

## CHAPTER V SUGGESTED STRATEGIES AND MEASURES

In this chapter, we try to explore some approaches or strategies that could be used to deal with anti-competitive practices in the pharmaceutical as well as health services industry. However, due to peculiarity of the market conditions, many common marketing practices that are followed in most other industries, can actually promote non-competitive or inefficient outcomes. As opposed to any other market, in health services, very often the seller decides what a customer would buy, and often the customer has little choice regarding the seller as well. For example, a patient with a sudden health problem may just visit the nearest hospital. But once in a hospital, it is for the hospital to decide on everything, ranging from what diagnostic tests to take, what kind of treatment to receive, what medicines to take, whether to go for a surgical operation, to how many days to stay in the hospital. Obviously, in such a situation, a profit-oriented hospital, would in all probability place very little premium on ethical values and impose huge and unnecessary costs on the patient.

Thus, the focus here would be on promoting competitive outcomes and efficiency rather than promoting competition *per se*, by evolving appropriate rules of the game or regulatory framework. The approaches and strategies outlined below are intended to promote competitive outcomes and efficiency in the health care industry including the pharmaceuticals sector, enhancing thereby access to affordable healthcare for the people, through promotion of competition as well as appropriate regulation where necessary.

As may be seen below, several policies and measures will be required to be implemented. This will require appropriate involvement of all stakeholder groups. Capacity building through awareness campaigns through print and electronic media on all relevant issues outlined below need to be carried out on a sustained basis for which the government need to provide adequate budgetary resources to the relevant authorities, existing and forthcoming. A dedicated website need to be created which would disseminate all relevant information. In addition to English language, publicity

should also be carried out in other Indian languages. State governments as well consumer organizations and other interested NGOs need be involved with this work.

### ***Promoting Generic Competition***

The market for pharmaceuticals is different from other markets in the fact that consumers do not make their buying decisions. They buy medicines as suggested by their doctors. The problem here is to ensure that the doctors make the best possible decisions for the patients. However, this is not easy. In economics, the problem of motivating one party to act on behalf of another is known as ‘the principal-agent problem’. The principal-agent problem arises when a principal engages an agency for performing certain acts which are useful to the principal, and where there are elements of the performance which are costly to observe. This is the case to some extent for all contracts which are performed in a world of information asymmetry, uncertainty and risk. In the case of a patient-doctor relationship, information asymmetry is rather extreme as the patient’s ignorance on the issue is often near total.

Here, principals do not know enough about whether (or to what extent) a contract is or has been satisfied. The chances of a doctor making a sub-optimal decision get higher as there is the problem of moral hazard as well, as pharmaceutical companies entice the doctors to push their medicines by offering huge incentives. The solution to this problem is to ensure (as far as possible) the provision of appropriate incentives so that agents act in the way principals wish them to. In terms of game theory, it involves changing the rules of the game, so that the self-interested rational choices which the principal predicts the agent will make, coincide with the choices the principal desires.

In this kind of a situation, the only way the rules of the game can be changed seems to be through promoting generic drugs.<sup>183</sup> This has been suggested by the Task Force formed under the chairmanship of Dr. Pronab Sen. Though opinion is divided on this issue, similar experiment has been quite successful in neighbouring Bangladesh. However, the idea was floated in India even in the past, by a committee formed in 1974, under the chairmanship of Rajya Sabha MP, Mr Jaisukhlal Hathi, to inquire into the conditions prevailing in the sphere of pharmaceuticals in the country.

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<sup>183</sup> Generic drugs, in this particular context, would mean drugs popularly sold under their chemical names only.

Interestingly, though the idea could not take off in India, it inspired Bangladesh to adopt a policy to make generic prescription mandatory for a select list of essential drugs.<sup>184</sup>

Presently, branded drugs dominate the market in India and there is a very small presence of the generic drugs. It is also seen that generally generic drugs are priced lower than the branded ones. Generic competition of bio-equivalent medicines is essential in order to arrive at the lowest and most sustainable prices for essential medicines. The promotion of generic drugs, as against branded drugs, will help the consumer to break free from the biased counselling of physicians.

However, as mentioned above, there is strong opposition to the proposal as well. One opinion is that the power the doctors hold today will simply shift to the pharmacists, as they will try to sell the more expensive brands. This is partly true, as the patients will move from a “no choice” to a “some choice” situation that might be influenced by the pharmacists. However, relatively more aware consumers will benefit as they will search for cheaper brands. Moreover, consumers can be made more aware through media interventions.

