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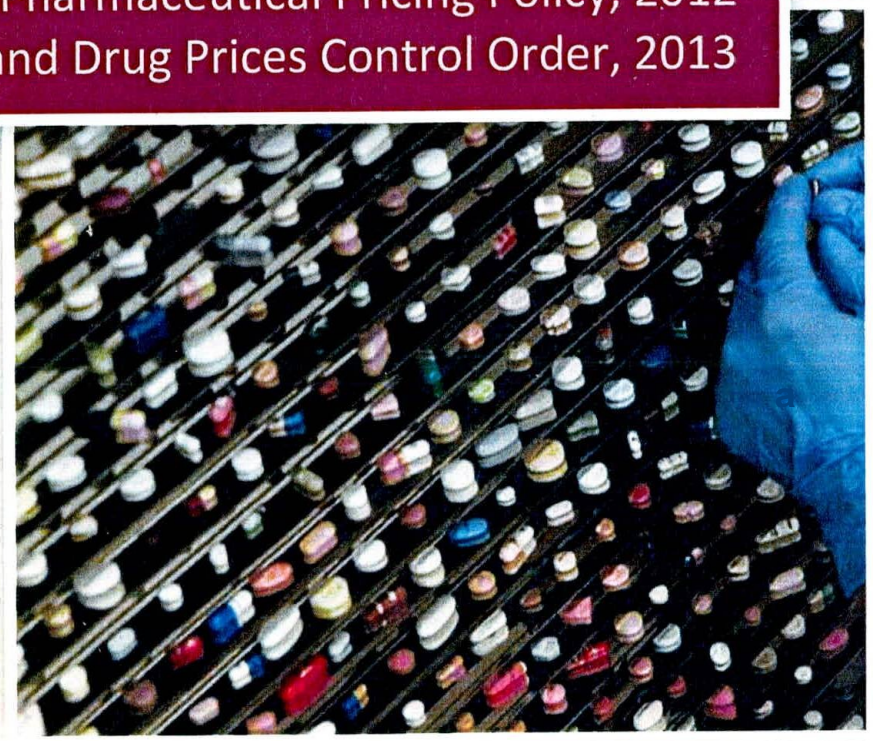
An Independent Evaluation of the National Pharmaceutical Pricing Policy, 2012 and Drug Prices Control Order, 2013



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An Independent Evaluation of National Pharmaceutical Pricing Policy, 2012 and Drug Prices Control Order, 2013

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CHAPTER 1
INTRODUCTION

India is often referred to as the pharmacy of the south. The Indian pharmaceutical industry currently produces over ₹1 00,000 crores (US $ 20 billion) worth of drugs, 40 per cent of which are supplied to patients in other countries. India currently boasts of having over 350 drug producing units that are endorsed by the EU (European Union) as Good Manufacturing Practices (GMP) complaint and several sites that are US FDA (United States Food and Drug Authority) approved, an achievement only few countries could dream of. Paradoxically, India is also home to where fifty to sixty-five per cent of the people do not have regular access to essential medicines[1]. The majority (70%) of healthcare expenditure is out-of-pocket expenditure of which in turn 70 per cent is spent on medicines alone[2,3]. This is the result of a historic neglect of public health institutions and continued poor investment in drug procurement and distribution systems. This means that in a country where poverty and deprivation are rampant, people are spending substantial proportions of their meagre disposable income on highly priced medicines from the private sector in the absence of an effective mechanism for price regulation. Regulation and control of medicine prices in the private sector is therefore critical to ensure affordable access to essential medicines for patients.

Critics of price control argue in favour of laissez-faire, leaving the market to its own devices. The fact however is that the pharmaceutical industry is characterised by high concentration where competition is based on market dominance, as is evident from the fact that the sales leader is often observed to be charging the highest price; extensive branding; and promotional practices. Moreover, because of information asymmetry, the demand for medicines is essentially supplier-induced. This gives the pharmaceutical firms an unfair advantage as they are able to push highly priced brands by influencing physicians and creating attractive incentives for pharmacists. In

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1 WHO (2004), The World Medicine Situation, WHO/EDM/PAR/2004-05.

2 Selvaraj, Sakthivel and Veena Nabar (2010), Access to Medicines in India: Issues, Challenges and Response, ed. in India Health Report, Business Standard Publications.

3 Garg CC & Karan AK 2009. Reducing out-of-pocket expenditures to reduce poverty : a disaggregated analysis at rural-urban and state level in India. Health Policy and Planning: 116-128

the face of such peculiarities of the pharmaceutical industry, price regulation is inevitable and most countries around the world have in fact adopted price regulation, sometimes in more ways than one, in the form of fixed margins for retailers and wholesalers, price freezes, ceilings on promotional expenditures, to name a few.

Table 1.1 provides a synoptic view of the history of price control of medicines in India, from 1963-2013.

In India, price control over drugs was introduced for the first time with the promulgation of the Drugs (Display of Prices) Order, 1962 & Drugs (Control of Prices) Order, 1963 under the Defence of India Act in light of Chinese aggression and prices of drugs were frozen with effect from 1st April, 1963. Subsequently, the Drugs (Prices Control) Order, 1966 was issued under the Essential Commodities Act, 1955 and medicines were declared to be essential commodities[4]. Under this order, it was obligatory for the manufacturers to obtain prior approval of the government before increasing the prices of all listed formulations. This was followed by the Drugs (Prices Control) Order of 1970, aimed at reducing the prices of essential medicines by curbing excessive profitability (over 15 per cent of sales turnover) and promoting research and development[5].

The Hathi Committee Report (1975) was the primary harbinger of pharmaceutical policies in India, which outlined 224 recommendations spread across eight themes on the various aspects of the pharmaceutical industry. In respect of price control, the committee came to the conclusion that rather than controlling the prices of all medicines, it would be desirable to be more selective in terms of size of the units, selection of items and controlling the price of only market leaders for particular products. The committee also recommended that ceiling prices be fixed based on an investigation of costs of production of two or three leading manufacturers. Further, it also endorsed the development of an effective and continuous system of monitoring

[4] Department of pharmaceuticals, 2011, National Pharmaceutical Pricing Policy, Ministry of Chemicals and Fertilizers, Government of India

[5] Task Force to Explore Options other than Price Control for Achieving the Objective of Making Available Life-saving Drugs at Reasonable Prices, 2005, Department of Chemicals & Petrochemicals, Government of India

production and stocks, costs, sales, profitability, raw material availability, emerging shortages etc. in respect of the pharmaceutical industry[6].

Recommendation of Hathi Committee Report, 1975

- A system of price regulation based on investigations of cost should continue for the bulk drugs for which production has not been established and imports are necessary.
- More selectivity should be adopted in the system of price regulation for formulations in terms of
  - i. size of units: units with annual turnover is < Rs.1 crore may be exempted
  - ii. selection of items: all formulations except those with an annual all India sale of Rs. 25 lakhs should be under price control whether the annual turnover is < Rs. 1 crore or not. Govt. may as an exception include any particular products under price control in public interest
  - iii. controlling the prices of only market leaders for particular: prices of only the leading products that account for say 60 percent of the sales of the relevant product group should be controlled on the basis of cost analysis.
- An effective and continuous system of monitoring production and stocks, costs, sales, profitability, raw material availability, emerging shortages etc. should be developed in respect of the pharmaceutical industry should be developed.

The Drugs (Prices Control) Order 1979 following the declaration of Drug Policy, 1978 placed 347 bulk drugs and their formulations under price control. The concepts of retention price, pooled price, Drug Prices Equalization Account (DPEA) and leader price were introduced. However, the order following the declaration of Drug Policy, 1986 reduced the number of bulk drugs and their formulations under control to 142 and the system of retention and pooled pricing was given up and, therefore, the DPEA stood abolished. The mechanism of ceiling price replaced the concept of leader price. Provision for recovering the amount accumulated by charging prices higher than those fixed or notified by the Government was made and the ceilings on pre-tax return were retained as earlier.

Following liberalisation measures, the Drugs (Price Control) Order, 1995 further reduced the number of bulk drugs and their formulations under control to 74 bulk drugs (1577 formulations in total were under price control by 2012) while also introducing for the first time, the mechanism of Cost-plus Based Pricing (CBP) for setting ceiling prices of formulations by taking into account the raw material cost, conversion cost, packaging material cost and the packing charges. Maximum

[6] The Committee on Drugs and Pharmaceutical Industry, 1975, Ministry of Petroleum and Chemicals, Government of India

Allowable Post Manufacturing Expenses (MAPE) to the extent of 100 per cent of manufacturing costs were sanctioned[7].

The formula was as follows:

Retail Price = (M.C + C.C. + P.M. + P.C.) X (1+MAPE/100) + E.D[8]

Where,

M.C denotes material cost including drug cost and other pharmaceutical aids

C.C. indicates conversion cost

P.M. means packing material cost of formulation

P.C. connotes packing of shipment

MAPE denotes Maximum Allowable Post-Manufacturing Expenses which includes trade margin

E.D. indicates excise duty.

The National Pharmaceutical Pricing Authority (NPPA) was established by the central government to monitor the prices of essential drugs in 1997. Later in 2002, a draft National Pharmaceutical Pricing Policy (NPPP) was formulated based on the recommendations of the Drugs Price Control Review Committee (DPCRC) set up in 1999 that sought to reduce the number of formulations under price control to less than 35 based on the criteria of (i) mass consumption nature of the drug and (ii) absence of sufficient competition in such drugs[9]. It can be noted that DPCRC and two earlier drug price policies sought to substantially reduce the number of bulk drugs and formulations under control (347 in 1978) to the proposed 34 in 2002. It is evident that price control over medicines in India was being gradually dismantled.

However, the 2002 draft policy was challenged in the Karnataka High Court which issued a stay order on its implementation. The order of stay was subsequently challenged by the government in the Supreme Court in 2003.

In the mean time, the draft pharmaceutical policy, 2006 recommended the revision of the MAPE structure in the cost plus formula, the use of the National List of Essential

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[7] Department of pharmaceuticals, 2011, National Pharmaceutical Pricing Policy, Ministry of Chemicals and Fertilizers, Government of India

[8] Department of pharmaceuticals, 1995, National Pharmaceutical Pricing Policy, Ministry of Chemicals and Fertilizers, Government of India

[9] Department of pharmaceuticals, 2002, Draft National Pharmaceutical Pricing Policy, Ministry of Chemicals and Fertilizers, Government of India

Medicines (NLEM), 2003 as the basis for price control of medicines, and fixing of prices for formulations only[10].

Table 1.1: Snapshot View of Key Pharmaceutical Policies in India, 1963-2013

Year	*Event*	*Description*
1963	Price control over drugs introduced for the first **time**	Price control over drugs was introduced with the promulgation of the Drugs (Display of Prices) Order, 1962 & Drugs (Control of Prices) Order, 1963 under the Defence of India Act; Prices of drugs were frozen w.e.f. 1st April, 1963
1966	DPCO , 1966	Order issued under the Essential Commodities Act, 1955; drugs declared to be essential commodities under the act.
1970	DPCO, 1970	Order aimed at reducing the prices of essential medicines by curbing profitability over 15 per cent on sales turnover and promoting R&D
1975	Hathi Committee Report	Recommended selectivity in price control, fixation of ceiling prices based on investigation of costs of production & the establishment of an effective and continuing system of monitoring production, profitability, costs etc.
1979	DPCO, 1979	Order following the declaration of Drug Policy, 1978 placed **347** bulk drugs and their formulations under price control.
1986	DPCO, 1986	Order following the declaration of Drug Policy, 1986 placed **142** bulk drugs and their formulations under price control.
1995	DPCO, 1995	**74** bulk drugs identified and both the bulk drugs & their formulations brought under price control. **Cost plus pricing** with 100 per cent MAPE introduced
1997	Establishment of NPPA	The National Pharmaceutical Pricing Authority established by the central government to monitor the prices of essential drugs.
2002	Draft pharmaceutical policy, 2002 challenged in Karnataka High Court	Draft policy, taking into account the recommendations of the Drugs Price Control Review Committee (DPCRC) 1999, sought to reduce the number of formulations under price control to less than **35**. Policy challenged in Karnataka High Court; stay order issued.
2003	Stay order challenged in the Supreme Court	Supreme Court directed the government to formulate appropriate criteria for ensuring that essential and life-saving drugs come under price control and directed a review of such drugs.
2005	Pronab Sen Task Force report, 2005	Recommended that NLEM 2003 (to be revised every 3 years) be the basis of medicine for price control/monitoring, that the ceiling price be based on the weighted average price of the top 3 brands by value for single ingredient formulations and the use of market data from IMS ORG.
2006	Draft NPPP, 2006	Proposed that 354 drugs under the NLEM (2003) be included under the span of price control based on cost plus pricing with revised MAPE. Policy was never implemented.
2011	NLEM, 2011	National List of Essential Medicines (NLEM) 2011 was notified by MoHFW in June 2011 listing **348** essential medicines
2012-2013	NPPP, 2012 and DPCO, 2013	NPPP, 2012 laid down three criteria: (i) regulation of prices based on "essentiality of drugs" (dosages and strengths as listed in NLEM-2011), (ii) control of formulation only and (iii) **Market based Pricing**. The NPPA notified ceiling prices for 432 medicines under the DPCO, 2013 as of Dec 20, 2013.

[10] Department of pharmaceuticals, 2006, Draft National Pharmaceutical Pricing Policy, Ministry of Chemicals and Fertilizers, Government of India

However, the policy never saw the light of the day, while the Supreme Court continued to hear pleas of both the parties. On March 10, 2003, the Supreme Court directed the Government of India to come up with a drug price policy that can accommodate all life-saving and essential medicines into the price policy net[11].

As a result, the Government of India formulated the National Pharmaceutical Pricing Policy (NPPP, 2012). The NPPP, 2012 laid down three criteria (i) regulation of prices based on "essentiality of drugs" (i.e. 348 formulations as listed under the National List of Essential Medicines notified by the Ministry of Health and Family Welfare in 2011), (ii) control of formulation prices only and (iii) Market based Pricing[12].

While NPPP, 2012 sought to bring a number of essential drugs (formulations) under control, the other two criteria sought to provide leeway to drug makers, creating a laissez-faire system in drug pricing. One of the key provisions laid emphasis on only prices of formulations. This meant that bulk drugs would remain outside the scope of control. Finally, the policy sought to move away from Cost-plus Based Pricing (CBP) to Market Based Pricing (MBP).

Under the new formula (MBP), the Average Price to Retailer (PTR) was computed as follows:

> Average PTR = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one per cent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one per cent of total market turnover on the basis of moving annual turnover for that medicine.)

Thereafter the ceiling price was obtained by adding a 16 per cent margin to retailer

> Ceiling Price = Average PTR.(1+M/100), where
> Average PTR = Average Price to Retailer for the same strength and dosage of the medicine as calculated above.
> M = % margin to retailer and its value =16

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[11] The Supreme Court directed the Union of India to consider and formulate appropriate criteria "for ensuring essential and lifesaving drugs not to fall out of price control should be put under price control" and further directed the Government of India "to review drugs which are essential and life saving in nature till 2nd May 2003." SLP (Civil) No. 3668/2003, 10 March, 2003.

[12] Department of pharmaceuticals, 2011, National Pharmaceutical Pricing Policy, Ministry of Chemicals and Fertilizers, Government of India

By December 20, 2013, the NPPA had notified ceiling prices for 432 formulations under the Drugs (Price Control) Order (DPCO), 2013. Further, the policy stated that market data from IMS Health would form the basis of computing ceiling prices and an annual increase in price would be allowed on the basis of the wholesale price index. Exemptions were built in for formulations developed through indigenous research and development for a period of five years.

This report critically evaluates the National Pharmaceutical Pricing Policy, 2012 and the Drugs (Price Control) Order, 2013. The chief argument in favour of replacing the system of cost-based pricing with market-based pricing is that it would help fulfil the dual objective of 'ensuring the availability of essential medicines at reasonable prices while at the same time supporting the growth of the pharmaceutical industry'. Is there any truth behind this supposition? What does the evidence point towards? This report attempts to unravel these and other questions that confront the current paradigm of health, pharmaceutical and pricing policies in India.

CHAPTER 2
OBJECTIVES AND METHODS

The overarching goal of this report was to undertake an independent evaluation of the National Pharmaceutical Pricing Policy (NPPA), 2012 and the Drugs Price Control Order (DPCO), **2013.**

The study was grounded in an access to medicines framework and the approach was from the dual perspectives of industrial policy as well as ensuring affordable access to essential medicines.

Specific objectives of the study were to:

- Assess the state of competition in the Indian pharmaceutical market
- Analyze the implications of DPCO 2013, in terms of:
  - the scope of coverage
  - the impact on medicine prices and market revenues
  - the potential impact on players in the pharmaceutical market
- Outline key limitations of DPCO 2013 and implementation of the market based price control mechanism
- Recommend policy options in light of our analysis and findings

Conceptual and analytical tools

In this section we describe the terms, concepts and analytical tools that were adopted in the study.

Market share: Market share is the percentage of the total market turnover of a particular firm or brand.

Moving Annual Total (MAT): Moving annual total is the cumulative sales value over the course of the previous twelve months

Market concentration: Estimates of market concentration were computed in order to study the degree of competition in the pharmaceutical market. The four firm concentration ratio (CR4) indicates the cumulative market share of the four largest firms. In this report, we have adopted the following norms: 80% or above (high concentration), 50%-79% (medium concentration and less than 50% (low concentration).

A second indicator of market concentration, the Herfindahl–Hirschman Index (HHI), is computed as the sum of the squares of the market shares of individual firms. Thus the HHI gives greater weightage to larger firms and is considered to be a more comprehensive measure of market concentration. In this report, we have adopted the following norms: 2500 or above (highly concentrated), >1500-2499 (moderately concentrated), >100-1500 (unconcentrated) and 0-100 **(competitive).**

Sales leader: The sales leader is assumed to be the firm or brand that holds the highest market share

Highest priced brand: The highest priced brand is the brand that has the highest price

Lowest priced brand: The highest priced brand is the brand that has the highest price

Market based pricing formula, Price to Retailer (PTR), Average PTR, Ceiling Price, Maximum Retail Price (MRP): The market based pricing formula is defined under Paragraph 4 of the DPCO 2013.

The Price to Retailer (PTR) is the price of a medicine at which it is sold to the retailer and is presumed to include duties but not local taxes. Prices to retailers are obtained from market data available through IMS Health.

The Average Price to Retail (PTR) is computed as: (The sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or

equal to one percent of total market turnover on the basis of moving annual turnover for that medicine).

Under DPCO 2013, the average PTR is calculated for formulations having the same strength and dosage.

The Ceiling Price is a price that is fixed by the Government for all formulations coming under price control in accordance with the provisions of DPCO 2013. It is computed as the Average PTR obtained plus a 16% margin to retailer.

The Maximum Retail Price (MRP) of formulations coming under price control is fixed by manufacturers on the basis of the ceiling price notified by the Government plus local taxes as applicable.

Wholesale Price Index (WPI): The Wholesale Price Index is a measure of inflation and means the annual wholesale price index of all commodities as announced by the Department of Industrial Policy and Promotion, Government of India.

Sources of Data

The National Pharmaceutical Pricing Authority (NPPA) is the implementing authority of the DPCO 2013. Policy documents on national pharmaceutical policies and drug price control orders were accessed from the NPPA website[1]. Official notifications for prices fixed between 14 June 2013 and 20 December 2013, and the worksheets related to prices notified were also obtained. Worksheets provided detailed information about the products considered for the fixing of prices for each formulation as well as the calculations under the market-based price formula.

The National List of Essential Medicines, 2011[2] which consists of 348 medicines classified under 27 therapeutic sections was used to identify formulations that would fall under price control (see Appendix 1).

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1 http://www.nppaindia.nic.in/index1.html

2 available through the official website of the Ministry of Health and Family Welfare at http://mohfw.nic.in/WriteReadData/l892s/7364497513National%20List%20of%20Essential%20Medicine,%202011.pdf

Approved medicine procurement rates for 2012-13 were taken from published tender documents from the Tamil Nadu Medical Services Corporation (TNMSC) and Rajasthan Medical Services Corportation (RMSC). State essential medicines lists for Tamil Nadu and Rajasthan were also obtained.

The National Pharmaceutical Pricing Policy 2012 has directed that data from IMS Health would form the basis of fixing prices. IMS Health is a global company operating in over 100 countries and provides information, services and technology for the healthcare industry. IMS pharmaceutical market data for India was independently procured by authors. The IMS dataset provides estimates of annual market sales, disaggregated up to the medicine pack-level. Market data for various years was used to analyse the structure of the Indian pharmaceutical market, independently compute ceiling prices under the market based pricing policy and study the potential impact of DPCO.

Sales data for the top selling medicines in 2012 were obtained from the PharmaTrac database which is marketed by AIOCD Pharmasofttech AWACS, a pharmaceutical market research company formed as a joint venture of the All Indian Origin Chemists & Distributors Ltd. Data were also taken from *The Market intelligence Report* for 2013 published by AIOCD AWACS.

Methods and Analysis

Market Structure

Analyses were undertaken to characterise the Indian pharmaceutical market in terms of its structure and competition. Using IMS data, market concentration was studied at both the therapeutic subgroup and individual formulation level through the four-firm concentration ratio (CR4) and Herfindahl–Hirschman Index (HHI). Therapeutic subgroups roughly correspond to therapeutically similar and substitutable medicines. Because we observe that firms strategise to establish themselves within therapeutic segments by engaging in competition at the 'therapeutically similar' level, we consider this is to be most appropriate level at which to study firm concentration. In addition, we looked at concentration within specific formulations coming under price contol in order to test the Government's assumption of competition at this level which forms the backbone of the market-based price formula.

We also studied the market share of foreign companies in the Indian pharmaceutical market in 2012 and compared the foreign firm market share among the top 20 companies in 2005 and 2012.

Author's independent calculations of ceiling prices using IMS data

Authors also attempted to calculate ceiling prices for formulations coming under the NLEM based on the DPCO guidelines for applying the market based formula and using market data from IMS Health. First, the NLEM was broken down into 622 formulations based on the medicines and their specific dosage forms and strengths. Each formulation was assigned a unique identifier. Next, for each formulation, we tried to identify the relevant packs in the IMS database and code them using the unique identifier. Coding was re-checked at least once by a second researcher. Any discrepancies were resolved after discussion. Challenges faced in using the market data are discussed in Chapter 6.

Where data were available in the database, we calculated ceiling prices for each formulation in the following way. First, the PTR per unit was calculated for each brand by dividing the sales value by the quanty. We observed that several brands had more than one pack size. Therefore the sales and quantity (in units) were collapsed across different packs of the same brand before calculating the PTR per unit for that brand. Next, the market share of each brand was determined. The average PTR was calculate as the simple average of the PTRs for brands having 1% or greater market share using STATA statistical software. To arrive at the ceiling price, a 16% margin was added to the average PTR.

Ceiling prices were calculated for 371 formulations using this methodology. We identified 100 formulations where there was only one brand with at least 1% market share and noted these as cases where the provisions of DPCO paragraph 6 would be applicable. However, we did not attempt to calculate the ceiling prices for these formulations. We determined that data were missing in IMS for 151 formulations.

Impact of DPCO on prices

Prices fixed by the NPPA and the published worksheets were used as the basis of studying the impact of the DPCO on price reductions. For each formulations, the

percentage price reduction of the ceiling price from the highest priced brand and the sales leader price (on the basis of PTR) were calculated. The market share of the sales leader in each formulation was also estimated.

Impact of DPCO on span of coverage

In order to study the implications of the DPCO for the span of coverage, we did an ad hoc analysis of the the National List of Essential Medicines to identify prominent ommissions and shortcomings. We also examined the state essential medicines lists for Tamil Nadu and Rajasthan to determine their overlap of the NLEM, and hence overlap with the new price control regime.

We estimated the market share of essential formulations under each therapeutic and subtherapeutic group as per IMS classification. This did not include formulations for which data were missing or could not be identified in IMS. We are unable to comment on whether the formulations have fallen out of production or the IMS database failed to capture them.

We also analysed a scenario where all additional dosages, strengths and combinations of the antiinfectives coming under the NLEM would be included under price control. For this analysis, the relevant packs of the additional antiinfective formulations were coded into the IMS database as a separate exercise. In this fashion, the new market share of antiinfectives that could be under price control were the DPCO expanded was estimated.

We used AIOCD AWACS's *Market intelligence Report 2013* to obtain rankings of top selling brands, top selling newly introduced brands, top selling brands used to treat chronic and acute conditions (as classified by AIOCD AWACS). We then classified brands as either falling under or outside the scope of price control based on whether the molecular description corresponded with medicines on the National List of Essential Medicines.

DPCO's potential to provide financial relief to patients

We estimated the monetary impact of DPCO 2013 in the sample of 371 formulations for which we had calculated ceiling prices. In each formulation, we identified brands

that would be affected by price control by comparing the brand PTR with the average PTR. We adjusted their PTRs to bring them down to the average PTR and then estimate the new market revenues assuming demand remaining constant. Hence we were able to estimate the shrinkage in sales turnover under price control at the level of each individual formulation as well as a percentage of the original market value.

Taking just the brands having at least 1% market share, we also explored the relationship of the market share of the lowest priced brand to the number of competitors in order to improve our understanding of the availability of the lower priced brands in the market.

We examined a scenario where the average PTR in the market-based formula was replaced with the lowest price PTR in brands having greater than or equal to 1% market share. Results were compared with the average PTR situation on a variety of indicators.

Methodological differences and limitations of using market based data in implementing price control

In order to understand the differences of our approach and that of the NPPA as well as the limitations of using market-based data, we identified discrepancies in a) the estimates of ceiling prices and b) determing missing data or monopolies for formulations. Data from the AIOCD AWACS PharmaTrac was also used to compare estimates of company sales turnover and rank in 2012 with the estimates from IMS Health.

Utility of public procurement to improve access to affordable essential medicines

We also compared public procurement rates from TNMSC and RMSC with prices notified under DPCO 2013 for a subset of scheduled formulations that were being procured by the state procurement agencies. Indicators were the ratios of the ceiling price to the state procurement rate and the percentage increase of the ceiling price over the state procurement rate.

CHAPTER 3
ACCESS TO MEDICINES IN INDIA

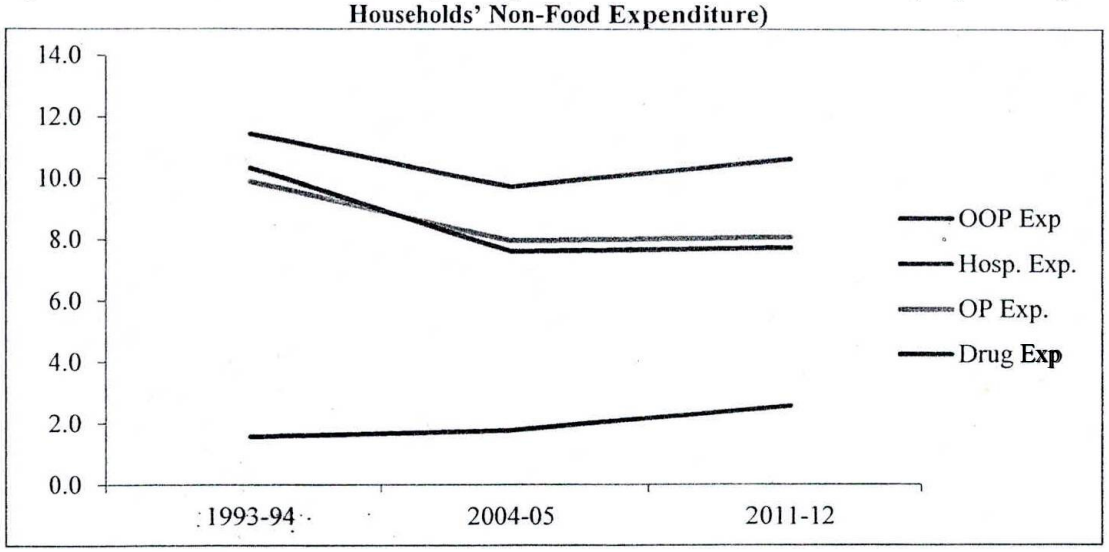
It is paradoxical that in India, whose credentials are established as a 'pharmacy of the global south', a large proportion of its population does not have access to essential medicines. Some of the critical factors that act as barriers to access to drugs include (i) inadequate and unfair health care financing mechanism; (ii) an inefficient procurement and ineffective distribution system; (iii) an unaffordable prices; (iv) production of banned, bannable, and inessential medicines, its promotion and irrational use of medicines; (v) a patent regime that promotes access to those who can afford to pay. This chapter attempts to draw evidence from various data sources to demonstrate several barriers outlined here, and will eventually locate the role and relevance of price ceilings in the Indian context.

Poor Financial Risk Protection: Prepayment and risk-pooling mechanisms - the bedrock of any health financing arrangements - is largely absent in India. Historically, the public health system was underfunded, both at the central and state government levels. Despite several major health financing interventions since the last one decade, both on supply-side and demand-side financing, the government has been spending around one per cent of its GDP on health care. As a result, households' spending on health care is not only high but accelerating rapidly and substantially in recent past. A higher households' OOP payment is considered to be inefficient and unfair.

Although the country currently spends about 4.2 per cent of GDP on health care, nearly 70 per cent of those funds come from households. And a large proportion of households' expenditure on health care goes into buying drugs (Chart 1). Despite recent attempts to raise the level of prepayment and risk-pooling through government-funded health insurance programs (such as, Rastriya Swasthiya Bima Yojana (RSBY), Rajiv Aarogyasri in Andhra Pradesh, Chief Minister's Health Insurance schemes in Tamil Nadu, etc.), emerging evidence clearly shows that such mechanisms did not bear results. While there has been a dramatic rise in health insurance coverage from less than 50 million persons in 2007 to almost 300 million in 2011, however, the major thrust of these programs has been on hospitalization coverage and not

outpatient coverage. Current evidence from nationally representative households' survey (NSS 2011-12) suggests that outpatient care, especially the drugs component, accounted for over 70 per cent of all household expenditure on health care.

Figure 3.1: Trends in Share of OOP Spending in India from 1993-94 to 2011-12 (As percentage of Households' Non-Food Expenditure)



Source: Estimated from Unit Level Records of respective Consumer Expenditure Rounds, NSSO

The figures in Figure 1, however, hide diverse spending patterns among states, with wide disparities in public and private expenditure. Household expenditure on medicines has been estimated to account for over 80 per cent of the health care expenditure in economically poor and advanced states such as Orissa and Punjab where the share of medicines' expenditure as a percentage of households' OOP expenditure has been in the order of 75-79 per cent (Table 1). While in some of the southern states such as Tamil Nadu, Kerala and Karnataka, with larger investments by the public sector, it is less than two-thirds of the total household expenditure. Tamil Nadu whose drug procurement and distribution system is known not only an efficient procurement and effective delivery of drugs, but also has been constantly spending a relatively large share of its public spending on drugs. As a result, OOP spending on drugs in that state is the least, which accounted for 56 per cent in 2011-12. This is considerably lower than the all-India share of about 66 per cent during this same period. Significantly, states in the latter category are the ones whose health status and health system indicators are relatively robust.

