Pharmaceutical Pricing Policy: A Critique

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The recently announced draft National Pharmaceutical Pricing Policy 2011 fails to ensure accessible and affordable medicines for all in India. This is due to the limited scope and market-based approach it offers to price control. Among other measures, policy should fix ceiling prices based on lowest priced alternatives instead of high-priced top sellers, aim to revive pharmaceutical public sector undertakings, and expand the current National List of Essential Medicines. Most importantly, pharmaceuticals must be brought under the remit of the Ministry of Health and Family Welfare to allow better coordination for public health interests.

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The Government of India recently announced a draft National Pharmaceutical Pricing Policy (NPPP) 2011. It may be recollected that in 2003, in response to a public interest litigation (PIL), the Supreme Court in its interim order of 10 March had granted a stay on an earlier order of the Karnataka High Court suspending the National Pharmaceutical Policy (NPP) of 2002. The Supreme Court had stated,

> We suspend the operation of the order to the extent it directs that the (Pharmaceutical) Policy dated 15 February 2002 shall not be implemented. However, we direct that the petitioner shall consider and formulate appropriate criteria for ensuring essential and life-saving drugs not to fall out of price control and further directed to review drugs which are essential and life saving in nature till 2 May 2003.

One of the putative consequences of the draft NPP 2002 would have been to reduce the number of medicines under price control from 76 in 1994 to less than 35. Two years after the Supreme Court directive, the Government of India had set up a task force to explore options other than price control for achieving the objective of making available life-saving drugs at reasonable prices chaired by the then principal advisor, Planning Commission, Pronab Sen.[1] After the task force submitted its report in 2005, two empowered groups of ministers during the tenures of the United Progressive Alliance (UPA) I and II, under Sharad Pawar as chairperson, were constituted to look into the pricing issue. Unfortunately, neither group made its recommendations public.

However, in July 2011, under pressure from the 2003 PIL, filed by the All India Drug Action Network, Medico Friends Circle, Low Cost Standard Therapeutics (LOCOST) and Jan Swasthya Sahyog, the government committed in the Supreme Court that a new revised pharmaceutical policy would be announced, based on the new list of essential medicines. The Ministry of Health and Family Welfare has recently notified the National List of Essential Medicines (NLEM) 2011, which contains 348 essential medicines. According to the NLEM 2011, "[e]ssential medicines are those that satisfy the priority healthcare needs of majority of the population" (Ministry of Health and Family Welfare 2011: 4). Cost, safety and efficacy are the three critical underlying principles on which essential medicines lists are based. The draft NPPP 2011 aims to bring all medicines in the NLEM 2011 under price regulation (Department of Pharmaceuticals 2011).

Key Features and Implications

The draft NPPP 2011 envisages controlling medicine prices based on three key principles: (1) essentiality of medicines; (2) market-based pricing; and (3) price control only on formulations. The inclusion of the first criterion, essentiality of medicines, is one of the long-standing demands of civil society organisations like the All India Drug Action Network and Jan Swasthya Abhiyan. This will mark a welcome departure from earlier price control regimes that relied largely on market share/dominance/monopoly of pharmaceutical companies. Moreover, this criterion will also allow the government to meet the Supreme Court's directive.

Market-based Pricing: However, the draft NPPP 2011 bats for a market-based pricing (MBP) mechanism versus the previous cost-based pricing (CBP). In most markets, when truly competitive conditions exist, and assuming no market collusion occurs, leading market players can reduce prices substantially while earning normal profits. However, the Indian pharmaceutical

market behaves abnormally. Under any given therapeutic category, there are hundreds of players with substantial variation in prices. However, the prices of leading players very often tend to be the highest, because of their aggressive promotional practices and oligopolistic positions. If there were a competitive market with complete consumer sovereignty, this would not be possible, since in other commodity markets, consumers prefer goods of good quality, available at competitive prices. Given the information asymmetry that creates supplier-induced demand, pharmaceutical companies have an upper hand in pushing through high-priced medicines.