Another concern is related to the quality of drugs as it has been argued by some that brands are important indicator of quality. However, it may be noted that de-branding can be done with sole reference to prescriptions by doctors, and the market will not be de-branded as the drugs will continue to carry manufacturers’ names. The issue of spurious medicines should not be linked with this issue as reputed brand names are very often used to market spurious medicines. The only solution to this is to ensure that spurious medicines are not injected into the distribution channel. In any case, utmost effort must be made to ensure that only medicines of certain minimum standards can enter the market. The French safety arrangement in this regard is worth studying.

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<sup>184</sup> Zafrullah Chowdhury, *The Politics of Essential Drugs: The Makings of a Successful Health Strategy: Lessons from Bangladesh*, Zed Books Ltd. London, 1995

### **Box 5.1 Distribution of Medicines: French Safety**

The distribution chain for medicines in France offers outstanding safety in the quality of products. The activities of the pharmaceuticals industry in France operate under a very strict regime laid down by the Public Health Code. A medicine may only be marketed after it has received a marketing permit (an AMM) from the Medicines Agency (the competent government authority), issued following studies to confirm the quality, safety and efficacy of the product. The Medicines Economic Committee is responsible for fixing the price of the product (France has the lowest pharmaceuticals prices in Europe) and the rate of reimbursement under the sickness insurance scheme.

To be marketed by pharmacies, the medicine produced by a pharmaceuticals group will then be stored at the premises of wholesale distributors. These form the sole link in France between the factory and the pharmacy: a closed system synonymous with security at a time when the world traffic in counterfeit pharmaceutical products is estimated to be some \$8bn dollars.

*Source: [http://www.diplomatie.gouv.fr/label\\_france/english/ECONOMIE/pharmac/pharmac.html](http://www.diplomatie.gouv.fr/label_france/english/ECONOMIE/pharmac/pharmac.html)*

De-branding of prescription for essential generic medicines thus seems to be an option worth exploring. This is the only way competition in real sense can be promoted at least in the generic segment of the market. However, considering the opposition from different quarters, a relatively smaller number of most-commonly used medicines can be brought under this scheme on an experimental basis.

### **Box 5.2: Promoting Generic Drugs – Experiment in Bangladesh**

Under pressure from the civil society, the Bangladesh Government promulgated its Drug Policy in June 12 1982, to promote use of generic drugs only (Although the policy has now been diluted, for reasons not fully clear, there are useful lessons to be learnt). The main purpose of this policy was to restrict the marketing of unnecessary and harmful drugs and:

- to ensure a strict quality control of medicines;
- to control the pricing of drugs;
- to make quality medicines available to the people at a fair price;
- to break the monopoly of multinational companies and encourage local producers;
- to use generic names only for essential medicines and avoid enticing brand names.

The law provided a penalty of 10 years imprisonment or a fine of up to two hundred thousand Taka, or both in the event of a violation

Substantial benefits were derived from Bangladesh's National Drug Policy. The gains are evident when prices, production figures and quality indicators, at the time the policy was introduced (1982), are compared with those of a decade later (1992).

1. Essential drugs increased from 30 to 80 percent of local production;
2. Drug prices stabilised, increasing by only 20 percent, compared with an increase of 180 percent in the consumer price index. The drop in price in real terms made drugs more affordable;
3. Bangladesh companies increased their share of local production from 35 percent to over 60 percent and overall local production increased by 217 percent;
4. Less dependence on imports and prioritisation of useful products saved the country approximately US\$600mn;

5. The quality of products improved – the proportion of sub-standard drugs fell from 36 percent to 9 percent.

*Source: Nitya Nanda and Ritu Lodha, Making Essential Medicine Affordable to the Poor, Wisconsin International Law Journal, Vol 20, No 3, 2002*

### ***Dealing with IPR Related Issues***

As mentioned previously, in the new patent regime, any new product entering the market would essentially be marketed by a monopolist. This means that in the new patent regime, abuse of dominance, which was almost non-existent earlier, is likely to become quite frequent. India, thus, needs to learn the art of dealing with abuse of dominance, in which its experience is almost non-existent. Moreover, the related provisions in the Competition Act (2002) are not strong enough.