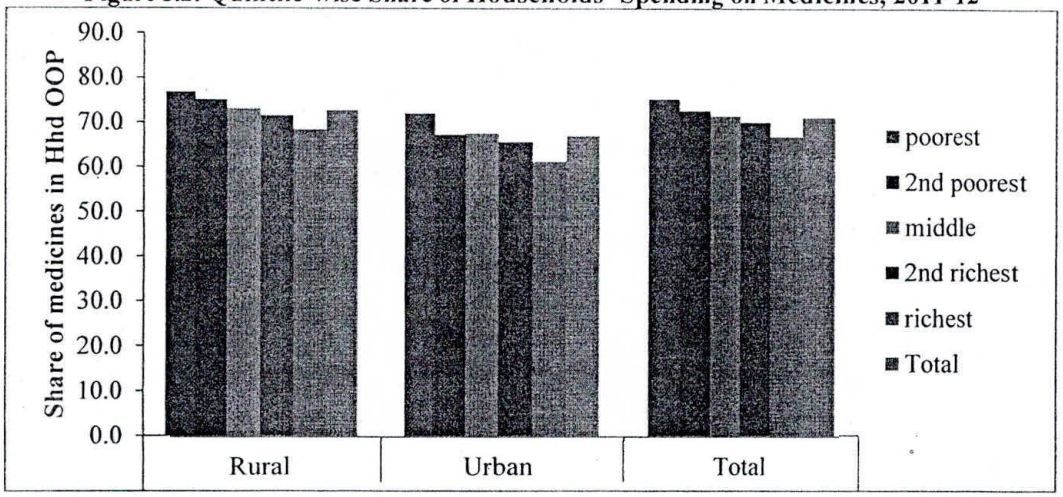
Table 3.1 Share of Household Expenditure on Health care and Medicines, 2011-12

States	*Share of OOP Payments (as % of HH Exp.)*	*Share of Medicines Exp. (as % of HH Exp.)*	*Share of Medicines Exp. (as % of HH OOP Exp.)*
Orissa	6.67	5.20	78.01
Punjab	8.17	6.17	75.53
Rajasthan	5.86	4.40	75.16
Bihar	5.46	4.11	75.23
Assam	2.98	2.25	75.57
Uttar Pradesh	8.85	6.50	73.49
Madhya Pradesh	5.96	4.10	68.72
Andhra Pradesh	7.37	4.91	66.56
West Bengal	8.24	5.16	62.64
Kerala	9.90	6.17	62.29
Gujarat	5.49	3.33	60.62
Karnataka	5.84	3.56	60.93
Maharastra	7.52	4.37	58.17
Tamil Nadu	7.06	3.99	56.56
All-India	6.84	4.54	66.44

Source: Authors' estimate from unit level records of NSS, 2011-12

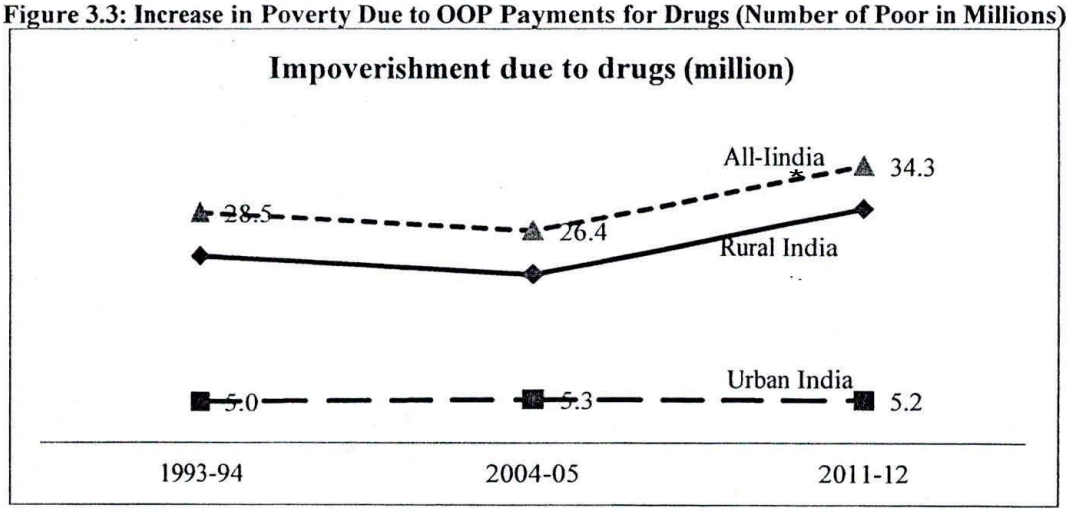
Households' OOP payment has been growing quite substantially in the past two decades and now accounts for around 11 per cent of non-food expenditure (Figure 1). Over two-thirds of that spend is on outpatient expenditure while the rest is accounted for by hospitalization. Given the presence of substantial financial and physical barriers, poor households either forego treatment or are forced to seek expensive health care, thus spending a significant amount of their resources. As a consequence of having to avail expensive health care, households become vulnerable to catastrophic spending, which leads them into impoverishment. It is to be observed that based on expenditure-quintiles (proxy for income), Figure 2 reveals two interesting pattern. On the one hand, a substantial share of households' OOP is not only spent on drugs, while on the other hand, poorer households end up spending much more than the relatively affluent segment of the population. This pattern is true both in rural and urban areas.

Figure 3.2: Quintile-wise Share of Households' Spending on Medicines, 2011-12



While it is important to understand the trends and pattern in OOP spending of households, it is also worth probing the impact of OOP expenditure on catastrophic spending and impoverishment status. As far medical impoverishment is concerned, there is clear evidence that OOP payments not only push a large number of households below poverty line, but plunge those into deeper poverty who are already poor. In India, while those pushed below poverty line due to OOP payments are over 50 million during 2011-12, the estimates of population below poverty due to medicines OOP is estimated to be 34 million (Figure 3). It is apparent that over two-thirds of all medical impoverishment is due to spending on medicines by households. The poverty impact of the OOP has been rising both in terms of proportion as well as absolute numbers. Thus, the absolute number of population below poverty due to OOP expenditure on medicines escalated from roughly 28 million in 1993-94 to nearly 34 million in 2004-05, an increase of 6 million during the 20 year period.

Figure 3.3: Increase in Poverty Due to OOP Payments for Drugs (Number of Poor in Millions)



The rise in the additional number of poor over the last decade because of OOP payments reflects the impact of households' OOP payments. Moreover, the impact of OOP payments in terms of poverty headcount was higher in rural areas in 2011-12, thus indicating increasing impoverishment impact of OOP on medicines in rural areas.

Table 3.2: State-wise Government Spending on Health care and Drugs, 2001-02 and 2010-11

State Name	*State wise Government Drug Expenditure in India*					
	Overall (2001-02) (Lakh)	*Per Capita (`)*	*Drug Exp. as % of HE*	*Overall 2010-11 (Lakh)*	*Per Capita (`)*	*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
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
Central Government	72649	7	12.2	253368	21	15
All India	188903	18	9.6	503447	43	13

Note: Many states report drug expenditure under the category of Material & supply. Material & supply includes the hospital accessories, bedding cloth, material supply, laboratory charges, others and X-ray materials, here we have include material & supply only. Estimates for the year 2010-11 are budget estimates. HE refers to Health Expenditure of the state/central government.

Source: Budget document, respective states and central government

While underinvestment in health care services is a key reason for poor health outcomes and distorted health sector development, one of the critical reasons for poor financial risk protection is overreliance on OOP, especially for drugs. This is a direct result of gross underfunding of medicine procurement by the government. It can be observed that the government (both central and state) allocates only 10 per cent of its funding on the procurement of drugs, supplies and consumables (Table 2). Although this may appear reasonable, the average hides inter-state disparities in spending. Several states spend less than 5 per cent of overall public spending on drugs. This includes economically advanced states like Punjab and economically poor states such as Uttar Pradesh and Assam.

Inefficient Drug Procurement and Ineffective Distribution Systems

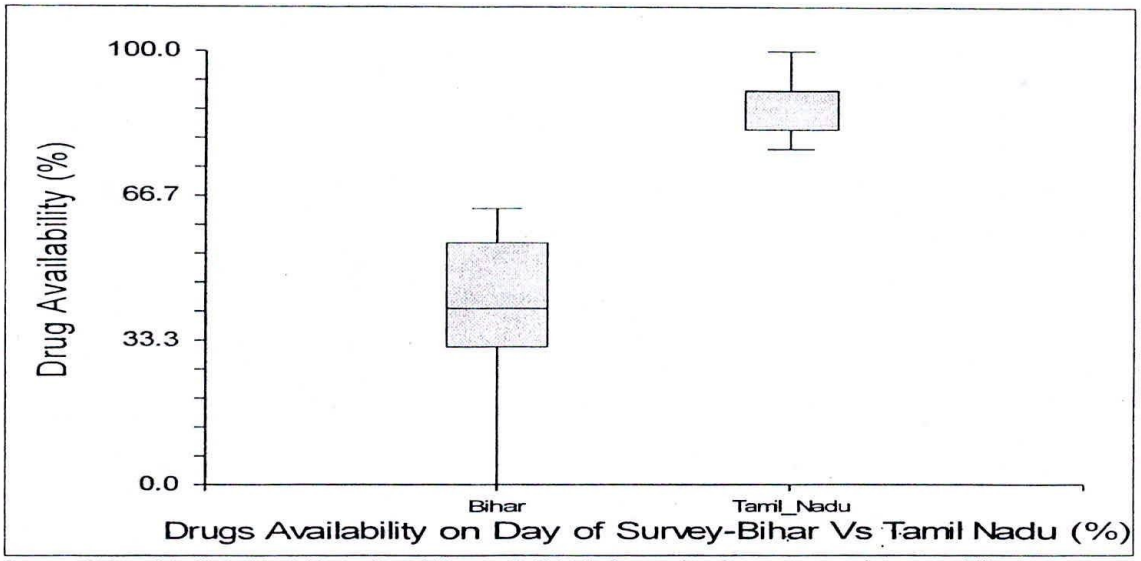
Higher budget allocations per se may not suffice in the face of a system plagued by weak institutions and poor governance. For instance, funds allocated for certain services such as drug procurement and distribution may not reach either the frontline service providers or the intended beneficiaries. Therefore, without a concomitant reliable and efficient supply chain management system extending from manufacturer to patient, the allotted funds may not reach the intended beneficiaries. This would result in acute shortages and chronic stock-out of drugs.

One of the key components underlying access to medicines is developing a reliable supply chain management system that includes the procurement and distribution of drugs and vaccines. An efficient procurement supply chain management system is predicated upon the principle of transparency in the process of selection of drugs, quantification of drugs, procurement process (including tendering process, bid opening process, award conditions, payment mechanism) and quality control procedures. Inefficiency in any one of these areas can lead to sub-optimal performance of the system resulting in frequent stock-outs and acute shortages of essential drugs. In addition, poor procurement practices may lead to a non-competitive environment with fewer choices of suppliers and higher prices of drugs for the health system.

As evident from the accompanying Figure 4, the findings from a recent survey of public health facilities in Tamil Nadu and Bihar clearly point to an unmistakable pattern of drug availability in various facilities across two different drug procurement and distribution models. The mean availability of basket of essential drugs in public health facilities (PHCs and CHCs) for Bihar on the day of survey was about 43 per cent as against roughly 88 per cent for Tamil Nadu, almost double than the former. It is clear from the chart as well as from other available nationally representative household surveys, such as, National Sample Surveys (NSS), availability of essential medicines in Tamil Nadu has been substantially far better in relation to other states. One of the major reasons is the time-tested model of Tamil Nadu Medical Service Corporation (TNMSC), anchored on the model of Centralised Procurement and Decentralised Distribution System. Its model of procurement is not only efficient, but

its distribution mechanism is considered effective, as the frontline public health facilities are able to supply key essential drugs uninterrupted.

Figure 3.4: A Comparative Scenario of Drug Availability in Bihar and Tamil Nadu



Source: Selvaraj S, Chokshi M, Hasan H and Kumar P (2011), Improving Governance and Accountability in India's Medicine Supply System, PHFI Study, Report submitted to Results for Development Institute.

To take advantage of economies of scale and monopsony power of the institutions (here the government), state and central governments must aim to procure drugs at a centralized level in each state and at the central level. Currently, the states of Tamil Nadu, Kerala and recently Rajasthan, for instance, procure drugs at the centralized level at rock bottom rates, closer to the manufacturer's cost. When such a model is replicated similar results ensue.

Summing Up

Access to medicines, can be accelerated by scaling up public spending on drugs, vaccines and other diagnostics. The current spending of governments (both state and central) must be scaled-up from 0.1 per cent of GDP to at least 0.5 per cent of GDP in the next five years. This is expected to result in a significant reduction in household OOP expenditure and thereby provide the much-needed financial risk protection. This is also likely to substantially reduce the current disparities existing in inter-state and inter-district public spending on medicines. In addition, government procurement and distribution system must be made more efficient and reliable. This could be modeled on the TNMSC/RMSC and could take the form of "Centralized Procurement and Decentralized Distribution". This would mean procuring medicines based on the EDL

at the centralized level in each state. Value for money could be achieved as such a model is expected to achieve economies of scale due to use of monopsony power. In order to obtain quality generic drugs for the system, a two-bid transparent procurement is required across all states. In addition, each district must be equipped with at least one warehouse, so that the centralized procurement unit and the public health facilities are reliably linked and acute shortages and chronic stock-outs in the facilities are avoided. However, as demonstrated in this chapter, given the poor track record of government procurement and distribution of drugs, households currently spend a large share of their OOP on drugs. Price ceilings of essential medicines therefore becomes inevitable, as any attempt to throw it to market forces will only expose people to higher financial risk and poor health outcomes.

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CHAPTER 4
CONCENTRATION, COMPETITION AND PRICE CONTROL

Introduction

Evidence from the international experience of performance of pharmaceutical markets is absolutely clear. A completely unregulated pharmaceuticals formulation market is unable to produce effective and efficient competition. Some core forms of regulation are required to be present and in force to foster healthy competition. The effects of limited information and knowledge of consumers, retailers and doctors about the price, quality and appropriate use of medicines tend to increase and have proved to be detrimental for the achievement of the goals of access to medicines and health outcomes in the pharmaceutical markets characterized by monopoly and oligopoly wherein effective competition is lacking. A range of policies need to be in place alongside competition law to ensure that competition is effective and efficient. Policy tool box of the countries all over the world include the tools in the form of control over pricing, regulation of the efficacy, quality, safety and appropriateness, public procurement, monitoring of prescribing and dispensing, code of conduct over advertising and promotion for industry, pharmacists and doctors. In this chapter we assess the actual state of competition that prevailsin the Indian pharmaceutical market and determine how effectivethe market based mechanism of price control formulated under the Drug Price Control Order (DPCO) 2013 is actually in position to stimulate in the retail market the force of competition and bring down the pricesof **medicines.**

Reality and rhetoric of competition

Competition exists in the Indian pharmaceutical market is a catchphrase utilized by the industry to argue in favour of the relaxation of price control mechanism. Criticism from the industry of the price mechanism under consideration from the policymakers has been on the basis of the following two claims, one of existence of sufficient competition in the pharmaceutical markets and two of encouragement to the realization of sufficient investment from the firms for the benefit of export and innovation activity. Both domestic and foreign pharmaceutical firmsseem to have

preferred a mechanism of market based price control. Both have not been in favour of the mechanism ofcost based regulation of prices of medicines.

Policymakers have also accepted the argument of existence of sufficient competition in the pharmaceutical markets in India. It is implicit in the choice of mechanism of price control. A proper assessment of the actual state of competition prevailingin the Indian pharmaceutical market seems to be telling a very different story. Argument that there exists sufficient competition in the Indian pharmaceutical markets is nothing new. Also the related argument of how the mechanism of price control is an impediment to promote the goals of efficient production,export and innovation for the benefit of autonomous industrial development and public health has been heard by the policymakers from the time the drug price regulation mechanism cameto be considered as a legitimate intervention to be utilized by the government to develop the domestic pharmaceutical industry in **India.**

As far as the argument of competition is concerned, first of all, the Indian rhetoric of competition has been that there are at least now twenty thousand small and large producers operating in the domestic pharmaceutical market in India. Although the available industrial statistics do not confirm the actual number of producers but what is more important is that the presence of a large number of producers does not tell us much about competition. Second, the representatives of industry have also argued that the market dominance is a thing of the past in India. The Indian pharmaceutical industry is no more under the control of big western pharmaceutical firms and the market driven by domestic investment in pharmaceutical industry is not exhibiting a concentrated market structure characteristic of the markets of developed market economies. The claim is that the pharmaceutical market has become competitive over the period due to the emergence of domestic pharmaceutical business growing rapidly during the period of last two decades of industrial and price deregulation in an independent way in India. As a result the government does not need to use the 'heavy hand' of price regulations to intervene in the Indian pharmaceutical market. This argument has been used to oppose the cost-plus based pricing formula which the policymakers adopted in 1979 to intervene in the pharmaceutical markets.

Evidence on the impact of price controls

Evidence available however about theimpact on prices of essential medicines of the dilution of the cost based price mechanism undertaken has also been quite clear. An analysis of the retail prices of medicines, involving 118 drugs and representing therapeutic groups that contribute a 54 per cent share of the retail market in a ten year period (1996-2006), indicated a greater rise in the prices of medicines that got decontrolled. Of this, drugs in the essential drug list (EDL) represented 24 per cent of the market and drugs under price control represented 12 per cent of the market, with drugs not in EDL or price controlled representing 18 per cent of the market. Analysis of the retail prices of drugs after adjustment against the consumer price index(CPI) over the period of 1996-2006 indicated a considerable rise in the prices of all medicines. Analysis showed that while the rise in prices of medicines in the price controlled category in the same ten year period was nominal - .02 per cent. The rise in prices of medicines in the essential drug list (EDL) was 15 per cent in ten years, largely explained by the fact that several of them are in the controlled category (Amit Sengupta, 2008)[1].

The rise in prices of medicines for drugs not in EDL and not price controlled was 137 per cent. The overall index for all drugs shows a rise of 40 per cent over 10 years, not very different from the rise in prices of other commodities, as the CPI would show. Price rise was far lower for all drugs than the rise in the CPI observed.Benefit was obtainable to the consumers from the mechanism of price controlput in place by the government. In the price controlled category of basket of drugs it actually meant a reduction in prices in real terms in the same period. However, the figures, while pointing to the effectiveness of price controls, also point to the need to continue the same and also to enlarge the span of control significantly. Further analysis also indicates that the prices in 1996 were already starting from a high base, resulting from the price decontrol in the 1995 DPCO. Immediately after DPCO 1995 there was a major spurt in the prices. Prices in both controlled and non-controlled category have been shown to be much higher than they could be. Comparison of retail prices of the corresponding period in India with prices of drugs in Sri Lanka (Dec.2006); with

[1] For details of the study see: Society for Economic and Social Studies New Delhi; and Centre for Trade and Development, New Delhi, Economic Constraints to Access to Essential Medicines in India, 2008, Society for Economic and Social Studies New Delhi, India. (available at: http://whoindia.org/en/Section2/Section5/Section446_1683.htm)

generic prices in India in Dec.2006; and generic prices in India in 2004 indicated a huge difference between retail prices and generic prices. Prices of essential medicines were allowed to rise unchecked in the category of drugs which remained after the mid-nineties out of the mechanism of price control. Analysis also clearly indicated that there was still a large scope to reduce drug prices. Price control measures were unable to affect the level of control that was possible for the government to achieve during the period of1996-2006.Actual impact of the dilution of price controls carried out by the government over the period of 1996-2006 is clearly reflected at the level of the products in the exercise undertaken on the state of competition for the year 2012.

Historical evidence of concentration

Let us start with the issue of a proper assessment of the claims concerning competition being made by the industry. Sufficient competition exists in the pharmaceutical industry has been the argument of the advocates of 'no direct price controls' needed in India. Concentration measures calculated at the level of industry as a whole do not necessarily give a robust insight about the state of competition in pharmaceutical industry. Several scholars have already brought out this point in their recent studies. Aditya Bhattacharya and Fiyanshu Sidhwani (2013) discuss this point by bringing out the fact that while the Indian pharmaceutical industry comprises a very large number of small firms and a small number of large firms, and the market share of even the largest firms is only about nine per cent, calculated at the industry sales level, it does not mean that that the industry is competitive. Price Cost Margin (PCM) of the Indian pharmaceutical firms to the margins is under pressure from imports. Aditya Bhattacharya (2013) also indicates that advertising and marketing expenditures have strong and positive impact on the PCM of the firms in the pharmaceutical industry and the results of such expenditure are realized with a lag in the Indian industry[2].

Because as the actual competition takes place either at the level of therapeutic segments or at the level of really the products Aditya Bhattacharya and Fiyanshu Sidhwani (2013) point out that industry level concentration measures would

2 Aditya Bhattacharya and Finyashu Sindhwani (2013), "Competition Issues in the Indian Pharmaceutical Sector", Centre for Development Economics, Delhi School of Economics, CUTS International

underestimate concentration. They point out themselves appropriately for this the following three reasons, concentration ratios should be computed for firms at the same stage of production, imports include increasingly very expensive patented drugs and actual competition takes place at the level of either therapeutic segments or products. Even the calculations of the Henfindahl Hirschman Index (HHI) made by Kaur (2012, pp318-24) for pharmaceuticals using Prowess data also show that though the HHI declined considerably during the 1990s but the increase in concentration in the more recent period does out far more significantly due to the enlargement of market shares of the top four firms[3].

Historical analysismade by us indicates that policymakers cannot accept the claim of competition to be ipso facto valid on the basis of arguments that the industry representatives are known to make on the market structure of the pharmaceutical industry due to the emergence of domestic pharmaceutical companies in India. Evidence from the literature is available to argue that even after the emergence of domestic pharmaceutical companies the problem of market dominance did not go away in India. Concentration in the Indian pharmaceutical market existed in the late nineties. Market dominance was quite visible in 1998. Almost all the domestic companies had entered by 1998 as significant players into the Indian pharmaceutical markets. The claim of pharmaceutical markets in India is based on the indicators that do not apply well to the pharmaceutical markets. Contribution made by the top 10 players declining from around 40 per cent in 1976 to 30 per cent in 1998 has been one of the arguments. The other important argument has been that a majority of the leading companies (7 out of 10) were multinational drug companies in 1976, but in 1998 7 out of 10 top companies were domestic companies.

Selvaraj (2005) provides the relevant evidence, and his analysis clearly suggests that in the Indian drug industry an extreme concentration across therapeutic groups was even persisting in 1998.Analysis of the top 300 products, which accounted for close to half of the total retail market in India in 1998, indicates that out of 32 therapeutic classes in 19 markets four and less than four companies retained dominant shares. In few cases the market shares already also ranged from 30 per cent to more than 90 per

[3] Kaur, Paramjeet (2012), Mergers in India: Exploiting Financial Synergies, Academic Foundation, New Delhi.

cent. Closely followed by the case of these 19 markets, another 13 therapeutic segments also showed slightly less extreme market concentration with 5-8 companies showing market shares in the range of 30 per cent to 70 per cent. There has never been anything like a competitive pharmaceutical market, evidence from the historical analysis of the state of competition prevailing in the pharmaceutical market for the decade of nineties in India is also quite clear in this regard.

The oligopoly element had started to cut across the entire spectrum of the drugs belonging to the essential therapeutic classes. Evidence is clear regarding the claim that the Indian pharmaceutical markets did not become extremely competitive with the entry of domestic pharmaceutical companies. Evidence of the persistence of market concentration in 1998 should be viewed as indicating the impact of the failures experienced in respect of the implementation of price controls. Evidence tells us that ineffective price control mechanism and gradual price deregulation can also lead to market consolidation over the period in the pharmaceutical industry.

Current state of market competition

Pharmaceutical market is not a single product market.It is a multi-product one. Pharmaceutical markets cannot be treated as homogeneous. Consequently as drug manufacturers do not compete on an industry wide basis the existence of competition cannot be deduced from the above described indicator of how many producers exist as a whole in the case of pharmaceutical market in India. We will have to take the indicator of the market dominance for each product or product group. Dominant market share held by a number of companies, in terms of sales, and ultimately the dominance of a small number of products within each therapeutic class will therefore have to be used as the indicators of market dominance to ascertain whether the market for pharmaceutical product is actually competitive.

In this section we deal with this issue of the current state of competition in the Indian pharmaceutical market at the level of therapeutic segments. In India, because of the industry being still characterized mainly by the off-patent drugs,even at the level of therapeutic segments measures of concentration are telling us only a partial and not the full picture of the state of competition. Beginning with an assessment of the state of competition undertaken within distinct therapeutic segments and within particular

classes of medicines that are perfectly or imperfectly substitutable, our analysis also indicates the degree of competitionthat prevails in the market to be on average at least far more than 25 per cent. Table 4.0 indicates it by the number of brands and the market segment being made up on average 30-100 per cent by thebrands havingat least 1 per cent market share within each therapeutic group.

Table 4.0
Market structure in terms of number of brands having at least 1 per cent market share in a sample of 371 formulations

	Market With All Brands	*Market Segment Made Up Of Brands Having At Least 1 Per Cent Market Share*
	Total Number Of Brands	*Brands With 1 Per Cent Market Share*
Anaesthetics	102	60
Analgesics, Antipyretics, Non-Steroidal Anti-Inflammatory Medicines (Nsaims),	424	132
Antiallergics And Medicines Used In Anaphylaxis	186	51
Antidotes And Other Substances Used In Poisonings	11	11
Anticonvulsants/Antiepileptics	81	41
Anti-Infective Medicines	2731	690
Antimigraine Medicines	27	10
Antineoplastic, Immunosuppressives And Medicines Used In Palliative Care	375	191
Antiparkinsonism Medicines	45	22
Medicines Affecting The Blood	127	49
Blood Products And Plasma Substitutes	8	4
Cardiovascular Medicines	628	261
Dermatological Medicines (Topical)	101	44
Diagnostic Agents	4	3
Disinfectants And Antiseptics	29	8
Diuretics	19	10
Gastrointestinal Medicines	350	89
Hormones, Other Endocrine Medicines And Contraceptives	262	111
Immunologicals	50	39
Muscle Relaxants (Peripherally-Acting) And Cholinesterase Inhibitors	25	14
Opthalmological Preparations	96	40
Oxytocics And Antioxytocics	97	35
Peritoneal Dialysis Solution	3	3
Medicines For Mental And Behavioural Disorder	358	129
Medicines Acting On The Respiratory Tract	29	14
Solutions Correcting Water, Electrolyte And Acid-Base Disturbances	26	16
Vitamins And Minerals	10	6
Total	6204	2083

Source: Authors' calculations for 371 formulations based on IMS Health

But it should be clear that more competition, in the usual sense of more producers, does not seem to be reflecting the actual state of affairs prevailing in respect of competition in the market. Branding in India plays a different role compared to most developed market economies. In India even generic drugs are branded and thus differentiated from chemically identical substitutes. This kind of practice permits the

large Indian firms to maintain high prices as well as market shares. Assessment of the state of emerging features of oligopoly and monopoly in each therapeutic group tells the actual state of affairs. Available evidence on the state of product wise competition indicates that the current situation of competition is worse in many cases. As analysed here below, both in terms of the degree of competition at the level of sub-therapeutic group and at the level of product, evidence of pharmaceutical markets not being truly competitive is actually truer.Contrary to the claims of sufficient competition exists in the pharmaceutical industry level analysis of the market structures reveals in the case of many therapeutic groups either high or medium level of concentration. See Table 4.1 and 4.2 for the details of competition as assessed by us at the level of sub-therapeutic groups in terms of Four-Firm Concentration Ratios (CR4).

Table 4.1—Total Number of sub-therapeutic segments and annual market value against different degrees of concentration (CR4 index) in 1998

Degree of Concentration as per CR4 index	*No. of Sub-therapeutic Segments*	*Cumulative market value in 1998 (Rs. Crore)*
High (80% or above)	758	6,039
Medium (50% - 79%)	106	4,910
Low (less than 50%)	4	687
Total	868	11,636

Source: Authors' calculations based on IMS Health

Table 4.2—Total Number of sub-therapeutic groups and annual market value against different degrees of concentration (CR4 index) in 2012

Degree of Concentration as per CR4 index	*No. of Sub-therapeutic Segments*	*Cumulative market value in 2012 (Rs. Crore)*
High (80% or above)	1150	30,687
Medium (50% - 79%)	276	28,452
Low (less than 50%)	42	12,107
Total	1468	71,246

Source: Authors' *calculations* based on IMS Health; market value is based on IMS Total Sales Audit (TSA)

Degree of concentration measured on the basis of four-firm concentration ratio already indicates the share of concentrated markets at the level of sub-therapeutic groups to be a feature of the Indian pharmaceutical market. Analysis brings out that many of the pharmaceutical markets are not truly competitive even at the level of sub-therapeutic groups. In the year of 1998 out of eight hundred sixty-eight sub-therapeutic groups seven hundred fifty-eight sub-therapeutic groups with annual market value of Rs. 6039 crores exhibited a high degree of concentration. In the year of 2012 out of one thousand four hundred sixty-eight sub-therapeutic groups one thousand one hundred fifty sub-therapeutic groups with annual market value of Rs. 30,687 crores exhibit a high degree of concentration. In the year of 1998 out of eight

hundred sixty-eight sub-therapeutic groups, one hundred and six sub-therapeutic groups with annual market value of Rs. 4910 crores exhibited a medium degree of concentration.In the year of 2012 out of one thousand four hundred sixty-eight sub-therapeutic groups, two hundred and seventy-six sub-therapeutic groups with annual market value of Rs. 28452 crores exhibit a medium degree of concentration. See Table 4.1 and 4.2 for the details.

Evidence from the calculations made of the Herfindhal and Hirschman Index (HHI) for the Indian pharmaceutical markets indicates that high level of concentration existed in the case of many sub-therapeutic groups. It continues to exist in 2012 for many of these sub-therapeutic groups. Table 4.3 shows that in 1998 high level of concentration existed in the case of seven hundred twenty-nine sub-therapeutic groups. Table 4.4 shows that in 2012 high level of concentration exists in the case of one thousand seventy sub-therapeutic groups. Table 4.3 shows that in 1998 medium level of concentration exists in the case of one hundred sub-therapeutic groups. Table 4.4 shows that in 2012 medium level of concentration exists in the case of two hundred thirty-three sub-therapeutic groups

Table 4.3 Total Number of sub-therapeutic segments and annual market value against different degrees of concentration (Herfindahl Hirschman Index) in 1998

Degree of Concentration as per Herfindahl–Hirschman Index (HHI)	*No. of Sub-therapeutic Segments*	*Cumulative market value in 1998 (Rs. Crore)*
High (2500 or above)	729	5,427
Moderate (>1500 - 2499)	100	3,256
Unconcentrated (>100 – 1500)	40	2,954
Competitive (0 – 100)		
Total	868	11,636

Source: Authors' calculations based on IMS Health

Table 4.4— Total Number of sub-therapeutic segments and annual market value against different degrees of concentration (Herfindahl Hirschman Index) in 2012

Degree of Concentration as per Herfindahl–Hirschman Index (HHI)	*No. of Sub-therapeutic Segments*	*Cumulative market value in 2012 (Rs. Crore)*
High (2500 or above)	1072	28,983
Moderate (>1500 - 2499)	233	15,757
Unconcentrated (>100 – 1500)	163	26,506
Competitive (0 – 100)		
Total	1468	71,246

Source: Authors' calculations based on IMS Health; market value is based on IMS Total Sales Audit (TSA)

Market competition at product level

Evidence to the contrary on the state of competition in the market in India comes out far more strongly at the product level. At the product level the Indian pharmaceutical

markets continue to exhibit a much weakerstate of competition. Avery high level of concentrationexists at the level of product markets in 2012.Out of four hundred seventy one (471) products four hundred fifteen (415) products are exhibiting highly concentrated market features. Not even one product market in 2012 is showing features of competitive market. In the case of thirty three products (33) the market structure exhibits moderate concentration features. Only twenty two (22) products exhibit features of un-concentrated market structure. See Table 4.5 for the details. Analysis is absolutely clear that at the level of product markets the Indian pharmaceutical market is highly concentrated, and the claim of markets in pharmaceuticals in India being competitive is not true.

In the case of newer drugs market shares are quite high. There are fewer producers. There is no true competition; the range of retail prices is also on the lower side. Of the 100 top selling brands in the Indian market, 55 of the brands fall outside the scope of price control which together account for annual sales of Rs. 6,142 crore. See Table 4.6 for the details of the products. Of the top 20 acute brands as identified in the Pharmatrac intelligence report, 8 of the brands fall outside the scope of price control. See Table 4.7 for details of the products. Of the top 20 chronic brands as identified in the Pharmatrac intelligence report, 13 of the brands fall outside the scope of price control. Analysis is clear that even today how more of the top selling brands for chronic disease, an area where India is experience a growing disease burden, are totally immune from price regulation.

Table 4.5—Concentration (Herfindahl Hirschman Index) in 471 formulationscoming under drug price control

Degree of Concentration as per Herfindahl–Hirschman Index (HHI)	*No. offormulations*
High (2500 or above)	416
Moderate (>1500 - 2499)	33
Unconcentrated (>100 – 1500)	22
Competitive (0 – 100)	-
Total	471

Source: Authors' calculations for 471 formulations coming under DPCO 2013 for which data was available through IMS Health

Table 4.6: Number of brands from top 20 new introductions under and outside the scope of price control order

Brands Outside The Scope Of Price Control					*Brands Under The Scope Of Price Control*		
Rank (Based On Mats For Last 24 Months)	*Brand*	*Subgroup*	*Corporate*	*Rank (Based On Mats For Last 24 Months)*	*Brand*	*Subgroup*	*Corporate*
1	Istamet	Sitagliptin + Metformin	Sun	7	VoveranGe	Diclofenac	Novartis
2	Silverex Ionic	Silver Nitrate	Ranbaxy	10	Macmika	Amikacin	Macleods
3	Biceltis	Trastuzumab	Emcure*				
4	Pegihep	Pegylated Interferon Alpha 2b	Zydus*				
5	Synflorix	All Other Vaccines	Gsk				
6	Uprise D3	Vitamin D - Cholecalciferol	Alkem*				
8	Cognistar	CerebroproteinHydrolysate	Lupin				
9	Fertigyn Hp-5000	Human Chorionic Gonadotropin	Sun				
11	Trivolib	Voglibose + Metformin + Glimepiride	Sun				
12	Casporan	Caspofungin Acetate	Ranbaxy				
13	Megaheal	Products For Wound Healing	Aristo				
14	Bio D3 Strong	Calcium + Calcitriol + Vit K2	Macleods				
15	Tayo 60k	Vitamin D - Cholecalciferol	Eris				
16	Retelex	Reteplase	Abbott*				
17	Ikgdar	Rituximab	Emcure*				
18	Mashyne	Ferrous Ascorbate	Usv				
19	Effoday	Lamivudine + Tenoforvir + Efavirenz	Ranbaxy				
20	Piranulin	Citocholine + Piracetam	Sun				

Source: Top selling brands were taken from AIODC-AWACS Market Intelligence Report 2013

Although a high level of concentration would exist, but the drug price control order 2013 has failed to bring the newly introduced drugs under its scope. Of the top 20 newly introduced brands (within last 24 months) the majority of products (18) turn out to be outside the scope of price control. Given that the primary objective of price control is to contain high prices of medicines, the scope of the DPCO 2013 will not extend to new market entrants. See Table 4.6 for the details of the products in terms of the coverage of products under price control from within the basket of top 20 selling products in the Indian pharmaceutical market. Similarly, one expects the drug price control order of 2013 to take into account the specific features of the market structure

evolving in terms of competition for the products being viewed as useful for acute and chronic conditions, it is to be noted that under the scope of price control order of 2013 from among the newly introduced products only two products are covered at present. The rest of eighteen products are outside the scope of price control order of 2013. See Table 4.7 and 4.8 for the details.

