Chapter 3

Access to Medicines, Vaccines and Technology

1. The Role of Medicines in Achieving Universal Health Coverage

Medicines are a major component of modern health systems today and have helped to significantly reduce the burden of deaths and disease the world over. Despite the availability of adequate knowledge, technology and skills to innovate and develop new drugs, the global community faces tremendous challenges in prioritizing and delivering essential medicines to vulnerable populations who are in urgent need of them, while limiting the consumption of non-essential and expensive medicines by those who do not need them.

The past six decades of health and drug policies in India reflect this trend and highlight these challenges. The 20 year period between 1950s and early 1970s witnessed high drug prices and the dominance of transnational drug companies. This eventually gave way to a self-sufficient era post-1970s. However, since the initiation of market friendly economic reforms, drug prices have risen significantly. India's drug market structure is presently vulnerable to control by multinational companies who are beginning to take over the dynamic domestic generic drug industry.

Due to under-investment in public health and under-funding of drug procurement, many Indians are experiencing an impoverishment and are driven to debt and asset loss. Targeted approaches have not yielded results and have even led to distortion of the health system. Access to healthcare and to drugs must be therefore based on the principles of universalism, equity, efficiency and quality. The primary objective of any strategy in providing universal access to medicines is to remove financial risks and make prepayment a prerequisite. This must be complemented by cross-subsidising those who cannot afford medicines (poor and non-poor alike).[1]

Governments need to commit a higher level of spending on drugs to reduce inter-state and inter-district disparities in drug spending which become barriers to access and affordability. Advancing the cause of Universal Health Coverage is predicated on the assumption that efficient use of resources will be achieved. Unnecessary spending on non-essential medicines has to be reduced and irrational use eliminated. Improving overall governance and accountability of medicine supply system is absolutely essential to make medicines available to one and all.

2. Situational Analysis

a) Barriers to Access to Medicines, Vaccines and Technology

India's drug policies over the years have created an environment of duality. The country not only produces enough drugs to meet domestic consumption, but as one of the largest exporters of generic and branded drugs, is also known as the 'global pharmacy of the south.' India exports life-saving drugs to developing countries and also supplies quality drugs to the rich nations at affordable prices. Despite this seemingly commendable performance, millions of Indian households do not have access to drugs.[2] This results from both financial (lack of the necessary purchasing power) and physical (lack of public health facilities) barriers.

Evidence from large sample surveys of households over the last 25 years suggests that the impediments to access of medicines have become steeper. During the mid 1980s, approximately a third of the drugs prescribed during hospitalisation were supplied for free. This declined sharply to only about 9 % by 2004. Free drug supply for out-patient care has fallen from 18 % to about 5 % over the same period (see Table 1).

TABLE 1. TRENDS IN ACCESS TO MEDICINES IN INDIA — 1986-87 TO 2004

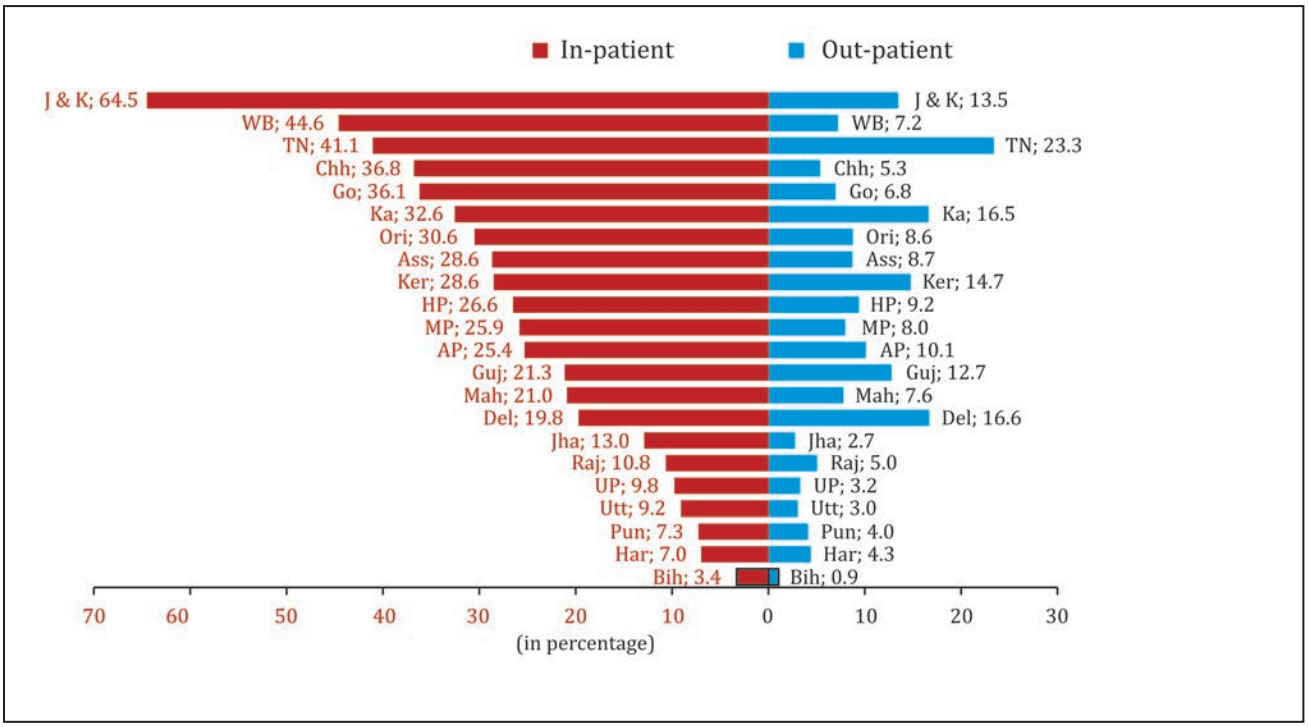
Period	Free Medicines	Partly Free	On Payment	Not Received	Total (In %)
In-patient					
1986-87	31.20	15.00	40.95	12.85	100
1995-96	12.29	13.15	67.75	6.80	100
2004	8.99	16.38	71.79	2.84	100
Out-patient					
1986-87	17.98	4.36	65.55	12.11	100
1995-96	7.21	2.71	79.32	10.76	100
2004	5.34	3.38	65.27	26.01	100

Source: Health data extracted from National Sample Survey Rounds 60, 52, and 42.[3-5]

During the same period, the number of hospitalisation episodes in which an ailing population paid out-of- pocket (OOP), has risen dramatically from about 41 % to close to 72 %. As far as out-patient care is concerned, the proportion of drugs fully purchased by households decreased from as high as 80% in the mid-1990s to 65 % in 2004. Table 1 shows that since medicines have started becoming unaffordable since the mid-1990s, by 2004, in over one-fourth of out-patient episodes, patients did not receive medicines because they could not afford them.

