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Assessing the Impact of Price Control Measures on Access to Medicines in India

July 2015

Contents

Preface

In 2013, IMS Health released a study on "Understanding Healthcare Access in India: What is the current state" which had mapped the healthcare status, prioritized the challenges based on the relative impact on access, and identified key levers for improving access. The study was a comprehensive assessment of the status of healthcare access in India, which was deemed critical for determining priorities, resource allocations and goals for the future.

Since then, various measures have been undertaken by the government to address the issues of healthcare access. In May 2013, India's Department of Pharmaceuticals published the Drug Price Control Order (DPCO) 2013 which increased the number of medicines on the NLEM from 74 to 348 and enforced price ceilings on 652 drugs.

Two years have passed since the release of the order, and we feel the time is right to understand its impact on healthcare access. We have now undertaken a similar effort for Organization of Pharmaceutical Producers of India (OPPI), to review the effectiveness of price control measures as means to improve access in India and identify critical levers which could aid this objective.

The study is an independent review to understand the relative impact of price control on the entire healthcare ecosystem; predominantly the true intended beneficiaries - the patients. The study involved data analysis and was supplemented by discussions with key stakeholders from the industry and policy makers/influencers.

We are optimistic that this study will help set context for further deliberation around the condition of healthcare access India with all stakeholders, so as to make calculated decisions and channelize efforts of the cohesive ecosystem in the direction of improving healthcare access for the country as a whole.

The sponsorship of this study by Organization of Pharmaceutical Producers of India is gratefully acknowledged. The contributions of Amit Mookim, Kunal Khanna, Amit Bhageria and Dhiraj Mendiratta in preparing this report are gratefully acknowledged. We would also like to express our sincere thanks to all advisory group members and policy makers for their contributions to the study.

Nitin Goel
General Manager, IMS Health South Asia

Background

Healthcare access can be broadly defined as the use of healthcare by those who need it. Access can further be viewed as a comprehensive concept which seeks to make healthcare available, accessible, accommodative, acceptable and affordable.

In countries that share characteristics with India such as high out-of-pocket expenditure, low degree of consolidated purchasing and limited healthcare infrastructure; access to health services and medicines is a challenge especially for rural and low income population groups.

The IMS Health report on "Understanding Healthcare Access in India" was the most comprehensive assessment of healthcare access since 2004 and had clearly identified the need to address all dimensions of healthcare access: physical accessibility, availability/capacity of the resources, quality/ functionality and affordability.

Pharmaceutical pricing in India is an important and contentious issue, because most patients lack public healthcare support, insurance coverage and pay out-of-pocket for their healthcare needs which tantamount to a massive burden on the patients.

India, like several other countries adopted the concept of essential medicines, launched the National List of Essential Medicines (NLEM) which contains medicines that are required to satisfy the priority healthcare needs for majority of the population. With a view to improving healthcare access in India and make medicines more affordable in India, the National Pharmaceutical Pricing Authority (NPPA) enforced the Drug Price Control Order (DPCO) on these essential medicines first in the year 1995. The DPCO'95 list contained 74 bulk drug molecules and was based on a cost based approach to compute the ceiling price.

Then, in May 2013, India's Department of Pharmaceuticals published the Drug Price Control Order (DPCO) 2013. Post this order, more than 652 drugs in India are now subjected to a price ceiling. The calculation of ceiling price was changed from a cost based to a market based approach. Further, the order specified the form and dosage of the molecules subject to the price control. While as an approach it was deemed to be better than the earlier drug price order of 1995, the true impact of this price control in bringing a holistic improvement to healthcare access remains to be determined.

Building up on the previous study on healthcare access, OPPI instituted this study to understand the effectiveness of price controls as means to improve access and create a roadmap for improving access including critical levers which could aid this objective.

Through this study we were able to make a fair assessment of the price control introduced in 2013 and in its backdrop, analyze the DPCO 1995, to understand the relative impact of price control on the entire healthcare ecosystem, predominantly the true intended beneficiaries - the patients.

To make this study a well rounded one, a basket of molecules under DPCO and counterparts/analogs not under the price order, representative of the whole universe and with strong statistical significance were chosen. The basket of molecules was analyzed on various parameters of growth and volume over a period time. Relevance of sample and statistical significance was ensured and validated with Prof. Viswanath Pingali (IIM-Ahmedabad) and other key stakeholders.

The study involved both extensive data analysis around access parameters based on growth and volume trends in price controlled and non-controlled molecules, and in-depth discussions with key stakeholders from industry and policy makers/influencers in order to understand their perspective around improving healthcare accessibility in India.

We are confident this study provides a solid foundation for the necessary deliberation that is required to align efforts by stakeholders and policy makers to advance healthcare access for all Indians in the years ahead.

Executive Summary

In India, the demand for healthcare services has outstripped supply and the majority of attention has focused on access to medicines at the expense of other aspects of healthcare delivery. In countries that share characteristics with India such as high OOP, low degree of consolidated purchasing (either though government distribution or social insurance) and low healthcare infrastructure, access to health services and medicines is a challenge especially for rural and low income population groups.

The report findings suggest that drug price control in India has not been able to achieve the objectives of access to medicines, especially to the target population. This is further corroborated by international experience across countries such as China, Philippines & South Korea, which implemented price controls, where such measures had limited impact on improving access. In fact, in China, market driven drug prices are set to replace government set prices in 2015.

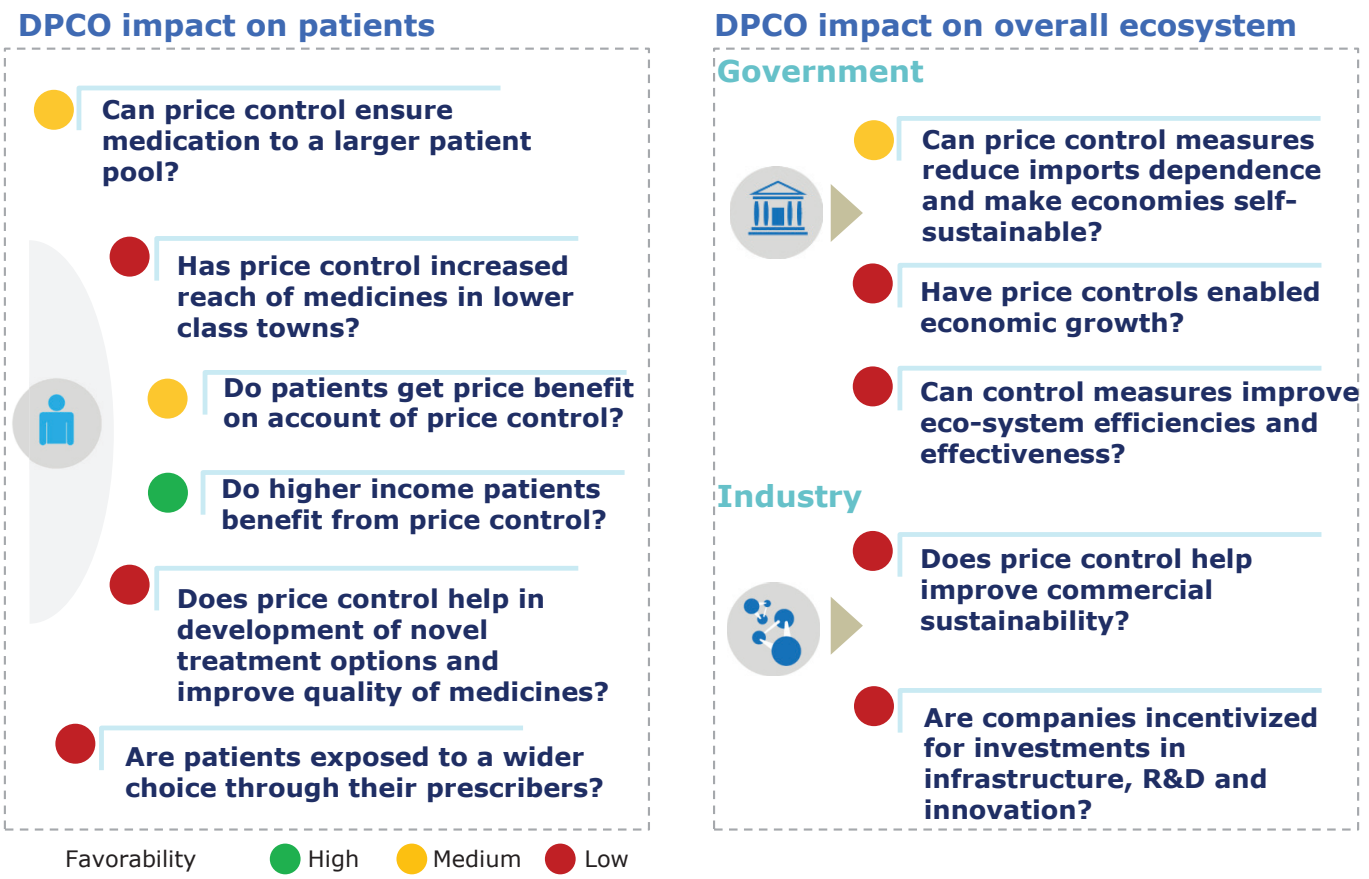
Prices of both price controlled and non-controlled medicines are already among the cheapest in India as compared to other developing and emerging countries and the increase in prices have always been below or at par with inflation. While the drug pricing order has led to overall marginal price benefit to patients, price control measures have not helped the low income groups which are the target population for these measures, and higher income patient groups benefitting more from the price controls.

Some of the key findings from the report include:

- For low-income households that are reliant on the government system for healthcare, DPCO would not improve the patient's ability to purchase drugs. This is supported by the fact that no significant penetration of price controlled molecules in rural markets is visible, with consumption in rural towns decreasing at ~7% over the last 2 years. The price controlled molecules has also witnessed muted growth in prescriptions outside metros (town class I) as compared to 5% Rx growth in non-DPCO molecules.
- DPCO has an impact on the tail-end brands than the leading players thereby increasing market concentration and resulting in discontinuation of brands, with average number of brands in DPCO molecules reducing from 36 in 2013 to 32 in 2015. These market forces can move towards strengthening of oligopolistic behaviour, which will result in reduced set of choices for the doctors/ patients.
- Decline in R&D resulting in fewer new introductions of generic products; Post DPCO 2013, the average number of new introductions in DPCO molecules has declined, which also indicates increasing concentration and reducing competitive intensity.
- Macro-economic impact: Price control and unstable regulatory environment has increased the margin pressures for companies, thereby impacting their sustainability especially small and mid-sized players. This further impacts the employment generation potential of the industry. These factors dampen the sentiments across the industry and potential domestic and international investors.

Price control is also counter-intuitive to government's "Make in India" objective, restricts internal capacity building and limits growth in developing internal expertise and local talent.

Based on our findings, the impact of price controls across stakeholder groups has been summarized below which is further substantiated in the report through in-depth data analysis.



The report outcomes suggest that direct price control measures will alone not help in improving access; alternate measures need to be adopted by the government to truly address the surmounting healthcare demands in the country. In the current healthcare scenario in the country, while the average out of pocket expenditure for the patient is higher than in other countries, an absence of a strong public health support system significantly burden the patient population in the country.

Some of the measures that the government could initiate through policy interventions in the immediate and long term are the following:

- Strengthen **healthcare financing**: extend universal health coverage across population segments with focus on providing cover for medicines
- Invest in **healthcare infrastructure and capability building agenda**
- Promote **joint and bulk procurement mechanisms,** e.g. TNMSC
- Establish a **cess on tobacco and liquor industry** to fund the healthcare sector. Subsidize essential medicines from taxes
- Mechanisms to ensure availability of generics at lower prices to improve affordability for patients i.e. setup dedicated generic medicine stores

In conclusion, this report would urge the key decision makers in the country to expand their purview of healthcare in the country, to define policies that address the pressing issues at hand by not merely resorting to a drug price control, but rather create an all encompassing healthcare model that is able to truly achieve the objective of improving healthcare accessibility in India.

