Draft Drug Price Policy 2011
Legitimising Unaffordable Medicine Prices?

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Pursuing its neo-liberal agenda of decontrol and liberalisation, the present government is planning to move towards market-based pricing from the current cost-plus-based pricing mechanism for drugs under price control. By refusing to include fixed dose combinations of essential medicines, sticking only to dosages and strengths involving essential drugs and leaving out "me too" drugs in similar therapeutic classes, the government is designing escape routes for companies to wriggle out of the price control mechanism.

The authors have benefited immensely from several discussions in public forum on this issue, especially from Chinu, Mira, Amit, Anant, Anurag and others.

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The wave of decontrol policies of the present government have been applied savagely across the board, and have left not even a critical sector such as pharmaceuticals untouched. The decontrol of prices for medicines, which are of life and death concern for a large number of people in the country, is slated to be next on the agenda of the government. The time-tested and hitherto unchallenged cost-plus-based pricing (CBP) is being replaced by market-based pricing (MBP). This is expected to have a significant negative impact on the affordability of medicines among households, as currently 80% outpatient visits and 60% hospital visits by households occur at private healthcare facilities/ chemists in India.

1 Current Policy Direction

For the last 10 years, the Government of India has been stonewalling formulating its strategy to control essential drug prices. Despite one task force report – the Pronab Sen Report 2005 – two consecutive Empowered Group of Ministers (EGOM), and finally a draft policy – the National Pharmaceutical Pricing Policy 2011 (NPPP) – the government is yet to take a final decision on the form of price control on drugs.

The last year has witnessed a flurry of activity from a tepid government forced to act by a Supreme Court directive, by first notifying a new National List of Essential Medicines (NLEM) of the Ministry of Health and Family Welfare (2011). The department of pharmaceuticals (DOP) later brought out the NPPP 2011. In the last six months, the EGOM held several rounds of meetings with various stakeholders including drug makers, pharmaceutical trading agencies, civil society groups, consumer groups and people's representatives. Not surprisingly, a consensus was eluding them as the big and medium pharmaceutical industries batted for an MBP mechanism, while others argued in favour of continuing the CBP. Even within the government, there were sharp divisions as to what type of price control mechanism to follow, although every stakeholder now is in agreement about bringing all 348 essential drugs on the NLEM under a ceiling.

A direct and coherent Drug Price Control Order (DPCO) was formulated as part of a broader set of pharmaceutical policies in 1979, later in 1986 and 1995. The DPCO draws its power from Section 3 of the Essential Commodities Act, 1955, while the 1979 policy and its avatars draw inspirations from one of India's most celebrated policy documents, the Jaisukhlal Hathi Committee Report of 1975. Paradoxically, while adequate supplies of medicines are produced in the country, a large section of our people does not get access to them, because they are unaffordable. A strong, efficient and effective public health delivery mechanism would have channelled our production capacity to ensure everyone has better access to medicines.

But due to the long and utter neglect of public health systems in the country, access to medicines has become a critical

issue. On the other hand, owing to India's liberalisation measures, which began in the early 1990s, the policies of decontrol were also extended to the pharmaceutical sector. The number of drugs under DPCO declined sharply from about 347 in 1979 to about 142 in 1987 and then to just 76 in 1995. The then proposed policy in 2002 would have reduced this further down to 35, but thanks to concerted civil society action, the policy was stayed by the Karnataka High Court in 2003. Since then, the case has been heard by a division bench of the Supreme Court. The series of activities by the government for formulating a new set of pharmaceutical policies is a direct result of strong observations from the Supreme Court bench, which not only directed the government to bring all essential and life-saving drugs into price control but in a significant observation also told the government not to alter the 1999 (1995 CBP) mechanism.

Over the last three decades of price control, the number of drugs (Active Pharmaceutical Ingredients) under price control has not only been reduced sharply, but the number of control categories has also been reduced while the percentage of maximum margins has been allowed to rise. Across the board, the price control order of 1995 fixed 100% Maximum Allowable Post-Manufacturing Expenses (MAPE) to all drugs. The MAPE was in the range of 40%-75% in 1979.

