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INDUSTRIAL DRUG POLICY

The Indian Experience*

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CHAPTER I

AN APPROACH TO DRUG POLICY - RATIONALE & PARAMETERS

1. Industrial drug policy pre-supposes a degree of Governmental intervention to ensure directional changes consistent with certain predetermined policy goals. A distinction has to be made between industrial drug policy and drug regulation, the latter can be a part of the overall policy but merely laying down parameters for drug regulation and control cannot be construed as laying down drug policy itself. To that extent, the concept of industrial drug policy would be relevant in the politico-economic context of countries where such an intervention to achieve the desired goals is not only possible but also considered necessary. At least for the purpose of this paper, it would be necessary to keep in mind this perspective.

I.1 Focus of industrial drug policy

2. Industrial drug policy will have to centre around the following product groups :

i) Formulations i.e. the finished dosage form in which drugs are administered e.g. tablets, capsules, etc.;

ii) The active ingredients of formulations which are generally known as bulk drugs;

iii) The speciality chemicals which are mainly used in the manufacture of bulk drugs and which are generally referred to as drug intermediates.

3. In addition to the product groups, certain sub-elements of the total policy also need to be identified. These can be :

i) Regulation of industrial production in desired areas and priorities, through licensing;
ii) Quality control and related matters which would broadly come under the category of "drug regulation";
iii) Research and development, upgradation and Transfer of Technology;
iv) Pricing and Tariff structure;
v) Indigenisation and basic stage manufacture;
vi) Rational use of Drugs.

4. The above are very broad aspects on which an industrial drug policy can focus. However, there may be certain other aspects which could be of an equal if not greater concern to certain regions/countries depending upon the overall objectives of Government policy and special circumstances of a country. Besides, there may have to be trade offs between different aspects of the policy to balance competing claims of various interests and concerns.

I.2 Special characteristics of the drug industry

5. It would also be worthwhile to consider in the context of an Industrial Drug Policy certain basic characteristics of the drug industry which distinguish it from the other sectors of the industry. Some of these are :

i) It is a highly R&D intensive industry requiring an ongoing R&D effort involving large expenditure. Some of the companies in the advanced countries are known to spend as much as 8 - 9% of their turnover on R&D.

ii) The industry is also characterised - at least in case of formulations - by a very strong brand preference. This results in a distortion in the normal market mechanism and enables companies which have a strong brand image in the market to exploit this image in a manner disproportionate to the intrinsic quality or value of the product. Any policy, therefore, has to take into account this special characteristic of the industry also.

iii) The drug industry is characterised by a comparatively high obsolescence rate. The level of obsolescence is not only determined by new advances taking place in various therapeutic groups but also by the Body resistance developed over the years as a result of extensive use of certain drugs.

iv) Unlike most other industries, the drug industry does not sell its products directly to the ultimate consumer. Except for some over-the-counter products, there is an intermediary in the form of the Medical Practitioner. This not only requires special marketing strategy on the part of the concerned companies, but is an important factor needing consideration at the policy formulation level in the context of providing adequate protection to the consumer.

v) Since this industry so intimately affects all segments of the society being an essential input in the health care, it has an interface

with a wide ranging segment of society and is consequently beset with controversies of various kinds vis-a-vis the consumer and other voluntary action groups. Questions like efficacy of drugs, their harmful effects, the rationality of drugs are, therefore, of significant concern to the policy makers.

vi) The drug industry is also, by and large, characterised by closely-held technologies. The question of transfer and absorption of technology particularly for the developing countries, therefore, assumes significance and has to be an important element of all policy thrusts.

vii) In most countries the price at which drugs are available is also a matter of concern particularly to the consumer protection groups. This is so even in societies which swear by a completely free market economy allowing the market forces a free play for determining the equilibrium price of various commodities. Thus, except perhaps in the United States, even in many developed countries of the West, there is some regulation - informal or otherwise - to prevent over-pricing of the products by the drug companies. It should, therefore, be a matter of concern to the policy makers to check the tendency of over-pricing on the one hand, to protect the consumer, and to ensure, on the other, a reasonable return on investment to the industry.

viii) The Drug Industry operates under very stringent controls and regulations of quality. It is the only sector of industry where prior approval of a regulatory agency is required even to introduce a new product and elaborate pharmacopoeial standards are laid down for each product.

6. The basic fact, however, is that drugs constitute a small, even though important, input in the overall health care system. To that extent, all industrial drug policy has to subserve the objectives of the Health policy. Therefore, the disease patterns obtaining in different regions and countries as also the strategy determined to provide health care to the people must have an important bearing on the Drug policy.

I.3 Span of regulations

7. The formulation of any Industrial Drug Policy would require consideration of the above factors. But all these may not be relevant to the same degree in all cases and situations. The range of policy regulations have a very wide spectrum in different countries. At one end of the spectrum is the U.S., which has the barest minimum of regulatory control confined to various aspects of quality control, although the intensity of control in this limited area is very strong; at the other end of the spectrum is India, which perhaps has the most comprehensive and complex policy impinging on almost all aspects of the industry - from control on quality to regulation of production parameters, to price control and profitability control. The concern of policy-makers with quality-related issues is understandable for obvious reasons but the other main concern with pricing is attributable to the higher degree of brand loyalties that the Drug Companies are able to exploit. The Industrial

Drug Policy being followed by different countries would reflect the concerns of the policy makers with different issues at any given point of time and this would determine the "span" of regulation or control. For instance, the need to conserve foreign currency or otherwise may determine emphasis on indigenisation or freedom to import. The determinants of Industrial Drug Policy would not only be conditioned by the socio-political predilections of the Government of the day, the constraints of the economy, the overall environment but also by the capacity of the different players to apply pressure. In the U.S., for instance, the extremely effective and vocal consumer movement may obviate the need for any major Governmental intervention in the consumer interests and the opposite may be the case in some of the developing countries.

I.4 Structure of the paper

8. A word about the way this paper is structured would be in order at this stage. It is proposed to treat the subject of this paper with the above perspective in view. The evolution of the Industrial drug policy in India would be discussed in the following chapter, followed by a detailed treatment of the important elements of the policy with an attempt at analysing the impact of these on the industry and the extent to which the objectives have been achieved; it is proposed to give an over view of the drug industry in India and its production particularly with reference to the health needs thereafter and finally an attempt is made to develop

a framework for a model of drug policy which may be of relevance particularly to the developing countries. It is conceded at the outset that the last of the above tasks leads one to extremely sticky terrain in that such a model cannot have a universal applicability and will have to be seen in the context of the local conditions as also the overall policy objectives of the concerned country. Nevertheless the relevance or otherwise of a conceptual model would depend upon the stage of development of a particular region or country and what may not be relevant for a region today may be so tomorrow, and it would be important to keep in mind this time-dimension to relevance.

I.5 The need for a drug policy

9. The question for a need to have an industrial drug policy has its answer in the necessity of relating in a coordinated manner the diverse objectives of State policies that are sought to be achieved in the context of meeting the health care requirement. This has to be the underlying objective of all industrial drug policy although there would be subsidiary objectives of attaining self-reliance in the drug sector thus reducing dependence on outside sources for meeting requirements of the country as also the overall objective of providing impetus to development thereby giving access to larger sections of the population to the benefits of the fall-out of industrial development in general. A detailed analysis of the objectives and the extent to which these have been met has been made in the following chapters as also, inter alia, of the need, in the Indian context, to have an industrial drug policy.

CHAPTER II

EVOLUTION OF INDUSTRIAL DRUG POLICY IN INDIA

II.1 Regulatory framework for industries in India

1. To understand and appreciate the complexities of Industrial Drug Policy in India, it is necessary to have an idea about the regulatory framework for industries in the country. Industrial production in India is regulated through a licensing regime covering a wide range of activities. The basic regulatory provision is the Industries(Development & Regulation) Act. In addition, there are regulations like Monopolies & Restrictive Trade Practices and Foreign Exchange Regulation Act which have been framed with a view to checking the growth of monopolies or market dominance and regulation of foreign equity respectively. In addition, there are certain other provisions which are contained in various guidelines and press notes issued from time to time laying down parameters in respect of licensing - related issues. Broadly, the Indian regulatory system has the following characteristics :

i) There is a broad division of industries on the basis of ownership into public sector (Government owned), private sector, joint sector (partly Government owned) and the foreign sector (foreign equity of more than 40%).

ii) There is also a very broad, though flexible, demarcation of area of activities assigned to each sector.

iii) Industries are also divided into sectors on the basis of investment in land and equipment as small scale (investment upto Rs. 3.5 million) medium and large scale, and also the "tiny" sector.

iv) There are restrictions on import of technology and capital which are governed by Foreign Exchange Regulation Act and import-export regulations.

v) There is prioritisation, of industries but such a prioritisation is basically relevant, in the present context, with reference to import of capital and technology, and ownership pattern between foreign and Indian sector.

2. The entire regulatory regime as evolved over the years is in consonance with the basic economic goals of the Government, namely self reliance and allocation of resources (both capital and material) in accordance with pre-determined national priorities. Resource allocation is sought to be effected through the instruments of licensing and regulating Financial flow through term lending institutions and both these have been used to channelise investment in the desired sectors. The Industrial Policy Resolution of 1956 formed the basis of the policy that has subsequently been followed. Although the Government of India had passed an Industrial Policy Resolution in 1948 itself, it only broadly defined the role of industrial development in the overall economy of the country. The Resolution passed in 1956 was more precise and gave direction to the industrial development of the country, and inspite of shifts in emphasis over

the years in licensing and related issues, the basic structure created by the Industrial Policy Resolution of 1956 still remains intact. Broadly, the Industrial Policy Resolution of 1956 determined the following thrusts for the industrial development of the country :

i) It accepted implicitly the principle of a mixed economy providing for the existence of the public and private sectors;

ii) It placed the public sector at "commanding heights of the economy" giving to it a major role in generating the necessary impetus to industrial development;

iii) It categorised industries into three categories - the first being the exclusive responsibility of the State, the second consisting of industries where State was expected to take the initiative in establishing new undertakings but which allowed the private enterprise to supplement the efforts of the State; and the third included the residuary industries the future development of which was left to the initiative and enterprise of the private sector.

3. The policy spelt out in the Resolution of 1956 was reviewed from time to time and the Government came out with Industrial Policy Statements in 1973, in 1977 and in 1980. Basically all these Policy Statements reflected the concerns and priorities of the Government of the day and also took into account the changing scenario - both domestic and international - and made corrections and adjustments keeping these factors in view. For instance, the Policy Statement of 1973 addressed itself

specially to the growth of industrial monopoly and market dominance by unfair means - tendencies which were evident at that time. It made certain adjustments to tackle these tendencies by passing regulations to check these. Similarly, the Statement of 1977 laid special emphasis on the interaction between the agricultural and industrial sectors of the economy and segmented the industry further by providing for what is known as the "tiny sector". It also laid emphasis on development of village and rural industries. The Statement of Industrial Policy of 1980 takes into account the fact that the country had reached a take off stage in the industrial development and laid emphasis on optimum utilisation of installed capacity; achieving higher productivity, promoting export-oriented industries; and producing high quality and internationally competitive products.

4. It is obvious that the policy guidelines or thrusts indicated from time to time had less to do with the ideological slant of the Government of the day than to a recognition of the ground realities of the situation. It can be said on hindsight that the policies which have been followed over the years were all relevant at the points of time when these were spelt out. For instance, initially the private sector was not fully developed and there were also gaps in the basic infrastructure of industry which needed greater State participation and involvement. There was also reluctance on the part of private sector to invest in projects having a longer gestation period and offering lower returns.

The situation, however, changed over the years and necessary directional thrusts were given through policy pronouncements, while taking cognizance of these changes. While sectoral prioritisation of industries has been the key note of policy over the years, concepts like the minimum economic size, higher emphasis on quality and competitiveness, greater utilisation of installed capacity have of late been given more importance. There has also been a distinct liberalisation both in policy and procedures for promoting rapid industrial growth. An important concern which flows from the basic objective of self-reliance has been the role of the foreign sector in India's industrial development. While there have been restrictions on injection of foreign equity in the Indian corporate sector, there has been considerable liberalisation in this area also during the last few years and the foreign sector has been assigned a role in high technology areas while its participation is regulated in such a way that investments made are in tandem with the priorities and objectives of State policy.

II.2 Stages of evolution of an industrial drug policy

5. It is in the above context that the evolution of Industrial drug policy in India has to be seen. Sector - specific policies have been determined by the Government from time to time and the drug sector has, due to its special characteristics, been considered for a separate treatment. No special policy for the drug industry existed till 1962 and the initial forays into

the area of determining drug policy were also confined basically to regulating the prices of end products to protect the interests of the consumer. The Drug (Display of Prices) Order, 1962 was the first of its kind and this Order merely required all manufacturers, importers and distributors of drugs to publish price lists of their products and the Chemists to display such prices. Subsequently, the Drug (Control of Pricing) Order, 1963 was promulgated freezing the sale prices of drugs at the levels obtaining on 1st April, 1963. Apart from these, the drug regulation aspect has been taken care of since 1940 itself when the Drugs & Cosmetics Act was passed. But it is not the intention of treating the developments in the field of drug standards and drug regulation as part of the process of evolution of the industrial drug policy although significant progress had been made in these areas also in the shape of development of the Indian Pharmacopoeia. These are, however, proposed to be discussed separately, though briefly under the heading of Quality control.

6. The rudiments of a drug policy can be traced to the Drug (Display and Control) Order of 1966 which provided for prior approval of the Government before increasing the prices of any formulations as also the approval of the Government of the prices of new drugs. Subsequent amendments made to the Order allowed for (a) exemption of drugs with pharmaceutical names from price approvals

and (b) exemption of drugs evolved out of original research and marketed for the first time from the price control.

7. It is for the first time thus that cognizance was taken of R&D efforts and the control Order did not merely concern itself with keeping the prices low in the interest of the consumers although this continued to be the primary concern. In 1966 the Government asked a Tariff Commission to study the cost structure of 18 specified drugs sold in bulk and single ingredient formulations manufactured from these drugs. The Tariff Commission took a sample of a few units for detailed cost study and made certain recommendations. Based on these recommendations the Drug Price Control Order of 1970 was promulgated with the principal objective to effect a measure of rationalisation in the prices of drugs and to build up a rational system of price control. The order aimed at :

i) Reduction in the prices of essential drugs which were high;

ii) Providing incentives to the industry to encourage its growth from the basic stage and to develop research facilities and expansion in a planned manner;

iii) Curbing excessive profits;

iv) Promoting diversification of entrepreneurship in the future development of the industry.

II.3 Hathi Committee and the 1978 policy

8. It would be seen from the above that while by 1970 the Government of India had taken some decisions with a view to developing the drug industry, the primary concern continued to be to check the prices in the interest

of the consumers. It is only in 1974 that the Government of India took a comprehensive look at the drug industry and appointed a Committee under the chairmanship of Jaisukh Lal Hathi who enquired into the various facets of drug industry in India. This Committee is popularly known as the Hathi Committee and was the forerunner of the Industrial Drug Policy of 1978 which, for the first time, covered all aspects of the drug industry. Therefore, the Hathi Committee can really be said to be a landmark in the historical evolution of the drug policy in India. The Committee was given the task of reviewing the status of drug industry in the country and of making appropriate recommendations with the following specific terms of reference :

i) To enquire into the progress made by the industry and the status achieved by it;

ii) To recommend measures necessary to ensure that the public sector attains a leadership role in the manufacture of basic drugs and formulations, and in research and development;

iii) To make recommendations for promoting the rapid growth of the drugs industry, and particularly of the Indian and small scale industries sector. In making its recommendations the Hathi Committee will keep in view the need for a balanced regional dispersal of the industry;

iv) To examine the present arrangements for the flow of new technology into the industry, and make recommendations thereof;

v) To recommend measures for effective quality control of drugs, and for rendering assistance to small scale units in this regard;

vi) To examine the measures taken so far to reduce the prices of drugs to the consumer and to recommend such further measures as may be necessary to rationalise the prices of basic drugs and formulations:

vii) To recommend measures for providing essential drugs and common house-hold remedies to the general public, especially in the rural areas: and

viii) To recommend institution and other arrangements to ensure equitable distribution of basic drugs and raw materials, especially to the small scale sector.

9. After considering the recommendations of the Hathi Committee, the Government came out with a Drug Policy covering a wide range of aspects of the industry. The broad objectives of the Drug Policy announced in 1978 were :-

i) To develop self-reliance in drug technology;

ii) To provide a leadership role to the public sector;

iii) To aim at quick self-sufficiency in the output of drugs with a view to reduce the quantum of imports;

iv) To foster and encourage the growth of the Indian sector;

v) To ensure that the drugs are available in abundance in the country to meet the health needs of our people;

vi) To make drugs available at reasonable prices;

vii) To keep a careful watch on the quality of production and prevent adulteration and malpractices;

viii) To offer special incentives to firms which are engaged in Research and Development; and

ix) To provide other parameters to control, regulate and rejuvenate this industry as a whole, with particular reference to containing and channelising the activity of foreign companies in accord with national objectives and priorities.

