CHAPTER VII
Summary, Conclusion and Policy Suggestions

7.1. Summary and Conclusion

Developing countries have been caught in the trap of 'double burden' of disease. Communicable and life-style diseases, drug-resistant and emerging new diseases have thrown enormous challenges and threatens to overshadow the gains made on the health front that is taking place in few third world countries. Rapid industrialisation, unplanned urbanisation, ecological disturbance all together is intensifying health problems in these countries. Developing countries have primarily failed to address the problem of nutrition, which mainly arises out of poverty. Malnutrition actually accentuates infectious diseases that are responsible for half of developing countries' burden of disease.

The emergence of preventive vaccines and curative drugs ushered in great promise, which even created an impression of 'pill for every ill'. However, the hope of universal and comprehensive administration of drugs to the needy was stalled, as the drug sector is exposed to the vagaries of market forces. In developing countries like India, expenditure on drugs accounts for a bulk of two-thirds of total health expenditure. Of this, households out-of-pocket expenditure forms a major chunk. Moreover, with hardly any social health insurance in place, the burden entirely falls on the hapless patients.

Market failure in health sector is well documented by now. The unique features of health care market, such as, irregular and unpredictable demand, uncertain product efficacy, and supplier-induced demand coupled with typical characteristics of pharmaceutical market like concentrated oligopoly market structure, high price and excess profitability have underscored the need for policy intervention.

In view of the above, pharmaceutical industry have been subject to public scrutiny of its conduct and performance in the 1950s and 1960s both in industrialised countries and in developing economies. In India too, various policy measures, direct
and indirect instruments, such as, drug licensing, drug price control, Patents Act, 1970, all have attempted to restrain and control drug industries' role to the benefit of larger health of the masses. This thesis primarily examined the implications of such policy measures on the growth and market structure of the industry, trends in controlled and decontrolled drug price over the years, profitability of the industry, and various other aspects and its overall repercussions on the health care of the society.

Unprecedented growth of Indian indigenous sector (organised private and small scale sector and public) since the 1970s has been the hallmark which had replaced the domination of drug transnationals. As the former gained substantial control, domestic production of bulk drugs along with formulations registered significant rise, which helped to bring down imports considerably. However, in view of drastic trade policy changes, the trend in the 1990s unmistakably point to a rapidly rising trend in the ratio of imports vis-à-vis production of bulk drugs.

Tremendous growth and presence of large number of companies, however, failed to break the strong oligopoly structure of the industry. An analysis of the market by sub-therapeutic segments reveals that 2-4 major players hold substantial market share. The leading few Indian domestic firms gradually substituted drug multinationals across therapeutic class in its domination, although the latter had a clear edge in formulation market while the former in bulk drugs category. In a span of two decades, the drug industry has seen considerable structural changes. In 1976, majority of the leading companies (i.e, seven out of 10) were multinational drug corporations while in 1998, seven out of 10 top companies were domestic companies. Over 80 percent of the bulk drugs market is now under domestic sector. On the formulations category, domestic industry caters to around 63 percent of the total market while the rest is shared by foreign sector in 1998-99.

The drug industry in India is typically characterised by product competition mainly due to the oligopoly structure of the market. In addition, in view of the success that domestic industry was able to achieve in adaptive research, Indian firms were able to churn out 'new' products at a rapid pace and market it at a relatively low price.
Although firms spearhead product competition by introducing ‘new’ pills to garner new markets and to retain its existing share, only a few leading domestic and transnationals engage in such an exercise to retain their monopoly. For instance, multinational enterprises held 4-6 brands out of the leading 10 products, both in 1981 and 2000 while the rest is shared by the domestic manufacturers.

The Indian drug industry represents a classic case of a therapeutic jungle, wherein an estimated 50,000 – 60,000 formulations dot the shelves of the pharmacies. A major chunk of these medicines are irrational, non-essential and hazardous in nature. Such skewed production does not match the larger disease profile of the country. Besides structural factors, such production priorities are basically a consequence of misguided policy regime. Non-essential drugs proliferate the market because the criteria for inclusion of drugs under pricing policy relate to production monopoly and sales turnover rather than the issue of essentiality. As a direct consequence, production of essential and life-saving drugs is made least profitable and contrarily the manufacture of non-essentials is provided with maximum returns. Tragically, an essential drug list that was long overdue along with the drug policy of 1978, was adopted as late as 1996. To cap it all, by 1995, the content of the policy has been substantially watered down leaving only 50 percent of the drugs under price control net. Unfortunately, ambiguity persists among different arms of the government policy making. While strangely the Department of Chemicals and Fertiliser under Petro-Chemicals Ministry prepares drug policy whereas an Essential Drug Policy was rightly formulated by the Ministry of Health. The much-needed coordination among different ministries dealing with all drug policies, which has health implications, has been eluding.

