Drug Policy: In the Past

Prior to India's independence, Government of India did not encourage indigenous drug production. Most of the medicines produced were either imported or only labelling or final formulations were done in India. The Government policy was to control and direct drug production. The ruling Britishers were interested in shipping various raw materials such as cinchona bark, nux vomica seeds, poppy pods and selling back the finished products.

After independence, a programme of planned industrialisation was launched. Drug production received a big push after the Second Five Year Plan. The philosophy was simple; it was the principle of self-reliance, massive public sector investment, and expansion of domestic market through restriction of imports and enlargement of the services sector. Government imposed heavy restrictions on import of drugs from foreign countries and intermediate formulations. But there was the policy of
non-discrimination between foreign and Indian companies with regard to investment; and adequate remittance facilities for dividends and profits were given.

Such a policy gave fillip to inflow of foreign technology along with associate skills and capabilities in manufacturing, marketing and finance. The result was the production of a wide range of drugs; there was also a significant growth and development of great variety of ancillary industries connected with drug production, such as raw materials, packing materials, machinery and equipment of every kind. Thus the story of pharmaceutical industry in India has been essentially one of transfer, development and assimilation of international technology during the first two and a half decades. Legislations during this period were mostly regulatory.

It is against this background that the Hathi Committee was appointed in 1974. Government of India was very much interested in finding out ways and means to meet the growing and full requirements of drugs and pharmaceuticals in the country as well as the broad social objectives of providing quality drugs at fair prices. Questions about the performance of the public sector units, the role of multinational corporations, licensing policy and prices were prominently raised in Parliament also from time to time. Following a suggestion made in Parliament,
Government of India set up, on 8 February 1974, a Committee under the chairmanship of Jaisukhlal Hathi and other members of Parliament along with various officials and non-officials, to enquire into the various facts of the drugs industry in India.

The Hathi Committee submitted its report to the Government in April 1975. After going through the usual parliamentary procedures, the first major drug policy was announced on 28 March 1978. In practice, this policy brought to the fore many problems faced by the consumers and the drug industry. And so, another policy statement was announced in 1986. These two policies (of 1978 and 1986) are taken up for the study to know their impact on pharmaceutical industry.

The Drug Policy of 1978

Overall aim of the New Drug Policy Statement of 1978 was to control, regulate and rejuvenate this industry as a whole, with particular reference to containing and channelising the activities of foreign companies in accordance with the national objectives and priorities. More specifically, objectives to be achieved by the policy were:

i) to attain self-reliance in drug technology through research and development;

ii) to achieve self-sufficiency in the production of essential drugs and to reduce imports;
iii) to provide a leadership role to the public sector;
iv) to make drugs available at reasonable prices; and
v) to ensure strict quality control and to prevent adulteration and malpractices.

Policy Outputs

Tangible and symbolic manifestations of public policy are the policy outputs. They are observable indicators of what governments in fact do. For the New Drug Policy of 1978, the following are the policy outputs:

1. The drugs open to licensing for (a) public sector, (b) Indian sector and (c) all sectors (including foreign companies) were listed. Accordingly, the responsibility for the production of 28 drugs was given to public sector, 51 drugs to Indian sector and 66 drugs to all sectors. In granting industrial license applications, preference was given to Indian companies over foreign companies.

2. The rate of growth of each sector also was carefully planned to avoid shortages. The public sector units were expected to meet major requirements of drugs for public health services.

3. The public sector was assigned a leading role in the production and distribution of drugs and adequate outlays were provided in the Plans to achieve this objective.

4. Further, public sector was permitted to obtain the best technology available to improve productivity and encouraged to earmark a suitable percentage of their net turnover for R and D activities.
5. The drugs were classified into four categories for pricing purposes. Reflecting the strength of demand prices allowing mark-ups of 40 percent, 55 percent and 100 percent for category I, II and III; for category IV, there was no price control.

6. The pre-tax return on sales turnover exclusive of excise duty was fixed between eight and thirteen percent. The gross profit beyond this specified rates were funded separately for such purposes including R and D as may be specified by the government.