Thus, by sleight of hand, the NPPP 2011 wishes to legitimise the rampant practice of profiteering in the pharmaceutical market at the cost of public health and patient access to treatment in India. It does so by entirely disregarding the fact that very often top-selling brands are the most expensive, and by turning on its head the entire logic of why medicine prices need to be controlled. The draft NPPP recommends an MBP regime, based on the weighted average price of the three top-selling brands in each segment, even though with over 100-plus pharmaceutical manufacturers slugging it out in each therapeutic segment, the price range offered by various players with similar quality is substantial.

Medicine quality should be judged not by its packaging but by its efficacy and safety. The lowest priced brands are often therapeutically similar to higher-priced brands of the same generic medicine. The draft NPPP, by choosing to fix ceiling price based on top-selling brands is legitimising the trend of high prices. This MBP approach will induce players in the currently lower priced segment to drive up prices closer to higher-priced competitors. This dangerous trend would unfortunately have been orchestrated by the government, which is supposed to be protecting the right to health of its people.

Table 1 provides a snapshot view of prevailing market conditions and associated prices across various therapeutic categories. It clearly reveals that prices of the leading market player or the top three players put together are the highest. In the sample provided here, the ratio of market leader prices to lowest priced medicines is in the range of 1.25 to 6.84. It is also interesting to observe that the Tamil Nadu Medical Services Corporation (TNMSC) tender prices are, in several instances, much lower than the average of the three lowest priced medicines in the market. This clearly shows that several players are making more than normal profits, even when their prices are the lowest among companies selling the same generic medicine.

Table 1: Comparison Prices for Therapeutically Similar Medicines: Market Leader versus Cheapest Priced

Alternative Market Leader Medicines	Active Pharmaceutical Ingredients (API)	TNMSC Prices	Market Leader/ Most Expensive/ Cheapest Price	Price Ratio of Market Leader to Lowest Priced Drugs	Average Price of Three Highest Priced Brands	Average Price of three Lowest Priced Brands
Anti-Bacterial Medicines						
Monocef (1 g injection)	Ceftrixone	12.39	63 (Aristo); 179 (Merind); 45 (Neon)	1.4	125.3	50.3
Cifran (50mg; 10 tabs)	Cifprofloxacin	9.82	98.6 (Ranbaxy); 98.6 (Ranbaxy); 29.7 (Hindustan)	3.3	88.6	34.6
Anti-Diabetics						
Amaryl (1 mg; 10 tabs)	Glimepride	0.75	65 (Aventis) 65 (Aventis) 9.5 (Kopran)	6.84	59.3	10.8
Glycomet GP (1 mg-500mg; 10 tabs)	Metformin + Glimepride	Not Available	36.5 (USV); 66.2 (Aventis); 17 (Blue Cross)	2.14	52.8	25.3
Anti-Ulcer						
Omex (20 mg; 10 caps)	Omeprazole	2.14	55 (Dr. Reddys); 79.4 (Zydus); 16.5 (Mankind)	3.33	51.6	20
Rantac (150mg; 10 tabs)	Ranitidine	1.85	5.98 (JB Chemicals); 18.9 (Cipla); 4.82 (Dr Reddys)	1.25	12.7	4.9
Anti-Hypertensives						
Aten (50mg; 14 tabs)	Atenolol	1.14	38.9 (Zydus); 57.5 (FDC); 12.4 (Blue Cross)	3.14	48.8	13.2
Storvas (10 mg; 10 tabs)	Atrovastatin	2.09	93.3 (Ranbaxy); 110 (Cadilla); 19 (Skymax)	4.89	103	22
Maternal and child health						
Methergin (0.2 mg/ml; injection)	Methyl Ergotamine	1.14	19.1 (Novartis); 19.1 (Novartis); 5 (M M Labs)	3.82	12.1	7.3
Zentel (400mg; 10 units)	Albendazole	4.55	17 (Glaxo); 17 (Glaxo); 7 (Bipha Labs)	2.43	16.5	7.3

Source: The market leader is determined based on 2009 data from IMS Health. Tamil Nadu Medical Service Corporation data is from tenders quoted on its website.[2] These TNMSC prices are for a pack of 10x10, but for the sake of consistency, we have converted them to the price equivalent for a pack of 10 tablets or capsule. Prices of three top and three least prices are obtained from the Patient India website.[3]

Price Regulation: In an earlier regime, when a medicine was put under the price control category, i e, notified in the Drugs Price Control Order (DPCO), its price was regulated at two levels. First, the price of the bulk drug, i e, the raw material or active pharmaceutical ingredient (API) used in its manufacture, was regulated by placing a ceiling on the profitability allowed in the manufacture of bulk drugs. Then the price of the formulation or the finished product sold in the market was regulated, by calculating the cost of manufacturing the formulation using the necessary bulk drugs and by placing a ceiling on the maximum allowable post-manufacturing expenses (MAPE). The MAPE allowed included profit for the company, at a rate of 100%, according to the 1995 DPCO. Thus, if the cost of manufacturing the formulation was Re 1, it could be sold at Rs 2.