Table 4.7: Number of brands from top 20 acute brands of the Indian pharmaceutical market under and outside the scope of order

Brands Outside The Scope Of Price Control				*Brands Under The Scope Of Price Control*			
Rank (Based On Mat Jun 13)	*Brand*	*Subgroup*	*Corporate*	*Rank (Based On Mat Jun 13)*	*Brand*	*Subgroup*	*Corporate*
2	Corex	Chlorpheniramine + Codeine	Pfizer*	1	Augmentin	Amoxycillin + Clavulanic Acid	Gsk
3	Revital	Ginseng Products	Ranbaxy	4	Monocef	Ceftriaxone	Aristo
8	Becosules	Vit B Complex With Vit C Only	Pfizer*	5	Volini	Diclofenac	Ranbaxy
9	Manforce	Sildenafil	Mankind	6	Calpol	Paracetamol	Gsk
13	Dexorange	Iron Ferrous	Franco	7	Voveran	Diclofenac	Novartis
14	Liv 52	Hepatic Protectors	Himalaya	10	Clavam	Amoxycillin + Clavulanic Acid	Alkem*
16	Phensedyl Cough Linctus	Chlorpheniramine + Codeine	Abbott*	11	Betadine	Povidone Iodine	Win-Medicare
20	Magnex	Cefoperazone + Sulbactum	Pfizer*	12	Taxim O	Cefixime	Alkem*
				15	Taxim	Cefotaxime	Alkem*
				17	Aciloc	Ranitidine	Cadila
				18	MoxikindCv	Amoxycillin + Clavulanic Acid	Mankind
				19	Zinetac	Ranitidine	Gsk

Source: Top selling brands were taken from AIODC-AWACS Market Intelligence Report 2013

Table 4.8: Number of top 20 chronic brands of the Indian pharma market not covered by the order

Brands Outside The Scope Of Price Control				*Brands Under The Scope Of Price Control*			
Rank (Based On Mat Jun 13)	*Brand*	*Subgroup*	*Corporate*	*Rank (Based On Mat Jun 13)*	*Brand*	*Subgroup*	*Corporate*
2	Glycomet Gp	Glimepiride + Metformin	Usv	1	Mixtard	Intermediate-Acting, Isophane	Abbott*
4	Foracort	Formoteral + Budesonide	Cipla	3	Asthalin	Salbutamol	Cipla
5	Seroflo	Salmeterol + Fluticasone	Cipla	11	Huminsulin	Intermediate-Acting, Isophane	Eli Lilly
6	Galvus Met	Vildagliptin + Metformin	Novartis	14	Clexane	Enoxaparin	Sanofi*
7	Skinlite	Hydroquin + Mometa + Tretinoin	Zydus*	15	Atorva	Atorvastatin	Zydus*
8	Cardace	Ramipril	Sanofi*	19	Storvas	Atorvastatin	Ranbaxy
9	Telma	Telmisartan	Glenmark	20	Aztor	Atorvastatin	Sun
10	Betnovate C	Betamethasone + Clioquinol	Gsk				
12	Januvia	Sitagliptin	Msd*				
13	Janumet	Sitagliptin + Metformin	Msd*				
16	Telma H	Telmisartan + Hydroclorthiazide	Glenmark				
17	Budecort	Budesonide	Cipla				
18	Aerocort	Levosalbutamol + Beclomethasone	Cipla				

Source: Top selling brands were taken from AIODC-AWACS Market Intelligence Report 2013

Price Control and nature of impact on large firms

Irrespective of their national origin, nature of ownership and control, still many large firms capable of exercising market power in the case of their product portfolios would be free to price a very large number of important products. Table 4.9 lists the domestic firms along and the number of products identified against their name that have been left free and are outside the coverage of drug price control order of 2013. For the domestic Indian firms out of the total 200 products under their controlfromwithin the top 300 products under sale in the marketplaceone hundred twenty four products (124) are outside the scope of drug price control order of 2013. For the large domestic Indian firms from within the basket of top 300 products only seventy six (76) products under their control are under the scope of price control mechanism.

Table 4.9— Company wise pattern of brands falling outside / under the scope of price control for the segment of domestic firms in the case of Top 300brands of the Indian pharmaceutical market

Domestic Firms	*Brands Outside The Scope Of Price Control*	*Brands Under The Scope Of Price Control*
Alembic	3	1
Alkem Laboratories India	7	6
Allergen India Ltd	1	-
Aristo Pharmaceutical Pvt Ltd	6	4
Apex Laboratories Ltd		1
Bharat Serum & Vaccines Ltd	1	1
Biocon Ltd		1
Biochem Pharmaceutical Inds	1	-
Blue Cross Laboratories Ltd	1	-
Bms India Pvt. Ltd.	1	-
Cadila Pharmaceuticals Ltd	1	-
Centaur Pharmaceuticals Pvt.Ltd	1	-
CharakPharma Pvt Ltd	1	2
Cipla Ltd.	14	8
Dabur India Ltd.	1	-
Dr.Reddys Laboratories Ltd	6	2
Elder Pharmaceuticals Ltd	2	-
Emcure Pharmaceuticals Ltd	4	1
Eris Life Sciences Pvt Ltd	1	-
Franco Indian Pharmaceuticals Pvt Ltd	3	1
Geno Pharmaceuticals Ltd	1	-
Glenmark Pharmaceuticals Ltd.	4	1
Himalaya Drug Company	1	-
Indoco Remedies Ltd	1	-
Intas Pharmaceuticals Ltd	2	1
Ipca Laboratories Pvt Ltd.	3	3
Lupin Ltd	4	1
Mankind Pharmaceuticals Ltd.	8	3
Medley Pharmaceuticals	1	-
Msd Pharmaceuticals Private Ltd.	3	-
Organon (India) Ltd	1	-
Panacea Biotec Ltd	1	-
Raptakos, Brett & Co. Ltd.	3	-
Sun Pharmaceutical Industries Ltd	12	4
Torrent Pharmaceuticals Ltd.	1	2
Unichem Laboratories Ltd	3	1
Usv Ltd	6	1
Wockhardt Ltd	5	2
Wyeth Ltd	1	3
ZydusCadila	7	12
Biological E Ltd	-	1
Fdc Ltd.	-	2
Jb Chemicals	-	3
Macleods Pharmaceuticals Pvt.Ltd	-	4
Micro Labs Ltd	-	1
Modi Mundi Pharma Pvt Ltd	-	1
Troikaa Pharmaceuticals Ltd	-	1
Danone	1	
Win-Medicare Pvt. Ltd.	-	1
Total	**124**	**76**

Source: AIOCD-AWACS Market Intelligence Report 2013; top selling brands are based on moving annual total sales for August 2013. Authors have classified brands as falling under/outside price control based on whether the molecular description corresponds with medicines on the National List of Essential Medicines.

From within the top 300 products under sale in the marketplace out of the 100 products in the case of large foreign firms under their control only thirty seven (37) productsare covered by the price control mechanism. From within the top 300

products under sale in the market place out of the 100 products under the control of foreign firms sixty three (63) products remain outside the scope of drug price control order of 2013. See table 4.10 for the details of the company wise pattern of brands falling under and outside the scope of price control order.

Table 4.10— Company wise pattern of brands falling outside / under the scope of price control for the segment of foreign firms in the case of Top 300 brands of the Indian pharmaceutical market

Foreign Firms	*Brands outside the scope of price control*	*Brands under the scope of price control*
Abbott Healthcare	7	4
Abbott India	8	2
AstrazenecaPharma India Ltd	1	1
British Biological	2	-
Glaxosmithkline Pharmaceuticals Ltd.	10	10
Johnson & Johnson	2	-
Merck Ltd	1	-
Novartis India Ltd	3	5
Novo Nordisk India Pvt Ltd	1	4
Pfizer Ltd	7	2
Ranbaxy Laboratories Ltd	10	5
Sanofi-Aventis	11	2
Eli Lilly And Company (India) Pvt. Ltd.		2
Total	63	37

Source: AIOCD-AWACS Market Intelligence Report 2013; top selling brands are based on moving annual total sales for August 2013. Authors have classified brands as falling under/outside price control based on whether the molecular description corresponds with medicines on the National List of Essential Medicines.

Market power and price control

Large firms exercise market power in pharmaceutical markets by investing in the activity of market promotion and advertising. Competition is stymied using the power of brand value by the large firms. See table 4.11 showing sub-therapeutic group the number of brands with at least 1 per cent share in a sample of 371 formulations. 197 formulations belong to the market segments where effectively the competition is between 2 to 4 brands. 97 formulations belong to the market segments where effectively the competition is between 5-7 brands. Only 77 formulations belong to the market segments where the brands competing exceed the number of 8 brands. A narrower spectrum of 2-4 brands dominates this sector establishing that there is virtually no scope for fair competition. This confirms that a vast majority of the formulations belong to the segments where large firms have the scope to exercise market power.

Table 4.11— Number of brands with at least 1 per cent market share in a sample of 371 formulations

Nlem Section No.	*Nlem Section*	*Number Of Formulations*		
		2 To 4 Brands	*5 To 7 Brands*	*8 Or >8 Brands*
1	Anaesthetics	16	2	0
2	Analgesics, Antipyretics, Non-Steroidal Anti-Inflammatory Medicines (Nsaims),	10	6	5
3	Antiallergics And Medicines Used In Anaphylaxis	2	5	1
4	Antidotes And Other Substances Used In Poisonings	4	0	0
5	Anticonvulsants/Antiepileptics	5	4	0
6	Anti-Infective Medicines	48	24	30
7	Antimigraine Medicines	3	0	0
8	Antineoplastic, Immunosuppressives And Medicines Used In Palliative Care	18	18	3
9	Antiparkinsonism Medicines	3	3	0
10	Medicines Affecting The Blood	6	1	2
11	Blood Products And Plasma Substitutes	1	0	0
12	Cardiovascular Medicines	18	12	9
13	Dermatological Medicines (Topical)	6	1	2
14	Diagnostic Agents	1	0	0
15	Disinfectants And Antiseptics	1	1	0
16	Diuretics	1	0	1
17	Gastrointestinal Medicines	7	5	4
18	Hormones, Other Endocrine Medicines And Contraceptives	13	4	5
19	Immunologicals	7	1	2
20	Muscle Relaxants (Peripherally-Acting) And Cholinesterase Inhibitors	4	0	0
21	Opthalmological Preparations	8	2	1
22	Oxytocics And Antioxytocics	5	1	2
23	Peritoneal Dialysis Solution	1	0	0
24	Medicines For Mental And Behavioural Disorder	1	4	10
25	Medicines Acting On The Respiratory Tract	6	0	0
26	Solutions Correcting Water, Electrolyte And Acid-Base Disturbances	0	3	0
27	Vitamins And Minerals	2	0	0
	Total	197	97	77

Source: Authors' calculations for 371 formulations based on IMS Health

See Table 4.12 for the details of the market share of the market sales leader for 419 formulations for which ceiling prices have been notified by the NPPA under the DPCO 2013. Out of 419 formulations for which prices have been notified by NPPA, in 394 cases (94%) the market leader is observed to hold a high market share (i.e., 25 per cent or greater). In fact, in 280 cases the share of market leader in the product market is even greater than 50 per cent. But the reduction in revenue for a majority of the market leaders would be limited to the extent of 10 per cent. In the case of 218 (48%) market leaders, shrinkage would be mere 10 per cent or less. Shrinkage to the

extent of 20 per cent or less would be felt in another 62 cases which is also only 18 per cent of the notified formulations.

Table 4.12— Market Share of the sales leader for 419 formulations for which ceiling prices have been notified by the NPPA

SNo	*Nlem Therapeutic Groups*	*Number Of Formulations*	*Percentage Of Formulations Where Share Of Sales Leader Is At Least 50%*	*Percentage Of Formulations Where Share Of Sales Leader Is 25% - 49%*	*Percentage Of Formulations Where Share Of Sales Leader <25%*
1	Anaesthetics	25	88	12	0
2	Analgesics, Antipyretics, Non-Steroidal Anti-Inflammatory Medicines (Nsaims), Medicines Used To Treat Gout And Disease Modifying Agents In Rheumatoid Disorders (Dmards)	23	83	13	4
3	Antiallergics And Medicines Used In Anaphylaxis	7	43	57	0
4	Antidotes And Other Substances Used In Poisonings	4	75	25	0
5	Anticonvulsants/Antiepileptics	14	100	0	0
6	Anti-Infective Medicines	92	55	35	10
7	Antimigraine Medicines	3	67	33	0
8	Antineoplastic, Immunosuppressives And Palliative Care	52	67	33	0
9	Antiparkinsonism Medicines	3	33	67	0
10	Medicines Affecting The Blood	11	73	27	0
11	Blood Products And Plasma Substitutes	4	75	25	0
12	Cardiovascular Medicines	49	63	14	22
13	Dermatological Medicines (Topical)	10	60	30	10
14	Diagnostic Agents	1	100	0	0
15	Disinfectants And Antiseptics	9	89	11	0
16	Diuretics	3	67	33	0
17	Gastrointestinal Medicines	21	81	19	0
18	Hormones, Other Endocrine Medicines And Contraceptives	20	70	20	10
19	Immunologicals	12	92	8	0
20	Muscle Relaxants (Peripherally-Acting) And Cholinesterase Inhibitors	6	83	17	0
21	Opthalmological Preparations	16	81	19	0
22	Oxytocics And Antioxytocics	9	78	22	0
23	Peritoneal Dialysis Solution	0	0	0	0
24	Medicines For Mental And Behavioural Disorder	12	42	50	8
25	Medicines Acting On The Respiratory Tract	5	100	0	0
26	Solutions Correcting Water, Electrolyte And Acid-Base Disturbances	5	80	20	0
27	Vitamins And Minerals	3	100	0	0
	Total	419	70%	24%	6%

Source: Authors' calculations based on data from the National Pharmaceutical Pricing Authority (NPPA)

Thinking only from within the framework of market based price control formula the choice of average PTR based ceilings tendsto reward those firms more who only investment more in advertising and market promotion and build market power through gifts and discounts to doctors and chemists their products at higher prices. Although market based price fixation is not a best process for providing the relief to consumers, yet it is worth noting that ceiling price has not been fixed by using the lowest price to retail. Table 4.13 shows that had the price ceilings of DPCO 2013 been framed in terms of lowest price to retail (PTR) rather than average price to retail (PTR) consumers would have benefitted to the extent of 20 per cent or more in price terms in the case of another 174 more products in addition. It provides a detailed sub-therapeutic groupwise breakdown of how many additional products would have attracted the benefit of more than 20 per cent to consumers in various therapeutic categories. Table 4.13 also gives the details of the range of market revenue shrinkage in terms of how many products would shift from oneband of market value shrinkage and the nature of price reduction for consumers for the firms capable of exercising market power in the case of all the different therapeutic categories. See table 4.13 for the number of formulations grouped sub-therapeutic group according to projected reduction in sales due to price control (as a per cent of original market value) and the consequent extent of change in percentage of sales from average to lowest price to retail (PTR) scenario.

Table 4.13— Comparison of impact on market sales under Average PTR (DPCO 2013) and lowest PTR scenarios

Nlem Section No.	*Nlem Section*	*Number Of Formulations Grouped According To Projected Reduction In Sales Due To Price Control (As A % Of Original Market Value)*					
		Average Ptr			*Lowest Ptr Scenario (Change)*		
		0-10%	*11-20%*	*>20%*	*0-10%*	*11-20%*	*>20%*
1	Anaesthetics	12	4	2	4 (-8)	4 (0)	10 (+8)
2	Analgesics, Antipyretics, Non-Steroidal Anti-Inflammatory Medicines (Nsaims),	13	6	2	8 (-5)	2 (-4)	11 (+9)
3	Antiallergics And Medicines Used In Anaphylaxis	4	4		1 (-3)	1 (-3)	6 (+6)
4	Antidotes And Other Substances Used In Poisonings	3	1		2 (-1)	1 (0)	1 (+1)
5	Anticonvulsants/Antiepileptics	6	2	1	2 (-4)	3 (+1)	4 (+3)
6	Anti-Infective Medicines	61	27	14	32 (-29)	7 (-20)	63 (+49)
7	Antimigraine Medicines	3			2 (-1)	1 (+1)	
8	Antineoplastic, Immunosuppressives And Medicines Used In Palliative Care	20	15	4	9 (-11)	5 (-10)	25 (+21)

Nlem Section No.	*Nlem Section*	*Number Of Formulations Grouped According To Projected Reduction In Sales Due To Price Control (As A % Of Original Market Value)*					
		Average Ptr			*Lowest Ptr Scenario (Change)*		
		0-10%	*11-20%*	*>20%*	*0-10%*	*11-20%*	*>20%*
9	Antiparkinsonism Medicines	5		1	3 (-2)		3 (+2)
10	Medicines Affecting The Blood	7	1	1	2 (-5)	2 (+1)	5 (+4)
11	Blood Products And Plasma Substitutes			1			1 (0)
12	Cardiovascular Medicines	17	19	3	2 (-15)	4 (-15)	33 (+30)
13	Dermatological Medicines (Topical)	4	4	1	1 (-3)	1 (-3)	7 (+6)
14	Diagnostic Agents	1			(-1)	1 (+1)	
15	Disinfectants And Antiseptics	1		1	(-1)	1 (+1)	1 (0)
16	Diuretics	1		1	(-1)		2 (+1)
17	Gastrointestinal Medicines	11	2	3	5 (-6)	4 (+2)	7 (+4)
18	Hormones, Other Endocrine Medicines And Contraceptives	17	4	1	6 (-11)	6 (+2)	10 (+9)
19	Immunologicals	5	3	2	3 (-2)	1 (-2)	6 (+4)
20	Muscle Relaxants (Peripherally-Acting) And Cholinesterase Inhibitors	4			1 (-3)	3 (+3)	
21	Opthalmological Preparations	6	2	3	2 (-4)	2 (0)	7 (+4)
22	Oxytocics And Antioxytocics	4	1	3	1 (-3)	3 (+2)	4 (+1)
23	Peritoneal Dialysis Solution	1			(-1)	1 (+1)	
24	Medicines For Mental And Behavioural Disorder	5	5	5	1 (-4)	(-5)	14 (+9)
25	Medicines Acting On The Respiratory Tract	4		2	2 (-2)	1 (+1)	3 (+1)
26	Solutions Correcting Water, Electrolyte And Acid-Base Disturbances	2	1		1 (-1)	(-1)	2 (+2)
27	Vitamins And Minerals	1		1	1 (0)		1 (0)
	Total	218	101	52	91 (-127)	54 (-47)	226 (+174)

Source: Authors' projections based on IMS Health

Prior to 2002 the policy on price control had also cost competitiveness as one of its goals. Today the stage of industrial development at which India stands the policymakers should be getting the local industry to prioritize cost competitiveness as a strategic goal. In the case of pharmaceutical production, China is already an important competitor of India. The goal of cost competitiveness is actively under encouragement from the government of China. Price control mechanism should be encouraging the investment in practices and technologies aimed at efficient manufacturing. Tighter price control combined with the measures of tax rebate on investment would help the country achieve better results in respect of the adoption of improved technology and practice of efficient manufacturing by the producers.Table 4.13 also makes quite clear that if the policymakers were really interested to serve the twin goals of affordable medicine and industrial development, then the selection of

mechanism based on the lowest price to retail (PTR) should have been preferred over the average price to control (PTR) based mechanism.

Table 4.14— Foreign or Indian status of sales leader, highest price and lowest price in a sample of 371 formulations

SNo	*Therapeutic Group*	*Sales Leader*		*Highest Price (1% Market Share)*		*Lowest Price (1% Market Share)*	
		Foreign	*Indian*	*Foreign*	*Indian*	*Foreign*	*Indian*
1	Anaesthetics	8	10	7	11	1	17
2	Analgesics, Antipyretics, Non-Steroidal Anti-Inflammatory Medicines (Nsaims),	7	14	5	16	1	20
3	Antiallergics And Medicines Used In Anaphylaxis	3	5	2	6	1	7
4	Antidotes And Other Substances Used In Poisonings	0	4	0	4	0	4
5	Anticonvulsants/Antiepileptics	5	4	3	6	1	8
6	Anti-Infective Medicines	36	66	29	73	14	88
7	Antimigraine Medicines	1	2	1	2	1	2
8	Antineoplastic, Immunosuppressives And Medicines Used In Palliative Care	15	24	13	26	6	33
9	Antiparkinsonism Medicines	3	3	3	3	0	6
10	Medicines Affecting The Blood	3	6	3	6	0	9
11	Blood Products And Plasma Substitutes	0	1	0	1	1	0
12	Cardiovascular Medicines	17	22	25	14	1	38
13	Dermatological Medicines (Topical)	3	6	3	6	0	9
14	Diagnostic Agents	0	1	0	1	0	1
15	Disinfectants And Antiseptics	0	2	0	2	0	2
16	Diuretics	0	2	0	2	0	2
17	Gastrointestinal Medicines	1	15	2	14	3	13
18	Hormones, Other Endocrine Medicines And Contraceptives	16	6	19	3	9	13
19	Immunologicals	2	8	4	6	0	10
20	Muscle Relaxants (Peripherally-Acting) And Cholinesterase Inhibitors	0	4	2	2	0	4
21	Opthalmological Preparations	3	8	2	9	0	11
22	Oxytocics And Antioxytocics	6	2	6	2	1	7
23	Peritoneal Dialysis Solution	0	1	0	1	0	1
24	Medicines For Mental And Behavioural Disorder	2	13	2	13	2	13
25	Medicines Acting On The Respiratory Tract	0	6	1	5	1	5
26	Solutions Correcting Water, Electrolyte And Acid-Base Disturbances	2	1	0	3	1	2
27	Vitamins And Minerals	1	1	1	1	1	1
	Total	**134**	**237**	**133**	**238**	**45**	**326**

Source: Authors' calculations for 371 formulations based on IMS Health; identification of foreign and Indian status based on IMS classification

Analyzed here below sub-therapeutic group, analysis of 371 formulations indicates that sales leader in the case of 137 brands are foreign firms. Indian firms are sales leader in the case of 234 products. In the case of highest price brands foreign firms account for 133 brands and Indian firms account for 234brands. But what is worth noting that in the case of lowest price brands table 4.14 shows that a vast majority of

brands are of Indian firms. In the case of lowest priced brands out of 371 brands 326 brands belong to Indian firms and only 45 belong to foreign firms. See also table 4.15 depicting the pattern of number of therapeutic groups with high and moderate concentration where the strong presence of foreign firms is an important characteristic of the pharmaceutical markets of 2012. In the segments characterised by the feature of high market concentration 48 sub-therpeutic groups exhibit the strong presence of foreign firms having at least 25 per cent share. In the segments characterised by the feature of moderate market concentration 22 sub-therapeutic groups exhibit the strong presence of foreign firms having at least 25 per cent share.

Table 4.15:-Sub-therapeutic segments in 2012 characterised by activity of foreign firms

Number of Therapeutic segment with high concentration (Herfindahl Hirschman Index)		*Number of Therapeutic segment with moderate concentration (Herfindahl Hirschman Index)*	
Foreign firms have at least 25% market share	*Foreign firms have less than 25% market share*	*Foreign firms have at least 25% market share*	*Foreign firms have less than 25% market share*
48	51	22	23

Source: Authors' calculations based on data from IMS Health; foreign firms were identified based on IMS classification

Impact of TRIPS on market structure

Changes introduced in the domestic patent law allow from 2005 onwards patent based monopolies to be established. In the case of introduction of the new products this change has affected significantly the state of competition in pharmaceutical markets in India. Generic medicine competition increases the availability of lower-priced products only when the market does not show the feature of market dominance of large firms, be Indian or foreign MNC. Analysis undertaken by Sudip Chaudhury (2012) of the sales of the basket of 180 new drugs being marketed in India which constituted about 9.1 per cent of the total pharmaceutical market in 2010 points out that there is a shift taking place in the market4.

[4] 180 drugs could be categorised into: (1) Sixty-two drugs for which patents have expired in the US (3.8 per cent of the Indian market); (2) Sixty-seven drugs for which patents were granted in the US before 1995 and hence not patentable in India in accordance with the TRIPS agreement (4.2%) and (3) Fifty-one drugs for which patents were granted in the US after 1995 and hence patentable in India subject to Section 3(d) provisions (1.2%). Five or more sellers for 43 products accounted for 97.9 per cent of the market for patent expired molecules. Analysis indicates that two TRIPS flexibilities explain much of the level of competition. Under Section 11A(7), Indian generic companies which have started manufacturing before 2005 are not required to suspend production even if patents are granted (after 2005). Section 3(d) has played a role, but the challenge of implementation remains. For the third category of post-1995 drugs, there are monopolies in 50 per cent of the products accounting for 20 per cent of the market.

Interest in the case of **new** drugs centres on the behaviour of the multinational corporations (MNCs). In India, they are involved in marketing 92 out of the 180 new drugs. MNCs have monopolies in 33 products accounting for 31 per cent of their sales of Rs. 517.14 crore of these 92 products. In fact, in 53 products accounting for more than three-fourths of their sales they have a market share of 50 per cent or more. Eight out of these 33 products, for example, anidulafungin, caspofungin, micafungin and pegaptanib, are pre-1995 molecules or patents have expired. Prices are exorbitant due to the market power of the MNCs. The pricing policy adopted by the MNCs for the 33 monopoly products which include life-threatening diseases such as cancer and where essential drugs are without effective substitutes indicates that the market based price mechanism would not be effective for a much larger basket of drugs in India.

Below we indicate the extent of problem that the patients are already facing in the case of post-1995 molecules in the Indian pharmaceutical market. A 50 ml injection of Roche's anti-cancer drug Herceptin (generic name: trastumuzab) costs Rs. 1,35,200. Merck's Erbitux (cetuximab) (Rs. 87,920), Bristol-Myers-Squibb's Ixempra (ixabepilone) (Rs. 66,430), Pfizer's Macugen (pegaptanib) (Rs. 45,350), Sanofi - Aventis' Fasturtec (rasburicase) (Rs. 45,000), Roche's Avastin (bevicizumab) (Rs. 37,180). There are six products costing between Rs. 10,000 and Rs. 45,000 (for example, Wyeth's Enbrel (etanercept): Rs. 15,761), eight products between Rs. 1,000 and Rs. 10,000 (GSK's Tykerb (lapatinib): Rs. 4,468).Prices mentioned are for a single injection/tablet, etc. The cost of treatment per person per year would of course be much higher. The price of a 70 mg dasatinib (lukemia) tablet is Rs. 3,905 using 100 mg per day, the cost of treatment per person per year exceeds Rs. 20 lakh. The corresponding cost in the UK is £30,477. Bristol Myers Squibb) is essentially charging the same price and not using differential pricing.

A similar story can also be told for the other life-extending drugs such as trastuzumab, cetuximab, ixabepilone, etc. Similarly, we can also tell about the prices of vital drugs such as Wyeth's Enbrel (etanercept) (Rs. 15,761 per injection) used for rheumatoid arthritis, which can incapacitate people, Pfizer's Macugen (pegaptanib) (Rs. 45,350 per 90 ml injection) used for preventing loss of vision in the case of age-related muscular degeneration, Sanofi-Aventis' Fasturtec (rasburicase) (Rs. 45,000 per injection) used to treat the side effects of chemotherapy for treating leukaemia and

lymphoma are very highly priced. The story is unending in the case of new drugs. Take the price of pegalytedinterferons beta (Roche's Pegasys) used for Hepatitis co-infected with HIV which costs between Rs. 14,000 and Rs. 18,000 per dose. Roche got the product patent in India. But due to patent disputes, some Indian generic companies are also manufacturing and marketing it.

Given the nature of post-TRIPS world it is clear that we need to analyse information in each therapeutic group on the state of product level competition.

Public procurement, control of prices of medicines and the Indian pharmaceutical market

The Indian pharmaceutical market has some special features. The most prominent feature is the fact that a very large proportion of drugs consumed in India are procured through retail sales. Retail sales of pharmaceuticals were US$ 6.2 billion while institutional sales were estimated around US$ 1.1 billion in 2006, i.e. 85 per cent of drugs were sold through retail outlets. Institutional sales which account for 15 per cent of the market include consumption through the public sector as well as through private hospitals and other institutions. This is very different from what is seen in developed country markets, where a bulk of drug consumption is through supplies from large institutional mechanisms (hospitals, health insurance, etc., both in the public and private sector). Given this, the major issues related to drug prices are related to those that impact on retail prices.

Sufficient evidence also exists that the state governments are able to lower the costs of financing of essential medicines for the public facilities through public procurement of medicines in their states. Using public procurement in India a few state governments have achieved remarkable results in terms of lowering the cost of financing of medicines to the exchequer and ensuring the supply of essential medicines to a larger population. Public procurement has been particularly used to achieve successfully lower prices for off-patent, multi-source essential medicines in Tamil Nadu, Rajasthan, Delhi, and Kerala in India. Table 4.16 presents the evidence of greater impact of government procurement on prices of medicines using the example of prices achieved through the system of procurement by the government in Tamil Nadu and Rajasthan. Number of formulations having ceiling prices in the **retail**

market in percentage terms prices greater than 100-500 when compared with RMSC rates are 109 out of 199 analysed. Number of formulations having ceiling prices in the retail market in percentage terms prices greater than 100-500 when compared with TNMSC rates are 41 out of 85 analysed. There is also evidence that the Central Government has been successfully utilising the mechanism of public procurement in the CGHS / Railways / Armed Forces for the supply of cancer drugs to bring down the cost of financing.

Table 4.16— Comparison of ceiling prices with procurement rates of Tamil Nadu Medical Services Corporation (TNMSC) and Rajasthan Medical Services Corporation (RMSC)

Percentage that ceiling price is greater than state procurement rates	*No. of formulations having ceiling prices percentage greater than TNMSC rate*	*No. of formulations having ceiling prices percentage greater than RMSC rate*
-1-(-50)	-	5
100-500	41	109
501-1000	17	38
1001-1500	9	20
1001-2000	7	14
2001-2500	4	7
2501-3000	2	2
3001-3500	2	2
3501-4000	1	1
4001-4500	1	-
4501-5000	1	-
5001-6000	-	-
6001-6500	-	-
6501-7000	-	-
7001-7500	-	1
Total	85	199

Source: Ceiling prices notified by the National Pharmaceutical Pricing Authority (NPPA); procurement documents from TNMSC and RMSC for 2012-13

Analysis of the above table makes it quite clear that competition is most effective when price conscious, publicly funded state procurement agencies and institutional purchasers are the purchasers rather than individual consumers. Both, the Government of Rajasthan and the Government of Tamil Nadu, were able to procure drugs at much cheaper rates from the industry. In the case of Government of Rajasthan, one hundred nine drugs out of one hundred ninety nine drugs procured were cheaper from the prices in retail market in percentage terms by not two or three times but by 100-500 times. Thirty eight drugs out of one hundred and nine drugs procured were cheaper in percentage terms by 501-1000 times. Twenty drugs out of one hundred nine drugs procured were cheaper in percentage terms by 1001-1500 times. In the case of

Government of Tamil Nadu, forty one drugs out of eighty five were in percentage terms cheaper by 100-500 times.

See Table 4.16 for the details of how cheap can the process of bulk procurement become when drugs are purchased through a transparent process of public procurement by the governments. Strong evidence of how publicly funded state procurement agencies and institutional purchasers of essential medicines are able to achieve better results in respect of inducing competition is self-evident from the figures presented in the table. When individual consumers purchase medicines out-of-pocket, pervasive asymmetry of information limits the potential for effective medicine price competition. Since most of the patients are forced to obtain even essential medicines from the retail market the introduction of an effective price control mechanism is a formidable challenge. The imperfections of uncompetitive pharmaceutical markets are known to be devastating for the consumers when they are uninsured. They do not have the benefit of medicine supply from public health facilities at lower cost.