Figure 1 shows how heavily the Indian population is dependent on private chemists. The availability of free or partially free drugs in out-patient care is extremely low. This highlights the limited protection offered by the government and the preponderance of private players in drug prescription and dispensing. State-wise evidence from Figure 1 shows that people in some of the southern states appear to have relatively better access to medicines than in the other states. The success of the Tamil Nadu Medical Services Corporation (TNMSC) model is clearly reflected in the proportion of people able to obtain medicines free/ partly free from public health facilities. The Tamil Nadu figure is close to 25% in the case of Tamil Nadu, followed by Karnataka, Kerala and Delhi. The lower percentage share in other states indicates higher reliance on private chemists.

FIGURE 1: STATE-WISE BREAK-UP OF FREE/PARTLY FREE MEDICINES FROM PUBLIC HEALTH FACILITIES DURING 2004

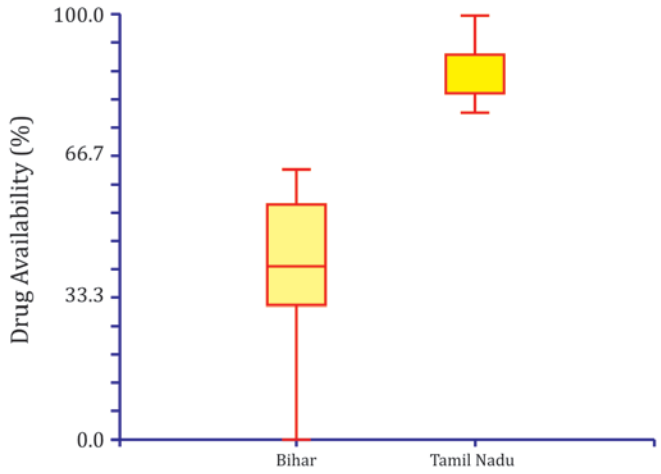


Source: Data extracted from Unit Level Records of Health Surveys of NSSO, 2004[5]

Published literature on drug availability and drug stock-outs in India is limited.[6-8] Cameron et al. (2008) show that the median availability of critical drugs in the public health system was about 30% in Chennai, 10% in Haryana, 12.5% in Karnataka, 3.3% in Maharashtra (12 districts) and 0% in West Bengal.[8] In Rajasthan, Lalvani et al. (2003) point out that the Essential Drug List (EDL) was inadequately implemented, resulting in the availability of essential drugs only to the extent of about 45%.[6] However, when EDL was expanded to include health facility lists, drug availability improved to about 76%. Further, their study also revealed that public facilities recorded out-of-stock drugs much more often (about 17% of the days) than the non-governmental health facilities (roughly 3% of the days).

A recent study of Tamil Nadu and Bihar by Selvaraj et al. (2010) shows that the mean availability of the basket of EDL drugs for Bihar on the day of the survey was about 43% as against roughly 88% for Tamil Nadu.[9] As far as drug stock-outs were concerned, Bihar's health facilities registered an average of 42% stock-outs, with a mean duration of 105 days, in the previous 6 months of the survey period. On the other hand, the proportion of drug stock-outs for Tamil Nadu stands at around 17%, with an average duration of about 50 days (Figure 2).

FIGURE 2: COMPARATIVE ANALYSIS OF AVAILABILITY OF DRUGS ON DAY OF SURVEY IN BIHAR AND TAMIL NADU (%)



Source: Selvaraj et al. (2010)[9]

Box 1: Acute Shortages & Chronic Stock-outs: A Study in Contrast (2010)

- The average availability of a basket of essential drugs in Bihar was 43% as against 88% in Tamil Nadu;
- Bihar's health facilities registered an average of 42% stock-outs of drugs with a mean duration of 105 days;
- The proportion of stock-outs for Tamil Nadu stands around 17%, with an average duration of 50 days

Within each state, moreover, there are wide variations between districts, especially in the health facilities of Bihar. In terms of availability of drugs, the variation ranged from 0% for the district of Darbhanga to 63.64% for Vaishali. Similarly, the period of drug stock-outs ranged from 100% for Darbhanga and Muzzafarpur to 22.73% for Nalanda. In Tamil Nadu, medicine availability ranged from as high as 100% at Nammakal to the lowest recorded at 77% at Nagapattinam and Tuticorin, which is far above the average of Bihar.

India has traditionally been self-sufficient in vaccine production and is also an exporter of certain vaccines. Despite this, immunisation coverage in the country has been extremely limited. Evidence from the last two decades, drawn largely from National Family Health Surveys (NFHS 1-3), shows only a marginal increase in or stagnant coverage rates of immunisation.[10] The Expanded Program of Immunisation (EPI) covers BCG, Polio, DPT, and measles. Full immunisation coverage, in children aged 12-23 months, stood at 44% in 2005-06 as against 42% in 1998-99. While eight economically advanced states reported a decline in immunisation coverage rates, a few backward states have reported marginally improved immunisation coverage rates during this period.[10] However, the recent shortages of vaccines in India created by the shutdown of vaccine producing Public Sector Units (PSUs) have raised doubts about maintaining self- sufficiency in vaccine production, especially for Universal Immunisation Program (UIP) vaccines.[11]

b) Factors Affecting Access to Medicines

Since access to essential medicines is a critical component of an effective health system, it is imperative that good quality and safe medicines remain accessible, available and affordable to the beneficiaries. However, many countries and regions face several barriers in expanding access to medicines. These include: 1) unreliable medicine supply systems; 2) poor quality of medicines; 3) irrational prescription, dispensing and use; 4) unaffordable drug pricing; 5) unfair health financing mechanisms; 6) inadequate funding for research in neglected diseases and finally; 7) a stringent product patent regime.[12]

i. Inefficient and Iniquitous Financing Mechanisms

An efficient financing mechanism in the health sector is predicated on the three principles of **prepayment, risk-pooling and cross-subsidisation.** Out-of-pocket (OOP) payment is the most inefficient way of financing, as all 3 principles are absent; while a tax-based financing mechanism relies on these 3 principles. India's underfunded public health system has, over the years, pushed households to rely largely on OOP spending as a mechanism of paying for healthcare. Currently, in India the ratio of private to public spending is nearly 4:1, with over 71% of all OOP expenditure of households accounted for by drugs alone.[13] Meanwhile, the current efforts of the Government (both Central and State governments) veer towards providing publicly-funded health insurance coverage to vulnerable populations for hospitalisation care.

It is argued that social health insurance could help provide financial risk protection to the population. The underlying focus of such health insurance schemes (the Central government sponsored Rashtriya Bhima Suraksha Yojana, Rajiv Aarogyasri in Andhra Pradesh, Vajpayee Aarogyasri in Karnataka and the Kalaignar scheme in Tamil Nadu) is hospitalisation coverage, which is intended to mitigate the problems of unpredictable low-frequency high-cost treatments. Available evidence, however, clearly points to the need for addressing OOP spending on out-patient care, especially on purchase of drugs by households. This arises from drip-by-drip household spending on drugs, which are a result of high-frequency low-cost treatment. None of the current health insurance schemes cover out-patient expenses.[14]

Under-funding has not only resulted in acute shortages and chronic drug stock-outs in the public health system, but also significant financial vulnerability for both the poor and non-poor. As a result of this, poor populations are pulled even deeper into poverty (poverty-deepening), while a large number of above-poverty line households are subsequently pulled below the poverty line every year.[15-17] In addition, a large section of society ends up making catastrophic payments for healthcare, leading to depletion of savings, sale of assets, and incurrence of debts from usurious moneylenders.

