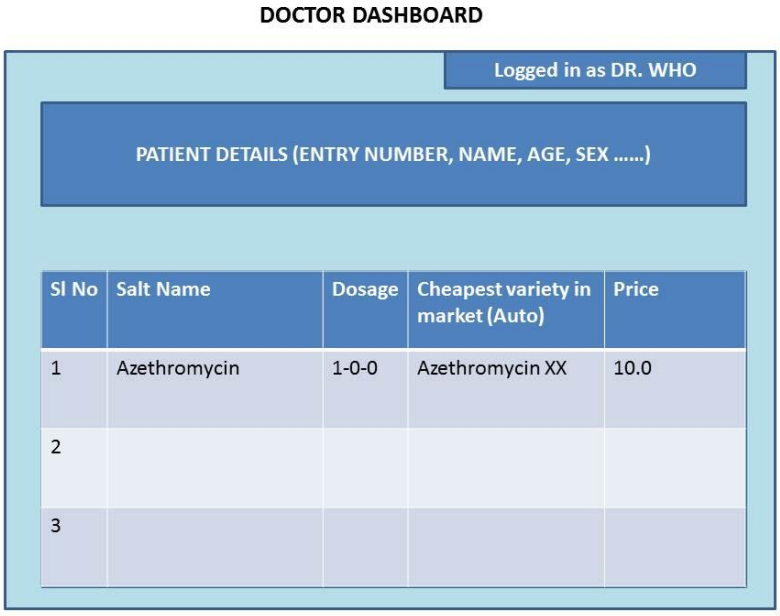


**Figure 10- Doctor Dashboard**

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The features proposed are

1. Patient details and case history to be made accessible
2. Auto complete for Salt name based on database of approved salts. Banned salts will be automatically removed from the database.
3. Cheapest variety will be an autocomplete column to show the patient the minimum total cost that can be incurred.
4. Through a Central Monitoring Setup, one can see which doctor has accessed whose prescriptions and when. This will counter the problems of data theft and ensure accountability.
5. One can also look at providing patients a password, which they enter in front of the doctor to ensure that data cannot be accessed by the doctor unless he/she has been granted access.

**5.1.2 Patient Dashboard**: The patient dashboard is accessible only by the patient. It is a comprehensive database of all diagnosis, prescriptions and case histories**.**