In India, mechanisms of public financing and social insurance are weak. Consumers are known to pay heavily for medicines when they purchase them out of pocket. Pharmaceutical markets functions quite imperfectly because of the practices of promotion used by the industry for the sale of medicines. Heavily branded generics are often sold at a high multiple of the price of low priced generics, with many people paying more than they need to. Market does not treat branded medicines and generics as perfect substitutes. Many factors play a role in the creation of imperfections: poor information, risk aversion about the information on quality of low priced generics, mistrust of drug regulatory environment, responsiveness to advertising. Lack of availability of low cost generics in private retail outlets and greater reliance on the advice of doctors and pharmacists who are also influenced by the practices of promotion of drugs by the companies is an integral feature of the concentrated markets.

CHAPTER 5
DPCO, 2013: COVERAGE AND ITS IMPACT

Since the DPCO was implemented, there has been wide speculation about the effects that it will have on affordability, market sales and the industry. In this chapter, we evaluate various aspects of the DPCO, and estimate the potential impact on access to medicines and the pharmaceutical market. Specifically, we examine the scope of control in the Indian pharmaceutical market, estimate the impact on medicine prices and market sales, and highlight weaknesses of the DPCO that diminish the success in achieving its stated goals.

Scope of coverage

'Essentiality' criterion is insufficient for fulfilling the Supreme Court's directive

The NPPP has identified 'essentiality of drugs' as the only criterion for bringing drugs under price control. This has been operationalised as the medicines listed on National List of Essential Medicines (NLEM) 2011, or subsequent revisions thereof.

In 2003, the Supreme Court directed[1] the government to "consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control" and"to review drugs which are essential and life saving in nature till 2nd May 2003." Following this, the Ministry of Health and Family Welfare revised the NLEM for the first time in 2003 and then subsequently in 2011.

Therefore, the NPPP has at most partially addressed the Supreme Court Order and violated it by excluding life saving medicines from the oversight of price control. No attempts have been made to identify a separate list of life saving medicines many of which may refer to newer, highly-priced treatments (e.g., anti-cancer drugs).

Furthermore, the concept of 'essential drugs' has been strictly confined to the 2011 NLEM. The NLEM is a key instrument in addressing the priority healthcare needs and disease burden of India[2]. It comprises a representative rather than comprehensive

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1 Supreme Court Order of March 10, 2003 in SLP (Civil) No. 3668/2003
2 National List of Essential Medicines of India 2011

list of 348 medicines selected on the basis of safety, efficacy and cost-effectiveness under 27 therapeutic categories, and which should be available at affordable cost and assured quality. In order to serve as a reference for rational prescribing, only a few model dosage forms and strengths have been mentioned for each medicine. Similarly, single ingredient formulations are preferred over fixed dose combinations, where appropriate. Given that the NLEM was not prepared with the explicit intention of regulating drug prices in the private sector, defining price control according to the NLEM is a matter of concern.

Shortcomings and deficiencies of the NLEM

Even though the NLEM purports to satisfy the priority health needs of the majority of the population, its completeness and appropriateness has been called into question by experts[3]. Because DPCO is based on the NLEM, any ommissions of clinically important medicines or their dosage forms, strengths or combinations will immediately be excluded from price control.

According to the stated intent of the NLEM, "medicines used in the various national health programmes, emerging and reemerging infections should be addressed in the list." However, ferrous sulphate and folic acid combination being used in the national nutritional anemia prophylaxis programme is conspicuously absent from the NLEM in spite of the widespread iron deficiency anemia in both adults and children.

In another instance, stavudine is listed on the NLEM even though it has been phased out due to toxicity and replaced by tenofovir in the HIV national programme. Even though tenofovir is being rolled out in combination with lamivudine and efivarenz (TDF/3TC/EFV) to people living with HIV as first line treatment under the national ART programme, it is missing from the national list. The NLEM should at the very least reflect the treatments under national programmes and function as a tool to ensure that prices of critical medicines remain affordable in the market.

[3] Srinivasan et al, 2013, Drug Price Control order 2013 As Good As a Leaky Bucket, Economic and Political Weekly, vol XLVIII nos 26 & 27; Bhargava, A (in print). Anomalies in the National List of Essential Medicines and Drug Price Control Order 2013 and their serious implications for public health in India.

Tenofovir in combination with lamivudine has a second indication for HBV treatment but access to low cost generic treatment regimens (that are also used in HIV treatment) is an issue for mono-infected hepatitis B positive patients, who are not eligible under the national ART programme.

Furthermore, the Department of AIDS Control is planning to roll out third line treatment for HIV/AIDS by April 2014 which will include a patented drug – raltegravir. Under the 2011 NLEM, raltegravir will be exempted from price control and can be sold at high prices in the private sector.

Standard-of-care medicines in several priority conditions for India are also missing from the NLEM. Although fixed dose combinations have been recommended by the WHO for optimal treatment of tuberculosis, none are mentioned on the essential medicines list. The number of cases of multi-drug resistant tuberculosis (MDR-TB), which develops as a consequence of improper use of antibiotics in drug-sensitive TB, has reached epidemic proportions in India and is the highest in the world. Faced with the challenge of extending access for MDR-TB patients to extremely expensive combination treatment under lengthy regimens and given that only 5% of patients are on treatment through the government's DOTS-Plus (Daily Observed Treatment Short) programme, the absence of drugs for MDR-TB on the NLEM (such as capreomycin, cycloserine, ethionamide, kanamycin and para-aminosalicylic acid which are included on the WHO Model Essential Medicines List) can only be construed as negligence.

The NLEM mentions neither the injection form of artesunate for the treatment of severe 'falciparum malaria', even though it is recommended by the WHO, nor does it list any alternate treatment options such as artemether–lumefantrine combination tablets.

The number of anti-diabetic medicines missing from the NLEM is mismatched with the burden of diabetes in India. Indeed, India has acquired a reputation as the 'diabetes capital of the world'. The NLEM lists only metformin and glibenclamide as oral anti-diabetics. Given that glibenclamide has been declared unsuitable for use above the age of 60 years, there is a desperate need to expand the list of medicines to other drugs in the sulfonylureas chemical class such as glimepiride and gliclazide. Classes of drugs such as glitazones (e.g., pioglitazone) and gliptins (e.g., sitagliptin)

are also absent from the NLEM. Newer, expensive insulin analogues are also not included.

A major shortcoming of the 2011 NLEM is the lack of sufficient dosage forms (dispersible and chewable tablets) and preparations that are appropriate for children. As a consequence, many children's formulations are left out of price control.

Additionally, there are no patented medicines on the NLEM. Since India came into compliance with the WTO TRIPS Agreement in 2005, generic competition is no longer a reliable option to reduce prices. In the absence of any policy to regulate patented medicines, prices are frequently unaffordable for the majority of the population. Several new, innovative molecules are associated with valuable health benefits and could easily be brought under the NLEM based on an assessment of their clinical value and the unmet need.

Our discussion of the shortcomings of the NLEM 2011 has highlighted prominent omissions of medicines and several instances where the national list is misaligned with the accepted standard of care. There is an urgent need to plug the gaps in the list and revise it in line with current treatment protocols.

Health being a state subject, essential medicines lists are often implemented at the state-level and linked to the procurement and distribution of medicines in the public health system. While the NLEM serves as a model for states during the formulation of their state essential medicines lists, selection of drugs is often also driven by practical considerations such as previous utilization, availability of suppliers, budget constraints and prescribing patterns, as well as state-specific health needs. Therefore, state lists do not overlap perfectly with the national list. As a result, significant number of medicines in state lists may remain outside the scope of price control despite the fact that these states consider them to be essential.

A comparison of the Rajasthan 2013 and Tamil Nadu 2012-13 essential medicines lists with the national list revealed that 50% of the medicines on the Rajasthan list and 43% of the Tamil Nadu list did not correspond with the NLEM and hence would not be covered by the new price control order. Hence, there is a disconnect between the concept of essentiality as defined by the NPPP 2012 and by individual states.

The NLEM should also be reviewed by taking into consideration the state lists, and be expanded to include medicines for diseases endemic to regions or relevant for particular minorities, so as to be truly relevant for all segments of the national population.

Coverage under DPCO 2013

Our findings reveal that the majority of the private sector market is untouched by DPCO. Drug pricing policy is targeted at only 17% (Rs. 11,798 crore) of the total pharmaceutical market, worth over Rs. 70,000 crore, as per our estimates. Table 5.1 presents the share of the market coming under regulation in various therapeutic groups.

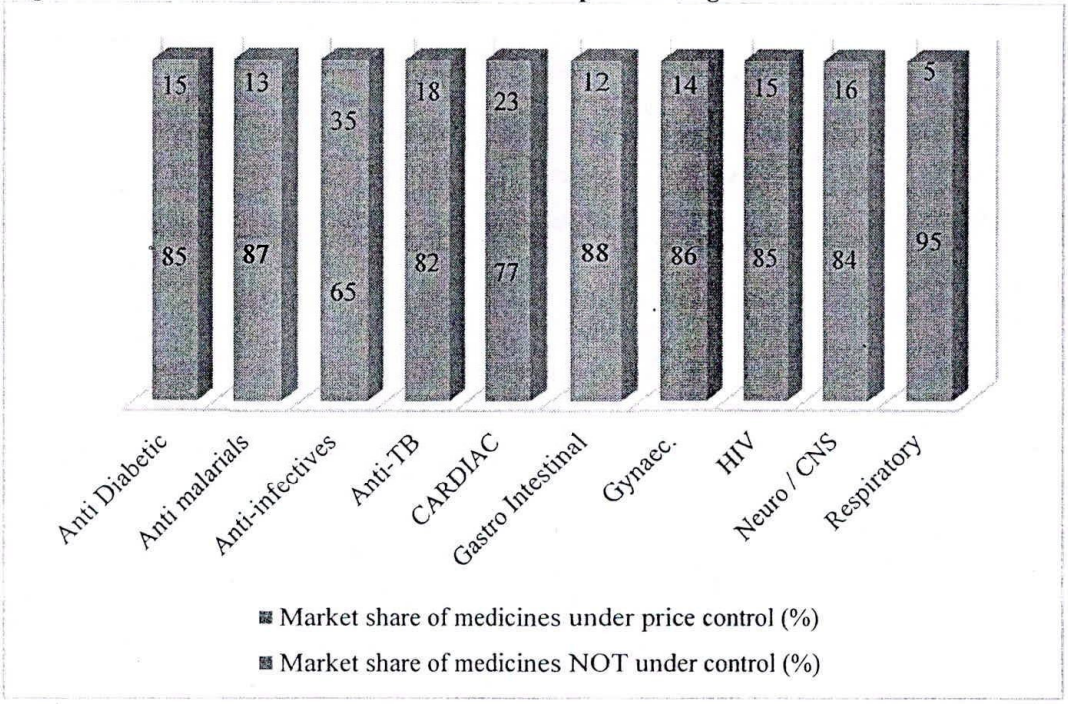
Table 5.1 Market coming under price control

Therapeutic ***group***	*Market sales 2012 (Rs. crore)*	*Market value of medicines NOT under control (Rs. crore)*	*Market share of medicines NOT under control (%)*	*Market value of medicines under price control (Rs. crore)*	*Market share of medicines under price control (%)*
Anti Diabetic	4802.3	4102.3	85	700.0	15
Anti malarials	543.9	475.0	87	68.9	13
Anti-infectives	11823.7	7692.9	65	4130.8	35
Anti-Parasitic	314.1	158.5	50	155.6	50
Anti-TB	388.3	319.0	82	69.3	18
Blood Related	325.1	323.2	99	1.9	1
Cardiac	8268.0	6327.0	77	1941.0	23
Derma	3911.0	3553.1	91	357.9	9
Gastro Intestinal	7426.8	6541.3	88	885.5	12
Gynaec.	4736.6	4089.4	86	647.2	14
Hepatoprotectives	711.5	711.5	100		
HIV	307.6	261.9	85	45.8	15
Hormones	1254.5	697.5	56	557.0	44
Neuro / CNS	4227.8	3549.4	84	678.4	16
Ophthal / Otologicals	1230.8	1165.5	95	65.3	5
Others	1295.1	1128.7	87	166.4	13
Pain / Analgesics	5821.5	5316.4	91	505.1	9
Parenteral	257.6	192.5	75	65.1	25
Respiratory	5608.7	5320.8	95	287.9	5
Sex stimulants / Rejuvenators	903.3	892.3	99	11.0	1
Stomatologicals	378.3	378.3	100		
VACCINES	1358.8	933.3	69	425.5	31
Vitamins / Minerals / Nutrients	5350.8	5318.1	99	32.7	1
Grand Total	**71246.0**	**59448.0**	83	**11798.0**	17

Source: IMS Health, authors calculations. Estimates are excluding formulations for which data was unavailable through IMS and where relevant products could not be identified in the IMS database

As depicted in Figure 5.1, only 5% of the market for respiratory drugs, 23% of cardiac drugs, 15% of anti-diabetics and 35% of anti-infectives fall under the ambit of price control.

Figure 5.1. Market under control in selected therapeutic categories

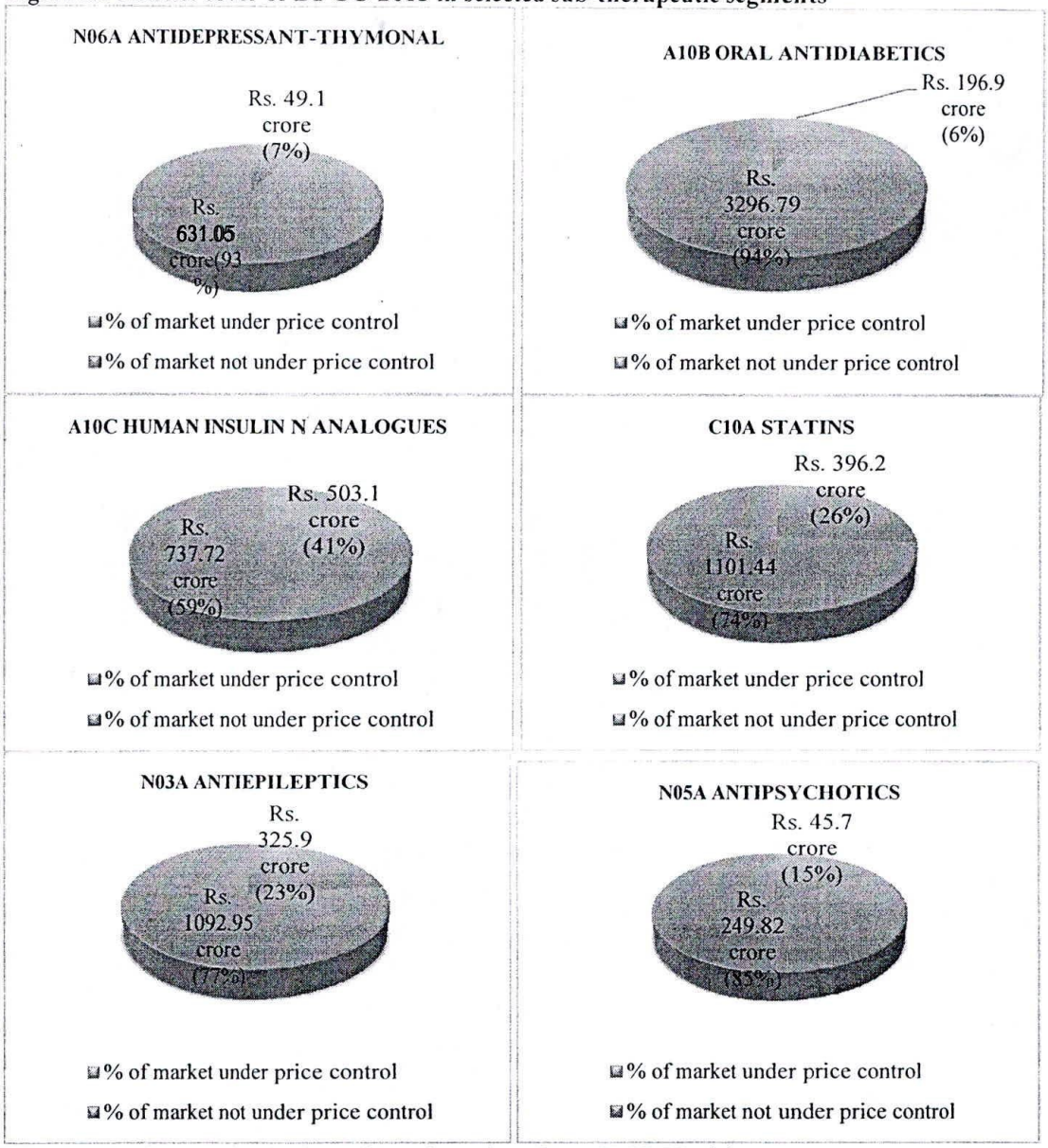


Source: Authors'calculations based on data from IMS Health

Breaking this down to the sub-therapeutic level, Figure 5.2 shows the extent of price control in various prominent non-communicable disease segments. Only 6% of the oral antidiabetics segment and 7% of the antidepressants segment correspond with the NLEM and hence fall under price control. Similarly, the reach of DPCO extends to approximately 26% of statins, 23% of antiepileptics, 15% of antipsychotics, and 41% of human insulin analogues.

The National Pharmaceutical Pricing Authority (NPPA) is charged with issuing ceiling prices under the DPCO. For this purpose, the NLEM which consists of 348 medicines has been broken down into the exact strengths and dosage forms that are mentioned in the document. By our estimation the there are approximately 622 formulations (i.e., unique strengths and dosages) that are drawn from the NLEM (see Appendix 1).

Figure 5.2 Market cover of DPCO 2013 in selected sub-therapeutic segments

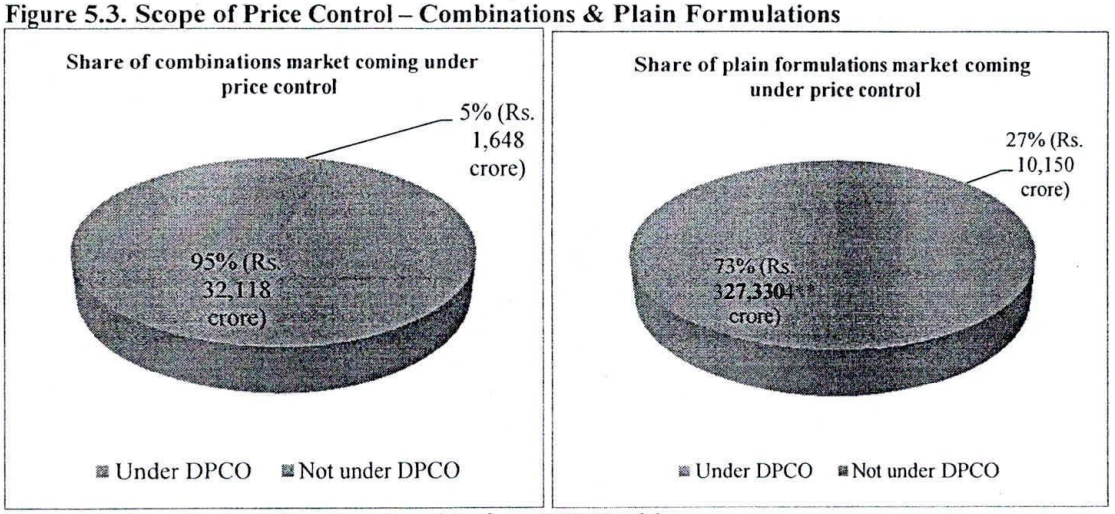


Source: Authors'calculations based on data from IMS Health

In essence this means that any additional strengths, dosage forms or combinations involving medicines on the NLEM remain outside the scope of price control. For instance, the price of paracetamol 500 mg tablet will be regulated because it is specified but the 650 mg strength tablet will not. Even though several dosage forms and strengths of paracetamol are covered under the NLEM (e.g., 150mg/ml injection, 125mg/5ml syrup, 80mg and 170 mg suppositories and 500mg tablet), numerous alternate strengths, pediatric formulations and all combinations that are being sold in the market remain outside price control.

Moreover, because the NLEM includes only a handful of few fixed-dose-combinations (FDCs), the scope of price control is disappropionately narrow within combinations, relative to plain formulations. Plain formulations and combinations constitute 53% and 47% the pharmaceutical market (by 2012 sales), respectively. Whereas 73% (~ Rs. 27,000) of the plain formulations market is left untouched, roughly 95% (~Rs. 32,000 crore) of the combinations market is excluded (see figure 5.3). In fact, combinations outside the span of price control alone make up 45%of the full pharmaceutical market.

Figure 5.3. Scope of Price Control – Combinations & Plain Formulations



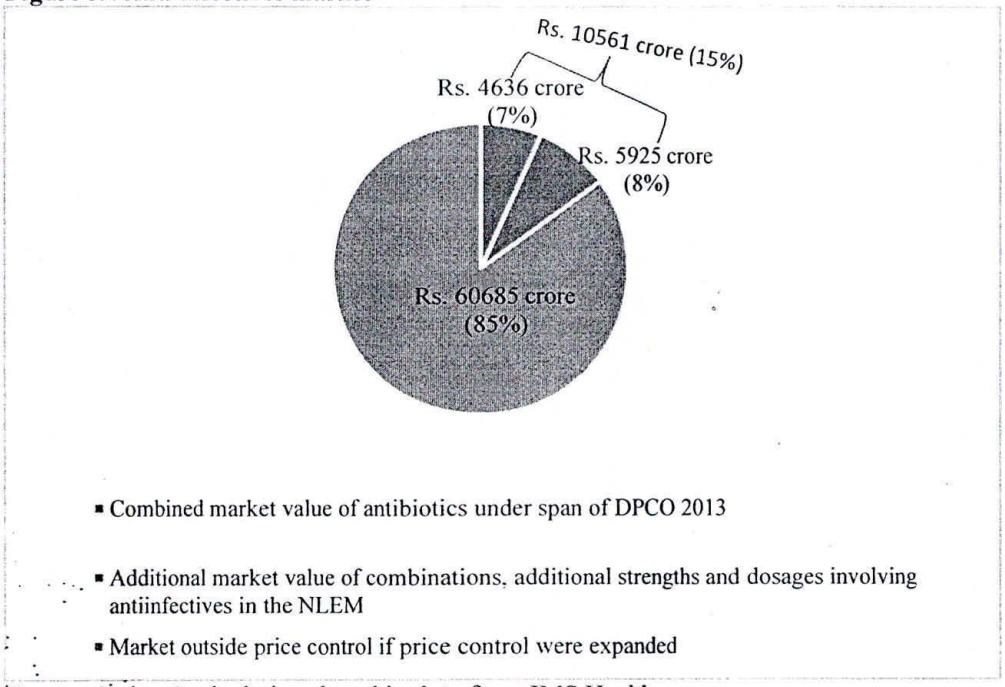
Source: Authors' calculations based on data from IMS Health

With the primary objective of promoting the rational use of medicines, the NLEM has purposely emphasised single ingredient formulations over FDCs and reflects an ideal scenario that is disconnected from actual utilization patterns. The DPCO, by excluding all combinations of NLEM medicines, has completely failed to address the reality of unfettered use of irrational combinations by patients who are often subjects of irrational prescribing and dispensing.

Noting the need to revise the scope of control, we explored the potential impact of broadening the scope of control by taking the example of antiinfectives. We explored a scenario where price control of antiinfectives under the NLEM was broadened to cover all additional strengths, dosage forms, and their combinations. The current market value of antiinfectives covered under DPCO was estimated at Rs. 4,636 crore or 7% of the entire market. The additional market value of anti-infectives were price control expanded under the hypothetical scenario was estimated to be Rs. 5,925 crore or 8% of the entire market. Hence, under the new scenario, the combined market

value of controlled anti-infectives as a percentage of the total market value would increase to 15% (see Figure 5.4).

Figure 5.4 Anti-infectives market



Source: Authors' calculations based in data from IMS Health

The case of anti-infectives clearly indicates that the market value of medicines under price control would increase considerably if the scope of control is broadened so as to increase coverage to all strength, dosages and combinations of formulations in the NLEM.

The new policy shrinks the scope of control dramatically by focusing solely on formulations. Previously under DPCO 1995, the prices of bulk drugs were being regulated such that over 1500 formulations as of 2012. Under paragraph 2(b) of DPCO 2013, active pharmaceutical ingredients or bulk drugs are defined as:

> 2(b) "active pharmaceutical ingredients or bulk drug" means any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to standards specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and which is used as such or as an ingredient in any **formulation;**

The NPPP has claimed that "price control in the form of formulations only ensures more specific pricing control of the required medicine which is in the interest of the

consumer from the point of view of the actual prescription by the Doctor." On the contrary, because the NLEM has no influence or bearing on prescribing practices and essential medicines account for only a small fraction of private sector sales, it becomes all the more important to regulate even the 'salts, esters, isomers, analogues and derivatives' related to formulations on the NLEM.

Particularly for sections of the NLEM where few therapeutic equivalents have been provided within the same class of drugs (e.g., atorvastatin is the only statin included), close substitutes should also be brought under price control.

Limiting price regulation to formulations in the NLEM poses a clear risk that companies will shift their production, marketing and distribution energies towards increasing the sales of formulations that lie outside the NLEM.

In summary, the scope of coverage under current implementation of DPCO 2013 is extremely inadequate and substantial measures should be taken to expand it. The government has recently conveyed an intention of revising the NLEM in 2014. We assert that in addition to revising the 2011 NLEM to address the problems described, an attempt should be made either separately or as part of the NLEM review to identify life saving medicines to be brought under price control. Further, implementation of DPCO should go beyond the literal reading of the NLEM to include a larger segment of the market in order to be viewed as an effective policy.

Impact on Prices and Sales

Reduction in prices

By December 2013, the NPPA had notified ceiling prices of 446 formulations using the market based formula, of which 419 were related to the NLEM and 27 were new formulations (i.e., new strengths or combinations of essential medicines that have not been marketed previously).

The simple goal of the DPCO and use of the market based formula is to see a reduction in the price of the highest priced brand for the specific formulation. The magnitude of the reduction is essentially considered to be irrelevant.

Yet, we observe that the reduction from the price of the sales leader is a more suitable indicator for evaluating the impact of price control. This is because the sales leader is the brand with the highest sales and therefore bringing about a significant reduction in its price has the potential to provide the maximum financial relief.

In order to ascertain the prominence of the sales leader, we determined the market share of the sales leader in 419 formulations for which the ceiling price had been notified by the NPPA. Table 5.2 shows the market share of the sales leader for formulations in each of the NLEM therapeutic categories. In 293 formulations, the sales leader has a market share of more than 50%. For another 101 formulations, the sales leader commands a market share between 25%-50%. This trend is consistent across all therapeutic categories.

Thus, in the majority of cases (394; 94%) the sales leader has a considerable and high market share, supporting our argument for studying the price reduction of the sales leader.

Table 5.2 Market Share of the Sales Leader

NLEM Section No.	*NLEM Section*	*Number Of Formulations*	*No. With Share Of Market Leader >50%*	*No. With Share Of Market Leader >25% But <50%*	*No. With Share Of Market Leader <25%*
1	Anaesthetics	25	22	3	0
2	Analgesics, Antipyretics, Non-Steroidal Anti-Inflammatory Medicines (Nsaims), Medicines Used To Treat Gout And Disease Modifying Agents In Rheumatoid Disorders (Dmards)	23	19	3	1
3	Antiallergics And Medicines Used In Anaphylaxis	7	3	4	0
4	Antidotes And Other Substances Used In Poisonings	4	3	1	0
5	Anticonvulsants/Antiepileptics	14	14	0	0
6	Anti-Infective Medicines	92	51	32	9
7	Antimigraine Medicines	3	2	1	0
8	Antineoplastic, Immunosuppressives And Palliative Care	52	35	17	0
9	Antiparkinsonism Medicines	3	1	2	0
10	Medicines Affecting The Blood	11	8	3	0
11	Blood Products And Plasma Substitutes	4	3	1	0
12	Cardiovascular Medicines	49	31	7	11
13	Dermatological Medicines (Topical)	10	6	3	1

NLEM Section No.	*NLEM Section*	*Number Of Formulations*	*No. With Share Of Market Leader >50%*	*No. With Share Of Market Leader >25% But <50%*	*No. With Share Of Market Leader <25%*
14	Diagnostic Agents	1	1	0	0
15	Disinfectants And Antiseptics	9	8	1	0
16	Diuretics	3	2	1	0
17	Gastrointestinal Medicines	21	17	4	0
18	Hormones, Other Endocrine Medicines And Contraceptives	20	14	4	2
19	Immunologicals	12	11	1	0
20	Muscle Relaxants (Peripherally-Acting) And Cholinesterase Inhibitors	6	5	1	0
21	Opthalmological Preparations	16	13	3	0
22	Oxytocics and Antioxytocics	9	7	2	0
23	Peritoneal Dialysis Solution	0	0	0	0
24	Medicines For Mental And Behavioural Disorder	12	5	6	1
25	Medicines Acting On The Respiratory Tract	5	5	0	0
26	Solutions Correcting Water, Electrolyte And Acid-Base Disturbances	5	4	1	0
27	Vitamins And Minerals	3	3	0	0
	Total	419	293	101	25

Source: IMS Health

We compared the percentage price reduction from both the highest price as well as sales leader for the 419 formulations using data available from the NPPA (see table 5.3).

Table 5.3 Price reduction of the notified price from the highest price and the sales leader

	Price reduction from highest price		*Price reduction from market leader*	
	No. of formulations	*%*	*No. of formulations*	*%*
No price reduction		0	113	27
Limited price reduction (</=10%)	49	12	64	15
Reduction is >10% to 20 %	86	21	72	17
Reduction is >20% to 30%	106	25	78	19
Reduction is >30% to 40%	62	15	36	9
Reduction is >40%	116	28	56	13
Total	419		419	

Source: NPPA price notifications

We observed that whereas the price reduction from the highest brand was greater than 40% in 116 formulations, only 56 formulations showed a price reduction of more than 40% from the price of the sales leader. There was a only a marginal reduction from the highest price in 49 formulations. In contrast, for 113 formulations there was no reduction in price of the sales leader and in a further 64 formulations the reduction

was very limited. Therefore, in 117 formulation or 42% of cases, there was limited to no impact on the price of the sales leader.

We also noted evidence of market failure based on 193 formulations where the sales leader was also the highest priced brand. This finding is not surprising and finds support in the literature; however, it also indicates that the assumption of vibrant competition that is the backbone of the market-based formula has been violated.

In the interest of undertaking an analysis and evaluation of the DPCO and its implementation, we attempted to calculate ceiling prices formulations coming under price control using independently procured data from IMS Health. Table 5.4 provides an overview of our **calculations.**

Table 5. 4. Overview of Independent Calculations

Authors' independent calculations		
Total number of formulations identified for the analysis	622	
No. of formulations for which prices have been calculated	371	60%
No. of formulations for which no data is available through IMS	140	23%
No. of formulations for which sales value is zero*	11	2%
No. of formulations determined to have monopolies	100	16%

*May 2012, MAT

Ceiling prices were calculated for 371 formulations out of a total of 622 formulations that were identified. We could not find data through IMS Health for 140 formulations and for an additional 11 formulation no sales had been recorded in the IMS dataset.

Paragraph 6 of the DPCO 2013 describes the application of special provisions for calculating the ceiling prices of formulations where there is only one competitor with a market share of 1% or greater. We identified 100 such monopoly cases but did not attempt to calculate the ceiling prices.

The analysis discussed further is based on the sample of 371 formulations for which we computed ceiling prices.

Reduction in market sales

We estimated the monetary impact of DPCO in the sample of 371 formulations considering only the brands having 1% or greater market share. Assuming there would be no change in demand (i.e., constant volumes), the reduction in sales value

was quantified as Rs. 1290 crore. This represents less than 2% of the total annual sales in 2012.