The retail price of the formulation is calculated based on the following formula:

$$\text{Retail Price} = (\text{MC} + \text{CC} + \text{PM} + \text{PC}) \times (1+\text{MAPE}/100) + \text{ED}$$

where MC denotes material cost including drug cost and other pharmaceutical aids, CC indicates conversion cost, PM means packing material cost of formulation, PC connotes packing of shipment, MAPE denotes Maximum Allowable Post-Manufacturing Expenses which include the trade margin and ED indicates excise duty.

Often multinational and large Indian drug makers deride CBP as being too intrusive and responsible for squeezing profit margins. In a CBP regime, the pricing regulator (National Pharmaceutical Pricing Authority or NPPA) collects cost data from the manufacturer directly by visiting the unit. The reluctance of the drug makers to part with actual cost data is a major concern for the drug price regulator. While such concerns were valid in the 1980s and 1990s, this is not true these days when the domestic producers are expected to file excise and value added tax (VAT) returns. The excise returns are filed based on the manufacturing cost data. The customs duty paid by importers on the raw materials would be a good proxy to arrive at the landed cost of the Active Pharmaceutical Ingredients (APIs).

Moreover, beginning in 2011-12, the Ministry of Corporate Affairs has made it mandatory for all manufacturers, including drug companies, to maintain and disclose cost records. Therefore, compliance by drug makers could be ensured for disclosure of cost data, which then would be utilised for fixing ceiling prices on drugs.

2 Implications of Market-Based Pricing

(a) Market Leaders Are Price Leaders: The peculiar nature of the pharmaceutical market is characterised by monopoly/oligopoly elements, where one or few market players tend to dominate the entire market.[1] While the market dominance power is derived by product patent rules, drug makers are also able to penetrate, perpetuate and sustain their market power through high voltage

Table 1: Market Leaders Are Price Leaders (Indian Rs)

Name of Medicine	Manufacturers (Number)	Market Leader	Most Expensive	Least Expensive	TNMSC Rates
Anti-diabetic					
Human Insulin (40 IU-packsize1)	10	128.1 Abbot	147.8 Eli Lilly	101.5 Biocon	47.84
Glibenclamide (5mg-packsize10)	11	7.1 Sanofi Aventis	7.1 Sanofi Aventis	3.7 Lupin	NA
Cardiovascular System					
Atenolol (50mg-packsize14)	46	26.3 Zydus	31.3 Torrent	4.0 Unison	1.20
Atorvastatin (10mg-packsize10)	58	68.0 Ranbaxy	68.0 Ranbaxy	9.1 Hetero	2.77
Antibiotics					
Cefixime (200mg-packsize10)	51	79.1 FDC	305.7 Admac	64.6 Laborate	NA
Ciprofloxacin (500mg-packsize10)	94	73.6 Ranbaxy	163.4 Ind Swift	11.7 Laborate	9.79
Gastro-Intestinal system					
Omeprazole (20mg-packsize10)	79	39.7 Zydus	75.2 Dolphin	2.5 Medley	2.4
Ranitidine (150mg-packsize10)	48	4.1 GSK	25.5 Ranbaxy	2.7 Welcure	1.87
Gynaecology					
Methylergometrine Inj (0.200-packsize1)	22	22.8 Novartis	22.8 Novartis	1.72 Zydus	0.97
Iron Syrup (packsize1)	113	47.9 Franco Indian	262.2 Glenmark	11.3 GSK	NA
Analgesic-Antipyretic					
Paracetamol (500mg-packsize10)	62	8.2 GSK	12.2 Hetero	1.9 UK Generics	1.32
Diclofenac (50mg-packsize10)	53	20.0 Novartis	39.7 Dr Reddy's	1.7 Lark	0.65
Respiratory system					
Salbutamol Inhaler (100y-packsize200)	6	66.7 Cipla	66.7 Cipla	61.9 German Remedies	NA
Cetirizine (10mg-packsize10)	80	27.8 GSK	35.8 Bactolac	0.98 Khandelwal	0.5
Central Nervous system					
Fluoxetine (20mg-packsize 10)	27	28.9 Cadila	38.6 Wockhardt	4.2 Indswift	2.16
Sodium Valporate (200mg-packsize10)	19	33.8 Sun	44.2 Modi	11.9 Indswift	4.7