Public spending on drugs is extremely low, with huge variation between states and across districts within a state. As evident in Table 2, data from 2010-2011 indicates that about 10-12% of the health spending in the states of Tamil Nadu and Kerala goes towards procuring drugs as against the 2-3% spent on drugs by states like Jharkhand, Punjab and Rajasthan. While there has been a significant improvement in drug procurement in the state of Bihar during this period as a result of increased allocation of NRHM funds, the financial allocation for drug purchase by the government and level of drug allocation and procurement were extremely low in earlier years. Despite a recent steep rise, states like Bihar are still spending a very little (Rs. 8 per capita) on drugs.

Skewed priorities in drug spending by governments are a stark reality in several states. At the one end of the spectrum are states like Rajasthan and Odisha, which are reported to have spent over 90% of resources on tertiary care medicines, followed by states such as Gujarat, West Bengal and Punjab who have allocated over 70% of their drug expenditure on tertiary care drugs.[9] At the other end of the list are states like Chattisgarh, Tamil Nadu, Jharkhand and Karnataka, where over half of all drug spending has gone into primary and secondary care.

TABLE 2. TRENDS IN STATE WISE GOVERNMENT DRUG EXPENDITURE IN INDIA						
State Name	State wise Government Drug Expenditure in India					
	2001-02			2010-11		
	Overall (Lakh)	Per Capita (Rs.)	Drug Exp. as % of HE	Overall (Lakh)	Per Capita (Rs.)	Drug Exp. as % of HE
Assam	1530	5.7	4.7	8635	28.5	5
Bihar	2203	2.6	3.1	13350	13.8	7
Gujarat	2693	5.3	3.7	15431	26.4	7.6
Haryana	3096	14.7	9.8	6090	24.2	5.5
Kerala	12420	38.9	17	24861	72.3	12.5
Maharashtra	20305	20.8	11.3	20882	18.7	5.2
Madhya Pradesh	7921	13.0	11.8	12213	17.1	9.3
Punjab	916	3.7	1.4	1545	5.6	1
Rajasthan	9045	15.9	9.3	3854	5.7	1.5
Uttar Pradesh	7104	4.2	5.2	31481	15.9	5.3
Jharkhand	NA	NA	NA	2716	8.7	3.4
West Bengal	5798	7.2	4.3	21403	24.1	6.8
Andhra Pradesh	12704	16.6	9.6	23458	27.9	10
Karnataka	7783	14.7	7.9	14831	25.1	6.3
Tamil Nadu	18097	28.9	15.3	43657	65.0	12.2
Himachal Pradesh	NA	NA	NA	1122	16.6	1.9
Jammu & Kashmir	NA	NA	NA	4550	39.2	4.3
Central Government	72649	7	12.2	253368	21	15
All India	**188903**	**18**	**9.6**	**503447**	**43**	**13**

Source: HLEG Secretariat, based on state-wise Budget Documents and Demands for Grants.

Note: HE – Denotes Health Expenditure

ii. High Drug Prices

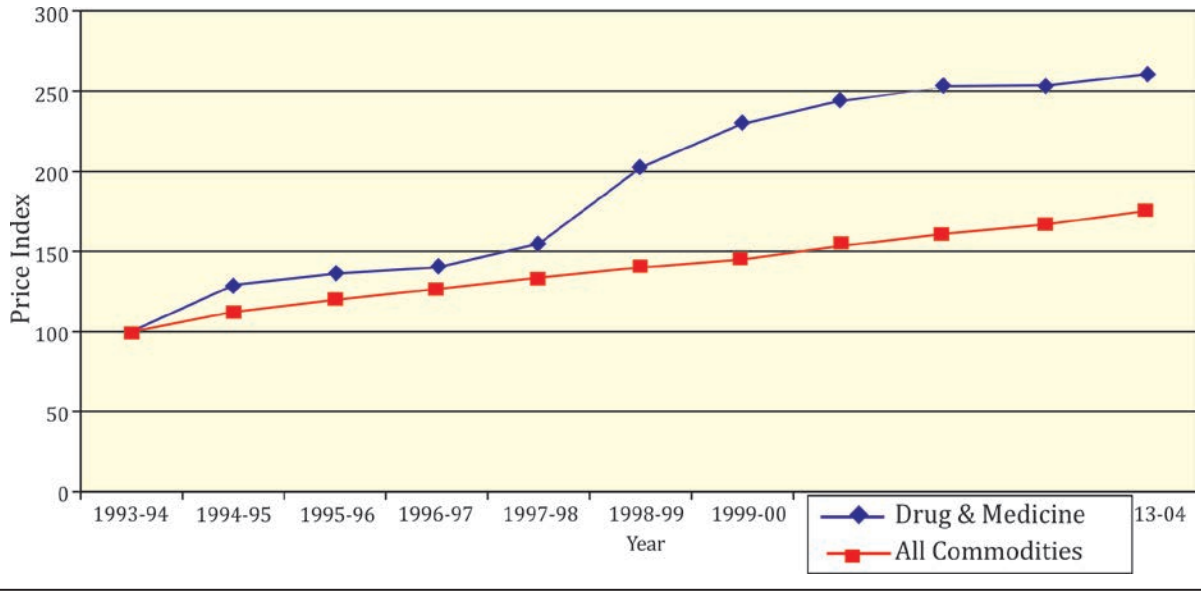
Drug prices play a significant role in the access to medicines, health service provision and financing particularly in low income countries dominated by the private sector and with weak to absent social health insurance systems. From a position of high drug prices in the pre-1970s era in India, rapidly growing domestic drug companies aided by effective drug policies are now capable of indigenously producing both bulk drugs and formulations, to a large extent. This has resulted in a situation in the country, where relatively speaking, drug prices are presently among the lowest in the world. However, policy changes in the 1990s reduced the coverage of drug price control from about 90% of the market in late 1970s to about 10% of the market in 1995.

Taking advantage of lax regulations on drug pricing, the pharmaceutical industry has been able to reap high margins through complex price setting activities. It has been observed that the price of a therapeutically similar drug could vary around 1000% between the most expensive and the cheapest brands.[18] Further, the variation between the market and procurement price of similar drugs could range anywhere between 100% to 5000%.[19]

Studies in the past few years have clearly demonstrated the effectiveness of price control. Sengupta et al. (2008) reported a nearly 40% increase in all drug prices between the period of 1996 and 2006.[18] During the same period, the price of controlled drugs rose only by 0.02% while the price of EDL drugs (Essential Drug List) rose by 15%. In contrast, the price of drugs that were neither under price control nor under the EDL grew by 137%. The price decontrol policies of the 1990s have contributed to an enormous price increase during the last 15 years.