Table 5. 5.Monetary impact of DPCO

Nlem Section	*Category*	*Number Of Formulations Considered*	*Original Market Value*	*Monetary Impact*	*Impact As A %*
1	Anaesthetics	18	106.4	11.4	11%
2	Analgesics, Antipyretics, Nsaims	21	423.9	44.7	11%
3	Antiallergics And Medicines Used In Anaphylaxis	8	329.1	44.0	13%
4	Antidotes And Other Substances Used In Poisonings	4	3.9	0.1	2%
5	Anticonvulsants/Antiepileptics	9	235.6	31.0	13%
6	Anti-Infective Medicines	102	4524.2	480.9	11%
7	Antimigraine Medicines	3	40.3	0.9	2%
8	Antineoplastic, Immunosuppressives And Palliative Care	39	340.5	41.8	12%
9	Antiparkinsonism Medicines	6	67.3	14.9	22%
10	Medicines Affecting The Blood	9	391.2	30.8	8%
11	Blood Products And Plasma Substitutes	1	59.2	9.7	16%
12	Cardiovascular Medicines	39	1513.3	210.1	14%
13	Dermatological Medicines (Topical)	9	129.1	36.4	28%
14	Diagnostic Agents	1	1.0	0.0	3%
15	Disinfectants And Antiseptics	2	87.2	27.7	32%
16	Diuretics	2	8.4	1.1	13%
17	Gastrointestinal Medicines	16	604.2	74.6	12%
18	Hormones, Other Endocrine Medicines And Contraceptives	22	1143.5	100.2	9%
19	Immunologicals	10	349.8	30.2	9%
20	Muscle Relaxants (Peripherally-Acting) And Cholinesterase Inhibitors	4	30.9	1.1	3%
21	Opthalmological Preparations	11	75.3	15.5	21%
22	Oxytocics And Antioxytocics	8	314.2	46.4	15%
23	Peritoneal Dialysis Solution	1	0.0	0.0	4%
24	Medicines For Mental And Behavioural Disorder	15	289.3	25.4	9%
25	Medicines Acting On The Respiratory Tract	6	114.9	7.2	6%
26	Solutions Correcting Water, Electrolyte And Acid-Base Disturbances	3	62.9	3.7	6%
27	Vitamins And Minerals	2	22.3	0.4	2%
Grand Total		**371**	**11267.9**	**1290.1**	11%
Impact as a percentage of 2012 annual sales turnover					1.8%

Taken as a per cent of original market value, the cumulative reduction in sales value for 15 formulations for mental disorders was 9%. Similarly, the cumulative reduction in sales value was 12% for 16 gastrointestinal formulations, 11% for 102 antiinfective formulations and 12% for 39 formulations in the anti-neoplastic, immune supressives and palliative care category. The highest impact observed was 32% for disinfectants and lowest impact was 2% for antidotes and substances used in poisoning.

Out of the total of 2083 brands having at least 1% market share, only 984 brands (47%) would be affected and experience a decrease in value of sales. The market

shrinkage as a percentage of the original value of affected brands varied across formulations but was 20% on average. Thereafter, the actual loss of profits would constitute only a portion of the decreased sales value.

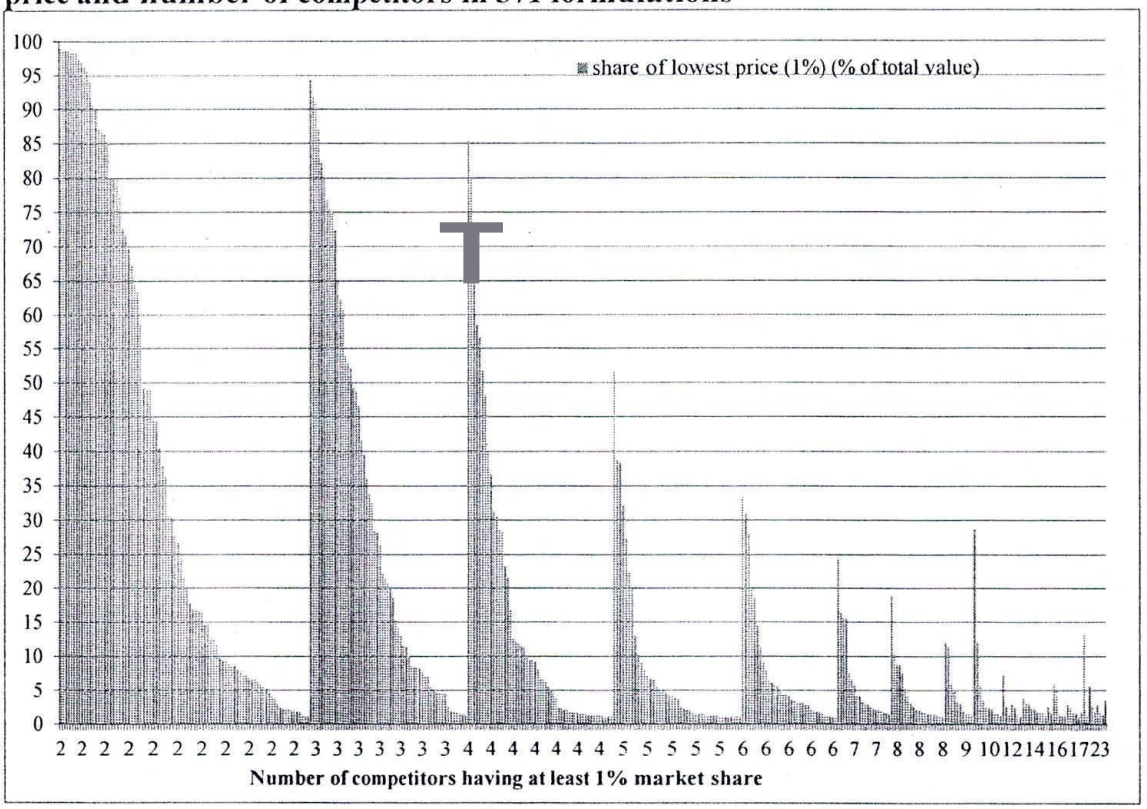
However it should also be kept in mind that DPCO allows for an annual price increase as per the WPI for all scheduled formulations. Brands which are priced at exactly the ceiling price can claim a higher absolute price increase than brands that are priced lower than the ceiling as the WPI is applied as a percentage. For unscheduled formulations which include a huge segment of irrational medicines, a 10% annual price hike is automatically assured.

Availability of lowest priced brand

As pointed out earlier, the sales leader is frequently observed to hold a high market share. In our sample of 371 formulations, the average market share of the sales leader was 62%. In comparison, the average market share of the highest price (with at least 1% market share) was 35% and of the lowest price (with at least 1% market share) was only 19%. This indicates that the availability of lower priced brands, even those that have a significant share of the national market, significantly lags behind the sales leader and highest priced brand.

In order to examine this further we considering only brands having at least 1% market share and plotted the market share of the lowest priced brand against the number of competitors in that formulation. Figure 5.5 depicts the interaction of market competition with share of the lowest price. We observe that in 231 formulations (of 371), the lowest price has a market share of less than 10%. Moreover, as the number of players increases, the share of the lowest price drops dramatically. We conclude that because of the nature of competition among firms, it is not safe to assume that the lowest priced brand is always accessible to patients as it often captures the smallest share of the market.

Figure 5.5. Depiction of the relationship between market share of the lowest price and number of competitors in 371 formulations



An alternate market-based formula

We also explored a scenario where the average PTR is replaced with the lowest PTR in the market-based formula and studied its implications. Table 5.6 summarises the expected market shrinkage under both the current and lowest PTR scenarios. This is of interest because the decrease in sales value directly translates to reduction in out-of-pocket spending. We assume that the lowest priced brand holding at least 1% share of the national market is able to serve the market while sustaining reasonable profits. Therefore we expect the see the greatest impact on patient expenditure under a variant of the market-based pricing that considers the lowest PTR as the basis for setting ceiling prices.

Table 5.6. Comparison of the average PTR and lowest PTR scenarios

	Average PTR	*Lowest PTR scenario*
Estimated market shrinkage in 371 formulations	1290 cr.	4205 cr.
Market shrinkage as a percent of original market value	1.8%	5.9%
Number of 1% brands affected	984	1711
Market shrinkage as a percent of original value of affected brands	19.8%	43.9%

Source: Authors' estimates

Under the lowest PTR scenario, there was more than a threefold increase in the sales value forfeited because of price control. Similarly, the value of affected brands would be eroded to a larger extent (~44%) and provide greater relief to consumers, compared with under the current formula (~20%).

As can be seen in Table 5.7, the monetary impact (percentage decrease in sales value) is greater than 20% for 226 formulations in the lowest PTR scenario and only 52 formulations in the average PTR setting. Whereas the majority of formulations face only a marginal impact on sales value under the average PTR price control (0-10%), this trend is reversed in the lowest PTR scenario with the majority of formulations facing an impact of more than 20%.

Table 5.7 Trend in decrease in sales value under two scenarios

NLEM Section Number	*NLEM Section*	*Number of formulations (decrease in sales value as a % of original market value)*					
		Average PTR			*Lowest PTR Scenario*		
		0-10%	*11-20%*	*>20%*	*0-10%*	*11-20%*	*>20%*
1	Anaesthetics	12	4	2	4	4	10
2	Analgesics, Antipyretics, Non-Steroidal Anti-Inflammatory Medicines (Nsaims),	13	6	2	8	2	11
3	Antiallergics And Medicines Used In Anaphylaxis	4	4		1	1	6
4	Antidotes And Other Substances Used In Poisonings	3	1		2	1	1
5	Anticonvulsants/Antiepileptics	6	2	1	2	3	4
6	Anti-Infective Medicines	61	27	14	32	7	63
7	Antimigraine Medicines	3			2	1	
8	Antineoplastic, Immunosuppressives And Medicines Used In Palliative Care	20	15	4	8	6	25
9	Antiparkinsonism Medicines	5		1	3		3
10	Medicines Affecting The Blood	7	1	1	2	2	5
11	Blood Products And Plasma Substitutes			1			1
12	Cardiovascular Medicines	17	19	3	2	4	33
13	Dermatological Medicines (Topical)	4	4	1	1	1	7
14	Diagnostic Agents	1				1	
15	Disinfectants And Antiseptics	1		1		1	1
16	Diuretics	1		1			2
17	Gastrointestinal Medicines	11	2	3	5	4	7
18	Hormones, Other Endocrine Medicines And Contraceptives	17	4	1	6	6	10
19	Immunologicals	5	3	2	3	1	6
20	Muscle Relaxants (Peripherally-Acting) And Cholinesterase Inhibitors	4			1	3	
21	Opthalmological Preparations	6	2	3	2	2	7
22	Oxytocics And Antioxytocics	4	1	3	1	3	4
23	Peritoneal Dialysis Solution	1			–	1	
24	Medicines For Mental And Behavioural Disorder	5	5	5	1		14
25	Medicines Acting On The Respiratory Tract	4		2	2	1	3
26	Solutions Correcting Water, Electrolyte And Acid-Base Disturbances	2	1		1		2
27	Vitamins And Minerals	1		1	1		1
	Total	218	101	52	90	55	226

Although it may be too early to appraise the full impact of the new price control order, it is clear that relief to patients would be marginal at best. Reductions in the prices of the most popular brands are mostly inadequate and the potential savings to consumers is only a drop in the ocean given the size of the pharmaceutical market.

Problematic clauses in the DPCO 2013

In addition to the above discussion, three aspects of the DPCO 2013 appear to be problematic in the implementation of price control.

First, the DPCO instructs in paragraph 13(2)[4] that manufacturers of scheduled formulations that are already pricing their brands below the notified ceiling price (plus local taxes) will not be allowed to raise the existing maximum retail price.

While this provision is seemingly well-intentioned it effectively imposes different ceiling prices for different producers. Manufacturers whose prices have been frozen below the ceiling price will be disadvantaged because they would not be allowed to raise prices even if the cost of production or raw materials increases (e.g., due to exchange rate fluctuations). The policy's impact will be disproportionately felt by small and medium firms that lack the financial resources of large companies and could potentially render it unsustainable for them to operate in situations where their profitability is threatened.

Also, annual price increases which are allowed in proportion to the WPI will unfairly result in greater increases for higher priced brands than those priced below the ceiling price.

Second, the DPCO has weak safeguards to prevent the discontinuation of production of essential formulations and migration to unscheduled formulations by companies. Even if the government has the power to mandate the continued production of an essential formulation[5], which is questionable, it will only be for a stipulated period of time during which production could easily be tapered off to minimal levels. A

[4] 13 (2) All the existing manufactures of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price lower than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government shall maintain their existing maximum retail price.

[5] Paragraphs 3 and 21 (b), DPCO 2013

producer is arguable entitled to stop manufacturing a product if it is no longer economically viable.

Moreover, there are no controls on the prices or production of alternate forms, strengths or combinations of essential medicines that are outside the NLEM and already exist in the market. Whereas DPCO 2013 intends to fix the prices of new market entrants involving essential medicines, it allows free pricing for similar formulations that pre-date the price control order.

Therefore, there are several aspects of the DPCO which could be viewed as unduly discriminatory and grounds to challenge the policy under Article 14 of the Constitution of India.

Lastly, we have serious concerns about the ability of the NPPA to monitor and enforce prices of scheduled formulations, particularly given the multiple ceiling prices, as well as formulations falling outside price regulation. It is naïve to imagine that the NPPA can monitor prices of tens of thousands of brands without developing a technical capacity and systematic mechanism to collect relevant data on a continuous basis.

Summing up

In conclusion, the implementation of DCPO presents an inadequate check on medicines prices, leaves the majority of the market untouched and is expected to deliver only marginal financial relief to patients. Not only does it permit the presence of a huge irrational medicines market but encourages its growth by allowing a 10% increase in prices each year.

CHAPTER 6:
LIMITATIONS OF NPPP 2012 AND DPCO 2013 IN FIXING CEILING PRICES

The National Pharmaceuticals Pricing Policy (NPPP), 2012 and Drug Prices Control Order (DPCO), 2013 define the regulatory framework for drug pricing and establish the principles and scope of price control. The primary implementing authority, the National Pharmaceutical Pricing Authority (NPPA), relies on the guidelines provided in the DPCO to notify ceiling prices for controlled formulations.

We undertook an independent exercise to estimate ceiling prices using market data from IMS Health, based on our understanding and interpretation of the DPCO. Three key elements of the pricing policy define the mechanism through which ceiling prices are fixed – a) the 'essentiality' criterion, b) market-based pricing, and c) reliance on market-based data. In this chapter, we highlight several limitations of the methodology as well as use of data in arriving at reliable ceiling prices.

Calculation of ceiling prices under DPCO 2013

As discussed earlier in this report, the NPPP defines price control on the basis of 'essentiality' as specified in the National List of Essential Medicines (NLEM) even though the NLEM was not explicitly prepared keeping its use in price control in mind.

The DPCO limits its control to the strengths and dosages of formulations in the NLEM. The NPPA, however, has taken a more literal approach by considering even the 'form' (e.g., tablet, capsule) in which the formulation is listed on the NLEM. For instance, where only a tablet form has been specified, the entire capsule market is excluded. For practical purposes no distinction is made between plain, time-released therapies (e.g., sustained, controlled, delayed, modified) or altered versions of the formulation. Sustained Release forms have been treated separately for price calculations only in the cases where they are specifically mentioned in the NLEM.

By December 20, 2013, the NPPA has notified prices for 446 formulations which include 419 formulations based on the NLEM and another 27 new formulations

involving new dosages or combinations of essential medicines that do not appear on the NLEM. Because price regulation under DPCO 1995 is still in effect for a small subset of formulations, NPPA is yet to release these ceiling prices.

Following a similar approach as the NPPA for identifying NLEM formulations, we identified 622 formulations based on unique strengths, dosages and forms (See Appendix 1). We attempted to calculate ceiling prices for all formulations using IMS Health data because according to DPCO, the date of the data to be used in price calculation is constant, irrespective of when the price ceiling is **notified.**

Methodological differences in applying the market-based pricing formula

The DPCO has instructed that the ceiling price of a specific formulation is calculated on the basis of the average Price to Retailer (PTR) and a 16% margin to retailer. The average PTR is defined on the basis of brands as follows:

> **"Average Price to Retailer, P(s)** = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.)" (Page 5, DPCO 2013)

However, it is frequently observed that even within the same formulation (i.e, same strength) a company may be marketing more than one brand, at different price points. For example, there are 134 brands for azithromycin-250mg tablet in the market which are marketed by only 104 companies. If we consider only the brands with appreciable market presence, i.e., that have at least 1% market share, the number of brands is 25 which are being marketed by 21 companies. Table 6.1 presents a few examples:

Table 6. 1 Examples of formulations with some companies marketing more than one brand

Name	*NLEM therapeutic section*	*market with all brands*		*segment of market made up of brands having at least 1% marketshare*	
		number of brands	*number of companies*	*brands with 1% market share*	*number of companies*
Metoprolol – tablet 50mg	Cardiovascular Medicines	45	36	21	19
Azithromycin – tablet 250mg	Anti-Infective Medicines	134	104	25	21
amoxicillin+clavulinic acid – tablet 625mg	Anti-Infective Medicines	108	80	21	16
Cefixime – tablet 200mg	Anti-Infective Medicines	120	87	22	20
Diclofenac – injection 25mg/ml	Analgesics, Antipyretics, Non-Steroidal Anti-Inflammatory Medicines (Nsaims),	74	51	23	19

Source: IMS Health

In order to address this reality, the NPPA has chosen a strategy of applying the 1% market share criteria to companies by combining the individual market shares of all brands marketed by a company. Therefore, even brands that individually might account for less than 1% market share have been taken into consideration in the NPPA's calculations. Each individual pack of the companies included has been retained separately in both the numerator and denominator of the NPPA's formula.

In contrast to the NPPA, our own calculations are based on aggregating sales of all the packs of the same brand (and company) for a specific formulation to determine if it captures at least 1% of the market share. Thereafter, the PTR for that brand is calculated as a weighted average by volume (in units) of the various packs sold under the brand. The average PTR is calculated as the simple average of the PTRs of the 1% brands as specified in the DPCO.

Based on our reading of the DPCO, our method is a more direct implementation of the market-based pricing compared with the NPPA. However, this does not necessarily imply that the method used by NPPA is incompatible with DPCO as the order fails to provide specific guidance on this issue and may be open to interpretation.

In 124 formulations, our calculated ceiling price differs from the NPPA's ceiling price by 10% or more. Sixty-three of these formulations show a ceiling price difference greater than or equal to 25%. In the case of several formulations, differences emerge

in the number of packs considered by the NPPA and the number of brands included in our price calculations. A few examples are presented in Table 6.2.

Table 6.2 Examples of differences in ceiling prices calculated by NPPA and authors

Name of formulation	*Unit*	*Issued by NPPA*		*Authors' calculation*			
		Number of Packs considered	*Ceiling price (Rs.)*	*Number of brands considered*	*Ceiling price (Rs.)*	*NPPA ceiling price- Authors' ceiling price (Rs.)*	*Difference greater than ±10% from NPPA ceiling price*
Mannitol Inj 10%	ml	2	0.03	2	0.68	-0.65	2182
Chlorpheniramine Maleate Tablets 4 mg	tablet	7	0.1	7	0.95	-0.85	854
Folic Acid tablets 5 mg	tablet	9	0.19	4	1.61	-1.42	746
Metoprolol Tablets 25 mg	tablet	30	0.47	17	3.41	-2.94	627
Cephalexin Capsules 250 mg	capsule	9	5.25	4	7.09	-1.84	35
Cefixime Tablets 100mg	tablet	48	7.69	23	5.78	1.91	25
Clotrimazole Pessary - 100 mg	pessary	3	8.47	5	6.62	1.85	22
Terbutaline Sulphate Tablets 2.5 mg	tablet	3	0.98	2	0.81	0.17	17
Cefixime Tablets 200mg	tablet	50	11.25	22	9.60	1.65	15
Sodium Valproate Tablets 500mg	tablet	29	7.18	8	6.21	0.97	14

Source: based on data from NPPA, IMS Health

It is important to note that the discrepancies between the NPPA and our calculations are only partly due to the methodological differences in applying the market-based formula. In order to estimate ceiling prices based on the market data, the relevant brands and packs for each individual formulation must painstakingly and meticulously be identified in the IMS Health database. Intrinsic limitations of the market-based data from IMS Health- incomplete information such as about pack descriptions, strengths and sales volumes- could lead to differences in selection of products that match the specific strength or description of the formulation. Thus, this leads us to a discussion of the limitations and challenges of using market-based data to implement drug price control.

Challenges of using market-based data

Under the shift to market-based pricing, the availability of market-based data has become a prequisite for regulating drug prices. Constrained by the lack of data available with the government or ability to develop an immediate capacity to collect market data, the NPPP stipulated that data from IMS Health[1] would be the basis for fixing ceiling prices.

The government not only specified IMS as the source for market data, presumably due to the long-standing relationship of the Department of Pharmaceuticals with IMS, but even went as far as to design the DPCO around the use of these data:

> "As the IMS data gives price figures for stockist level prices hence in order to arrive at ceiling Price (which will be the maximum retail price), the IMS price will be further increased by 16% as margin to the retailer so as to arrive at a reasonable ceiling price chargeable from the consumers." (Page 12, NPPP 2012)

Based on our experience of working with market datasets, we observe several challenges associated with the use of privately-owned data for implementing national pricing policy.

First, contradicting the claim that market-based pricing will be "based on widely available information in the public domain...which would result in more transparent and fair pricing", the government has chosen to rely on commercial data that are neither available for public scrutiny nor easily accessible due to the high cost of the database.

While it is commendable that NPPA has put all worksheets in the public domain, these by themselves are not adequate for external verification of ceiling prices as access to the entire raw database for essential medicines would be needed. Moreover, the government is admittedly bound by a legal agreement not to make the raw data publicly available[2] and stated in the November 2013 affidavat filed in the Supreme Court that "regarding the data available with NPPA relating to 348 drugs under

[1] IMS Health is a multinational company that specialises in collecting pharmaceutical market data and providing information on sales and market trends in various countries.

[2] Department of Pharmaceuticals affidavit to the Supreme Court....[complete citation]

NLEM 2011, it is submitted that answering respondents are under obligation not to share the data with third party as per memorandum of understanding with IMS Health."

Second, the government has depended heavily on data provided by IMS Health without the means to assess its quality or reliability. In India, IMS collects data from a panel of roughly 5600 stockists using a sampling approach. The IMS Total Sales Audit (TSA) database is based on the stockists panel data which are extrapolated to the entire universe of stockists (~25,000 total stockists). Details of the methodology or its limitations and biases are not readily known. There is little to instill confidence in the use of proprietary data derived from modeling methods and about which few details are available, for price **fixation.**

Third, we estimated that data for more than 20% of the NLEM formulations for which NPPA is supposed to fix price ceilings is missing in the IMS database. Appendix 2 a) lists 140 formulations for which no data is available with IMS and Appendix 2 b) lists an additional 12 formulations for which the operative sales value (May 2012 moving annual total) was zero. Notably, of the 152 formulations missing data in IMS, sales data was available for 38 formulations (25%) in an alternate market database, AIOCD-AWACS PharmaTrac.

Similarly, on 23 November 2013, the NPPA notified a list of 99 formulations for which no data were available through IMS. This list is likely to expand because ceiling prices for formulations falling under DPCO 1995 are still being notified. Under DPCO, NPPA must enable the collection of data in these circumstances. But the fact that only a few prices have been notified on the basis of independent data collection demonstrates a lack of foresight in prospectively setting up a mechanism for collection and validation of market data.

We also note that a significant amount of information on pack sizes and strengths is missing in IMS for formulations coming under price control, particularly for parenterals and liquids. This finding has direct implications for the stability of the data. As described earlier, Table 6.2 shows formulations where significant discrepancies are observed between the NPPA and our independent calculations. Some proportion of these differences are attributable to the gaps in data that lead to

greater subjective use of the data and necessitate greater judgement calls on the part of the analyst.

This result is bolstered by Appendix 3 which presents evidence of further discrepancies between the NPPA and our use of the IMS data. In 33 formulations we observed that there was only one manufacturer holding at least 1% marketshare. The NPPA, however, has identified more than one pack with 1% marketshare in the same cases. For another 37 formulations, we determined that there was no data available in IMS for the specific molecule, dose or form; or the lack of details precluded identification of relevant products. NPPA on the other hand was able to notify prices on the basis of IMS data. Lastly, we did not treat the sustained release forms for Metoprolol Tablets- 50mg and 25mg as separate formulations as they are not specified in the NLEM but NPPA has done so.

Fourth, because market estimates are modeled based on the results of stockist sales audits, differences in methodology, survey sample size and other factors can significantly influence the market estimates. We compared market data from IMS Health with AIOCD-AWACS's PharmaTrac database. AIOCD AWACS is a pharmaceutical market research company formed by All Indian Origin Chemists & Distributors in a joint venture with Trikaal Mediinfotech and provides market data on pharmaceuticals through the PharmaTrac database.

Table 6.3 summarizes cases where market estimates vary widely between IMS Health and PharmaTrac. The annual sales estimates for 2012 (at the PTR level) for the top 300 selling brands was Rs. 22,257 crore and Rs. 21,211 crore according to IMS and PharmaTrac, respectively. At the brand level, we observed that the estimates could differ not only in terms of annual sales value but also the rank. For example, Human Mixtard marketed by Novo Nordisk was ranked number 4 in both datasets. However, the sales estimates for 2012 differ by approximately Rs. 40 crore. Lantus marketed by Sanofi-Aventis ranked number 14 in IMS Health with estimated market sales in 2012 of Rs. 151 crore. However, the same brand was estimated to have maket sales of only Rs. 75 crore in 2012 and was ranked number 91 according to PharmaTrac.

Table. 6.3. Glaring variations across two sources of private data –IMS Health and AIODC-AWACS data on top selling brands in Dec 2012

BRAND	*SUBGROUP*	*COMPANY*	*IMS Health Rank**	*IMS 2012 annual sales (Rs. crore)*	*PharmaTrac **Rank****	*PharmaTrac 2012 annual sales (Rs. crore)*
Phensedyl Cough Linctus	Chlorpheniramine + Codeine | R5e1	Abbott Healthcare Pvt. Ltd	2	258.18	17	150.95
Human Mixtard	Intermediate-Acting, Ispophane (Nph) | A10c4	Novo Nordisk India Pvt Ltd	4	258.62	4	218.67
Voveran	Diclofenac | M1a12	Novartis India Ltd	5	241.58	6	194.66
Lantus	Other Human Insulins | A10c9	Sanofi-Aventis	14	151.08	91	75.78
Mox	Amoxycillin | J1c1	Ranbaxy Laboratories Ltd	15	166.60	55	96.84
Azithral	Azithromycin | J1f1	Alembic Ltd	21	143.50	29	127.75
Calpol	Paracetamol | N2b1	Glaxosmithkline Pharmaceuticals Ltd.	38	157.78	7	190.52
Eptoin	Phenytoin | N3a12	Abbott India Ltd.	39	127.16	75	84.42
Pan	Pantoprazole | A2c4	Alkem Laboratories Ltd.	47	117.03	28	128.14
Sporidex	Cefalexin | J1d1	Ranbaxy Laboratories Ltd	50	107.09	196	46.90
Januvia	Sitagliptin | A10b66	Msd Pharmaceuticals Private Ltd.	61	92.55	38	111.48
Cifran	Ciprofloxacin | J1g1	Ranbaxy Laboratories Ltd	89	95.16	101	71.22
Huminsulin	Intermediate-Acting, Ispophane (Nph) | A10c4	Eli Lilly And Company (India) Pvt. Ltd.	99	78.76	53	98.35
Dilzem	Diltiazem | C8a6	Torrent Pharmaceuticals Ltd.	146	58.63	272	39.35
Bett	Tetanus | J7a2	Biological E Ltd	163	68.66	180	49.28
Dalacin C	Clindamycin | J1f3	Pfizer Ltd	181	53.22	94	74.93
Zyloric	Allopurinol | M4a4	Glaxosmithkline Pharmaceuticals Ltd.	223	43.66	152	55.00
Mt Pill	Mifepristone | G3x2	Cipla Ltd.	251	44.23	115	63.68
Dexona	Dexamethasone | H2a5	Zydus Cadila	260	43.29	123	61.45
Cefolac	Cefixime | J1d26	Macleods Pharmaceuticals Pvt.Ltd	285	47.19	274	39.25

based on December 2012 sales
Source: AIOCD-AWACS PharmaTrac; IMS Health

In conclusion, we have highlighted several challenges with implementing the market-based calculations to fix ceiling prices under the DPCO 2013. Some of these relate to the literal reading of the NLEM in imposing price control and further narrowing of the scope from the DPCO guidance. Other concerns arise from the use of privately-owned

market data which is not available for public review. Lastly, we question the reliance on market data which are not proven to be complete or stable for the purposes of determining the prices patients should pay for **medicines.**

CHAPTER 7
INNOVATION, EXPORTS AND PRICE CONTROL

Besides the rationale of adequate market competition which is implicit in the choice of market determined price control mechanism policymakers have been using the rationale of how the activity of innovation in pharmaceuticals should not be adversely affected. Innovation needs to be encouraged is also a key reason for the Indian policymakers to stick to the mechanism of market led price control. But the reality is that the extent of innovation is first of all quite low. Second, it is separately awarded through the policy of R&D subsidies being made available anyway to the companies undertaking R&D. Support for R&D and innovation is available in the form of incentives as government grants, tax rebates and price exemptions. Evidence presented here below that it would be totally counterproductive for the policymakers to depend on the mechanism of market led price control to encourage innovation which is nothing more than the activity aimed at product differentiation rather than substantive innovative activity.

Drivers of the innovation are also the profits anticipated from the export of products to the regulated markets of US and Europe. Para IV filings which provide 180 days of market exclusivity to the companies that are successful in beating others in the innovation race for entry into the markets of US and Europe have determined the extent and nature of innovation. In the case of Indian pharmaceutical industry extent of the efforts of product innovation have been geared to the exploitation of opportunities available in the innovation space of formulation and dosage forms.

Evidence built on the basis of industry-wide patenting activity itself clearly shows that as far as investment orientation toward in-house R&D of domestic pharmaceutical companies is concerned, work seems to have been mainly focused on developing capabilities, innovations and technological know-how for off-patent generics that the industry thought could be exported to regulated markets of Europe and USA. See Table for the historical time line of capability development profile mapped by the authors on the basis of patents filed by the Indian pharmaceutical industry with the United States Patents and Trade Mark Office (USPTO).

Table 6.1: Evolution of domestic pharmaceutical industry patents in USPTO 1992-2013

S.no	*Nature of patent*	*1992-1995*	*1996-1999*	*2000-2003*	*2004 - 2007*	*2008-2013*	*Total*
1	Process patent		11	51	133	176	371
2	NDDS patent			18	23	10	51
3	NCE patent		3	6	10	-	19
4	Method of treatment Dosage, Formulation Composition, Combination & Product Patent	14	26	102	261	202	403
5	New forms of substances		6	63	156	250	475
Grand total		**14**	**46**	**240**	**583**	**638**	**1521**

Source- Emerging patterns of pharmaceutical Patent innovations for top 15 domestic pharmaceutical firms, data collected from USPTO of 1992-2013. Changes in the domestic to foreign firm status accounted for these firms in the above table.

Notes: Patent Classification (Process, product, NDDS, Method of treatment, NCE, Dosage, Formulation, Composition, New forms of substances (Salt, Polymorphs, *Derivative, Amorphous, Analog, Conjugate, Crystalline, Esters, Isomers,* Metabolite, Solvates) is done by using *International Patent Classification* (*IPC*). Abbreviation-NDDS-New drug delivery system, NCE-New Chemical Entity

Evidence is compiled on the patenting activity of Indian pharmaceutical companies on the basis of patents filed by them in USPTO in Table. It clearly shows that product development is not first of all the main strength. Bulk of the "innovative outputs" still belongs to the areas of dosage / formulation/ composition of matter and process related R&D. Their patenting activity continues to be largely tilted in favour of the development of processes, new forms of substances, dosages and formulations, new drug delivery systems. Table shows that the chemistry driven process research leading to non-infringing processes for active pharmaceutical ingredients (APIs), introduction of cost effective routes, identification and characterization of impurity profiling pertaining to APIs, reduction of impurity levels, acceptable dosage forms and formulations came to be pursued as the main priority in the Indian pharmaceutical industry during the post-TRIPS period.

This emphasis has continued to date. Tables 6.1, 6.2, 6.3 and 6.4 confirm that the economic opportunity created by the Hatch-Waxman Act of 1984 has been the most important stimulus for the domestic pharmaceutical firms to invest in the processes of learning, competence building and innovation making activity. The other area of R&D pertains to formulations where new drug delivery systems (NDDS) based products are the focus of introduction by the industry in the market. The number of patents granted to these companies for the new chemical entities (NCEs) is small. Assessment indicates that attempts are still limited to the activity for product development being confined to the development of analogue molecules.

Another major area of competence building has been related to the improvement of good manufacturing practice. Table clearly shows the key areas of competence building in the case of domestic pharmaceutical firms in relation to the registration of Drug Master Files (DMFs) and Abbreviated New Drug Applications (ANDAs) prior to registering products (generics) in EU, USA and other developing countries. Even the assessment of Para IV filings which offer 180 days market exclusivity to the producers of generic products in the US market and of the new drug applications (NDAs) filed with United State Federal Drug Regulation Authority (USFDA) shows that the number of NDAs and ANDAs related to Para IV filings have still been few and far in the case of Indian pharmaceutical industry.