Objectives & Approach

This study has been undertaken with the backdrop of the Drug Pricing Control Order of 1995 and 2013, keeping the interest of the patients at the core. The primary objective of the study was to assess the impact of price control on providing affordable medicines to all and identify other critical levers to improve healthcare access. Key elements of the study include:

- Understand effectiveness of price controls as means to improve access and affordability in India
- Analyze the impact of DPCO 1995 and 2013 pricing policy along the following lines:
  - Are controlled drugs reaching lower town classes and consumption in lower town classes is higher than non-controlled drugs?
  - Are more players entering/more new brands available in controlled segment to benefit patients?
  - Are higher numbers of brands/packs being discontinued under controlled segment?
- Outline successful case studies and learnings, if any, from within India or in other similar countries
- Conduct comparative pricing analysis of selected drugs in emerging markets
- Analyze the various parameters required for overall healthcare ecosystem improvement, such as
  - Healthcare financing/pre-payment coverage – Role of social insurance
  - Supply chain infrastructure
  - Delivery infrastructure

The study was designed by keeping the impact on patient at the centre, but ensuring that the impact on other stakeholders was also assessed. The major questions which are addressed through the study include:

(i) DPCO impact on patients

- Can price control ensure medication to a larger patient pool?
- Has price control increased reach of medicines in lower class towns?
- Do patients get price benefit on account of price control?
- Does price control help in development of novel treatment options and improve quality of medicines?
- Are patients exposed to a wider choice through their prescribers?

(ii) DPCO impact on overall ecosystem

- Can price control measures reduce imports dependence and make economies self-sustainable?
- Have price controls enabled economic growth?
- Can control measures improve eco-system efficiencies and effectiveness?
- Does price control help improve commercial sustainability for the industry?
- Are companies incentivized for investments in infrastructure, R&D and innovation?

For the study, a basket of DPCO 2013 molecules across therapy areas was selected for detailed assessment. A comparative analysis was done for Non-DPCO counterparts not under price control.

Therapy area	DPCO molecule	Non-DPCO counterpart
Anti-Diabetic	Metformin	Glimepride
Dermatology	Fluconazole	Ketoconazole
Cardiac	Amlodipine	Clinidipine
	Atorvastatin	Rosuvastatin
	Losartan	Telmisartan
	Acetylsalicylic Acid	Prasugrel
	Metoprolol	Carvedilol
Gastro Intestinal	Bisacodyl	Lactulose
	Metoclopramide	Prochlorperazine
	Ondansetron	Granisetron
Neurology/ CNS	Alprazolam	Etizolam
Pain/ Analgesics	Diclofenac	Aceclofenac
	Paracetamol	Matamizole
Respiratory	Cetirizine	Levocetirizine
Anti-parasitic	Albendazole	Mebendazole
Anti-infectives	Amoxicillin	Piperacillin
	Azithromycin	Lincomycin
	Ceftriaxone	Cefoperazone

Selection of molecules was done in a manner to achieve statistically reliable quantitative data, which is representative of the trends in the IPM.

- Molecules were chosen exclusive of DPCO 1995 to independently assess the impact of DPCO 2013
- Moreover, a diverse mix of molecules across growing therapy areas was ensured to perform therapy-level analysis

For assessing the impact of DPCO, a basket of DPCO'95 molecules and Non-DPCO molecules across therapy areas was selected for detailed assessment.

Therapy area	DPCO molecule	Non-DPCO counterpart
Cardiac	Frusemide	Hydrochlorthiazide
	Verapamil	Amlodipine
Pain/ Analgesics	Ibuprofen	Diclofenac
Dermatology	Griseofulvin	Miconazole
	Betamethasone	Beclomethasone
Respiratory	Dexamethasone	Budesonide
	Pheniramine Maleate	Cetrizine
	Salbutamol	Salmeterol
Gastro Intestinal	Famotidine	Pantoprazole
	Ranitidine	Omeprazole
Anti-infectives	Cefotaxime	Ceftriaxone
	Ciprofloxacin	Ofloxacin
	Erythromycin	Azithromycin
	Gentamicin	Amikacin

These select set of molecules and their analog counterparts were analyzed across several key parameters including sales and prescription trends over a period of time and across geographic/ townclass comparisons. At a molecule level, further studies were also made around the levels of market fragmentation, introduction of new brands in the market, impact on domestic vs. international companies, effect of DPCO on market leaders vs. tail-enders and so on. These analyses were aggregated into therapy level comparisons in order to draw macro-level inferences.

At an overall level, impact on the healthcare industry, post DPCO was studied based on value and volume. Also, price comparisons against other developing economies were made to understand the relative significance of such measures.

All of these analysis were used develop conclusive insights to corroborate the objective of the study and develop a case for improving healthcare access in India with DPCO as its backdrop.

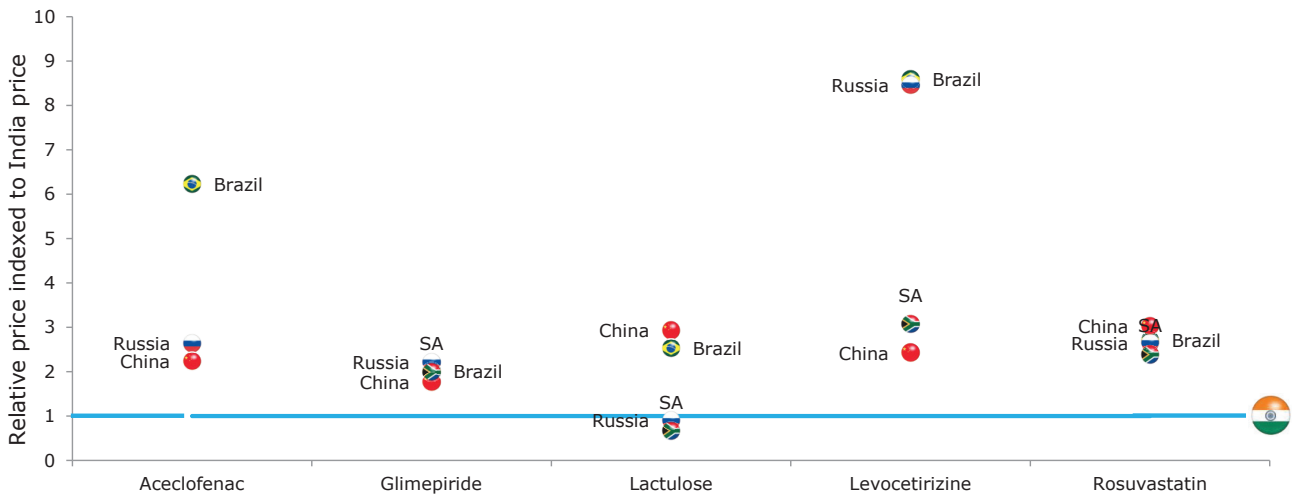
Key findings from the study: Lessons from other countries

The study found key insights for pricing comparisons and control measures adopted across countries with similar healthcare systems:

Indian medicines are amongst the lowest priced in the world, a trend well reflected when compared to BRIC and SAARC countries.

- Indian medicines are among the lowest priced in the world, even for non DPCO molecules
- Prices of Indian drugs are ~65% lower than their BRICS counterpart (Exhibit 1) and ~20% lower than their SAARC counterparts (Exhibit 2)

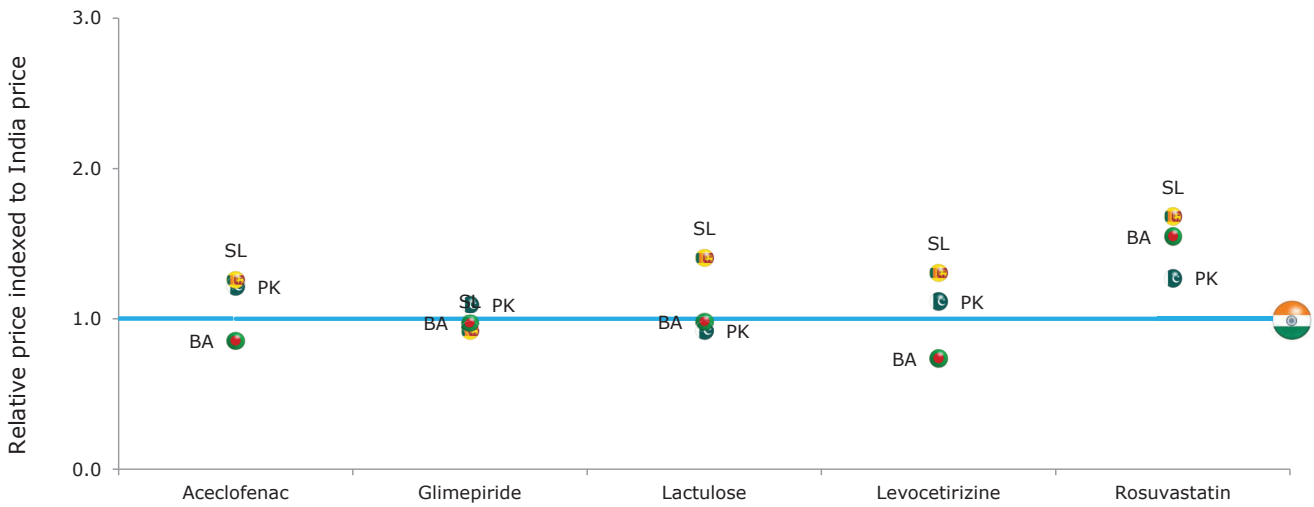
Exhibit 1: Price benchmarking (PPP level) of medicines across BRICS - MAT Mar 2015



Notes for Exhibit 1 & 2

1. *Above analysis is for the selected basket of analog molecules is based on IMS Midas data*
2. *Aceclofenac: 100 mg, Glimepiride: 2 mg, Lactulose: 3.35 g/5 ml, Levocetrizine: 5 mg and Rosuvastatin: 10 mg. All prices indexed to India (=1).*

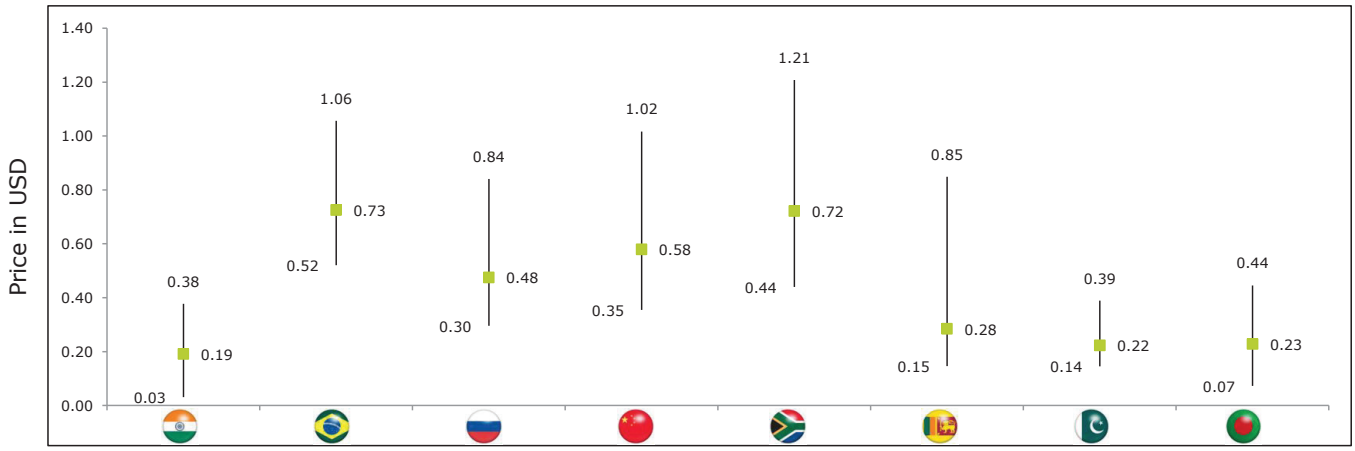
Exhibit 2: Price benchmarking (PPP level) of medicines across SAARC - MAT Mar 2015



Further, price disparity and India's relatively low drug prices are evident while comparing high, low and average prices across the countries

- Across developing economies in the World and Asian subcontinent, the prices of Indian drugs are the lowest across all 3 categories (Highest, average & lowest)
- Price disparity among brands exist even in other countries

Exhibit 3: Price Dispersion (PPP level) of medicines across BRICS & SAARC



Source: IMS Midas MAT Mar 2015

Notes:

1. *Above analysis is for the selected basket of analog molecules is based on IMS Midas data; 2. Prices calculated as total value sales/ total volume sales for the respective molecules; 3. The three price points indicate high (above) , average (Green) and low (below) brand prices; 4. Aceclofenac: 100 mg, Glimepiride: 2 mg, Lactulose: 3.35 g/5 ml, Levocetirizine: 5 mg and Rosuvastatin: 10 mg; 5. PPP conversion factor source : International Monetary Fund*

Based on evidence from countries such as China, Philippines & South Korea, price control measures had limited impact in improving access. In fact, in China, market driven drug prices are set to replace government set prices in 2015.

