



Policy Brief for Parliamentarians

Draft Pharmaceutical Policy, 2006:

Tilting balance from Public Health to Corporate Interest

Introduction

For securing access to essential medicines, it is essential that the draft Pharmaceutical Policy, 2006 is directed towards public health concerns rather than corporate interests. The intention of this policy brief is to inform and sensitise parliamentarians on the need for a national pharmaceutical policy that promotes and preserves public health. It is also intended to remind Members of Parliament of their influential role in policy making deliberations, which should ultimately reflect the interests of the people whom they represent. We hope that this policy brief will sufficiently enable them to act in the interest of public health concerns in the country.

Access to Medicines: An Overview

India's health system is typically characterised by a poor public health system and unregulated and high cost private healthcare. In a country with virtually no health security cover, the burden of healthcare on the poor and even on the larger populace unfortunately falls on households. Drugs and medicines account for a vital and substantial share of healthcare in India. Household out-of-pocket (OOP) expenditure in India constitutes a sizeable 69 percent of overall healthcare expenditure. Of this, three-quarters of the total OOP health expenditure is spent on drugs. Estimates derived from National Sample Survey (NSS) data for 2004-05 suggest that over 12 percent of household non-food consumption expenditure was directed into paying for healthcare. Further evidence shows that, while 70 percent of the households' OOP health expenditure in urban India goes into buying drugs, in rural India the share is as high as 77 percent.

Major Recommendations of the Draft Pharmaceutical Policy, 2006

The last couple of years have seen several initiatives by the Government of India in the arena of pharmaceutical policy. The present draft Pharmaceutical Policy, 2006 is essentially an amalgamation of various inputs received from different

committees and stakeholders, in particular the Sandhu Committee (2006) and Pronab Sen Committee (2005), apart from industry associations, public interest groups, etc. In line with the earlier policy regimes, the overall objectives of the legislations appear to have a number of similarities. The draft pharmaceutical policy (2006) envisages to: i) ensure availability of good quality drugs at reasonable prices; ii) improve accessibility of essential medicines; iii) promote greater R & D in the drug sector; iv) facilitate higher growth in exports of drugs; v) develop India as an internationally acclaimed source for both drug R & D and manufacturing.

One of the contentious issues underlying the present draft pharmaceutical policy is the proposed expansion of drug price control from the present 74 bulk drugs to include all 354 drugs under the National List of Essential Medicines (NLEM). The apparent

Salient features of the Pharmaceutical Policy, 2006

Some of the salient features of draft Pharmaceutical Policy, 2006 include:

- i) Expansion of the number of medicines under price control from the present 74 bulk drugs and its formulations to all essential and life-saving medicines (the number of formulations covered under National List of Essential Medicines, 2003).
- ii) Trade margins for various categories of medicines to be fixed;
- iii) Replacement of the present Essential Commodities Act with the Drug (Price Regulation and Control) Act, 1955 for controlling drug prices;
- iv) Strengthening of drug regulatory system and patent office;
- v) Provision of long-term fiscal and price incentives for R & D drug units;
- vi) Rationalising excise duty on pharmaceutical goods;
- vii) Promotion of generic drugs and control on pharmaceutical brands; and
- viii) Encouragement of medical bio-technology.

shift in the criteria from market monopoly and dominance to the use of the tool 'essentiality' has been a long-standing demand of public interest groups. The proposed move will contain the intra-industry distortion caused by the earlier practice of price control on both upstream bulk drugs as well as formulations, since the draft policy is likely to control only the latter. Even after the present policy is put into practice, the market for price control will not be as substantial as is claimed by industry representatives. The share of price controlled medicines will still be around one-third of the market as against the current share of roughly one-fifth.

Although it is encouraging to observe that the government is considering harnessing a variety of price regulating measures – direct price control, price monitoring and price negotiations – in the era of product-patent regime, price negotiations alone may not be sufficient. The government must not abdicate its responsibility of using other safeguards enshrined in the TRIPS agreement, such as direct price control, compulsory licensing, and parallel exports to protect public health in the country. Governments in Thailand, Brazil and sub-Saharan countries have been harnessing such proactive measures in recent years to protect the health of their citizens.

One of the other crucial draft proposals marked the intention of the government to revive the sick central drug PSUs. This is an important piece of legislation, since robust and functioning PSUs would not only ensure adequate and sustained supply of medicines to the public health institutions but also help in moderating market prices of medicines. Additionally, this would block the current policy of selling national assets for a 'song' and land grab by private real estate lobbyists. Interestingly, the current market value of the real estate of the combined sick drug PSUs is estimated to be roughly the value of the entire Indian pharmaceutical market.