Drug prices have shot up phenomenally, as shown in Figure 3 and have widened vis-à-vis general price trends during 1993-94 to 2003-04. The current practice of drug price control is based on cost-plus pricing. This can be an effective mechanism if the government is able to obtain cost data accurately. However, it is nearly impossible to get accurate cost data from companies, as it is not mandatory for them to provide such data. In the absence of precise cost data, pharmaceutical companies tend to project a higher base cost in the initial period, in addition to higher margins charged by manufacturers, wholesalers, stockists and retailers.

FIGURE 3: TRENDS IN PHARMACEUTICAL AND ALL COMMODITY PRICE INDEX



Source: HLEG Secretariat, Aggregated data from Respective Monthly Bulletin of Reserve Bank of India, Mumbai

When the list of medicines under price control is limited and close substitutes are not price controlled, companies find ingenious ways to circumvent price control. GlaxoSmithKline (GSK), for instance, markets 'Actified,' a drug used for cold and cough in India. While GlaxoSmithKline uses the active pharmaceutical ingredient pseudoephedrine in its global product 'Active,' in India it uses Phenylpropanolamine (PPA). PPA enhances the risk of cerebro-vascular accidents and has been banned in several countries, while pseudoephedrine is under price control in India.[18]

iii. Unreliable and Inefficient Procurement and Distribution Systems

While adequate allocation of funds is important, the concomitant presence of a reliable and efficient public procurement and distribution system is equally vital for avoiding shortages and drug stock-outs. In India, several different procurement mechanisms can be clearly identified: i) pooled procurement at the state level as in Tamil Nadu and Kerala, ii) decentralised procurement as in Chattisgarh; and iii) a combination of the two, as in Bihar. The procurement model of the Tamil Nadu Medical Services Corporation (TNMSC) has stood the test of time over the last 15 years, and has been hailed as the most efficient, reliable, transparent and replicable model (see Box 2). Neighbouring Kerala has adopted that model recently, while other states such Bihar, M.P. and Odisha are in the process of replicating it.

An efficient procurement system is characterised by pooled (centralised) purchasing of drugs at each state level and one at the central level. Currently the central government has four procurement agencies procuring drugs, vaccine and diagnostics. Several state governments procure drugs at district level with a rate contract. Given the fragmented nature of such purchases, price quotes are non-competitive, resulting in less value for money. Monopsony purchase can result in competitive buying practices as demonstrated in the Tamil Nadu and Kerala models.

It is often noted that states which do not follow the EDL in their procurement process create a scenario where physicians prescribe and dispense irrational drugs in the public health system, thereby compromising cost-effectiveness. During 2008-09, out of 239 drugs procured by the state of Bihar, only 82 drugs (34.89%) were found to be on the state EDL list (both in-patient and out-patient).[9] These accounted for approximately 71% of the state drug budget. Expenditure on procuring rate contract drugs, which are on EDL, was approximately 43% of the state's drug budget; while on the other hand, the rest of the funds (57%) are spent on non-rate contract drugs. Substantial

Box 2: Key Characteristics of Reliable & Efficient Medicine Supply Systems

- At least 15% allocation of public funding for health to drugs;
- State must procure all EDL medicines;
- Separate AYUSH, EDL and centralised procurement at state level;
- Prescription & Dispensing in accordance with Standard Treatment Guidelines (STG);
- A two-bid open transparent tendering process;
- Quality generic drugs ensured;
- Warehouses at every district level;
- An autonomous procurement agency for drugs, vaccines & diagnostics;
- An empanelled laboratory for drug quality testing;
- Enactment of Transparency in Tender Act;
- Prompt payments.

amounts of funds are not efficiently utilised, due to the system of decentralised procurement and distribution of drugs.[9]

Forecasting and procurement planning is critical to the cycle of drug procurement. Currently, several states do not have a forecasting or a planning mechanism for drug procurement. Evidence suggests that in Bihar, over a period of three years from 2005-08, the list of the drugs acquired in Bihar which were not on the EDL list or on rate contract, varied considerably. The number of drugs that were procured in 2007-08 was 369, as compared to 91 and 89 in previous two years.[9] All these factors invariably have an adverse effect on competition, price, quality, and the timely availability of drugs to frontline healthcare providers in the public health system.

The lack of overall governance and efficient administrative systems for the procurement and distribution of medicines is partly responsible for shortages and drug stock-outs. This can be improved through initiatives enhancing transparency and accountability of the system. The Tamil Nadu Medical Services Corporation (TNMSC) follows the Tamil Nadu Transparency in Tenders Act (43), 1998 and the Tamil Nadu Transparency in Tenders Rules, 2000. The Act and its Rules have clear and illustrative provisions for methods of tendering, publicity requirements, technical specifications, commercial conditions, evaluation criteria, place and time for receipt of tenders, minimum time for submission of bids, opening of bids, extension of tender validity, determination of the lowest evaluated price, preparation of the evaluation report and award of tenders. Such a system of transparency is absent in most Indian states.

iv. Widespread use of Irrational Medicines

India has the dubious distinction of having its pharmaceutical market flooded with about 90,000 formulation packs and brands.[19] The market is awash with irrational, non-essential and hazardous drugs. Of the top 10 products which accounted for 10% of the medicines sold in the market, two belong to the category of irrational vitamin combinations and cough syrup while the other is a liver drug of unproven efficacy. Ten of the top 25 products sold in India in 1999 belonged to one of these categories: blood tonic, cough expectorant, non-drug formulations, analgesics, nutrients, liver drug, etc. which are either hazardous, non-essential or irrational.[19] According to estimates available from DCGI (2007), about 46 banned Fixed Dose Combination (FDC) drugs continue to be marketed despite the ban.[20]

About 1067 FDCs are freely marketed with the state drug controllers' approval, but without the concurrence of the DCGI. The drug licensing approval for marketing is the prerogative of the DCGI, while state drug controllers are required to only approve manufacturing and selling license of drugs in the state. Drug makers conveniently circumvent this process by approaching state drug controllers for obtaining marketing approval licenses. Almost all the major medicine producers are engaged in producing irrational medicines. To further illustrate this point, during 2004, over 100 new combination drugs (FDCs) were introduced in the market, capturing a market share of Rs. 130 crore (Table 3).

A large number of these medicines are in segment pertaining to cardiac care. Table 4 profiles the changing pattern of drug consumption, which does not reflect the disease profile of our country. In addition, there has been a rapid increase in the range of lifestyle drug categories such as cardiovascular drugs, hormones, anti-diabetic drugs and nutraceuticals in the last few years. As an example, although 'alimentary & metabolism' drugs accounted for one-fourth of the market in the therapeutic drug category in 2006, the major segments within that category in 2006 were: i) anti-diabetic therapy, ii) vitamins and mineral supplements, iii) antacids and anti-flatulents, which accounted for 4.4%, 6.5% and 4.8%, respectively. Part of this increasing market share of such drugs also reflects the growing disease burden, especially diabetes. As far as systemic anti-infectives are concerned, this category accounts for one-fifth of the Indian pharmaceutical market.