Country	Price calculation method	Impact
 Philippines	Imposition of a ceiling price (c. 50% of drug price)	• Failed to help poor sections of society who could not afford the drugs • Negative impact on sales of generics & local companies who were forced to further reduce their price • Delay in introduction of new molecules depriving patients of better treatments • Reduced availability of drugs under price control
 China	Mark-up above the average production cost	• Reduced availability of drugs under price control • Replacement of drugs under control with more expensive drugs in hospitals & stores • Drugs reformulated, repackaged, rebranded and sold at a higher price
 South Korea	IATP method and A-7 pricing method for innovative drugs	• Unfair practices and underhand dealings between drug companies and wholesalers became rampant • High prices of innovative drugs affecting accessibility • Financial condition of the national health insurance budget deteriorated • Initial reimbursement prices incorrectly estimated

Philippines: Drug price control was not able to improve affordability, availability and industry competitiveness[1]

Drug price controls were implemented in Philippines, and a ceiling price was imposed (c. 50% of drug price). The notified price was determined by simply adding a wholesale margin and a value-added tax to the ex-factory cost. The effects of scale and variation in the production process were not taken into account when determining the prices. This led to reduced availability of drugs under price control. The sale of generics did not increase significantly even after the imposition of the ceiling price, with poor still not able to afford drugs. Only the rich and middle class benefited. Price controls further had adverse impact on generic and local pharma companies whose revenues declined by more than 50%. The consumers shifted to the branded drugs by innovator pharma companies, as their prices became lower, generic and local pharma companies were forced to reduce their prices further. Lower profitability also led to delay in introduction of new molecules. Only old drugs or near patent- expiry drugs would be brought here, thus patients were deprived of new and stronger drugs. Patients were forced to buy drugs from overseas, making treatment expensive.

China: Drug price control failed to improve affordability and led to a shortage of drugs in the market[2]

A price ceiling was imposed which was based on cost-based approach (mark-up above the average production cost). This led to near zero profitability for pharma manufacturers and drug stores. Neither the companies, nor the hospitals wanted to sacrifice their profitability by selling drugs under the price control which led to reduced availability of drugs under price control. Hospitals and stores also started prescribing and selling more expensive drugs, not impacted by the price control leading to adverse impact on affordability of drugs. Manufacturers stopped producing low-priced drugs if costs were not recovered under DPC. Drugs were repackaged under a new brand name, and sold them for a higher price. The new drugs represented only a small change in dosage, route of administration, usage, or packaging.

South Korea: Price controls increased underground transactions and raised prices of innovative drugs[3]

Individual 'Actual transaction Price' (ITAP) method and A-7 pricing method for pricing of innovative drugs was implemented in South Korea. Drug companies often gave buyers kickbacks in order to issue false transaction reports, stating that purchases were within the government-fixed allowable level. Wholesalers allegedly reported false transaction documents and underground transactions became more common.

A-7 pricing method allowed companies to raise prices of innovative drugs to average prices of A-7 countries, thus Korea prices were higher than in some A-7 countries. The per capita GDP of some of these countries was more than double that of Korea – thus impacting accessibility.

1 Minimal Government Thinkers, Secondary Research;

2 Issues in Drug Pricing, Reimbursement, and Access in China with References to Other Asia-Pacific Region, The Regulation and Approval of New Drugs in China, Pharmaceutical Policy In China;

3 Interest Groups' Influence over Drug Pricing Policy Reform in South Korea, Growing Application of Pharmacoeconomics and Outcomes Research in Health-Care Decision-Making in the Asia-Pacific Region]

Key findings from India: Impact of DPCO on patients

DPCO 2013 focuses on improving access and tries to encourage competition as it is market based; trends witnessed in the past one and half years indicate that price control measures have not benefitted a broader set of patient groups.

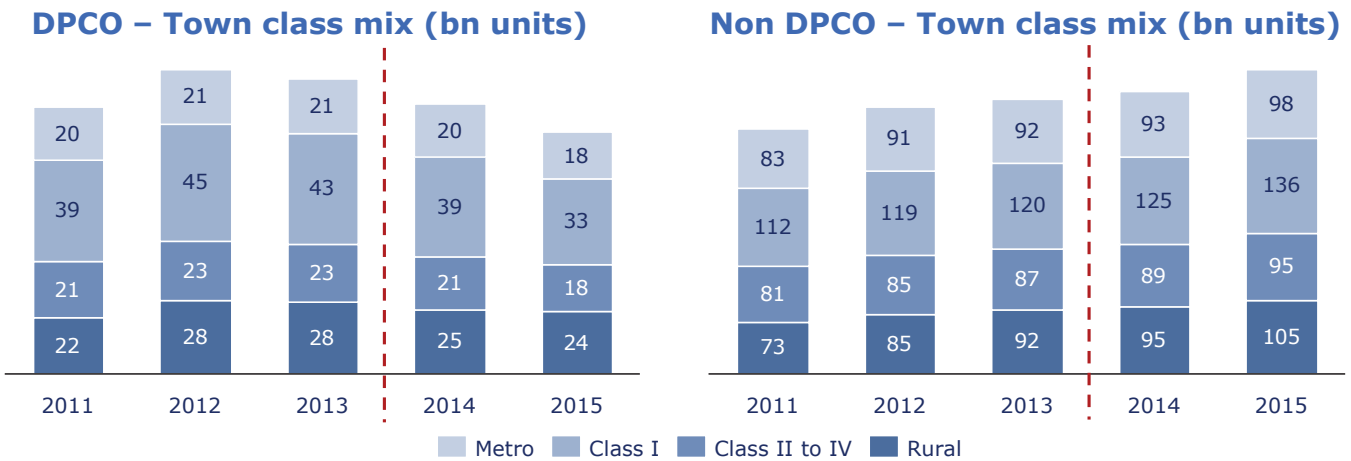
- Control measures have had minimal impact in improving the access of DPCO drugs in Class II and beyond town classes
- Volume share of DPCO molecules has started declining
- Market forces are leading towards strengthening of oligopolistic behaviour, which can result in reduced choices for doctors/patients

Price control has not resulted in improving reach of drugs in Class II and beyond town classes

Post DPCO 2013, while consumption of Non-DPCO molecules in rural town class has increased at ~7%, consumption of DPCO molecules actually decreased at the same rate. However, pre DPCO 2013, volume sales of DPCO molecules was increasing at CAGR of 12% which suggests that DPCO limits ability of players to focus/ invest in last mile marketing and distribution which is critical for increasing access to Class II and beyond town classes.

Reduction in generic prices only weakens the ability of players to make inroads in rural markets and creates a commercially non-sustainable environment. Given that prices are already low compared to elsewhere in the world; further reduction has a potential impact on availability and quality of generic medicines.

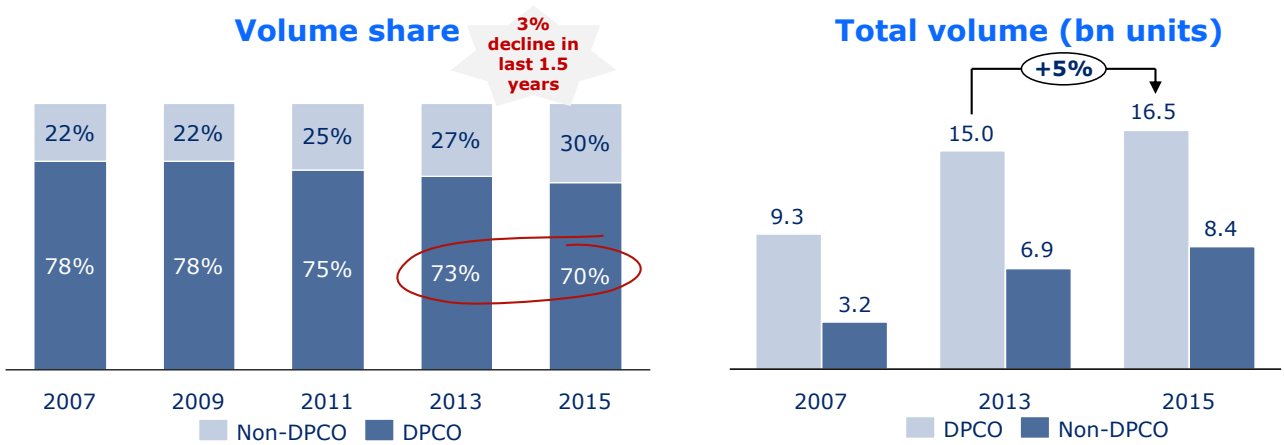
Exhibit 4: Price Town Class Wise Trend of Volume of All Molecules



Note: Analysis is for all the molecules in the IPM and is based on IMS MAT TSA data

In-fact, volume share of DPCO molecules has started declining across therapies. The contribution of DPCO molecules to total volume sales has decreased from ~78% to ~70% between 2007-2015. Analysis also indicates muted growth trends in DPCO molecules: Post DPCO 2103, volume of DPCO molecules has increased at CAGR of ~5% compared to a CAGR of ~8% pre DPCO 2013. This has largely been on account of slower volume growth of DPCO molecules with companies exiting the market. Volume sales of DPCO molecules have increased at CAGR of ~5% only as compared to ~10% for Non-DPCO molecules between 2013 and 2015.

Exhibit 5: Volume trends for DPCO & Non-DPCO molecules

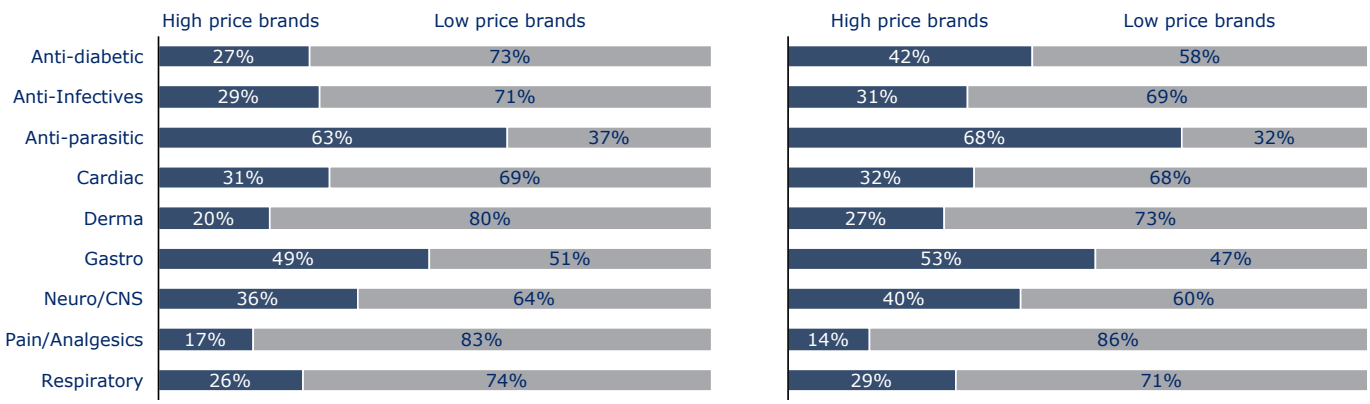


Note: Above analysis is for the selected basket of DPCO 2013 molecules and their counterparts and is based on IMS MAT SSA data

Decline in volumes in lower class towns can be attributed to the stronger negative bearing on the tail-end brands than the leading players.

