Briefing Paper

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Access to Medicines

Challenges and the Way Forward

The purpose of this paper is to discuss and inform consumers about the issues related to access to medicines in India and provide feedback to the concerned authorities to take the suggested action to enhance access to medicines.

Background and Need

The first UN Millennium Development Goal (MDG) is to halve the proportion of population whose income is less than US$1 per day by year 2015. However, the out-of-pocket expenses on healthcare of such population is a major barrier in achievement thereof. Household surveys conducted by the World Health Organisation (WHO) globally shows that on an average 100 million people are impoverished and another 150 million face severe financial difficulties in any given year due to direct health expenditures. In year 2010, India spent about US$66bn on healthcare out of which 61 percent was spent by households.[1]

Expenditure on medicines accounts for a major proportion of health costs in developing countries. Access to treatment, therefore, is heavily dependent on the availability of affordable medicines.

India's health allocation has been hiked by 14 percent in the budget for 2012-13 with special focus on affordable life-saving drugs and better health facilities for the rural and urban poor. Yet, large numbers of citizens are deprived of affordable healthcare and medicines, which prevents them to come out of the vicious circle of poverty.

It is widely acknowledged that there is a direct correlation of expenditure on healthcare and development. Increasing cost of healthcare in India restricts many poor households to seek healthcare, on the one hand, and causes severe disruption in the living status of those who go for purchasing even the bare essential healthcare, on the other. Many people have to discontinue treatment due to the high cost of medicines and some fall prey to quack doctors.

Medicines account for about 70 percent of out-of-pocket expenditure of healthcare. Even if patients receive free check consultation at government clinics, they are often forced to pay for medicines prescribed out of their own pockets. Medicines purchased by patients from the local chemist can be between 2 to 40 times more expensive than the bulk prices offered to retailers, private hospitals, nursing homes and government agencies.[2]

The Government of India issued The Drugs Prices Control Order (DPCO) 1995 under Section 3 of the Essential Commodities Act, 1955 to regulate the prices of drugs. For the purpose of implementing provisions of DPCO, powers are vested in National Pharmaceutical Pricing Authority (NPPA).

Only 74 out of about 500 commonly used bulk drugs (called scheduled drugs) are kept under statutory price control. All formulations containing these bulk drugs either in a single or combination form fall under price controlled category.

In the context of changed global environment for the industry as well required changes in the mechanism to make available essential medicines to the masses, a new National Pharmaceutical Pricing Policy (NPPP-2012) was approved by the Cabinet on November 22, 2012 and notified on December 07, 2012. The regulation of prices of drugs under the Draft Policy 2011 would be on the basis of regulating the prices of formulations through Market Based Pricing (MBP). The NPPP-2012, would bring 348 essential drugs under price control. Also, all essential medicines, which are 348 drugs plus combination products making it over 400 drugs, will come under price control after the policy is approved. The implications and implementation of this new policy remains to be seen.

Major Issues

Affordability

India is emerging as a hub for production of low cost medicines; yet medicines for many diseases are not affordable for the common citizens in India. For example, Hepatitis C Virus treatment for people is currently

unavailable in the public healthcare system and unaffordable in the private sector as its cost ranges from ₹14,000 to ₹18,000 per dose.[3] The latest cancer drugs Tarceva is priced at ₹1.5 lakh for a month's dosage, while Novartis AG markets Glivec at about ₹1.2 lakh for a five week course.

It is not the cost of production but the intellectual property rights (IPRs) that cause high pricing. While IPRs are required to promote innovation and research in field of medicines but there should be a balance between private interests and public good at large. On January 01, 2005 India conformed to the Trade Related Aspects of Intellectual Property Rights provisions of the World Trade Organisation amending its laws to fulfill international obligations.

Access to essential medicines has been discussed at length in a recent order of the Delhi High Court in the case of *F. Hoffman-La Roche Ltd. and Anr. Vs. Cipla Limited* where the court refused to grant an interim injunction to La Roche and permitted Cipla to market its generic version of lung cancer treatment drug 'Erlocip', a copy of the plaintiff's patented drug 'Tarceva' in public interest.