The major way of dealing with abuse of dominance by a patent-holder is through compulsory licensing. India was not in need of using this since 1970 as its patent regime did not grant product patent. However, it would be worth recalling its experience in this regard prior to 1970, when a product patent regime was in place, under its old patent law of colonial vintage. Unfortunately, the experience was far from satisfactory as granting compulsory license proved to be almost impossible. The legal provisions regarding compulsory licensing as per the new amended patent law are hardly any different from those of its 1911 law. It is hence quite doubtful if providing compulsory licence under the new patent regime would be easy.

It is also quite unfortunate that the competition authority would hardly have any role in granting compulsory licence. In any case, patent offices are created to look into issues of patentability and granting of patent on ground of ‘innovativeness’. Hence they are unlikely to have the capacity to understand if a patent holder is abusing its monopoly status granted through patent rights. Considering this, it would be more appropriate to give the competition authority the responsibility of granting compulsory licence in consultation with the patent office rather than the other way round. In fact, this is how the issue is handled in most developed jurisdictions.

### **Box 5.3 Balancing IPR and Competition: A Canadian Case Study**

On November 2005, the Federal Court of Appeal of Canada delivered an interesting judgment in the case of Eli Lilly et al v. Apotex Inc., on the matter of achieving balance between competition law and patent laws. The crux of the ruling was that an assignment of patent may, as a matter of law, unduly lessen competition. As the privilege of assigning patents is a right granted to a patentee in India as well, this case is being highlighted.

One of the key questions in the case was if a company already owns patents that would give it a monopoly in the relevant market upon assignment of other related patents by another company/s, would such an assignment of patents be considered as anti-competitive or valid in light of the exclusive rights granted to a patentee to assign patents to whomsoever the patentee wishes.

The court held that rights granted to the patentee under patent law does not immunise an agreement to assign a patent from the purview of competition law [Sec 45 (1) of the Competition Act which is analogous to Sec 3 of the Competition Act, 2002 of India], when the assignment increases the assignee's market power in excess of that inherent in the patent rights assigned.

In India, this may well be an issue, but there has been no such case or even discussion on this matter. The Eli-Lilly case may serve as a useful future reference as the principle facilitates access to medicines and healthcare. The case also is indicative of the fact that any consolidation of patent rights by way of an assignment or license between two parties, when the assignment or license potentially transfers more market power than that inherent in the patent assigned or licensed, should now be carefully considered from a competition law perspective by the relevant authorities and also by parties to ward off possible allegations of anti-competitive conduct.

*Source: Fasken Martineau DuMoulin, Federal Appeal Court Gives its Verdict in Eli Lilly Case, available at <http://www.internationallawoffice.com/Newsletters/Detail.aspx?r=11922&I=1049738>*

It is worth noting that the patented drugs (formulations under product patent) that are launched in India in the new patent regime are proposed to be subjected to mandatory price negotiations before granting them marketing approval. It has been proposed that the Department of Chemicals and Petrochemicals in consultation with the Department of Health would lay down necessary guidelines for determining the negotiated prices. While framing such guidelines, India can look at the experiences of other countries particularly Canada, France, Germany, Italy, Japan and UK and some other countries in this regard who follow such practices of price negotiations. In determining prices of patented medicines, countries look at different factors, ranging from prices of existing drugs used to treat the same disease, prices in other countries, to the therapeutic value of the new drug as well as control on maximum profits.

#### **Box 5.4: Pricing of Patented Drugs in Select Countries**

To determine the price of a patented drug sold in Canada, the PMPRB applies factors set out in the *Patent Act* and in its price guidelines as:

- Most new patented drug prices are limited so that the cost of therapy is in the range of the cost of therapy for existing drugs sold in Canada used to treat the same disease;
- Breakthrough drug prices are limited to the median of the prices for the same drugs charged in other specified industrialized countries that are set out in the *Patented Medicines Regulations* (France, Germany, Italy, Sweden, Switzerland, U.K. and the U.S.).
- Existing patented drug prices cannot increase by more than the Consumer Price Index (CPI);
- In addition, the Canadian prices of patented medicines can never be the highest in the world.

