CHAPTER II

GOVERNMENT'S POLICY AND TECHNOLOGY ACQUISITION IN THE PHARMACEUTICAL INDUSTRY

In the previous chapter we have shown how the industrial policy in general and science and technology policy in particular had played a crucial role in determining the technological effort in the pharmaceutical industry in India. We have also shown the evolution and the transformation of Indian policy in regulating the technology generation and acquisition through various periods starting from 1947 until 2002. In this chapter we bring out the main features of drug and pharmaceutical policies.

II.1 GOVERNMENT’S POLICY TOWARDS THE DRUG INDUSTRY

The Indian pharmaceutical industry was under the supervision of Department of Chemicals and Fertilizers in the Ministry of Industrial Development, until recently. Now it is under the purview of Ministry of Petroleum, Chemicals and Fertilizers.

Whilst the general guidelines set in the various industrial policies used to govern the overall approach towards the pharmaceutical industry the specific problems were tackled on a legal rather than the policy plane. The Indian government had adopted from the British, the Drugs and Cosmetics Act of 1940 and amended it at regular intervals. This act governed the manufacture, sale and distribution of various drug products used in the Allopathic, Ayurvedic and Unani systems of medicine practiced in India. The Drugs and Cosmetics Act of 1940 was first amended in 1955 as Drugs (Amendment) Act followed by further amendments in 1960 and in 1962. This Act was replaced by the Drugs and Cosmetics (Amendment) Act of 1964 with subsequent additions in
1972 and in 1979. The Act entrusted the government with the power to prevent the emergence of spurious drugs, to maintain quality in production and to provide for the import of drugs wherever necessary. The prices of drugs were however controlled from time to time by the promulgation of various statutory orders. The first such order was the Drugs (Display of Prices) Order in 1962 and later the Drugs (Control of Prices) Order in 1963 that were promulgated under the Defence of India Act. However, their impact was minimal in arresting the upward trend in prices, which continued to rise despite the statutory measures. The drug price index calculated on the basis of the prices of a static group of drugs had risen by 41.9 points by 1970-71 with 1961-62 as base. A Tariff Commission study was also conducted during 1965-66 to determine the prices of 18 basic drugs and their 69 formulations, which led to the announcement of Drugs (Prices Control) Order in 1970 later. Strangely, the DPCO appears to have had no adequate impact and the highest annual increase of 12 points occurred in 1970-71 with the declaration of DPCO. The drug prices were regulated under DPCO 1970 until it was replaced by a new order in March 1979, which was the result of the New Drug Policy in 1978.

The questions concerning joint-ventures, technological collaborations and foreign participation in the pharmaceutical industry were more or less governed by the general guidelines set by the Reserve Bank of India and later on by the Foreign Exchange Regulations Act.

The Hathi Committee, which went into various questions concerning the drugs and pharmaceuticals industry, submitted its voluminous report to the government in April 1975. It took almost three

4 P. S. Agarwal et al., ibid.
years for the government to come out with a clear and coherent policy on drugs, which apparently incorporated the Hathi Committee recommendations into it.

II.2  NEW DRUG POLICY OF 1978

A comprehensive drug policy based on the recommendations of the Hathi Committee was announced by the government in March 1978, followed by Drug (Prices Control) Order of 1979 in place of the old Drug Prices (Display and Control) Order of 1969. The major objectives of these policy measure were to develop self-reliance in the drug industry, accord leadership role to the public sector, encourage the growth of Indian sector and ensure availability of drugs in abundance at reasonable prices.\(^5\) Promotion of self-reliance in drug technology through adequate efforts in research and development (R&D) by providing special incentives to those firms, which undertake it, formed another major plank of the new drug policy.\(^6\) Since, this policy was based on the recommendation of the Hathi Committee, it certainly reflected a progressive bias in favour of the national sector; it also reflected priorities of planned industrialization for self sustained economy. As regards the execution of the policy, it was found that most of the provisions were either not fully implemented or were not adequate for effective achievement of intended objectives in terms of reducing foreign control, developing indigenous technologies and increasing production.\(^7\)

The new policy, however, was able to restrict the expansion of the foreign sector; it encouraged the national sector to grow and helped the public sector establish pre-eminence over other sectors at least in the sphere of bulk drug production. This certainly was not in the required magnitude and measure. The government is on record that it was not

\(^6\) Ibid.
\(^7\) For a detailed discussion about various aspects of NDP and its implementation particularly with regard to production, pricing and technology in the drug industry, see J. Manohar Rao, op.cit.
able to implement fully the drug policy of 1978 for “lack of power under the Industries (Development and Regulation) Act, 1951” and certain “practical problems” experienced during the implementation.  

It is interesting to note that the government has advanced the logic of inadequacy of powers in the I(DR) Act as a basis for impending modification and reorganization of the Drug Policy of 1978. Simple logic demands that immediate steps should have been taken to rectify the deficiencies in the existing I(DR) Act, even though it remains a puzzle why it should have taken four decades for the government to realize the inadequacies in that Act. However, the reorganized drug policy of 1986 with amended clauses, and without any modification in the existing I(DR)Act is less than likely to yield positive results.

Reorganization of the Drug Policy of 1978 did take place, however; it was replaced by a new policy formulated in March, 1986. This was followed closely by the announcement of an amended Drug (Prices Control) order in 1987, which was expected to generate ‘buoyancy’ in the pharmaceutical capital market. All these developments can be viewed as a part of the general liberalization of the economy resorted to by the government. The drug industry and the drug policy had to undergo the same kind of changes, as did the economy at large. It is unlikely that this sector would have remained insulated from the macro-policy changes that occurred the quinquennium 1980-85.

The Drug Policy of 1986 set a larger agenda for the free flow of foreign investment, and technology, coupled with delicensing, broad banding and relaxation in pricing procedures, under the rubric of

---

8 Answer to Rajya Sabha Question NO.2 by the Minister of Industry dated 18 November 1985, *Rajya Sabha Debates*, November-December, 1985, Lok Sabha Secretariat.

9 The statement of the Minister of Industry (in foot note 48) asserts the need to reorient the drug policy although it contained a “large number of positive aspects” (emphasis added).
'rationalisation', The hitherto existing norms in the case of bulk-drug production by the FERA companies had been modified.