10. These objectives were sought to be achieved through a number of measures covering broadly areas of licensing, rational use of drugs and price control. The major thrust of the above measures was to encourage development of indigenous industry vis-a-vis the foreign dominated industry on the one hand, and to control prices of a large number of drugs in the interests of the consumer, on the other. For achieving the first of these thrusts, a number of restrictions were put on the foreign companies (all companies were deemed to be foreign if they had a foreign equity of more than 40%). These included: Restricting them to the manufacture of "drug intermediates" from the basic stage; and to production of high technology bulk drugs from the basic stage and formulations based thereon"; restricting the import of technology for the bulk drugs by the foreign drug companies in accordance with the terms and conditions laid down by the Government; requiring a foreign drug company having a turnover of over Rs.50 million per annum to have R&D facilities within the country on which capital investment had to be at least 20% of their net block and requiring them to spend at least 4% of their sales turnover as recurring

expenditure on R&D facilities. Foreign drug companies were perceived at that time as making unduly large profits specially on formulation activity because of their brand strengths. It was also felt that the Indian market was being used by these companies to push their products developed as a result of R&D carried out outside India. The idea, therefore, was not only to restrict the entry of foreign companies to high-technology areas only but also to ask them to have R&D within the country. This was considered necessary to encourage basic stage manufacture and to shift away from manufacture from penultimate intermediates imported by most of these companies from their principals at transfer pricing. Besides these measures, the 1978 policy also laid emphasis on encouraging dilution of foreign holdings in the foreign companies to levels so as to make the total foreign holdings not more than 40% of the total equity. The results of these measures were apparent after a few years. The number of companies covered under the definition of foreign companies was as high as 38 in 1978 but it came down to 9 by 1986. Similarly the production of bulk drugs by foreign companies was of the order of Rs.560 million in 1978 but it came down to Rs.400 million in 1985. At the same time the production of the Indian sector went up from Rs.750 million in 1978 to Rs.1910 million in 1985 (at constant prices of 1979-80) These figures, prima facie, indicate a sharp rise in production of bulk drugs by Indian companies against

a corresponding decrease in the case of foreign companies. But this may be deceptive in that a number of erstwhile foreign companies became Indian as a result of equity dilution and to that extent their production got clubbed with that of the other Indian companies. On the other hand, even with equity dilution there was hardly any change in the basic management characteristics of trans-national companies whose management structure and the focal points of decision making remained more or less the same. This was so because of the widely dispersed nature of the Indian equity preventing it from exercising any clout to influence Management policies in a significant manner and these continued to be determined as per the global interests and strategies of the foreign transnational companies. Notwithstanding these observations, the fact remains that the 1978 policy gave considerable fillip to the Indian sector of the industry which developed in a big way after the implementation of the policy.

11. The other major thrust of the 1978 policy was on price control of drugs, although the policy also took care of some of the other concerns like discouraging manufacture of formulations alone by prescribing ratios on bulk drugs and formulation production for every company; encouraging the use of generic names by decreeing that in case of Analgin, Aspirin, Chlorpromazine, Ferrous Sulphates, Piperazine and its salts, brand names shall be abolished and only generic names shall be used.

All these measures together with the price control regime were primarily aimed at protecting the consumer against profiteering.

12. The price control regime spelt out in 1978 policy was more comprehensive than had been the case hitherto. It provided for fixation of maximum retail prices by the Government in respect of as many as 347 bulk drugs and their formulations. It also provided for a normative system of pricing. In the case of bulk drugs the price fixation was to be based on a detailed cost-cum-technical study providing for a fixed post-tax return. In the case of formulations three different mark-ups on the ex-factory price were prescribed depending upon the category to which a drug belonged.

13. The mark-ups were again allowed on ex-factory prices which in turn were determined by the Government on the basis of prescribed norms. Thus the Policy provided for fixation of prices by the Government on a fairly large number of bulk drugs and their formulations and the fixation of ex-factory prices was determined by certain prescribed norms.

II.4 Impact of the 1978 policy

14. Even though the 1978 Drug Policy constitutes a significant step in the evolution of a Comprehensive Policy, its restrictive provisions particularly price control regime tended to slow down the growth and investment. Ironically this stagnation in growth was most

marked in the case of products which were regarded as more essential for the common diseases and for the masses which was completely the opposite of what had been intended. There was a fall in production in drugs; like Penicillin, Dapsone, Chloroquin. There was also a decline in investment and a number of Drug Companies started moving away from pharmaceutical business to other activities. However, the objective of encouraging the growth of indigenous industry was achieved in spite of these constraints. This is shown by the increase in the share of the indigenous sector in the production of bulk drugs and formulations. This increased from 29% in 1976 to 65% in 1985. Besides, Table at Annexure I which gives the production (1984-85) of 30 major drugs would indicate that in a large number of cases the Indian Companies had a hundred percent share in production.

15. These achievements notwithstanding, a review was made of the impact of the various elements of the Drug Policy and it was felt that the restrictive provisions of the policy were certainly having a deleterious effect on the Drug Industry as a whole. A study conducted by National Council of Applied Economic Research in 1984-85 tended to reinforce this view. The study had examined 33 companies and came to the conclusion that the profitability of the industry as a whole had come down. The study found that the post tax profits of 5% of the units in 1977-78 were in the range of 2-5% while in the case of one unit it was over 10%. In 1980-81 none of the sample units had enjoyed a post tax return of over 8%. The number of units with

less than 2% pre-tax profit showed an increase from 6% in 1977-78 to 11% by 1980-81. However, the number of units whose pre-tax profit was in the range of 2-5% remained unchanged during this period. Of the 33 units that the study had examined, 16 had a Profits Before Tax(PBT) as percent of sales of over 10% in 1977-78 while it came down to 8% in 1981-82. While on the issue of profitability the study cannot be said to be conclusive for the reason that it confined itself to a limited number of Companies and also did not go beyond the period 1981-82, the trends certainly indicated, if not a decline, certainly a stagnation in the profitability of the Industry as a whole. The Industry certainly attributed the decline in profits and profitability to the restrictive price control regime.

II.5 Measures for rationalization, quality control and growth of drug industry in India

16. Government took up a review of the Industrial Drug Policy of 1978 after considering the recommendations and the reports of a number of Expert Committees set up for the purpose and set about to correct imbalances in the earlier Policy. Government of India came out with what it called "Measures for Rationalisation, Quality Control and Growth of Drugs & Pharmaceutical Industry in India", in December 1986. As would be seen from the fact that the Government chose to call what it announced in December 1986 a series of measures, it continued to retain the basis of the 1978 Drug Poli., and the measures which were announced were in the nature of corrective steps. Another aspect which has not been

taken into consideration in 1978 was the formulation of a National Health Policy. Such a policy was announced by the Government of India in 1983 with the basic objective of providing Health for all by 2000 A.D. The measures of 1986 seek to subserve this objective. A brief description of relevant portions of the Policy Statement would give an idea about the context and the objectives which the Government had in view while announcing these measures, extracts from which are reproduced below :-

"The National Health Policy of 1983 marks a significant step in the national endeavour to improve public health. It reiterates India's commitment to the goal "Health for all by the year 2000 A.D." through the universal provision of comprehensive primary health care service. The attainment of this goal requires an accelerated development of all inputs to the health care system, including essential and life saving drugs and vaccines of proven quality. Drugs alone are not sufficient to provide health care. However, if rationally used, they do play an important role in protecting, maintaining and restoring the health of the people and in controlling population. The Indian Pharmaceutical Industry has, therefore, a vital role in serving the basic health needs of the people."

"The Report of the Hathi Committee (1975) is an important landmark in the development of the Indian pharmaceutical industry. The Hathi Committee emphasized the achievement of self-sufficiency in medicines and of

abundant availability at reasonable prices of essential medicines. Since 1975, the Indian pharmaceutical industry has grown to be the most diversified and vertically integrated pharmaceutical industry in the entire Third World. The country has achieved self-sufficiency in formulations and also in a large number of bulk drugs. In 1984-85, imports of formulations were only Rs.10.17 crores or about 0.5% of the total formulation production in the country and imports of 49 bulk drugs were negligible. Technologies for the production of several bulk drugs, including antibiotics like Ampicillin, Amoxycillin, Erythromycin, Anti-infectives like Sulphamethaxazole and Trimethorpim, anti-TB drugs like Ethambuto-Cardio Vascular drugs like Methyl Dopa; Analgesics like Ibuprofen and Isopropyl antipyrine; anti-amoebics like Metronidazole and Tinidazole, anti-cancer drugs like Vinblastine, Vincristire and Cisplatin were indigenously developed. The trade balance in pharmaceuticals is also improving as a result of increasing exports. In 1984-85, exports of drugs and formulations were Rs.217.49 crores while imorts were Rs.215.62 crores. A wide range of bulk drugs and formulations are being exported to several countries, including the U.S. and the West European countries. Some Indian firms have also set up production facilities in other countries and are also engaged in the sale of turnkey plants and technical services. The diverse production and technological capabilities developed by the Indian pharmaceutical industry are

valuable assets in achieving the goals of the National Health Policy and in fully harnessing the export potential."

"While these achievements are impressive by themselves, there are many areas where the industry has to re-orient itself if it has to effectively serve the health needs of the people. The present production pattern does not adequately reflect the genuine requirements of the health care needs of the country. The proliferation of formulations and packs without adequate therapeutic rationale is a matter of concern. While many firms in the organised as well as small scale sector have excellent internal testing facilities and a good record of quality control and adoption of good manufacturing practices, the same cannot be said of a large number of firms manufacturing formulations. The present institutional and statutory arrangements for enforcing quality control for registration of new formulations for monitoring adverse reactions and for dissemination of unbiased information about the safety and efficacy of products marketed in the country are far from being adequate."

17. The Policy Statement itself indicated the key note of the Policy as being "abundant availability on a continuous basis, at reasonable prices of essential life saving and prophylactic medicines of good quality". The emphasis thus shifted to the need to increase production and the implied inference of the market forces taking care of the prices after the production increased. A detailed enunciation of the objectives of the new

measures indicated that these aimed at :

(a) ensuring abundant availability, at reasonable prices, of essential 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 investment into the 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.

18. The above objectives were proposed to be achieved by making changes in the policy and systems of :

(a) Rational use of drugs;
(b) Quality control;
(c) Pricing Policy;
(d) Licensing Policy.

19. As regards (a) and (b) above, the new policy measures proposed to strengthen the infrastructural facility for quality control; to ensure internal testing facilities to be maintained by the manufacturers; to give statutory effect to Good Manufacturing Practices; to have a system of certification by reputed institutions of Good Manufacturing Practices and of quality control products; to make procedure for clearances of new drugs more stringent; to strengthen packing and batching.

20. As regards the pricing and licensing policy, the

measures of December 1986, while retaining the basic framework of the 1978 policy, aimed at liberalising the existing procedures and systems with a view to channelising investment towards manufacture of more essential drugs and implementing a system of control which would be in conformity with the overall objective of increased production, reasonable prices and abundant availability of medicines.

21. Thus the measures of 1986 were more wide ranging encompassing the health needs of the country and addressing to certain basic issues like rationalisation of drugs and pricing policies in a more pragmatic manner. The emphasis had clearly shifted to increased production by not only higher utilisation of capacity but also by channeling fresh investment in the drug sector by making such investments attractive in terms of reasonable returns.

22. Specifically, the measures of 1986 (a) strengthen the infrastructure of quality control and internal testing facilities and also make GMP a statutory requirement; (b) reduce the span of control in pricing and also increase the return or mark-ups to the manufacturers to ensure reasonable profits; (c) define the role of the foreign companies more clearly by specifying the list of products which these companies were allowed to enter; (d) while retaining the importance of the public sector, give definite signals for a shift in this basic policy also

by de-reserving certain items which were hitherto reserved for exclusive manufacture by the public sector;(e) gi encouragement to indigenous R&D by delicensing of products which were indigenously developed through local R&D; (f) further liberalise the licensing regime by delicensing 94 bulk drugs; (g) allow for greater manufacturing flexibility by broad banding 31 groups of bulk drugs; and (h) regularize production in respect of formulations being hitherto manufactured on the basis of questionable approvals.

II.6 Impact of the "Measures" of 1986

23. The measures which were announced in 1986 have since been implemented in full but it is too early to assess accurately their complete impact. Nevertheless, if one goes by the share market which is at any rate indicative of the perception of the shareholder regarding the future of a particular industry or a group of industries, these measures appear to have substantially achieved the objectiv of giving a boost to the industry, since the share prices of most of the major drug companies have gone up since 1987. The trends of stock prices of a few companies, namely, Hoechst, Sarabhai, May & Baker, Cipla, Claxo are given in the graphs in Annexure II which would indicate the buoyancy of share prices of these companies during a period quite relevant in the context of impact of the Policy measures. Similarly, there has been significant increase in production in the case of a number of key products. A review by the Office of the Economic Adviser to the Government of India which covered 6 drugs showed

an increase of 41.55% during April, January 1988 over April-January 1987. The data collected from another source namely the Central Statistical Organisation for the index of industrial production covering 13 drugs showed an increase of 63.8% during April-January, 1988 over April-January, 1987. The data collected from a third source namely the Drug Monitoring Cell of the Department of Chemicals & Petrochemicals of the Government of India in respect of 28 drugs showed an increase of 32.91% during January-March, 1988 over January-March, 1987. The above three sets of data are in respect of different drugs and the sources are also different. The period taken is significant since it gives sufficient time to enable the effect of the policy measures to be felt at the ground level. As stated earlier, it is still too early to realize the measure of the complete impact of the various steps that have been taken but the trends are indicative of at least the right responses. Having said that, however, it is necessary to point out that the policy measures have been subjected to severe criticism from a number of quarters particularly the consumer groups and their representatives in Parliament The measures have been variously described by the critics as "pro-industry", "anti-consumer" and "a sell-out to the multinationals". The pricing policy contained in these measures has come in for a particularly scathing condemnation by the critics and it is proposed to discuss this separately at some length in the chapter on pricing policies. But it appears that the underlying assumption

in all this criticism is that the interests of the consumer and the industry are diametrically opposite - an assumption which is not necessarily correct. The fears which have been voiced by the critics of the measures are quite genuine and indicate a concern for the interests of the common masses. But it is too early to say whether these are justified or not since the impact of the policy has still to be fully evaluated. If it is measured in terms of increase in production and a buoyancy of the industry, the impact so far has certainly been positive. Whether these results serve the interests of the consumer in the ultimate analysis - the underlying assumption made in the 1986 policy pronouncements - only time can tell.

24. The evolution of industrial drug policy in India has thus been gradual, based on an indepth consideration of the various parameters and balancing of the various goals of the Government in this sector. The Drug Policy pronouncements have also been in tandem with the overall economic and industrial policy of the Government and of late the attempt at liberalisation and de-regulation of the industry as a whole has been reflected in the Drug policy measures too.

CHAPTER III
INDUSTRIAL LICENSING

III.1 Parameters of licensing

1. The broad parameters of the licensing regime in India have already been spelt out in Chapter II. Basically, industrial licensing involves issuance of letters of approval for manufacture and determination of parameters of product-mix and capacities. Industrial licensing in the context of the drug sector has a connotation distinct from approval to introduce a drug which is based on clinical trials, and is given on consideration of therapeutic efficacy and safety. Industrial licensing is used as an instrument to regulate industrial production in consonance with the objectives of industrial policy. Self-reliance, basic stage manufacture, encouragement of domestic industry, discouragement of monopolistic tendencies have been the main planks of industrial policy in general. There have been shifts in the methods used for achieving these objectives over the years starting from very strict regulation in the 60s or early 70s to liberalisation in the 80s with more emphasis on utilisation of capacity, international competitiveness, high quality of manufacture and minimum economic sizes. The industrial licensing for the Drug sector has been in tandem with the general licensing policy. However, drug licensing, owing to the special characteristics of the industry has certain features which do not exist in the case of other sectors of the industry.

III.2 Foreign sector

2. To regulate the operations of the foreign sector, the latest policy document of 1986 mentions that the business operations of foreign companies would have to be in accord with the national objectives and priorities and that these companies would be eligible for entry mainly in those areas where such an entry is desirable from the objectives of better health care. According to the policy document, companies other than foreign companies would continue to be eligible for industrial approvals in respect of bulk drugs which are approved for use in the country and related formulations, subject to sectoral reservations for public and small scale sector. Thus the foreign sector which really means all those companies having foreign equity of more than 40% is restricted to entry in areas in accordance with the above priorities. Further, the latest policy identifies these specific areas as consisting of 66 drugs which are open to the foreign companies for manufacture.

III.3 Delicensing, broad-banding, ratio parameters, and PMP

3. Another important component of the latest licensing policy is the one relating to reduction of controls by delicensing a number of bulk drugs. The overall industrial policy of 1986 lays great emphasis on ensuring "abundant availability of drugs" and consequently on increase in production and for achieving this seeks to remove all bottlenecks coming in the way of high production. It is in this context that the policy talks of progressive delicensing in addition to the 94 bulk drugs

already delicensed. These include anti-cancer drugs as well as all new bulk drugs developed through indigenous research. In effect, delicensing implies that no prior approval is necessary for the manufacture of a particular product once it has been cleared for manufacture by the Drug Regulation authorities. The scheme for progressive delicensing is subject to the following criteria :

(a) Bulk drugs whose imports are allowed on Open General Licence;

(b) Bulk drugs, whose production is limited to three producers or less in the organised sector;

(c) Bulk drugs whose formulations are of essential and mass consumption nature;

(d) Formulations and drug intermediates related to bulk drugs which are delicensed.

4. In order to ensure higher utilisation of already created capacity and flexibility of manufacture consistent with the special features of the drug industry, 31 groups of drugs have also been "broad-banded". This implies that within the bands indicated the manufacturer can manufacture any of the items without the need for a specific approval for the same depending upon demand at a given point of time. Other special licensing provisions for the drug sector include determination of a Phased Manufacturing Programme, Ratio-parameters and relationship between associated and non-associated formulators. Phased Manufacturing Programme is aimed at encouraging cost-effective indigenisation and basic stage manufacture and ensuring that bulk drug production is not confined to processing of later intermediates

only. Phased Manufacturing Programme has accordingly been determined for over 230 drugs and involves going basic in a phased manner over a period of time the time-frame varying from product to product. The viability of the Phased Manufacturing Programme has been determined in terms of the domestic resosurce cost of production with suitable shadow rate of foreign exchange.