The French pricing system allows pharmaceutical companies to sell their products at any price. However, if these companies want the national health care system to reimburse patients for the cost of the drug, the companies must agree to a lower, negotiated price. These negotiated prices and reimbursement rates paid by the healthcare system are based on;

- the therapeutic value of the drug, and
- the price of the drug in other countries.

Italy's national health care system allows manufacturers to sell their drugs at any price. However, if these drugs are to be eligible for reimbursement under the national health care system, pharmaceutical companies must set the price of the drug at a cost that does not exceed a twelve country European average price.

Japan, like most other developed countries, has a national health care system. The prices paid by this health care system are generally determined via a reference system. Prices for new drugs are determined by comparing them with similar drugs that are already on the market. Prices are based upon the safety and effectiveness of the drug; drugs that are shown to be more effective or innovative than existing drugs are priced higher. If there is no comparable drug on the market, the price of the drug is determined by factors such as manufacturing cost and the price of the drug in other countries.

*Source: "Prescription Drug Prices in Canada, Europe, and Japan" Prepared by Minority Staff, Special Investigations Division, Committee on Government Reform, US House of Representatives, April 2001.*

The proposal for negotiated price for patented medicines has attracted criticism from certain sections of the industry arguing that it will dampen R&D efforts in the country. However, the experience of France shows otherwise. France is considered to have the toughest regulatory regime for pharmaceuticals with the lowest pharmaceuticals prices in Europe. Yet, France is now the country ranked third as discoverer of drugs and the world's third largest exporter of medicines. In fact, the US and Germany have now become major markets for French medicines. One may wonder, if strict regulatory regime has forced French pharmaceutical industry to be more efficient and internationally competitive!

Under the Competition Act, IPR related agreements have been exempted if they impose only reasonable restrictions without defining what is reasonable. This will create unnecessary confusion. Moreover, many of the anti-competitive provisions that may enter into IPR related agreements are purely anti-competitive and cannot be justified that they are in the interest of promoting innovation. These practices should be treated like normal anti-competitive practices rather than testing their reasonableness. The Competition Act should be amended accordingly.

### ***Checking collusive activities***

As previously indicated, collusive activities among the Indian manufacturers of pharmaceuticals have not yet been discovered. However, existence of such a tendency in certain segments, where there are just a few manufacturers, cannot be ruled out.

Collusive behaviour of the pharmacies in India in ensuring higher trade margins is a matter of grave concern. As mentioned before, the issue has engaged the attention of the Government. The issue of trade margins has been the subject of intense debate from time to time and different views have been expressed on this issue.

To create deterrence, the government is charging excise duties on the basis of MRP rather than ex-factory prices. However, such a strategy has its own limitations. Such deterrence can work only when the rate of excise duty is reasonably high. But high excise duty on such essential goods like medicines will ultimately harm the ordinary people. Moreover, as has been noted before, high prices need not necessarily imply loss of consumers due to peculiar nature of the market. Thus, the strategy of collecting excise duty on the basis of MRP can be a cure worse than the disease itself from the viewpoint of ordinary people.

Whatever course of action is taken, it is not going to be easy to take strong action when about half a million pharmacists are involved. Should the manufacturers be also allowed to engage in collective bargaining with the pharmacists; Should there be a trade margin fixation regime; Or should there be a negotiated settlement in the short run? - may be the questions that will dog the regulators. In any case, such collusive

behaviour must be done away with, in the long run, to ensure growth of the industry, and a fair deal for the consumers.

### ***Controlling Tied Selling***

Tied-selling is a genuine concern in health services as came out in the survey of stakeholders. However, the issue is far from being a simple one. Quality of medicines and reliability of testing services are serious issues. Although there is regulatory framework to ensure genuine medicines in the market, there is significant scope for improvement in its enforcement. In the area of diagnostic testing, however, the regulatory framework is almost non-existent. It seems that the regulatory failure in one area can create difficulties in enforcing appropriate regulation in another area. Thus, before any serious attempt is made in removing tied selling of testing services, it would be important to put in place an appropriate regulatory framework to promote and maintain service standards in testing laboratories.

One thing that came out of the survey is that people with relatively lower income are more bothered about the anti-competitive practices that occur at grassroots level. The survey was done at major cities and some smaller ones. There are indications that such practices are more prevalent in smaller cities and town. It would not be surprising if they were even more prevalent in smaller towns and rural areas. However, it is unlikely that the implementation mechanism envisaged in the Competition Act would be able to deal with such problems. Nevertheless, if the competition policy of the country is to be made pro-poor such issues cannot be ignored and appropriate alternatives need to be explored.