Recently, the Intellectual Property Appellate Board (IPAB) on November 2012, revoked a patent granted to Roche for Pegasys, a medicine used to treat hepatitis C. The order follows an appeal filed by a Mumbai-based non-profit organisation, Sankalp Rehabilitation Trust, challenging the rejection of its post-grant opposition against the patent by the India Patent Office in 2009.[4]

On September 15, 2012 the IPAB rejected a petition of Bayer Corporation, seeking a stay on an order of the Controller of Patents, granting compulsory licence to the Hyderabad-based Natco Pharma Limited, a generic drugmaker, for a drug used to treat liver and kidney cancer. Bayer obtained a patent in India in 2008 for Nexavar, which cost ₹2.8 lakh for a pack of 120 tablets, equivalent to a month's dosage. Natco was told to sell the pack at ₹8,800.[5]

These are welcome reliefs to patients in India. There is urgent need to harmonise and interpret laws in the larger interest of public.

Availability

Apart from prices, other issues such as availability of certain medicines depend largely on the marketing of drug companies affecting prescription by doctors and commission provided to chemists. Consumers can only obtain certain medicines prescribed by doctors with certain chemist shops. This is also violation of consumer right to choice.

CUTS recently conducted a nationwide sample study on State of the Indian Consumer 2012[6] with support from the Department of Consumer Affairs, Government of India. The report found that according to 57 percent respondents, doctors do not generally prescribe generic or competitively priced drugs/medicines. Even if they prescribe generic or competitively priced medicines, they are not easily available in the market according to 43 percent of the respondents. Majority of such people are from rural areas and largely belong to below poverty line households.[7]

Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 says that "Every physician should, as far as possible, prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and use of drugs." Central government and some state governments have issued instructions to all government hospitals and Central Government Health Scheme (CGHS) dispensaries to prescribe generic medicines to the maximum extent possible but these guidelines are rarely followed by the doctors.

Information Asymmetry

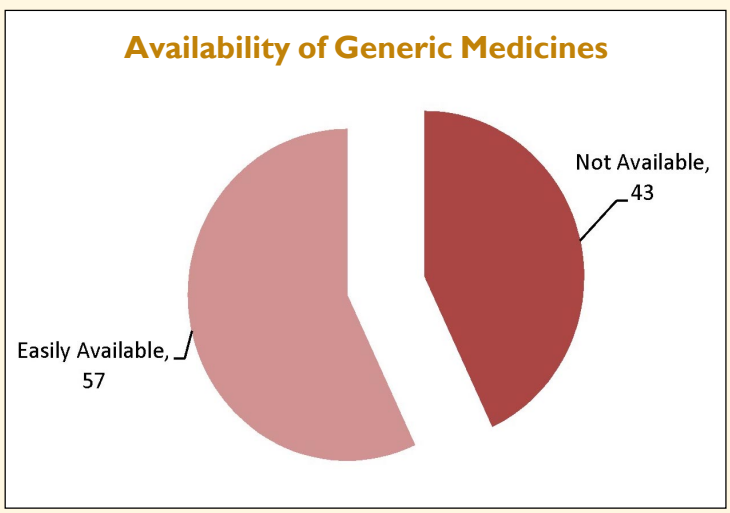
There is a big information gap between medicine manufactures/doctors and common consumers which is being used to take undue advantages. Consumers do not have much information about medicines, alternative low cost options etc. Moreover, even the informed consumers do not have options but to be bound by prescription of the doctor.

Unethical marketing/professional practices

To maximise profits, drug manufacturers are adopting unethical means and the medical professionals and chemists are hand-in-glove with them. This unholy alliance is exploiting consumers. Drug companies are spending more on marketing than research and development.[8]

A recent study done by CUTS under a project 'Collusive Behaviour in Healthcare Delivery in India: Need for Effective Regulation',[9] on some of these inter-relations (arrangements) between providers in the healthcare value chain in two states of the country – Assam and Chhattisgarh also exposed this unholy alliance to cheat consumers.