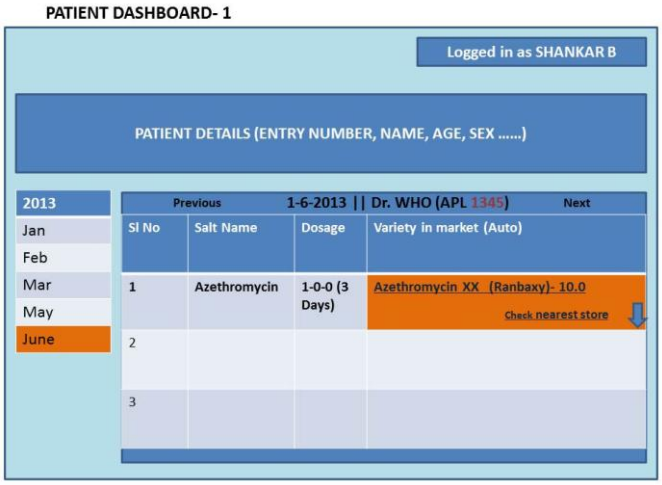


Figure 11- Patient Dashboard 1

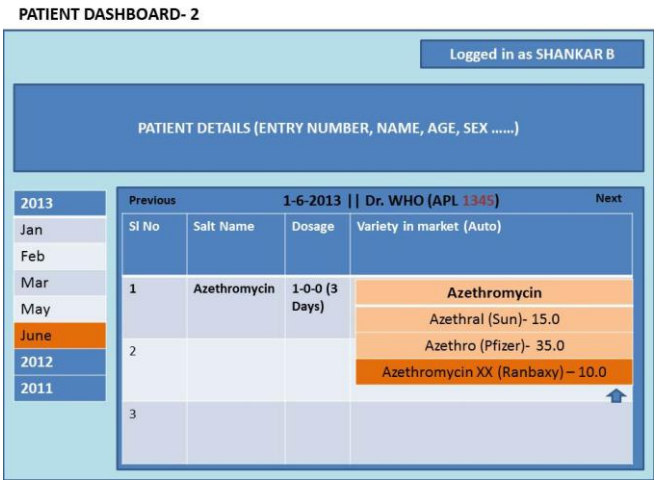


Figure 12- Patient Dashboard 2

The main features of Patient Dashboard are

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1. Prescription and Case History with Doctor Code (APL 1345 in Figure 6)
2. Variety of drugs in the market with a dropdown menu available. Once clicked, it will show the various brand names, manufacturers and price in the following format: *Drug Name(Manufacturer)- Price per unit.* This will solve the problem of lack awareness regarding alternates. Only those brands will be listed which are government approved. These will be subject to 3rd party quality verification as well. Additional quality measures need to be thought of to ensure patients do not get spurious/ low quality drugs.
3. Also available is the option to check the nearest store. One can assume that by basic market economics that pharmacists will put up the drugs available in their stores to ensure sale. In this way, the patient knows which drug is available where.

**5.1.3 Pharmacist Dashboard**: The pharmacist dashboard will give the pharmacist access to the patient's recent prescriptions and the current prescription. It will also tell the patient what all drugs prescribed (salts) have been provided, and which brand.

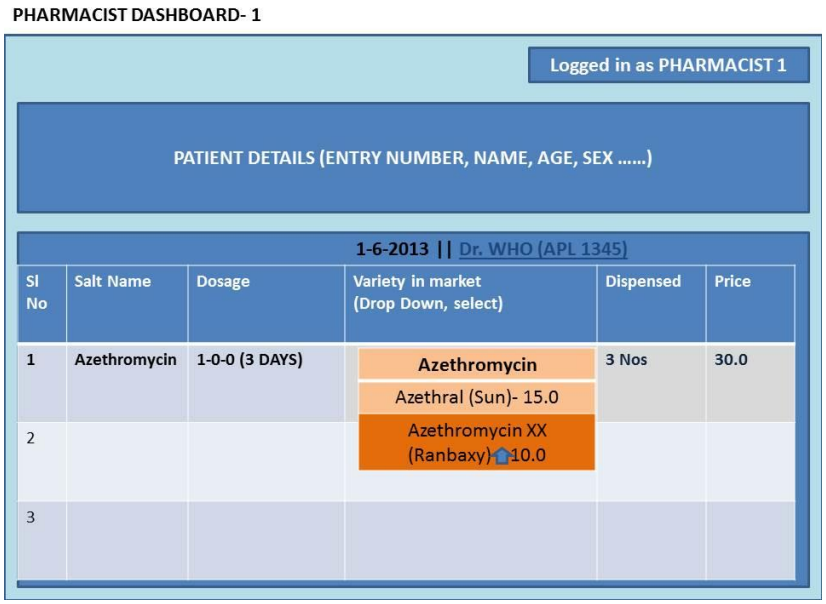


Figure 13- Pharmacist Dashboard 1

The features of Pharmacist Dashboard 1 are

1. Access to patient prescriptions (recent + current)
2. Access to patient information to ensure only those drugs are provided which are MCI approved for a particular demography.
3. Amount dispensed which will give the patient an idea of how many more drugs need to be purchased of the same type