Now the draft NPPP 2011 seeks to change this scenario. The draft policy states (Department of Pharmaceuticals 2011: 9):

> [T]he Bulk Drug – API (Active Pharmaceutical Ingredient) – may not fully reflect the 'Essentiality' of the actual drug formulation – now the subject of focus – due to the possible applicability of the API in manufacture of various formulations which may or may not be considered "Essential" for the larger healthcare needs of the masses.

This means that companies will be allowed to make inessential formulations from essential bulk drugs. These

formulations will fall outside price control even if the basic single ingredient medicine comes under the price control list because it is included in the NLEM 2011. Typically companies could misuse this provision by reducing production of single ingredient essential medicines and manufacturing inessential or irrational combinations using essential APIs instead.

We already have a situation where a very large number of irrational formulations exist in the market, with over 92,000 brands. Given the therapeutic jungle that India has allowed itself into, the policy will only deepen that crisis and lead to shortages of essential single ingredient medicines. The provision needs to be scrapped. It also contradicts the other provision that "formulations containing combination of drugs under NLEM 2011 with drugs not listed in the NLEM 2011" would also be under price control (Department of Pharmaceuticals 2011: 16).

The naïve faith in markets that pervades current political economy and policymaking processes is clearly reflected in the draft NPPP, which argues (Department of Pharmaceuticals 2011: 12-13):

> The Indian economy is today largely market-driven and, particularly in the area of pricing of manufactured products, prices are determined by market conditions and market forces. Administered prices exist in a few areas, such as pricing of petroleum products and procurement prices of foodgrains but these are closely connected with a regime of subsidies paid by the government. The pharmaceutical industry is a [Rs] 1 lakh crore industry of which about Rs 48,200 crore is the domestic market.

Apparently, what is important for policy is to safeguard the interests of the one trillion rupee industry, not those 40 million people who are pushed below the poverty line and an equal number who incur catastrophic payments due to high medicine prices (Selvaraj and Karan 2009). The policy patently disregards the acute financial barriers to access to medicines.

Scope of Price Control: The draft NPPP also stipulates that essential medicines whose weighted average price is less than or equal to Rs 3 per unit be exempted from price control. If this is done, it will provide a leeway for increase in prices of dozens of essential medicines, including many painkillers, anti-inflammatory agents, antihistaminics, anti-asthmatics, some antidiabetics, anti-hypertensive, etc, which are currently available at prices far below Rs 3 per unit. With today's information technology, it is easy to estimate the ceiling price of all 348 essential medicines. Hence, none of them should be exempt from price-control.

The other major limitation of price control as envisaged in the NPPP is that it would be limited to only those medicines on the NLEM 2011. This brings its own set of issues. The NLEM 2011 itself should be subject to thorough review as it appears to omit critical medicines that the government itself provides in its treatment programmes. For instance, key medicines provided by the government as part of its acquired immune deficiency syndrome (AIDS) treatment programme do not appear on the NLEM 2011 nor do AIDS medicines

likely to be required by the government programme in the near future.

There also appears to have been too much reliance on the "cost" factor in drawing up the NLEM 2011, raising the question of how key patented medicines will be dealt with in terms of the NLEM. With the draft NPPP focusing on the NLEM 2011 for price control, this gap has the potential of setting off a vicious cycle: patented medicines will remain out of the ambit of price control and being costly, will have little chance of being included in the NLEM. The draft NPPP 2011 is therefore incomplete and only partially addresses the problem of affordability and access to medicines.