The so called 'ratio parameter', which means the ratio between the value of production of bulk drugs to that of formulations was reduced from 1:5 to 1:4. The scheme of delicensing had already been extended to 34 bulk drugs, along with broad banding of 31 groups of bulk drugs. A good deal of optimism was expressed in the policy that delicensing would give impetus to indigenous R&D, though "import of know-how would continue to be favourably considered on merits".

The new policy had evoked large-scale enthusiasm from the industry, particularly, the organised and foreign sectors. This had to do mainly with the delicensing of 94 bulk drugs (together with their formulations) and some intermediates earlier in 1985. Excitement among those quarters could also be due to measures like broad-bandning of bulk drugs and formulations, minimum economies of scales of operations, dereservation of penicillin from public sector and so on. The larger firms also saw the DPCO of 1987 as a boon. Small-scale sector, which was hitherto forbidden for the firms of foreign lineages, had been opened up and equity participation had also been allowed. In the new scheme a multi-ingredient drug would be out of purview of DPCO, if produced under generic name; thus the therapeutic dominance and "essentiality criterion" as suggested by the Hathi Committee were to be ignored. Present policy makers have abandoned a very innovative

10 Ministry of Petroleum, Chemicals and Fertilizers, Drug Policy 1986: Measures for Rationalization, Quality, Control and Growth of Drugs & Pharmaceutical Industry in India, Government of India, New Delhi, 1986. It is interesting to observe that in the history of policy the term 'rationalisation' had peculiar connotation. For example, in production it amounted to dereservation of items specifically meant for small-scale sector, in licensing it would imply deregulation of capacities and this list can expand. On the whole, it appears, 'rationalisation' has been employed as a cover, for whenever a massive liberalization programme is undertaken.

11 Ibid.

12 Ibid. para 6.12.

concept—"leader price" – developed by the Hathi Committee and included in the Drug Policy of 1978 and DPCO of 1979. It is substituted by what is known as “Maximum Allowable Post-Manufacturing Expenses” (MAPE) for fixing up drug prices; this is put at 75% and 100% for Category-I and Category-II formulations respectively. It is argued that these measures would lead to higher productivity levels, greater profitability and sufficient availability of medicines at reasonable prices. Strangely enough, the policy makers representing larger public interests and private interests in the industry, both argued in unison that the Drug Policy of 1978 and DPCO 1979 with their ‘rigid controls’ were not capable of generating further growth in the industry, which necessitated an immediate revision. It is interesting to see that the government itself had backed out on their previous policy proclamations;\(^\text{14}\) possibly this became the justifying basis of revision of both the drug policy and the price control order.

Often, it is argued, that the drug industry could not attract sufficient amount of capital investments into it in the post-1978 drug – policy period thereby causing sluggishness in the growth of the industry. The fact that capital investments in the drug industry had increased by 170 percent from Rs.500crores in 1979 to Rs.850crores in 1987 shall prove to the contrary. This might not have been a sufficient amount when compared to the tasks that were lying ahead. But by no account it can be dismissed as a meagre magnitude. Further, the rate of growth of capital investments in the post-1978 period was reasonably on the higher side as compared to pre-1978.

The questions that were examined by the Hathi Committee during 1975 seem to have come back once again with greater vigour than before.

\(^{14}\text{Author's discussions with certain members of Kelkar Committee-which are responsible for the formulation of DPCO 1987, had confirmed the retracting attitude of the policy makers on the previously declared objectives. Also see, answer to Q.No. 2 of Rajya Sabha, Op.cit.} \)
Nevertheless, the policy makers, however, were optimistic on two counts; (a) the new policy was capable of generating scale economies through a general liberalization programme; and (b) the new policy was capable of strengthening efficiency through generation of new technologies by collaborative agreements with foreign participants in the production process.

II.3 DRUG POLICY OF 1986

As we have discussed in the previous section, the 1978 drug policy, which was known by the name New Drug Policy, though it was the first ever systematized Drug Policy in India, was more or less the reflection of the nationalist endeavour towards a self-reliant Indian pharmaceutical industry contemplated by the Jaisukhlal Hathi Committee Report of 1975. Replacement of 1978 Drug Policy by the Drug Policy of 1986 and as also the replacement of the DPCO of 1979 by the DPCO of 1987 marked a substantial transformation of the Indian drug and pharmaceutical industry; it meant giving up the path of self-reliance and moving towards 'opening-up', which was representative of the emerging mood of the time. When the general industrial scenario moves in a particular direction, the pharmaceutical industry cannot remain an exception. In the pharmaceutical industry the move from sub-period-3* (dirigisme in retreat) to sub-period-4 (dirigisme under siege by WTO), which we have mentioned in the previous chapter, was not as smooth as might have been expected; it had to wade through the bumpy and inhospitable terrain of organised protests from the elected people's representatives, active intellectual groups concerned with public health policies, NGOs and so on. Hence, at each stage the government had to resort to the erection certain defensive statutory structures, which would rationalize its prospective agenda of fully liberalizing the pharmaceutical industry. One such attempt, before launching the a revised Drug Policy in 1994, and replacing the DPCO of 1987 by DPCO 1995, both of which
are in current operation, was to place a paper on the Table in Parliament on 12th August 1992 by Chinta Mohan, the then Minister of State for Chemicals and Fertilizers, which supervises the functioning of the pharmaceutical industry. It is very interesting to note that the paper, entitled “Background Note on Review of Drug Policy, 1986”, issued by the government of India, Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, gives a graphic description of how the government laboured hard to justify its position to change from the philosophy of self-reliance to the logic of liberalisation.