- Post DPCO 2013, the volume based market share of brands which were priced higher than ceiling price is steadily increasing
- The negative impact of DPCO is more on these brands who are usually the small and mid-sized firms
- Given a continuing decline, these low price brands are more likely to be driven out of the market

Exhibit 6: Change in Market Share of higher and lower priced brands

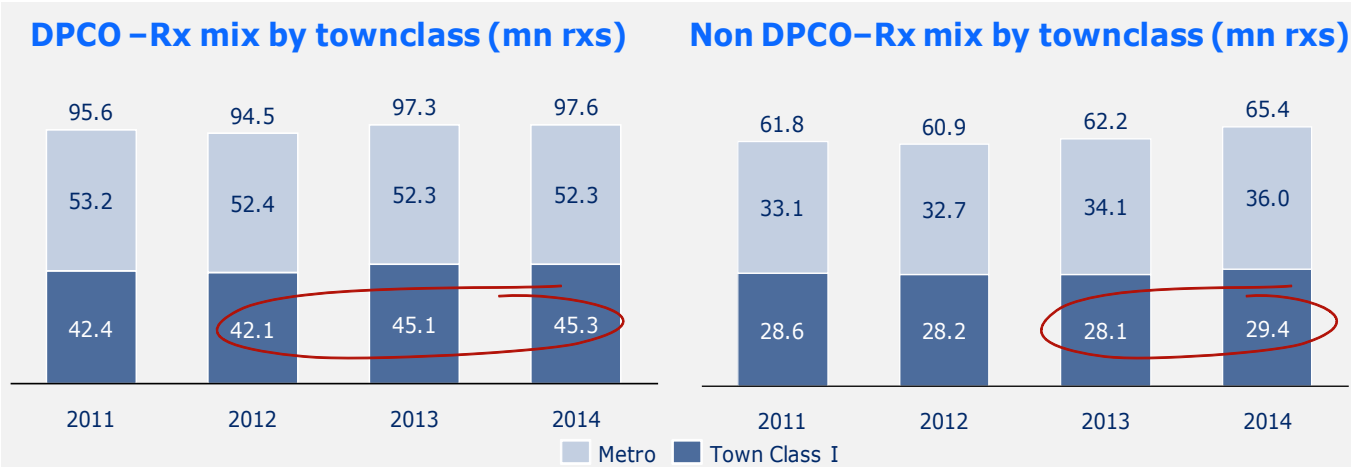


Note: Above analysis is for the selected basket of DPCO 2013 molecules and their counterparts and is based on IMS MAT SSA data

Prescription analysis also indicates no significant improvement in access

- Post DPCO 2013, Rx penetration has remained same in Town Class I compared to an increasing trend observed in pre DPCO 2013 which also hints at negative impact of price control on accessibility
- Limited choice for prescribers on account of brand exits and lack of new introductions will impact the access to a wider population

Exhibit 7: Town Class Wise Trend of Prescriptions – DPCO vs. Non-DPCO



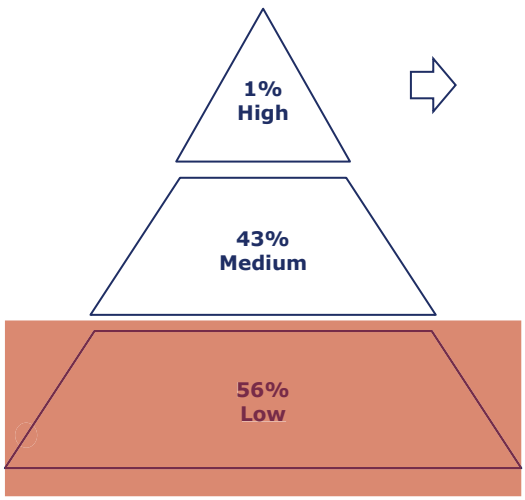
Note: Above analysis is for the selected basket of DPCO 2013 molecules and their counterparts and is based on IMS annual Rx Audit

With increasing pressure on small and midsized players, price control measures seem to benefit the high and middle income class segments more

The pressing need is increased coverage and support for medicines for low income groups. Current price control measures are not able to address the affordability gap, especially for low income patient groups. Price controls have not helped low income groups which are the target population for these measures, and have helped high income groups.

Exhibit 8: Healthcare Access – Income class wise

% of Population in Income class



Type of treatment & affordability

In-Patient	Out Patient	Comments
●	●	Price control measures appear to be subsidizing the medication cost of high and middle income segments who can already afford these medicines
◑	◑	
◑ Basic aspects of secondary care covered by RSBY, all other treatments hard to meet expenses	○	For low-income households that are reliant on the government system for healthcare, due to poor healthcare infrastructure and low availability of drugs in public sector, DPCO would not improve the patient's ability to purchase drugs

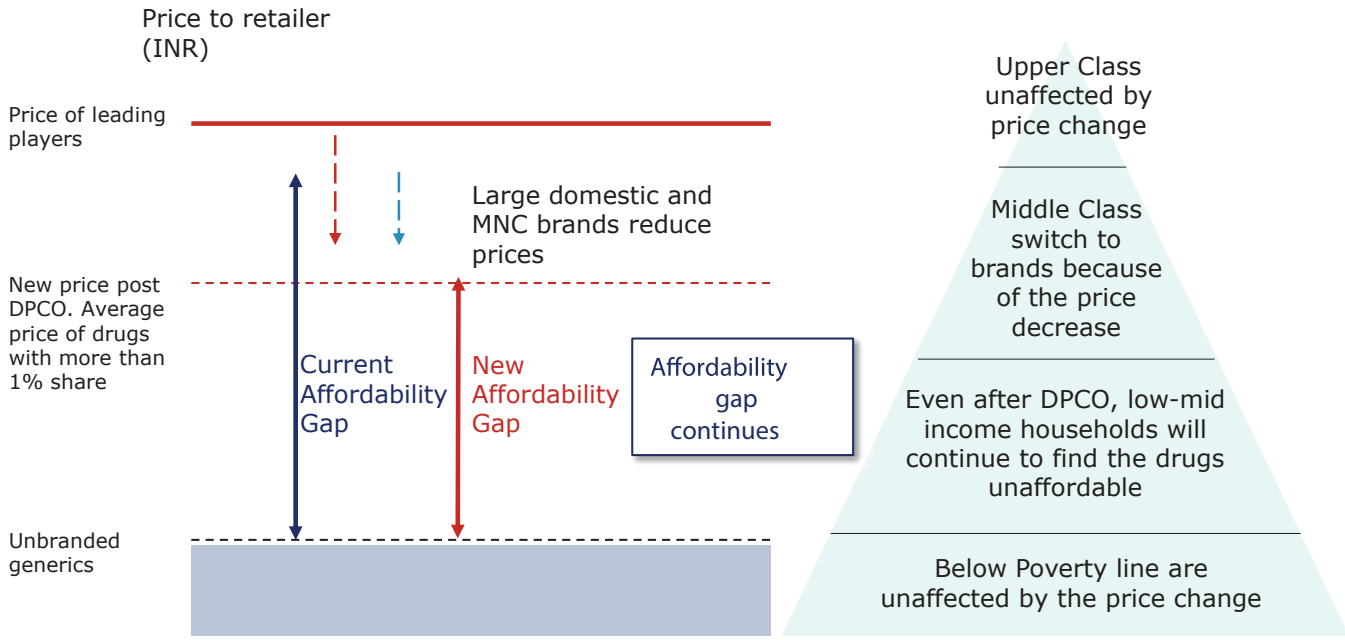
Affordability and coverage

Low ○ ⟷ ● High

Source: NCAER-CMR household survey 2010;
High Income: >17 Lakhs per annum (16 Million people)
Middle Income: 1.5 to 17 Lakhs per annum (519 Million people)
Low income : <1.5 Lakhs per annum (684 Million people)

Exhibit 9: Affordability Gap continues for low income segment

Illustrative

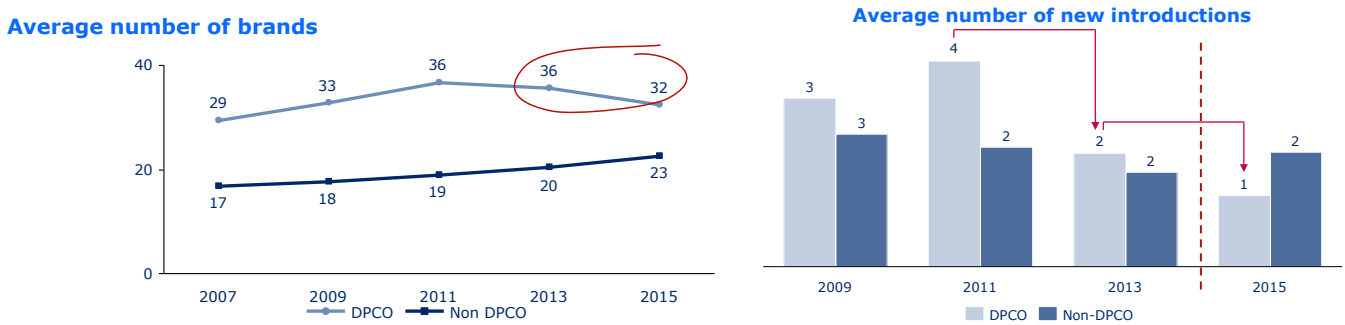


Price control and unstable regulatory environment has increased the margin pressures for companies, thereby impacting their sustainability especially small and mid-sized players. For smaller and mid-sized companies, commercial sustainability becomes a challenge due to market share erosion which further restricts access benefits for low income segments in lower town classes who are mainly serviced by small and mid-sized players.

DPCO has more impact on the tail-end brands than the leading players resulting in discontinuation of brands, thereby increasing market concentration

Post DPCO 2013, number of brands per DPCO molecule has started showing a declining trend while Non-DPCO molecules are witnessing an increasing trend.

Exhibit 10: New Introductions & Average numbers of brands

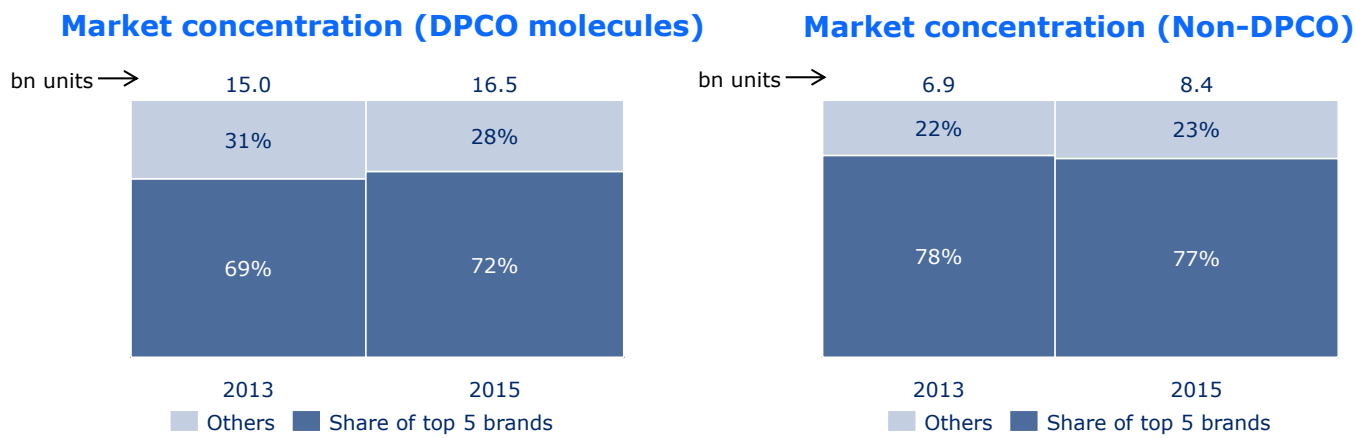


Note: 1. Analysis is for the selected basket of DPCO 2013 molecules and their counterparts and is based on IMS annual MAT data 2. Only those brands are considered which have atleast 500,000 units/year

Price control measures restrict investments for R&D even for generics as is reflected in declining new introductions. In a country like India, small but incremental innovations in formulations are important as it improves the therapy adoption and compliance variables. Post drug price controls, the number of new introductions in DPCO molecules has fallen across therapy areas.