The Department of Pharmaceuticals is planning to bring "Uniform Code of Pharmaceutical Marketing Practices (UCPMP)", but still it is in draft form and most consumers are not aware of it.



No proper monitoring and implementation mechanism

On paper the country has a good structure of regulatory bodies and implementation agencies. The mechanisms to regulate the healthcare provider market are quite blurry, although there are several key institutions that could play a valuable role, i.e.the Medical Council of India (MCI); departments of Health in individual states; associations of qualified practitioners (such as the Indian Medical Association); a judicial system that allows consumers to approach a consumer court to seek justice for medical negligence. However, none of these can effectively address India's key regulatory concerns.

A recent phenomenon that has invited a lot of public attention and criticism by observers, especially from the perspective of availability of medicines, is the changing anatomy of the pharmaceutical sector in the country.[10] This sector has witnessed an unprecedented number of M&As involving big Indian pharmaceutical companies by large multinational companies, who specialise in patented drugs. This is likely to take the price of medicines further northwards, and restrict the volume of generic medicines' supply in the market. The government has taken cognisance and recommended the use of tools like 'compulsory licencing' to maintain supply of drugs in the market, in case there is a fall.

A common man knows little about these agencies or their regulations and actions. The MCI has found only 16 doctors guilty between 2007 and 2011.

Present Redressal Mechanism

Contravention of any of the provisions of DPCO, 1995 is punishable in accordance with the provision of the Essential Commodities Act, 1955. As per Section 7 of Essential Commodities Act, the penalty for contravention of DPCO is minimum imprisonment of three months, which may extend to seven years and the violator is also liable to a fine. The NPPA, the Food and Drug Administration (FDA)/Drugs Controller of the State, and Drugs Inspector of the District are the enforcing authorities at National/ State/District Levels.

Charging more than printed maximum retail price (MRP) of a medicine attracts the penal provisions of Drugs Price Control Order, 1995. Quality aspects of a medicine attract the provisions of Drugs and Cosmetic Act, 1940. The FDA/ Drugs Control Organisation of the State is the enforcing agency of Drugs and Cosmetics Act and DPCO at State level.

Therefore, all complaints on prices of scheduled drugs as well as quality of medicines can be lodged with the Drugs Inspector of the District or the State Drug Controller. Complaints regarding violation of prices can be lodged with NPPA directly also. NPPA has set up a Grievance redressal cell. For this purpose, NPPA has prescribed formats for submission of complaints.

The MCI is a statutory body with the responsibility of establishing and maintaining high standards of medical education and recognition of medical qualifications in India. There are also State level Medical Councils. If the medical practitioner is found guilty, Medical Council may award such punishment as deemed necessary or may direct the removal altogether or for a specified period, from the register the name of the delinquent registered practitioner. Deletion from the Register shall be widely publicised in local press as well as in the publications of different Medical Associations/ Societies/Bodies.

The Way Forward

While there are positive developments in enhancing consumers' access to medicines in India, following steps will further help ensuring access to medicines. Some are only corrective measures to strengthen the present mechanism; others are new steps to be taken. Some of these steps were recommended by the Pronab Sen Committee Report 'The Task Force to Explore Options other than Price Control for Achieving the Objective of Making Available Life-saving Drugs at Reasonable Prices' constituted by the Department of Chemicals & Petrochemicals, Government of India.