In fact the title of the Drug Policy of 1986 itself was peculiarly apologetic using euphemisms to carve the shift towards a liberalisation programme. The title was: “Measures for Rationalisation, Quality Control and Growth of Drugs and Pharmaceuticals Industry in India”, which we have already discussed at length in the previous section. Without denying or contradicting the objectives laid down either in the Drug Policy of 1978 or in the Drug Policy of 1986, the Review Paper (RP) of 1992 proposed to revise the provisions in industrial licensing, foreign investment, so that there is some consonance with the Industrial Policy of July 1991. In other words, the RP suggested a substantial broad banding of the products and further delicensing of the drug products reserved for the public sector. As a part of the modified Trade Policy and Fiscal Policy under the new EXIM Policy of 1992-97, “any item can be imported without any restriction”, since the actual user's condition is also removed, except for a few items placed under negative list. To bring the Drug Policy in consonance with the spirit and philosophy of the Industrial Policy of 1991, it was stated in the RP, that the Industrial Licensing be abolished forthwith, and the stipulation of mandatory
supply of a percentage of bulk-drug production to non-associated formulators be done away with.\textsuperscript{15}

Now the provision in RP, which later would grow into a statute in the Drug Policy of 1994 of doing away with the clause of non-associated formulators had been a big blow to the national (Indian) sector of the pharmaceutical industry and more particularly to the small scale sector.\textsuperscript{16}

In the RP another proposal relates to removal of the provision regarding ‘ratio parameter’ linking bulk drugs to formulations. Again this is also an anti-Hathi Committee recommendation aimed at strengthening the large companies in general and the foreign firms in particular.

As regards the liberalisation towards foreign participation RP is an intermediary stage, with suggestion for 51 percent automatic approval of FDI, which later to become 71 percent automatic approval and where necessary 100 percent automatic participation.

\textbf{II.4 DRUG POLICY OF 1994}

The major contents of the Review Paper of 1992 were verbatim retained in the Drug Policy-1994, which was announced by the

\textsuperscript{15} The Hathi Committee had recommended in its Report, that the foreign companies should provide 50 percent of their total bulk-drug production to \textit{non-associated Indian formulators} (emphasis mine). But the New Drug Policy of 1978 made a provision for bulk-drug production to be given to \textit{any non-associated formulator} (emphasis mine). This itself we argued at the time, was an anomaly which would invariably result in one foreign company giving material to another foreign company, nullifying the intended objective of the provision. See, J. Manohar Rao, (1981), Op.cit. Chap.II.

\textsuperscript{16} The letter by the then President of All India Small Scale Bulk Drugs Manufacturers Association (AISSBDMA), V. U. Shah, to the Members of Parliament is a proof of this development. It reads: “We are deeply disturbed and shocked to learn that the multinational companies and some of the Indian companies of the organised sector have made a joint representation on the proposed new drug policy which if implemented will prove detrimental to the growth of SSI units. If under the pretext of leader price concept the SSI sector is brought under price control it would destroy the Small Scale Industry and over 8000 small units would be rendered sick and over 3,25, 000 work force skilled and semi-skilled could be out of jobs creating mass unemployment.” Vinoobhai U. Shah, “New Drug Policy: Some Considerations”, Letter submitted to Members of Parliament, reprinted in \textit{The Eastern Pharmacist}, April 1993, pp.39-41.

The Drug Policy-1994 reiterated the objectives mentioned in the Drug Policy of 1986. Since, we had not made a mention of these objectives in the discussion before, it is in order to present them now:

a) Ensuring abundant availability at reasonable prices of essential and life-saving and prophylactic medicines of good quality;
b) Strengthening the system of quality control over drug production and promoting the rational use of drugs in the country;
c) Creating an environment conducive to channelising new investments into pharmaceutical industry to encouraging cost effective production with economic sizes and to introducing new technologies and new drugs; and
d) Strengthening the indigenous capability for production of drugs. 17

It is also acknowledged therein, that to make available drugs at reasonable prices and to strengthen the indigenous base, the government has over the years been guided by I (D&R), Industrial Licensing Policy, the DPCOs and so on (which we discussed at length) but no where does it mention either one or all the policies were responsible either directly or indirectly in stalling the progress of the pharmaceutical industry in India. In fact, one of the major allegations levelled by the US multinationals led by organisations such as PhRMA and IFPMA, against the Indian Pharmaceutical industry is that the controls and the protectionist regime along with the IPA 1970 were responsible for such stupendous growth recorded over the years. Without pointing out the flaws in the existing system, the government wants to execute the modifications, just to bring "Drug Policy in consonance with the spirit

and philosophy of the New Industrial Policy”; this change without any justification appears quite illogical.


They are:

a) A new drug which has not been produced elsewhere if developed through indigenous R & D would be put outside price control for a period of 10 years from the date of commercial production in favour of the company who undertook R & D (sic).

b) A bulk drug introduced in the country for the first time would not be brought under price control for a period of three years from the date of its commercial production.

c) Ministry of Finance would set up an Inter-Ministerial Group to consider the following suggestions.

1. incentives and tax benefits offered earlier by the Government on authentic R & D investments and expenditure be reintroduced. [e.g. 100 to 133 percent tax exemption under section 35 (1) (c) of the Income Tax Act.]

2. All government approved and recognised laboratories be treated at par with Universities/National Research Centres for the purpose of exemption from customs duty on imports of capital equipments, chemicals and necessary spares.

70
3. Alternatively, the duty shall be reduced significantly to say 15% *ad valorem*.

4. New Drugs discovered and produced indigenously be exempted from excise duty.

5. For basic manufactures the basic imported materials should attract customs duty as compared to finished or semi-finished products.

6. A scheme of soft loans be evolved by the Government Financial Institutions for capital expenditure for setting up R & D facilities and for running them as well as for setting up hi-tech manufacturing units based on indigenous development.

d) The required procedures and steps for quick evaluation and clearance of new drug applications especially those developed through indigenous R & D would be streamlined.\(^{18}\)

To the above, a new sentence has been added in the Drug Policy-1994, which is as follows:

"However, in view of GATT accord and impending changes in patent laws the subject matter of Basic Research in drug sector has assumed greater importance and needs to be attended to on urgent basis."\(^{19}\)

As can be seen clearly the RP-1992 and the subsequent DP-1994 are documents full of contradictions. Probably there is some kind of confusion in the minds of those who drafted these documents, in


administering a switchover from long standing philosophy that governed the industry for more than four decades to a new found panacea in the post-1991 economic reform agenda. Or it could be that the government itself had been trapped in to the quagmire of “running with the hare and hunting with the dog”. The complete self-sufficiency in the production of bulk drugs and formulations, and a clear competitive edge in pricing of the products in the global pharmaceutical market which provides the indigenous firms substantial export potential has to be given due importance by the present policy, which it does. However, there is this hope that there could be greater access to markets across the globe as a part of the WTO agreement, which is not supported by evidence.