A way forward could be regulatory authorities at the state level are properly empowered to ensure standards of medicines and services offered at the diagnostic laboratories. This should be complemented with encouraging the consumer forums both at district and state levels to take up such cases to ensure that patients are not exploited. Voluntary consumer organisations should also be made more aware and active on these issues to prevent them from happening.

### ***Regulating the Health Delivery System***

The level of health care spending in India is currently at over 6 per cent of its total GDP. More than three-quarters of this spending includes private ‘out-of-pocket expenses’. Almost all of this private spending is on curative care: consultations, diagnostics and in-patient care. Despite such a high share of expenditure by individuals, the provision of health care, that is adequate in terms of quality and access, is becoming more and more problematic. Currently, there is no appropriate law to regulate or monitor the functioning of private hospitals, nursing homes and other medical care establishments in the country. Some states have state level laws, however, with limited mandate for regulation and poor implementation.

The private health sector will continue to be a major player in providing health services, especially curative health care. Given that private sector health care is predominant in India, and that it is likely to grow even more under the liberalised environment, there is an urgent need for recognition of its far-reaching impact on the health of the people. This means, there is an urgent need for licensing and regulating private health providers.

The absence of regulation not only means that there are no minimum standards, it also implies that consumers do not have adequate information in taking the right decisions. One of the essential conditions in promoting or maintaining competition in a market is availability of sufficient information on the goods and services that are offered in the market. However, as noted before, lack of information is a serious problem here. People, by and large, depend on private health facilities for their health care needs. Yet, little is publicly known about the quality and type of services as well as prices of different private hospitals. Patients normally collect such information through informal channels, which often lead to huge costs on their part. Thus, making information on types of services provided by different hospitals and other medical establishments (including government establishments) and their quality and prices easily available, is essential to promote competition in the health services sector. Even the insurance companies are unable to establish criteria for appropriate reimbursements for treatment at different levels of facilities.

There is need for a programme of strict licensing of all hospitals, nursing homes, and medical practitioners. Regulatory authorities should be established at both central and state levels with appropriate division of responsibilities and mechanism for coordination. The fee structure at private facilities should be formalised and monitored, mainly to avoid exploitation of uneducated patients but also to facilitate the establishment of appropriate reimbursements for specified procedures by insurers.

#### *Hospital accreditation*

Health services monitoring agencies can be created at the state as well as the central level that will collect relevant information from all hospitals within their jurisdiction. It should be made mandatory for all hospitals to provide the necessary information to the monitoring agencies. Directories of hospitals with their rating can be prepared and made widely available. Directories for ordinary hospitals can be maintained at district level, while directories for speciality and super-speciality hospitals can be maintained at state and central levels respectively. Such directories can be made available through websites of central and state government health departments and district administrations. They can also be made available through market as well as different government health centres and NGOs.

#### *Regulation of diagnostic laboratories*

In diagnostics, quality assurance and accuracy of test results are critical, as the doctor's diagnosis and patient's treatment are dependent on the results. Yet, there is hardly any mechanism to ensure quality and standards of services offered by the diagnostic laboratories all over the country. Shocking but true — all it takes to start a diagnostic laboratory is a municipal corporation licence, which essentially equates a clinical laboratory with a general merchandise store or even a garment shop. In some States such as Uttar Pradesh, even this is not required. Some of the practices followed by the laboratories are questionable. Moreover, absence of standards leads to tied-sales as many doctors use this as a pretext to send patients to their chosen laboratories. However, in reality, even doctors are not well aware of the quality of services provided by these laboratories.

There is a system of accreditation with National Accreditation Board for Testing and Calibration Laboratories (NABL) which comes under the Union Ministry of Science

and Technology. However, the accreditation process is non-mandatory and as a result, of the more than 25,000 clinical laboratories in India, barely 59 are accredited with the NABL as on 28.02.2006, and only about two per cent of the people get their tests done at accredited laboratories.

There are other reasons for accreditation not becoming popular. Red tape and the expensive nature of the process of NABL accreditation, being forced to meet associated expenditure not strictly linked to the professional aspects of the process, like the use of specified colours of paint on the walls of a laboratory, air-conditioned facilities, are some of them. If the NABL standards were strictly enforced, more than 80 per cent of the laboratories would be closed. Hence, there is a need for accreditation for different grades of services. However, a well-enforced system of certification and meaningful regulatory legislation are simply essential.