** Tamil Nadu Medical Services Corporation (TNMSC) values are 2008-09 prices.
Source: Table extracted from IMS Health, 2008 database.

brand promotion and marketing prowess. Except over-the-counter medicines, direct advertising to consumers is illegal, especially in the prescription category. By targeting physicians and chemists, drug makers find it extremely profitable to push their drugs. The industry's peculiar nature derives its source of manipulation from "information asymmetry". Typically, in healthcare, it is often either the physician or the chemist who decides and chooses on behalf of the patient – what medicines are required to be procured and consumed. Therefore, the demand is created by the suppliers rather than the consumers, termed as "supplier-induced demand". Despite awareness of drugs and the range of choice that is available in the market, even a highly educated patient cannot decide on her/his own what to consume or not to consume in several circumstances.

This scenario is more pronounced in the Indian market than anywhere else. Despite availability of several medicines in each category supplied by over 50-plus drug manufacturers, the prices of market leaders (by market share) are either the highest or one among the highest. In India, a large number of pharmaceutical companies producing similar medicines should mean competitive prices for patients. The top sellers are expected to pitch their prices at the lowest level. But this does not obtain in the Indian pharmaceutical market. Table 1 (p 14) clearly demonstrates that market leaders are price leaders in several scenarios. The data is derived from IMS Health database, 2008 where two critical medicines in 10 key therapeutic segments are provided here for illustrative purposes.

Glibenclamide is one of the key medicines in the anti-diabetes treatment. Sanofi Aventis, which sells the medicines, is not only a market leader in terms of market share but its prices are also the highest in the market, despite the presence of a dozen producers. Atorvastatin (10 mg, 10 tablets), a critical drug used in the treatment of high cholesterol, prevention of heart attacks and strokes, is manufactured and marketed in India by over 50 plus producers. However, Ranbaxy clearly has an edge over the others. It is not only a market leader but its prices are also the highest. Similar evidence emerges from Table 1 in several other cases.

It is also interesting to observe that the least expensive brand in a similar category of medicines is several times cheaper than the most expensive/market leader. However, the pharmaceutical industry argues that the least expensive ones may not be of high quality. As far as medicines are concerned, the quality of the product is measured through safety and efficacy. There is no evidence to prove that the least expensive are of poor quality. The illustrative examples accompanying Table 1 also provide interesting insights into this issue.

In several instances, the least expensive ones are manufactured by India's leading manufacturers – from GSK, to Lupin, to Biocon, to Zydus. It is also true that the prices of the least expensive drugs are often several percentage points higher than the procurement prices obtained by state government-run procurement agencies, such as the Tamil Nadu Medical Services Corporation (TNMSC). Although comparing procurement and market prices is akin to comparing apples and oranges, it is worth observing the extent of price difference obtained while doing so. It clearly suggests the magnitude of margins for a variety of intermediaries (from manufacturers, super-stockists, wholesalers, stockists, retailers) and the extent of profiteering by the producers. It is interesting to note that retailers and stockists argue that their margins are low and thin, compared to what the producers get.

(b) Moving from CBP to MBP: The draft NPPP 2011 and other measures being floated recently by concerned ministries independently and by the EGOM for approval before the cabinet call for moving away from CBP to MBP. For a government that swears by a neo-liberal ideology, this move in the pharmaceutical market is only a logical step to decontrol prices. Although the form and content of price control varies, price caps are common in all rich industrialised nations in the pharmaceutical sector. But our government which pays lip service to serving the common man is out to desert this segment soon. In a free market environment, the new MBP mechanism is only expected to sharpen the price rise and legitimise sky-high drug prices.