As can also be seen in RP-1992, most of the clauses smack of redundancy and *fait accompli*; for example, clauses (a) and (b) talk of providing incentives to firms making R & D efforts in terms of placing them outside price controls. In a largely generalized liberalisation programme, which is on the anvil, there is likely to be a general reprieve from price controls in the long run in any case. In certain drugs where already broad banding is allowed the clause becomes irrelevant altogether.

The acceleration of the pace of economic reforms can be seen from 1996 onwards, as a part of the TRIPS Agreement and India joining the WTO. Most of the measures in the post-1995 scenario were initiated either for compliance with the WTO norms or to “convince the world that India has come out of the protectionist regime and is ready to welcome FDI without any restrictions in all spheres”. The steps initiated towards revocation of customs duty of 5 % from 28th February 1999, and abolition of special customs duty was in the same direction. The automatic approval of FDI up to 74%, and on selective basis up to 100% in the pharmaceutical industry has been hailed as decisions that would

---

speed up growth of innovation and expansion in the industry. The decision to allow weighted tax deduction up to 125% on R & D until March 31, 2005 is being welcomed by the large firms in the industry and particularly by the foreign MNCs and their affiliates.  

II.5 THE POST-WTO PRICING POLICY

The pricing policy for the drugs and pharmaceutical industry in the WTO era can be seen to emanate from both the Drug Policy-1994, which is based on RP-1992, and the Drugs (Price Control) Order 1995.

As we have noted earlier, pricing in the pharmaceutical industry has been fraught with controversy and vacillation on the part of the government when faced with the contradictions between its commitment to the welfare of consumers (in this case disease-ridden, suffering public) and the demands raised by the large drug firms belonging to the organised sector, particularly those of the MNCs. The *raison d'etre* of price control order of 1969 could be traced to unethical pricing practices of drug firms during 1960-65 period. In fact, the prices of drug products during 1967 reached a record high and the only reasonable step the government could initiate in order to protect interests of the hapless diseased population was to announce the first ever price control order in the drug industry, the Drug Prices (Display and Control) Order of 1969. A systematic streamlining with scientific methods was possible only after some of the Hathi Committee recommendations were incorporated and DPCO-1979 was announced.

While the Drug Policy-1978 and DPCO-1979 represented a move towards self-sufficiency and an endeavour of the government to make drugs available in sufficient quantities to large masses at reasonable prices, the other policies which emerged later had attempted

---

21 OPPI Vice-Chairman (Pricing & taxation), Keval Handa said: "This is the first time that the government has looked at the pharmaceutical industry as knowledge based industry and not merely as manufacturers of tablets and capsules. They have also realised the need to do away with regulations and focus on development". In *Chemical Business*, April 1999, Vol. 33 (4), pp.65-73.
progressively to dilute the provisions embedded in DP-1978 and DPCO-1979, and replace them with regressive measures from the point of view of consumer welfare and domestic self-sufficiency. For example, the DP-1994 quoted the objectives laid in the DP-1986 and endorsed the fact that those "objectives are relevant today". These objectives were:

a) To stimulate production of drugs and formulations which are essential to the needs of large majority of the people of the country;

b) To make the price control system less cumbersome but more effective, by reducing the span of control;

c) To ensure a reasonable return to the producers of essential drugs, while at the same time restricting undue increase in their price."

The DPCO-1979 consisted of four categories of formulations all of which make use of the bulk drugs listed under different schedules, which come under the purview of price control. The pricing of formulations in categories I and II were worked out on the basis of 'therapeutic equivalence' of product groups, which claimed to utilize the 'leader product' concept suggested by the Hathi Committee. In Category III formulations, individual pricing for each product was adopted; and in certain cases 'leader price' method was applied, too. There was no 'mark up' for Category IV formulations since they were treated as 'no price control' category. Though the intended objectives of the Hathi Committee Report (HCR) were not completely captured in the DPCO-1979, the overall philosophy of self-reliance reflective of the period.

23 Ibid.
24 The criterion of identifying a 'leader product' was on the basis of 60 percent of sales, of a product in a specific therapeutic group, accounted between different manufacturers. Maximum prices could be prescribed on that basis and price range should be within that ceiling. Government of India, Hathi Committee Report 1975, Ch. VIII, paras 36 and 37. The concept of 'leader product' and leader price' was partially adhered to and in certain cases distorted in the DPCO-1979 itself. However, on the whole the DPCO-1979 could uphold the spirit of HCR.
suggested by the HCR was almost visible in it. It must be kept in mind that the fundamental principle of making life-saving drugs available to the larger masses rests on the concept of "essential drugs", which was introduced by the World Health Organisation (WHO) way back in 1975. The HCR made a serious reference to the essentiality criterion and drew a list of 117 essential drugs on the lines of the WHO. This was in the year 1975 itself. The current list of essential drugs drawn by the WHO has increased up to 350. Since the level of drug prices determines the access to medicines of millions of people the world over, the WHO keeps monitoring essential drugs, and their supply, pricing and distribution. The post-WTO situation indicates that access to essential medicines had reached an abysmally pathetic nadir. So much so that academics, social activists, public health advocates, government officials and politicians from Africa, Asia, South and North America, Australia and Europe, met in Oslo on 22-24 May 2000 at a Workshop entitled 'Patent Rights Vs Patient Rights' to discuss access to essential drugs, including treatment for AIDS. They issued a statement, a part of which, we reproduce below:

"We noted that the public's undoubted right to health, as set out in the Constitution of the WHO, brings with it a need and right to have access to medicines.... Price is the major obstacle for access to many essential drugs since most drugs are priced far beyond the means of individuals or even of governments in developing countries. This results in a global tragedy marked by avoidable ill health and deaths on a large scale".

Viewed from the angle presented above, counterfactually the HCR recommendations seem to be valid even in the present context of post-TRIPS and post-WTO scenario. Whereas, the government of India in its

---

26 The International Workshop on "Patent Rights Vs Patient Rights", jointly organized by the University of Bergen and University of Tromso, Medicins Sans Frontiers (Doctors without Borders) and Diakonhjemmet International Centre, Oslo, Norway, August-September 2000.
DPCO-1987 chose to prune down the list of price controlled drugs and reduced the categories from four to two.