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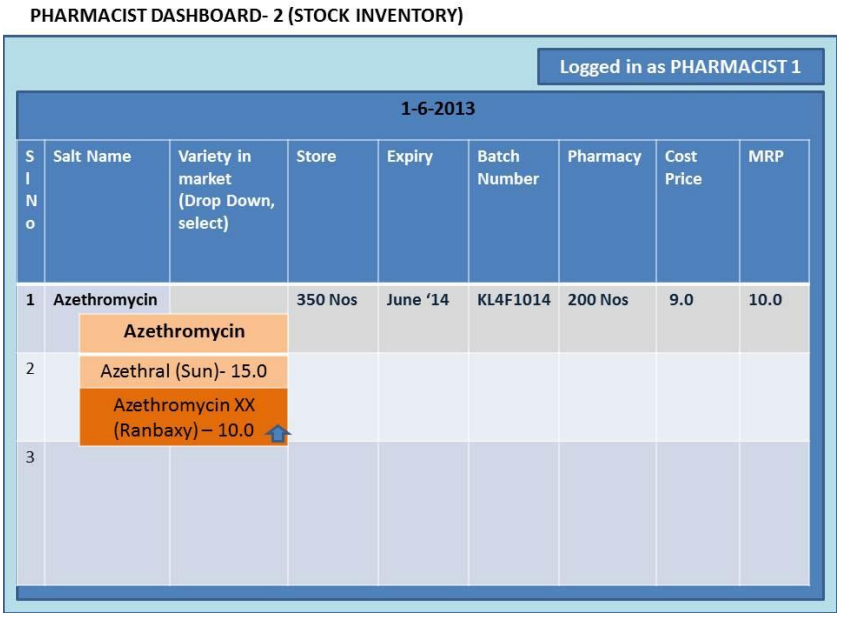


Figure 14- Pharmacist Dashboard 2

The features of Pharmacist Dashboard 2 are

1. Basic stock inventory which can be accessed remotely
2. Option of giving brand wise stocks listed under a salt to ensure patients are given true information

**5.1.4 Issues and Solutions**: These are some of the issues that one could think of with possible solutions

**ISSUE**

With the existing IT infrastructure, it might not be possible to setup this system in a PAN-India scale. Also, data security becomes a major issue as some patients might not want their data to be electronically stored.

**SOLUTION**

One could do a Pilot run in Delhi NCR where many of the hospitals have begun computerization. The software could be outsourced to specialists in the sector such as TPP of UK. This will eliminate the need for paper and ensure that one knows which doctor is prescribing what drug. For the same, we need a compatible computer to be setup in all consultation rooms of hospitals (both private and government).

Also, the government needs to pump in more resources to develop cheaper computing infrastructure. Aakash 4 tablets which are presently being developed by IIT Madras could be customized to support doctors.

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**ISSUE**

Data security becomes a major issue as some patients might not want their data to be electronically stored.

**SOLUTION**

Awareness can be created regarding how useful the same is. Even though the proposed system (majorly meant for prescriptions, but can be customized for diagnosis also) would not be implemented in the next 5 years, there can be a strong drive from the government.

In the UK, an option is given to the patient to opt out of the system. Also, there needs to be dedicated data security teams in place who can ensure that data security is not compromised.

**ISSUE**

Fake logins could come about which might spur the growth of quacks

**SOLUTION**

Doctors to be warned as in UK, that if they compromise on patient data, then their licenses might get suspended and access revoked from the system. Also, they must be encouraged to not share their logins with anyone.

The logins could be given to the upcoming doctors as soon as they finish their graduation. The senior doctors could be asked to take their logins from a government office.

**ISSUE**

Patients might not have the required IT infrastructure to access information and hence might not be able to utilize the system's capabilities fully.

**SOLUTION**

The government's plan of ensuring computer literacy for atleast one member of every family is a good initiative. Also, the staff at the Common Service Centers could be trained to support the patients in this. The HIMS, if implemented, could be a useful tool for e-governance.

**ISSUE**

Pharmacists might not put up the data regarding their stocks

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**SOLUTION**

Patients could be duped by pharmacists who will not be transparent. The best way to ensure this is to have a chain of government shops that dispense medicines at reasonable price for the community it caters to. Jan Aushadhi stores need to be revamped and till such a HIMS comes through, one could go for the IVRS based patient information accessibility method as is used by the Rajasthan government.

### 5.2 Revamping the CDSCO

The Central Drug Standards Control Organization needs to be fully equipped andstaffed. The BrajeshPathak Parliamentary Committee report highlights some major issues with the quality control body for drugs in India.

1. CDSCO should inspect the manufacturing facilities of all drug marketersin the country
2. Reports should be published which highlight comparativequality study and this data should be used for promotional campaigns ( Section 5.6)
3. The banned drugs should be removed from the HIMS and doctors should be notified via e-mail
4. Comparative study of results obtained by CDSCO test labs and 3rd party labs should be done.