Market concentration for DPCO 2013 has already started projecting an increasing trend combined with reduction in number of brands.

Exhibit 11: Market Concentration of DPCO 2013 & Non-DPCO Molecules



Note: 1. Analysis is for the selected basket of DPCO 2013 molecules and their counterparts and is based on IMS annual MAT data

Increasing market concentration and reduction in number of brands is limiting patients and prescribers' choice

Though it cannot be concluded if this will result in creation of oligopolistic market but the likelihood is high. This may result in significant repercussions in the form of exit of small and midsized players.

This impacts capabilities of players to continue servicing lower class towns. With reduced operating margins, players are withdrawing brands and resources from markets – illustrated in brand exits and lesser number of new introductions.

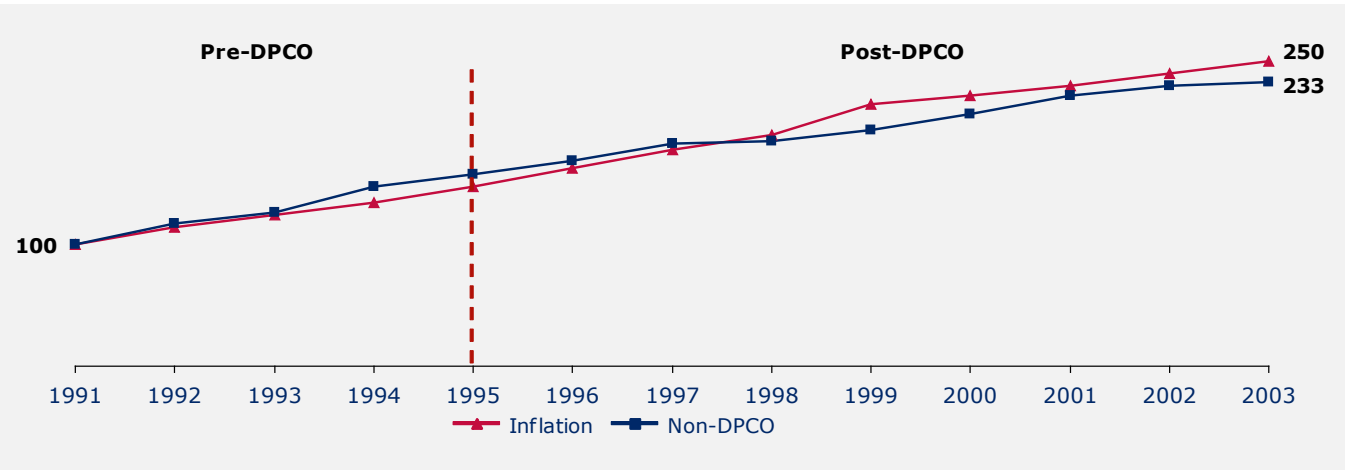
This further limits the ability of companies to:

- Strengthen distribution infrastructure
- Deploy resources for reaching out to lower town classes

The trends being seen post DPCO 1995 are similar to DPCO 2013, which had resulted in a marginal price benefit, but the restricted volume growth did not help meet objectives of ensuring medicines to a larger patient pool.

Historically, prices of drugs in India have not risen drastically. Assessment of Non DPCO segment (1991-2003) indicates that overall increase in medicine price index has been under inflation for major part of the time period.

Exhibit 12: Price movement of non-DPCO molecules vs. Inflation

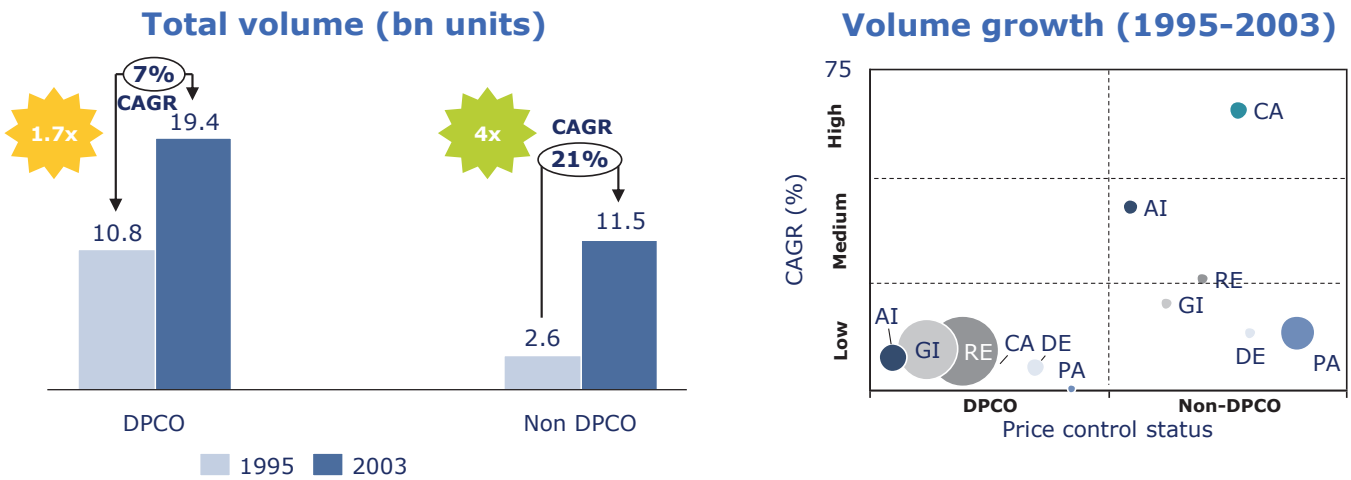


Note: 1. Analysis is for the selected basket of Non DPCO molecules and is based on IMS Annual MAT data. 2. Inflation source data is CPI average yearly inflation from RBI website 3. Prices calculated as total value sales/ total volume sales for the respective molecules

DPCO molecules were not able to increase penetration in newer markets or serve expanded pool of patients, and major market expansion and penetration appears to be driven by Non DPCO molecules.

- Growth in DPCO molecules post 1995 was in line historical trend of ~7% between 1991-1995, with no significant uptake witnessed
- Non-DPCO molecules grew at a faster pace of almost 21% CAGR between 1995-2003 compared to historical growth of ~19% between 1991-1995
- Volume growth of DPCO molecules was slower across various therapies, while in non DPCO, molecules in key therapies like Cardiac & Anti-infectives had fuelled growth

Exhibit 13: Volume growth-DPCO'95 and Non-DPCO Molecules

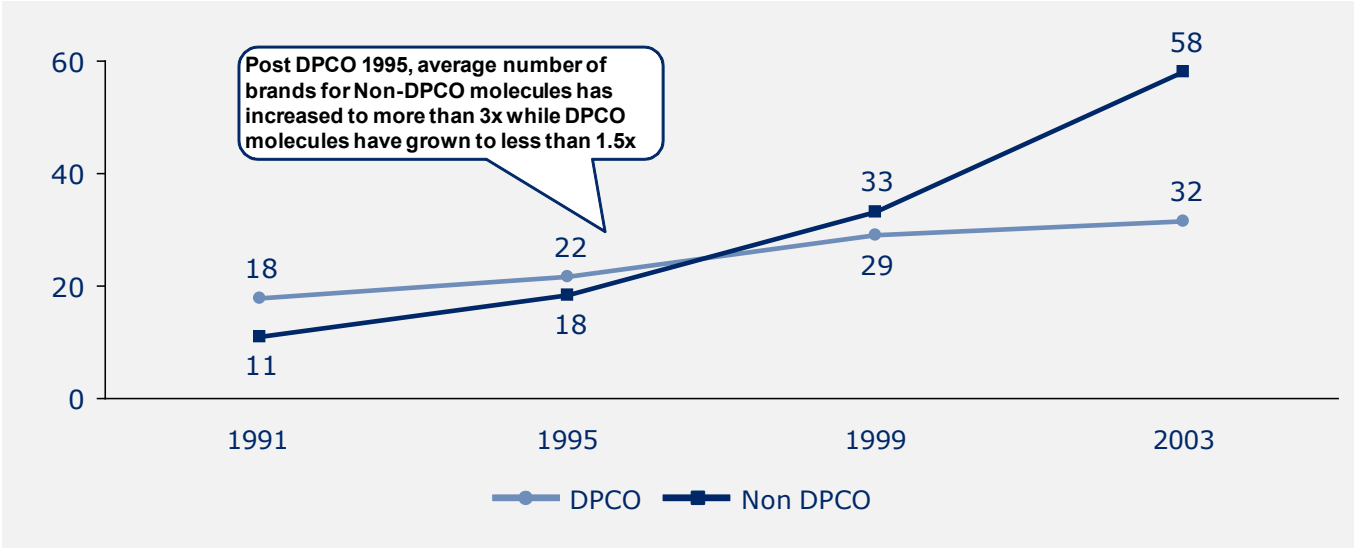


Note: 1. Above analysis is for the selected basket of DPCO 1995 molecules and their counterparts and is based on IMS IRI base file 1991-2003; 2. Therapy nomenclature is as follows: AI – Anti-infectives, GI – Gastro Intestinal, RE – Respiratory, CA – Cardiac, DE – Derma, PA – Pain/ Analgesics; 3. Size of the bubble represents the size of the market in volume The trend of decreasing New Introductions and reduced number of brands was witnessed post DPCO 1995 also.

The trend of decreasing New Introductions and reduced number of brands was witnessed post DPCO 1995 also.

- Between 1991-2003, average number of brands per DPCO molecule increased from 18 to 32 but the increase was very slow compared to Non-DPCO molecules (11 in 1991 to 58 in 2003)
- The market witnessed exits in the DPCO segment
  - Absence of a robust support infrastructure limits players' ability to scale up
  - In most cases, small and mid-sized players find it economically unviable to continue with specific product categories

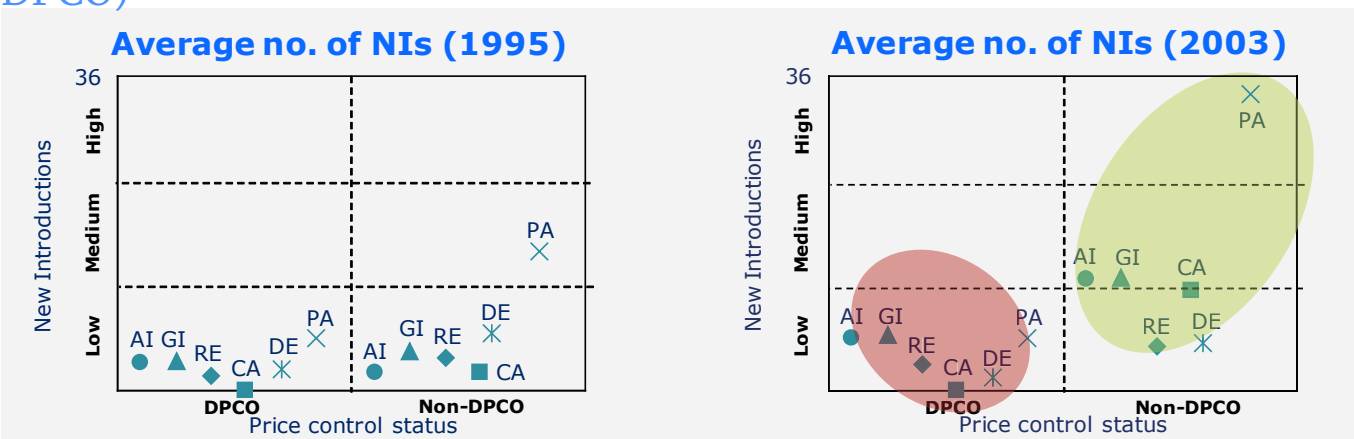
Exhibit 14: Average number of brands within selected molecules (DPCO 95)