Drugs under category-I are those required for National Health programmes and the Department of Chemicals and Petrochemicals prepared the list in consultation with the Ministry of Health. Drugs under Category-II consist of other essential drugs, which were identified by Kelkar Committee\textsuperscript{27} from a basket of 418 drugs by applying what they called 'exclusion criteria'.

The criteria included drugs with negligible consumption levels, new drugs for which processes were developed locally, drugs whose supply is more important than the price, and drugs with adequate market competition. On this basis, 143 drugs were brought under price control in 1987, which over a period of time has further declined.

The major modifications, which were brought about and included in the DPCO-1995, can be summed up as follows:

I. Single list of price control drugs, in place of multiple Categories of drug formulations which was in use until the DPCO 1979 and was pruned down by the DPCO 1987, with the Maximum Allowable Post-Manufacturing Expenses (MAPE) of 100 percent.

II. Minimum turnover criterion (in the vicinity of Rs.4 crores per annum) for inclusion of drugs under price control.

III. Drugs with even lesser turnover than the minimum prescribed (Rs.4 crores) in whose cases there is a monopoly situation could also be kept under price control.

IV. Ceiling prices would be fixed for commonly marketed standard pack sizes of price controlled formulations and it

\textsuperscript{27} The present researcher had extensive discussions with certain members of the Kelkar Committee over three sittings, during 1989-91, the recordings of which are in our possession. There were two members who had strong reservations from within the group about changing to new system of categorization. However, about MAPE, there was some kind of unanimity, since the Committee felt that MAPE was an innovation of sorts.
would be obligatory for all including small scale units to follow the prices so fixed.28

V. Price fixation and other related matters were entrusted to a new body, as a result of which the National Pharmaceutical Pricing Authority (NPPA) was set up.

It is also important to take note of the way a retail price is calculated under DPCO-1995, since it has serious implications for the common consumers. The Government according to the formula given below shall calculate the retail price of a formulation:

\[
R.P. = (MC + CC + PM + PC) \times (1 + \frac{MAPE}{100}) + ED
\]

Where RP-retail price; MC-material cost, and includes the cost of drugs and other pharmaceutical aids used including 'overages',29 if any plus process loss thereon specified as a norm from time to time by notification in the official Gazette; CC- conversion cost worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette; PM-cost of the packing material used in the packing of concerned formulation, including

28 The 'ceiling price' of DP-1994 and DPCO-1995 has nothing to do with the 'leader price' of DP-1978 and DPCO-1979, and in fact in DPCO-1995 it is a total detour from the charted course proposed by the HCR. In fact, this is the aspect (ceiling price) on which Vinoobhai Shah, the then President of AISSDDMA expressed strong displeasure about in his letter to the Members of Parliament. It read: "We are deeply disturbed and shocked to learn that the multinational companies and some of the Indian companies of the organized sector have made a joint representation on the proposed new drug policy which if implemented will prove detrimental to the growth of SSI units. If under pretext of leader price concept the SSI sector is brought under price control it would destroy the small scale industry and over 8000 small units would be rendered sick and over 3,25,000 work force skilled and semi-skilled could be out of jobs creating mass unemployment." Vinoobhai U. Shah, "New Drug Policy: Some Considerations", Letter submitted to the Members of Parliament, reprinted in The Eastern Pharmacist, April 1993, pp. 39-41.

29 This term is used by the Department of Drugs and Pharmaceuticals under the Ministry of Petroleum and Chemicals to represent marginal cost over runs due to lapse in time.
process loss, and shall be fixed as a norm every year by notification in the Official Gazette; PC-packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette; MAPE-Maximum Allowable Post Manufacturing Expenses, which includes all costs incurred by a manufacture from the stage of ex-factory cost to retailing and includes trade margin and margin for the manufacture and it shall not exceed one hundred percent for indigenously manufactured scheduled formulations; ED-excise duty.

In case of imported formulations the landed cost shall be the basis of fixing price, which shall not exceed fifty percent of the landed cost and wherein, landed cost includes customs duty and clearing charges.

The problem with the above formula is that if there is an increase in any one of the components of RP, namely, either MC, CC, PM, or PC by a single unit then the drug firms are allowed to charge twice that amount. That is

\[
R.P. = (MC + CC + PM + PC)(1 + \frac{MAPE}{100}) + ED
\]

\[
R.P. = (MC + CC + PM + PC)(X2) + [ED]
\]

II.6 IMPLICATIONS OF THE WTO ON PHARMACEUTICAL PRICING IN INDIA

The implications of TRIPS Agreement on pharmaceutical patents in the post-WTO order will have direct bearing on first, the pricing of drug products and second on the access to essential medicines and their supply. The effects on technology generation, innovation capabilities and R & D are primarily the 'long-run effects' whereas the 'short-run' and immediate effects are the prices and availability of drugs as described above which have tremendous impact on the developing countries, and more specifically the least developed countries belonging to sub-Saharan
Africa. Countries like Ghana, Thailand and so on which are afflicted with the scourge of 21st century, AIDS, are in dire straits without proper supply of anti-HIV drugs in adequate quantities at reasonable prices. In fact it is shown that some of the top research based pharmaceutical MNCs of the world have been playing havoc with the lives of the poor and suffering, living in those countries, by wrongly invoking the patent clause, when they do not have any. Dr. Bernard Pecoul, who was the Executive Director of Medicins Sans Frontiers (Doctors Without Borders) from 1991 to 1998 and is currently the head of the organization’s Access to Essential Drugs Project, illustrates a case where one of top most MNCs of the world tries to hoodwink the government and public in Ghana in the name of ownership of a particular patent, whereas in reality it did not own any patent. The compelling example is that of pharmaceutical giant Glaxo Wellcome PLC. In Ghana, it successfully blocked access to less costly generic versions of its top selling anti-retroviral medicine.30 In the year 2000, Health-care Ltd., a pharmaceutical distributor in Accra, Ghana, purchased a small consignment of Duovir, Indian generic manufacturer Cipla’s version of Glaxo’s Combivir. Soon afterward, Glaxo sent letters to Cipla and Healthcare charging, “importation of Duovir into Ghana by Cipla or its affiliates represents an infringement of our company’s exclusive patent rights”. As a result Cipla stopped selling Duovir in Ghana even though officials at the multilateral African agency that issued the Glaxo patents in question stated that they were invalid in Ghana. A few months later, Glaxo finally acknowledged the “mistake”, blaming it on an “overzealous official”.31

Leaving aside the individual cases, there is a good deal of evidence to suggest that prices of pharmaceutical products, indeed have risen in the developing countries in the WTO aftermath. In mid-1999,

---

30 Anti-retrovirals are used in the treatment of AIDS affected patients.
Consumers International and Health Action International (CI/HAI) conducted a survey on the retail prices of 16 drugs in 36 countries. The objectives of the survey were to: (a) study the impact of pharmaceutical patents on the availability and price of essential drugs, and (b) suggest solutions to ensure regular access to essential drugs in developing countries.