**ISSUE**

Possibility of reports being tampered or quality reports being bribed through

**SOLUTION**

CDSCO to be given the CAG status of a watchdog, rather than a facilitator of quality assurance certificates.In this regard, the CDSCO is to be made powerful by policies.

### 5.3 Public Private Partnership Workshops

From Dr. Kalra's study [46] we were able to understand that post-intervention, the prescriptionpercentage of drugs by generic name goes up. This gradually comes down in about 2 months.

There is a lack of emphasis placed on Continuing Medical Education. Doctors in manycases come to know of pharma developments only via the medical representatives.To support intervention programs that impart valuable knowledge to doctors, the CSR funds of MNCs can be tapped into. We can go about the PPP Workshops in 2 ways

1. Training by government doctors, resources supplied by private companies
2. Training by private agency, resourcesfrom government

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Based on the present scenario with regard to initiatives/ PPP in India, option 1 seems like a better choice

**ISSUE**

Difficult to conduct trainings and follow up with doctors all over the country. A program of this size will face many hurdles with regard to implementation.

**SOLUTION**

Conducting intervention camps at district level (department-wise) would be an option. Also, a good mechanism of post-intervention follow up needs to be arrived at. It will be worked on while continuing the project.

**5.4 Supportive Care at Hospitals:**While interacting with some doctors from a government hospital in New Delhi,it was suprising to learn about the high rate of prescriptions of Line 2 and Line 3 drugs, even to young children. This will greatly increase the possibility of microbes getting resistant to antibiotics and result in MDR organisms.

Dr. Sangeetha Rani, Head of Department at GGSGH, who I had met on the recommendation of my mentor, had emphasized on the willingness and proper training of support staff like Nurses. If good supportive care is provided to the patient, the need of going for higher line drugs will be non-existent except in exceptional cases. Usually doctors blindly follow their seniors and not the guidelines in prescribing higher line drugs because they want assured results. But the doctors at GGSGH, New Delhi insist on the fact that Line 1 drugs are equally effective and sometimes more effective, while being less harmful to the body.

**5.5 More generic drug stores to be setup; Jan Aushadhi revamp!**

Pharmacists in the private sector should be given an option of stocking up on good quality government drugs. That would be the ideal case. Else, the government needs to speed up the process of setting up Jan Aushadhi stores in conjunction with the various NGOs that work in the area. Rajasthan, Karnataka and recently, Jammu & Kashmir have been in the news for taking up such initiatives. Below are outlined the steps which Dr. Samit Sharma[17] (the iconic IAS officer portrayed in SatyamevJayate) who was responsible for setting up generic drug stores in Rajasthan recommends.

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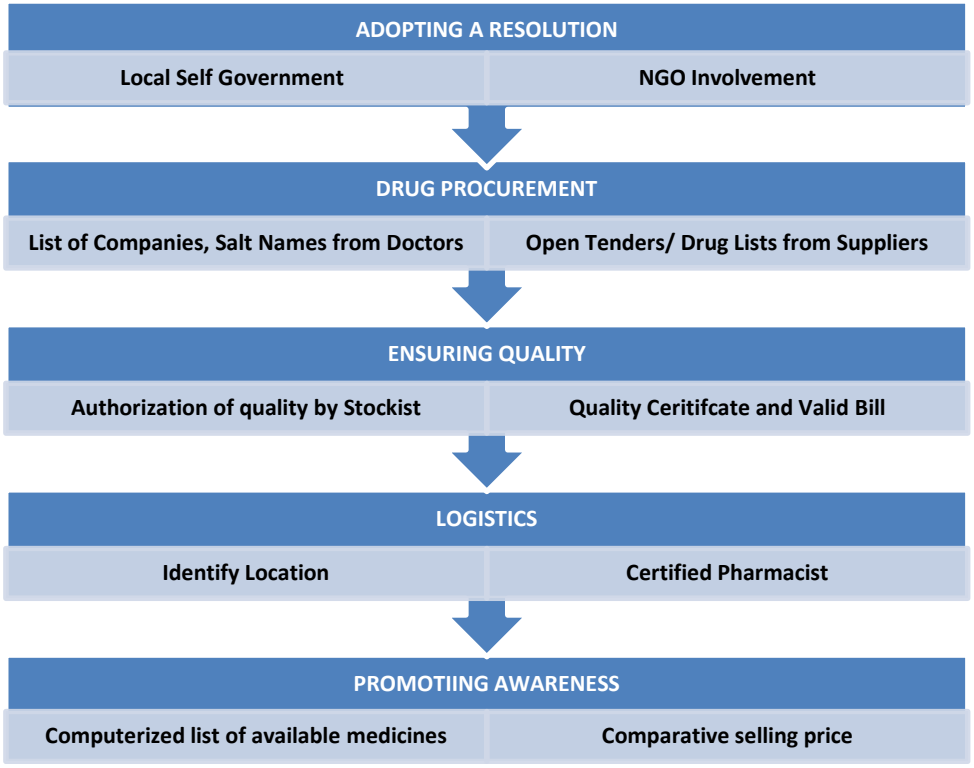