Table 2 brings out the price variation that exists for the

Table 2: Comparator Medicine Prices – Current versus Proposed Price Mechanism (Value in Rs)

Therapeutic Category	Name of Drug	Tablets Per Strip	Cost-based (DPCO Prices)	TNMSC Prices	WAP Top Three Brands	WAP 1% by Volume	Market Leader Prices
Anti-diabetics	Human insulin 40 IU	40IU vial	NA	47.8	128.0	128.1	123.6
	Glibenclamide tab 5 mg	10 tab	1.42	0.33**	7.04	7.04	7.08
Cardiovascular system	Atenolol tab 50 mg	14 tab	3.49	1.20	27.1	23.2	26.3
	Aspirin tab 75 mg	14 tab	2.46	0.99***	3.1	3.1	3.1
Antibiotics	Ciprofloxacin tab 500 mg	10 tab	26.57	9.79	67.0	50.4	73.3
	Cefixime tab 200 mg	10 tab	NA	NA	96.8	97.6	79.1
Gastro-intestinal system	Ranitidine tab 150 mg	10 tab	NA	1.87	4.22	4.25	4.1
	Pantoprazole cap 40 mg	10 tab	NA	NA	50.3	42.2	50.0
Gynaecology	Iron syrup	Bottle	NA	NA	50.4	42.8	47.9
	Mifepristone tab 200 mg	Strip of 1	NA	NA	272.2	274.1	275.4
Analgesics	Paracetamol tab 500 mg	10 tab	4.48	1.32	7.8	7.14	8.1
	Diclofenac sodium 50 mg	10 tab	NA	0.65	23.0	14.1	20.0
Respiratory system	Cough syrup	Bottle	NA	3.36	42.8	38.9	46.2
	Cetirizine 10 mg	10 tab	NA	0.5	24.1	13.6	27.8
Central nervous system	Phenytoin tab 100 mg	100 tab	NA	10.4	121.7	121.8	121.1
	Fluoxetine 20 mg	10 tab	NA	2.16	27.0	26.4	28.9

(i) The cost-based DPCO prices are worked out-based on raw materials (RM) cost, including excipients, based on August-September 2012 RM prices. Conversion and other costs are based on SO 2973(E) issued by the Ministry of Chemicals and Fertilisers NPPA, in supersession of the previous order of the Ministry of Chemicals and Fertilisers (NPPP), 16 December 2010. DPCO-based prices from LOCOST obtained by personal communication.
(ii) ** TNMSC 2011-12 rates. (iii) *** 150 mg.
Source: Based on IMS Health, 2008 database figures.

same set of medicines under different pricing mechanisms and therefore the likely implications of moving away from cost-based to market pricing. For similar dosages and strengths, we have worked out comparative drug prices obtained under various pricing environments. Under the current scenario, Glibenclamide, the anti-diabetics drug (5 mg,10 tablets), is procured by the TNMSC at Re 0.33 while the same could be obtained in the open market at a price of Rs 1.42 if it was to be price controlled under the current CBP. It is apparent that the CBP (DPCO prices) provides for a maximum cushioning with a 100% MAPE. On the other hand, the current market leader price is Rs 7.08.

It is worth observing that the mechanism suggested earlier in 2011 by the government, using the Weighted Average Price (WAP) of top three brands and the one suggested by the government recently in 2012 (WAP of brands with one percentage market share by volume), all tend towards the highest market leader prices. Across therapeutic groups, the prices obtained by (1) WAP of top three brands, and the (2) WAP of brands with 1% market share by volume, are either mostly similar or only marginally different. Except in a few markets, the two new pricing mechanisms are not very different from the market leader prices.

Although the number of manufacturers in each category of drugs ranges from 10 to 100 plus, one expects a wide price range in the market. This is the case, for instance, in the market for Ciprofloxacin with 94 manufacturers. The most expensive and least expensive brands currently can be bought at Rs 163.4 and Rs 11.7 respectively in that segment. However, the market leader in that sector sells at Rs 73.3. In both scenarios, the price ceiling would be in the middle, if we were to use the WAP 1% market share by volume or even the WAP top three brands. The price tends towards the middle range, while in the case of the WAP 1% market share the ceiling price tends towards the middle.

Therefore, depending on the number of manufacturers in the market, the latest price mechanism (WAP of brands with 1% volume) would behave in a fashion where ceiling prices would tend towards market leader prices.