### ***Dealing with Health Insurance***

Often one source of market distortion in health care services is health insurance. Since insurance-holders do not pay their medical bills directly, they care less about the choices they make. Even doctors or hospitals when come to know that a particular patient is insured, care less (or probably more) about the financial implications of their counselling or treatment to the patients. Thus, the healthcare market with prevalence of health insurance is faced with severe moral hazards that promote inefficiency in the market. Ultimately, of course, the patients bear the costs of this inefficiency. Though prevalence of insurance in India is quite low at present, it is growing as public health coverage is quite poor in the country.

However, the issue has become quite important as the government is planning to provide public health coverage to poor people in the country through the insurance route rather than through creating a better healthcare infrastructure of its own. Thus, it would be useful to look at the experiences in this regard, especially in other countries where health insurance is widely prevalent. This essentially takes us to the US as it is the only developed country that does not guarantee universal health coverage. Most Americans receive health insurance through their employer, with government paying the insurance bill for the poor (through Medicaid) and the elderly (through Medicare), though a huge number of people remain uninsured and vulnerable.

The American system has a distinct advantage as it gives wider choice to consumers, compared to other developed countries where public health coverage is public health facilities driven. However, per capita expenditure on health in the US is almost double of that of other rich countries. It is also estimated that about 30 percent of US health spending is simply wasted. In fact, in the US, there are serious concerns that the healthcare system is in need of a thorough revamp. Many also believe that, in the longer run, US may have no choice other than to accept a more overtly European-style system.<sup>185</sup> These lessons should be kept in mind while promoting health insurance in the country.

A new health insurance scheme by the name of ‘Rashtriya Swasthya Bima Yojana’ is proposed to be launched in the country for providing free healthcare to the families below the poverty line (BPL). The scheme would include benefit of hospitalisation cost upto Rs15000 and costs for medicines as outpatient upto Rs5000 per annum per family. The Government of India would pay the full cost of the premium amount for all BPL families. The Scheme is to be implemented by the four public sector insurance companies in the country.

Under this scheme, the BPL families would approach any government doctor in the area. Based on the prescription of the government doctor the BPL cardholder would approach the authorized chemist shop for obtaining medicines free of cost. The chemist would send the bill to the insurance company which would reimburse him for the amount of the medicines purchased by the BPL family

However, in any insurance scheme, the company would fix the premium in such a way that the total premium collected would be more than the total of expected claims. That being the case, the government would be paying much more to insurance companies than the actual costs that these BPL families would incur on hospitalisation and medicines. Buying an insurance policy is sensible for an individual or family to cover the risks. However, buying a group insurance for such a huge population could be really expensive.

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<sup>185</sup> *America's headache: How to start fixing the world's costliest health-care system*, The Economist, January 28, 2006.

Thus, it would be a far better option if the medicines are provided free of costs to the BPL families through the government health centres only, especially when the patients need to visit government doctors anyway. Moreover, government can buy in bulk for all its clinics and can get the medicines at much better price compared market prices that would be charged by the private chemists.

What is more worrying is, there seems to be no credible safeguard to limit corruption in the scheme. It is almost a certainty that a nexus would develop among the government doctors, chemists and the BPL families. This would ensure that all these families would avail their full quota for accounting purposes though actual medicines or hospitalisation services sold would be much much less. The claimed transparency of accounts through computerised statements would be of no use to stop such deals. This would be quite likely as the beneficiaries would not share any burden of the insurance costs and would have no incentive to be honest.

Even the basic objective of the scheme may not be fulfilled as many families might avail their full quota early in the year getting just a small share, conceding the rest to the doctors and the chemists; and when they actually fall ill, they would have no treatment. Access to healthcare would still remain a problem if instead of reinforcing the system of health centres, government launches insurance scheme which is unlikely to help develop health facilities in rural areas. The question arises, whether a developing country like India should tolerate US-type inefficiency and wastage just to have more consumer choice. In fact, majority of the poor being in rural areas would not have much choice any way, particularly when they have to consult a government doctor. In any case, an insurance-oriented healthcare system, though generally promotes choice, does not make the system competitive or efficient.