The drug industry is one of the few industries that have been registering persistently two-digit growth since 1970s. Given the peculiar features of the market with a continuous and immediate demand for drugs, the industry is inflation-proof. This has provided the drug industry to extract abnormal profits. Despite the pharmaceutical industry’s vehement denials of high profitability, an examination of
various profitability ratios in comparison to all-industry average, during the last three decades spanning from 1970s points to a consistently high profit. A higher profitability in the industry is being justified on the ground of significant contribution towards R&D. But a casual examination of R&D expenditure among Indian companies in the 1990s point to an insignificant (1-2 percent of the sales turnover) contribution made by drug companies in India, both by subsidiaries of transnationals and private domestic players. On the contrary, higher profitability in this sector seems to have been sustained by notably tall marketing and advertising expenses ensured under a brand-name. This is mainly made possible by a high concentration of firms competing under product competition rather than price competition. Policies that attempted to place a ceiling on profitability have gradually been dismantled. The number of mark-up categories underwent complete reversal from four in 1979 to one category in 1995, with a maximum mark-up of 100 percent now.

Did price controls in the past have had any perceptible impact on drug prices? A formal price control mechanism was put into place way back in 1970s followed by a more comprehensive measure in 1979 and later in 1987 and 1995. The DPCO, 1979 brought under its net as many as 347 drugs that has ultimately been brought down to just 76 drugs in 1995. The drastic reduction in the number of drugs under price control has been the subject of controversy over the years.

To understand the implications of DPCO, this thesis attempted to analyse price trends of: i) controlled drug prices and ii) decontrolled drug prices. Drug prices, under the ambit of DPCO 1995, have either displayed downward movement or have remained constant during 1994-2000 period, across all therapeutic groups. As far as decontrolled drugs are concerned, (these decontrolled drugs were part of DPCO, 1987) considerable price rise have been registered across therapeutic segments, for the seven year period spanning 1994 through 2000. The analysis further reveals that drug price decline under controlled regime has been modest whereas drug price rise under decontrolled policy environment has been steep in many therapeutic groups.
Higher profitability in the pharmaceutical industry has been justified for its heavy reliance on R&D. In India, the robust rise of domestic industry could be traced to the strengths of reverse engineering that triggered and sustained the indigenous sector. An examination of relative research spending by multinational drug firms in the world show that in view of its strengths in basic research, it allocates nearly 15 percent of the sales turnover on R&D as against India’s one-two percent. However, process research, do not involve considerable amount of financial resources, and hence the thrust on reverse engineering by Indian companies.

The pattern of drug research spending by multinational drug corporations typically reflects the epideomologic profile of industrialised countries. For instance, of the total allocation to global research, the money spent on degenerative diseases like central nervous system, neo-plasms (cancer), endocrine system and metabolic diseases and cardiovascular drugs collectively accounted for more than half of the total research spending. In view of less purchasing power and low commercial attractiveness in third world countries, multinational corporations have generally desisted from investing on research involving infectious diseases. While most of the transnational corporations originating from developed countries have their base and operations in third world countries but seldom concentrate on drug research relating to these countries. Infectious diseases still account for half of total burden of disease in developing countries like India. It is reported that only 4.3 percent of the global drug R&D spending went into tropical diseases and a meagre 0.2 percent was devoted to research in pneumonia, diarrheal disease and T.B., which otherwise is responsible for 18 percent of global burden of disease in the mid-1990s.

On the question of what determines research effort and intensity in drug firms in India, the study analysed few important factors influencing the research intention of companies. Evidence from this study show that firm size, profitability of the enterprise, and export-orientation of the firm is positively and significantly related to R&D intensity of drug firms. The import intention of a firm is reported to be significantly but negatively associated with R&D intensity reflecting the argument that
higher the dependence of an enterprise on import, research activity tends to be lower and vice versa. However, except the variable exports, the coefficients of all other factors turned out to be very less. Interpreted, among the other things, it means that higher firm size do not appear to induce pharmaceutical enterprises in India to invest heavily in R&D. In fact the above analysis clearly rejects the contentions of current thinking that higher firm size leads to higher R&D. In effect, the inference that is drawn from the results implies that mergers & acquisitions and other mode of R&D coordination being pursued appears empirically fragile for any worthwhile R&D efficiency.

Substantial and escalating cost coupled with long gestation period involved in basic drug research were the main plank on which drug multinationals have been forcefully arguing for a strong patent policy. However, developing countries have largely refrained from adopting a strong patent system allowing wider diffusion of technology and further sought to protect the fragile food and health security of the country. The dominance of foreign patents in any third world countries is beyond any doubt. The amendment to Indian Patent Act in 1970, was essentially meant to clip the wings of foreign players. Interestingly, foreign patents witnessed erosion in its share since this amendment, from a range of 80 – 85 percent in the 1950s and 1960s to a reduced range of 60 – 70 percent during the period since 1970s till mid-1990s. But a reversal of this trend is discernible in the late 1990s, with an increase in foreign patenting activity particularly in the pharmaceutical sector, a move in anticipation of product patent regime.

Process patent provided immense opportunity to the growth of domestic industry and indirectly provided enough opportunity for consumers to avail drugs relatively at a cheaper price and at much faster pace than the pre-patent regime. The domestic industry outpaced the foreign sector both in both drugs and formulation category. The former now accounts for over 80 percent of bulk drugs and nearly two-third of the formulations market. As far as prices are concerned, a comparative cross-country analysis of price level in developing and developed countries reveal that in
countries like Pakistan, which allows product patent, certain drug price is over 25 times higher than in India. While a relative examination of drug price in India vis-à-vis U.K. and U.S. shows that in many therapeutic segments, the price is in the higher range of 40 times.