However, while the overall thrust of the policy as underlined in the key objectives is unmistakable, a deeper reading of the fine-print clearly reveals a structural shift in focus from drug policy being pro-public health to pro-industry. This is clearly spelt out in the draft policy, which aims to capitalise on the current boom in the pharmaceutical sector. The proposed policy envisages a significant thrust on drug exports, setting up several pharma-ceutical/biotechnology parks, encouraging drug R & D, launching the country to be the hub of the clinical trial business, and encouraging and expanding institutes like NIPER (National Institute of Pharmaceutical Education and Research) in order to supply unhindered skilled manpower to feed the

growing appetite of the industry. The draft policy proposes to dole out several fiscal and non-fiscal incentives to promote the Indian drug industry, such as duty cuts, tax-holidays, soft loans, land acquisition at throw-away prices: the list is galore.

Existing Drug Regulatory System in India and Necessary Reforms

In India, the regulatory system in the drug sector has been poor and neglected over the years, although much has been written and recommended by various Committees. Shoddy enforcement mechanisms and multiple interpretations of the Drugs and Cosmetics Act have virtually rendered regulation in this sector unviable. In spite of the booming manufacturing/wholesale/retail units in the country, the inadequacy of the regulatory infrastructure and manpower to monitor and regulate drug quality, spuriousness, etc. are a serious affliction. Even in some of the major states there are reportedly no drug testing laboratories. Assuming a norm of one inspector for every 50 manufacturing units and one inspector for 200 sales units, the gap between the required norm and the actual number of available drug inspectors is woefully bigger. It is estimated that one drug inspector is currently serving around 320 wholesale and retail units instead of a norm of 200. This could explain why a relatively lower number of spurious drugs and sub-standard quality drugs were

Impact of IPR Regime on Access to Medicines

India's shift to a stringent patent regime in 2005 is likely to raise many drug prices to international price levels, placing them out of reach for broader sections of society.¹ One sensitive and highly controversial issue as regards to TRIPS under WTO is the high price of medicines. Several recent simulation studies in the Indian context all clearly show that the extent of price increase and loss of consumer welfare is likely to result, in the near future, into a transfer from the earlier process patent system to a patent monopoly era. In fact, India's changeover to product from process patent is likely to endanger a critical source of access to lifesaving generic medicines, not only in India but around the world (Baker 2007; MSF 2007; Grace 2004). The refusal to sell anti-cancer drugs at lower price and the move by Novartis to take the Glivec-patent case to the court reflects the grim scenario that public health faces today in low-income economies. A recent study (SESS 2007) in India provides ample evidence of significant and rapid growth of frivolous patents and patents intended for ever-greening in the post-patent era, which are likely to endanger access to medicines in the very near future.

found than expected; they were simply not being detected.

With adequate manpower and infrastructure alongside a strong surveillance mechanism relating to the movement of spurious/counterfeit drugs, inspection of manufacturing and sales premises could be carried out and spurious items unearthed far more rigorously.

State of Drug Research and Development in India

The global drug industry has grown enormously due to heavy emphasis on research and development since the 1940s. In India, the robust rise of the domestic industry can be traced to the strengths of adaptive process research, aided by the availability of abundant intellectual capital, diversified research institutes, and a highly skilled manpower available at a fraction of international wage. The relative research spending by India's pharma industry is roughly on average three-four percent each year. Process research, however, does not involve a considerable amount of financial resources, hence the thrust on reverse engineering. In the 1990s, the top Indian pharmaceutical companies seem to have woken to the challenges posed by globalisation (opening up of the economy, mergers and acquisitions, transition to product patents) and a slight reversal of the trend is perceptible. As far as the intensity of research efforts is concerned, domestic firms in India reportedly spent consistently more on research activity while foreign affiliates shied away from investing, acting more as conduits for their parent-companies (basically multinationals).

Further evidence from global drug research spending suggests that the share on tropical diseases is less than three percent of total global allocations. A large chunk of the world's resources on drug research is primarily directed towards degenerative diseases such as cardiovascular system, metabolic disease, diabetes, etc. Infectious diseases, which account for major death and disease in third world countries like India, have received very limited attention. This mainly arises because drugs for preventing and curing infectious diseases are low-value business, hence drug multinationals shy away from investment due to lower profits and the possibility of dented bottom lines. Unfortunately, domestic firms in India cannot match the drug research spending pattern of transnationals; their total sales turnover is nowhere near the amount that some individual multinationals can spend on developing and marketing a new drug. Alternatively, the only option available to third world countries is to collaborate and develop mechanisms to fund research efforts that reflect their disease patterns. Only public funding can match the magnitude in the

current circumstances. It must be ensured that any product or process developed through public investment should be free of patents and placed within the public domain for the benefit of society, through open-source financing mechanisms. A serious attempt needs to be made in developing and marketing products shaped through the research efforts of public health institutions.