5. The concept of ratio parameters is very significant from the point of view of discouraging companies from manufacturing formulations alone or in manufacturing formulations in excessive quantities. There is a natural tendency for companies to engage in formulation activity which is less capital-intensive and less technological intensive but promises higher returns depending upon Brand-strength. In order to check this tendency, certain ratios have been prescribed between the manufacture of bulk drug and that of formulations. These ratios are related to the size of the company as also whether the company is a foreign company or an Indian company. In the case of foreign companies the ratios are more weighted in favour of bulk drug manufacture than in the case of Indian companies. All foreign companies have to conform to a ratio of 1:4 between the bulk drug and formulation production in terms of value. In the case of Indian companies these ratios vary with the ex-factory value of production, and range from 1:5 in case of annual production upto Rs.250 million to 1:10 in cases of production upto Rs.100 million. It is thus

recognised that companies with a higher turnover - can sustain higher levels of bulk drug production as compared to those having a lower turnover.

III.4 "Non-associated" formulators

6. In order to prevent market dominance based on technological strength as distinct from Brand-strength in the area of bulk drug manufacture, it has also been provided in the licensing policy that all those companies which are foreign and/or are covered under the provisions of the Monopolies and Restrictive Trade Practices Act shall market 50% of their bulk drug production to non-associated formulators while other companies would market 30% of the bulk drug production to such formulators. This is primarily aimed at presenting market dominance by large companies who may, on the basis of their technological strength in the bulk drug manufacture, deprive the lesser endowed companies of their share of the raw material by cornering it either themselves or through their associates. While the licensing regime subserves policy thrusts of the Government to a substantial degree there are a few aberrations which have to be commented upon. Thus, while the foreign companies are restricted entry only into high technology areas, the definition of a foreign company allows a large number of companies that are foreign in character to be clubbed with the Indian companies and to be eligible for entry into areas reserved for the Indigenous sector. This is so because the dilution of equity 40% does not necessarily change the essential character of a company because of widely dispersed nature of the Indian shareholdings. The criticism on this score is, therefore, valid to substantial

extent. This criticism is met only partly by the argument of the equity dilution reducing remittances abroad considerably and distributing the profits within the country to a greater extent. The basic point of there being no change in the essential character of the foreign companies including their decision making structure, even after equity dilution, still remains valid.

III.5 Impact and limitations of licensing

7. These reservations notwithstanding, the ground reality is that the licensing regime has helped the Indian companies to come up in a big way. While in the year 1984 among the top 5 companies in the drug sector in terms of turnover 3 were of foreign origin (including those having equity of 40% or less but foreign in origin) while in 1988 this number came down to 2.

8. The concern for basic stage manufacture, the concern with creating a strong base for indigenous industry, the overall concern to increase production, the concern for preventing market dominance with a view to protecting the consumer, have all found place in the various elements of the licensing system. It must, however, be mentioned that over the years of evolution of industrial policy in general and industrial drug policy in particular in India, industrial licensing as an instrument has ceased to be as potent in achieving the declared goals of Government policies as it was in the initial years of industrial development. Other more effective instruments like channelising financial assistance from Government institutions, tinkering with the tariff structure etc. have been found to be much more effective in recent times for achieving policy goals.

CHAPTER IV

PRICING OF PHARMACEUTICAL PRODUCTS - POLICY & IMPLEMENTATION AND TARIFFS

IV.1 Administered prices - concept with reference to drug sector

1. The concept of "administered prices" is common in the Indian context and there are a number of industries covered under this, notably among these are the steel industry, the cement industry and the fertilizer industry. Although the cement industry has been price decontrolled recently, these controls still exist in some of the other sectors. Statutory price control is essentially a means to protect the interest of the consumer used in a situation where it is expected that the normal market forces of demand and supply will not have a free play. The concept of administered prices, however, is somewhat wider and apart from the interest of the consumer, there is also an element of protection to the domestic industry. What constitutes a 'fair price' is also a matter of perception which varies from the side one is positioned at. While it is commonly believed that price controls act to the disadvantage of the industry this is not necessarily true in all cases and in some cases the system of administered prices can lead to encouragement of inefficient manufacture which is inherent in any system based on a cost-plus concept, particularly in the absence of competition.

2. The price control regime as it operates in the pharmaceutical industry sector is, however, far more complex and detailed than is the case with the operation of the scheme of administered pricing in the other sectors.

This is as much a result of an anxiety to protect the consumer as of the nature of the industry itself which has a large and multifarious product range as compared to, say, the steel industry or the cement industry or even the fertilizer industry. The primary objective of the statutory price control is obviously to protect the consumer by providing drugs at reasonable prices. However, in the case of price control in the pharmaceutical industry, this mechanism has of late been also used to provide incentives and disincentives for encouraging certain pre-determined policy thrusts and for discouraging certain tendencies. Of course, along with the protection of the consumer it has to be borne in mind that the manufacturer also needs a reasonable return and to that extent the price control system tries to balance two apparently contradictory objectives.

IV.2 Principles and regulatory framework for drug pricing

3. The Drug Price Control system in India is based on the principle of selectively and the regulatory framework for the same is provided by the Drug Price Control Order. The Order lists certain drugs for which prior price approvals of both bulk and formulations from the Government is required. Further, it lays down the parameters and the procedure for such price fixation and specifies certain penalities including recovery of overcharged amount in the event of the breach of the provisions. In addition to the requirement of seeking prior approval in respect of specified bulk drugs and formulations, the Order also prescribes in information Format for even

those drugs which are not in the price controlled category to enable price monitoring of these by the Government.

4. The Drug Price Control Order was first promulgated in 1970 but it was made more elaborate and detailed in 1979. Although it was amended in 1987 by reducing the span of control to a considerable extent, the basic framework provided in the DPCO of 1979 still remains and the principle of selectivity has been retained. While discussing the various provisions of price regulation as also the implications and impact of the same, the DPCO of 1987 would form the reference point for the purposes of this analysis.

IV.3 Procedure for pricing of drugs

5. Price control as also tariff control in the drug sector have to focus on the following product groups:

(a) Bulk drug
(b) Formulations
(c) Drug intermediates

The price regulation procedure varies in respect of each of these products. In fact, in the case of drug intermediates there is no price control although there is regulation on tariffs. In respect of bulk drugs and formulations the underlying principle behind the price fixation is that of a normative system of pricing. This is significant in that except for the cost of raw materials (which also incidentally is based on information available with the agency fixing the price and not necessarily based on the claim made by the company) there are prescribed norms for all the other activities of

conversion, packaging etc. and actuals are not considered. This is an important issue of contention between the industry and the Government since according to the industry the actuals rarely correspond with the norms and are invariably higher. On the other hand, it is also experienced that at times the actual costs are really lower than the norms. In any case, the implications and the impact of the system would be discussed in some details in the following paragraphs. First about the procedure itself.

6. Bulk drugs : Manufacturers of bulk drugs are given the following three options for determining the basis of fixing the ex-factory price :

i) 14% post-tax return on net worth;
ii) 22% return on capital employed;
iii) Long term marginal costing with 12% internal rate of return in the case of new plants.

Government fixes the fair price of bulk drugs on the basis of any of the three options exercised by the manufacturers concerned, by conducting detailed cost-cum-technical study. This cost-cum-technical study involves the analysis of production of a number of manufacturers but makes certain assumptions regarding conversion norms as also input costs like the cost of utilities etc. It also assumes a certain minimum capacity utilisation which may or may not correspond with the actual utilisation of capacity. The purpose behind this is to encourage efficient manufacturers, on the one hand, and on the other, to give adequate protection to new plants in

the matter of price determination. The fair price determined by the Government is normally valid for a period of three years and has an inbuilt escalation formula. Expenses which can be treated as costs and the allocation of these expenses on individual products is also determined on the basis of certain guidelines and practices but recently it has been provided that all expenses on basic research even those which cannot be directly attributed to a specific product shall be considered while computing the ex-factory price of a bulk drug.

7. Formulation pricing : There are two elements in fixation of formulation prices - one is the determination of category to which a bulk drug and its formulation belongs and the other involves fixation of the price according to a formula based on the prescribed mark-up. The Drug Price Control Order, 1979 had prescribed three different categories of bulk drugs and its formulations which permitted respective mark-ups of 40%, 55% and 100%. The Drug Price Control Order of 1987 had reduced these categories to 2 in line with the objective of the Government to "reduce the span of control". This objective is further subserved by reducing the number of bulk drugs and formulations based thereon under control from 347 in 1979 to 116 now. The mark-up allowed to formulations of these two categories has also been increased to 75% and 100%. Thus, apart from the span of control being reduced, the manufacturer had been given a much higher return by way of higher

mark-up indicating recognition of the fact that the earlier mark-ups were totally unremunerative and in some cases did not even cover the operating costs. A word about the basis for categorisation. The principle of selective price control on which the 1979 DPCO was based has been retained but the manner in which drugs in controlled category have been determined appears to be more rational in 1987 than was the case in 1979. Government had appointed a Committee consisting of experts from various disciplines including costing, medical profession etc. to draw up a list of essential drugs to be included under Category II of the DPCO, Category I consisting of drugs used for the National health programme. Thus the Category I list of drugs which had a lower mark-up of 75% was in a way pre-determined and was conditioned by the requirements of the National health programme while the Category II list which allowed higher mark-up of 100% was drawn up by an Expert Committee. This Committee considered a basket of drugs consisting of the drugs included in the WHO list of essential drugs plus an almost equal number of other drugs which the Committee felt were relevant to the Indian conditions. The Committee thereafter applied certain exclusion criteria based on economic parameters and came up with the final list. The underlying objective was to keep only those drugs (out of the basket which the Committee considered to be essential) under the price control which did not allow for the operation of free market

forces to stabilise their prices. The exclusion criteria of the Committee included considerations like number of manufacturers, share of the market and so on plus as a deliberate and conscious incentive to R&D, those drugs the process of which had been indigenously developed. The Government considered the recommendations of this Committee and by and large accepted the same and incorporated these in the shape of the Schedules to the DPCO 1987. Thus the principle of selectivity tampered with the concept of essentiality has been the hallmark of the DPCO of 1987.

8. The formula for calculating the maximum retail price of formulation has two components, namely, (a) ex-factory cost (b) mark-up. The ex-factory cost is sum of the material cost, conversion charges, packing material cost and packaging charges. But as in the case of bulk drugs the ex-factory cost is arrived at on the basis of applying prescribed norms to various activities like conversion, packing material and so on and not on the basis of the actual cost. The mark-up consists of all the costs including distribution and selling expenses as also the profit to the manufacturer, and is a percentage of ex-factory cost.

IV.4 Incentives through pricing regime

9. There are certain incentives provided in the pricing regime to subserve certain objectives of policy. These include - total exemption from price control to industries in the small scale sector; exemption from price control for a period of 5 years in respect of drugs developed

through indigenous R&D; exemption from price control in respect of drugs having new delivery system; exemption from price control of all drugs sold under generic name. It is clarified that in case of price-controlled drugs, Government only fixes the maximum retail prices and manufacturers are free to sell at prices lower than these.

IV.5 Tariffs

10. On tariffs, the basic policy of the Government is to complement the measures in the areas of licensing and pricing by progressively reducing import and excise duties and to ensure that the cumulative incident of duty on the bulk drug is higher than that on the inputs and the drug intermediates. There is, however, no control on the prices of the drug intermediates. Most of these are petroleum based and their availability and price depend to a large extent on the availability and price of petroleum products. In fact this is a gap in the entire policy where the price of the end-product is sought to be controlled while there is no control on the prices of inputs. This is further complicated by the rapid fluctuations in the value of the rupee in the international market in recent times consequently increasing the landed cost of imported inputs and thus putting an additional strain on the price control mechanism.

IV.6 Analysis of DPCO, 1987

11. Brief analysis : An analysis of the Control Order of 1987 almost a year after it had been promulgated resulted in the following revelations :

i) Although there was such a lot of emphasis on reducing the span of control, it was found that actually this had not come down by any substantial degree in terms of the value of production. The number of drugs under price control had certainly been reduced to less than half thereby facilitating the work of the Government machinery in processing price approval applications but in terms of turnover the reduction in the span of control was only around 5-6% as compared to the DPCO 1979. The objective of making the price control mechanism more manageable had been achieved but from the point of view of industry as a whole the turnover under price control did not undergo substantial change. Obviously, the high turnover products are still under price control. A sectorwise analysis showed that the Indian private sector enjoyed the maximum degree of decontrol on production turnover being 27.8% while it was 25.4% in the case of the foreign sector. However, in terms of comparison with the position obtaining in 1979 the biggest gainer was the public sector since under the 1979 DPCO almost its entire production was price controlled.

ii) While on the basis of statutory price fixation, the range of increase in the bulk drug prices was between minus 18.4% to 117% (the increases having taken place because of increase in the cost of inputs over which the manufacturers had no control) in the case of formulations the average increase in respect of the decontrolled category of drugs was around 30%. There were also cases where the prices of the decontrolled category of drugs had come down. However, the figure of around 30% was a weighted average and there were individual cases of much higher increase in the prices but most of these related to extremely low turnover items. All this tends to reinforce the view that competition had set in the decontrolled category as

a result of an expectation of higher returns prompting a shift towards manufacture of decontrolled drugs and the market forces had given a degree of stability to the prices which had not risen to the extent that might have been expected on the basis of a 'lid-off' effect.

iii) There were a number of drugs both bulk and formulation which came under the price controlled category but which were selling in the market at prices much lower than those fixed by the Government. Notable among these were Ampicillin and Amoxicillin. Both these products had a very large number of manufacturing units and here again market forces butteressed by competition had helped in keeping the prices under check, even lower than the statutorily fixed prices by the Government.

IV.7 Criticism of the price control regime

12. Perhaps no aspect of the industrial drug policy has been subjected to so much criticism and pressure from different quarters than the one relating to price control. The criticism of the price control system is on diametrically opposite counts from, on the one hand, the consumer groups supported by the Members of Parliament and, on the other, from the industry. Taking the criticism of the consumer groups first, the criticism is on two counts : One, that Government has gone too far in decontrolling prices and in increasing the mark-ups to the industry and two the selection of drugs for purposes of price control is arbitrary and questionable. The concern for the interest of the consumer in a country where significant portions of the population live below the poverty line is understandable and justified but it is not certain that more rigid controls and less

remunerative prices to the Industry would serve the cause of the consumer better. The experience of the 1979 drug policy which allowed comparatively lower mark-ups and also had a much larger basket of controlled drugs showed that a number of companies were moving away from the pharmaceutical business to other activities and also there was a sharp decline in the production of some essential drugs - although not in the overall production of drugs. There are no easy solutions to this problem, though, and perhaps one approach that could be considered is to subsidize on a selective basis the distribution of drugs to the poorer section of the society by the Government. Another point that needs to be considered is the cost of medicines in the total cost of medicare. Medicines constitute an important though not necessarily a dominant input into the health care and while there is need to keep the prices of medicines in check a view also needs to be taken on the cost of other inputs in health care which are outside the purview of any control. However, the second point of criticism regarding the arbitrariness of categorisation of drugs into price controlled and price decontrolled ones, would appear to be more valid. Although the latest DPCO promulgated by the Government in 1987 is based on a more rational exercise than its predecessor, the inherent shortcomings in the concept of selective productwise price-control nullify the fruits of all such exercises and no amount of rational basis can protect those involved in such

exercise from the charge of arbitrariness. Perhaps the answer to this problem may also lie in moving away from product-wise control to some other methods of controlling prices. Some of these approaches have been discussed later in the chapter dealing with conceptual framework of a model industrial drug policy but it is considered necessary to highlight these concerns at this juncture, not with a view to depicting the existing regime as a policy failure but to highlight the difficulties involved in formulating a rational price control system. It may also be added that in addition to the product-wise price control, the DPCO has a ceiling on profitability on formulation activity which varies from 6-11% depending on the turnover of a unit. Significantly, the ceiling relates to formulation activity alone and not to the bulk drug activity. This is an obvious attempt to check profiteering as a result of brand preferences which are predominant in formulations alone. There could thus be an alternative and simpler approach based on a statutory profitability ceiling to protect the consumer from unwarranted profiteering.

13. The criticism from the manufacturers centres round (a) wrong categorisation of drugs for purposes of price control and (b) inadequacies in the system of price fixation itself. As regards (a) this is a concern which is shared by consumer groups also and has already been dealt at length in the foregoing paragraphs. As regards (b), according to the industry the price control

regime suffers on two counts, one the insistence on normative system of fixation of prices rather than the actuals and, two, the delays involved in getting price approvals. Both these factors tend to erode the profitability of the companies and it is being represented on behalf of the industry that they should be allowed price fixation on the basis of actual costs of raw materials and other inputs. Interestingly, there is very little concern with the quantum of mark-ups that are presently allowed which seem to be adequate and perhaps the market itself may not be able to absorb higher mark-ups than what had been allowed. It is, however, true that delays in price approvals result in the industry not even getting what is due to it in terms of Government-determined norms, in time. Delays in giving price approvals are inevitable inspite of the best efforts. In a situation prone to inflationary pressures as also fluctuations in the exchange rates in the international market, the pressure on the regulating system is further increased and it does not have the flexibility either to remove delays altogether or to undertake price-revision exercises with the frequency demanded by rapidly fluctuating input costs. Thus both on the counts of administrative expediency as also intrinsic merits the present situation demands a fresh approach to the price control regime which should be effective as well as flexible and satisfy both the consumer as well as the manufacturer. From the analysis of the immediate impact of the DPCO 1987 indicated in para 11, it would be tempting to argue for a total price decontrol since the market forces have tended to play

a more dominant role in the recent past. However, given the nature of the Drug Industry and the fact that perfect market conditions, in the best of circumstances, rarely exist, even less so, in the drug sector, some kind of price control or at least monitoring of prices backed up with a mechanism which enables the Government to take quick corrective action, appears to be still necessary and the stage for a complete decontrol does not appear to have been reached as yet, even though there is a strong case for relaxing controls in a phased manner.

