

CHAPTER VI CONCLUSION

The pharmaceutical industry, which till now has been characterised by its complexity, intense competition, low prices, and high level of fragmentation, is on the verge of a major shift as it prepares to meet the challenges of the forthcoming product patent regime. Post-2005, the pharmaceutical industry will see a major shakeout, with a lesser number of players, and an increasing focus on higher value areas like drug discovery, drug delivery systems and technology licensing. The top bracket companies, having a strong R&D focus to deliver better products to the consumer, and innovate cost-efficiency, will survive and become even stronger.

It is estimated that in the next five years, over US\$50bn worth of drugs will go off-patent. This will enable Indian companies to launch their generic equivalents in these markets. The global generics market is widely expected to grow faster than the global pharmaceutical market, in the next few years.

The prices of vital medicines, under patent, are bound to go up manifold in the new patent regime. The Government should be careful and must take all the precautions to protect the rights of the third party, and the party affected i.e. the public at large. The pharmaceutical manufacturers are demanding more liberalisation, arguing that competition, and not price control, will improve availability and affordability of essential drugs.¹⁸⁹ Several arguments are advanced as to why price controls would hurt, not help, consumers.

There is a definite trend towards price decontrol today, however, it is another matter as to whether or not such a trend can sustain. Given that only about 74 drugs are under

¹⁸⁹ The Indian Pharmaceutical Alliance (IPA), comprising 11 big companies, said that they would oppose any restriction on the prices of 'branded' drugs manufactured by them. The pharmaceutical industry has assured the Government of a price-freeze till March 31, 2005. This has been echoed by the Indian drug manufacturers' association (IDMA), as well as the Organisation of Pharmaceutical Producers of India (OPPI). The IDMA is a premier association of the Indian pharmaceutical industry and has come to be regarded, in different circles, as the 'Voice of the National Sector.' IDMA members comprise large, medium and small companies from all over India, manufacturing bulk drugs and formulations. The OPPI is another premier organisation of pharmaceutical manufacturers in India. Its membership consists of companies with international collaboration, and large Indian companies. It represents primarily research-based companies in India.

price control, the entire issue of price decontrol is not really of much significance. But given the likely increase in prices in the new patent regime, it is of paramount importance that the government not give in to industry pressure but maintain some semblance of regulation. India prides itself on its low drug prices. But there were two primary reasons responsible for such pricing patterns. Process patents and price control. Process patents have now been consigned to a practice of the past and decontrol is steadily gaining ground in the pharmaceutical sector. What then is in store? That industry interests must be protected is justified. But these interests need to be balanced with adequate access to health.

However, despite Finance Minister P. Chidambaram's indication that the Government will reduce the rigours of price control, where it has become counter-effective, reducing the number of essential drugs on the DPCO will not be easy. Firstly, the United Progressive Alliance Government's National Common Minimum Programme has promised to "take all steps to ensure the availability of life-saving drugs at reasonable prices". Secondly, any move to reduce the number of drugs in the DPCO may be considered to be in contravention of the Supreme Court order. This is relating to the K.S. Gopinath case ruling on March 10, 2003, in which the Government was directed to ensure that "... essential and life-saving drugs do not fall out of price control" ¹⁹⁰

In most developed countries, the regulation of drug prices is considered necessary to contain public expenditure due to the government's role in funding social health and insurance schemes that cover hospitals and outpatient drugs. In these countries, a substantial portion of the population is covered through health insurance and public health schemes. As a result, consumers are not affected directly by the high prices of drugs or the high costs of medical services but are made to pay for the increased costs through a high insurance premium. As opposed to this, a substantial portion of the population in India is market-dependent and has to meet all their expenses on this account out of their own pocket, making price regulation of pharmaceutical products unavoidable.

¹⁹⁰ Siddarth Narrain, *A Life Saving Order*,
<http://www.flonnet.com/fl2115/stories/20040730004110300.htm>

Given the peculiarity of the health market, ensuring competition is easier said than done. The Indian pharmaceutical regulatory regime has been quite hard on the manufacturers, but has been extremely soft on the two other groups of important players: the doctors and the pharmacists. Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, have sufficient provisions to ensure good behaviour on the part of the doctors. However, it is more of a good endeavour rather than binding rules. Moreover, there is no mechanism to monitor if the doctors are following them.

One way, often suggested, of checking the rent-seeking behaviour of the doctors, as has been successfully experimented, even in neighbouring Bangladesh, is to mandate doctors to prescribe drugs with generic names. Even the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 state that, “Every physician should, as far as possible, prescribe drugs with generic names.” However, given the enormous clout of the pharmacists in India, this mandate may not work, and could even make the situation worse. What is, thus, desperately required in India, is an effective mechanism to contain the rent-seeking behaviour of the pharmacists as well.

If it is difficult to promote and maintain competition because of the peculiarity of the market, in the sense that consumers do not decide their purchases, then the same may not be true for bulk drugs. It has, in fact, been indicated previously that more archetypal competition prevails in the bulk drug industry. There is a need to study the behaviour of the bulk drug market more closely and, if desirable, to further decontrol the sector.

It is essential for the pharmaceutical sector in India, to operate under a law that curbs anti-competitive activities. Despite ubiquitous regulations, competition is not entirely excluded from this industry. Competition is the key driving force behind the development of new innovative drugs, and a significant factor in keeping down the prices and production costs of off-patent drugs. Few aspects of the pharmaceutical industry, even though highly regulated, are unaffected by regulatory controls. The MRTP Act, 1969, did not have adequate provisions to deal with a large number of anti-competitive practices, like collusion or cartelisation, mergers and acquisitions,

and abuse of intellectual property rights, which is a very common practice in the pharmaceutical industry, if viewed globally. The new Competition Act, 2002, is a much improved law, and has the required provisions, including extra territorial jurisdiction, though the provisions on IPRs is rather weak. This needs to be buttressed.

The fact that the private healthcare market that is expected to cross a turnover of US\$40bn by 2012 is completely unregulated, despite quality and standards being serious and complex issues for the industry, does not augur well. India is also keen on promoting the country as a destination for medical tourists from neighbouring countries and the West, and it is estimated, at its current pace of growth, healthcare tourism alone can bring in over US\$2bn as additional revenue by 2012. However, just a few medical accidents can frustrate this effort. Hence, the government must take the issue of regulating the healthcare industry seriously, not only to ensure quality services to its own citizen, but also to realize its ambition of becoming a global player in the field.