Price Control of Drugs in India

Although current Indian drug prices are among the lowest in the world, poor affordability coupled with decontrol of drug prices means that prevailing prices are still out of reach for considerable sections of society. Prices of drugs in India were once considered to be one of the highest in the world (Govt. of India, 1975). The trend of high prices has tended to reverse since the 1970s in the wake of a series of policy measures, such as drug price control, process patents for drugs, etc (Govt. of India 2005).

Over the years, however, price controls are gradually being dismantled and the number of bulk drugs under price control has been reduced to a minimal level. In 1979, 347 bulk drugs were under price control, which diminished to 166 in 1987 and was then further reduced to 142. Drastically pruning the list of drugs under control, the Drug Price Control Order (DPCO) of 1995 sought to limit the control to just 76 drugs. The DPCO delineates certain benchmarks on which price control is based. These are: i) sales turnover, ii) market monopoly and iii) market competition. Further, a significant share of drug cost consists of trade margins both wholesale and retail trade. Trade margins range from 100 to 5000 percent in different therapeutic segments.

Setting relatively lower prices is made possible in the Indian context because of direct price control along with process patent regime, which in turn actively introduces and diffuses new drugs by mushrooming growth of new companies in the multi-therapeutic drug market. However, drug companies have previously been vociferous in seeking to dismantle the existing price control regime. The pharmaceutical companies, both multinational and domestic ones, argue that price control affects their bottom line in terms of reduced profit. Further, the multinational drug companies also attribute the existing price control regime to slow introduction of new drugs in India. But available evidence on both counts shows the opposite. Drug companies in India reflecting global trends have consistently registered super-normal profits over the last two decades, as compared to other commodity sectors. This is true against whatever criteria one chooses to examine Gross Profits to Sales, Profit after Tax to Net

Worth, or Return on Capital Employed (ROCE) (Sakthivel 2001; Economic Times 2001). Similarly, relative to other developing countries, India's market is awash with new products, while the process of introducing generic versions of global drugs in India is now so much more rapid.²

Policy Recommendations:

- ◆ In its present form, DPCO is as ineffective as it is inadequate in its coverage and to a large extent does not serve its purpose. There is an urgent need to spruce up the existing criteria for price control. The present practice of using monopoly and market dominance measures should be replaced with the criteria of 'essentiality' of drugs. This would have maximum spill-over effect on the entire therapeutic category, and is also likely to prevent the present trend of circumventing price controls through non-standard combinations. At the same time, such a measure would discourage producers from moving away from controlled to non-controlled drugs.
- ◆ Direct price control should be applied on formulations rather than bulk drugs. This is likely to minimise intra-industry distortion in transaction. In this regard, the proposed draft policy moves in the right direction.
- ◆ Other than overt regulatory controls, accelerating access to drugs can also be ensured by shoring up the mechanism of bulk procurement of drugs. The success of this move is largely vindicated in a few states in India, which have become role models in recent years (Tamil Nadu Medical Services Commission TNMSC, Delhi State Procurements Agency).
- ◆ Huge trade margins are rules rather than exceptions in the Indian drug industry. In view of this, there is a need to fix a ceiling on trade margins, which could lead to significant declines in medicine prices.
- ◆ Needless to say, to ensure uninterrupted supply of drugs to public health institutions, there is an urgent need to spruce up the languishing sick central drug PSUs. This move would also help in moderating market prices of certain therapeutic categories.
- ◆ We argue that a strong regulatory institution needs to be established, to ensure drug security in India.
- ◆ There is a strong need to strengthen the infrastructure

and manpower relating to drug monitoring/surveillance/inspection mechanism, both at central and state levels.

- ◆ Further, measures are required to tone up the Drugs & Cosmetic Act, providing it with more penalties to be used against manufacturers and distributors.
- ◆ We reiterate the long-standing demand for setting up a Central Drug Administration (CDA), to be brought under the charge of the Ministry of Health and Family Welfare with independent charge.
- ◆ And, there is a need to comprehensively review Schedule H and Schedule K of prescription and over-the-counter drugs respectively.

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- ¹ The recent controversy surrounding Glivec, a cancer drug used to treat chronic myeloid leukemia patented by Novartis in India is a cause for major concern among patient groups. The drug is marketed by Novartis in India at around US \$ 26,000 per annum as against one-tenth of its price offered by Indian domestic generic companies. See Mueller, 2007.
- ² According to IMS-ORG (2004), new launches of drug products in India for the year during 2002-2004 constituted eight percent of the total market.

Other Resources:

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Policy brief series: No. 1: 2008, July
Draft Pharmaceutical Policy, 2006: Tilting balance from Public Health to Corporate Interest
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Editorial inputs:
Centad team
Support provided by:
Centad
Centre for Trade and Development, New Delhi

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* [Supported by a grant from Foundation Open Society Institute (Zug)]. **Centad** is an independent, not-for-profit organisation that carries out policy research and advocacy on issues around trade and development, with a focus on South Asia. Centad aims to strengthen the ability of governments and communities to make trade and globalisation work for development.

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Published by:

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