

## EXECUTIVE SUMMARY

The right to health is recognised in a number of international legal instruments. In India too, there are constitutional commitments to provide access to healthcare. However despite the existence of any number of paper pledges assuring the right to health, access to health remains a problem across the world. In India, according to one estimate, only 35 percent of the people have access to essential medicines.

There are several factors that are responsible for such deprivation. Market malpractices in general, and in particular, anti-competitive conduct in the pharmaceutical industry and the health delivery system are also among them. Examining legal and policy options to effectively eliminate or curb anti-competitive practices in the health sector is the focal point of this study.

### *The pharmaceutical industry and the health delivery system*

The pharmaceutical industry is currently acknowledged as one of the leading industries in India. India is ranked among the top 15 drug manufacturing countries in the world. However, today, the Indian pharmaceutical sector is in a state of flux, in face of the sweeping changes in the patent regime and the increasingly de-regulated environment. Especially threatened in this new scenario is the access to medicines by the poor. Further exacerbating the current situation is the market distortions and skewed competition norms, unique to the pharmaceutical industry, with particular reference to market concentration, barriers to price competition and lack of independent consumer choice (patients are guided by the advice of doctors and pharmacists).

India currently has a vast health delivery system in place though not comprehensive enough to serve a population of over one billion. For the purpose of this report the health delivery system has been taken to comprise of doctors, pharmacists and hospitals. As in the pharmaceutical industry, the health delivery system is also characterised by a market failure uncommon in other markets, that is, consumers are mostly not involved in the decision making process of their purchase of goods and services, which in this case are medicines and healthcare facilities.

### ***Competition concerns***

Apart from the distinct competition scenario, it is to be noted that a number of anti-competitive practices pervade the pharmaceutical industry worldwide, including in India. Such practices may be categorised into primarily three classes: intellectual property rights related breaches, abuse of competition norms arising from mergers and acquisitions and collusive and other anti-competitive practices. Though knowledge about most anti-competitive practices is not in plenty, as India did not have an effective competition regime, several mergers and acquisitions have taken place in recent years and many of them might have had serious implications for competition in the market.

Anti-competitive practices in the health delivery system range from receiving kickbacks by doctors from pharmaceutical companies for influencing drug sales, to tied selling. With specific reference to doctors, suggesting more tests than necessary and accepting commission for referrals are practices, which may have anti-competitive implications. With particular reference to pharmacists, the anti-competitive practices most commonly engaged in are reflective of collusion.

### ***Legal and policy options***

There are multiple legal and policy options, which may be utilised to deal with anti-competitive practices in the pharmaceutical industry and the health delivery system. These options have been considered herein in light of facilitating access to medicines and healthcare by the poor. Using competition law is the obvious choice of legal remedy to deal with anti-competitive practices in the pharmaceutical industry and health delivery system. The key element in successfully enforcing the provisions of competition law is building the capacity of the competition agencies.

Competition law apart, patent law and drug price control are crucial for efficacious elimination of competition violations in the pharmaceutical industry. Price control is a tool that is used in a situation when maintaining a competitive market is extremely difficult. India has been following a price control regime for pharmaceutical products since 1960s. However, there has been substantial decontrol in this regard since 1990s, with the effect that prices of many medicines have seen unprecedented rise.

The report critically analyses the strengths and weakness of all three areas of legal remedy and examines whether there is any need for change in the law.

Apart from competition law, there is no concrete regulatory mechanism addressing anti-competitive conduct in the health delivery system. With specific reference to doctors, the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 may also be used to deal with anti-competitive practices.

### ***Suggestions and recommendations***

Apart from identifying areas of concern in existing legislations, the report provides certain recommendations which encompass both legal and policy considerations. The salient recommendations of this report may be summed up under the following heads:

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

Pharmaceutical companies often give incentives to doctors to push their brand of medicine, which may be more expensive than other alternatives available in the market. This vitiates the competition principle, “best possible goods and services at the least possible prices”. The doctor-drug manufacturer nexus is to be viewed in light of near complete dependence of patients on their doctors for information relating to drug purchase. This report focuses on the need to deal with the aforementioned nexus by promoting generic drugs. This promotion may be done by debranding of prescriptions for essential generic medicines. However, there are strong arguments against this proposition, which to some extent are legitimate concerns. It is, therefore, recommended in this report that a selected number of most commonly used medicines be brought under the ‘debranding of prescriptions’ scheme on an experimental basis.

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

The monopoly rights which patents award to patent holders, which in the case of the pharmaceutical industry are the pharmaceutical companies, is susceptible to abuse, especially in the form of excessive pricing. Compulsory licensing is an effective way to deal with such abuse of monopoly rights. The experience in India’s previous product patent regime indicates that the practical aspect of license issuance needs to

be given due attention if there is to be any likelihood of actualising the grant of compulsory licenses.