TABLE 3. NEW INTRODUCTIONS INVOLVING COMBINATION THERAPIES, 2004				
New Combinations	**Category**	**Launch Date**	**No. of Brands**	**Value in Crores**
Aspirin + Clopidogrel	Cardiac	2002	23	40.9
Glimepiride + Metformin	Diabetic	2002	24	29.1
Pantoprazole + Domperidone	Gastro-Intestinal	2002	13	17.7
Pioglitaz + Glimepride	Diabetic	2002	18	7.2
Pipracillin + Tazobactum	Antibiotic	2002	5	5.4
Valdecoxib + Tizanidine	Pain/Analgesic	2003	8	3.1
Peridopril + Lindapamide	Cardiac	2002	2	2.8
Amlodipine + Atenolol	Cardiac	2003	6	2.1
Mosapride + Pantoprazole	Gastro-Intestinal	2004	1	21
Losartan + Atenolol	Cardiac	2003	4	1.3
Grand Total			**104**	**130.6**

Source: Intercontinental Market Services (IMS), 2005

Antibiotics and anti-bacterial formulations account for nearly 18% of the pharmaceutical market, clearly demonstrating the huge supply-driven demand created by pharmaceutical companies. Recent controversies related to high levels of antibiotic drug resistance in India are a clear reflection of this induced demand. Almost one tenth of the current market caters to the demand for cardiovascular therapies. Apart from a rising disease burden, this may also, in part, reflect a supply-induced demand: for instance, the industry spent over 25% of its annual sales turnover on sales promotion alone as against a paltry 7% on Research and Development expenditure during 2008-09.

TABLE 4. INDIAN THERAPEUTIC MARKET			
Therapeutic Category	**Market Share of Value in Percentage (%)**		
	May-04	**May-05**	**May-06**
Alimentary & Metabolism	24.6	24.8	25.0
Systemic Anti-Infectives	20.3	20.1	20.5
Cardiovascular System	9.3	9.7	9.8
Respiratory System	10.0	9.5	9.3
Musculo-Skeletal System	7.7	7.6	7.2
Central Nervous System	6.8	6.7	7.0
Dermatologicals	5.4	5.4	5.4
Blood + B. Forming Organs	4.0	4.2	4.1
GU System & Sex Hormones	3.4	3.6	3.6
Others	3.1	2.9	2.7
Sensory Organs	1.8	1.7	1.8
Parasitology	1.4	1.4	1.4
Systemic Hormones	1.4	1.5	1.4
Hospital Solutions	0.4	0.5	0.5
Antineoplast + Immunomodul	0.3	0.4	0.4
Diagnostic Agents	0.1	0.1	0.1
Indian Pharmaceutical Market	100	100	100

Source: IMS, 2007

The large scale promotion and publicity of these non-essential drugs by the pharmaceutical industry has resulted in physicians and pharmacists in both private and public health facilities being incentivised to prescribe and dispense drugs that are irrational. Irrational practices in the prescriptions and dispensing of drugs continues to be rampant in the country, and is largely observed through the number of injections and antibiotics prescribed, prescriptions by brand names rather than generic names, polypharmacy, and related practices. Standard Treatment Guidelines (STGs) are rarely followed and adhered to.

v. Lack of Regulation of Drugs and Diagnostics

Poor enforcement and multiple interpretations of the Drugs and Cosmetics Act of 1940 have made regulation in the health sector an unviable proposition.[21] An effective drug regulatory system has significant bearing on the prices, quality and availability of drugs.

The Central Drugs Standard Control Organisation (CDSCO) of India is vested with the task of approving new drugs and clinical trials, laying down standards, import control, overall coordination of state drug control authorities. State drug control authorities, on the other hand, are responsible for regulating the manufacture, sale and distribution of drugs.

Poor drug regulation results in the production and sale of spurious and substandard drugs. The overall quality of drugs is affected as, over time, any medicine could turn out to be inefficacious or unsafe. The recent deaths of pregnant women in Jodhpur due to contaminated IV fluids have brought this issue to the forefront again. Drug quality has especially become an issue in recent years with allegations, of ineffective and sub-standard drug production, levelled against small-scale drug manufacturers.

Since 2005, drug manufacturers in India have been mandated to abide by and comply with Good Manufacturing Practice (GMP) regulations, concordant with global standards, to produce quality drugs. A 2009 government survey of drugs reveals that 0.3% of all sample drugs were found to spurious, while 6-7% of drugs in the country were found to be sub- standard in quality.[22]

Despite growing awareness and compliance with GMP regulations, the quality of Indian drugs has been questioned time and again. According to Gulhati (2011), there are different terms and definitions which create confusion regarding nomenclature, such as fake/substandard/spurious and counterfeit drugs.[23] For example, in the United States of America, counterfeit drugs include even genuine, foreign medicines/brands that are not approved by the United States Food and Drug Administration (FDA). According to the Drugs and Cosmetics Act (Section 17B), the term 'spurious' drugs is not only limited to fake medicines but also includes products that use unauthorised names or are produced by unrecognised manufacturers. As Gulhati (2011) illustrates: "a strip of 10 good quality genuine paracetamol tablets will be deemed to be 'spurious,' by the FDA, if that product uses the name 'Crocin' without permission from the trade mark holder GSK."[23] Indian quality labels, therefore, must follow rational and well-enforced Indian criteria.

vi. Stringent Product Patent Regime

India's changeover from process to product patent regime since 2005, has been viewed as a barrier which limits access to new medicines. This is expected to provide monopoly rights to drug makers in certain therapeutic categories, such as, oncology, AIDS/HIV, and mental conditions. In view of these changes in patent climate, market structure is likely to gradually undergo changes with immediate impact on prices of new medicines. For instance, it was with the arrival of Indian generic pharmaceutical companies on the global scene in 2001, that the prices of ARVs began to decline sharply - from US$10,439 in late 1990s to about US$350 per annum per patient for first-line AIDS treatment in 2005.[24] Currently, the drug is quoted at less than US$70 per patient. This scenario clearly demonstrates the importance of empowering Indian generic drug makers with process patent and the forces of competition that it unleashed. Patented medicines, without close substitutes, are unaffordable for large sections of society, in India as well as in several developing countries where drug purchase occurs without social health insurance coverage. For instance, the price of pegylated interferon alfa-2a, a drug used in the treatment of Hepatitis C, costs about Rs. 18,200 (US$390) per 180mg Pre-Filled Syringe (PFS). The annual cost of such treatment could run into a mind-boggling amount, placing it clearly out of reach of many middle class patients.[24]

Developing economies were able to exercise their right in getting safeguards and flexibilities under the Trade-Related Intellectual Property Rights (TRIPS) regime to protect national public health. Nations can utilise safeguards such as compulsory licensing, parallel imports, etc. to protect their citizens from national health emergencies. In addition, it is also argued that countries can implement national price control policies as a means to arrest drug prices from spiralling high.