Table 6.2: DMFs filed by Indian Pharmaceuticals from 2008-2013

Company name	*Type I*	*Type II*	*Type III*	*Type IV*	*TYPE V*
Aarti Industries Ltd	-	10	13	4	-
Alembic Pharmaceuticals	-	37	1	15	-
Apotex Pharmachem Inc	-	45	1	15	-
Aurobindo Pharma Ltd	-	45	16	2	1
Biocon	-	10	1	2	-
Cadila Healthcare Ltd	-	45	23	5	1
Dr Reddys Laboratories Ltd	-	60	21	9	2
Fresenius Kabi	-	21	2	1	1
Glaxosmithkline Llc	-	9	-	-	-
Glenmark Generics Ltd	-	20	11	1	1
Hetero Drugs Ltd	-	102	8	5	-
Hikal Ltd	-	2	1	-	-
Ind Swift Laboratories Ltd	-	8	4	1	-
Lupin Ltd	-	56	11	13	2
Matrix Pharma	-	2	1	-	-
Micro Labs Ltd	-	8	-	-	-
Novartis Pharmaceuticals Corp	-	3	1	1	-
Piramal Healthcare Uk Ltd	-	3	-	1	-
Ranbaxy Laboratories Ltd	-	17	7	1	-
Torrent Pharmaceuticals Ltd	-	9	6	4	-
Wockhardt Bio Ag	-	6	10	6	-
Sun Pharma	-	35	14	8	2
Total		553	152	94	10

Source: No. of *DMF* Data from http://www.betterchem.com (Drug master file database) and no. of *Abbreviated New Drug Application* (ANDA) from individual company website.

Table 6.3: ANDAs granted in US to Indian Pharmaceutical Firms from 2008-2013

Company Name.	*2008*	*2009*	*2010*	*2011*	*2012*	*2013*
DR Reddy's labs	1	4	6	5	6	5
Ranbaxy	1	3	1	1	-	-
Glenmark	-	1	3	3	2	5
Aurobindo Pharmaceuticals	3	3	-	2	8	-
Sun Pharma	2	5	2	4	5	5
Alembic ltd	-	-	1	-	-	-
Lupin	1	-	2	2	3	2
Orchid	-	2	1	-	1	-
Torrent	-	1	1	2	5	-
Wockhardt	-	1-	-	1	3	-
Cipla	-	1	-	-	1	-
Fresenius Kabi Oncology	-	1	3	-	-	-
Matrics	1	-	-	-	-	-
Strides	-	-	-	-	2	-
TOTAL	**9**	**22**	**20**	**20**	**36**	**17**

Source: No. of DMF Data from http://www.betterchem.com (Drug master file database) and no. of *Abbreviated New Drug Application* (ANDA) from individual company website.

Fig. 6.1: 180 Days Exclusivity received during the period 2004-08 by the generic players

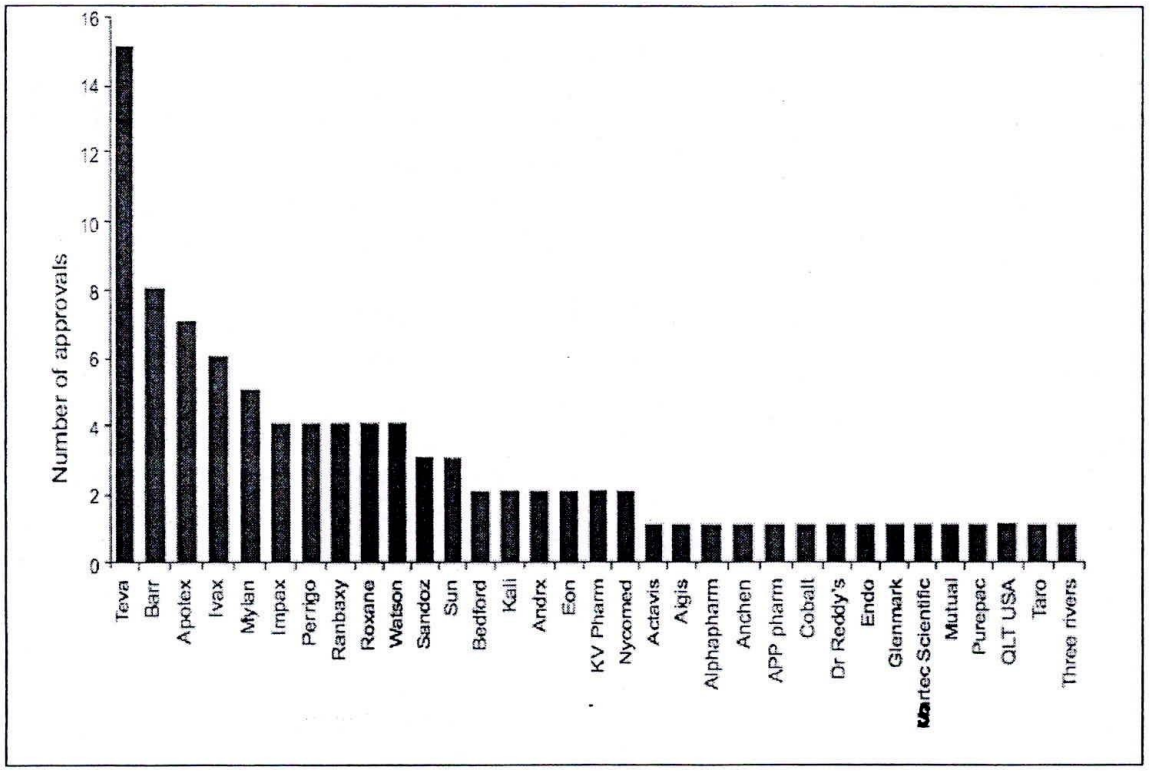


Table 6.4: DMFs, ANDAs and NDAs received by the top Fifteen Indian Companies

Company	*No. of DMFs**	*No. of ANDAs*	*No. of NDAs*	*Sales turnover as of 2008 in CMIE Prowess Data base (in Crores)*
Total (Top Fifteen Companies)	1242	1129	19	78963.13

Similarly the assessment of the DMFs filed for molecules from India and China also reveals that the Indian pharmaceutical industry is absent from several fermentation and biotech products. India has presence in small molecular chemistry, and is mostly absent in peptides, biopharmaceuticals and biotech products. According to IMS-Health the market for fermentation technology products and other biotech products is growing at double the rate of the pharmaceutical product. See Table 6.5 for the list of biotechnology drugs showing China's strength in molecules where India has no DMFs.

Table 6.5: List of biotechnology drugs showing China's strength in molecules where India had no DMFs (DMFs as on September 2008)

Sl. No.	*Molecule*	*Total no. of DMFs*	*DMFs by China*	*Method of production*
1	Acarbose	4	2	Fermentation
2	Bivaluridine	2	1	Fermentation
3	Bleomycine	4	2	Fermentation
4	Capreomycin	2	1	Fermentation
5	Clavulanic Acid	15	1	Fermentation
6	Cyclosporine	10	3	Fermentation
7	Dactinomycin	2	1	Fermentation
8	Desmopressine	8	1	Fermentation
9	Floxuridine	2	1	Fermentation
10	Flumethasone	4	1	Fermentation
11	Gentamicin	3	2	Fermentation
12	Heparin	17	8	Extraction from animal intestine
13	Hydrocortisone	19	5	Fermentation
14	Ivermectin	2	2	Fermentation
15	Monoclonal Antibody	27	0	Cell culture
16	Mupirocin	6	1	Fermentation
17	Prednisolone	29	4	Fermentation
18	Thiostrepton	1	1	Fermentation
19	Vancomycin	6	2	Fermentation
20	Various salt of Penicillin	20	4	Fermentation

Source: Research of data available at Drug@FDA (CDER US FDA) and as compiled and analyzed by D.K Jena, V. Mohan, P. V. Appaji, L.Srinivas & P Balaram in Journal of Generic Medicine, Vol 6, 333-344

Even from the above analysis of the ANDAs and DMFs of D.K. Jena and his colleagues it is also clear that while India accounts for one out of every four ANDA approvals in the years 2007 and 2008, ranks first in total Type II active DMFs with USFDA but the Indian firms could not enter into the areas involving cutting edge technologies in formulations and processes developed for the markets of Europe and the US. They could only internalize competencies needed for those market segments which are technologically less advanced. Innovative activities from India have been confined to a small number of highly competitive molecules. India is yet to move into the new orbit of working in complex chemistry, Biotech based medicines, and

advanced formulations. They point out that India has confined to limited number of molecules (156), whereas top generic companies like Teva, Sandoz and Watson have presence in 200 molecules each. Of course, with 1000 molecules still left out India has opportunity to expand in US market.

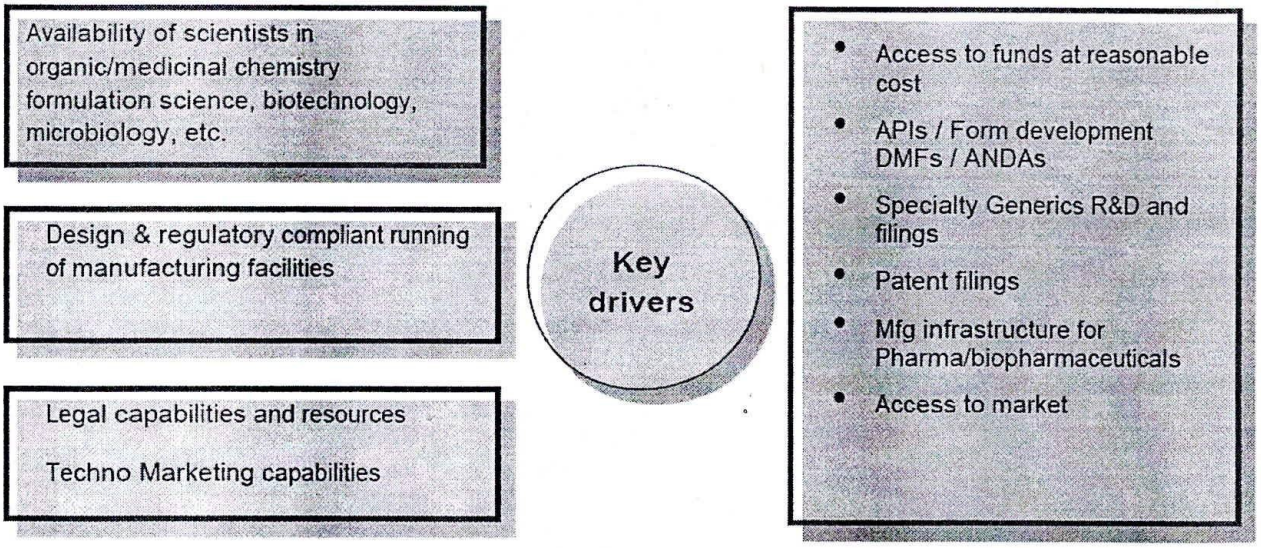
As per the Price water house Coopers report of 2010 for the Chinese pharmaceutical industry China surpassed India in the exports of bulk drug during the year 2007. China is a large scale producer of several bulk drug intermediates. China has the capability to offer at competitive prices patent protected molecules up to a pre-API stage (a strategy China uses to avoid patent violations) and exports them to other countries. China is also lead exporter of drugs and pharmaceuticals to India. It is becoming difficult for the Indian Bulk Drug producers to compete with China. India is more efficient in converting active pharmaceutical ingredients (APIs) in to finished products and is significantly ahead of China in formulation export. While it is true that China lags behind in formulation manufacturing expertise and

Governmental support and promotion of innovation and export

The Department of Pharmaceuticals, under the Ministry of Chemicals and Fertilisers, is already separately incentivising the firms by formulating policies and implementing programmes for achieving growth and development of the Indian Pharmaceutical Industry. The areas of responsibilities for the department include Pharmaceutical Research and Development (R&D), education, training and capacity building in pharmaceutical sector, related environment and hazard management, as well as promoting higher exports for greater share in the global market.

The Union government in the Eleventh 5-Year Plan focused on reviving Pharmaceutical PSUs for manufacturing critical bulk and formulation drugs, setting-up of more institutes like the National Institute of Pharmaceutical Education and Research, introducing interest subsidy scheme for Schedule "M" compliance etc. The Planning Commission approved a Budgetary Support of Rs 13,960 mn for various schemes of the pharmaceutical sector during the Eleventh plan period. In FY09, an expenditure of Rs 1,098.3 mn was incurred under various schemes of the Pharmaceutical sector.

Exhibit 2: Key Drivers for Promoting Indian Generic Pharmaceutical Industry



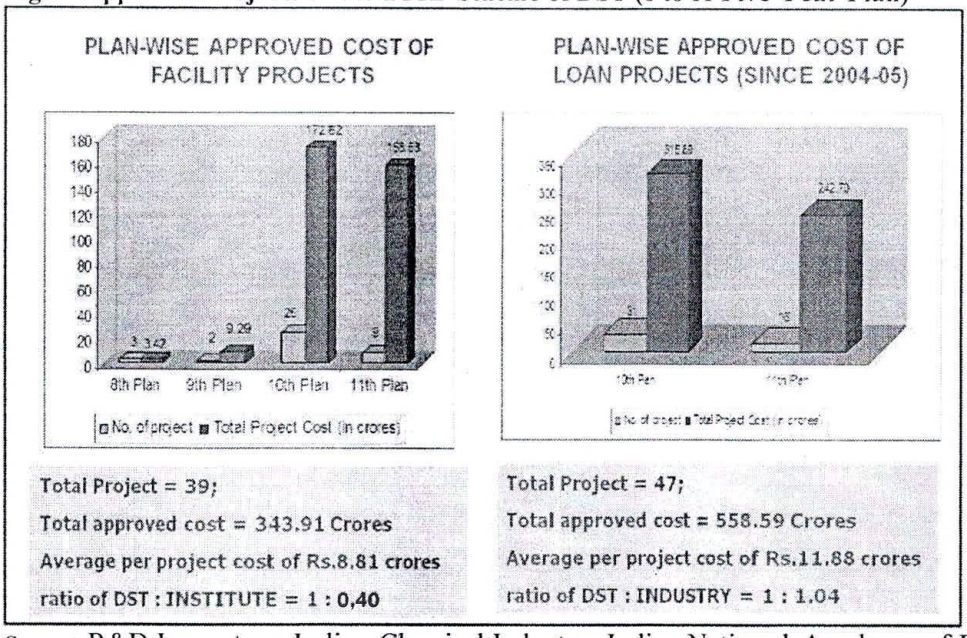
The government has taken various policy initiatives for the pharmaceutical sector: the government has offered tax-breaks to the pharmaceutical sector. Units are eligible for weighted tax deduction at 150% for the R&D expenditure incurred. Steps have been taken to streamline procedures covering development of new drug molecules, clinical research etc. Government has launched two new schemes—New Millennium Indian Technology Leadership Initiative and the Drugs and Pharmaceuticals Research Programme—especially targeted at drugs and pharmaceutical research. In a bid to promote new drug research in the country, the government is planning to create a special purpose vehicle (SPV) with insurance cover that will be used to fund new drug research. The Department of Pharmaceuticals is also planning to create drug research facilities and centres that can be used by private companies for such research work on a pay-and-use basis.

These schemes are operated by different ministries / departments of the government, financial Institutions and others. They are intended for all categories of units' viz., large, medium and small and even individuals in various subsectors. Considering the new challenges faced by the industry from time to time on account of liberalization and new obligations undertaken by India under the WTO, the Government of India took active interest in supporting the following initiatives for the Indian drugs / pharmaceutical industry:

- Modification of Drug Policy (1986) in 1994 to promote accelerated growth and to enhance the global competitiveness of the industry.
- Recognition of the industry as the most important knowledge based industry
- Abolition of industrial licensing except for bulk drugs produced by the recombinant DNA and related technologies
- 100% foreign investment through automatic route
- Extending the facility of 150% weighted deduction of R&D expenditure under section 35 (2AB) of Income Tax Act till 31 March 2012.
- Second Amendment to the Indian Patent act to allow product patenting in India from 1st January 2005
- Pharmaceutical policy 2002 (a) to improve incentives for R&D (b) further reduce the rigors of drug price control (c) strengthen the quality control system (d) provide incentive framework for attracting new investment into the pharma industry and new technologies and (e) reduce trade barriers for pharma exports.
- Setting up Pharmaceutical Research and Development Committee (PRDC) for
- Setting up Drug Development Promotion Foundation (DDPF) and Pharma Research and Development Fund
- Setting up a chain of National Institutes of Pharma Research and Education (NIPERs) to achieve excellence in Indian pharmaceutical sciences and technologies. A centre of excellence on bulk drugs will be established at Hyderabad by the NIPER in the near future.

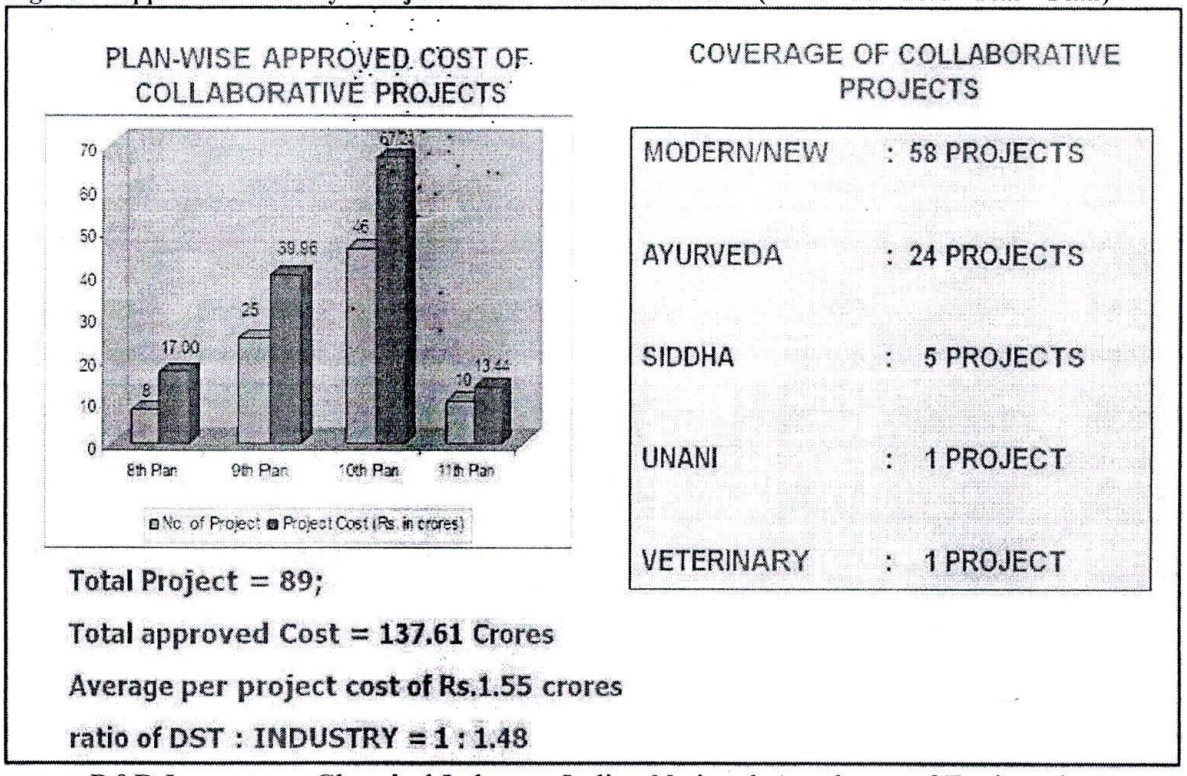
The DPRP programme initiated in 1994 specifically addresses the R&D needs for the growth of the Indian drugs/pharma industry. The specific objectives of the programme are: Synergizing the strengths of publicly funded R&D institutions and Indian pharmaceutical industry to generate the collaborative R&D projects; creating an enabling infrastructure, mechanisms and linkages to facilitate new drug development; Stimulating skill development of human resource engaged in R&D and Enhancing the nation's self-reliance in drugs and pharmaceuticals, especially in areas critical to national health requirements.

Fig. 1: Approved Projects under DPRP Scheme of DST (8 to 11 Five Year Plan)



Source: R&D Impact on Indian Chemical Industry, Indian National Academy of Engineering, May 2011

Fig. 2: Approved Facility Projects under DPRP Scheme (8 to 11 Five Year Plan)



Source: R&D Impact on Chemical Industry, Indian National Academy of Engineering, May 2011

Export promotion

Like many governments elsewhere, the Government of India also has been giving export incentives to Indian pharmaceutical exporters. Such schemes provide both

direct and indirect subsidies and included Cash compensatory support, Replenishment import license, Tax exemption of export income, subsidised export credit and export credit insurance, bonded warehouses, support for export marketing and so on. Export incentives are primarily given by the Ministry of Commerce through its Directorate General of Foreign Trade (DGFT), abd by the Ministry of Finance. Major incentives given by DGFT include Export Promotion Capital Goods (EPCG) Scheme and Duty Exemption/ Duty Remission Schemes. The Ministry of Finance tax exempts export profits i.e. profits from exports are exempted from income tax. Export incentives to the pharma sector are already being made separately available with a view to help improve the quality to make the Indian export sustainable in long run. Pharmaceutical firms do not need to be compensated doubly through the price control mechanism in any special way.

A new facility of input combination for pharma products manufactured through Non-Infringing process, allowing actual quantum of duty free inputs is also underway for manufacturing such export product. This will facilitate our pharma manufacturers to work towards getting a major share of exports of such products to potential regulated markets such as US or EU. The pharmaceutical products are being required to affix barcodes on their export products. The provision has been effective from 1st July 2011, as per GS 1 global standards, to facilitate tracing and tracking of their products. See Table 6.6 for the evolution of growth in exports of Indian pharmaceutical firms from the period of 1991-2011. Analysis shows that export incentives provided by the government have been working and the Indian companies do not need to be rewarded doubly.

Table 6.6: Exports by Indian Pharmaceuticals from 1991-2011

CMIE Rank	*Domestic companies*	*1991-93*	*1994-96*	*1997-99*	*2003-05*	*2006-08*	*2009-11*
		Export as a % of production	*Export as a % of production*	*Export as a % of production*	*Export as a % of production*	*Export as a % of production*	*Export as a % of production*
1	Cipla Ltd.	9.97	10.53	12.27	42.15	51.42	54.26
2	Dr. Reddy'S Laboratories Ltd.	16.71	29.57	27.25	56.61	66.92	66.04
3	Ranbaxy Laboratories Ltd.	27.73	43.05	35.88	67.32	73.93	69.59
4	Lupin Ltd.	0.00	0.00	2.84	45.23	52.74	56.76
5	AurobindoPharma Ltd.	7.81	33.93	33.14	47.97	58.41	67.00
6	Sun Pharmaceutical Inds. Ltd.		5.04	10.58	23.20	33.13	38.46
7	Piramal Healthcare	0.62	4.07	9.30	9.39	18.76	24.03

CMIE Rank	Domestic companies	1991-93	1994-96	1997-99	2003-05	2006-08	2009-11
		Export as a % of production	Export as a % of production	Export as a % of production	Export as a % of production	Export as a % of production	Export as a % of production
	Ltd.						
9	Cadila Healthcare Ltd.		12.05	11.04	12.82	20.85	50.28
10	Matrix Laboratories Ltd.		15.98	12.97	56.15	62.36	81.39
11	Wockhardt Ltd.	11.60	11.43	16.91	37.62	37.20	38.89
12	Ipca Laboratories Ltd.	26.52	34.39	35.94	52.21	46.92	49.70
13	Divi'S Laboratories Ltd.			29.12	83.32	90.72	90.11
14	Orchid Chemicals & Pharmaceuticals Ltd.		98.47	87.83	77.45	79.69	
15	Alembic Ltd.	10.95	14.45	13.84	19.87	23.83	32.05
17	Ankur Drugs &Pharma Ltd.			0.00	0.00	0.12	0.07
18	Biocon Ltd.				52.43	53.89	44.76
19	Glenmark Pharmaceuticals Ltd.		8.34	3.33	15.75	40.29	27.24
21	Nectar Lifesciences Ltd.			7.22	20.98	42.50	36.09
22	Panacea Biotec Ltd.		6.06	21.35	4.76	12.72	39.31
23	Surya Pharmaceutical Ltd.		3.94	18.63	42.92	21.01	27.58
25	J B Chemicals & Pharmaceuticals Ltd.	23.15	26.10	30.24	49.67	53.10	61.83
26	Unichem Laboratories Ltd.	12.47	5.58	2.85	12.41	20.50	19.59
27	Elder Pharmaceuticals Ltd.		11.46	11.61	4.78	3.01	2.50
29	Strides Arcolab Ltd.			12.11	91.98	87.09	86.23
30	F D C Ltd.	4.98	9.56	12.94	17.71	8.99	8.98
31	Ind-Swift Laboratories Ltd.			26.26	40.04	42.61	36.98
32	Ind-Swift Ltd.	0.00	0.00	6.05	0.29	1.67	6.57
33	Shasun Chemicals & Drugs Ltd.	29.43	38.49	30.37	67.16	63.04	63.49
34	Plethico Pharmaceuticals Ltd.			2.26	41.35	58.98	59.53
36	Dishman Pharmaceuticals & Chemicals Ltd.				77.21	68.37	
37	Sharon Bio-Medicine Ltd.				12.80	4.40	4.78
38	Aarti Drugs Ltd.	29.79	40.75	30.48	28.62	30.28	33.25
40	Twilight LitakaPharma Ltd.	1.98	3.57	2.03	5.91	7.32	9.05
41	Indoco Remedies Ltd.	0.00		1.51	8.49	18.91	28.24
42	Ajanta Pharma Ltd.			29.04	64.71	46.57	56.55
43	Neuland Laboratories Ltd.	42.01	39.51	40.96	61.40	60.79	74.55
44	NatcoPharma Ltd.		39.21	13.81	49.27	42.88	36.64
45	Fresenius Kabi Oncology Ltd.				40.72	56.93	78.78
46	S M S Pharmaceuticals Ltd.			45.99	34.70	24.72	39.29
47	Granules India Ltd.		87.43	51.92	60.36	68.51	76.51
48	Themis Medicare Ltd.	20.44	31.26	35.74	32.14	37.83	34.09
49	MarksansPharma Ltd.		0.00	21.18	17.21	18.90	36.55

CMIE Rank	Domestic companies	1991-93	1994-96	1997-99	2003-05	2006-08	2009-11
		Export as a % of production	Export as a % of production	Export as a % of production	Export as a % of production	Export as a % of production	Export as a % of production
50	Wanbury Ltd.	0.00	0.00	0.00	42.20	47.61	40.48
	Torrent Pharmaceuticals Ltd.	0.00	0.00	18.12	12.98	20.62	32.41
8	Glaxosmithkline Pharmaceuticals Ltd.	2.91	4.25	7.76	2.93	4.54	5.46
16	Aventis Pharma Ltd.	11.33	12.41	21.83	25.68	21.77	27.02
20	Pfizer Ltd.	1.92	1.75	6.42	3.91	3.10	3.11
24	Abbott India Ltd.	2.13	0.31	4.92	0.74	0.78	1.10
28	Novartis India Ltd.	5.12	9.29	14.06	1.69	1.32	1.16
35	Merck Ltd.	5.86	5.06	11.49	4.47	6.09	9.35
39	AstrazenecaPharma India Ltd.	2.72	9.18	5.14	1.46	3.93	7.23

CHAPTER 8
POLICYMAKING FOR PRICE CONTROL MECHANISM

The Indian policymakers are best placed among the low and middle income countries in respect of addressing the challenge of providing the population with safe, effective, good quality drugs at the least possible cost. India is in fortunate position on account of the better state of indigenous development of the domestic drugs and pharmaceutical industry. Affordability is a major pharmaceutical policy challenge in several countries. Involvement of the governments in pharmaceutical pricing is already under practice with the aim of achieving the public health objectives in some of the countries of developed world. Among the policy measures for keeping the prices low and making the drugs available and affordable to the people the main ones that can be tried count in India are the 'national list of essential drugs', 'price control', 'public procurement', 'production control' and the 'regulation of practices of promotion and prescription of medicines'.

Policymaking for the design of price control mechanism shall begin with the following understanding that competition in the Indian pharmaceutical markets has been most effective in the recent times only when price conscious, publicly funded state procurement agencies and institutional purchasers were the purchasers rather than individual consumers. Publicly funded state procurement agencies and institutional purchasers of essential medicines have achieved better results in respect of inducing competition. They have been able to speed up generic entry on the basis of the products being manufactured by both small and large companies. They have been able to bring down the prices. Today the practice of public procurement is under perusal in only five states out of twenty nine states in a systematic manner.

There is also evidence from the recent experience of Tamil Nadu and Rajasthan that when the state governments adopt the policy of strengthening of the practice of public procurement of medicines in the states with the help of the central government they are also able to lower the costs of financing of universal access to essential medicines for the state exchequer. Public procurement has worked well to achieve lower prices for off-patent, multi-source essential medicines successfully in the case of the Central

Government Health Service (CGHS). In the states like Tamil Nadu, Rajasthan, Delhi, and Kerala in India by using public procurement they have been successful in ensuring the supply of essential medicines to a larger population. Similarly there is also evidence available that the Central Government has been able to utilise the mechanism of bulk procurement in the case of patented drugs in the Central Government Health Service (CGHS) / Railways / Armed Forces for the supply of cancer drugs.

Domination of the market forces can play havoc with the prices of medicines when the third party payment systems are missing. In a society where the mechanisms of public financing and social insurance are weak and the consumers in retail market are known to pay heavily out of pocket for medicines. In India, there exists neither social insurance nor public delivery systems. The imperfections of pharmaceutical markets are known to be devastating for the consumers who are uninsured and do not have the benefit of medicine supply from public health facilities at lower cost.

Much has been written by the leaders of Federation of Medical Representatives Associations of India (FMRAI) and Jan Swasthya Abhiyan (JSA) about the irrational practices of promotion used by the industry for the sale of medicines in India. Heavily branded generics are often sold at a high multiple of the price of low priced generics, with many people paying more than they need to. The pharmaceutical markets are known to function quite imperfectly. Market does not treat branded medicines and generics as perfect substitutes. When individual consumers purchase medicines out-of-pocket, pervasive asymmetry of information limits the potential for effective medicine price competition.

Policy formulation for the development of an effective price control mechanism remains a formidable challenge for the Government of India. If the Indian State is serious about the implementation of the policy of universal access to essential medicines then the central government should enable the state governments to allocate adequate sums in their own budgets for the purpose of strengthening of their mechanism of public procurement along with the mechanism of price control designed to promote universal access to essential medicines and indigenous industrial development. The Central Government should enable the State governments to foster collectively in their regions a network of medium and small scale pharmaceutical

firms in their own regions. The Government of India as well the Indian Supreme Court should look into the issue of how to get the NPPA to undertake the design of price control to simultaneously take care of the twin challenges of affordable access to essential medicines and indigenous industrial development.

Price control mechanism needs the presence of competition from the domestic firms. In Chapters 4 and 5 we have shown that though the impact of the entry of Indian firms in the Indian pharmaceutical market on the behavior of producers (with respect to price and quantity of production decisions) was initially positive but over the period the positive influence has been on wane due to the increase in share of foreign firms in the industry after the implementation of TRIPS. There is also the problem of growing domination of the large Indian domestic firms on the market. See Table 8.1, 8.2 and 8.3 which indicate that the presence of foreign firms is growing. Further the presence of large firms, both domestic and foreign firms is already a distinguishing feature of the Indian pharmaceutical markets.