### TABLE II.1

**COMPARISON OF THE LOWEST AND HIGHEST RETAIL PRICES IN US $ OF 100 UNITS OF NINE ORIGINATOR'S PROPRIETARY BRANDS OF EIGHT DRUGS IN DEVELOPING COUNTRIES**

<table>
<thead>
<tr>
<th>Generic of Name of drug</th>
<th>Originator Proprietary Name</th>
<th>Retail Price of 100 units (US$)</th>
<th>Ratio of Lowest to Highest Price</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Country</td>
<td>Price</td>
<td>Country</td>
</tr>
<tr>
<td>Acyclovir 200mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acyclovir 800mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atenolol 25 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ciprofloxacin 500mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diclofenac 50mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nifedipine 20gm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Omeprazole 20mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ranitidine 150mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zidovudine 100mg</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Acyclovir Glaxo-Wellcome/ Zovirax | Togo | 50 | Indonesia | 371 | 1:7 |
| Acyclovir Glaxo-Wellcome/ Zovirax | India | 94 | S. Africa | 790 | 1:8 |
| Atenolol 25 mg Zeneca/Tenormin | India | 03 | Cameroon | 53 | 1:18 |
| Ciprofloxacin 500mg Bayer/Ciproxin | India | 15 | Mozambique | 740 | 1:49 |
| Diclofenac 50mg Novartis/Voltaren | India | 02 | Argentina | 118 | 1:59 |
| Nifedipine 20gm Seneca/Adalat | India | 03 | Peru | 96 | 1:32 |
| Omeprazole 20mg Astra/Losec | Zambia | 30 | Brazil | 477 | 1:11 |
| Ranitidine 150mg Glaxo-Wellcome/Zantac | India | 02 | S. Africa | 116 | 1:58 |
| Zidovudine 100mg Glaxo-Wellcome/Retrovir | Pakistan | 81 | Argentina | 316 | 1:4 |

**Source:** K.Bala and K. Sagoo, op.cit.
countries in a globalised economy with tighter intellectual property system.\textsuperscript{32}

The results and data analysis revealed that the drug MNCs market their proprietary brands at widely different prices in different developing countries. Table II.1 gives a comparison of retail prices of nine originator's proprietary brands of eight drugs sold in developing countries. There are wide variations in retail prices between countries ranging from 1:4 to 1:59. Of all the 36 countries India has recorded the lowest prices for six out of the nine dosage forms.

The retail prices of generic equivalents do not show the very wide variations seen in proprietary drugs, as shown in Table II.2. This table shows the range and ratios of the retail prices of three originators' proprietary drugs and their generic equivalent in developing countries. The range is given in the table II.2 below.

\begin{table}[h]
\centering
\begin{tabular}{|l|c|c|c|c|}
\hline
\textbf{Generic Name & Strength} & \textbf{Generic Drugs} & \textbf{Proprietary Drugs} \\
\hline
 & \textbf{Range of Prices} & \textbf{Ratio of Lowest to Highest} & \textbf{Range of prices} & \textbf{Ratio of Lowest to Highest} \\
\hline
Atenolol 100mg & 4 – 27 & 1:27 & 7 – 109 & 1:16 \\
\hline
Diclofenac 50 mg & 2 – 23 & 1:12 & 2 – 118 & 1:59 \\
\hline
Ranitidine 150mg & 2 – 35 & 1:18 & 2 – 116 & 1:58 \\
\hline
\end{tabular}
\caption{The Range and Ratio of the Retail Prices of the Originators' Proprietary Brands and the Generic Equivalents}
\end{table}


The very wide variations in retail prices among developing countries are not seen in the OECD countries. In fact, the retail prices of multi-source drugs show that price competition has enabled competing firms to put into the market their drugs at lower prices. The competition is intense in some developing countries like India, due to availability of cheaper generic substitutes in those countries. The above study points to some instructive inferences about price competition in the pharmaceutical industry. It is a well-documented fact that product competition by virtue of proprietary hold over knowledge pool via the patents drives out the price competition in the pharmaceutical industry. Over the years countries such as India and Brazil by devising their own systems of patent regimes (for example IPA 1970 in India) had leveraged their national domestic firms to generate, innovate and reverse engineer the products successfully and introduce close substitutes at competitive prices not only in domestic markets but in the international markets, too. In the case of pharmaceutical products it is the close generic substitutes (which again can be branded) to existing branded products in the market. Further, it is shown with that in the absence of a reasonable price competition the drug MNCs are capable of reaping super normal monopoly profits (with exorbitant prices as shown in Tables II.1 and II.2) wherever they can and up to as long as they can. Several instances are documented in literature which show that the research based pharmaceutical MNCs, which keep on flaunting the "high R & D costs-for-new-drugs", are just ready to bring down the prices, much below the price of competitors’ closest substitutes whenever they appear in the market. This example from Bolivia, illustrates the point. In 1997 100 units of 100mg of Retrovir (a proprietary drug of Glaxo-Wellcome) was priced at $ 626, in Bolivia. A competitor had produced the same drug zidovudine (generic name) and made it available at $ 427 in 1998. Immediately, as soon as the generic substitute appeared in the market Glaxo had reduced the price of Retrovir to $ 258 in 1998 itself, which is
half the price of its competitor who introduced the substitute. However, given the material resource endowments and technological capabilities most of the developing countries are not in a position to develop generic substitutes in the pharmaceutical market with the speed and timing that is desired. There is a certain time lag between the introduction of a new drug in the world market, and its introduction in a country like India by national firms which take some years to copy the products and reverse engineer, in which craft they are recognised even by PhRMA as experts.