IV.8 Impact of price control system

14. The above gaps notwithstanding, the existing price control system has certainly achieved the basic objective of keeping the prices of drugs low. This is so even though the prices of bulk drugs as also the intermediate chemicals are higher in India as compared to the corresponding international prices. While the ratio between indigenous prices and adjusted international prices of major chemicals used for the manufacture of drugs varies from 1.06:1 to as high as 3.43:1 and that of major bulk drug prices from 1.33:1 to as high as 4:1, the prices of formulations of most of the drugs are much lower in India as compared to those prevailing in the International markets. Formulations like Aspirin, Tetracycline, Vitamin-B, etc. are selling at much lower prices in India as compared to those prevailing in the U.K. and some other Western countries. It is, therefore, remarkable that even with higher input costs the prices of formulations have been kept at levels which are not only reasonable but cheap from international standards. Some of the reasons for

this apparent anamoly could be, apart from the statutory price controls, (a) the material costs in India are less than 35% of the retail price and thus there is a wide margin for absorption of part of the higher bulk drug prices (b) the industry in countries like USA is more governed by brand competition than price competition and producers do not necessarily have to bring down the retail prices in line with costs particularly in cases where product performance is well established.

15. Apart from the comparison with international prices, drug prices in India have also increased to a lesser extent as compared to the prices of other commodities. Thus with 1970 base price as 100, while the prices of commodities in general rose from 105.6 in 1971-72 to 450.4 in 1978-79, Drug prices during the same period rose from 99.7 to 222.4.

CHAPTER V

R&D, INDUSTRIAL USE OF MEDICINAL PLANTS AND TRANSFER OF TECHNOLOGY

V.1 Concept of R&D in the drug sector

1. R&D connotes with reference to the Drug Industry, broadly three types of activities :

(a) Development of new molecules and drugs which can be termed as basic research;

(b) Process and product development - the latter in case of formulations and not coming in the purview of isolation of new molecules;

(c) Resolution of plant-specific bottlenecks and related process problems.

2. While most companies allocate their R&D expenditure on all the above three activities, for the purpose of discussion here the activity indicated at (c) above is being excluded since it does not entirely qualify as an R&D activity leading to substantial developments in the area of drug manufacture of a general nature.

V.2 Government policy on R&D

3. Government policy in India has been concerned with development and encouragement of R&D right from the beginning but it was in 1983 that a Sub-group of National Drug & Development Council was set up to give specific recommendations about steps to develop R&D in the Drugs Sector. The recommendations of this Sub-group were quite wide-ranging but those relating to provision of incentives for R&D are briefly given below :

(i) Since research costs have to be met out of the generation of revenue from sales, it is necessary that the pricing system should be

so devised as to enable the units engaged in basic R&D to recover such costs.

ii) Custom duty should be waived on the import of capital goods, such a waiver presently being available to R&D units attached to non-commercial establishments only.

iii) There should be a weighted rebate under Section 35 (2A) of the Income Tax Act for sponsoring research in Universities, medical and pharmacy institutions and inhouse research units.

iv) Liberal licensing policies should be followed for products developed through indigenous research.

4. These recommendations were considered by the Government and by and large accepted in principle. Concrete policy measures containing incentives to encourage R&D in the drug sector were announced from time to time. The major incentives that are available at present for this activity are : (i) All new bulk drugs and related formulations have been brought under the scheme of delicensing which means that specific approvals for manufacture of these drugs shall not be required once the Drug Controller has cleared the production of such a drug; (ii) all drugs, the process of manufacture of which has been developed through indigenous R&D are exempted from price control for a period of 5 years from the date of commercial production; (iii) all formulations based on new drug delivery systems are exempted from price control; (iv) it has been recently decided to allow the entire expenditure on Basic research as cost while computing the ex-factory price of a bulk drug.

V.3 R&D infrastructure in India, basic and process research

5. A fairly strong infrastructure for R&D exists both in the Government and the private sectors in India and the two are complementing the efforts of one another. Research laboratories in the Government sector like Central Drug Research Institute, and the Regional Research Laboratories are engaged in developing new processes as also new molecules. Quite often there is a tie-up between the industry and the laboratory for taking up research in a specific area and often such a research project is partly financed by the concerned company. Similarly, the public sector drug companies have their own fairly well developed facilities of both basic and process R&D.

However, when one compares the levels of R&D expenditure incurred by the industry in India (exclusive of direct Government expenditure through research laboratories etc.) with those in the advanced countries, these are quite low. The Indian industry spent around Rs.480 million on R&D which comes to about 2% of its turnover although a number of Indian companies spent as much as 4% of their turnover on R&D. The above figure relates to the financial year 1985-86 and is a substantial improvement on the figure of Rs.105 million spent on R&D in 1976-77 both in real terms and also as percentage to the sales turnover which was 1.05 at that time. As against this, according to available information, expenditure levels on R&D by companies like Upjohn's (380 million US dollars) Merck (650 million US dollars), Pfizer (219.8 million US dollars) are even individually much more than those of the entire

Indian industry. In terms of percentage to turnover also the expenditure in the West is around 8-9%. It would, prima-facie, appear from these fugures that the Indian companies have a long way to go particularly in the area of basic research. But a closer scrutiny would show that the problem is related to the size of turnover also and the level of expenditure of the trans-national companies mentioned above can only be sustained by their global scale of operations. This is a point which is reinforced by the recent trends of mergers in the drug sector the world over to absrob escalating R&D costs. There might thus be a case of research of this kind capable of being undertaken by companies having global operations which gives them access to larger markets. Besides the high costs involved, basic research is also time consuming and the returns are uncertain. Discovery of a new drug can cost as much as Rs.600 to 1200 million and take as long as 10-15 years requiring the synthesis and screening of 15-20 thousand organic and inorganic compounds to discover therapeutically efficacious molecules. Given the scales of operations of most Indian companies (a maximum turnover of around Rs.800-1200 million annually), it follows that the major thrust of R&D activity has to centre on process and product development rather than development of new bulk drugs. It would be noticed that incentives provided by the Government for R&D also focus mainly on process research. This is not to suggest that no basic research has taken place in India. On the contrary, the expendi-ture on R&D by Indian drug industry although low from

international yardsticks is still quite high compared to other sectors of the industry. It is in fact higher than that of most other sectorsas a percentage of turnover. Annexure III gives the industry-wise comparison of expenditure on R&D. Over 100 companies in India have Inhouse R&D facility recognised by the Government and 9 of these spent more than Rs.10 million per year on this. Even though, for the reasons indicated above, a major portion of the expenditure on R&D in 1985-86 (Rs.280 million which comes to 60% of the total) has been spent on process and product development, whatever amount has been spent on basic research (Rs.200 million) has yielded good results. Quite naturally, basic research in India is focussed on finding drugs for the tropical diseases like amoebiasis and malaria (which has recurred recently). Apart from the two public sector undertakings, Indian Drugs & Pharmaceuticals Ltd.(IDPL) and Hindustan Antibiotics Ltd.(HAL), there are just around six Indian drug companies engaged in basic research. But these have extensive facilities for synthesising, isolating and screening hundreds and thousands of synthetic and plant products. Even though the discovery of final products i.e. therapeutically effective drugs has been limited to a few, CDRI and other laboratories have come out with a large number of chemical molecules which have a potential for being screened and tested for therapeutic efficacy and it is the latter activity because of costs and time involved that the laboratories are unable to undertake on a scale which is necessary.

Some of the drugs that have been developed in India as a result of basic research are given below:

Sintamil, an anti-depressant discovered by Hindustan Ciba-Geigy has reached the second rank in sales in its segment within a few years of introduction.

Tromaril, an anti-inflammatory drug, discovered by RRL Hyderabad, and marketed by Unichem Laboratories.

Hamycin, an antifungalagent, discovered by Hindustan Antibiotics.

Centimazone, an anti-thyroid agent, from the Central Drug Research Institute, Lucknow.

Forskolin, an anti-glaucoma and cardiotonic agent, discovered by Hoechst India.

Satranidazole, an anti-amoebic and anti-trichomonal agent, from Hindustan Ciba-Geigy.

6. Apart from these, there are more than 20 others which are at an advanced stage of clinical trials one of which is an anti-arthiritic drug developed by IDPL and has reached the final stages of clinical trials.

V.4 Research on medicinal plants

7. The Indian region is extremely well-endowed with rich flora and a lot of drug research is concentrated on material of natural origin. A number of Indian companies have taken up investigation of potential of plant life as starting material for use as intermediates in the manufacture of bulk drugs. The work in the area of exploitation of medicinal plants for industrial uses is two-fold. On the one hand, it involves separation of therapeutically efficacious active ingredients from the herbal plants that are in existence either for use

as a drug or an intermediate, and on the other, it involves cultivation of these plants on a commercial scale. The latter involves genetic upgradation, and improvement in utilization and extraction processes. An illustration of this work is mentha crop producing 13% higher herb yield and richer mentha content. An example of successful isolation of active therapeutic ingredient from plants is the work on Rauwolfia Serpentina. The dioscorea tuber is used in the manufacture of a number of steroidal compounds including corticosteroids, androgens, estrogens, etc. A number of medicinal plants have been investigated apart from the above and used for drugs like Solasodine (plant Solanum Khasianum), Sennosides (Senna), Menthol (Mentha arvensis), Vinbalstine and vincristine (Vinca Rosa), the latter being effective Anti-cancer Drugs. Diosgenin which is an important intermediate for a number of drugs has been extracted from Dioscorea which is being grown in the Northern and Eastern parts of the country.

V.5 Herbal plants and traditional system of medicine

8. Apart from drugs obtained after isolating active chemical ingredients conforming to the standards laid down in the pharmacopoea, a number of drugs based on herbal plants have also been developed in the traditional system of Indian medicines like Ayurveda and Unani. These are natural products and do not necessarily involve extraction and isolation of an active ingredient but find a wide-ranging use as such particularly for common ailments like coughs and colds. Chronic ailments like

ailments of the liver also respond to some of these drugs effectively. One example of such drugs is the preparation popularly known as Live-52 which is based entirely on substances of herbal origin. Companies like Dabur and Zandu Pharmacy have done a lot of work on these products. The traditional Indian system of medicines like Ayurveda and Unani also have a distinctive system of diagnosis and treatment of diseases which is different from the allopathic system and the use of medicines by practitioners of these systems has to be considered on a different footing which would be beyond the scope of this paper. It must, however, be mentioned that the Industrial Drug Policy of 1986 does talk about encouraging the traditional Indian system of medicines and also for developing appropriate pharmacopoeial standards for the same. It is recognised that given the present level of access to modern medicines in India, which is very low, and given the fact that large sections of the Indian population which live in villages not only suffer from problem of affordability of medical treatment but also have an inherent faith in the traditional system of Indian medicines, it is but natural that the traditional system of medicines in India should receive an equal, if not, higher importance in the overall health care scheme of the country. However, an interesting development in recent times has been the entry of a number of companies in the organised sector, both indigenous and transnational, in the area of so-called "Home remedies" which can be used without medical prescription. Some of these medicines are Vicks,

Amrutanjan, etc. which are supposedly effective in curing aches and pains and have an increasing demand. These are not prescribed by medical practitioners either of the traditional system or of the modern system of medicines but are generally used by the consumers themselves. These preparations are, characterised by the fact that they are all herbal-based and do not conform to any pre-set pharmacopoeial standards of chemical entities.

V.6 Advances in process research

9. As already indicated, the focus of R&D in India has been and continues to be on process and product development. This has also been helped by the present patent protection laws prevalent in India which afford protection to the process patent. The underlying thread in the industrial policy in the drug sector has all along been the goal of achieving self-reliance in order to reduce pressure on scarce foreign exchange and a consequent thrust on basic stage manufacture. The emphasis on basic stage manufacture and backward integration in production which has been central to the Indian drug policy all through has triggered, indigenous research in development and improvement of processes. As a result, more than 250 bulk drugs are manufactured in India from the basic stages. During the last two decades or so, the Indian drug industry has indigenously developed and improved high technology processes involved in the manufacture of over 100 essential basic drugs. A large number of companies have successfully upscaled highly complex processes from the pilot plant to the commercial scale.

10. During the early part of the development of the drug industry in India, a number of drug companies established high process technology in manufacturing Antibiotics, Sulpha drugs and Vitamins from the basic stage. These included Penicillin, INH, Sulphadiazine, Dapsone, Vitamin A and B12, Prednislone, Betamethasone, Cortisone, Chloramphenicol, Amodiaquin, Tetracycline, PAS, Diethyl carbamazine, etc. Since then, basic stage process has been developed for the manufacture of many more new essential drugs which include Insulin, Salbutamol, Ephedrine, Chlorpropamide, Ibuprofen, Metronidazole, Mebendazole, Naproxen and Tinidazole. One of the challenges that has been faced by the R&D teams has been development of processes based on locally available starting material. With availability of foreign exchange always posing problems, development of indigenous substitutes and processes based on these with a view to effecting import substitution has been a vital objective and to that extent, technologies involving imported intermediates or raw materials have to have a lower priority. The process development exercises have not been confined to the field of synthetic drugs alone but have also seen improvement in fermentation techniques as well as development of new strains. A seven stage process for testosterone has now been reduced to two stages and methanol extraction has been simplified to a one-stage operation as a result of innovative development.

11. There has also been considerable stress on development of optimum dosage forms in formulations. Indian drug

companies have undertaken extensive phyto-chemicals, bioavailability and clinical sub-studies to explore absorption, dispersion and dissolution rates and drug inter-action. This has resulted in evolving better drug delivery systems as also producing drugs of a better quality. A number of new products have also been launched in the shape of formulations notable among these being new dosage forms of Ranitidine, Cimetidine, Cephalosporin and Nifedipine etc. However, there are a number of areas which require attention for further development. Some of these areas of urgent relevance to the Indian context are :-

(a) Immunoprophylaxis and immunodiagnostics etc.
(b) Beta-Lactam antibiotics.

Recent developments in the fields of genetic engineering and bio-technology have made available a large number of technologies for the production of new and improved Vaccines, Hormones, Antigens and other biological products useful for immunisation, making immunoprophylaxis an important option in the mass health care particularly in India where a number of infectious and communicable diseases of bacterial, viral and protoszoal origins still take a heavy toll. Hence the need for sustained R&D effort in this field. Similarly, the newer Betalactam antibiotics will find increasing use as speciality drugs for highly specified problems and this area would need special attention in terms of R&D, even though some of the Cephalosporin group of drugs are already being used in the country. It is necessary to pay special

attention to development of those products which have the special virtue of highly selective action against micro-organism with minimal toxicity.

V.7 Technology transfer and upgradation

12. The questions of technology transfer and technology upgradation are closely interlinked to R&D. A basic pre-requisite is the presence of a strong and resilient infrastructure to absorb the transferred technology and even to upgrade it. However, before analysing the results of technology transfer in the Indian context, it may be useful to see how the process development has accelerated the development of the Indian drug industry. The chart given in Annexure IV gives a list of 13 drugs starting from the period 1972 to 1987 and indicates the dates of their international launch and their introduction in India. The drug Pentoxiphylline was internationally launched in 1972 and introduced in India in 1987. There was thus a gap of 15 years between the two. In the case of Nifedipine this gap came down to 10 years; in case of Cefotaxine the gap came down to 7 years and in the case of Insulin it came down to 4 years. In the case of Ciprofloxacin the gap has come down to 2 years. The infrastructure of R&D for process development has thus now reached a stage where sophisticated products are being introduced in India within a period of 2-4 years from their launch in the international market which is a testimony to the strength of the process development of R&D in India.

13. Since most technologies in the drug sector are very closely held and are also very costly, the access is limited to technologies which can be regarded at best as second rate or even out-of-date. This is another reason why it is imperative for developing countries to have a strong infrastructure capable of not only absorbing the technology but also of upgrading it. While the access to information about the efficacy and impact of technology transfer in the private sector is limited for reasons of market confidentiality, there is ample evidence available to show that the technologies which have been obtained by the Indian companies from the developed countries have by and large been absorbed and also upgraded effectively in a number of cases.

14. A striking case is that of the Penicillin technology. HAL a public sector company first obtained Penicillin strain having productivity of 15,00 u/ml in 1963 which the company subsequently improved to 15,000 u/ml by 1976 through Inhouse R&D and strain improvement programme following conventional mutation and natural selection methods. HAL decided to obtain a high yielding strain and technology from Toyo Jozo of Japan in 1976 and this technology was absorbed and adapted initially with the help of Toyo Jozo at the pilot plant level and upgraded to the productivity level, 30,000 u/ml in 200 hours with an extraction and recovery efficiency of 65%. R&D efforts thus substituted the imported raw materials with indigenously available ones; simultaneously by improving strain productivity through mutation and

natural selection methods and also alterations in the environmental conditions of the fermentor, yields of a productivity of around 38,000 u/ml in 180 to 200 hours as also an improvement in the downstream extraction to 75% have been possible. Interestingly, the same technology was later transferred by HAL to IDPL, another public sector undertaking, which along the way obtained technology for this product from the USSR also. IDPL also was able to upgrade the Penicillin technology to such an extent that recently it has even offered to transfer the same to USSR which was one of the sources of its Penicillin technology.

15. Similarly, in the case of Streptomycin, HAL obtained the technology from Merck Sharp and Dhome of USA in the year 1960-61 with a yield of 8000 to 10,000 u/ml. This technoldogy had some inherent problems of productivity of both Streptomycin A and B and HAL subsequently obtained a better strain from Glaxo Laboratories, U.K. in 1973-74 which was directly established on the main plant with productivity of 16,000 to 18,000 u/ml having Streptomycin content of around 10-15%. Interestingly, in this case it was the IDPL which gave HAL the technology in 1985 having a higher productivity of 18,000 to 20,000 u/ml. HAL through its own R&D efforts was able to synthesise all the three technologies that it obtained and developed a commercially viable down-stream technology thereby increasing the extraction and recovery efficiency and minimising the cost of production. HAL is able to manufacture around 120 tonnes per annum of Strepto-

mycin through this upgradation.