Table 8.1: Company wise Sales and Market Shares of the Top 10 Indian Companies and Top 10 MNCs in the Indian Pharmaceutical Markets

Rank	*Top 10 Indian Companies*	*2012 Sales value (Rs. in crores)*	*Top 10 MNCs*	*2012 Sales value (Rs. in crores)*
1	Cipla	3542.67	Abbott	5068.25
2	Sun	3067.83	Ranbaxy	3008.69
3	Zydus Cadila	2841.89	Glaxosmithkline	3004.72
4	Mankind	2437.12	Pfizer	2287.03
5	Alkem	2365.46	Sanofi	2034.87
6	Lupin Limited	2003.58	Novartis Intl.	1172.47
7	Macleods Pharma	1970.64	Msd Pharmaceutical	763.64
8	Intas Pharma	1765.34	Merck Limited	586.34
9	Emcure	1571.74	Astrazeneca	361.15
10	Aristo Pharma	1554.71	Janssen	311.03
Total		23120.97		18598.18
Market share (%)		32		26

Source: IMS Health

Table 8.2: Market Shares of the Indian Companies and MNCs in the Indian Pharmaceutical Markets in 2012

	2012 Sales	*Market share (%)*
	Rs. Crore	
Indian	50706.21	71%
MNC	20539.80	29%
Total market	71246.01	100%

Source: IMS Health

Table 8.3: Changes in the Patterns of Decline in the Market Shares of the Indian Companies from 2005 onwards and the Extent of Growth in the Share of MNCs in the Indian Pharmaceutical Markets in 2012

Company rank	*2005**				*2012**			
	Company name	*Sales (Rs. in crores)*	*Market share (%)*	*Domestic /MNC*	*Company name*	*Sales (Rs. in crores)*	*Market share (%)*	*Domestic/MNC*
1	Glaxosmithkline	1339.68	5.8	MNC	Abbott	5068.25	7.1	MNC
2	Cipla	1185.27	5.1	Indian	Cipla	3542.67	5.0	Indian
3	Ranbaxy	1158.38	5.0	Indian	Sun	3067.83	4.3	Indian
4	Piramal Healthcare	1062.11	4.6	Indian	Ranbaxy	3008.69	4.2	MNC
5	Zydus Cadila	864.34	3.7	Indian	Glaxosmithkline	3004.72	4.2	MNC
6	Sun Pharma	754.81	3.2	Indian	Zydus Cadila	2841.89	4.0	Indian
7	Alkem	686.37	3.0	Indian	Mankind	2437.12	3.4	Indian
8	Pfizer	563.27	2.4	MNC	Alkem	2365.46	3.3	Indian
9	Sanofi Aventis	560.99	2.4	MNC	Pfizer	2287.03	3.2	MNC
10	Aristo Pharma	543.11	2.3	Indian	Sanofi	2034.87	2.9	MNC
11	Dr Reddys Labs	541.68	2.3	Indian	Lupin Limited	2003.58	2.8	Indian
12	Alembic	521.25	2.2	Indian	Macleods Pharma	1970.64	2.8	Indian
13	Lupin Labs	513.81	2.2	Indian	Intas Pharma	1765.34	2.5	Indian
14	Abbott	480.88	2.1	MNC	Emcure	1571.74	2.2	Indian
15	Torrent Pharma	444.19	1.9	Indian	Aristo Pharma	1554.71	2.2	Indian
16	Wockhardt	434.75	1.9	Indian	Dr Reddys Labs	1436.66	2.0	Indian
17	Micro Labs	431.67	1.9	Indian	Torrent Pharma	1414.00	2.0	Indian
18	Novartis	412.07	1.8	MNC	Micro Labs	1307.96	1.8	Indian
19	Intas	382.41	1.6	Indian	U S V	1306.67	1.8	Indian
20	Unichem	378.91	1.6	Indian	Glenmark Pharma	1253.97	1.8	Indian
MNC share in top 10 companies (%)			**14.4**				**21.6**	

* Sales value reflects changes in IMS sampling methodology

Source: IMS Health

Cost plus formula of price fixation needed

Prices and availability of drugs are determined by market structure, the perceptions of entry barriers and measures of market concentration, producers' conduct (such as collusive behaviours) and consumers conduct (such as search behaviours). Barriers to entry and concentration of supply against the small and medium scale domestic firms can induce prices higher than normal. Large scale firms as suppliers can also gain market power and charge higher prices through collusion, market segmentation and price discrimination. The customer in pharmaceutical market is a combination of the physician, the payer / the insurer and the final patient. Product differentiation and market power are closely correlated in the case of pharmaceutical industry.

Elements defined as the extent to which the physicians, payers and final patients are able to distinguish and have preference between competing products also indicate that the Indian pharmaceutical market is an imperfect market. Elements of product differentiation are observable in the case of large firms. Market power of large pharmaceutical firms can be controlled if the price control mechanism is appropriately designed. We have seen that at the level of whom among the producers the DPCO rewards to what extent and who all are outside the scope of mechanism of price control is not at all well regulated through the selected market based price control mechanism. Cost plus formula for price control would do a better job, allow the consumers to gain more, encourage the small and medium scale companies to provide more competition and incentivise better large firms to achieve higher productivity and become more cost **effective.**

In Chapter 4 and Chapter 5 we have also shown that if the price ceilings of Drug Price Control Order (DPCO) 2013 had been framed by NPPA in terms of lowest price to retail (PTR) rather than average price to retail (PTR) in India the consumers would have gained to the extent of 20% or more in terms of price terms in the case of another 174 more products in addition. We can expect substantial price rise for the regulation of prices of the formulations in the case of 74 essential drugs on account of the shift away from the cost plus price control formula to market based price control formula. Similarly we can expect major gains to accrue to the producers of all those brands that were allowed to be sold beyond the ceiling price fixed by the government of India under the earlier price control mechanism.

Analysis points out to the lapses and of adverse consequences likely to arise in the future on account of the shift away from the cost plus formula of previous DPCO to the market based price fixation mechanism of DPCO 2013. In the previous DPCO cost plus based price control mechanism reduced the prices of controlled medicines far more effectively. It checked sharp rise of prices due to the adoption of price control right from the stage of bulk drugs. Availability of essential medicines would also be better ensured through the adoption of a cost-plus price control mechanism. The DPCO 2013 would encourage in the market the proliferation of irrational combination medicines. Cost plus price fixation mechanism would be keeping all fixed dose combinations under price control. The DPCO 2013 applies price control to a limited set of specific dosage forms. We expect a lesser production of all those dosages whose prices are controlled by the DPCO 2013. It is not desirable to confine the price control to certain specific dosage forms. Price control mechanism should cover all forms of drugs irrespective of their delivery system. Availability of essential medicines would also suffer because the DPCO 2013 is ultimately going to encourage the Indian pharmaceutical industry to distort the pattern of domestic production and sales of pharmaceuticals. Production of irrational combinations whose market needs to be consciously eliminated would not be built-into the market based price control mechanism.

It is also not to be forgotten that the use of cost-plus pricing formula also eased the entry of domestic companies in the past when the western multinationals were in total control of the pharmaceutical industry. Although this aspect is completely ignored by the industry leaders because their profitability would be affected to some extent, but also it should be clear to the policymakers that the business model of the big western pharmaceutical markets is rapidly undergoing change. This role of the cost-based price control is once again relevant. Price controls facilitated the emergence of large domestic pharmaceutical firms[1]. As new incumbents they got the chance to build their market power in the domestic pharmaceutical markets. These firms were able to establish for several important drugs their own brands which are today accepted in the

[1] Prices of drugs once considered to be among the highest in the world. The Drug Price Control Order of 1970 brought all drug formulations in two categories: essential and non-essential. Essential formulations were allowed a mark up of only 75% and the 'non-essential' category formulations were allowed 150%. Because at the point of time when the domestic companies were young and enter into the industry incumbents had less problem compared to multinationals with the lower mark up allowed in the case of drugs identified as essential formulations.

regulated markets of US and EU. But using the price control mechanism they are today interested to nip the competition from small and medium scale companies in the bud.

In India the challenge of introduction of effective, country-specific and suitable form of internal price control for the regulation of pharmaceutical markets comes also from the fact that the government is now thinking of implementing the benefit of universal health coverage. In the near future the state governments will be under pressure to finance the expenditure on drugs from the state finances. The state governments would be compelled to keep the health budgets in check. There must be enabling supply side policies and complementary demand side practices of generic prescribing, generic dispensing and generic awareness. In order to ensure a reliable system of supply and continuous availability of medicines the nature of optimal mix of the supply side policies and the demand side practices must be anticipated appropriately. Ensuring policy and regulations coherence is of importance.

Evidence exists that while the public / private pharmaceutical payer / purchaser market based perspective on price helps the policymakers to establish the upper limit on a sustainable (viable) price range, the return on investment consideration of pharmaceutical companies can help them to fix the lower limit on sustainable (viable) prices. Therefore, the scheme for viable pricing will have to be determined appropriately using the information available on how the state of efficiency, innovation and affordable access is and would be affected by the price regulation and associated policy measures.

CHAPTER 9
CONCLUSIONS AND RECOMMENDATIONS

We have made several observations about the implication of price control under the Pharmaceutical Pricing Policy (NPPA), 2012 and the Drug Prices Control Order (DPCO), 2013.

Firstly, one can expect the outcomes of prices of medicines in the price control basket to remain market led since the Drug Price Control Order (DPCO) of 2013 utilizes the formula of market determined pricing to undertake price regulation, i.e., prices of product leaders of medicines under DPCO 2013 will continue to have no relation to the cost of production. Rather than price competition, brand based competition will prevail. Market will continue to be led by large firms and small and medium scale firms will continue to be at disadvantage.

Further, the practice of market based price control mechanism has been combined with the use of National List of Essential Medicines (NLEM) 2011, which requires substantial revision. Restricting price control only to medicines mentioned in the NLEM is also flawed as many chemical/therapeutic equivalents of a medicine as well as its combinations are out of the price control net. Also out are a number of useful drugs, including those being used in national treatment programmes, that are not in the NLEM 2011. As a result price control under the DPCO 2013 is limited to only about 17% of the drugs being prescribed and promoted at present in the country. Analysis of the impact of the DPCO 2013 on the prices of market sales leaders and those who have a share of 1% in the market indicates that the price impact outcome of the implementation of DPCO 2013 is marginal for the consumers buying drugs from the retail market. The absolute decrease in sales because of price control is estimated as less than 2% (~Rs. 1300 crore) of the value of medicines sold in the country. Therefore, not much relief can be expected to flow to the consumers. The DPCO 2013, through its shortcomings, also provides pharmaceutical companies several escape routes from price control. It not only permits the presence of a substantial inessential/irrational/unsafe medicines market, but also encourages its growth by allowing a 10% increase in prices each year.

By not being logically related to the cost of production, the DPCO 2013 obfuscates real costs and by default legitimizes higher prices. Paradoxically it also punishes manufacturers who had priced their products lower than the ceiling price by freezing it at the same levels. Many of them will be rendered unviable as raw material prices increase, for instance with the falling rupee. The current mechanism of applying for revision of ceiling prices is tortured and in the absence of an automatic revision formula or an immediate response mechanism from the NPPA, genuine manufacturers with reasonable pricing policies will be put to hardship.

Lastly, DPCO 2013 does not address the challenge of cost-competitiveness and the challenge of the indigenous development of the bulk drug industry. Therefore, the choice of the drug price control mechanism must be made keeping in view the prevailing market situation and the need to safeguard regional industry networks and scope for the development of competitive public procurement by states.

Based on these observations, our recommendations follow.

Reverting to a cost-plus price control mechanism is critical. DPCO 2013 has been brought in defiance of the Supreme Court order of October 2012 that asked the Government not to change the cost-based mechanism for fixing prices. Evidence clearly indicates that market-based pricing will be unsuccessful at providing adequate relief to patients. Keeping in mind that the share of patented drugs is growing in the Indian market, the solution lies in the adoption of a mechanism of price control by which policymakers can effectively address the challenges of essentiality, rationality, affordability and availability. A suitably designed cost plus formula for price control would allow the consumers to gain more, encourage the small and medium scale companies to provide more competition and better incentivise large firms to achieve higher productivity and become more cost effective.

An urgent revision of the National List of Essential Medicines is needed. Indeed the list needs to be revised once in 2 years if not annually by a regular ongoing committee. Members of such a committee must be clearly told that the NLEM is to be used inter alia as the basis for price regulation. The revision should rectify prominent omissions and misalignment with current standards of providing treatment. The revision should also take into consideration the state lists, and be expanded to include

medicines for diseases endemic to regions or relevant for particular minorities, so as to be truly relevant for all segments of the national population. A list of life saving medicines should be identified in conjunction with the review of the NLEM and should be brought under price control.

The implementation of the price control mechanism should not be narrowed to a literal reading of the NLEM. The scope of coverage should be expanded to include all additional dosages, strengths, delivery mechanisms and combinations of medicines under the NLEM. Acknowledging that the NLEM is only a representative list of medicines that are recommended for various therapeutic areas, the mechanism should also include therapeutic equivalents and close substitutes of medicines in the NLEM.

The use on privately owned market data is against the principles of transparency and evidence-based public policy making, and has led to anomalies in the implementation of DPCO 2013 that cannot be overlooked. It is imperative that the Government develops institutional machinery for independent collection of data on the pharmaceutical market.

In order to implement the cost-plus formula, the NPPA would need to be considerably strengthened. Development of a systematic mechanism for the continuous monitoring of production levels, costs of raw materials and manufacturing and market prices is necessary. An effective system for timely monitoring and enforcement of prices for both scheduled and non-scheduled medicines must be put in place.

Finally, if the Indian State is serious about the implementation of the policy of universal access to essential medicines then the central government should support the state governments in replicating a 'centraised procurement and decentralized distribution of medicines' mechanism. Tamil Nadu and Rajasthan have been recognized for their success in providing free access to generic medicines and serve as powerful models for other states.

Appendix 1.
National List of Essential Medicines (NLEM) 2011 - all unique strengths and dosages identified by the authors

S.No.	*Molecular Description*	*Strength*	*Description*
Section 1. ANAESTHETICS			
1	diazepam	2mg	Tablet
2	diazepam	5mg	Tablet
3	morphine sulphate	10mg	Tablet
4	atropine sulphate	0.6mg/ml	Injection
5	atropine sulphate	1mg/ml	Injection
6	bupivacaine hydrochloride	0.0025	Injection
7	bupivacaine hydrochloride	0.005	Injection
8	diazepam	5mg/ml	Injection
9	ketamine hydrochloride	10mg/ml	Injection
10	ketamine hydrochloride	50mg/ml	Injection
11	lignocaine hydrochloride	5% + 7.5% glucose (spinal)	Injection
12	lignocaine hydrochloride + adrenaline	0.01	Injection
13	lignocaine hydrochloride + adrenaline	2% + adrenaline 1:200,000	Injection
14	midazolam	1mg/ml	Injection
15	midazolam	5mg/ml	Injection
16	morphine sulphate	10mg/ml	Injection
17	propofol	1% oil suspension	Injection
18	thiopental sodium	0.5g	Injection
19	thiopental sodium	1g powder	Injection
20	ether		Inhalation
21	halothane with vaporizer		Inhalation
22	isoflurane		Inhalation
23	nitrous oxide		Inhalation
24	oxygen		Inhalation
25	sevoflurane		Inhalation
26	atropine sulphate	0.01	Drops - opthamological
27	atropine sulphate	0.01	Ointment - opthamological
28	EMLA cream		Cream
29	lignocaine hydrochloride	2-5%	Gel or Jelly
30	lignocaine hydrochloride	2-5%	Ointment
31	lignocaine hydrochloride	2-5%	Solution
32	diazepam	2mg/5ml	Syrup
33	promethazine	5mg/5ml	Elixir or Syrup
34	diazepam	5mg	Suppository
Section 2. ANALGESICS, ANTIPYRETICS, etc.			
35	acetylsalicylic acid	75mg	Tablet
36	allopurinol	100mg	Tablet
37	azathioprine	50mg	Tablet
38	colchicin	0.5mg	Tablet
39	diclofenac	50mg	Tablet
40	hydroxychloroquine phosphate	200mg	Tablet
41	ibuprofen	200mg	Tablet
42	ibuprofen	400mg	Tablet
43	leflunomide	10mg	Tablet
44	leflunomide	20mg	Tablet
45	methotrexate	2.5mg	Tablet

S.No.	Molecular Description	Strength	Description
46	methotrexate	5mg	Tablet
47	methotrexate	7.5mg	Tablet
48	methotrexate	10mg	Tablet
49	paracetamol	500mg	Tablet
50	tramadol	100mg	Capsule
51	tramadol	50mg	Capsule
52	diclofenac	25mg/ml	Injection
53	fentanyl	50ug/ml 2ml ampoule	Injection
54	paracetamol	150mg/ml	Injection
55	tramadol	50mg/ml	Injection
56	ibuprofen	100mg/5ml	Syrup
57	paracetamol	125mg/5ml	Syrup
58	paracetamol	80mg	Suppository
59	paracetamol	170mg	Suppository
Section 3. ANTIALLERGICS AND MEDICINES USED IN ANAPHYLAXIS			
60	acetylsalicylic acid	100mg	Tablet
61	cetrizine	10mg	Tablet
62	chlorpheniramine maleate	4mg	Tablet
63	dexamethasone	0.5mg	Tablet
64	prednisolone	10mg	Tablet
65	promethazine	10mg	Tablet
66	promethazine	25mg	Tablet
67	adrenaline bitartrate	1mg/ml	Injection
68	dexamethasone	4mg/ml	Injection
69	hydrocortisone sodium succinate	100mg/ml	Injection
70	pheniramine maleate	22.75mg/ml	Injection
71	prednisolone	25mg (as sodium phosphate or succinate)	Injection
72	cetrizine	5mg/ml	Syrup
73	dexchlorpheniramine maleate	0.5mg/5ml	Syrup
Section 4. ANTIDOTES AND OTHER SUBSTANCES USED IN POISONINGS			
74	penicillamine	250mg	Tablet
75	penicillamine	250mg	Capsule
76	calcium gluconate	100mg/ml	Injection
77	calcium gluconate	100mg/ml in 10ml ampoule	Injection
78	desferrioxamine mesylate	500mg	Injection
79	dimercaprol	50mg/ml (in oil)	Injection
80	flumazenil	0.1mg/ml	Injection
81	methylthioninium chloride (methylene blue)	10mg/ml	Injection
82	N-acetylcystiene	200mg/ml (5ml)	Injection
83	naloxone	0.4mg/ml	Injection
84	pralidoxime chloride(2-PAM)	25mg/ml	Injection
85	sodium nitrite	30mg/ml	Injection
86	sodium thiosulphate	250mg/ml	Injection
Section 5. ANTICONVULSANTS/ANTIEPILEPTICS			
87	carbamazepine	100mg	Tablet
88	carbamazepine	200mg	Tablet
89	phenobarbitone	30mg	Tablet
90	phenobarbitone	60mg	Tablet
91	phenytoin sodium	50mg	Tablet
92	phenytoin sodium	50mg	Capsule

S.No.	Molecular Description	Strength	Description
93	phenytoin sodium	100mg	Tablet
94	phenytoin sodium	100mg	Capsule
95	lorazepam	2mg/ml	Injection
96	magnesium sulphate	500mg/ml	Injection
97	phenobarbitone	200mg/ml	Injection
98	phenytoin sodium	50mg/ml	Injection
99	sodium valproate	100mg/ml	Injection
100	carbamazepine	100mg/5ml	Syrup
101	phenobarbitone	20mg/5ml	Syrup
102	phenytoin sodium	25mg/ml	Syrup
103	sodium valproate	200mg/5ml	Syrup
Section 6. ANTI-INFECTIVE MEDICINES			
104	acyclovir	200mg	Tablet
105	acyclovir	400mg	Tablet
106	albendazole	400mg	Tablet
107	amoxicillin	250mg	Capsule
108	amoxicillin	500mg	Capsule
109	amoxicillin+clavulinic acid	625mg	Tablet
110	ampicillin	250mg	Capsule
111	ampicillin	500mg	Capsule
112	artesunate (to be used only in combination with sulfadoxine + pyrimethamine)	50mg	Tablet
113	azithromycin	100mg	Tablet
114	azithromycin	250mg	Tablet
115	azithromycin	500mg	Tablet
116	cefixime	100mg	Tablet
117	cefixime	200mg	Tablet
118	cephalexin	250mg	Capsule
119	cephalexin	500mg	Capsule
120	chloroquine phosphate	150mg base	Tablet
121	ciprofloxacin hydrochloride	250mg	Tablet
122	ciprofloxacin hydrochloride	500mg	Tablet
123	clindamycin	150mg	Tablet
124	clindamycin	300mg	Tablet
125	clofazimine	50mg	Capsule
126	clofazimine	100mg	Capsule
127	cloxacillin	250mg	Capsule
128	cloxacillin	500mg	Capsule
129	co-trimoxazole (sulfamethoxazole + trimethoprim)	80+400mg	Tablet
130	co-trimoxazole (sulfamethoxazole + trimethoprim)	160+800mg	Tablet
131	dapsone	50mg	Tablet
132	dapsone	100mg	Tablet
133	didanosine (ddI)	250mg	Tablet
134	didanosine (ddI)	400mg	Tablet
135	diethylcarbamazine citrate	50mg	Tablet
136	diloxanide furoate	500mg	Tablet
137	doxycycline	100mg	Tablet
138	efavirenz (EFV or EFZ)	200mg	Capsule
139	efavirenz (EFV or EFZ)	600mg	Capsule
140	erythromycin estolate	250mg	Tablet
141	erythromycin estolate	500mg	Tablet
142	ethambutol	200mg	Tablet
143	ethambutol	400mg	Tablet
144	ethambutol	600mg	Tablet
145	ethambutol	800mg	Tablet
146	fluconazole	50mg	Tablet
147	fluconazole	50mg	Capsule

S.No.	Molecular Description	Strength	Description
148	fluconazole	100mg	Tablet
149	fluconazole	100mg	Capsule
150	fluconazole	150mg	Tablet
151	fluconazole	150mg	Capsule
152	fluconazole	200mg	Tablet
153	fluconazole	200mg	Capsule
154	griseofulvin	125mg	Tablet
155	griseofulvin	125mg	Capsule
156	griseofulvin	250mg	Tablet
157	griseofulvin	250mg	Capsule
158	indinavir (IDV)	200mg	Tablet
159	indinavir (IDV)	400mg	Tablet
160	isoniazid	50mg	Tablet
161	isoniazid	100mg	Tablet
162	isoniazid	300mg	Tablet
163	lamivudine (3TC)	150mg	Tablet
164	lamivudine + nevirapine + zidovudine	300mg+150mg+200mg	Tablet
165	lamivudine + nevirapine + stavudine	150mg+200mg+30mg	Tablet
166	lamivudine + stavudine	30mg+150mg	Tablet
167	lamivudine + zidovudine	150mg+300mg	Tablet
168	mefloquine	250mg base	Tablet
169	metronidazole	200mg	Tablet
170	metronidazole	400mg	Tablet
171	nelfinavir	250mg	Tablet
172	nevirapine (NVP)	200mg	Capsule
173	nitrofurantoin	100mg	Tablet
174	nystatin	500,000 IU	Tablet (vaginal)
175	ofloxacin	100mg	Tablet
176	ofloxacin	200mg	Tablet
177	piperazine	4.5gm	Tablet
178	praziquantel	600mg	Tablet
179	primaquine	2.5mg	Tablet
180	primaquine	7.5mg	Tablet
181	pyrazinamide	500mg	Tablet
182	pyrazinamide	750mg	Tablet
183	pyrazinamide	1000mg	Tablet
184	pyrazinamide	1500mg	Tablet
185	pyrimethamine	25mg	Tablet
186	quinine sulphate	300mg	Tablet
187	rifampicin	50mg	Tablet
188	rifampicin	50mg	Capsule
189	rifampicin	150mg	Tablet
190	rifampicin	150mg	Capsule
191	rifampicin	300mg	Tablet
192	rifampicin	300mg	Capsule
193	rifampicin	450mg	Tablet
194	rifampicin	450mg	Capsule
195	ritonavir	100mg	Capsule
196	saquinavir (SQV)	200mg	Capsule
197	stavudine (d4T)	15mg	Capsule
198	stavudine (d4T)	30mg	Capsule
199	stavudine (d4T)	40mg	Capsule
200	sulfadoxine + pyrimethamine	500mg+25mg	Tablet
201	sulphadiazine	500mg	Tablet

S.No.	Molecular Description	Strength	Description
202	zidovudine (ZDV or AZT)	100mg	Tablet
203	zidovudine (ZDV or AZT)	300mg	Tablet
204	acyclovir	250mg	Injection
205	acyclovir	500mg	Injection
206	amikacin	250mg/2ml	Injection
207	amoxicillin+clavulinic acid	1.2gm	Injection
208	amoxicillin+clavulinic acid	600mg	Injection
209	amphotericin B	50mg	Injection
210	ampicillin	500mg	Injection
211	azithromycin	500mg	Injection
212	benzathine benzylpenicillin	6 lacs	Injection
213	benzathine benzylpenicillin	12 lacs units	Injection
214	cefotaxime	125mg	Injection
215	cefotaxime	250mg	Injection
216	cefotaxime	500mg	Injection
217	ceftazidime	250 mg	Injection
218	ceftazidime	1 g	Injection
219	ceftriaxone	250 mg	Injection
220	ceftriaxone	1 g	Injection
221	chloroquine phosphate	40mg/ml	Injection
222	ciprofloxacin hydrochloride	200mg/100ml	Injection
223	cloxacillin	250mg	Injection
224	gentamicin	10mg/ml	Injection
225	gentamicin	40mg/ml	Injection
226	metronidazole	500mg/100ml	Injection
227	pentamidine isothionate	200mg	Injection
228	quinine sulphate	300mg/ml	Injection
229	sodium stibogluconate	100mg/ml	Injection
230	streptomycin sulphate	0.75g	Injection
231	streptomycin sulphate	1g	Injection
232	vancomycin hydrochloride	1g	Injection
233	vancomycin hydrochloride	500mg	Injection
234	clotrimazole	0.02	Gel
235	cloxacillin	125mg/5ml	Liquid
236	amoxicillin	125mg/5ml	Powder for suspension
237	amoxicillin+clavulinic acid	228.5mg/5ml	powder for suspension
238	ampicillin	125mg/5ml	Powder for suspension
239	piperazine	750mg/5ml	Solution
240	acyclovir	400mg/5ml	Suspension
241	albendazole	200mg/5ml	Suspension
242	azithromycin	100mg/5ml	Suspension
243	co-trimoxazole (sulfamethoxazole + trimethoprim)	40+200mg/5 ml	Suspension
244	nevirapine (NVP)	50mg/5ml	Suspension
245	cephalexin	125mg/5ml	Syrup
246	chloroquine phosphate	50mg/5ml	Syrup
247	erythromycin estolate	125mg/5ml	Syrup
248	isoniazid	100mg/5ml	Syrup
249	metronidazole	100mg/5ml	Syrup
250	ofloxacin	50mg/5ml	Syrup
251	rifampicin	100mg/5ml	Syrup
252	ritonavir	400mg/5ml	Syrup
253	clotrimazole	100mg	Pessaries
254	clotrimazole	200mg	Pessaries

S.No.	Molecular Description	Strength	Description
255	nystatin	100,000 IU	Pessaries
Section 7. ANTIMIGRAINE MEDICINES			
256	acetylsalicylic acid	300mg	Tablet
257	acetylsalicylic acid	325mg	Tablet
258	acetylsalicylic acid	350mg, 350 soluble/dispersible	Tablet
259	dihydroergotamine	1mg	Tablet
260	propranolol hydrochloride	10mg	Tablet
261	propranolol hydrochloride	40mg	Tablet
Section 8. ANTINEOPLASTIC, IMMUNOSUPPRESSIVES, MEDICINES FOR PALLIATIVE CARE			
262	busulphan	2mg	Tablet
263	chlorambucil	2mg	Tablet
264	ciclosporine	10mg	Capsule
265	ciclosporine	25mg	Capsule
266	ciclosporine	50mg	Capsule
267	ciclosporine	100mg	Capsule
268	cyclophosphamide	50mg	Tablet
269	cyclophosphamide	200mg	Tablet
270	danazol	50mg	Capsule
271	danazol	100mg	Capsule
272	etoposide	100mg	Capsule
273	flutamide	250mg	Tablet
274	imatinib	100mg	Tablet
275	imatinib	400mg	Tablet
276	melphalan	2mg	Tablet
277	melphalan	5mg	Tablet
278	mercaptopurine	50mg	Tablet
279	ondansetron	4mg	Tablet
280	ondansetron	8mg	Tablet
281	prednisolone	5mg	Tablet
282	prednisolone	20mg	Tablet
283	procarbazine	50mg	Capsule
284	raloxifene	60mg	Tablet
285	tamoxifen	10mg	Tablet
286	tamoxifen	20mg	Tablet
287	5-fluorouracil	250mg/5ml	Injection
288	actinomycin D	0.5mg	Injection
289	alpha interferon	3 million IU	Injection
290	bleomycin	15mg	Injection
291	carboplatin	150mg	Injection
292	carboplatin	450mg vial	Injection
293	ciclosporine	100mg/ml (concentrate for injection)	Injection
294	cisplatin	10mg/vial	Injection
295	cisplatin	50mg/vial	Injection
296	cyclophosphamide	500mg	Injection
297	cytosine arabinoside	100mg/vial	Injection
298	cytosine arabinoside	500mg/vial	Injection
299	cytosine arabinoside	1000mg/vial	Injection
300	dacarbazine	500mg	Injection
301	daunorubicin	20mg vial	Injection
302	doxorubicin	10mg	Injection
303	etoposide	100mg/5ml **vial**	Injection

S.No.	Molecular Description	Strength	Description
304	filgrastim	1ml vial	Injection
305	folinic acid	3mg/ml	Injection
306	gemcitabine hydrochloride	200mg	Injection
307	gemcitabine hydrochloride	1 gm	Injection
308	ifosfamide	1gm/2ml vial	Injection
309	L-asparaginase	5000KU	Injection
310	mercaptopurine	100mg/ml	Injection
311	mesna	200mg	Injection
312	methotrexate	50mg/ml	Injection
313	mitomycin-c	10mg	Injection
314	ondansetron	2mg/ml	Injection
315	oxaliplatin	50mg vial	Injection
316	paclitaxel	30mg/5ml	Injection
317	prednisolone	20mg	Injection
318	vinblastine sulphate	10mg	Injection
319	vincristine	1mg/ml	Injection
320	ondansetron	2mg/5ml	Syrup
321	ondansetron	2mg/ml	Syrup
Section 9. ANTIPARKINSONISM MEDICINES			
322	bromocriptine mesylate	1.25mg	Tablet
323	bromocriptine mesylate	2.5mg	Tablet
324	carbidopa + levodopa	100mg+10mg	Tablet
325	carbidopa + levodopa	100mg+25mg	Tablet
326	carbidopa + levodopa	250mg+25mg	Tablet
327	trihexyphenidyl hydrochloride	2mg	Tablet
Section 10. MEDICINES AFFECTING THE BLOOD			
328	ferrous sulphate/fumrate	Tablets equivalent to 60mg elemental iron	Tablet
329	folic acid	1mg	Tablet
330	folic acid	5mg	Tablet
331	pyridoxine	10mg	Tablet
332	warfarin sodium	5mg	Tablet
333	cyanocobalamin	1mg/ml	Injection
334	enoxaparin	40mg	Injection
335	enoxaparin	60mg	Injection
336	heparin sodium	1000IU/ml	Injection
337	heparin sodium	5000IU/ml	Injection
338	iron dextran	50mg iron/ml	Injection
339	phytomenadione	10mg/ml	Injection
340	protamine sulphate	10mg/ml	Injection
341	ferrous sulphate/fumrate	25mg elemental iron (as sulphate)/ml	Oral Solution
Section 11. BLOOD PRODUCTS AND PLASMA SUBSTITUTES			
342	albumin	0.05	Injection
343	albumin	0.2	Injection
344	cryoprecipitate		Injection
345	dextran-40	0.1	Injection
346	dextran-70	0.06	Injection
347	Factor IX complex (coagulation factors II,VII, IX, X)	Dried	Injection
348	Factor VIII concentrate	Dried	Injection
349	fresh frozen plasma		Injection
350	hydroxyethyl starch (hetastarch)	0.06	Injection

S.No.	Molecular Description	Strength	Description
351	platelet rich plasma		Injection
352	polygeline	0.035	Injection
Section 12. CARDIOVASCULAR MEDICINES			
353	amiodarone	100mg	Tablet
354	amiodarone	200mg	Tablet
355	amlodipine	2.5mg	Tablet
356	amlodipine	5mg	Tablet
357	atenolol	50mg	Tablet
358	atorvastatin	5mg	Tablet
359	atorvastatin	10mg	Tablet
360	clopidogrel	75mg	Tablet
361	digoxin	0.25mg	Tablet
362	diltiazem	30mg	Tablet
363	diltiazem	60mg	Tablet
364	enalapril maleate	2.5mg	Tablet
365	enalapril maleate	5mg	Tablet
366	glyceryl trinitrate	0.5mg	Tablet
367	hydrochlorthiazide	12.5mg	Tablet
368	hydrochlorthiazide	25mg	Tablet
369	hydrochlorthiazide	50mg	Tablet
370	isosorbide 5 mononitrate/dinitrate	10mg	Tablet
371	isosorbide 5 mononitrate/dinitrate	20mg	Tablet
372	losartan potassium	25mg	Tablet
373	losartan potassium	50mg	Tablet
374	methyldopa	250mg	Tablet
375	metoprolol	25mg	Tablet
376	metoprolol	50mg	Tablet
377	nifedipine	5mg	Capsule
378	nifedipine	10mg	Tablet
379	nifedipine	10mg	Capsule
380	nifedipine	10mg	SR tab
381	nifedipine	10mg	SR cap
382	nifedipine	20mg	Tablet
383	nifedipine	20mg	SR tab
384	nifedipine	20mg	SR cap
385	procainamide hydrochloride	250mg	Tablet
386	verapamil	40mg	Tablet
387	verapamil	80mg	Tablet
388	adenosine	3mg/ml	Injection
389	amiodarone	50mg/ml (3ml ampoule)	Injection
390	digoxin	0.25mg/ml	Injection
391	diltiazem	5mg/ml	Injection
392	dobutamine	50mg/ml	Injection
393	dopamine hydrochloride	40mg/ml	Injection
394	enalapril maleate	1.25mg/ml	Injection
395	esmolol	10mg/ml	Injection
396	glyceryl trinitrate	5mg/ml	Injection
397	ligocaine hydrochloride	0.01	Injection
398	ligocaine hydrochloride	0.02	Injection
399	metoprolol	1mg/ml	Injection
400	procainamide hydrochloride	100mg/ml	Injection
401	sodium nitroprusside	50mg/5ml	Injection
402	streptokinase	7,50,000 IU	Injection
403	streptokinase	1500,000 IU	Injection
404	urokinase	500,000 IU/ml	Injection
405	urokinase	**10,00,000**	Injection