The draft NPPP 2011 ignores the fact that it is not enough to bring only one medicine a given category under price control. For example, out of the category of angiotensin converting enzyme (ACE) inhibitors, used for the treatment of high blood pressure, it is not enough to single out only Eenalapril for price control. Though there is hardly any difference between Eenalapril and the other ACE inhibitors Lisinopril, Ramipril and Perindopril regarding efficacy, side effects, etc, there is a significant price difference between Enalapril and others. The generic version of Enalapril 5 mg costs less than Rs 5 per strip of 10 tablets; its branded version costs around Rs 25. In contrast, the branded versions of Lisinopril, Ramipril and Perindopril for equivalent dosages are priced at Rs 38, Rs 67 and Rs 79, respectively per strip! If all ACE inhibitors are not under price control, pharmaceutical companies would mislead and entice doctors into prescribing the costlier ACE inhibitors. Hence, such "me too" drugs should have the same price ceiling.

Policy Options

The draft NPPP 2011 falls far short of the goal of ensuring the accessibility and affordability of medicines in India, both in terms of scope of price control, which includes only medicines on the NLEM 2011, and in terms of its market-based approach. Often industry and government complain that CBP is difficult to administer since pharmaceutical companies are not mandated to declare the true cost of making a medicine. A proxy way to get around this problem is to obtain tender prices (as in Tamil Nadu or Kerala) and treat these as reference prices. The retail price can then be calculated by adding a suitable margin to the reference price. Given the unique but distorted nature of the Indian pharmaceutical market, reference prices based on the lowest, rather than the highest, prices are the way forward. By fixing reference prices, the government can signal to industry that adequate margins, with above-normal profits, are allowed. Contrary to the dire threats made by industry, such pricing will keep them engaged in the business of making medicines. Despite price controls in the past, the industry has consistently registered supernormal profits. Even if floor-plus prices were to be considered, they would reap above-normal profits.

The CBP approach would have been possible if the government had allowed pharmaceutical public sector undertakings (PSUs) to function smoothly and efficiently. But over the years, the government preferred letting these PSUs become sick, foregoing a golden opportunity for robust benchmarking. The revival of pharmaceutical PSUs is extremely vital, for these and related reasons. If the government were to issue compulsory licences for patented products, pharmaceutical PSUs would need to operationalise the licence. Moreover, in an environment where the top Indian private pharmaceutical companies are being acquired by drug multinational corporations (MNCs) or have licensing arrangements with them, PSUs need to play a significant role in providing medicine security. As Indian private players migrate towards the business philosophy of MNCs, with their eye on high profits in developed country markets and away from low-profit medicines, PSUs are also essential for ensuring the continued manufacture and supply of medicines that profit-driven private companies may discontinue.

Both the central and state governments currently spend too little on medicines. There is a need to scale up public spending to at least 15% of the overall budget allocation to the healthcare sector. While doing so, governments must put in place a transparent mechanism to centralise procurement and decentralise distribution in order to achieve value for money. Replicating the time-tested TNMSC model in medicine procurement is the way forward for other states. This will result in supply of free medicines to all patients visiting government health facilities and will create strong competitive forces for bringing down prices of medicines in the open market.

The Department of Pharmaceuticals must be brought under the Ministry of Health and Family Welfare in order to serve the interests of public health, and also for ensuring coordination of the various functions under the drugs and medicines sector. The department must be required to continuously collect and disseminate pharmaceutical market data, such as market share, consumption patterns, prices, etc, a function currently carried out by a private data-collecting agency, like IMS Health. The prohibitive costs of obtaining this data from a private agency make independent evaluation by health and public interest groups an impossible task. Such data should be available in the public domain. It is well within the powers of the government under the Essential Commodities Act to gather and disseminate such data.

NOTES

1 For a copy of the report, see Task Force to Explore Options other than Price Control for Achieving the Objective of Making Available Life-saving Drugs at Reasonable Prices, report submitted to the Department of Chemicals and Petrochemicals, Government of India, 2005. eSocialSciences Working Paper 295, last accessed 9 January 2011: http://ideas.repec.org/p/ess/wpaper/id295.html

2 TNMSC website, last accessed 13 January 2012: http://www.tnmsc.com/tnmsc/new/index.php

3 Last accessed 13 January 2012: http://patientindia.com/resultDetails.php?searchC=1&brandId=510&genId=50&sta

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