Average number of new introductions in Non-DPCO segment far outpaced introductions in the DPCO'95 segment

- New Introductions in Non-DPCO molecules were ~75% more than the NIs in DPCO molecules between 1995-2003 which further substantiates the point that DPCO'95 did not incentivitize new players to enter the market
- Decreased innovation was observed across therapy areas particularly in Pain/ Analgesics, Cardiac, Anti-infectives and Gastro Intestinal therapies

Exhibit 15: Number of New Introductions across TAs (DPCO vs. Non-DPCO)

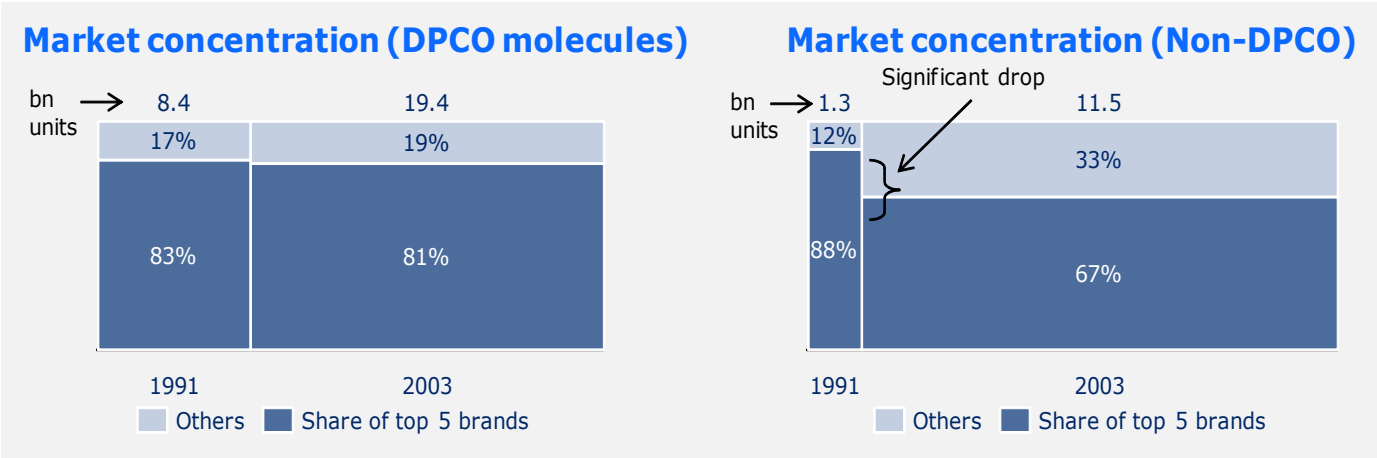


Note: 1. Above analysis is for the selected basket of DPCO 1995 molecules and their counterparts and is based on IMS IRI base file 1991-2003; 2. Therapy nomenclature is as follows: AI – Anti-infectives, GI – Gastro Intestinal, R – Respiratory, C – Cardiac, D – Derma, P/A – Pain/ Analgesics; 3. Only those brands are considered which have atleast 500,000 units/year

Discontinuation of brands, player exits & slow movement in new introductions strengthened the oligopolistic market situation

- Between 1991-2003, competitive intensity for Non-DPCO molecules increased significantly as compared to DPCO molecules
- Oligopolistic behaviour limits choice, impairs industry competitiveness as a result of which some smaller existing players lose interest and the segment also fails to attract attention of newer players.
  - Limited efforts in market shaping. It depends on decisions/choices of top 3-5 players, who may not always wish to invest in market segments
  - Limited innovations in same molecule segment
  - Limited options for prescribers

Exhibit 16: Market concentration of DPCO'95 & Non-DPCO Molecules

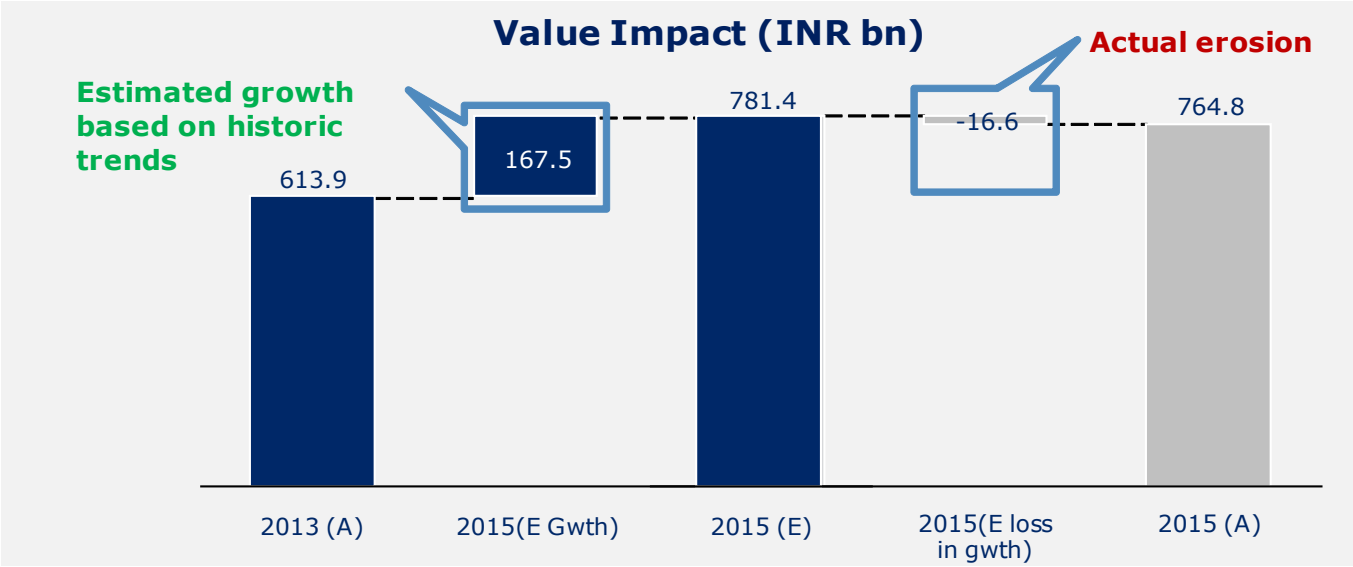


Note: 1. Above analysis is for the selected basket of DPCO 1995 molecules and their counterparts and is based on IMS IRI base file 1991-2003

DPCO impact on overall ecosystem

Slower growth rate of industry post DPCO poses economic challenges and other macro level impact on exports and employment

Exhibit 17: Value Impact of DPCO

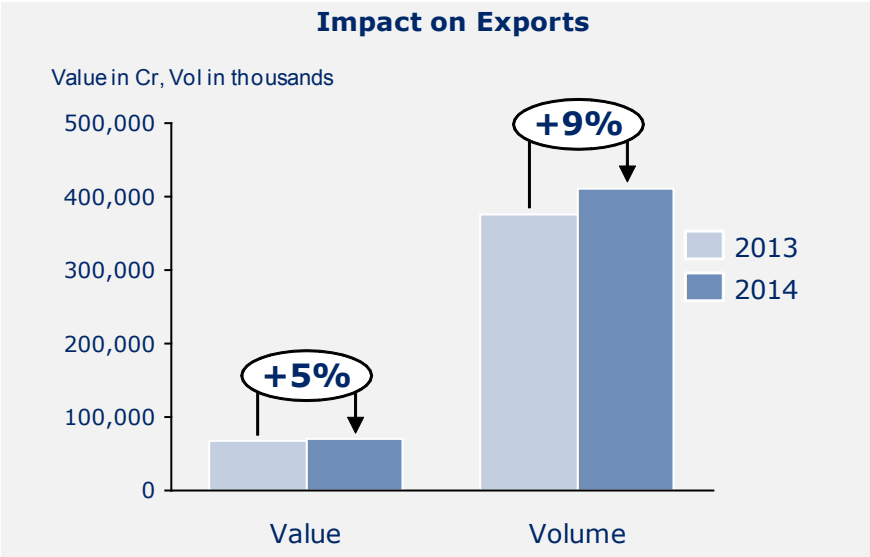


Note: Above analysis is for the whole IPM and is based on IMS MAT data

Contrary to the historical CAGR of 12.8% between 2011–13, the actual CAGR was 11.6% resulting in lower revenue generation for the industry. Total revenue loss for industry is INR 17 bn which can have other macro level impact.

- **Impact on employment:** The sector has the potential of creating nearly 4 million additional jobs by 2030 and price controls can lead to margin pressures which can impact the job creation potential of the pharma industry
- **Dilution of "Make in India" :** With no monetary motivation to expand, investment in R&D becomes limiting to domestic advancements
- **Poor investment culture :** Negative sentiments from sudden regulatory changes leads to skepticism from internal and external investors leading to diminishing investments
- **Impact on exports:** Post 2013, while the volumes grew at 9%, value growth was significantly lesser at 5%. India's pharma exports to other developing countries accounts for ~12% of our total exports of pharmaceuticals. PPP wise price comparison against these countries indicates that average prices of Indian drugs is lower than the prices in these countries. These countries could benchmark their prices against domestic Indian prices and negatively impact our growing exports market

Exhibit 18: Impact on Exports (2013-14)



Source: Department of Commerce: Import-Export Data Bank '2015

Recommendations

Given the current situation and complex realities of healthcare in India, the government will need to play a lead role in driving India's healthcare transformation journey. Direct price control measures will not help in improving access and a combination of healthcare financing and non-financing measures need to be adopted by the government to address the issues of access and affordability:

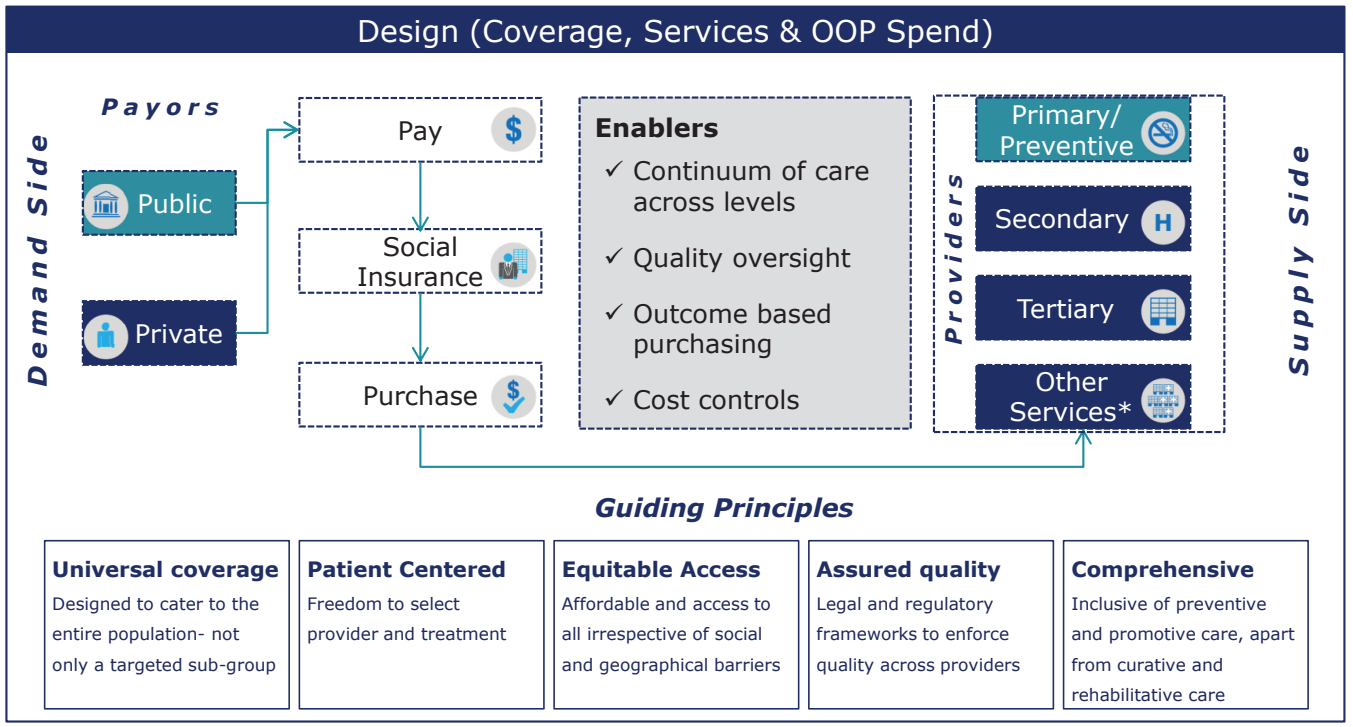
- ✓ Strengthen **healthcare financing**. Extend universal health coverage across population segments with focus on providing cover for medicines
- ✓ Develop a robust **patient access framework**
- ✓ Establish a **cess on tobacco and liquor industry** to fund the healthcare sector. **Subsidize essential medicines** from taxes
- ✓ **Incentivize** states to implement generic drug distribution schemes such as **Jan Aushadhi** scheme
- ✓ Invest in **healthcare infrastructure** and **capability building agenda**
- ✓ Promote **joint and bulk procurement** mechanisms. E.g. TNMSC