(c) Designing Escape Routes: The governments' attempt to keep the number of price-controlled drugs at a minimum is expected to defeat the whole purpose of the price control mechanism. The number of price-controlled drugs under the MBP would be 348 essential drugs and their dosages and strengths, as in the NLEM of 2011. This would mean that a total of over 600-plus drugs would have their ceiling prices based on market-based principles. Again, unlike other well-regulated markets in the west where Fixed Dose Combinations (FDCs) are rarely found, in India, FDCs are the rule rather than the exception. As an illustration, Table 3 exhibits the market share of the single molecule in comparison to FDCs in similar therapeutic categories. For instance, in the market for human insulin, used among advanced stage diabetic patients, the plain molecule accounted for less than one-third of the overall human insulin market. Since under the proposed price cap mechanism, FDCs are excluded from controls, by producing essential molecules with one or more non-controlled drugs pharmaceutical companies would simply circumvent the regulations. This has largely been the practice of companies under the earlier DPCO regimes. By sticking to minimum controls, the government is only paving the way for pharmaceutical companies to find escape routes, ultimately leading to the suggestion that the drug price control authorities do not have adequate powers to prevent circumvention.

Table 3: Market Share for Fixed Dose Combinations Involving Essential Drugs

Name of Drug	Market for Fixed Dose Combinations (Rs in Crore)	Market for Single Molecule (Rs in Crore)	Percentage Share of Single to FDCs
Anti-diabetic			
Human insulin	508	160	31.4
Glibenclamide tab	101	33	32.6
Cardiovascular			
Atenolol tab	443	137	30.9
Aspirin tab	143	26	18.1
Antibiotics			
Ciprofloxacin tab	423	313	73.9
Cefixime tab	596	357	59.8
Gastro-intestinal system			
Omeprazole cap	227	150	66.0
Pantoprazole cap	300	152	50.6
Analgesics			
Paracetamol tablets	273	130	47.6
Diclofenac sodium	425	125	29.4

Source: Based on IMS Health, 2008 database figures.

Another easy escape route designed by the government is to regulate only dosages and strengths of essential drugs listed under the NLEM 2011. If these criteria were to be applied, in several markets, a significant share of essential drugs would be left out of price caps. In Table 4, an illustrative list of essential medicines with all dosages is compared to medicines with only NLEM dosages. It is apparent from Table 4 that in the case of Human Insulin (40 IU), only about half of the insulin market would be covered under price control. Similarly, the percentage share of NLEM dosages to non-NLEM dosages for Atorvastatin and Furosemide accounted for 68.7% and 57.1% respectively.

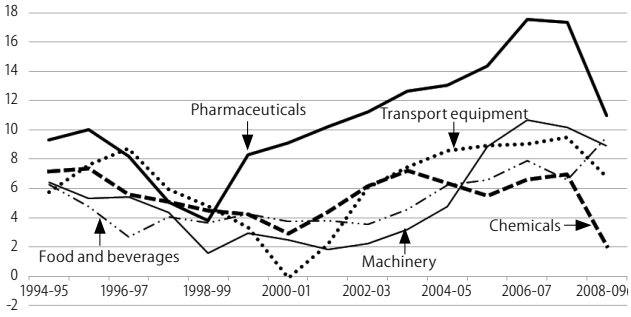
The evidence presented here clearly suggests that by not covering non-NLEM dosages, drug companies would be allowed to escape price caps to a significant degree. Given their superior

Table 4: Market Share of Essential Medicines Involving All Dosages vis-à-vis NLEM Dosages