Notwithstanding these flexibilities and country experiences (of Brazil and Thailand) in using TRIPS safeguards, India is yet to make use of these TRIPS provisions to its advantage. Despite the fact that several households face tremendous public health challenges and financial vulnerabilities, not a single compulsory license has been issued to date. Alarmingly, the country now faces the challenge of TRIPS plus provisions which will 'evergreen' patents for a longer than 20 years duration. Under a data exclusivity clause that is negotiated under the India- European Union (EU) and India-Japan bilateral agreement, India has been called upon to provide data exclusivity to transnational drug conglomerates, which would then enjoy the benefit of extended monopoly rights. The country is also being advised to soften clause 3(d) clause of the amended Indian Patent Act of 2005 which limits the scope of patentability criteria, so as to permit frivolous patents or allow minor improvements of known pharmaceutical products.

vii. Insufficient Research & Development Focus

Under-funding of public health research institutions, alongside a general lack of focus on priority diseases by private sector, hinders current drug research efforts in the country. The other major area where India could have taken a lead, like China, is in adequately utilising its indigenous traditional medicine base. India had so far failed to take advantage of this huge traditional knowledge base. Weak institutional frameworks and poor regulation of clinical research and trials endanger the safety of research subjects. A plethora of new medical technologies and devices are introduced and utilised without any clear guidelines and policies. This arises from the lack of capacity for technology assessment and evidence-based decision-making. Many of these drug and device technologies are introduced without due assessment of cost-effectiveness, safety and efficacy. For examples, new vaccines which vie for inclusion in the Expanded Programme of Immunization (EPI) must satisfy the criteria of national relevance, cost-effectiveness and safety, without which they would be wasteful, unaffordable or harmful.[25]

3. Recommendations and Way Forward

The availability of most essential drugs in India is not a serious concern; it is rather that access to drugs in the public health system has been poor, despite the country being a global leader in supplying quality generic medicines at affordable prices. Overall Under-funding of the governmental health system, along with paltry allocation of government resources to procure drugs, has resulted in poor access to drugs in the public health system. In addition, poor governance and accountability have also compromised the system. By directly improving health outcomes and providing financial risk protection to the population, expanding access to medicines is the key driver in achieving universal access to healthcare. To meet this important goal, government policies and strategies must be grounded in the principles of universality, equity, efficiency and quality. This is clearly feasible and implementable, and the results can be demonstrated rapidly and scaled up within a short span of 1-2 years, with minimum resources and maximum benefits.

Recommendation 1: Increase Public Spending on Drug Procurement to 0.5% of the GDP and provide free essential medicines to all.

Currently the public health system in India spends about Rs. 6000 crores (0.1% of GDP) for procuring drugs. An additional four fold rise in medicine purchase by the public health system is required at Rs. 24,000 crores (0.4% of GDP). This works out to about Rs. 30,000 crores (0.5% of GDP), roughly half a percent of GDP. This resource is adequate to supply essential medicines free to everyone, distributed through public and private channels. This is expected to result in substantial reduction in Out of Pocket (OOP) expenditure and thereby provide much-needed financial risk protection to households. This measure is

likely to result in a supply of quality generic drugs. Their rational use, through a pooled public procurement for supply through the public health system as well as through private chemists contracted into the UHC system, will achieve substantial gains in drug access. The inter-state and inter-district disparities in the availability of drugs must be minimised, through planned allocation of funds in an equitable manner.

Recommendation 2: Enforce price regulation and apply price control on all formulations in the Essential Drug List.

India's current drug price control mechanism is inadequate in its coverage and does not serve its purpose to a large extent. The current practice of using monopoly and market dominance measures needs to be replaced with the criteria of 'essentiality,' which is expected to have maximum spill-over effect on the entire therapeutic category. This is also likely to prevent the present trend of circumventing price controls through non-standard combinations and at the same time would discourage producers moving away from controlled to non-controlled drugs. Direct price control should be applied to formulations rather than on basic drugs. This is likely to minimise intra-industry distortion in transaction and reduce as well as prevent a substantial rise in drug prices.

Recommendation 3: Ensure drug and vaccine security by strengthening the public sector and protecting the capacity of Indian private sector companies to produce low cost drugs and vaccines needed for the country. [a]

It is ironic that despite India supplying quality generic drugs around the world, the country has concerns about sufficient domestic drug supply and vaccine security. With the increasing acquisition of Indian companies by transnational drug corporations, there is a pressing need to rethink our country's drug strategy. Even when multi-national drug firms are not acquiring Indian owned drug manufacturing companies, effective control on policies and pricing may be gained through 'strategic alliance' agreements. Various options are proposed below for the government's consideration:

a) In order to reduce our vulnerability to restructuring and its serious implications, we suggest that the government strengthen Public Sector Units (PSUs), which have drug manufacturing capability. This is possible through infusion of capital into existing but 'sick' PSUs such as, Indian Drugs and Pharmaceuticals Ltd. (IDPL), Hindustan Antibiotics Limited (HAL), and state owned enterprises, in addition to providing them with autonomous status.

b) The use of PSUs will offer an opportunity to produce drug volumes for use in primary and secondary care facilities as well as help in 'benchmarking' drug costs. The existence of PSUs would also provide an opportunity to utilise the provision of Compulsory Licensing under TRIPS.

c) In addition, we also need to urgently revisit India's FDI regulations to amend the present rules of an automatic route of 100% share of foreign players in the Indian industry to less than 49%, so as to retain predominance of Indian pharmaceutical companies and preserve our self-sufficiency in drug production. Another option is to move the drug industry from an automatic route to the Foreign Investment Promotion Board (FIPB) route, which would ensure that all proposals of foreign mergers and acquisitions of Indian drug companies are scrutinised thoroughly. Alternatively, a provision for separation of 'financial' ownership from 'legal' ownership may be enforced, analogous to the

[a] This recommendation did not have unanimity within the HLEG. One member was of the view that reviving public sector capacity for pharmaceutical production, without examining the reasons for failure of previous public sector drug manufacturing units, would not be an appropriate use of resources.

Reserve Bank of India (RBI) rules, which limit the voting rights of the foreign investor.

d) The domestic drug manufacturing industry should transition from the current scenario of import dependency to self-sufficiency with respect to ingredients. The Active Pharmaceutical Ingredients (APIs) industry has placed the drug-making (formulation) sector in jeopardy in recent years. India, which was to a large extent self-sufficient in API manufacturing until the 1990s, has found itself in an awkward position in recent times with several disruptions and cost-escalation of largely Chinese import. There is a need to incentivise domestic production of APIs in the private sector, while at the same time actively engage drug PSUs to manufacture quality and cost-effective APIs.

e) There is also a need to engage medium and small-scale drug industries in the production of quality generic medicines for UHC by helping them to transit to Good Manufacturing Practice (GMP)-compliant status, by providing financial and non-financial assistance.

f) Vaccine security is equally vital, given the large disruption the country experienced in vaccine supply recently. We suggest that existing public sector vaccine-manufacturing units be strengthened with additional infusion of capital and the provision of autonomous status, and new vaccine parks be set up immediately. Indian private sector units manufacturing vaccines must be safeguarded against external interference with their mandate to prioritise Indian needs, as in the case of drugs.