Table II.3 shows the time lag between introduction of new drug in the world market and its introduction India.

**TABLE II.3**

**TIME LAG BETWEEN ORIGINATOR AND LOCAL FIRM IN INTRODUCING THE PRODUCT.**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Introduction by Originator</th>
<th>Introduction Local firm in India</th>
<th>Lag in years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salbutamol</td>
<td>1973</td>
<td>1977</td>
<td>4</td>
</tr>
<tr>
<td>Mebendazole</td>
<td>1974</td>
<td>1978</td>
<td>4</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>1974</td>
<td>1980</td>
<td>6</td>
</tr>
<tr>
<td>Naproxen</td>
<td>1978</td>
<td>1982</td>
<td>4</td>
</tr>
<tr>
<td>Bromhexin</td>
<td>1976</td>
<td>1982</td>
<td>6</td>
</tr>
<tr>
<td>Ranimidine</td>
<td>1981</td>
<td>1985</td>
<td>4</td>
</tr>
<tr>
<td>Captopril</td>
<td>1981</td>
<td>1985</td>
<td>4</td>
</tr>
<tr>
<td>Norfloxacin</td>
<td>1984</td>
<td>1988</td>
<td>4</td>
</tr>
<tr>
<td>Ciprofloxac</td>
<td>1985</td>
<td>1989</td>
<td>4</td>
</tr>
<tr>
<td>Acyclovir</td>
<td>1985</td>
<td>1988</td>
<td>3</td>
</tr>
</tbody>
</table>


In a multi-country study of India, Indonesia, Pakistan, Philippines and Thailand, in 1995 it was found that welfare and price effects of the new IPR regime were negative. Price increases estimated for patented drugs ranged from 5 to 67%.

---

analysis of detailed market data on patentable drugs in the pre-product patent stage in India, an average increase in price of about 51%. Likewise for Argentina, in 1995, a significant drug price increase of 71% was calculated.34

In a simulation exercise, using actual data on largely oligopolistic, patentable pharmaceutical markets in India at the time of WTO and TRIPS (1995) Agreement, Watal has shown that prices are likely to increase and welfare likely to decrease, in moving from current market structure to patent monopoly. The extent of simulated price increase over the patented pharmaceutical segment differed widely, depending upon the assumption made on demand functions. The maximum weighted mean price increase of 26% was observed if the demand function was linear, and this could be as high as 242% if it was constant elasticity type of demand function.35

In view of the adverse implications of WTO and TRIPS agreement on the Indian pharmaceutical industry particularly on the pricing front, a number of activist groups, public spirited organisations working in the field of health and related aspects, together with some elected public representatives had systematically mobilized opinion against the proposed Amendment to the Indian Patents Act, 1970 and impending Review of TRIPS Agreement in 1998. The National Working Group on Patent Laws, an independent non-governmental body constituting a group of medical practitioners, pharmaceutical experts, legal and judiciary specialists, economists and policy planners, had made repeated appeals to the government to constitute a National Commission to examine the issues relating to intellectual property rights and to work


out an approach towards the TRIPS Agreement. After failing to secure any response from the government, the Working Group set up on its own “The Peoples Commission on Intellectual Property Rights”, on October 22, 1998, which submitted its “Quick First Report” in December 1998. The Commission in its Report strongly felt that “an EMR regime amounts to the institutionalization of monopoly in its worst form, and must be avoided under all circumstances. First, an EMR holder cannot be obliged to produce domestically; nor can any domestic producer be enabled to produce the product over which such exclusive marketing rights are held. In other words, the EMR holder is given the right to hold a monopoly position in the domestic market entirely on the basis of the imports he brings into the country. These imports no doubt are of a product he has patented somewhere else, but being a Multinational firm he would be in a position to use aggressive marketing strategy to create a larger for himself by capturing the markets of domestic producers who may be producing similar products. The EMR regime in other words would not only institutionalize monopoly, but would cause de-industrialization as well, i.e., supplanting of domestic production by imports. The result would be both exorbitant prices, owing to monopoly, and reduced employment, owing to de-industrialization.”

The other contentious issue relates to “Compulsory licensing” and parallel imports. The Peoples’ Commission’s view on compulsory licensing scheme is as follows: “First, it does not address the problem of monopoly; compulsory licensing in China (and elsewhere) is concerned with ensuring production within the country by some entity if the patentee is not doing so; but it does not address the question of curbing the monopoly of this entity. Secondly, in such compulsory licensing the

---

36 Members of the People’ Commission on Intellectual Property included, Justice V. R. Krishana Iyer, Prof. Yash Pal, Prof. Prabhat Patnaik and National Prof. S. K. Sinha. The Report has created a reasonable impact among the academics, industry circles etc., all over the world.

terms of settlement are open to challenge before a court of law. In the Indian context, making compulsory licensing justiciable in courts of law would mean that production may be held up for years; and unless production monopoly is broken up, consumers would be adversely affected.38

II.7 EQUITABLE PRICING POLICIES

In order to overcome the problem of monopoly hold and discriminatory pricing policies of drug MNCs and the recent TRIPS clauses on the drug products, various experts and international (supranational) institutions have been prompted to come up with alternative propositions which would ensure reasonable prices and access of essential medicines to the poor and needy nations.

One such methods of pricing is a global “tiered pricing” system which would offer lower prices for medicines in developing countries while maintaining prices in the developed countries, which has come to be known as “equitable pricing”. This is a concept that reverses the practices of discriminatory pricing of the drug MNCs. The concept of equitable pricing gained momentum with the WHO taking it up as a policy to be prescribed to the world, particularly in view of its apparent success in the implementation for vaccines and oral contraceptives, with drugs costing as much as 200 times less, as shown earlier in Tables II.1, and II.2 for the poor countries.39 The WHO Background Paper had also endorsed that bulk purchasing of contraceptives and vaccines, even for on-patent drugs, has brought substantial gains to the developing countries.40

38 We have discussed the problems relating to EMRs, Compulsory licensing and “parallel imports” in Chapter IV below.
39 Bernard Pecoul, op.cit.
The WHO background paper has stated that equitable pricing is the safer alternative at present: “Differential pricing—also referred to as “equitable pricing”—refers to the concept that essential drugs prices should in some way reflect countries' ability to pay as measured by their level of income. The goal of differential pricing is to help ensure that price is not a barrier to low-income countries for securing access to essential drugs for their populations, price being one of the four essential components of access to essential medicines”.41

Though the WHO approach has acquired some kind of popularity, there are other approaches as well, which could be employed as a means of lowering drug prices.