7. The post-tax return on bulk drugs required for production of category I and II formulations which were highly essential and life-saving was allowed upto 14 percent and on other bulk drugs it was 12 percent on networth, i.e., equity plus free reserves.

8. The import of necessary raw materials was done on behalf of the manufacturers by the State Trading Corporation (STC). The process was known as "drug canalisation". The objectives of canalisation were to prevent transfer-pricing and to ensure a reliable supply of raw materials to indigenous manufacturers at fair prices.

9. Indian drug manufacturers were allowed formulation licences upto ten times the value of their bulk drug production.
Thus, a new thrust and direction were given in the policy frame to encourage growth of pharmaceutical industry. Further impetus came with the National Health Policy of 1982, which marked a significant step in the national endeavour to improve public health, and so India committed herself to the goal of "Health for All the Year 2000 A.D." through the universal provision of comprehensive Primary Health Care Service. The attainment of this goal required an accelerated development of all inputs to the health care system, including essential and life saving drugs and vaccines of proven quality. The Indian pharmaceutical industry found a vital role in it. Specific strategies followed by the Government to help the industry deserve detailed discussion.

First, the goal of self-sufficiency in medicines, ensuring availability of essential drugs at reasonable prices was set and actions were initiated. The Indian pharmaceutical industry found encouragement to diversify production and to vertically integrate. The results were that the country achieved self-sufficiency in formulations and also in a large number of bulk drugs. By 1984-85, the value of imports of formulations was only Rs10.17 crores or about 0.5% of the total formulation production in the country while imports of 49 bulk drugs were negligible. Technologies for the production of several bulk drugs, including antibiotics, anti-infectives, anti-TB drugs,
antipyrine, anti-amoebics and anti-cancer drugs were indigenously developed. A wide range of bulk drugs and formulations were exported to several countries, including USA and the West European countries. Some Indian firms had also set up production facilities in other countries and were also engaged in the sale of turnkey plants and technical services. In 1984-85, exports of drugs and formulations were valued at Rs217.49 crores, while imports were valued at Rs215.62 crores. Those diverse production and technological capabilities developed by the Indian Pharmaceutical Industry were also valuable assets in achieving the goals of the National Health Policy and in fully harnessing the export potential.

While these achievements were impressive in themselves, there were many areas where the industry had to reorient itself if it had to effectively serve the health needs of the people in the country. According to the mid-Plan review by a Committee in 1982, the proliferation of formulations and packs without adequate therapeutic rationale was a matter of concern. While many firms in the organised as well as small sector had excellent internal testing facilities and a good record of quality control and adoption of good manufacturing practices, the same could not be said of a large number of firms manufacturing formulations. The 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 were far from being adequate.

Secondly, as shown by the review Committee, experience gained in the implementations of the Drugs (Prices Control) Order 1978 had clearly shown that the pricing system needed to be simplified and rationalised, if the benefits of the price control were to be effectively realised by the consumer, particularly the weaker sections of the society. The span of price control was impractically large covering 347 bulk drugs and over 4000 formulations marketed in about 20,000 packs, and it needs to be narrowed down.

Thus it was reasonable to conclude that the New Drug Policy of 1978, had helped the industry grow impressively and also to diversify and export. There was fairly good quality control as evidenced by the impressive export performance. However, there seemed to be important constraints in achieving social goals of supply at reasonable prices and price control in general.
Drug Policy of 1986

It is against the above backdrop that the Government reviewed the functioning of the 1978 Drug Policy and again restructured the policy in the light of the experiences gained earlier and announced Second Drug Policy of 1986. Emphasis of this policy was--

i) to ensure abundant availability of essential life-saving and prophylactic medicines of good quality at reasonable prices;

ii) to strengthen the system of quality control over drug production and promote the rational use of drugs in the country;

iii) to create an environment conducive to channelising new investment into the pharmaceutical industry;

iv) to encourage cost-effective production with economic sizes;

v) to introduce new technologies and new drugs; and

vi) to strengthen the indigenous capability for production of drugs.  