Extend universal health coverage across population segments with focus on providing cover for medicines

Evolution of the health sector has seen decades of low public spending on healthcare. While Health is a concurrent subject, with the bulk of responsibility is with the states. The spending in per capita terms itself ranked very low globally, remained stagnant for many years. The contributions from States stands at ~64% of the total public spend. Even the limited public spending remained skewed towards curative tertiary care as against preventive, primary and secondary care. The states themselves failed to accord enough priority to the health sector and spent very limited amount out of their budget.

India needs to design the health systems which are customized at the state level, in line with the overall framework of UHC (Exhibit 20).

Exhibit 19: Universal Health Coverage Framework



**Other Services include Diagnostics, ambulatory services, non-medical services, etc.*

The design of the Universal Health Coverage has to address the issues in Pricing and Patient Access that can ensure effective, appropriate, equitable and sustainable access in the context of UHC.

Develop a robust patient access framework

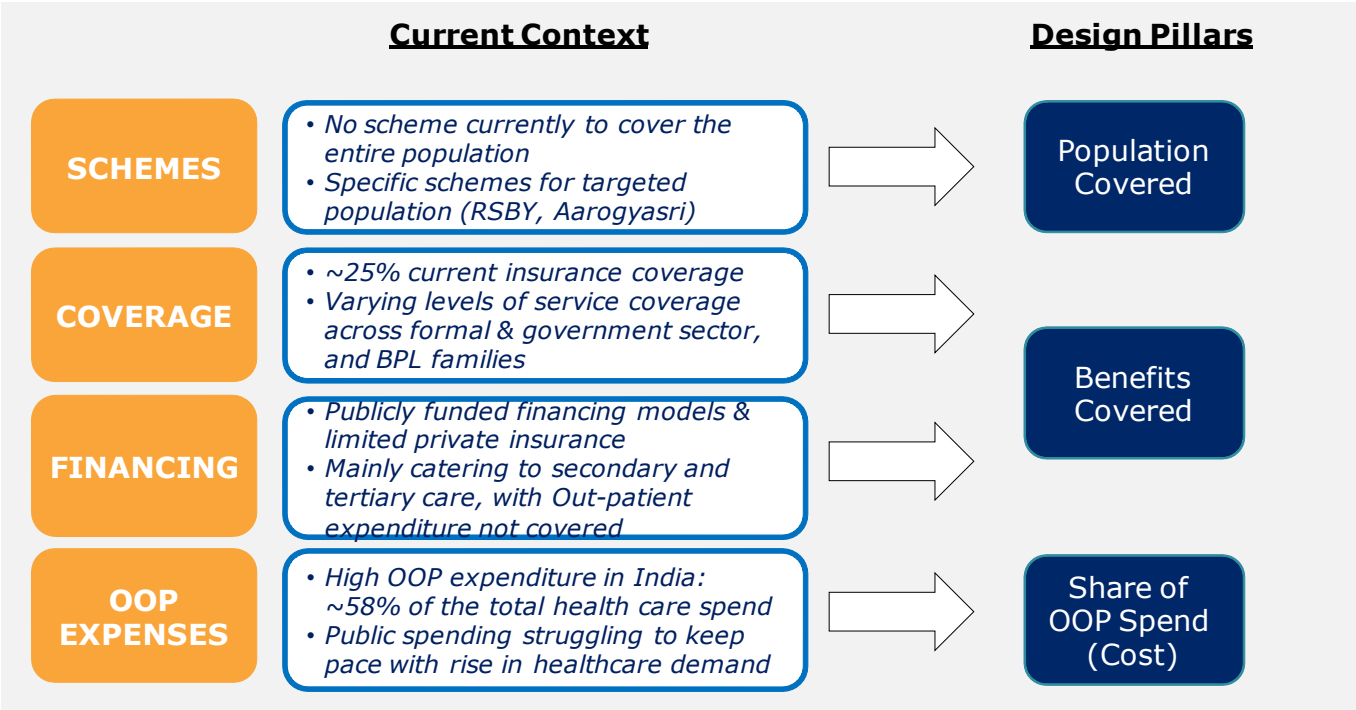
Effective financing/reimbursement needs to cover three aspects: Population coverage, benefits coverage and cost coverage.

Population Coverage: While in the long-term a completely public coverage model may be possible, a hybrid model is recommended in India in the short to medium term. Given budget constraints, public coverage can be targeted towards key patient segments, especially in the short term. Priority population segments can include poor income groups, older people with high risk and patients in rural /inaccessible geographies. Middle to high income patients can be covered through increased access to private insurance, at least in the short to mid-term.

Benefits Coverage: Not all medicines need to be reimbursed. Reimbursement of medicines can be prioritised with a particular focus on reimbursing essential drugs, treatments with high public health impact, high cost treatments, and hospital based treatments.

Cost Coverage: Given limited budget, there needs to be a balance between government contribution and patient contribution to the cost of medicine. A well defined co-payment system can help in achieving this balance, with lower or no co-pays for poorer patients and chronic treatments.

Exhibit 20: Design Pillars for Universal Health Coverage



Existing tariffs and taxes on essential medicines could also be abolished as this increases the price of medicines

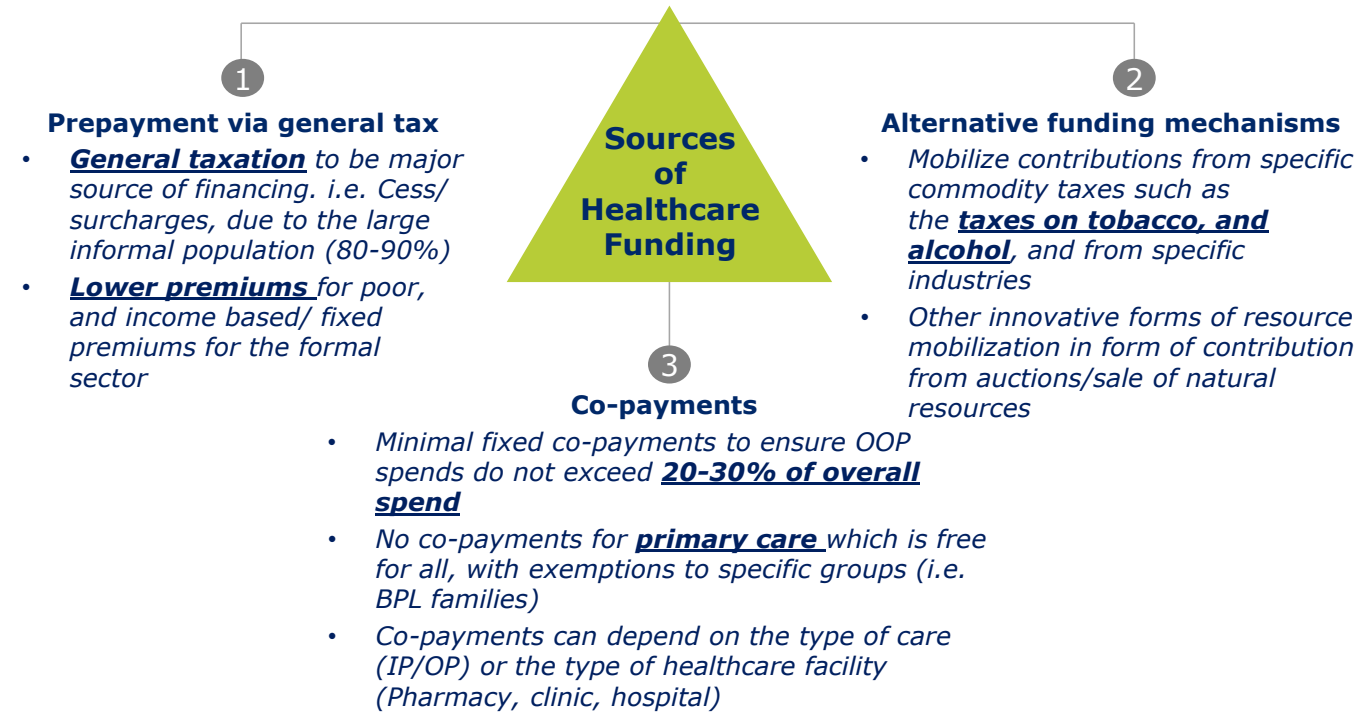
India imposes import duty on medicines, including vaccines and antibiotics. After the MSP and mark-ups, domestic taxes such as VAT or sales tax are often the third largest component in the final price of a medicine in India. The total domestic taxes and tariffs increase the price by nearly 8-10%.

Many countries, including countries much poorer than India, such as Kenya, Cameroon, Rwanda, etc. have abolished tariffs on medicines. The Assistant Minister for Public Health and Sanitation in Kenya has stated that his country's removal of taxes and tariffs on malaria products has contributed to a 44% decline, between 2002 and 2009, in the rate of infant mortality and disease.

According to WHO, India derived revenue worth only 0.0094% of its GDP in 2001 from tariffs on medicines, even though the tariffs then were between 30% and 35%. The tariffs therefore provide increasing price to patients, provide very little revenue for the government.

Increase contribution from alternative funding mechanisms such as cess on tobacco and liquor industry to fund the healthcare sector.

Exhibit 21: Sources of Healthcare Financing

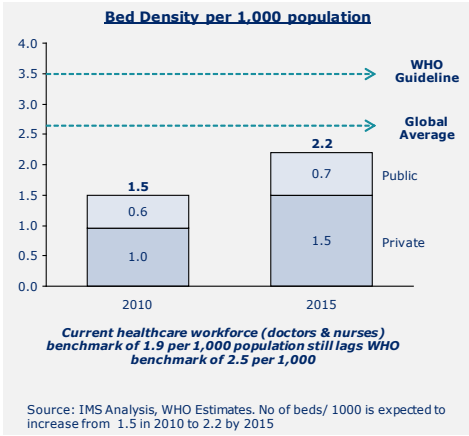


Incentivize states to implement generic drug distribution through Jan Aushadhi scheme

Schemes such as Jan Aushadhi if implemented effectively can play a large role in the quest of improving access to affordable medicines. Jan Aushadhi stores as a source of affordable and quality generic medicine will improve the access if such stores are opened at convenient locations instead of only coming up at government hospitals/dispensaries. If a patient has to travel a long distance or time to buy medicines from Jan Aushadhi stores, it will defeat the very purpose of increasing access to affordable medicine. Similarly maintaining tight control on stock levels and indenting as well as a control on quality of drugs supplied through such stores, will be utmost important to make it a sustainable source of affordable and quality medicines.