Recommendation 4: Strengthen institutional mechanisms for procurement and distribution of allopathic and AYUSH drugs.

Various mechanisms have been considered for ensuring delivery of drugs to the public:

a) A Centralised Procurement and Decentralised Distribution Model: This system is based on the TNMSC model for centralised procurement to achieve economies of scale and the use of monopsony purchasing methods for procuring drugs, vaccines and medical devices at substantially marked down prices. It is recommended that state and central governments establish a centralised procurement mechanism for procuring drugs, vaccines and medical devices. They should follow an open, transparent two-bid tendering system. Such drugs should be procured based on the Essential Drug List (EDL), which are generic in nature and rational in content.

b) In order to facilitate and streamline drugs and vaccine storage and distribution logistics, it is proposed that at least one warehouse be built in each district to ensure ease of availability of drugs and vaccines to all front-line providers, preventing stock-outs or wastage of drugs.

c) The government may contract-in private chemists, at least one at every block level and four to five at district headquarters. Drug supply to such stores would be linked to centralised procurement at state level to ensure uniform drug quality and cost minimisation by removing intermediaries. This is expected to not only significantly reduce costs but also enforce much-needed rational prescription and dispensing methods.

d) AYUSH medicines should be brought under the National Essential Drugs List (NEDL). Thereby, procurement will move towards purchase of only NEDL drugs which should include identified and approved chemical, biological and traditional Indian medicines or AYUSH medicines. This will also ensure that AYUSH drugs are available at PHCs, where presently many AYUSH doctors are handicapped by the lack of AYUSH drug supplies.

e) For provision of diagnostic services, government diagnostic centres should be strengthened at the block and district levels. Private diagnostic facilities may also be contracted into the system.

Recommendation 5: Promote rational use of drugs through prescriber, patient and public education.

a) There is a clear need to phase out hazardous, non-essential and irrational medicines and irrational 'Fixed Dose Drug Combinations' from the market. Recent reports on 'superbug' nosocomial infections indicative of anti-microbial drug resistance in India, clearly point to the need to end the irrational drug prescription and dispensing practices.

b) Efforts will need to be backed by education and behaviour change among doctors, towards the adoption of rational prescribing and dispensing procedures for drugs, possibly through the advocacy of National and State Health Promotion Trusts (see chapter on Management and Institutional Reforms).

c) Standard Treatment Guidelines should be implemented in the NHP system, and should include only rational formulations.

d) Unethical or aggressive marketing practices by drug and devices manufacturers and sales persons as well as incentives offered to doctors to promote prescriptions should be banned and penalised.

Recommendation 6: Strengthen Central and State regulatory agencies to effectively perform quality and price control functions.

a) Regulatory mechanisms need to be tightened for better drug quality control. Existing state regulatory agencies in India have neither an adequate workforce nor appropriate testing facilities. Fresh investments should be made to set up regulatory facilities in each state and recruit additional regulators, essential for regulating manufacturing drug units as well as drug outlets.

b) Global practices in drug regulation involve a variety of functions and mechanisms that range from food control, drug quality and safety, pharmaceutical price regulation and medical devices and equipment standardisation. The problem in India is that while only some of these functions are undertaken by the Central Drugs and Standard Control Organisation (CDSCO), there are multiple additional authorities and departments that fail to coordinate among themselves for efficient and effective functioning. For instance, the Department of Pharmaceuticals under the Ministry of Chemicals and Fertilisers is responsible for drug price control while the Essential Drug List is prepared by the Ministry of Health and Family Welfare. Therefore, there is a need to integrate the role of drug price control into the CDSCO. In addition, the CDSCO should responsibility for collecting, tabulating and disseminating data on drug production, category-wise sales, company level information on drugs and undertake the responsibility of carrying out prescription audits. Currently, various Ministries rely on private data on drug consumption (which is both expensively priced and whose methodology is not very robust) to formulate drug price policies. To make the policy-exercise more credible, the Health Ministry must be empowered to take necessary action in this direction.

c) Adding new drugs and vaccines to the government drug procurement system must be based on scientific evidence, with due regard to safety, efficacy and cost. We propose an institute akin to the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom to critically evaluate the evidence needed to guide decisions on inclusion of new drugs and vaccines into the public health system.

Recommendation 7: Protect the safeguards provided by the Indian patents law and the TRIPS Agreement against the country's ability to produce essential drugs.

a) India's current amended patent law includes several key safeguards such as restriction on the patenting of insignificant or minor improvements

of known medicines (under section 3[d]); this provision needs to be protected from any dilution.

b) Secondly, Compulsory Licenses (CL) should be issued to companies, as necessary, to make available at affordable prices all essential drugs relevant to India's disease profile. This provision, under India's own Patents Act and Trade-related aspects of Intellectual Property Rights (TRIPS) as clarified by the Doha Declaration, allows countries to use such licenses in public interest and can be invoked in the interest of public health security.

c) Finally, the 'data exclusivity clause' must be removed from any Free Trade Agreement that India enters into, since such a clause extends patent life through 'evergreening' and adversely affects drug access and affordability.

Recommendation 8: Transfer the Department of Pharmaceuticals to the Ministry of Health.

The manufacture of drugs is under the purview of the Department of Pharmaceuticals, which is presently a part of the Ministry of Chemicals and Fertilisers. This department is also responsible for drug price control. Since the Ministry of Health is not only responsible for ensuring the quality, safety and efficacy of drugs but is also accountable for the unhindered availability of all essential drugs in the UHC system, public interest would be best served by transferring the Department of Pharmaceuticals to the Ministry of Health. This would help to better align drug production and pricing policies to prioritised national health needs.

4. Financial Implications and Timeline

India's presently underfunded health system not only requires a significant scale up of public spending on healthcare including drugs, but also needs to efficiently utilise available resources (as well as additional investments) in a manner that achieves better health outcomes and reduces OOP spending on health, especially on drugs. While increased investments are critical, reorganisation of government spending strategies would achieve significant savings to both the administration and to the society at large. Table 5 provides a clear pathway to achieve universal access to medicines under different scenarios and the associated cost savings achievable by rationalizing prescription and dispensing patterns.