The growing body of literature invariably points to the adverse impact that product patent regime is likely to bring. Whatever success that has been achieved in terms of price, market structure, import dependence, self-reliance, etc. the impending product patent regime is likely to reverse the trend. Many studies have argued that price rise which would result due to the new patent regime can be checked by invoking price control measures, compulsory licensing and parallel import provisions of TRIPS.

If policy trends in the last decade are any indication in India, price control mechanism is being dismantled drastically over the years, virtually sealing the possibility of stemming price rise. On the issue of compulsory licensing and parallel imports, the latest controversy over anti-retroviral drugs to combat AIDS/HIV epidemics apparently demonstrates the powerful resistance of drug transnationals against liberally harnessing these provisions. Although the retreat by Western multinational drug companies appear to be temporary due to pressures from different international quarters, the retreat is also due to the fact that such provisions are being used only in health emergency situation.

The above conclusively suggest a drastic churning occurring within the drug industry over the past five decades. The changes are sweeping both in structural and policy-level. As restrictions and controls are being dismantled drastically giving way to liberalization and globalisation of the economy, a delicate sector like drugs have become more vulnerable today. And as markets inherently fail to signal social needs, the instrument of price and its functioning will undoubtedly entail distortions. This is likely to intensify further the drug divide among the society. In view of this situation, to address the problem, the following are suggested as remedies.
7.2. Policy Suggestions

The conclusion reached above calls for addressing and remedying issues which are of prime importance in the present context:

i) This thesis conclusively proves that Indian market for therapeutic categories is highly concentrated and displays all elements of oligopoly. In a country with absolutely no health security, with two-thirds of health spending under market sphere, and a bulk of drug expenditure coming from out-of-pocket expenses of households, it is imperative on the part of the government to put in place a stricter and a transparent anti-competitive policies to curb such oligopoly practices in drugs sector;

ii) The practices adopted by multinational drug corporations are by now well-documented in the literature. All efforts need to be put in place to resist and reassess the strategy of allowing 100 equity to transnational corporations to set-up wholly-owned subsidiaries;

iii) A growing volume of literature on price control policies in India in particular and in other developing and rich industrialised world apparently shows that it has relatively worked effectively in curbing excessive price rise. In a world where market forces are gaining currency and the global finance capital is tightening its noose around the poor third world countries, a simple but a stricter price control regime is the need of the hour. An unanimous evidence from examination of repercussions of patent policy change reveals that drug prices would sky-rocket in future. The importance of price control measure, therefore, assumes an added significance in view of changes that are being brought in under the erstwhile patent regime.

iv) An area of complete neglect in drug research is on killer diseases that afflict the poor developing economies. The multinational drug corporations have consistently neglected and failed to even allocate a marginal share of their profit appropriated from the soils of third world countries on drug research of tropical diseases. It is in this context countries like India must lead from the
front in demonstrating to the world of the necessity to innovate drugs that are required by the masses. Public funding must be mobilised and increased adequately to focus on diseases like malaria, T.B., cholera, etc. Any drug that are innovated successfully must be provided with facilities to develop and market such drugs at minimal prices both in India and other poor developing countries whose purchasing power is low.

5) As has been repeatedly pointed out earlier, the growing body of literature is evident enough to show that a strong patent policy is likely to push drug price manifold, an adverse transformation on the market structure for drugs in favour of multinationals, not so promising future on R & D front involving diseases of tropical world and consequently a significant net welfare loss to the consumers and society at large. Besides literature, ground level scenario is more murkier than what it was promised earlier. Recent controversy surrounding triple antiretroviral AIDS cocktail in South Africa is a grim reminder of things shaping post-patent regime. The South African government was reportedly taken to court by 40-odd drug transnational corporation for allegedly 'violating' patent regime by seeking to import cheap AIDS drugs from India. Cipla, India’s offer to market AIDS drugs in South Africa for around US $ 350 a year per patient against multinationals price of around US $ 10,000 per patient annually came as a rude shock to the latter in view of losing share in the market and a beating that it would take in its bottomline. But ultimately, pressures from different quarters and a growing international displeasure at the strategies of transnationals finally saw them to retreat temporarily. Since the drug under consideration is made out to be significantly important in view of the magnitude of the problem of AIDS, the present tactical retreat by the multinationals. However, one must remind that there are equally more dangerous and killer diseases like malaria, T.B., cholera, etc., which are extremely requiring to be addressed by life-saving drugs.
India therefore must coordinate with other similar countries to push for the review of strong patent policy under the present TRIPS. Meanwhile, countries which have already put in place a strong patent regime or are contemplating to change their existing patent regimes like India must seriously consider and adopt measures in the amendment. It must necessarily contain a compulsory licensing provision to enable diffusion of innovation to the benefit of larger wealth and health of the nations. Working of patents must be made mandatory so that reckless drug import can be checked.