Revamping and reinforcing the existing public healthcare system can be a better option than the proposed insurance scheme. A better public healthcare system would help even the non-BPL families. Moreover, it is well known that targeting of such scheme based on poverty line has its own problems as many families with higher income make into the BPL list, while many people with actually lower income fail to make it to the list.

#### **Box 5.5: Rajasthan Model of Medicare Relief Societies**

In Rajasthan Medicare Relief Societies have been set up in all the government hospitals at State, Divisional, District and sub-division level for the purpose of –

- better maintenance and upkeep of the hospitals;
- providing cheaper medicines to the common man through outlets known as life-line fluid stores opened within the hospital premises.
- providing medicines free of cost to BPL families.

These Medicare Societies mainly comprise of the doctors in the hospitals. Their source of income is primarily the user charges levied by them for the services provided in the hospitals. Through these medicare societies several critical medicines, injections, antibiotics, IV Fluids etc. are purchased in bulk through open tender from the manufacturing companies and sold through the lifeline fluid stores in the hospital premises. As a result the prices are reduced considerably and some of the medicines are sold at prices as low as or even lower than 50 percent of the prevailing market rates.

An example is the Intra-venous (IV) fluid, a bottle of which is being sold to patients between Rs.10 to Rs.11 as against its ceiling price of Rs.17. Running of the Stores is contracted out and these are generally open all the 24 hours.

Thus, it could probably be a better idea to explore other alternatives instead of insurance-driven public health coverage that will benefit only the BPL families but others as well who are not rich anyway. In this regard, the government can explore the possibility of replicating Rajasthan model of Medicare Relief Societies, and enhancing the coverage and effectiveness of National Illness Assistance Fund. The issue of health insurance can be left to the market. In any case, an insurance-driven health care system cannot ensure universal health care as the government is willing to pay the bill for the poor only and most Indians are employed in the informal sector unlike in the US where employers play important role in paying the insurance bill.

#### **Box 5.6: National Illness Assistance Fund**

The Central Government under the Ministry of Health and Family Welfare operates the National Illness Assistance Fund (NIAF) through which financial assistance is provided to states for the medical treatment of people living below poverty line and other poor families. Out of this fund assistance is provided to States upto 50 percent of their share in the State Illness Assistance Fund (SIAF). Also revolving funds have been set up in some of the leading Government Hospitals for providing financial assistance to BPL families upto Rs 50,000. A Rashtriya Arogya Nidhi has been set up for this purpose. Some states are making good use of these schemes for the BPL families while some have not yet set up the State Illness Assistance Funds.

#### ***Promoting Innovation***

With the advent of the product patent regime it is imperative for the Indian pharmaceutical industry to accelerate its efforts in R&D. This is because the share of

generic market upon which most Indian companies depend is going to shrink and they would be able to introduce generic drugs only after they go off patent. The present level of spending on R&D (about 1.9% of turnover) is much lower as compared to most of the developed countries (10 to 16%).

Globally, the sophisticated, research-based part of the global pharmaceutical industry, is highly concentrated in a handful of countries, notably the USA, the UK, Germany, and Switzerland, and is composed of just a few companies. However, some developing countries have made significant progress over the last couple of decades. According to some experts, countries can be classified into five categories, according to the stage of development of their pharmaceutical sector, as outlined in Table 5.1. India is considered to be in the second category, just after the group of sophisticated industry, and is recognized to have significant innovative capabilities.

**Table 5.1: The Structure of the Global Pharmaceutical Industry**

Stage of development	Number of countries		
	Industrial	Developing	Total
Sophisticated pharmaceutical industry with a significant research base	10	Nil	10
Innovative capabilities	12	6 (Argentina, Brazil, China, India, Korea and Mexico)	18
Those producing both therapeutic ingredients and finished products	6	7	13
Those producing finished products only	2	87	89
No pharmaceutical industry	1	59	60
Total	31	159	190

Source: Nitya Nanda and Ritu Lodha, Making Essential Medicine Affordable to the Poor, Wisconsin International Law Journal, Vol 20, No 3, 2002

In India, it is not only that some top companies have taken R&D efforts seriously, the country is also emerging as the most favoured destinations for collaborative R&D, contract research and manufacturing, clinical research and R&D base of some big foreign companies. The future of pharmaceutical R&D in India, thus, seems to be quite bright and it should be promoted.