Figure 15- Steps to setup a Generic Store

**5.6 Promoting awareness of Generic Drugs:** Not only the low-income class, the middle class are also unaware of the alternates available for the expensive drugs. To target them, the best option would be to go for a multi-pronged approach.

1. Use of Social Media to target youngesters
2. Use of Doordarshan, All India Radio to target the low-income group
3. Use of FM stations to give info-beats as a part of CSR
4. Newspapers and magazines to run coverages on CDSCO functioning and drug scenario in the country

The above are just few of the possible measures that could be undertaken.

**5.7 Interactive Voice Response System:** For those who have limited access to internet, IVRS offers the perfect way to know more about the drug alternates. Once a doctor prescribes a drug, if the name is readable or even if it's barely recognizable (diagnosis can help), one can ring up a government line which gives the enquirer information regarding the availability of the drug nearby or the possible alternates (government approved)

**5.8 Feedback Loop between Doctors and Administrators:** As of now, doctors are the ones on-ground who know about the efficacy of the drugs which are available in the generic stores. They have to be consulted while shortlisting tenders for supply and if a supplier has not met the quality standards then they have to be penalized/ fined.

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**Figure 16- Feedback Loop between Doctors and Policy Makers**

## ISSUE

Trust deficit at multiple levels. Doctors could be accused of bias. However, this will ensure quality is not compromised for price (assuming doctors are recommending a drug genuinely)

## SOLUTION

Consider opinions only for the sake of elimination. Acceptance to be governed by CDSCO which will put all drugs of good quality on common grounds.

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# 6. Future Work


Figure 17- Future Work

**6.1 PPP Workshops:** (as discussed in Section 5.3)

**6.2 Prescription Analysis:** The prescriptions of doctors from a Government Hospital in New Delhi were studied. Private consultants' prescriptions and those from PHCs, CGHS Wellness Centers and Government Hospitals in Tamil Nadu where generics are prevalent need to be studied

**6.3 Predictive Analysis for Stock Outage:** This is just a trial run. Data from a government hospital was obtained for 6 days. A sample graph is shown below.