Drug Market	All Dosages (Rs Crore)	NLEM Dosages (Rs Crore)	NLEM to All Dosages (%)
Anti-diabetic			
Human insulin-40 IU	508	274	53.93
Glibenclamide-2.5 mg, 5 mg	33	31	100.0
Cardiovascular			
Atorvastatin-5 mg, 10 mg	384	264	68.7
Furosemide-40 mg	14	8	57.1
Antibiotic			
Cefixime- 100 mg, 200 mg	357	331	92.7
Ciprofloxacin-250 mg, 500 mg	285	274	76.7
Gastro-intestinal			
Ranitidine-150 mg	208	174	83.6
Pantoprazole-40 mg	30	27	90.0
Gynaecology			
Methylergometrine-0.125 mg	24	24	100
Mifepristone-200 mg	177	177	100
Analgesic-antipyretic			
Paracetamol-250 mg, 500 mg	131	84	64.1
Diclofenac sodium 50 mg	124	51	41.1
Respiratory system			
Salbutamol inhaler-100 microg/dose	75	53	70.6
Cetirizine	94	91	96.8

Source: Based on IMS Health, 2008 database figures.

Figure 1: Profitability in Pharmaceuticals versus Other Sectors in India
(Profit before tax, as % of sales)



Source: PROWESS Database, Centre for Monitoring the Indian Economy (CMIE).

marketing and distribution networks, drug makers would find it easier to push through non-NLEM dosages into the market. In addition, by restricting the price caps to NLEM 2011, several drugs in similar categories would be left out of the price control mechanisms. For instance, under the category of Angiotensin-converting enzyme (ACE) inhibitors, used for the treatment of high blood pressure, several categories of drugs exist in the market, including Enalapril, Lisinopril, Ramipril and Perindopril. While their efficacy and side effects are almost the same in most circumstances, bringing into price control only one of them and leaving the rest would lead to a situation where pharmaceutical companies would mislead and entice physicians into prescribing the costlier ACE inhibitors. Hence, such "me too" drugs must also be brought under the price ceiling.

3 Implications for Industry

Drug companies have been vociferous in the past in seeking dismantling of the existing price control regime. The pharmaceutical companies, both multinational and large domestic ones, argue that price control affects their bottom line in terms of reduced profit. Further, multinational drug companies also attribute the slow introduction of new drugs in India to the existing price control regime. But available evidence on both counts reveals the opposite. Drug companies in India, reflecting global trends, have registered super-normal profits consistently in the past as compared to other commodity sectors. This is true regardless of the criteria – gross profits to sales, profit after tax to net worth, or Return on Capital Employed (ROCE). A casual look at Figure 1 clearly demonstrates that the profitability (measured by profit before tax as percentage of sales) of the pharmaceutical industry has consistently recorded higher levels than other comparable sectors. The last decade also witnessed double-digit profitability consistently. The greedy industry continues to look for profiteering opportunities, by dismantling existing price caps and moving towards market-based mechanisms.

Both multinational and big domestic pharmaceutical companies often complain that CBP hits exports and that overall foreign direct investment is likely to suffer. But a casual examination of the export intensity of top Indian drug companies demonstrates that it is not only high but has been rising over the years. Currently, over 40% of all production by the Indian drug industry is exported to other countries. For several top domestic drug makers in India, exports have been substantially higher than the domestic market. While exports of Dr Reddy's Laboratory accounted for 82.1% of overall production, others such as Biocon (85.1%), Ranbaxy (75.6%), Wockhardt (72.2%), Strides Arcolab (96.6%) and Lupin (69.8) also have large shares in the export market (Government of India 2012).

Since export prices are not governed by Indian price caps, medicine exports are unlikely to be affected. In fact, the export intensity can be expected to sharply intensify further as pharmaceutical companies would prefer to supply to other unregulated markets.

Therefore, in India, the role of the over 5,000 small scale and medium industries assumes critical importance in providing access to affordable medicines. These manufacturers will accept the current CBP practice. The small-scale industries represent one million employees, which produce reportedly about half of the overall domestic production. And several big pharmaceutical companies also source their production from small-scale units. The small-scale industries have come out openly in support of the CBP.[2] The big companies cry hoarse, stating there will be significant job losses. The threats neither of job losses, nor export decline are substantiated with evidence by big pharma but are merely ploys to divert the attention of the government by scaremongering.

NOTES

1 Also see a commentary by the authors and others (Selvaraj et al 2012) for more argument and data to substantiate this critique.

2 This was conveyed by personal communication to civil society groups by Jagdeep Singh, secretary general, SME Pharma Industries Confederation on 6 October 2012.

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