These goals mark a refinement of the earlier policy statement and policy outputs to translate them into action are:

i) to establish a National Pharmaceutical Authority (NPA), which would function as an advisory body on matters of development of the pharmaceutical industry;
ii) to give statutory effect to good manufacturing practices through a certification system under which recognised institutions with proven expertise and testing facilities would certify the adoption by formulators of good manufacturing practices and the quality of formulations manufactured;

iii) to monitor drug pricing practices closely;

iv) to progressively extend the system of de-licensing; and

v) to encourage further production, domestic supply and export of drugs.

What the drug policy of 1986 did address was the need to ensure that the production of bulk drugs and formulations germane to the National Health Programme was raised significantly.

Operational Strategies

With the active support of the advisory body (NPA), the government took several measures to improve the performance of the industry and to relax constraints. First, all bulk drugs and their formulations were freed from price control except for a priority list of 166 bulk drugs. As against the existing three categories of drugs and pharmaceuticals (category I, II & III), there would be two categories. Category I will consist of drugs programme necessary for the National Health Programme and category II would consist of other essential drugs. However,
the existing Drug Price Control Order (DPCO) would continue to 
be in force till a new one was announced after the finalisation 
of drugs in these two categories. The mark-up on finished drugs 
in controlled categories I and II increased from 40 percent and 
55 percent to 75 percent and 100 percent respectively of manu-
ufacturing costs. Small units with turnover of under Rs5 million 
per year continued to be exempted from price control. Finished 
drugs in category II produced by companies with investments 
totalling less than Rs3.5 million, were also exempted from price 
control. All single-ingredient formulations sold under generic 
names were also freed from price control. Production of these 
Drugs and their formulations should, subject to government monitoring, 
account for 20 percent of the total output in value of every 
manufacturer in India. The government would retain the right 
to bring within the ambit of control any drug in the decontrolled 
category whenever considered necessary.

However, this reduction in the span of price control 
would need a very strong monitoring system to protect the interests 
of the consumers. Therefore, the new policy emphasised that 
the prices of drugs in the decontrolled category be constantly 
and closely monitored and an effective monitoring system developed 
for these.
The system of delicensing extended to 94 bulk drugs including all anti-cancer drugs, all new bulk drugs developed through indigenous research, and related formulations as well as two drug intermediates. The scheme would progressively be extended subject to the bulk drugs where imports were allowed an Open General License (OGL); bulk drugs whose production was limited to three producers or less in the organised sectors and bulk drugs whose formulations were of essential and of mass consumption nature and formulations and drug intermediaries related to bulk drugs were de-licensed. It was proposed to extend the scheme of broad-branding to 31 groups of bulk drugs and formulations. Consistent with the liberal policy, the new Drug Price Control Order was issued in August 1987. This new pricing policy was expected to improve the availability of essential drugs, though at costs likely to be higher 13 percent and 45 percent above the current prices.

Policy outputs discussed above would tell little if anything about the performance of the policy, they just show the intentions and approaches. This study on impact of the drug policy would require to know the extent to which the policy outputs have accomplished their stipulated goals. This policy impact analysis requires, therefore, first identification of performance variables to assess the policy impact.
Above analyses of the content and goals of the Drug Policy Statements of 1978 and 1986, would show that the latter was but a corrective to the former on the basis of the experience. While the policy goals remained the same, operational strategies changed. Important goals are (i) growth in production, domestic supply and export of drugs; (ii) self-sufficiency in domestic supply; (iii) diversification in production; (iv) technological progress; (v) quality control, and (vi) stability in prices of drugs, especially essential drugs at reasonable level. These would therefore be the performance variables to evaluate the impact of the policies.

There is another dimension also. While the Drug Policy Statement of 1978 implied a strong control over production, quality, pricing, distribution and export of drugs, the Policy Statement of 1986 favoured a large measure of decontrol to achieve the same goals. Therefore, a comparative study of the performance of the industry before and after 1986 was done to understand the impact of the process of decontrol.

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