II.7.1 THERAPEUTIC VALUE PRICING

This approach has been adopted in Australia. The Pharmaceutical Benefit Pricing Authority, (PBPA) which is an official and independent body, determines the drug price on the basis of therapeutic value. When a new drug becomes available for marketing, the benefits and health outcomes of the new drug are carefully compared with similar, existing drugs and a comparative price is estimated. For example, a new drug may provide a small benefit compared to an existing drug, so the Pricing Authority may declare that the government will be willing to purchase the new drug at a 10% increase over the price of existing drug. The manufacturer then determines if it wishes to sell its drug at this price. Sometimes, negotiation for a mutually acceptable price can take months.

II.7.2 POOLED PROCUREMENT

For countries with small national populations, pooled procurement may be an option. This has been tried in the Caribbean where seven different countries have joined together to purchase drugs. This approach, which started in the 1980s has enabled these countries to

41 Ibid.
reduce prices by around 50%. In addition, this combined operation has allowed the countries involved to develop a single multi-country unit with expertise in drug evaluation and price negotiation.

II.7.3 NEGOTIATED PROCUREMENT

Large organizations buying drugs in large quantities can also bring down prices. For instance, some large health maintenance organisations in the United States have been able to negotiate significantly lesser prices than the official price of drug that is more than the official discounts of bulk orders.

II.7.4 PLANNED DONATIONS

In the past, many countries have received donations of about-to-expire stocks of drugs. The WHO is now encouraging planned donation programmes for drugs that are still in use. For example, Johnson and Johnson now have a planned giving programme, addressing a range of diseases, with three years of donations planned three years in advance.

II.7.5 LOBBYING PHARMACEUTICAL COMPANIES

UNAIDS has lobbied pharmaceutical companies to lower the prices of their drugs in developing countries. Their current four-country treatment pilot initiative has resulted in slightly lower initial prices for retroviral and other drugs brought through the pilot programme. In addition, treatment activists in many countries have been lobbying many pharmaceutical companies directly for some years. One result was the decision by Glaxo-Wellcome in 1997 to halve the then cost of an annual course of AZT; the price is still substantial, however.

It is to be noted here that the above approaches are only indicative of the practices available in the world, which can increase the welfare of the consumers in developing countries and improve the access to essential medicines. These policies, too, are fraught with a number of shortcomings. However, it is not possible to discuss at length the problems involved in these approaches. What remains essentially
important is the fact that individual nation states' sovereignty is primary, and keeping in view the national priorities, the imperative for these nation states is to strengthen, evolve and consolidate “national innovation systems” and formulate policies to gear up to those goals.

II.8 SUMMARY

The general guidelines set in the Industrial Policy Resolutions were made use to govern the overall approach towards the pharmaceutical industry. The specific problems pertaining to this industry were however, tackled on a legal rather than the policy plane for a long time. The general governance of the drug industry was through the Drugs and Cosmetics Act of 1940, which was inherited from the British. Various amendments were made to this Act from time to time through 1955 until 1979. A systematic pricing policy, however, has not been formulated till date.

Price regulation has been resorted to through various Price Control Orders starting from 1962. The latest Drug Price Control was announced in 1995.

The first ever systematic Drug Policy in India was announced in 1978. This was also known by the name New Drug Policy. This policy was a reflection of the nationalist endeavour towards a self-reliant Indian Pharmaceutical industry contemplated by the Hathi Committee Report of 1975. The Drug Policy of 1986 marked a substantial deviation from the path self-reliance and indigenous strength in the drug industry. We have argued that the developments on the policy front in the drug industry were on similar lines that were witnessed in the Indian economy and generally coincided with phases of progressively diluting 'state activism' in the Indian economy at large. We have also showed that the abandonment of Industries (Development and Regulation) Act, Industrial Licensing Policy, the DPCOs and the dilution of the IPA of 1970, were all the result of international pressure brought mainly by the American drug
companies. India's zeal in joining the WTO also seems to have complicated the situation. A number of incentives, tax concessions and 'on par' treatment of the firms, irrespective of the country of their domicile, has also blunted the advantage of the Indian drug firms. The acceleration of the pace of economic reforms from 1996 onwards is essentially linked to the TRIPS Agreement and India joining the WTO, with the objective to "convince the world that India has come out of the protectionist regime and is ready to welcome FDI without any restrictions in all spheres".

In the post-WTO pricing policy the government has done away with the Category I and II formulations, which were conceived on the basis of efficacy of the drug equivalence and set aside the Hathi Committee recommendations in this regard. In fact, the Drug Policy of 1978 had incorporated these recommendations on the principle of 'essential drugs' criterion that was also the recommendation of the World Health Organization. This was necessary for making available life saving drugs at affordable prices. With the current policy these objectives are difficult to realize.

The implication of the TRIPS Agreement on pharmaceutical patents in the post-WTO order will have direct bearing on first, the pricing of drug products and second, on the access to essential medicines and their supply. The available evidence from a number of studies, has shown that the implications of post-WTO pricing on the pharmaceutical product is adverse on the consumer welfare. India has demonstrated a clear price advantage in various products. This was mainly the result of it long pursued policies over the years, and particularly due to the advantage created by its Patent Act apart from many other factors.

In order to overcome the adverse impact of the post-WTO situation it is suggested above, that the developing countries are likely to benefit if they adopt equitable pricing policies. These include, therapeutic value
pricing, pooled procurement, negotiated procurement, planned donations, lobbying pharmaceutical companies and the like. This may bring temporary succour to the third world population.

In the next Chapter we shall discuss the specific theoretical and empirical issues on IPRs arising in the context of the WTO and globalization.