TABLE 5. SCALING UP TO ACHIEVE UNIVERSAL ACCESS TO MEDICINES

Overall Drug Consumption	Present Market Pattern (Non-EDL+EDL) Current Scenario (Rs. Crores)	Retail Market Price Converted to Procurement Price (EDL) Scenario I (Rs. Crores)	EDL Substituted for Non-EDL in Open Market Scenario 2 (Rs. Crores)
Essential Drugs	20,000	4,000 ~ 5,000	4,000 ~ 5,000
Non-Essential Medicines	36,000	36,000	8,000 ~ 15,000
Govt Procured Drugs	6,000	6,000	6,000
Total Market	62,000	46,000 ~ 47,000	18,000 ~ 26,000

Source: *Figures obtained from IMS and government budgetary documents for private market and government procurement data respectively. The estimates are based on various assumptions and scenarios. Selvaraj and Hasan (2011)*[26]

Note: *The figures above are indicative and should not be considered final. This is because the assumptions and scenarios are based on situation when non-EDL drugs in the open market are substituted by EDL drugs, assuming that physicians prescribe by the EDL and abide by Standard Treatment Guidelines. In such a scenario, the upper bound would be on the higher side while the lower bound appears feasible. Price inflation is not considered here due to the fact that government procurement data based on TNMSC show that price change has been extremely insignificant in the past, in that system.*

a) The Current Scenario

The current pattern of drug consumption in the country reveals several disturbing trends which carry significant implications for the government, private sector providers and individual consumers. Estimates from IMS data reveal that nearly Rs. 56,000 crores worth of medicines consumed in the domestic open market, were sold through roughly 600,000 private chemists in March 2011. On the other hand, governments at central and state levels continued to procure drugs at the rate of Rs. 6,000 crores during the same period, a number which is about one-tenth the price rate supplied by retail chemists. The ratio of essential (EDL) and non-essential (Non-EDL) drugs in the retail market is 2:3. Non-essential medicines consist of irrational combinations, superfluous and useless drugs, in addition to drugs that are prescribed and dispensed without any adherence to Standard Treatment Guidelines. Table 6 presents and details current and future implications for drug security and consumption in the country.

i. Scenario One

In scenario one, we demonstrate how cost savings could be achieved, if essential drugs that are sold in the retail market could be bought by the government at procurement prices (for instance, TNMSC prices). This yields a total savings of Rs. 15,000 to Rs. 16,000

crores to the nation. The significant difference between retail market and procurement price is due to exorbitant margins charged by drug manufacturers, in addition to a number of intermediaries including stockists, wholesalers and retailers. However, this is based on the assumption that all essential drugs would be bought by the government for its facilities. Presently, however, private players dominate the market, especially in medicine purchase for out-patient facilities. Therefore, in order to achieve these outcomes, there is a tremendous need to shore up the public procurement and distribution system, in addition to higher allocation of public funds for drugs.

ii. Scenario Two

In scenario two, while the cost savings through bulk procurement prices are factored into estimations, an attempt is also made to substitute essential medicines for non-essential drugs through Standard Treatment Guidelines (STG). The cost savings here are likely to be enormous, to the tune of Rs. 36,000 to Rs. 44,000 crores, simply by phasing out irrational drugs to a large extent from the market. On the whole, by moving to an efficient procurement policy complemented by rationalizing the drug market, system inefficiencies can be brought down from Rs. 62,000 crores to an amount ranging from Rs. 18,000 to Rs. 26,000 crores. This yields a substantial saving of Rs. 36,000 to Rs. 44,000 crores to the nation, which amounts to about 0.5 to 0.6 % of the GDP.

5. Expected Outcomes

We believe that our recommendations could tremendously improve and enhance physical and financial access to medicines in the country in a short span of time. Overall governance and accountability of both public and private players involved in drug procurement, distribution, financial allocation, and drug quality requirements should improve. This is likely to be reflected in regular availability of all essential medicines and elimination of drug stock-outs. Other key outcomes as a result of these recommendations will include:

a) Scaling up public spending on health and allocating at least 15% of that funding for drugs is expected to dramatically reduce OOP spending for households. The adverse ratio of Government to Households on drug spending -which is presently at 1:10- is likely to be reversed or at least substantially reduced.

b) Significant reduction in impoverishment and catastrophic spending due to OOP expenditure on drugs.

c) A centralised drug procurement and decentralised distribution mechanism would produce much needed economies of scale through monopsony purchasing, significantly reducing drug prices and creating better value for money. This system can be further strengthened by allowing the purchase of only generic drugs from the essential drug list. Since physicians in the public health facilities would be required to prescribe only EDL drugs and follow STGs, rational prescription and dispensing would increase.

d) Bringing all essential medicines under price control would have a beneficial effect on open market drug prices, resulting in large savings to households.

e) Strengthening drug control institutions and staffing drug control authorities with a skilled workforce will reduce the production and sale of spurious and sub-standard drugs and increase the confidence of the Indian public in drug quality.

TABLE 6. CRITICAL PATHWAYS TO ACHIEVE UNIVERSAL ACCESS TO MEDICINES

Drug Insecurity (Current Scenario)	Partial Drug Security (Scenario 1)	Complete Drug Security (Scenario 2)
Current Landscape & Its Implications: 1. Gross under-investment & significant inter-state & inter-district disparities of public expenditure on drugs with enormous burden on households-ratio of government: household current spending on drugs is 1:10; 2. Partial EDL, Generic & Rational use of drugs in public health facilities; 3. Largely fragmented public procurement & distribution system; 4. High drug price due to liberalisation of drug price control; 5. Rampant use of irrational medicines and non-essential drugs in the private healthcare system;	**Significant Scale-up & Its Implications:** 1. Scaling up public spending on drugs with considerable reduction in household spending-government: household ratio to 1:1; 2. Government health facilities to substantially procure EDL drugs with focus on generic and rational drug use; 3. Strengthened Public procurement & distribution system; 4. All essential drugs under price control; 5. Considerable reduction in irrational medicine use & substantial weeding of irrational medicines.	**An ideal but achievable scenario & its implications:** 1. Reversal of current ratio of government :household expenditure to 2:1, with financial burden moving to government; 2. Centralised public procurement & public distribution system of medicines; 3. Centralised public procurement and private drug distribution (prescriptions based on contracted-in General Practitioner from private sector); 4. Price control for essential drugs while non-essential drugs are price monitored; 5. Minimise use of irrational medicines in both public & private medical facilities;
Key Outcomes: a. High Impoverishment & catastrophic payments of households; b. Acute shortages & chronic stock-outs of drugs in public health facilities; c. Wastage of resources to the tune of 0.4 to 0.6% of GDP; d. Poor prescription & dispensing practices leading to inefficiency and safety concerns; e. Lack of governance and poor accountability mechanism.	**Expected Outcomes:** a. Large decline in impoverishment & catastrophic payments to households; b. Public facilities provide uninterrupted drug supply; c. Significant savings to the exchequer and large reduction in wastage of resources to households to the tune of 0.2 to 0.4% of GDP; d. Prescription & Dispensing practices in public health facilities improve; e. Governance & accountability enhanced.	**Potential Outcomes:** a. Insignificant share of OOP on drugs leading to very low impoverishment & catastrophic spending of households; b. Drug shortages & stock-outs eliminated; c. Savings to the tune of 0.5 - 0.6% of GDP to the exchequer; d. Prescription & dispensing of drugs through EDL and STGs, both in public & private facilities; e. Good governance & high accountability ensured.
Timeline: Current Scenario	**Timeline: 1-2 years**	**Timeline: 5-7 years**

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