S.No.	Molecular Description	Strength	Description
		IU/ml	
406	verapamil	2.5mg/ml	Injection
407	digoxin	0.05mg/ml	Elixir
Section 13. DERMATOLOGICAL MEDICINES			
408	miconazole	0.01	Drops - opthamological
409	povidone iodine	0.006	Drops - opthamological
410	dithranol	0.1-2%	Ointment
411	neomycin + bacitracin	5mg+500IU/g	Ointment
412	miconazole	0.02	Ointment
413	miconazole	0.02	Cream
414	acyclovir	0.05	Cream
415	framycetin sulphate	0.005	Cream
416	permethrin	0.05	Cream
417	silver sulphadiazine	0.01	Cream
418	betamethasone dipropionate	0.0005	Ointment
419	betamethasone dipropionate	0.0005	Cream
420	benzyl benzoate	0.25	Lotion
421	calamine		Lotion
422	permethrin	0.01	Lotion
423	permethrin	0.05	Lotion
424	zinc oxide		Dusting Powder
425	coal tar	0.05	Solution
426	povidone iodine	0.05	ointment
427	methylrosanilinium chloride (gentian violet)	0.005	Aqueous solution
428	glycerin		Solution
429	salicylic acid	0.05	Solution
Section 14. DIAGNOSTIC AGENTS			
430	iopanoic acid	500mg	Tablet
431	calcium ipodate	3g	Injection
432	meglumine iothalamate	60%w/v (iodine=280mg/ml)	Injection
433	sodium iothalamate	70%w/v (iodine=420mg/ml)	Injection
434	sodium meglumine diatrizoate	60%w/v (iodine conc.=292mg/ml)	Injection
435	sodium meglumine diatrizoate	76%w/v (iodine conc.=370mg/ml)	Injection
436	meglumine iotroxate	5-8 iodine in 100-250ml	Solution for Injection
437	propyliodone	500-600mg/ml	Injection, Oily Suspension
438	fluorescein	0.01	Eye drops
439	lignocaine	0.04	Eye drops
440	tropicamide	0.01	Eye drops
441	barium sulphate	100%w/v	Suspension
442	barium sulphate	250%w/v	Suspension
Section 15. DISINFECTANTS AND ANTISEPTICS			
443	gentian violet	0.005	Paint
444	gentian violet	0.01	Paint

S.No.	Molecular Description	Strength	Description
445	benzoin compound		Tincture
446	acriflavin+glycerin		Solution
447	hydrogen peroxide	0.06	Solution
448	cetrimide	20% (conc. For dilution)	Solution
449	chlorhexidine	5% (conc. For dilution)	Solution
450	ethyl alcohol 70%		Solution
451	povidone iodine	0.05	Solution
452	povidone iodine	0.1	Solution
453	potassium permanganate		Crystals for solution (non-human use)
454	bleaching powder	Contains not less than 30%w/v of available chlorine (as per I.P)	Powder (non-human use)
455	formaldehyde solution	Dilute 34ml of formaldehyde solution with water to produce 100ml (as per I.P)	Solution (non-human use)
456	glutaraldehyde	0.02	Solution (non-human use)
Section 16. DIURETICS			
457	furosemide	40mg	Tablet
458	spironolactone	25mg	Tablet
459	furosemide	10mg/ml	Injection
460	mannitol	0.1	Injection
461	mannitol	0.2	Injection
Section 17. GASTROINTESTINAL MEDICINES			
462	5-amino salicylic acid (5-ASA)	400mg	Tablet
463	aluminium hydroxide + magnesium hydroxide		Tablet
464	bisacodyl	5mg	Tablet
465	dicyclomine hydrochloride	10mg	Tablet
466	domperidone	10mg	Tablet
467	famotidine	20mg	Tablet
468	hyoscine butyl bromide	10mg	Tablet
469	metoclopramide	10mg	Tablet
470	omeprazole	10mg	Capsule
471	omeprazole	20mg	Capsule
472	omeprazole	40mg	Capsule
473	dicyclomine hydrochloride	10mg/ml	Injection
474	hyoscine butyl bromide	20mg/ml	Injection
475	metoclopramide	5mg/ml	Injection
476	pantoprazole	40mg	Injection
477	promethazine	25mg/ml	Injection
478	ranitidine*	25mg/ml	Injection
479	aluminium hydroxide + magnesium hydroxide		Suspension
480	domperidone	1mg/ml	Syrup
481	metoclopramide	5mg/5ml	Syrup
482	zinc sulfate	20mg/5ml	Syrup
483	oral rehydration salts	Glucose:	Powder for

S.No.	Molecular Description	Strength	Description
		13.5g/L, Sodium chloride: 2.6g/L, Potassium chloride: 1.5g/L, Trisodium citrate dihydrate+: 2.9g/L, Powder for dilution in 200ml;500ml; 1000ml (as per I.P)	solution
484	ispaghula		Granules
485	bisacodyl	5mg	Suppository
Section 18. HORMONES, OTHER ENDOCRINE MEDICINES AND CONTRACEPTIVES			
486	carbimazole	5mg	Tablet
487	carbimazole	10mg	Tablet
488	clomiphene citrate	50mg	Tablet
489	clomiphene citrate	100mg	Tablet
490	ethinylestradiol	0.01mg	Tablet
491	ethinylestradiol	0.05mg	Tablet
492	ethinylestradiol + levonorgesterol	0.03mg+0.15 mg	Tablet
493	ethinylestradiol + norethisterone	0.035mg+1.0 mg	Tablet
494	glibenclamide	2.5mg	Tablet
495	glibenclamide	5mg	Tablet
496	levothyroxine	50microg	Tablet
497	levothyroxine	100microg	Tablet
498	medroxyprogesterone acetate	5mg	Tablet
499	medroxyprogesterone acetate	10mg	Tablet
500	metformin	500mg	Tablet
501	norethisterone	5mg	Tablet
502	testosterone	40mg (as undecanoate)	Capsule
503	25% dextrose	100ml	Injection
504	glucagon	1mg/ml	Injection
505	insulin injection (soluble)	40IU/ml	Injection
506	intermediate-acting (Lente/NPH insulin)	40IU/ml	Injection
507	methylprednisolone	40mg/ml	Injection
508	premix insulin 30:70 injection	40IU/ml	Injection
509	testosterone	25mg/ml (as propionate)	Injection
510	IUD containing copper		piece
511	hormone releasing IUD	IUD	
512	condoms		
Section 19. IMMUNOLOGICALS			
513	anti-D immunoglobin (human)	300microg	Injection
514	antitetanus human immunoglobin	250IU	Injection
515	antitetanus human immunoglobin	500IU	Injection
516	BCG vaccine		Injection
517	diphtheria antitoxin	10,000IU	Injection
518	DPT vaccine		Injection

S.No.	Molecular Description	Strength	Description
519	hepatitis B vaccine		Injection
520	measles vaccine		Injection
521	oral poliomyelitis vaccine (LA)		oral drops
522	polyvalent antisnake venom	10ml	Injection
523	rabies immunoglobulin	150IU/ml	Injection
524	tuberculin, purified protein derivative (PPD)	1TU	Injection
525	tuberculin, purified protein derivative (PPD)	5TU	Injection
526	rabies vaccine		Injection
527	tetanus toxoid		Injection
Section 20. MUSCLE RELAXANTS (PERIPHERALLY-ACTING) AND CHOLINESTERASE INHIBITORS			
528	neostigmine	15mg	Tablet
529	pyridostigmine	60mg	Tablet
530	atracurium besylate	10mg/ml	Injection
531	neostigmine	0.5mg/ml	Injection
532	pyridostigmine	1mg/ml	Injection
533	succinyl choline chloride	50mg/ml	Injection
534	vecuronium	2mg/ml	Injection
Section 21. OPTHALMOLOGICAL PREPARATIONS			
535	acetazolamide	250mg	Tablet
536	methyl cellulose	0.02	Injection
537	chloramphenicol	0.004	Drops - opthamological
538	chloramphenicol	0.004	Ointment - opthamological
539	chloramphenicol	0.01	Drops - opthamological
540	chloramphenicol	0.01	Ointment - opthamological
541	ciprofloxacin hydrochloride	0.003	Drops - opthamological
542	ciprofloxacin hydrochloride	0.003	Ointment - opthamological
543	betaxolol hydrochloride	0.0025	Drops - opthamological
544	betaxolol hydrochloride	0.005	Drops - opthamological
545	gentamicin	0.003	Drops - opthamological
546	homatropine	0.02	Drops - opthamological
547	phenylephrine	0.05	Drops - opthamological
548	pilocarpine	0.02	Drops - opthamological
549	pilocarpine	0.04	Drops - opthamological
550	prednisolone acetate	0.001	Drops - opthamological
551	prednisolone sodium phosphate	0.01	Drops - opthamological
552	sulphacetamide sodium	0.1	Drops - opthamological
553	sulphacetamide sodium	0.2	Drops - opthamological
554	tetracaine hydrochloride	0.005	Drops - opthamological

S.No.	Molecular Description	Strength	Description
555	timolol maleate	0.0025	Drops - opthamological
556	timolol maleate	0.005	Drops - opthamological
Section 22. OXYTOCICS AND ANTIOXYTOCICS			
557	mehyl ergometrine	0.125mg	Tablet
558	mifepristone	200mg	Tablet
559	misoprostol	100microg	Tablet
560	terbutaline sulphate	2.5mg	Tablet
561	betamethasone	4mg/ml	Injection
562	mehyl ergometrine	0.2mg/ml	Injection
563	oxytocin	5IU/ml	Injection
564	oxytocin	10IU/ml	Injection
565	terbutaline sulphate	0.5mg/ml	Injection
Section 23. PERITONEAL DIALYSIS SOLUTION			
566	intraperitoneal dialysis solution	Of approximate composition	Injection
Section 24. MEDICINES FOR MENTAL AND BEHAVIOURAL DISORDER			
567	alprazolam	0.25mg	Tablet
568	alprazolam	0.5mg	Tablet
569	amitriptyline	25mg	Tablet
570	chlorpromazine hydrochloride	25mg	Tablet
571	chlorpromazine hydrochloride	50mg	Tablet
572	chlorpromazine hydrochloride	100mg	Tablet
573	fluoxetine hydrochloride	20mg	Capsule
574	imipramine	25mg	Tablet
575	imipramine	75mg	Tablet
576	lithium carbonate	300mg	Tablet
577	olanzapine	5mg	Tablet
578	olanzapine	10mg	Tablet
579	sodium valproate	200mg	Tablet
580	sodium valproate	500mg	Tablet
581	chlorpromazine hydrochloride	25mg/ml	Injection
582	haloperidol	5mg/ml	Injection
583	chlorpromazine hydrochloride	25mg/5ml	Syrup
Section 25. MEDICINES ACTING ON THE RESPIRATORY TRACT			
584	codeine phosphate	10mg	Tablet
585	dextromethorphan	30mg	Tablet
586	salbutamol sulphate	2mg	Tablet
587	salbutamol sulphate	4mg	Tablet
588	hydrocortisone sodium succinate	200mg	Injection
589	hydrocortisone sodium succinate	400mg	Injection
590	beclomethasone dipropionate	50microg/dose	Inhalation
591	beclomethasone dipropionate	250microg	Inhalation
592	ipratropium bromide	20microg/metered dose	Inhalation
593	salbutamol sulphate	100microg/dose	Inhalation
594	codeine phosphate	15mg/5ml	Syrup
595	salbutamol sulphate	2mg/5ml	Syrup
Section 26. SOLUTIONS CORRECTING WATER, ELECTROLYTE AND ACID-BASE DISTURBANCES			
596	glucose	0.1	Injection
597	glucose	0.15	Injection
598	glucose	5% isotonic	Injection

S.No.	Molecular Description	Strength	Description
599	glucose with sodium chloride	**5%+0.9%**	Injection
600	N/2 saline		Injection
601	N/5 saline		Injection
602	normal saline	0.009	Injection
603	potassium chloride	11.2 sol	Injection
604	ringer lactate	as per IP	Injection
605	sodium bicarbonate	as per IP	Injection
606	water for injection	10ml	Injection
607	water for injection	2ml	Injection
608	water for injection	5ml	Injection
Section 27. VITAMINS AND MINERALS			
609	ascorbic acid	100mg	Tablet
610	ascorbic acid	500mg	Tablet
611	calcium carbonate	250mg	Tablet
612	calcium carbonate	500mg	Tablet
613	nicotinamide	50mg	Tablet
614	riboflavin	5mg	Tablet
615	thiamine	100mg	Tablet
616	vitamin A	100,000IU	Capsule
617	vitamin A	50,000IU	Capsule
618	vitamin A	5000IU	Tablet
619	vitamin D (ergocalciferol)	0.25mg	Capsule
620	vitamin D (ergocalciferol)	1mg	Capsule
621	multivitamins (as per Schedule V of Drugs and Cosmetics Rules)		Tablet
622	vitamin A	50,000IU/ml	Injection

Appendix 2 a).

Formulations for which data is not available through IMS Health

S.No.	*Name of the medicine*	*Strength*	*Description*	*Reason*
1. ANAESTHETICS				
1	morphine sulphate	10mg	Tablet	no IMS data as single ingredient
2	lignocaine hydrochloride + adrenaline	1.0%	Injection	hard to determine relevant products
3	morphine sulphate	10mg/ml	Injection	no IMS data (only FDCs available)
4	atropine sulphate	1mg/ml	Injection	no IMS data for specific dose
5	ether		Inhalation	no IMS data
6	nitrous oxide		Inhalation	no IMS data
7	oxygen		Inhalation	no IMS data
2. ANALGESICS, ANTIPYRETICS, NON-STEROIDAL ANTI-INFLAMMATORY MEDICINES (NSAIMs),				
8	hydroxychloroquine phosphate	200mg	Tablet	no IMS data (only sulphate salt is available)
9	ibuprofen	100mg/5ml	Syrup	no IMS data for syrups (susp available, same strength)
10	tramadol	100mg	Capsule	no IMS data for capsules
3. ANTIALLERGICS AND MEDICINES USED IN ANAPHYLAXIS				
11	cetrizine	5mg/ml	Syrup	no IMS data fro specific dose (only 5mg/5ml available)
12	prednisolone	25mg	Injection	no IMS data for specific dose
4. ANTIDOTES AND OTHER SUBSTANCES USED IN POISONINGS				
13	penicillamine	250mg	Tablet	no IMS data for tablets
14	desferrioxamine mesylate	500mg	Injection	no IMS data
15	flumazenil	0.1mg/ml	Injection	no IMS data
16	methylthioninium chloride (methylene blue)	10mg/ml	Injection	no IMS data
17	sodium nitrite	30mg/ml	Injection	no IMS data
18	sodium thiosulphate	250mg/ml	Injection	no IMS data
19	dimercaprol	50mg/ml (in oil)	Injection	no IMS data for specific dose
20	calcium gluconate	100mg/ml	Injection	no IMS data for specific dose
21	calcium gluconate	100mg/ml in 10ml ampoule	Injection	no IMS data for specific dose
5. ANTICONVULSANTS/ANTIEPILEPTICS				
22	phenytoin sodium	50mg	Capsule	no IMS data for capsules
23	phenytoin sodium	25mg/ml	Syrup	no IMS data for syrups
24	magnesium sulphate	500mg/ml	Injection	no IMS data for specific dose
6. ANTI-INFECTIVE MEDICINES				
25	nevirapine (NVP)	200mg	Capsule	no IMS data for capsules

S.No.	Name of the medicine	Strength	Description	Reason
26	griseofulvin	125mg	Capsule	no IMS data for capsules
27	griseofulvin	250mg	Capsule	no IMS data for capsules
28	pyrimethamine	25mg	Tablet	no IMS data for single ingredient
29	diloxanide furoate	500mg	Tablet	no IMS data for specific dose
30	indinavir (IDV)	200mg	Tablet	no IMS data for specific dose
31	indinavir (IDV)	400mg	Tablet	no IMS data for tablets
32	isoniazid	50mg	Tablet	no IMS data for specific dose
33	rifampicin	50mg	Tablet	no IMS data for specific dose
34	didanosine (ddI)	400mg	Tablet	no IMS data for tablets
35	zidovudine (ZDV or AZT)	100mg	Tablet	no IMS data for tablets
36	clindamycin	150mg	Tablet	no IMS data for tablets
37	saquinavir (SQV)	200mg	Capsule	no IMS data for specific dose
38	stavudine (d4T)	15mg	Capsule	no IMS data for specific dose
39	rifampicin	50mg	Capsule	no IMS data for specific dose
40	piperazine	4.5gm	Tablet	no IMS data for tablets
41	praziquantel	600mg	Tablet	no IMS data for tablets
42	cloxacillin	125mg/5ml	Liquid	no IMS data for liquids
43	isoniazid	100mg/5ml	Syrup	no IMS data for syrup
44	ritonavir	400mg/5ml	Syrup	no IMS data for syrups
45	metronidazole	100mg/5ml	Syrup	no IMS data for syrups
46	pentamidine isothionate	200mg	Injection	no IMS data
47	ciprofloxacin hydrochloride	200mg/100ml	Injection	no IMS data for specific dose
48	sodium stibogluconate	100mg/ml	Injection	no IMS data for specific dose
49	nystatin	100,000 IU	Pessaries	no IMS data for specific dose
7. ANTIMIGRAINE MEDICINES				
50	acetylsalicylic acid	300mg	Tablet	no IMS data for specific dose
8. ANTINEOPLASTIC, IMMUNOSUPPRESSIVES AND MEDICINES USED IN PALLIATIVE CARE				
51	cyclophosphamide	200mg	Tablet	no IMS data for specific dose
52	ondansetron	2mg/ml	Syrup	no IMS data for specific dose
53	mercaptopurine	100mg/ml	Injection	no IMS data
54	ifosfamide	1gm/2ml vial	Injection	no IMS data for specific dose
55	L-asparaginase	5000KU	Injection	no IMS data fro specific dose
10. MEDICINES AFFECTING THE BLOOD				
56	ferrous sulphate/fumrate	25mg elemental iron (as sulphate)/ml	Oral Solution	no IMS data for oral solution
57	cyanocobalamin	1mg/ml	Injection	no IMS data for specific dose
11. BLOOD PRODUCTS AND PLASMA SUBSTITUTES				
58	cryoprecipitate		Injection	no IMS data

S.No.	Name of the medicine	Strength	Description	Reason
59	Factor IX complex (coagulation factors II,VII, IX, X)	Dried	Injection	no IMS data
60	fresh frozen plasma		Injection	no IMS data
61	platelet rich plasma		Injection	no IMS data
62	hydroxyethyl starch (hetastarch)	6.0%	Injection	no IMS data (only FDCs available)
63	polygeline	3.5%	Injection	no IMS data (only FDCs available)
64	dextran-40	10.0%	Injection	no IMS data for injection
65	dextran-70	6.0%	Injection	no IMS data for injection
12. CARDIOVASCULAR MEDICINES				
66	hydrochlorthiazide	50mg	Tablet	no IMS data for specific dose
67	nifedipine	20mg	SR cap	no IMS data for specific dose
68	procainamide hydrochloride	250mg	Tablet	no IMS data for tablets
69	digoxin	0.05mg/ml	Elixir	no IMS data for elixirs
70	procainamide hydrochloride	100mg/ml	Injection	no IMS data
71	digoxin	0.25mg/ml	Injection	no IMS data for relevant dose
72	dobutamine	50mg/ml	Injection	no IMS data for specific dose
13. DERMATOLOGICAL MEDICINES (topical)				
73	benzyl benzoate	25.0%	Lotion	no IMS data
74	methylrosanilinium chloride (gentian violet)	0.5%	Aqueous solution	no IMS data
75	glycerin		Solution	no IMS data
76	dithranol	0.1-2%	Ointment	no IMS data (only FDCs available)
77	zinc oxide		Dusting Powder	no IMS data for dusting powder
78	coal tar	5.0%	Solution	no IMS data for solution
79	salicylic acid	5.0%	Solution	no IMS data for solution
80	framycetin sulphate	0.5%	Cream	no IMS data for specific dose
81	neomycin + bacitracin	5mg+500IU/g	Ointment	no IMS data for this combination
82	miconazole	1.0%	Drops - opthamological	no IMS data for eye drops
83	povidone iodine	0.6%	Drops - opthamological	no IMS data for eye drops
14. DIAGNOSTIC AGENTS				
84	iopanoic acid	500mg	Tablet	no IMS data (radiocontrast media)
85	barium sulphate	100%w/v	Suspension	no IMS data
86	barium sulphate	250%w/v	Suspension	no IMS data
87	calcium ipodate	3g	Injection	no IMS data

S.No.	Name of the medicine	Strength	Description	Reason
88	sodium iothalamate	70%w/v (iodine=420mg/ml)	Injection	no IMS data
89	sodium meglumine diatrizoate	60%w/v (iodine conc.=292mg/ml)	Injection	no IMS data
90	sodium meglumine diatrizoate	76%w/v (iodine conc.=370mg/ml)	Injection	no IMS data
91	meglumine iotroxate	5-8 iodine in 100-250ml	Solution for Injection	no IMS data
92	propyliodone	500-600mg/ml	Injection, Oily Suspension	no IMS data
93	fluorescein	1.0%	Eye drops	no IMS data for eye drops
94	lignocaine	4.0%	Eye drops	no IMS data for eye drops
15. DISINFECTANTS AND ANTISEPTICS				
95	gentian violet	0.5%	Paint	no IMS data
96	gentian violet	1.0%	Paint	no IMS data
97	benzoin compound		Tincture	no IMS data
98	acriflavin+glycerin		Solution	no IMS data
99	ethyl alcohol 70%		Solution	no IMS data
100	hydrogen peroxide	6.0%	Solution	no IMS data for solution
101	chlorhexidine	5% (conc. For dilution)	Solution	no IMS data for specific dose
102	potassium permanganate		Crystals for solution (non-human use)	no IMS data (non-human use)
103	bleaching powder	Contains not less than 30%w/v of available chlorine (as per I.P)	Powder (non-human use)	no IMS data (non-human use)
104	formaldehyde solution	Dilute 34ml of formaldehyde solution with water to produce 100ml (as per I.P)	Solution (non-human use)	no IMS data (non-human use)

S.No.	Name of the medicine	Strength	Description	Reason
105	glutaraldehyde	2%	Solution (non-human use)	no IMS data (non-human use)
17. GASTROINTESTINAL MEDICINES				
106	dicyclomine hydrochloride	10mg	Tablet	no IMS data for specific dose
107	aluminium hydroxide + magnesium hydroxide		Tablet	no IMS data for tablets
18. HORMONES, OTHER ENDOCRINE MEDICINES AND CONTRACEPTIVES				
108	ethinylestradiol + norethisterone	0.035mg+1.0 mg	Tablet	no IMS data for specific dose
109	hormone releasing IUD	IUD		no IMS data
110	condoms			no IMS data
19. IMMUNOLOGICALS				
111	diphtheria antitoxin	10,000IU	Injection	cannot determine dose
112	tuberculin, purified protein derivative (PPD)	1TU	Injection	no IMS data
113	tuberculin, purified protein derivative (PPD)	5TU	Injection	no IMS data
114	rabies immunoglobulin	150IU/ml	Injection	no IMS data for specific dose
20. MUSCLE RELAXANTS (PERIPHERALLY-ACTING) AND CHOLINESTERASE INHIBITORS				
115	pyridostigmine	1mg/ml	Injection	no IMS data fo injection
21. OPTHALMOLOGICAL PREPARATIONS				
116	methyl cellulose	2.0%	Injection	no IMS data (only FDCs available)
117	tetracaine hydrochloride	0.5%	Drops - opthamological	no IMS data for single ingredient
118	chloramphenicol	0.4%	Ointment - opthamological	no IMS data for specific dose
119	chloramphenicol	0.4%	Drops - opthamological	no IMS data for specific dose
120	chloramphenicol	1.0%	Drops - opthamological	no IMS data for specific dose
121	phenylephrine	5.0%	Drops - opthamological	no IMS data for specific dose
122	prednisolone acetate	0.1%	Drops - opthamological	no IMS data for specific dose
24. MEDICINES FOR MENTAL AND BEHAVIOURAL DISORDER				
123	chlorpromazine	25mg/5ml	Syrup	no IMS data for syrups

S.No.	Name of the medicine	Strength	Description	Reason
	hydrochloride			
124	chlorpromazine hydrochloride	25mg/ml	Injection	no IMS data for specific dose
25. MEDICINES ACTING ON THE RESPIRATORY TRACT				
125	codeine phosphate	10mg	Tablet	no IMS data for tablets
126	dextromethorphan	30mg	Tablet	no IMS data for tablets
26. SOLUTIONS CORRECTING WATER, ELECTROLYTE AND ACID-BASE DISTURBANCES				
127	N/2 saline		Injection	no IMS data
128	ringer lactate	as per IP	Injection	no IMS data
129	glucose	15.0%	Injection	no IMS data for specific dose
130	potassium chloride	11.2 sol	Injection	no IMS data for specific dose
131	water for injection	2ml	Injection	no IMS data for specific dose
132	N/5 saline		Injection	no IMS data
133	normal saline	0.9%	Injection	no IMS data
27. VITAMINS AND MINERALS				
134	multivitamins (as per Schedule V of Drugs and Cosmetics Rules)		Tablet	hard to determine relevant products
135	vitamin D (ergocalciferol)	0.25mg	Capsule	no IMS data as ergocalciferol
136	nicotinamide	50mg	Tablet	no IMS data as single ingredient
137	riboflavin	5mg	Tablet	no IMS data for specific dose
138	vitamin A	100,000IU	Capsule	no IMS data for specific dose
139	vitamin A	5000IU	Tablet	no IMS data for specific dose
140	vitamin D (ergocalciferol)	1mg	Capsule	no IMS data for tablet

Appendix 2 b).

Formulations with no sales recorded in the IMS Health databse

S. No.	NLEM section number	NLEM section name	name of formulation	description	strength
1	1	ANAESTHETICS	diazepam	Syrup	2mg/5ml
2	6	ANTI-INFECTIVE MEDICINES	nystatin	Tablet	500,000 IU
3	6	ANTI-INFECTIVE MEDICINES	sulphadiazine	Tablet	500mg
4	7	ANTIMIGRAINE MEDICINES	acetylsalicylic acid	Tablet	350mg, 350 soluble/dispersible
5	8	ANTINEOPLASTIC, IMMUNOSUPPRESSIVES AND MEDICINES USED IN PALLIATIVE CARE	busulphan	Tablet	2mg
6	8	ANTINEOPLASTIC, IMMUNOSUPPRESSIVES AND MEDICINES USED IN PALLIATIVE CARE	folinic acid	Injection	3mg/ml
7	10	MEDICINES AFFECTING THE BLOOD	pyridoxine	Tablet	10mg
8	12	CARDIOVASCULAR MEDICINES	urokinase	Injection	10,00,000 IU/ml
9	12	CARDIOVASCULAR MEDICINES	nifedipine	SR cap	10mg
10	17	GASTROINTESTINAL MEDICINES	zinc sulfate	Syrup	20mg/5ml
12	25	MEDICINES ACTING ON THE RESPIRATORY TRACT	beclomethasone dipropionate	Inhalation	50microg/dose

Appendix 3. Discrepancies arising from differences in use of market based data

S. No.	*Name of Formulation*	*Unit*	*NPPA reported number of packs*
Formulations identified as monopolies by authors			
1	Halothane with vaporizer Inhalation --	ml	3
2	Phenobarbitone Tablets 60 mg	tablet	4
3	Quinine sulphate Injection 300 mg / ml	ml	5
4	Phenobarbitone Tablets 30 mg	tablet	3
5	Phenytoin Sodium Capsules 100mg	capsule	2
6	Bisacodyl Tablets 5 mg	tablet	2
7	Methotrexate Injection 50 mg / ml	ml	4
8	Cetrimide Solution 20% (conc. for diluti	ml	2
9	Pyrazinamide Tab 1500mg	tablet	2
10	Sevoflurane Inhalation	ml	3
11	Lignocaine Hydrochloride +Adr, 2% +Adrenaline 1:200,000	ml	2
12	Allopurinol tablets 100 mg	tablet	3
13	Pilocarpine drops 2%	ml	2
14	Sodium Bicarbonate Injection	ml	2
15	Water for Injection 5 ml	Ampoule	2
16	Water for Injection 10 ml	Ampoule	3
17	Calcium Carbonate tablets 250 mg	tablet	6
18	Clindamycin Tablet - 300mg	tablet	2
19	Cyclosporine concentrate for Inj - 100 mg/ml	ml	2
20	Melphalan Tablet - 2 mg	tablet	2
21	Melphalan Tablet - 5 mg	tablet	2
22	Mercaptopurine - 50 mg	tablet	3
23	Procarbazine capsule - 50 mg	capsule	3
24	Vinblastine Sulphate Inj - 10 mg/pack	pack	3
25	Daunorubicin Inj - 20 mg vial/pack	pack	3
26	Chlorambucil tablet - 2mg	tablet	2
27	Factor VIII Concentrate Dried	pack	2
28	Omeprazole Capsules 40 mg	capsule	3
29	Hyoscine Butyl Bromide tab- 10mg	tablet	2
30	Sulphacetamide Sodium Drops - 10%	ml	2
31	Mitomycin-C Inj - 10 mg	pack	3
32	Succinyl Choline Chloride Injection 500mg /10ml		6
33	Nifedipine Sustained release tablets 10mg	tablet	3
Formulations for which no data is available through IMS Health for the specific molecule, dose, or form; formulations for which relevant products could not be determined			
34	Indinavir Capsules 400 mg	capsule	2
35	Ringer Lactate Injection	ml	14
36	Dextran-40 Inj - 10%	ml	6
37	Condoms	condom	102
38	Desferrioxamine mesylate Inj - 500mg	pack	monopoly
39	Praziquantel tablet - 600 mg	tablet	monopoly
40	Isoniazid Syrup - 100 mg/5ml	ml	monopoly
41	Hydroxyethyl Starch (Hetastarch) Inj - 6%	ml	monopoly
42	Glycerin solution	ml	8
43	Benzyl Benzoate lotion 25%	ml	23
44	Benzoin Compound tincture	ml	5
45	Potassium Permanganate crystals for solution	gm	monopoly
46	Nitrous Oxide	cubic metre	9
47	Oxygen Inhalation	cubic metre	9
48	Ethyl Alcohol 70% (Gel Base)	ml	monopoly
49	Gentian Violet Paint 1%	ml	monopoly
50	Hydrogen Peroxide Solution 6%	ml	monopoly

S. No.	Name of Formulation	Unit	NPPA reported number of packs
51	Gluteraldehyde 2%	ml	6
52	Morphine Sulphate Injection 10	ml	2
53	Morphine Sulphate tablets 10 mg	tablet	4
54	Hydroxychloroquine phosphate Tablets 200 mg	tablet	11
55	Digoxin Inj - 0.25 mg/ml	ml	monopoly
56	Dobutamine Injection 50 mg / ml	pack	5
57	Cetrizine Syrup 5 mg / ml	ml	20
58	Calcium Gluconate 100mg in 10ml Ampoule	Ampoule	2
59	Magnesium sulphate Inj - 500 mg /ml	ml	3
60	L- Asparaginase Inj - 5000 KU./pack	pack	2
61	Rabies immunoglobin Inj- 150 IU	ml	2
62	Chloramphenicol Drops - 1%	ml	2
63	Diloxanide Furoate Tablet - 500 mg	tablet	monopoly
64	Sodium Stibogluconate Inj - 100 mg/ml	ml	monopoly
65	Ifosfamide Inj - 1 gm / 2m Vial	pack	3
66	Phenytoin Sodium syrup 100 mg	ml	monopoly
67	Beclomethasone Dipropionate	inhaler	monopoly
68	Diphtheria Antitoxin Inj - 10,000 IU/pack	pack	2
69	Lignocaine Hydrochloride + Adrenaline Injection 1%+1:200,000/pack	pack	3
70	Busulphan Tablet - 2 mg	tablet	monopoly
Sustained release forms not considered as separate formulations as per the NLEM			
71	Metoprolol Tablets 25 mg-SR/CR/XR	tablet	32
72	Metoprolol Tablets 50 mg-SR/CR/XR	tablet	43