16. While there has been transfer of technology from developed countries to India, there have also been lateral transfers within India in a number of cases to the mutual advantage of all parties. The basic pre-condition for a successful technology-transfer, as already stated, is the availability of infrastructure to absorb and upgrade the same which exists in good measure in India. Given the present international environment the access to "state of the art technology" of developing countries is likely to remain limited. There does not seem to be any escape from laying hands on whatever technology is available, and then adopting and upgrading it through inhouse R&D. The need for developing countries for creation of infrastructure to enable this cannot be over-emphasized.

CHAPTER VI

QUALITY CONTROL & RATIONAL USE OF DRUGS

VI.1 Relevance of quality control to industrial drug policy

1. Even though quality control and drugs standards do not strictly come under the purview of an Industrial Drug Policy per se, to the extent that one of the primary objectives of the comprehensive drug policy announced by the Government of India in 1986 has been "strengthening the system of quality control over drug production and promoting the rational use of drugs in the country", it is necessary to briefly consider these aspects particularly in terms of availability of infrastructure.

VI.2 Regulatory framework for quality control

2. Quality control and related regulations are administered by the Ministry of Health in the Government of India with an apex controlling authority in the shape of Drug Controller of India. The States have parallel regulatory authorities called the State drug control authorities and the basic regulatory framework for drug regulation is the Drugs & Cosmetics Act and the rules framed thereunder. The Act together with the rules regulate the import, manufacture, distribution and sale of drugs. No drug can be manufactured or even introduced in the market without the prior approval of the drug controlling agency which is done on the basis of clinical trials etc. While the Drugs & Cosmetics Act and the rules framed thereunder cover a very wide range of activities related to manufacture and distribution of drugs and are, therefore, all encompassing in their scope, and applicability as also sanctions, provided for violation,

the infrastructure available for implementing these provisions is not as strong as is warranted by the size and the spread of the industry and the sale points. As against over 20,000 listed manufacturing premises and around 2,00,000 sales premises spread all over the country the number of Drug Inspectors is only around 700. The regulatory system is also based on the federal concept and the power is concurrently shared between the federal and the State Governments, even though the power to make rules rests with Federal Government.

3. The Drugs & Cosmetics Act defines drugs, misbranded drugs, adulterated drugs, spurious drugs, new drugs and also lays down specific standards of quality drugs. A Drug is defined as :

i) All medicines for internal or external use of human beings or animals and all substances used for or in the diagnosis, treatment, etc. of any disease in human beings or animals.

ii) Substances intending to affect the structure or function of human body.

iii) Substances intended for use as components of a drug.

iv) Devices intended for internal and external use in the diagnosis, treatment, mitigation or prevention or disorder in human beings.

A misbranded drug is defined as under :

a) If it is so coloured, coated, powered or polished that damage is concealed or appear of better of therapeutic value than it really is.

b) Not labelled in the prescribed manner.

c) If the label bears any statement, design or

device which makes false claim or misleading in any particular.

An adulterated drug is defined as under :-

a) If it is filthy, putrid or decomposed.

b) If prepared, packed or stored under insanitary conditions whereby it may be contaminated with filth or rendered injurious to health.

c) If its container is composed of any poisonous or deleterious substance which may cause injury to the health.

d) If it does not contain any permitted colour.

e) If it contains any harmful or toxic substance which may be injurious to health.

f) If it is mixed with any substance to reduce its quality or strength.

A "spurious drug" is defined as under :

i) If imported under a different name.

ii) If it is imitation of, or substitute for another drug or resembles another drug to deceive. If it is conspicuously marked to reveal to its true character and its lack of identify with some other drug.

iii) If its label or container bears name of the manufacturer or company which is fictitious or does not exist.

iv) If it is substituted wholly or in part by another drug.

v) If it purports to be the product of a fictitious manufacturer.

A "new drug" is defined as under :

a) A new substance of chemical, biological or Biotechnological origin, in bulk or dosage

form, used in prevention of diseases in man or animal.

b) A drug which is already approved by the licensing authority for certain claim.

c) A fixed dose combination of two or more drugs, individually approved earlier for certain claims but contain ingredients in a fixed ratio.

d) For this purpose all vaccines shall be new drugs as approved by the licensing authority.

e) A new drug shall be considered as new drug for a period of four years from the date of its approval or its inclusion in I.P.

The Act then lists offences and lays down penalties for the same. The Indian Pharmacopoea has also been developed and updated from time to time. It lays down standards for a very large number of substances and is recognised in large parts of the world as a reliable standard. There are a number of Central drug laboratories for testing samples, which are under the control of the federal Government. In addition to the Central drug control organisation, each State has got its own Drug Control Organisation which varies in strength from State to State.

VI.3 Gaps in the quality control regime

4. Even though the legislative framework for quality control of drugs in India is quite strong and adequate, considering the size of the industry and distribution points, there are gaps in the infrastructure. These gaps were highlighted in recent times by a Commission popularly known as the Lantin Commission which had gone into the quality control infrastructure and its implementation in the State of Maharashtra in the light of

some deaths resulting from sub-standard drugs. The Commission made an open and very detailed enquiry and has come up with important recommendations after pointing out serious lapses in the organisation as well as implementation of the Drug Control Regulations. The Commission has made a scathing attack on the functioning of the Federal drug administration in the State of Maharashtra and has recommended action against a number of functionaries, as also corrective action.

5. It is in the context of the gaps in the drug regulation and quality control machinery and the varying degree of efficacy and strength of the infrastructure in the States that the policy measures announced by the Government in 1986 recommended the creation of a National Drug Control Authority. The idea was to have an apex authority which would be responsible for the entire gamut of activities relating to quality control of drugs starting from laying down of uniform standards to implementing the quality control measures not only through a post-check but also by strengthening internal testing system. The modalities of creation of such an authority are still being examined and the problems in evolving a framework are compounded by the delicate nature of the federal-State relations.

VI.4 Rational use of drugs

6. The Government policy also lays emphasis on the rational use of drugs. In specific terms the policy

statement mentions that "new formulations based on drugs already approved for use in the country would not be allowed to be manufactured unless their therapeutic efficacy and rationality are adequately tested and approved." This is a general statement and the concretisation of this policy objective runs into difficulties for obvious reasons. For one, definition of what is rational and what is irrational takes one into the domain of subjective judgement since no amount of rational justification or arguments can fully result in the conclusiveness of a particular drug being rational or otherwise. Even drugs having the same or similar composition may be considered necessary by different physicians as suiting individual body constitutions. Like elsewhere in the world, these issues are being hotly debated in India also and it is the considered view of a lot of people that irrational drugs are being marketed in the country through high pressure sales techniques, particularly by the trans-national companies. It is argued that there are only limited number of essential drugs which alone should be manufactured in the country and the rest should be banned. While the question of banning of harmful drugs can be tackled easily, the problem of irrational drugs does not lend itself to such easy solutions.

7. Notwithstanding the complexities involved, Government in India has taken some steps to protect the consumers from undue proliferation of drugs. One of these steps

involves a statutory requirement to display generic names on all the drugs marketed in the country in a size twice that of the brand name. The earlier decision to abolish brand names altogether in a number of products ran into legal difficulties when some companies approached the courts. Another decision, though having only an indirect bearing on the question, relates to controlling the prices of certain vitamin combinations while keeping out the single ingredient formulations from price control thereby discouraging the proliferation of unnecessary combinations and putting a premium on such proliferation. Nevertheless, exercises to determine what would constitute a list of rational drugs and for weeding out irrational combinations are going on a continuous basis.

CHAPTER VII

PRODUCTION PROFILE AND STATUS OF DRUG INDUSTRY IN INDIA WITH SPECIAL REFERENCE TO THE HEALTH SITUATION

VII.1 An overview of the Indian drug industry

1. Having analysed the major components of the Industrial drug policy in India, it would be worthwhile to take an over view of the Indian Drug Industry and its production profile not only to assess the impact of these policy measures but also with reference to the health situation and the relevance of the industry to the same. The Indian Pharmaceutical Industry is among the largest and more diversified in the developing world. The growth of this sector took place primarily after the country attained independence although there was some indigenous production of allopathic medicines as early as in 1901 with the establishment of Bengal Chemicals & Pharmaceuticals Limited. The extent to which the industry owes its present position to the policies of the Government or the entrepreneurship shown by the industrialists particularly the technocrats, is difficult to assess. Perhaps both the factors were responsible for these developments in equal measures and it would be unfair for either the Government or the entrepreneurs to claim the entire credit for whatever developments have taken place in this sector.

2. At the time of the independence of the country the output value of the pharmaceuticals was nearly Rs.100 million which basically consisted of imported bulk drugs being converted into formulations. From a very small

base the industry grew very rapidly in terms of physical output as also product diversification, basic stage manufacture and technological advancement. Today the industry produces a very wide range of bulk drugs including antibiotics, harmones, sulpha drugs and other synthetic phyto-chemicals and biological products besides practically the entire range of formulations required by the medical profession. The technology adopted for the production of different bulk drugs covers intricate and sophisticated fermentation technology, syntehtic formulations and extractions and purification of active bands contained in the plant and animal kingdom. The growth of industry over the years can be seen from the following table which indicates the pattern in the post-independence period :

(Rs. in millions)

	1952	1962	1979-80	1987-88
1. Investment	240	560	4500	7500
2. Sales value				
(a) Bulk drugs	N.A.	150	2260	4800
(b) Formulations	350	1000	11599	23500

VII.2 Sector-wise performance of the industry

3. The pharmaceutical sector in India is segmented broadly into the public sector, the Indian sector, the foreign sector and the small scale sector. There are around 250 units in the organised sector, 5 of which are Central Government public sector undertakings as also 7 joint ventures. Companies which are treated as strictly foreign in terms of the Foreign Exchange

and Regulation Act are only 9 in number at present and there are over 5000 units operating in the small scale sector. The number of active units among these varies and may be around 2000 at any point of time. While these are mostly engaged in the manufacture of formulations, about 100 units in the small scale sector also produce important bulk drugs. The composition of these small scale units is nevertheless multifarious and ranges from genuine small-scale units primarily engaged in formulation activities to sophisticated small scale units which are linked or associated in some way with trans-national companies manufacturing bulk drugs. These companies float small scale units to take advantage of some of the regulations favouring this sector. The comparatively high turnover to investment ratio in the drug sector coupled with the fact that in India the definition of small scale units is based on investment in capital equipment, add to confuse the real character of these units. Questions relating to quality efficacy of drugs manufactured by some of these units have also been raised from time to time and this is an area which the Government has been addressing itself to for resolution. The total turnover of the industry which is of the order of around Rs.30,000 million does not perhaps justify such a large number of manufacturing units. The share of each of these sectors in the production of bulk drugs from 1978-79 onwards is shown in the following

table :

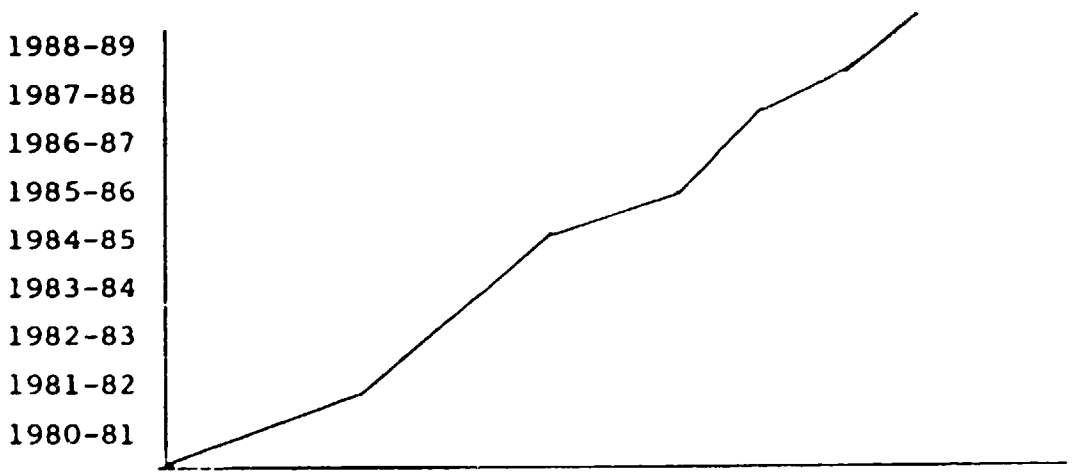
(Rs. in millions)

Sector	1978-79	1979-80	1080-81	1981-82	1982-83	1983-84	1984-85
Public Sector	490	590	620	670	610	610	640
Foreign Sector	560	530	560	730	720	650	680
Large Indian Sector	750	900	950	1200	1210	1550	1660
Small Indian Sector	200	240	270	300	650	740	790

4. It would be seen from the above that there has been a remarkable growth in the share of the large Indian sector in production of bulk drugs and the share of the foreign sector has gone down considerably even though the actual production has marginally increased. Similarly, the share of public sector in percentage terms has also gone down but the share of small scale sector has increased to a considerable extent. Although the public sector and the private sector playing a complementary role in the overall advancement of the pharmaceutical sector are producing a wide range of bulk drugs falling under therapeutic groups like cardiovascular, diuretics, vitamins, anti-TB, anti-cancer etc, there are still a large number of basic chemicals and intermediates going into the production of bulk drugs which are being imported by the country. Presently around 350 bulk drugs are being manufactured in the country, but in spite of this, the country has to import certain essential items. Even though imports are likely to continue since no country can possibly be wholly self-sufficient, the pharmaceutical sector, as on date, gives a substantial trade surplus.

VII.3 Export of drugs

5. The industry has developed sufficient sophistication to export its products to other countries. Today the import of pharmaceuticals in India is of the order of 6 to 8% of the total value production whereas India is exporting about 10 to 12% of its product and the present level of export of drugs from India is around Rs.4600 million. The growth of export over the years is indicated by the following chart :



Value Rs. in Millions

The countries where these exports are taking place includes Canada, USA, West Germany, UK, France as also a number of East European countries.

VII.4 Projections for demand

6. The demand for drugs depends upon various factors such as nutrition, primary health care facilities etc. In India the coverage of the population with health care is also quite low and the delivery system is being strengthened to increase this coverage. The National Health Policy has accepted the goal of health for all by the year 2000 A.D. On the basis of the population, the growth in the health care infrastructure and the expected increase in the coverage of population, it is anticipated that by the turn of the century India would require medicines worth Rs.1,30,000 million which

shows an increase in demand from 1980-81 level at cumulative rate of 14.4% per annum. The policy thrust enunciated in recent mes aim at increasing investmen in the sector and optimising production to meet thi. kind of demand. The thrust areas requiring specia. attention would be technology upgradation and infusior of new technology in selected therapeutic groups; develop ment of technologies in the field of drug delivery for achieving better results and greater emphasis on cost effective manufacture of drug intermediates and the chemicals going into the production of bulk drugs.

VII.5 Production profile in terms of therapeutic groups

7. The production profile of the Indian Drug Industry in terms of various therapeutic groups with reference to the health needs of the country shows that the industry is self-sufficient to a considerable degree in conforming to the diseased patterns obtaining in the country. Like in most developing countries, in India also the health care scenario is characterised by malnutrition, unsatisfactory sanitary conditions, inadequate water supply etc., even though over the years there has been some improvement in facilities like drinking water, sanitation, etc. The policy of the Government for realising the objective of health for all the 2000 A.D. also envisages strengthening of basic health care system. The objectives in the National health policy include control and eradication of communicable as well as non-communicable diseases, expansion of immunisation programme and pr for prevention of diseases like Diabetes, Hyperten. a,

etc. In the case of communicable diseases Malaria, Leprosy, Tuberculosis are to receive prime attention while the attack on non-communicable diseases centres on blindness control, Goitre and cancer. There is also emphasis on immunisation programme in order to reduce incidence of Polio, Tetanus, Diphtharia etc. The production profile of the Pharmaceutical Industry in India has conformed to these requirements by and large as is evident from the growth rate in the major therapeutic groups which are used for combating diseases coming in the thrust areas identified by the National health policy. Thus the growth rate projected per year in the case of Anthelmintics has been from 10-15%, that in the case of Antibiotics around 15%, in the case of Antiamoebics/diarrohals it has been around 10%, in the case of Antiasthmatics it has been around 5%, in the case of Anti-tuberculars it has been around 10%, in the case of Gastro-Intestinals it has been around 10%. The future projections of demand for bulk drugs and formulations from the year 1990 to 1995 based on factors like past trends of consumption, disease pattern, the objectives of National health programme, likely obsolescence of existing drugs, are given below, in terms of total value :

(Rs. in million)

Year	Value of bulk drugs	Value of formulations
1990-91	8800	34050
1991-92	9600	37340
1992-93	10450	40800
1993-94	11400	44400
1994-95	12550	48900

CHAPTER VIII
APPROACH TO A MODEL DRUG POLICY

VIII.1 Pre-requisites of a drug policy

1. Any Industrial Drug Policy would necessarily have to be country-specific and region-specific and would reflect the concerns and priorities of the Government and society. What is being attempted here is to develop, in brief, an approach towards formulation of such a policy and the degree of relevance of this would vary from region to region, for obvious reasons. The basic assumption while developing such a model is of course the need to develop an indigenous drug industry. Such an assertion is necessary since there might be a situation of a trade surplus of such comfortable magnitude as to allow for free imports of all the requirements of drugs needed for a country. Such a scenerio would prima facie obviate the need for development of an indigenous drug industry but even here a careful assessment of comparative cost-benefits not only in economic but also in social terms would be necessary before such a view can be supported. The theory of comparative advantage if applied at the global level may also militate against each country having a well developed industry of its own but to carry this concept to the global level would itself be fallacious in that such an argument would preclude large sections of the world from any industrial development at all - something that would be repugnant to the aspirations of Developing Countries for sharing the fruits of Industrial development. It is also clarified that the approach being discussed in this chapter is based on the Indian experience.