It has been made clear in Chapter IV that there is no need to make the industry further profitable to promote R&D through the route of price decontrol. What is needed is a carrot and stick approach. There has to be incentives (or disincentives) directly linked with R&D efforts. This is what is done in most developed countries where companies take substantial R&D initiatives. Some fiscal incentives are already available for R&D. These incentives are at present available only up to March 31, 2007. However, since R&D activity has to be carried over long periods of time, they should be made available over a longer period or even permanently, with provisions for periodical review. The required incentives should also be made available with some safeguards to ensure that these are available to the deserving cases only.

Though the patent regime gives adequate incentives for investing in R&D, it may not be possible for some companies to make such investment, if those companies do not have patents or are not likely to have patents in the near future, though they may be keen to graduate to a patent-holding company. It may be noted in this context that the Pharmaceutical Research and Development Committee headed by Dr R A Mashelkar in its report submitted to Government in November 1999, recommended that R&D intensive companies fulfilling certain conditions should be given price benefits for the drugs under DPCO. This recommendation may be taken up for implementation though with caution.

Although private R&D should be promoted, it cannot be a substitute for public R&D. They should be complements rather than substitutes. It may be noted in this context, that some public laboratories have made significant inventions that have helped the pharmaceutical industry immensely.<sup>186</sup> Moreover, private companies may not be interested in making substantial investment on diseases that affect mostly the poor. Even in developed countries, it has been observed that many pharmaceutical companies are more interested in new 'slimming tablets' that rich people are interested in, rather than finding out new medicines for diseases. Furthermore, private companies would be more interested in curative medicines, rather than preventive medicines. The benefits that preventive medicines provide through reduced chances of infection, and even eradication of certain diseases, cannot be fully captured by

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<sup>186</sup> Supra n. 16

‘profits’. Government intervention in this regard is, thus, necessary. In fact, such an approach is followed in many developed countries including the US. For example, the National Institutes of Health (NIH), the national agency in the United States, spends about \$27bn per year on research, a substantial amount of which is directed towards drug development, including clinical trials.<sup>187</sup>

At present, the Pharmaceutical Research and Development Support Fund (PRDSF) has a corpus of Rs.150 crores (where only interest income is available for spending) is utilized for funding R&D projects of research institutions and industry in the country. It is not adequate to meet the present day and the emerging requirements of this sector. It needs to be sufficiently augmented over years. This process of augmentation has already been initiated with the government’s decision to utilize the entire Rs.150 crore drug research corpus fund this year itself. With this, public funded research is expected to witness a spurt in the country.<sup>188</sup>

The Indian companies should try to exploit the Indian traditional knowledge in ayurveda and herbal cures. They should engage in R&D in herbal medicine and file as many patents for herbal medicine as they can. For this, the Government should set up R&D laboratories undertaking research exclusively in the area of herbal medicines and support the companies in their research and patent filing. Efforts should also be made to integrate use of herbal medicines into allopathic methods of treatment.

**Box 5.7: Highlights of the Recommendations**

- Promoting generic drugs in select categories, along with better quality control
- Mandatory price negotiations for patented drugs
- Monitoring of prices of all drugs outside price control
- Giving the Competition Commission of India the authority to grant compulsory licence for patented drugs
- No data exclusivity should be granted as it is not in the best interest of the country and it is not required under TRIPS
- Checking collusive practices, particularly of the pharmacists and monitoring trade margins
- Checking anti-competitive practices like tied-selling at local level and empowering consumer forums to deal with such cases.

<sup>187</sup> Tim Hubbard and James Love, “A New Trade Framework for Global Healthcare R&D”, Plos Biology, Vol 2, No 2, 2004.

<sup>188</sup> Gireesh Chandra Prasad, *Drug Cos to get more funds for research*, Economic Times, January 25<sup>th</sup>, 2006.

- Regulation, accreditation and rating of hospitals and diagnostic centres with appropriate mechanism at state and central levels
- Monitoring and checking anti-competitive practices arising from availability of health insurance
- Finding alternatives to the proposed government sponsored health insurance cover, like replication of Rajasthan model of Medicare Relief Societies or National Illness Assistance Fund
- Providing adequate incentives for R&D, including in herbal medicines
- Creating awareness involving all stakeholders, namely, central and state governments and NGOs