Some Good Initiatives in the Direction

- *The Government of Rajasthan launched a scheme (Chief Minister's Free Medicine Scheme for All) on October 02, 2011 to provide free medicines to all the patients in government hospitals in state.*
- *Acknowledging the vital role the livestock plays in the economy, Rajasthan became the first State to come up with a scheme of free medicines for the bovine population in August 2012.*
- *Madhya Pradesh and Tamil Nadu are also other states where Free of Cost Medicine Distribution Scheme has been introduced.*
- *The Department of Pharmaceuticals, Government of India started Jan Aushadhi Campaign with the opening of the first Jan Aushadhi store at Amritsar on November 25, 2008 and now various stores across India are selling low cost generic medicines.*
- *On November 03, 2012, Prime Minister Manmohan Singh announced that free generic drugs will be made available through all public hospitals in the country to help "reducing out of pocket expenditure of the poor" on health.*

Create Public Awareness

The level of public awareness on legislations, regulation, redressal mechanisms and the implementing authorities responsible to ensure access to medicines is very low. Empowered consumers will help making regulations and policies more consumer friendly and activating/ strengthening the monitoring mechanism. There is a need for a national campaign on the issue including the generic drug options.

Strengthen monitoring mechanism

Lack of a strict monitoring mechanism, results in violation of laws and regulation by the drug manufacturers, which is meant to protect interest of consumers.

- Prescription audits should be made mandatory for all doctors.
- Budget details of drug manufacturing companies on product marketing should be closely monitored and there should be strict actions against violation of the code of ethical marketing.
- Medical Councils and the other agencies like NPPA, Drug Controllers etc. should be more proactive and consumer sensitive.
- There is also a need for the Competition Commission of India to monitor whether drug companies are engaged in collusive practices to fix high prices of medicines.

Pronab Sen Committee recommended establishing a National Authority on Drugs and Therapeutics, as an independent regulatory agency integrating the offices of the Drugs Controller General of India, the Central Drugs Standard Control Organisation and the NPPA along with all the powers and functions of these bodies. Such a body can be helpful in better coordination and monitoring.

Harmonisation of IPR and other laws/policies

There is need to harmonise the present IPR and other laws/policies keeping in view the larger interest of community rather than only promotion of business. Recently, there have been such consumer sensitive judgements. The proposed new National Pharmaceuticals Pricing Policy (NPPP) should take care of this issue.

Better pricing system for medicines

Initiatives like free medicines in government hospitals, *Jan Aushadhi* stores are welcome but a better pricing of medicines be evolved so that everyone can get medicines at low price irrespective of source of purchase or treatment. New NPPP has raised some hopes by bringing more medicines under control but the pricing method seems to be in favour of drug manufacturers rather than patients.

Even the generic medicines are branded by companies and sold at very high MRP, as there is no check on the fixation of MRP.

Revival of Pharma PSUs

There is a need to ensure availability of majority of drugs through the Public Sector. Revival of Public Sector Units needs to be given priority. Public sector medicine companies such as Indian Drug & Pharmacueticles Ltd and Hindustan Antibiotics Ltd should be revived and provided with the support in the form of sectoral reservation, preferential treatment in the cases of governemnt purchases, etc. Pooled purchasing will minimise costs in the public sector.

ENDNOTES

1 WHO Global Health Expenditure Atlas, 2012

2 Medicine Pricing and Universal Access to Treatment- (Fact Sheet)- by Prayas & Jan Swastha Abiyan

3 www.weeklyblitz.net/1905/costly-medicines-mean-debt-or-death-for-people

4 Complete order in the case is available at: www.ipab.tn.nic.in/250-2012.htm

5 The Hindu September 16, 2012 (http://www.thehindu.com/news/national/article3901725.ece)

6 State of the Indian Consumer Report 2012' is available at : www.cuts-international.org/CART/ConsumersUp/pdf/Report_State_of_the_Indian_Consumer-2012.pdf

7 www.cuts-international.org/CART/ConsumersUp/pdf/Report_State_of_the_Indian_Consumer-2012.pdf

8 www.huffingtonpost.com/2012/08/09/pharmaceutical-companies-marketing_n_1760380.html

9 *www.cuts-ccier.org/cohed/*

10 Mehta, Pradeep S, *Overseeing Pharma mergers through the Competition lens*, The Financial Express, 20th June 2010

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