VIII.2 Assumptions for developing a model

2. Before attempting an approach to an industrial drug policy, certain assumptions are being made without which it would not be possible to develop a cogent set of policy options capable of being applied with a degree of universality. These assumptions are :

i) Development of an indigenous bulk drug and formulation industry is a conscious objective of the policy makers;

ii) There exists the necessary legal framework for regulating industrial development;

iii) Making medicines available at reasonable prices is a policy objective;

iv) There is a growing market and an unsatisfied domestic demand for drugs;

v) There is access, to a reasonable degree, to drug technology either domestically or internationally;

vi) The environment allows manufacture and distribution of drugs directly to the consumers through private enterprise. In other words, the State does not monopolize the entire apparatus of manufacture and distribution of drugs.

VIII.3 Elements of the policy

3. An Industrial Drug Policy can be extremely intricate and detailed covering a wide range of aspects and, on the other hand, it can focus on a limited aspects of the industry. For purposes of developing a model, it is broadly proposed to focus on :

(a) The health policy and the disease patterns prevalent in the region;

(b) Instruments to regulate industrial manufacture of drugs;

(c) Technology development and upgradation;

(d) Incentives for developing indigenous capabilities of the industry; and

(e) Pricing policies.

VIII.4 Components of the model

4. As a first step, the health policy of the country and, in the absence of a formal policy, the disease pattern and the priorities of medi-care needs would have to be examined. The production of drugs will have to be in conformity with these. As a next step, it would be worthwhile to draw up a list of essential drugs to cover the disease patterns. There are some inherent problems in developing such a list and there may be arguments and counter-arguments as to what would constitute "essential" as against "non-essential". Nevertheless, going by the local conditions, such a list can certainly be prepared. The WHO list of essential drugs can form the basis for such an exercise. It is considered necessary to have such a list to ensure focus of governmental attention on these drugs both in terms of investment and control. It may not be necessary to ban other drugs - in fact it may be legally counter-productive to do so but the approach should be to encourage production of drugs contained in this list by means of Government policy, as also to control, wherever necessary, only the drugs contained in this "essential" basket. The Indian experience has shown that having a policy for the entire range of drugs and pharmaceuticals increases

the range of coverage to almost unmanageable proportions and stretches the regulatory system unduly.

5. Having identified the essential drugs which should be focused upon in terms of policy support, it would be necessary to encourage production of these. This can be done by not only giving incentives for increased investment in these areas but at the same time having disincentives for production of the so-called non-essential drugs. A regulatory mechanism with a legal basis which could control investment, creation of capacity and production of bulk drugs and formulations and channelise the same in the desired areas would be a necessary pre-requisite. Since one of the assumptions made at the outset also relates to the encouragement of development of indigenous industry, to the extent the foreign companies tend to stifle its growth, their activities will have to be regulated. Encouragement to the use of generic vis-a-vis brand names through incentives could be considered in order to achieve not only this objective but also to afford a measure of protection to the consumer. There are pros and cons to the encouragement of generic names vis-a-vis brand names and one argument given against encouragement of generic names relates to the quality aspect, the underlying idea being that brand names engender confidence in the minds of the consumer regarding Quality. On balance, however, it appears to be a desirable strategy to encourage generic drugs in order to restrict the capacity of exploitation of brand preferences to the detriment of the consumer.

6. Another area which needs to be encouraged is cost-effective indigenisation of production. This can be done by developing a Phased Manufacturing Programme (PMP) for each of the items of bulk drugs and to regulate imports in conformity with this PMP. Care, however, has to be taken that indigenisation is cost-effective and does not lead to higher costs due to manufacturing inefficiencies or deficiencies.

7. Suitable incentives may be given not only for encouraging the manufacture of selected bulk drugs and formulations based thereon but also the intermediate chemicals which go into these manufacture. This is an important area which requires policy support since the non-availability of these intermediates as also excipients can render all efforts at encouraging manufacture of selected drugs infructuous.

8. Technology development and upgradation comprises an important input to any industrial drug policy. This would mean creation of adequate and strong infrastructure as also the legal back-up for encouraging process and product development. It has been assumed at the beginning that the country or the region concerned has some access to technology. However, it is common knowledge that in the drug sector access to the state of the Art technology is rare and one has to make do with whatever technology is available. The need for adaptation and upgradation of the same is, therefore, imperative and this would require necessary infrastructural and legal support.

9. Since bulk drug manufacture is technology-intensive there is a natural tendency to go in for manufacture of formulations alone where the margin of profit is higher and the investment and technology content much lower. The policy thrust would, therefore, have to provide for a package of incentives for Bulk drug production to avoid a situation where the manufacturing activity is confined mainly to formulations. Dependence for Bulk Drugs on sources outside the country or even sources within the country which have a monopoly, would lead to problems in achieving the objective of increased availability of formulations and, to that extent, a positive incentives package for development of bulk drug industry would be an essential component of any industrial drug policy which aims at comprehensive development of the Drug industry.

10. Coming to the most sensitive and contentious question of pricing policy, there may be arguments in favour of and against State intervention in determining the prices of drugs. The basic objective of any Government from the point of view of the consumer should be to ensure that the latter gets the product at reasonable prices. To the extent that this objective is subserved by the operation of free market forces of demand and supply there may not be any need for controlling the prices once it is ensured that adequate production is generated to meet the demand. However, experience shows that ideal market conditions do not exist specially in the formulations

sector of drugs and aberrations are caused in the free play of market forces due to : (a) Monopoly, (b) Market dominance and (c) Shortages. Different approaches to price control can be considered but the basic objective should be to help the consumer by adjusting for the aberrations that might be caused in the market mechanism, and also to give a reasonable return to the manufacturer. While there is nothing wrong in the manufacturer trying to maximise profit, what should be checked is profiteering.

11. One approach to price control could be a selective product-wise price control as is in vogue in India. There are obvious advantages of such a system in that it enables the Government to fix the exact sale prices of the products the price of which it wishes to control and to that extent nothing is left to the market forces, the consumer is protected, and if the norms for fixation of such prices are reasonable, the manufacturer also gets protected. But in practice it is found that disadvantages of such a system outweigh the advantages as detailed in Chapter IV. The first problem starts with the principle of selectivity itself. However rational the process of selection might be, there is always an element of subjectivity in it and what should be price controlled and what should not be price controlled is always open to question. Secondly, such a system involves a lot of administrative work and with the best of intentions, there is always a time lag between the application for price approval and the actual price approval which goes

against the interests of the manufacturer specially in an inflation-prone economy. Conversely, the selective price control system tends to hit the consumer also by diverting investment from price-controlled products to decontrolled products, and there may even be a situation where, as a result of such a diversion competition is able to protect the interests of the consumers in the decontrolled products more effectively than is the case with the controlled basket.

12. A second approach could be to move to a tariff-based control from a product-wise control. In other words, the Government could use the mechasism of import tariffs to control domestic prices. In such a situation, tariffs have to be used in the interest of consumer and not for protecting indigenous industry. However, tariff based controls require a lot of fine tuning as also sufficient flexibility in the system to allow for frequent changes. In a situation where tariffs are considered an important source of revenue for the Government, and are linked to the Budget-formulation exercise which takes place once in a year, tariff based controls may not be the ideal solution. Besides, it is not easy to determine what price would be fair to the consumer. Comparison with international prices may also lead to distortions if these prices are "dumping prices".

13. A study conducted by the National Council of Applied Economic Research in 1984 in respect of about 55 companies in India showed that in most of the companies 2-4 top

selling products had a major contribution to total sales. This figure was as high as 80% or more in some cases. If these results are extapolated and it is assumed that most companies would depend upon a small number of products for most of their sales turnover, the imposition of a ceiling on profitability could be considered as an ideal way of checking profiteering by drug companies at the expense of the consumer. This ceiling can be imposed on the formulation activity of companies since it is this activity which brings them into interface with the ultimate consumer. It is also this activity which lends itself to a propensity to profiteering. A logical question would, however, be as to what happens if a consumer requires only those drugs at a point of time which constitute a small segment of the sales of a particular company. Obviously as far as that consumer is concerned, the profitability ceiling may not be of much help to him. To take care of such distortions, it may be possible to combine the concept of profitability ceiling with controlling the prices of those drugs where there is market dominance. To concretise this concept, it may be possible to control the prices of all drugs which are manufactured by less than three manufacturers or where though the number of manufacturers is large, the market share of a single manufacturer is say, more than 30%, or for that matter, any pre-determined figure. This should take care of the two factors primarily responsible for aberrations in the free play of market forces, namely monopoly and market dominance. The numbers and percentages indicated

above are flexible and would depend upon the degree of sensitivity of the market to these factors.

VIII.5 A note of caution

14. What has been stated in the foregoing paragraphs is only an approach to a possible industrial drug policy and should be treated as such only. It is not being put forward as a "prescription" for the problems of the industry or the consumer, nor is it being suggested that this approach would have universal applicability. Nonetheless, the model which has been suggested can form the basis for further discussion and each country may then be able to arrive at its own model in the light of its own priorities and socio-economic environment.

SUMMARY

Chapter I

An Approach to Drug Policy - Rationale & Parameters

The concept of industrial drug policy would be relevant in the politico-economic context of countries where governmental intervention to achieve the desired goals is not only possible but also considered necessary.

Industrial drug policy will have to center around three product groups, namely, formulations, bulk drugs and bulk intermediates.

The special characteristics of the drug industry which distinguish it from other sectors of the industry will also have to be taken note of while formulating an industrial drug policy and certain sub-elements of the total policy need to be identified. The policy could mainly focus on regulation of industrial production; quality control; R&D; indigenisation and basic stage manufacture; pricing of products; and rational use of drugs.

Any industrial drug policy will have to be seen in the context of subserving the objectives of the health policy; and the strategy for health care.

The range of policy regulations inherent in the drug policy would vary from country to country and would depend on the degree of relevance of the various factors indicated above to a particular situation, the socio-political predilictions of the Government of the day, constraints of the economy and the overall environment.

The question for a need to have an industrial drug policy has its answer in the necessity of relating in a coordinated manner the diverse objectives of State policies that are sought to be achieved in the context of meeting the health care requirements.

Chapter-II

Evolution of Industrial Drug Policy in India

To understand and appreciate the complexities of Industrial Drug Policy, it is necessary to have an idea about the regulatory framework for industries in the country.

The basic regulatory provisions relating to industries are Industries (Development & Regulation) Act, Monopolies and Restrictive Trade Practices Act, Foreign Exchange Regulation Act and certain guidelines and press notes issued from time to time which lay down parameters in respect of licensing - related issued.

The Indian regulatory system is characterised by a broad division of industries on ownership basis; demarcation of industries into sectors on the basis of capital investment; restrictions on imports; and prioritisation of different types of industries.

The entire regulatory regime evolved over the years in consonance with the basic economic goals of the Government, namely, self-reliance and allocation of resources in accordance with pre-determined national priorities.

The Industrial Policy Resolution of 1956 gave direction to the industrial development of the country and continues to be the guiding force for the same even today, although the policy spelt out in 1956 has been reviewed from time to time - in 1973, 1977 and 1980. But basically these latter policy statements reflected the concerns and priorities of the Government of the day taking into account the change in scenerio and made corrections and adjustments keeping these in view.

The evolution of Drug Policy in India has to be seen in the context of the overall Industrial policy of the country, although due to its special characteristics the drug sector has been considered for separate treatment with regard to policy formulation.

Till 1962, no special policy for the drug sector existed and the first policy was initiated in 1962 through the Drug (Display of Prices) Order 1962 which was primarily concerned with controlling prices of drugs. This Control Order was amended from time to time and the rudiments of a conscious policy can be traced to the Drug (Display and Control) Order 1966 which provided for prior approval of the Government before increasing the prices of any formulations, as also for fixing the prices of new drugs. This Order was further refined and amended to provide for (a) exemption of drugs with pharmaceutical names from price approvals and (b) exemption of drugs evolved out of original research and marketed for the first time from the price control. Thus it is the first time that cognizance was taken for R&D efforts and the Control Order did not merely concern itself with keeping the prices down.

In 1966 Government asked the Tariff Commission to study the cost structure of certain drugs and based on the recommendations of the Tariff Commission, the Drug Price Control Order of 1970 was promulgated with the main objective of effecting a measure of rationalisation in the prices of drugs and to build up a rational system of price control.

While by 1970, the Government of India had taken some steps for developing the drug industry, the primary concern continued to be the control of prices in the interest of the consumers and it was only in 1970 that Government took a comprehensive look at the drug industry and appointed a Committee under the chairmanship of Jaisukh Lal Hathi to enquire into the various facets of drug industry in India. This Committee was the forerunner of the Industrial Drug Policy of 1978, which for the first time, covered all aspects of the drug industry ranging from licensing, price control, imports, role of foreign companies, quality control, etc. The major thrust of the policy of 1978 was to encourage development of indigenous industry vis-a-vis the foreign dominated industry and to control prices of a large number of drugs in the interests of the consumer.

A number of restrictions were put on the activities of the foreign companies (which meant all companies having a foreign equity of more than 40%) to be in consonance with the objectives of State policy and quite stringent and detailed provisions were made for regulating and fixing the prices of over 347 bulk drugs and their formulations. Emphasis was laid on the foreign drug companies for setting up R&D facilities within the country and spending a minimum percentage of their turnover on R&D. The entry of foreign companies was sought to be restricted to high technology areas.

The results of these measures were quite remarkable in that the number of companies covered under the Definition of "foreign companies" came down from 38 in 1978 to 9 by 1986. The policy of 1978 also provided for a normative system of pricing of Drugs.

Even though the 1978 drug policy constituted a significant step in the evolution of a comprehensive policy, its restrictive provisions particularly the price control regime tended to slow down the growth and investment. This led the Government to make a review of the impact of the various elements of the policy particularly in the context of revealtions from studies to the effect that the post tax profits of a number of companies were showing a declining trend and a number of essential products were also showing a declining trend in production.

Based on the above, the Government of India came out with what it called "Measures for Rationalisation, Quality control and Growth of Drugs & Pharmaceutical Industry in India" in December 1986. These measures continued to retain the basis of the 1978 drug policy but tended to correct some of the anomalies. The key note of the policy of 1986 was "abundant availability on a continuous basis, at reasonable prices of essential life saving and prophylactic medicines of good quality." The emphasis thus shifted to the need to increase production and the implied inference of market forces taking care of the prices after production increased. The policy of 1986 also laid considerable stress on strengthening of quality control measures and promoting rational use of drugs; on creating an environment conducive to channelising new investment into the pharmaceutical industry and encouraging cost-effective production, and above all, on making the price control regime more effective by reducting the span of control. While indications point to a positive trend of the impact of the policy of 1986, it is too early to assess the complete effect of the same.

However, the policy measures of 1986 have been subjected to severe criticism from a number of quarters particularly the consumer groups and their representatives in Parliament on a number of counts and the measures have been variously described by the critics as "pro-industry", "anti-consumer", and "a sell out to the multinationals".

The evolution of drug policy in India has been gradual and has also been in tandem with the overall industrial policy of the Government.

Chapter-III

Industrial Licensing

Basically, industrial licensing involves issuance of letters of approval for manufacture and determination of parameters of product-mix and capacities, as distinct from approval to introduce a drug which is based on clinical trials and is given on consideration of therapeutic efficacy and safety.

Self-reliance, basic stage manufacture, encouragement of domestic industry, discouragement of monopolistic tendencies have been the main planks of industrial policy in general and have been reflected in the industrial licensing regime which has been used as an instrument to subserve the objectives of industrial policy.

The latest licensing regime as spelt out in the 1986 Industrial drug policy restricts the entry of the foreign sector to 66 bulk drugs which have been identified specifically.

Another important component of the latest licensing policy is the one relating to delicensing of a number of bulk drugs. 94 such drugs have been delicensed which implies that no prior approval is necessary for the manufacture of these drugs once these have been cleared by the drug regulation authorities. The policy also spells out a scheme for progressive delicensing subject to a given criteria.

The higher utilisation of capacity already created and flexibility of manufacture consistent with the special features of the drug industry have been ensured with "broad-banding" of 31 groups of drugs which implies that within the bands created the manufacturers can manufacture any of the items without needing a prior approval.

Other special licensing provisions for the drug sector include determination of a Phased Manufacturing Programme, Ratio-parameters and relationship between associated and non-associated formulators. Phased Manufacturing Programme is aimed at encouraging cost effective indigenisation and basic stage manufacture and ensuring that bulk drug production is not confined to processing of later intermediates only.

The concept of ratio parameters has been used to discourage companies from manufacturing formulations alone or in manufacturing formulations in excessive quantities. For doing so, certain ratios between the bulk drugs and formulations production in terms of value have been prescribed.

In order to prevent market dominance based on technological strength in the area of bulk drug manufacture, the licensing regime also provides for a certain minimum percentage of the total production of bulk drugs to be made available to non-associated formulators by bulk drug manufacturers.

The licensing regime, on the whole, has helped the Indian companies to come up in a big way as is evident from the increase in the number of Indian companies among the top five in 1988 as compared to those in 1984 vis-a-vis the foreign companies.

While the various concerns of the policy makers including the concern for basic stage manufacture, concern for preventing market dominance etc. have found place in the various elements of the licensing system, over the years, Industrial licensing as an instrument has ceased to be as potent in achieving the declared goals of Government policies as it was in the initial years of industrial development.

Chapter-IV

Pricing of Pharmaceutical products - Policy & Implementation and Tariffs

The concept of "administered prices" is quite prevalent in the Indian context but while in the case of other industries it is not only consumer-oriented but also has a domestic industry angle to it, in the case of pharmaceutical industry the pricing regime is far more complex and detailed and is primarily aimed at protecting the consumer.