Invest in healthcare infrastructure and capability building agenda to improve public health and improving accessibility

Low spending on healthcare in India has resulted in inadequacies of health infrastructure & resources leading to poor health outcomes. The total spending on healthcare in India is about 4.1% of GDP with the public spending on healthcare is only 1.04% of GDP which is about 4% of total Government expenditure. Even the limited public spending remained skewed towards curative tertiary care as against preventive, primary and secondary care. Tamil Nadu has been regarded as one of the most successful states in improving public health and improving accessibility, and can be used a model for other states.



Source: IMS Analysis, WHO Estimates. No of beds/ 1000 is expected to increase from 1.5 in 2010 to 2.2 by 2015

Notable Achievements in Tamil Nadu

- Drastic fall in infant mortality rate : Between 1980 - 2005, infant mortality fell by 60% , compared to 45 % nationally, with the greatest gains in rural areas
- Reduction of maternal mortality : from 319 deaths per 1,00,000 live births in the early 1980s to 111 deaths per 1,00,000 live births in 2004–06, the second lowest of any State. This decline was much faster than in India overall
- High healthcare coverage: 90 % of deliveries are attended by a skilled birth attendant, almost 25% of deliveries take place in primary health-care facilities, and 81% of infants are immunized
- Highest immunization coverage in India : the narrowest gap between the richest and poorest quintiles and between rural and urban areas
- Significant lowering in occurrences of diseases : The state has witnessed minimal incidences of both communicable & non communicable diseases, esp Measles, Polio etc
- Low cost drugs & health services: Owing to the centralized procurement by TNMSC the relative prices have reduced significantly

Key success factors

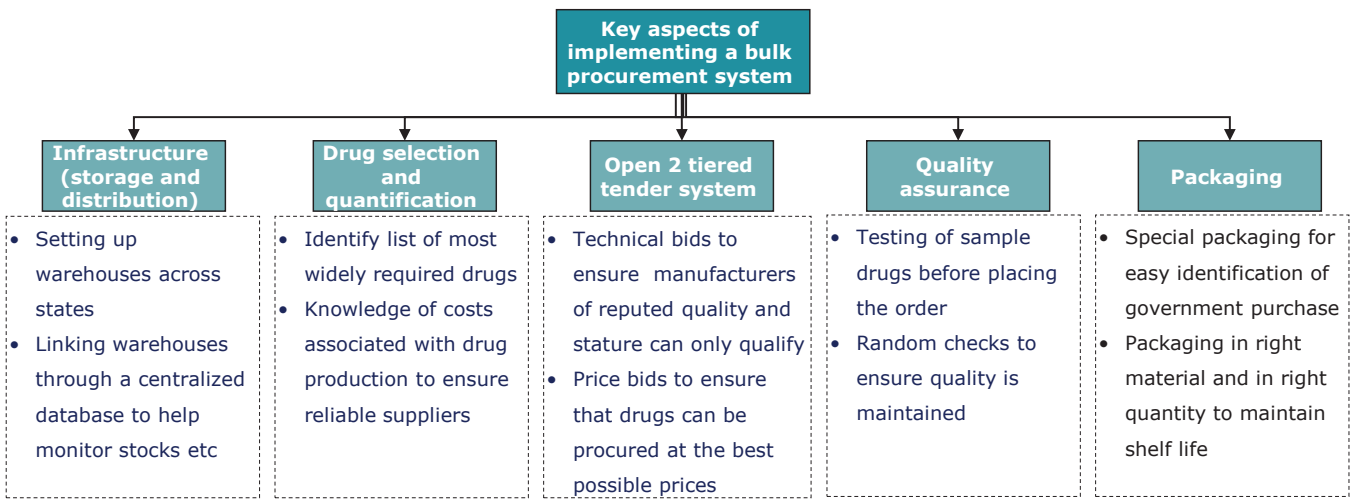
- Training & Development: One of the first states to implement a large scale multipurpose worker scheme. Women with at least 10 years of schooling were trained for 18 months to become village health nurses. Existing maternity assistants were retrained and new training facilities were built
- Large network of primary healthcare centres : With over 11,000 public health establishments, TN is one of the largest network in the country
- Reliable supply of essential drugs through TNMSC: The new system, providing ~300 generic essential drugs, is credited with substantial improvements in drug supply and transparency. It has also contributed to driving down the cost of drugs supplied in the private sector
- Standardized process and regulations : All healthcare process run by the government are highly process driven, driven by well laid norms and therefore carried out highly effectively & efficiently

Promote joint and bulk procurement mechanisms to harmonize drug policies and reduce drug cost

There are numerous benefits of a bulk procurement system

- Increased bargaining power of purchasing entity leading to high discounts and increased affordability
- Competitive bidding in the tendering process will result in low prices
- Standardizing requirements reducing duplication of efforts
- Assurance of high quality medicines to end users
- Better utilization of government funds

Exhibit 22: Implementation of Bulk Procurement System



One of most successful programs has been TNMSC (Casestudy). The establishment of TNMSC has been the largest contributor to the success of the state's public health system. Tamil Nadu government has developed an effective way of improving accessibility of medicines in the state through the following approach:

- 40% of the population with low affordability are provided free essential medicines through TNMSC which currently is being able to purchase medicines worth market price of ~INR 35 bn from its exiting annual budget of ~INR 3.5 bn
- Top 300 non-essential medicines can be purchased at subsidized rates (~40% lower) from the "Amma stores"
- Remaining drugs can be purchased through the open market
- Through this approach, 70-80% of drugs in the market are either provided free or at subsidized rates

Case study: Overview of Tamil Nadu Medical Services Corporations

What is TNMSC?

- It is a state set up body with the primary objective of ensuring ready availability of all essential drugs and medicines in the Govt Medical Institutions throughout the state by adopting a streamlined procedure for their procurement, storage and distribution. TNMSC aims to make the drugs and materials available to the poorest of the poor and "Service to the Public"

What are the key services provided by TNMSC?

- Procurement, testing storage and distribution of drugs, equipment & kits to government institutions
- Finalization of Annual Rate Contract for Speciality Drugs and Medicines for direct procurement by the medical institutions in the State
- Operating Testing centers like CT Scan centers, MRI Centers, Lithotripsy centers in the medical institutions of the State on user charge collection basis
- Consultancy services on the procurement logistics systems to other states in India
- Sale of selected life saving medicines to the Public

How does it operate?

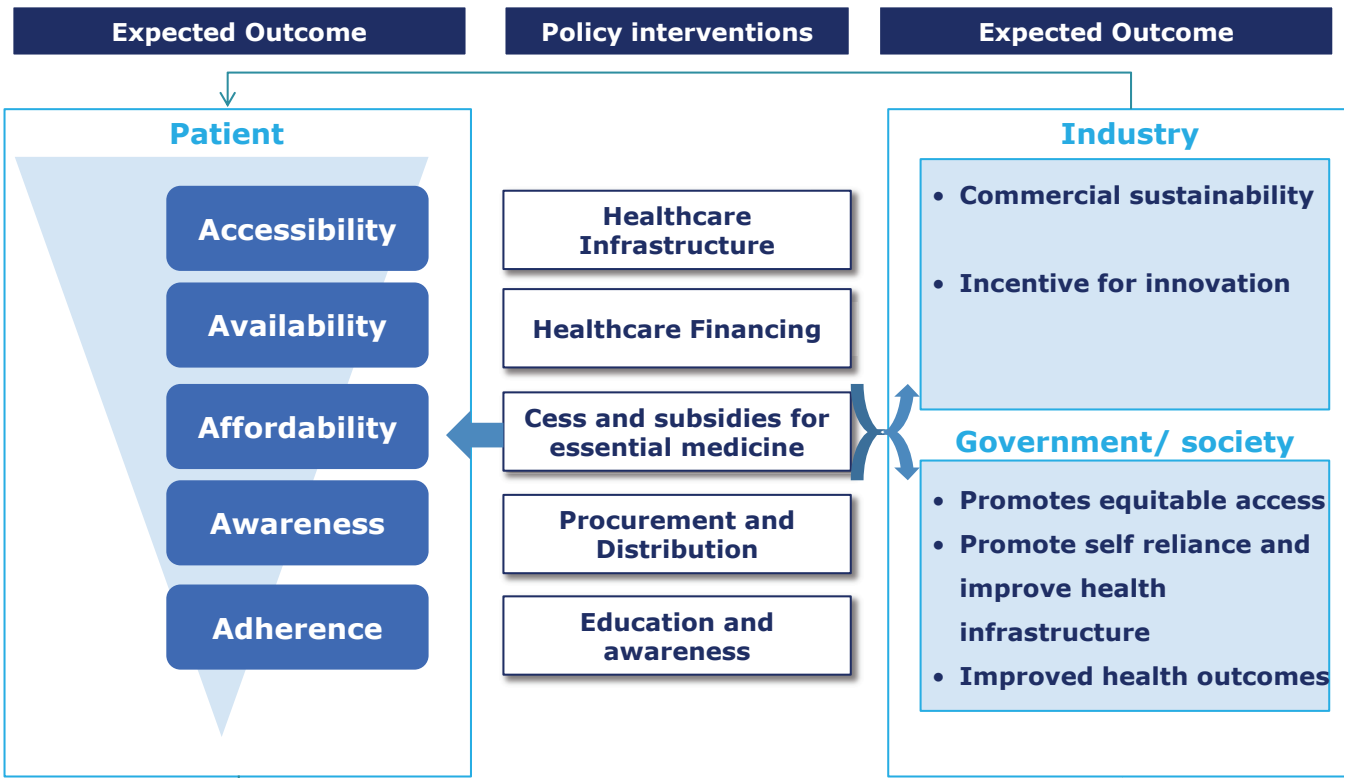
- Through an appointed drug committee, a list of essential drugs is created & periodically revised
- Through a transparent bidding process, procurement is carried out from well established manufacturers
- Post packaging in requisite forms stringent quality tests are done on each and every batch
- Only quality cleared batches are distributed through a well networked system of supply
- Payment is rendered to manufactures only post seeking reasonable quality assurance
- Overall management through a central logistics team, technology support through well established MIS and well trained and diligent resources

Conclusion

India needs to gain momentum across the gamut of healthcare reforms and to truly improve access to healthcare, it is critical to advance sustainable policy solutions to healthcare financing, infrastructure, and human resources challenges, among others.

The government needs to play a lead role and increase the investment towards healthcare. Without the required investment this will continue to represent a critical barrier to broader access for healthcare.

The measures and policy interventions highlighted to address healthcare access would ensure the desired health outcomes are achieved for the patients, while addressing the needs of other stakeholders.



Abbreviations

AI:	Anti-infectives
API:	Active Pharmaceutical Ingredients
BRICS:	Brazil-Russia-India-China-South Africa
CA:	Cardiac
CAGR:	Compounded Annual Growth Rate
CPI:	Consumer Price Index
DE:	Derma
DPCO:	Drug Price Control Order
GDP:	Gross Domestic Product
GI:	Gastro Intestinal
IATP:	Individual 'Actual transaction Price'
IPM:	Indian Pharmaceuticals Market
MIS:	Management Information System
MNC:	Multi-National Company
MSP:	Minimum support price
NLEM:	National List of Essential Medicines of India
OOP:	Out-Of-Pocket
PA:	Pain/ Analgesics
PPP:	Public-Private-Partnerships
PPP:	Purchasing power parity
RE:	Respiratory
RSBY:	Rashtriya Swasthya Bima Yojna
Rx:	Prescription
TNMSC:	Tamil Nadu Medical Services Corporations
UHC:	Universal Health Coverage
VAT:	Value added tax
WHO:	World Health Organization.

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- Growing Application of Pharmacoeconomics and Outcomes Research in Health-Care Decision Making in the Asia-Pacific Region
- Minimal Government Thinkers, Philippines

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