It has been recommended in this report that it would be more appropriate to give the competition authority the responsibility of granting compulsory licenses in consultation with the patent office rather than the other way around.

This report is in agreement with the proposed policy of mandatory price negotiations of patented drugs before the grant of marketing approval. It is recommended that while framing guidelines in this respect, India may look at the experiences of other countries, which follow such practices, such as Canada, France, Germany, Italy, Japan and the UK.

The IPR related agreements have been exempted in the Competition Act even if they contain anti-competitive provisions which are reasonable, without defining what is reasonable. This will create confusion. Moreover, some of them can be purely anti-competitive and cannot be justified in the interests of promoting innovation and hence should not be exempted even with a rider of reasonableness.

#### *Checking Collusive Activities*

Collusive activities among Indian manufacturers of pharmaceuticals have not yet been discovered. However, their prevalence cannot be ruled out. Pharmacies engage in collusive practices in India to ensure higher trade margins. The government has created deterrence mechanisms. However, these have their own limitations and need to be re-examined. The report emphasizes the need to eliminate collusive practices by pharmacies to ensure growth of the industry, and a fair deal for the consumers. There are many questions for regulators to consider. Should the manufacturers be also allowed to engage in collective bargaining with the pharmacists? Should there be a trade margin fixation regime? Should there be a negotiated settlement in the short run? These options need to be considered in light of existing law, the practicalities involved and long-term implications.

#### *Controlling Tied Selling*

Tied selling in the health delivery system, although anti-competitive in effect may partly be driven by safety considerations as well rather than profit concerns only. Although, there is regulatory framework to ensure genuine medicines in the market, the report stresses that there is significant scope for improvement in its enforcement. In the area of diagnostic testing, however, the regulatory framework is almost non-existent. The report recommends that regulatory authorities at the state level should be properly empowered to ensure standards of medicines and services offered at the diagnostic laboratories. Consumer forums ought to be actively involved to ensure that patients are not exploited. Accreditation of diagnostic laboratories is another way in which diagnostic laboratories may be effectively regulated. Once safety and reliability issues in the health sector are addressed, dealing with tied selling will become easier.

#### *Regulating the Health Delivery System*

Given the predominance of the private sector in the health delivery system and the lack of any regulatory regime to monitor the functioning of private hospitals, nursing homes and other medical care establishments in the country, this report identifies an urgent need for licensing and regulating private health providers. Hospital accreditation is another method, which may be used to regulate hospital conduct. There is also a need for a programme of stricter licensing of medical practitioners.

Bridging the huge information gap, which exists between consumers and persons responsible for health delivery, may also assist in stemming the incidence of anti-competitive practices in the health delivery system.

#### *Health Insurance*

The most pernicious effect of nearly all anti-competitive practices in the health sector is medicines and health services being rendered costlier. Health insurance is one way to lessen the impact of high prices on the consumer. However, health insurance itself causes market distortion in the health sector. Ultimately patients end up bearing the cost of market inefficiencies. Health insurance thus has a multi-dimensional impact.

This report arrives at the conclusion that with respect to insurance driven public health coverage as per the proposed government scheme that will benefit only families below the poverty line, other alternatives ought to be explored, which will

benefit a wider range of health consumers. In this regard, it is recommended that the government explore the possibility of replicating the 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. It is further suggested that lessons may be drawn from other countries where health coverage through insurance is more prevalent than presently in India.

### Promoting Innovation

With the transition of India to the product patent regime, it is imperative for our domestic pharmaceutical industry to accelerate its efforts in research and development. This study emphasises that total price decontrol as suggested by industry representatives, is unnecessary to promote R&D and suggests a carrot and stick approach to encourage R&D by companies. There has to be incentives and disincentives directly linked with R&D efforts.

Furthermore this report emphasises the need to not only focus on private R&D, but also to actively promote public R&D. This report also advocates that Indian companies should file as many patents for herbal medicine as they can. The Indian Government should actively support such initiatives in whichever way possible.

### Creating Awareness

The implementation of many of the aforementioned policies and measures will require the involvement of all stakeholder groups. The report suggests that there should be capacity building of all involved groups through awareness campaigns through the media on all of the aforementioned issues and other means as well. The central government, the state governments and all interested NGOs need to be involved in creating awareness.

### **Conclusion**

Given the peculiarity of the market, ensuring competition is easier said than done. The new Competition Act, 2002, is better equipped than the earlier law to deal with the anti-competitive practices prevalent in the health sector. Currently the regulatory regime has been quite hard on manufacturers, but extremely soft on two other groups of important players, the doctors and pharmacists. This situation needs to be given

due consideration by the relevant authorities. Finally, it may be mentioned that to deal with anti-competitive practices in the pharmaceutical sector and the health delivery system in order to facilitate access to health, taking recourse to the legal and policy options available is not sufficient; there is need for efficacious implementation of appropriate policy tools as well.