The price control regime in India is based on the principle of selectivity and the regulatory framework for the same is provided by the Drug Price Control Order (DPCO) which lists certain drugs for which prior price approvals from the Government is required.

The Drug Price Control Order was first promulgated in 1970, was made more elaborate and detailed in 1979 and has been amended in 1987 by reducing the span of control to a considerable extent. While discussing the various provisions of price regulations as also its impact, the DPCO of 1987 has been made the reference point.

There are three product groups on which price control and tariff control focusses, namely, bulk drugs, formulations and drug intermediates. The price regulation procedure varies in respect of each of these products but a normative system of pricing is followed in all cases.

Bulk drug pricing is based on a detailed cost-cum-technical study for determining the ex-factory price and gives three options to the manufacturers viz. 14% post tax return on networth; 22% return on capital employed and 12% internal rate of return.

Formulation pricing is based on a formula prescribing a certain mark-up on the ex-factory price. The mark-up presently allowed on formulations of the two categories of drugs prescribed in the DPCO is 75% and 100%.

The drug price control regime has two aspects - (i) determination of the price-controlled basket and the category to which a particular drug belongs for purposes of determining the mark-up; and (ii) fixation of the price of those drugs which come under the controlled category. The principle of selectivity tampered with the concept of essentiality is the hall-mark of the DPCO 1987.

In addition to protecting the consumer by controlling the prices of drugs, the pricing regime has also been used to provide certain incentives to subserve objectives of policy. These include - total exemption from price control to industries in the small scale sector; exemption from price control for five years for drugs developed through indigenous R&D; exemption from price control of drugs having new delivery system; exemption from price control of drugs sold under generic name.

The basic policy of the Government on tariffs is to progressively reduce the import and excise duties and to ensure that the cumulative incidence of duty on the bulk drug is higher than that on the inputs and the drug intermediates.

The analysis of DPCO 1987 a year after it had been promulgated reveals that (i) although the number of drugs under price control has been reduced to less than half, there was reduction of only 5-6% in terms of turnover which showed that the high turnover products were still under price control; (ii) the average increase in the prices of decontrolled formulations was around 30% as compared to a wide range of minus 18.4% to 117% in case of bulk drugs whose prices were statutorily controlled. The analysis showed that competition had set in the decontrolled category due to expectation of higher returns prompting a shift towards manufacture of decontrolled drugs and the market forces had given a degree of stability to the prices; (iii) a number of drugs under the price controlled category were selling in the market at prices much lower than those fixed by the Government.

No aspect of the Industrial Drug Policy has been subjected to so much criticism and pressure from different quarters than price control system. The criticism is voiced by the consumer groups on the one hand and by the industry on the other. The criticism of the consumer groups centres round the fact that Government had increased the mark-ups more than was necessary and that the selection of drugs for purposes of price control was arbitrary and questionable. The criticism from the industry was basically against the insistance on normative system of price fixation rather than the actuals, as also the delays in getting price approvals.

Both on the counts of administrative expediency as also intrinsic merits, the present situation demands a fresh approach to the price control regime which may be effective as well as flexible and satisfy both the consumer and the manufacturer. Some of the approaches to the problem have been dealt with in the Chapter on a Model Drug Policy.

The gaps in the price control system notwithstanding, it has certainly achieved the basic objective of the prices of drugs being low in India.

Chapter-V

R&D, Industrial use of Medicinal Plants and Transfer of Technology.

R&D connotes with reference to the Drug Industry broadly three types of activities: (a) development of new molecules and drugs, which can be termed as basic research; (b) process and product development - the latter in case of formulations and not coming in the purview of isolation of new molecules; (c) resolution of plant-specific bottlenecks and related process problems.

Government policy in India has been concerned with development and encouragement of R&D right from the beginning but was concretised in 1983 when some specific steps were taken to develop R&D in the drug sector through recommendations of a sub-group set up for this purpose.

The major incentives available for R&D are: (i) All new bulk drugs and related formulations have been brought under the scheme of delicensing which means that specific approvals for manufacture of these drugs are not required once the Drug Controller has cleared the production of such a drug; (ii) all drugs, the process of manufacture of which has been developed through indigenous R&D are exempted from price control for a period of 5 years from the date of commercial production; (iii) all formulations based on new drug delivery systems are exempted from price control; (iv) it has been recently decided to allow the entire expenditure on Basic research as cost while computing the ex-factory price of a bulk drug.

Although a fairly strong infrastructure for R&D exists both in the Government and the private sectors in India, the levels of R&D expenditure incurred by the industry in India (exclusive of direct Government expenditure through research laboratories etc.) are very low compared to those in advanced countries. However, whatever allocations have been made for R&D by the industry have been fruitfully utilised and a number of new products have been developed as a result of basic research.

Given the scales of operations of most Indian companies, the major thrust of R&D activity has to centre on process and product development and the incentives provided by the Government also focus mainly on process research. More than 250 bulk drugs are manufactured in India from the basic stage and during the last two decades or so the Indian drug industry has indigenously developed and improved high technology process involved in the manufacture of over 100 essential basic drugs.

The Indian region being extremely well-endowed with rich flora, a lot of drug research is concentrated on material of natural origin. Separation of therapeutically efficacious active ingredients from the herbal plants has been supplemented by cultivation of these plants on a commercial scale.

Apart from the drugs obtained after isolating active chemical ingredients, a number of drugs based on herbal plants have also been developed in the traditional system of Indian medicines like Ayurveda and Unani.

While considerable stress has been laid on development of optimum dosage forms in formulations, there are a number of areas which require attention for further development, some of which are : (a) Immunoprophylaxis and immunodiagnostics etc. (b) Beta-Lactam antibiotics.

The questions of technology transfer and technology upgradation are closely inter-linked to R&D. The infrastructure of R&D for process development has reached a stage in India where sophisticated products are now being introduced within a period of 2-4 years from their launch in the international market as compared to a gap of 15 years or so in 1972.

Given the fact that technologies in the drug sector are closely held and access to best technology is limited, it is imperative for developing countries to have a strong infrastructure capable of not only absorbing the technology but also upgrading it. Specific instances show that the technologies which have been obtained by the Indian companies from the developed countries have, by and large, been absorbed and upgraded effectively.

Apart from transfer of technology from developed countries to India, there have also been lateral transfers within India in a number of cases to the mutual advantage of all concerned.

Chapter-VI

Quality Control and Rational use of Drugs

Even though Quality control and Drug standards do not strictly come under the purview of an Industrial Drug Policy per se, it is necessary to briefly consider these aspects particularly in terms of availability of infrastructure since the comprehensive drug policy announced by the Government in 1986 has laid great stress on strengthening the system of quality control.

The regulatory framework for quality control is provided by an Apex controlling authority in the shape of Drug Controller of India with the States having parallel regulatory authorities called State Drug Control Authorities. The basic regulatory framework is the Drugs & Cosmetics Act and the Rules framed thereunder.

While the regulatory framework is quite strong, the infrastructure for implementing the various provisions is not as strong as is warranted by the size and the spread of the industry and the sale points.

The Drugs & Cosmetics Act defines drugs, misbranded drugs, adulterated drugs, spurious drugs, new drugs and lays down specific standards of quality for these.

The Act also lists offences and lays down penalities for the same. The Indian Pharmacopoea has also been developed and updated from time to time and it lays down standards for a very large number of substances.

The gaps in the infrastructure of quality control in India were strikingly highlighted in recent times by a Commission popularly known as the Lentin Commission which had gone into the quality control infrastructure and its implementation in the State of Maharashtra in the light of some deaths resulting from sub-standard drugs.

The policy of the Government in India lays emphasis on Rational use of drugs. In spite of complexities involved in segregating rational from irrational, Government in India has taken some steps to protect the consumers from undue proliferation of drugs and one of these involves a statutory requirement to display generic names on all the drugs marketed in the country in a size twice that of the brand name.

Chapter-VII

Production profile and status of Drug Industry in India with special reference to the health situation

Having analysed the major components of the Industrial Drug Policy in India, it would be worthwhile to take an over view of the Indian Drug Industry and its production profile not only to assess the impact of these policy measures but also with reference to the health situation and the relevance of the industry to the same. The Indian Pharmaceutical Industry is among the largest and more diversified in the developing world.

The Indian industry has grown rapidly after the attainment of Independence, when the output value was just Rs.100 million which basically consisted of imported bulk drugs being converted into formulations and has now grown to a size of around Rs.30,000 million producing a very wide range of bulk drugs as well as formulations.

The Pharmaceutical Industry in India is broadly segmented into public sector, the Indian sector, the foreign sector and the small scale sector. There has been a remarkable growth in the share of the large Indian sector in production of bulk drugs over the years and the share of the foreign sector has gone down considerably even though the actual production has marginally increased. Similarly the share of public sector in percentage terms has also gone down while the share of small scale sector has increased.

The Indian industry has developed sufficient sophistication to export its products to other countries. Today, the import of pharmaceuticals in India is 6-8% of the total value of production whereas the export is round 10.12% of its production and the present level of export is around Rs.4600 million.

The National Health Policy has accepted the goal of health for all by the year 2000 A.D. and the projections for achieving this objective indicate a requirement of 12,550 million rupees worth of bulk drugs and 48,900 million rupees of formulations by the year 1994-95.

Apart from increasing investment in the sector and optimising production to meet the demand, the areas requiring special attention for future development are technology upgradation; infusion of new technology in selected therapeutic groups; development of technologies in the field of drug delivery; and, cost effective manufacture of drug intermediates and chemicals going into the production of bulk drugs.

Chapter-VIII

Approach to a Model Drug Policy

Any Industrial Drug Policy would necessarily have to be country-specific and region-specific and would reflect the concerns and priorities of the Government and the society. It would also have to be assumed that there is need to develop an indigenous Drug industry.

Other assumptions while attempting an approach to an Industrial Drug Policy would include that (a) the development of an indigenous drug industry is a conscious objective of the policy makers; (b) there is a legal framework for regulating industrial development; (c) there is access to drug technology; (d) the environment allows manufacture and distribution of drugs directly to the consumers through private enterprise, and (e) making medicines available at reasonable prices is a policy objective.

The various aspects to be covered under an Industrial Drug Policy would include the health policy and the disease patterns; instruments to regulate industrial manufacture of drugs; technology development and upgradation, pricing policies; incentives for developing indigenous capabilities.

It would be useful to first identify the essential drugs based on the diseease pattern and the medi-care needs.

The essential drugs may then be focussed upon in terms of policy support by giving incentives for increased investment in these areas as also disincentives for the production of the so-called non-essential drugs.

A Phased Manufacturing Programme (PMP) for each of the products identified as essential may be developed in order to encourage cost effective indigenisation of production and imports regulated in conformity with the PMP.

Apart from the drugs, incentives need to be given for the manufacture of intermediate chemicals which go into their production.

Adequate and strong infrastructure as also the legal back-up for encouraging process and product development also needs to be created.

A package of incentives encouraging bulk drug production to avoid over-manufacture of formulations also needs to be drawn up since over-dependence on bulk drugs on sources outside the country or even monopoly sources within the country would not be conducive to attaining the overall objective.

The basic objective of any Government from the point of view of the consumer should be to ensure availability of the product at reasonable prices and to the extent that this objective is subserved by the operation of free market forces, there may not be any need to control the prices, once adequate production is generated. However, aberrations in the free play of market forces are caused due to (a) Monopoly (b) Market dominance and (c) Shortage. Some price control to take care of these aberrations is, therefore, necessary.

Different approaches to price control could be based on selective, product-wise price control; tariff based control; and a profitability ceiling.

A combination of the approaches of profitability ceiling on formulation activity together with controlling the prices of those drugs having market dominance could be used to take care of the two factors primarily responsible for aberrations in the free play of market forces, namely, monopoly and market dominance.

The above suggestions only constitute an approach to a possible Industrial Drug Policy; there cannot be a uniform prescription for a universal applicability. The approach which is being suggested can form the basis for further discussion and each country may then be able to arrive at its own model in the light of its own priorities and socio-economic environment.

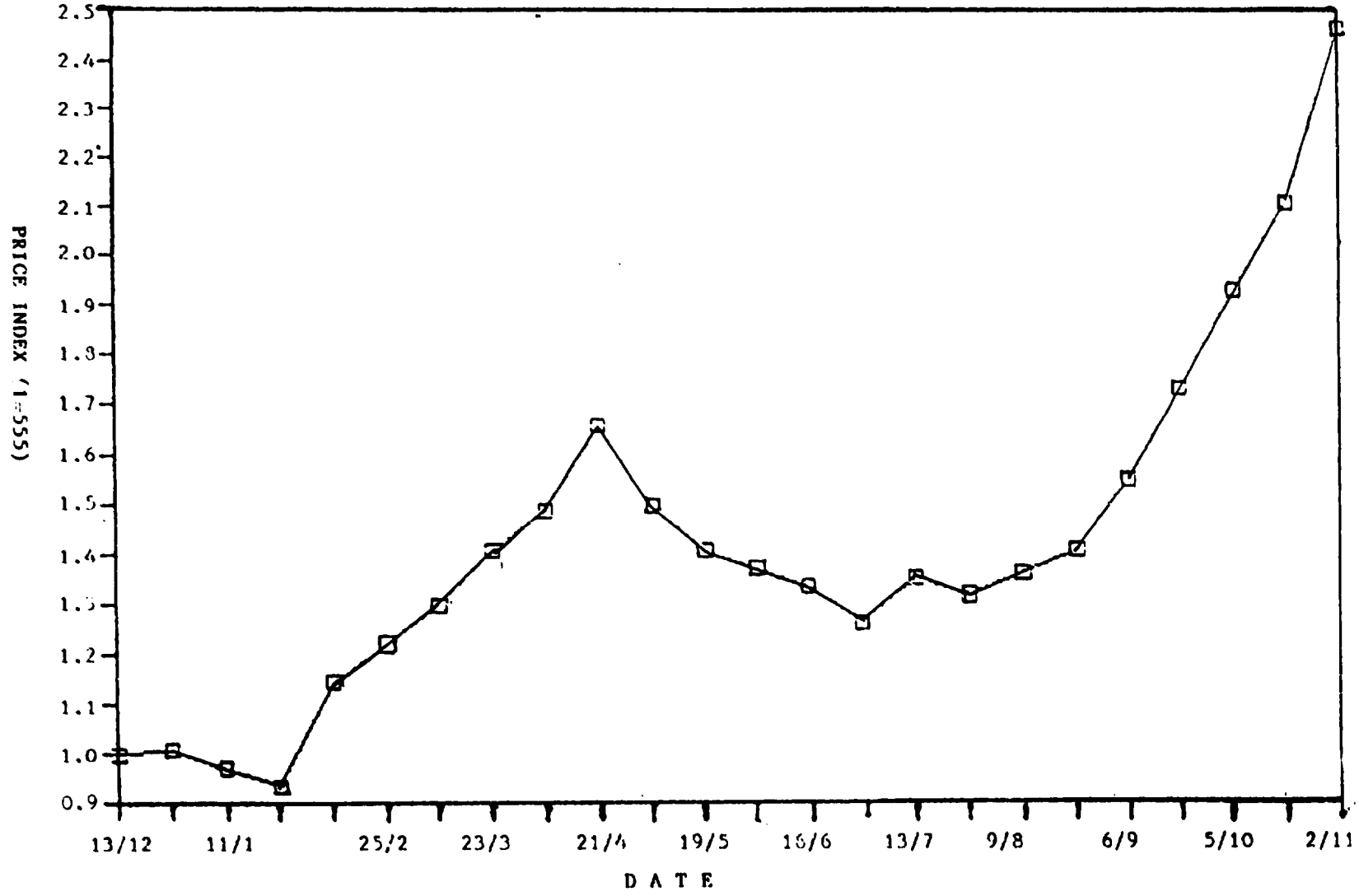
ANNEX 1

Supply & demand of selected essential pharmaceuticals

		Registered Licenced capacity (Tonne)	Imports 1984-85 (Tonne)	Production 1984-85 (Tonne)	1989-90 Demand (Tonne)	% age Shares of Indian Companies production
	1.	2.	3.	4.	5.	6.
1.	Ampicillin	252.5	3.3	190.79	580	100
2.	Doxycyline	22.5	.005	4.56	11	100
3.	Vitamin C	1385.50	0.35	716.23	1210	100
4.	Metronidazole	401.00	1.5	295.07	572	96
5.	Chlorpropamide	76.1	Nil	60.55	49	70
6.	Thiacetazone	152.6	N.A.	47.19	85	100
7.	Sodium PAS	1190.0	Nil	119.07	250	88
8.	INH	525.0	12.15	192.57	450	59
9.	Bepheniumbydro-xynaphthoate	5.0	-	N.A.	17	Nil
10.	Pethidine	0.5	0.15	0.39	1.76	100
11.	Diethyl Carbamazine Citrate	56.0	Nil	40.95	89	46
12.	Xylocaine	80	N.A.	13.87	80	100
13.	Phenylbutazone	174	1.00	120.44	100	87.5
14.	Oxyphenbutazone	92.5	Nil	103.86	220	100
15.	Caffeine	97	7.5	40.27	140	100
16.	Diazepam	13.58	Nil	9.67	5	100
17.	Phthalyl Sulphathia-zole	100	Nil	28.92	32	75
18.	Sulphaphenazole	50	N.A.	51.17	90	26
19.	Sulphamethoxazole	565	20.13	638.84	720	100
20.	Sulphasomidine	190	Nil	72.76	85	25
21.	Diloxanide Furoate	55.95	Nil	49.95	53	74
22.	Ethambutol	684	Nil	269.24	450	80
23.	Theophyline)					
24.	Aminophylline)	427	117.2	N.A.	290	100
25.	Nitrofurantoin	2.0	0.10	1.67	5	100
26.	Furazolildone	2.0	54.85	15.0	225	100
27.	Nitrofurazone	2.0	N.A.	N.A.	-	100
28.	Dextropropoxyphene	26	Nil	N.A.	19	100
29.	Imipramine	3	1.0	N.A.	3.87	100
30.	Amitriptyline	0.2	1.90	N.A.	3.12	N.A.