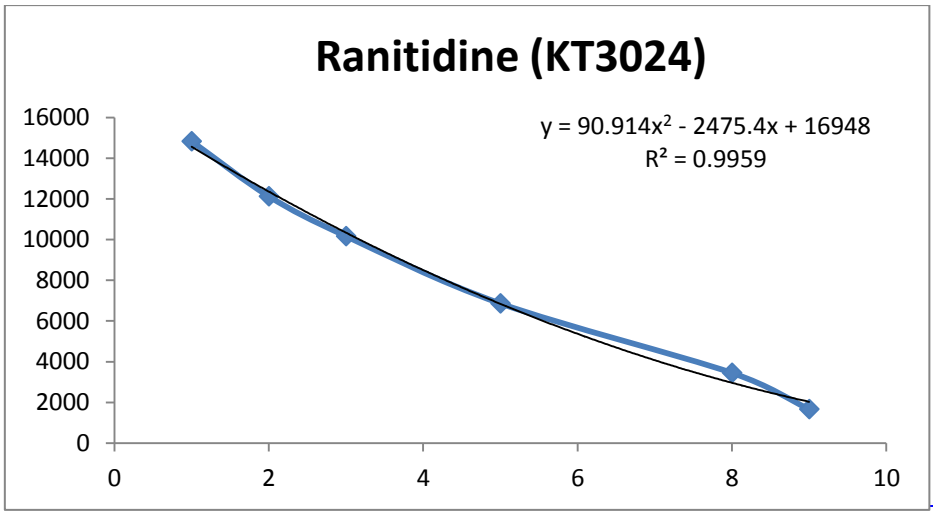


Figure 18- Ranitidine stock behaviour

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**6.4 Policy to strengthen CDSCO:** Identification of problems regarding quality monitoring have been presented in multiple reports. CDSCO should be as powerful as the CAG which regulates accounts. For that one needs to suggest possible policy measures.

**6.5 Feedback Loop for Doctors-Administration:** This was discussed in Section 5.8.

**6.6 Comparative Study of Drugs Quality:** The quality of multiple brands of the same salt will be studied. Through this one will be able to ascertain whether the cheaper versions are of same quality as the branded generics.

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## Appendix A

**Meetings and Interviews**

**Date:** May 19, 2013

**Time:** 11:30 AM

**Duration of Discussion: 5** minutes

**Discussion**

1. Meet with officials in the different government organizations
2. Dr. Kaur to identify field areas which could be optimal considering the duration of the internship
3. Sample space for the project (interviewees) to be not elaborate but feasible
4. CHS and ESI to be probable organizations to study in New Delhi

**Action Items before Next Discussion**

1. Review literature with a paragraph summary and send it to Dr. Kaur once the tally reaches ~15 (1 week)
2. Buy Park's "Textbook of Preventive and Social Medicine 21E"

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**Date:** May 24, 2013

**Time:** 5:30 PM

**Duration of Discussion: 5** minutes

**Discussion (in Detail)**

1. RTI Format which had been sent to review approved. List of drugs which need to be enquired of to be sent by Dr. Kaur after consulting the latest National List of Essential Medicines, which is to be obtained from the Ministry of Health and Family Welfare
2. The Sample Field is to be identified by next weekend. 3 major hospitals- ESI Hospital (Okhla), General Hospital of the Govt. of Delhi, CHS
3. Appointments with the officer responsible for Generic Drugs (Deputy Drug Control General) to be fixed by Dr. Kaur
4. Post-talking to the DDCG, Joint Secretary and other officials to be met. Dr. Kaur to fix appointments before June 4th, 2013.
5. Field Area: Pharmacists, Doctors to be interviewed. The pharmacists can be approached early in the morning once the pharmacy opens to avoid rush.
6. Field Area: Patients need to be screened via Knowledge Aptitude Practice to test awareness of generic drugs before interview. Reasons for lack of awareness to be identified.

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7. Field Area: Tools (questionnaires) to be prepared for Interview, Feedback
8. Mid June- Appointments and Interviews done

   End June- Data collection ends

   Early July- Data Analysis

9. Government general stores at the regional level and state level, State stores and CHS stores to be visited for site visits. Delhi depot and Karnal depot to be visited after appointments have been fixed by Dr. Kaur

**Action Items before Next Discussion**

1. Appointments with regard to Generic Drugs in Ministry, Hospital Visits, Pharmacy/ Store/ Depot visits (1 week)
2. Essential drugs for RTI filing to be identified as early as possible (3 days)

"The highest measure of democracy is neither the
'extent of freedom' nor the 'extent of equality' but
rather the highest measure of participation."
- A.D. Benoist

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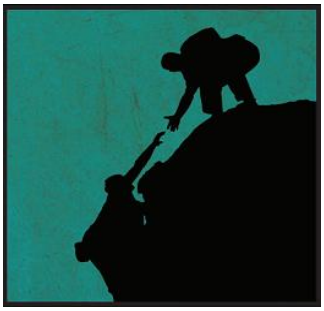

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