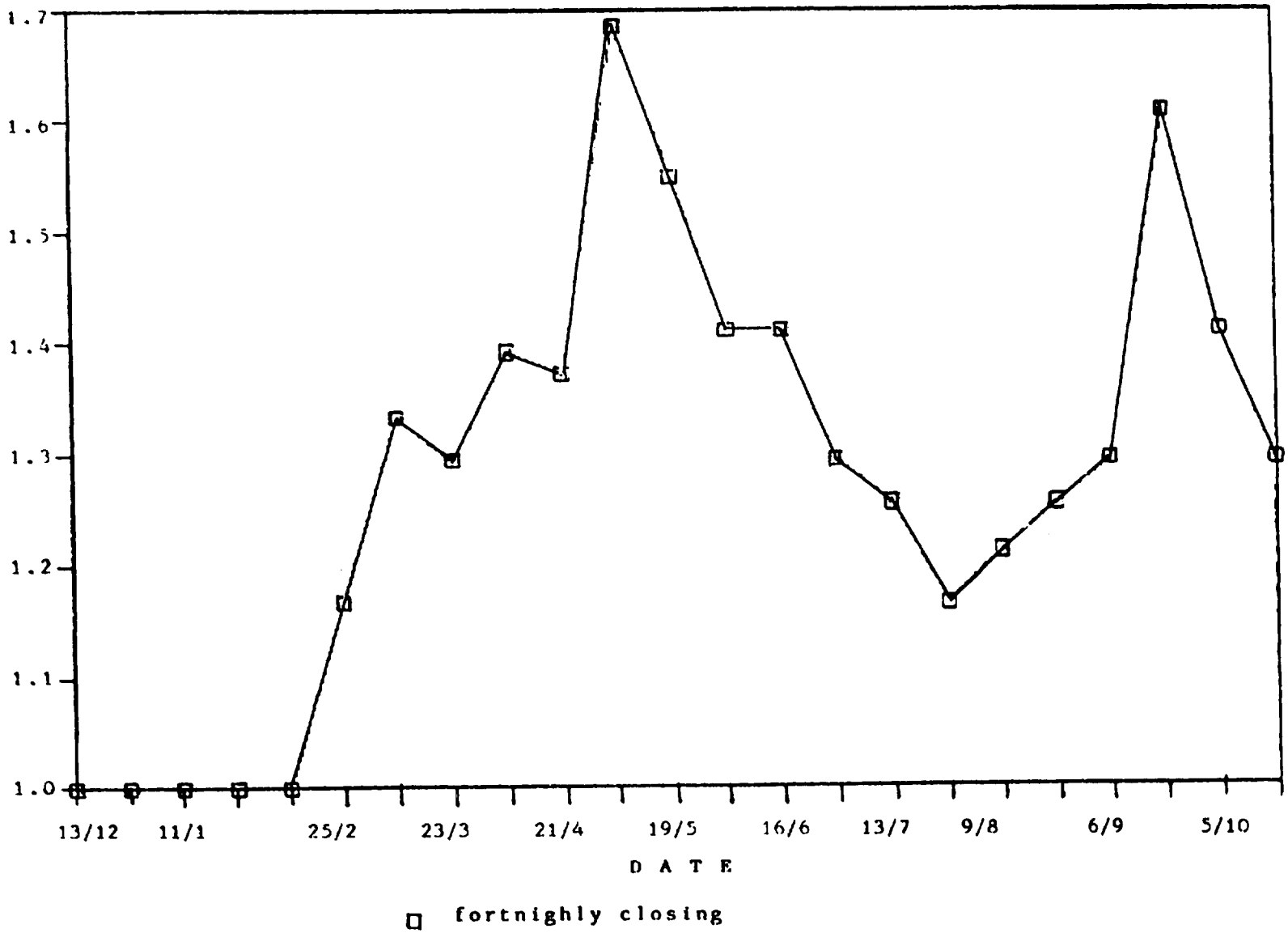
HOECHST - STOCK PRICE TREND

from 13/12/88 to 2/11/89



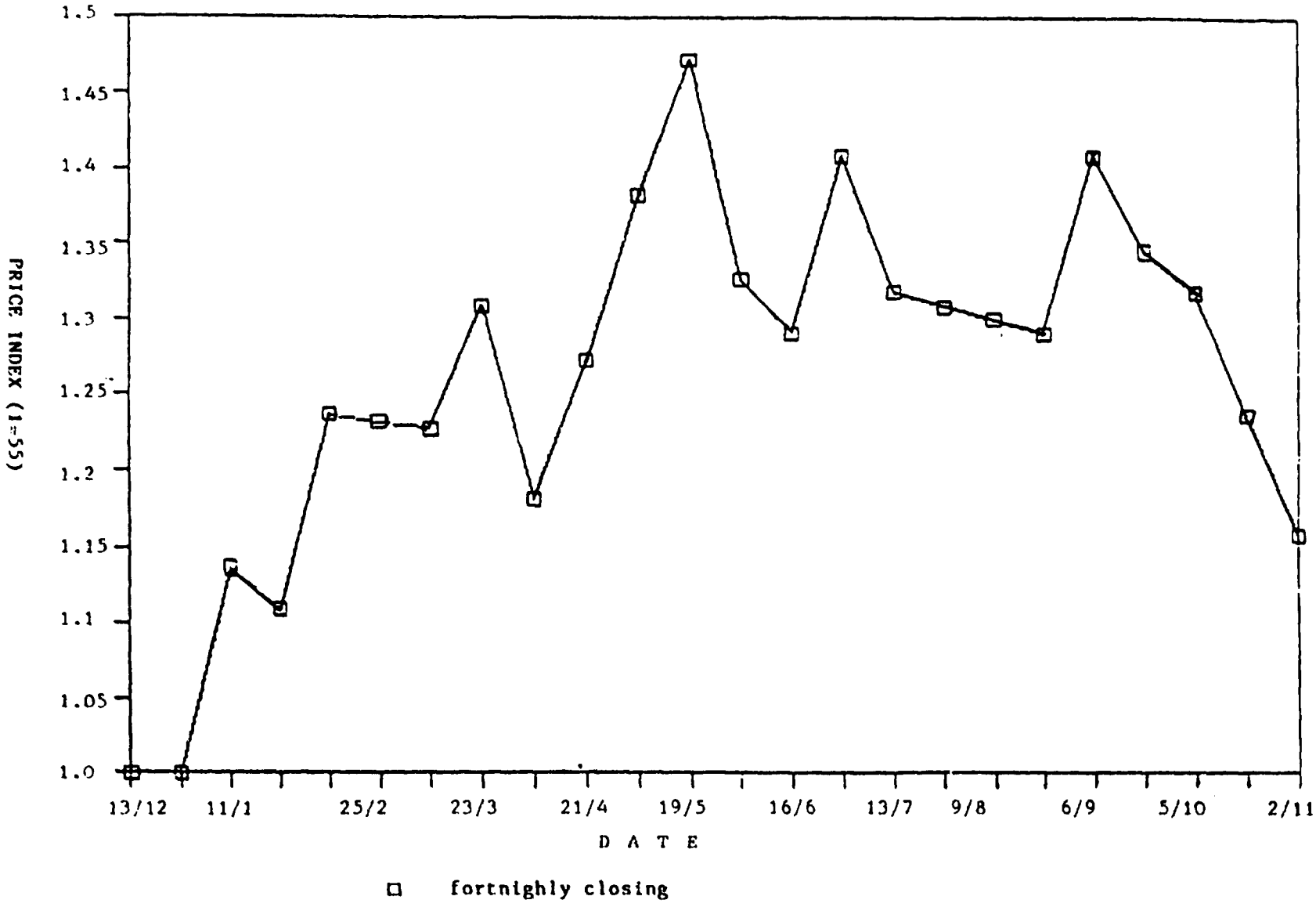
ANNEX II (contd.)

SARABHAI - STOCK PRICE TREND
from 13/12/88 to 5/10/89



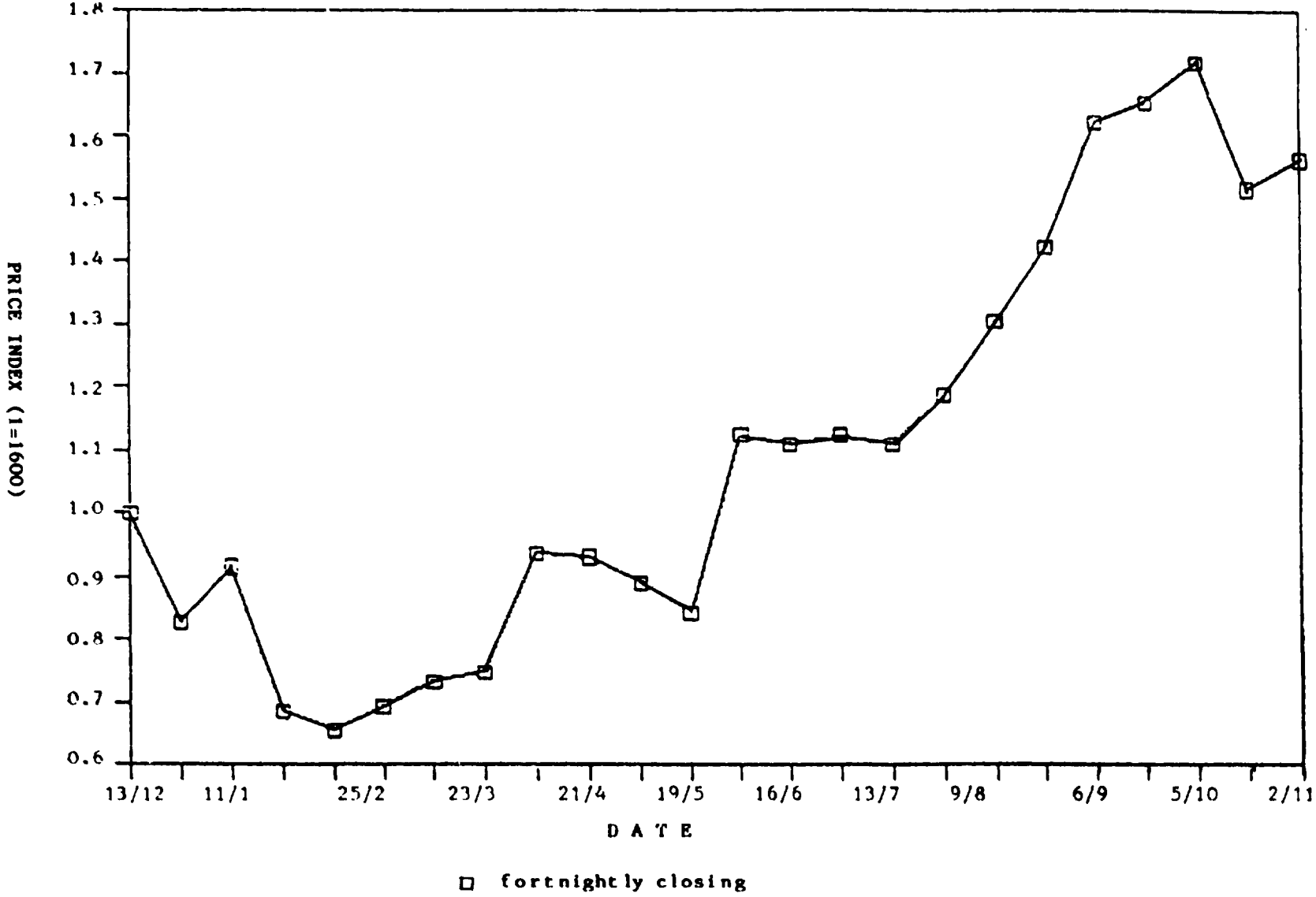
MAY & BAKER - STOCK PRICE TREND

from 13/12/88 to 2/11/89

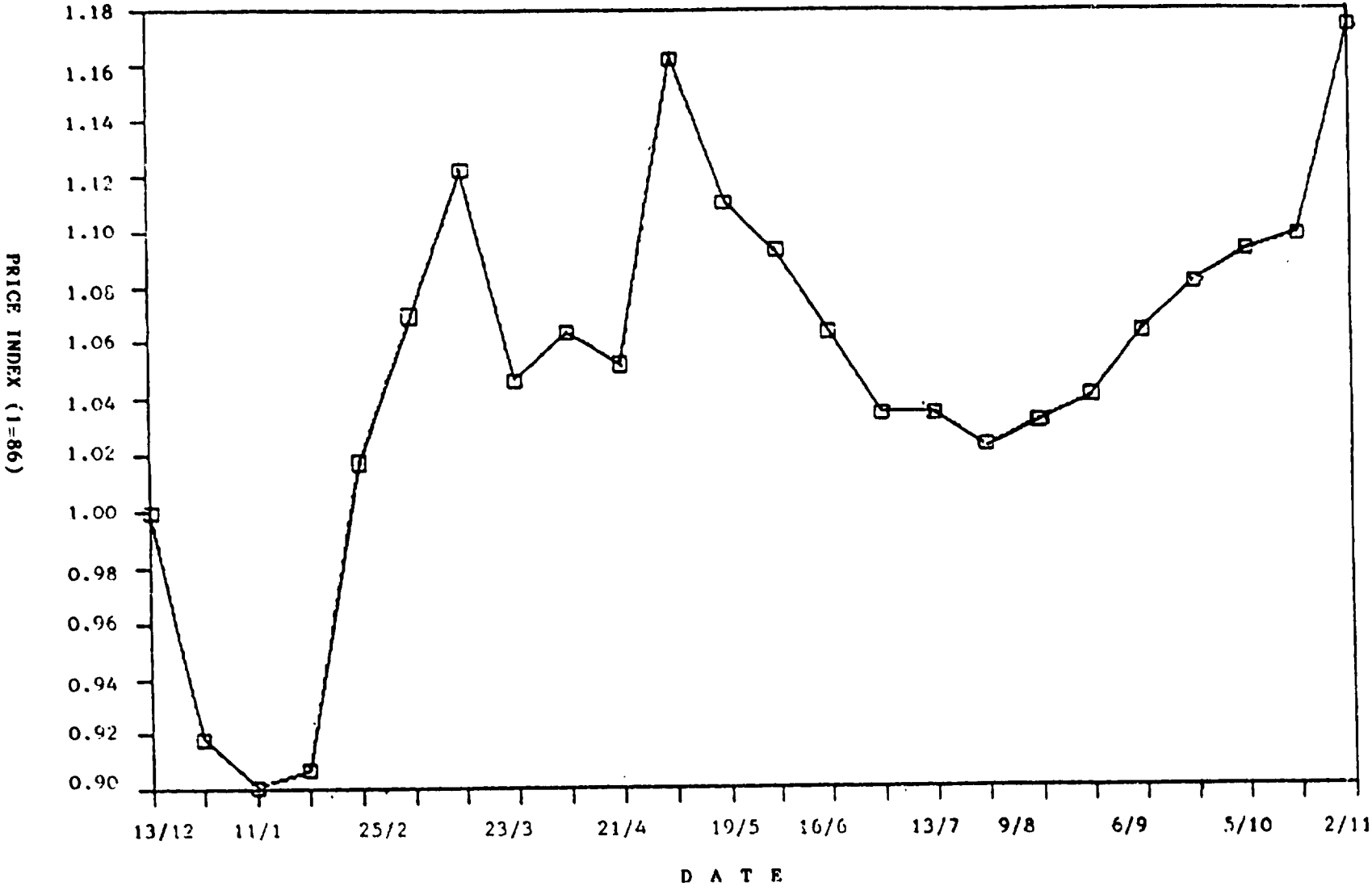


CIPLA - STOCK PRICE TREND

from 13/12/88 to 2/11/89



GLAXO - STOCK PRICE TREND
from 13/12/88 to 2/11/89



= fortnightly closing

ANNEX III

R&D Expenditure - an inter-industry Comparison (Private Sector)

	Number of units	R&D Expenditure as % of sales turnover		
		1980-81	1981-82	1982-83
1. Metallurgical industries	44	0.44	0.53	0.47
2. Fuels	5	0.21	0.11	0.19
3. Electronics & electrical equipment	115	0.84	0.83	0.72
4. Industrial machinery	35	1.03	1.19	1.16
5. Chemicals (other than fertilizers)	133	0.87	0.99	1.00
6. Fertilizers	4	0.45	0.58	0.43
7. Dyestuffs	9	1.07	1.10	1.00
8. Drugs & Pharmaceuticals	54	2.05	1.72	2.01
9. Textiles	22	0.35	0.45	0.55
10. Paper and pulp	13	0.59	0.45	0.42
11. Sugar	8	0.42	0.28	0.63
12. Vegetable oils & vanaspati	3	0.05	0.16	0.13
13. Soaps, cosmetics & toiletries	6	0.51	0.44	0.16
14. Machine tools	6	4.85	4.47	2.44
15. Scientific instruments	6	4.84	5.01	4.21
Total (including Others)	600	0.77	0.76	0.68

ANNEX IV

Dates for launching of drugs in international and Indian markets

Substance	International Launch	Introduced in India	Gap in Years
Pentoxifylline	1972	1987	15
Diltiazem	1974	1988	14
Nifedipine	1975	1985	10
Atenolol	1976	1986	10
Labetolol	1977	1987	10
Cefotaxime	1980	1987	7
Ranitidine	1981	1986	5
Insulin (Highly Purified)	1982	1986	4
Astemizole	1983	1988	5
Norfloxacin	1983	1987	4
Ceftazidime	1984	1989	5
Famotidine	1985	1989	4
Ciprofloxacin	1987	1989	2