Pharmaceutical Legislations

HATHI COMMITTEE

Health is a fundamental human right. The Constitution of India directs the State to regard the improvement of public health as among its primary duties. The Five Year Plants have been providing the framework within which the Centre and States have developed their health services infrastructure and programmes. Since the attainment of Independence considerable progress has been achieved in the promotion of health status of the people – as reflected in the eradication/control of diseases like small-pox, malaria etc., reduction in mortality rate, rise in life expectancy, creation of a fairly extensive network of health care institutions and the availability of a large stocks of medical and health personnel.

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 of "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 Trimethoprim., 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 imports 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 reorient 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 organized 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.

Abundant availability on a continuous basis, at reasonable prices, of essential, life saving and prophylactic medicines of good quality, is the corner stone of the new measures. It shall be the endeavour of the Government to ensure that the above objective, which is in consonance with the Government's Policy of reaching Healthcare facilities to the common masses and with that of ensuring Health for all by the year 2000 A.D., is achieved. In order to subserve this objective, changes have been brought about in the system of price control of drugs as well as in the licensing and approval procedures. Experience gained in the implementation of the Drugs (Prices Control) Order, 1979 has clearly shown that the pricing system needs to be simplified and rationalized, if the benefits of the price control are to be effectively realised by the consumer, particularly the weaker sections of the society for safeguarding whose interests the Government is committed. The span of price control at present is impracticably large covering 347 bulk drugs and over 4,000 formulations marketed in about 20,000 packs. It is proposed to reduce to a considerable extent this span of control and to make the price control system less cumbersome but more effective.

Recommendations:-

As prices of drugs are also determined by the cost effectiveness of domestic production, it is imperative to impart a technological and productivity thrust to the Indian Pharmaceutical Industry which would also enable it to harness export opportunities. The objective of ensuring abundant availability of medicines at reasonable prices, will be best served by promoting competition and economic scales of production and also by removing unnecessary barriers to growth. To this end, licensing and approval procedures have been simplified and greater flexibility given in order to those of essential and life saving drugs. The validity of this premise has already been established by the experience, in recent years, with the market prices of bulk is produced by a good number of manufacturers. At the same time, FERA companies will continue to be regulated by Government to ensure that their operations are in consonance with the national objectives and priorities.

It is against this backdrop that the Government has reviewed the functioning of the Drug Policy and now restructured the Policy in the light of the experience gained and keeping in mind the objective of achieving “Health for All by the Year 2000 A.D.”

Health survey and development committee(BHORE COMMITTEE)

•The most comprehensive health policy and plan document ever prepared in India was the `Health Survey and Development Committee Report' popularly referred to as the Bhore Committee. • This committee was appointed in 1943 with Sir Joseph Bhore as its Chairman. • It made comprehensive recommendations for remodelling of health services in India.

Objectives:

1. The services should make adequate provision for the medical care of the individual in the curative and preventive fields and for the active promotion of positive health;

2. These services should be placed as close to the people as possible, in order to ensure their maximum use by the community, which they are meant to serve;

3. The health organization should provide for the widest possible basis of cooperation between the health personnel and the people;

4. Provisions should be made for enabling the representatives of medical and auxiliary professions to influence the health policy of the country.

5. “Group” practice, should be made available – In view of the complexity of modern medical practice, from the standpoint of diagnosis and treatment, consultant, laboratory and institutional facilities of a varied character, which together constitute;

6. Special provision will be required for certain sections of the population, e.g. mothers, children, elderly etc.,

7. No individual should fail to secure adequate medical care, curative and preventive, because of inability to pay for it and

8. The creation and maintenance of as healthy an environment as possible in the homes of the people as well as at work.

Recommendations

1. Integration of preventive and curative services of all administrative levels.

2. Major changes in medical education which includes three months training in preventive and social medicine to prepare “social physicians”.

3. Development of Primary Health Centres in 2 stages : a) Short-term measure – One primary health centre • for a 40,000 population. • 2 doctors, 1 nurse, 4 PHN, four midwives,

four trained dais, two SI, two HA, one pharmacist and 15 class IV employees. • Secondary health centre provide support, coordinate and supervise PHC. b) A long-term programme (also called the 3 million plan) of setting up

• primary health units with 75 bedded hospitals for each 10,000 to 20,000 population and

• secondary units with 650 bedded hospital, again regionalised around district hospitals with 2500 beds.

• In the fifties and sixties the entire focus of the health sector in India was to manage epidemics.

• Mass campaigns were started to eradicate the various diseases. – These separate countrywide campaigns with a technocentric approach were launched against malaria, smallpox, tuberculosis, leprosy, filaria, trachoma and cholera. – Cadres of workers were trained in each of the vertical programmes.

• The policy of going in for mass campaigns was in continuation of the policy of colonialists who subscribed to the percepts of modern medicine that health could be looked after if the germs which were causing it were removed.

• But the basic cause of the various diseases is social, i.e. inadequate nutrition, clothing, and housing, and the lack of a proper environment. These were ignored. • National programs were launched to eradicate the diseases.

• The NMEP was started in 1953 with aid from the Technical Cooperation Mission of the U.S.A. and technical advice of the W.H.O. Malaria at that period was considered an international threat.

• The tuberculosis programme involved vaccination with BCG, T.B. clinics, and domiciliary services and after care. The emphasis however was on prevention through BCG. These programmes depended on international agencies like UNICEF, WHO and the Rockefeller Foundation for supplies of necessary chemicals and vaccines.

• The policy with regard to communicable diseases was dictated by the imperialist powers as in the other sectors of the economy.

• During the first two Five Year Plans the basic structural framework of the public health care delivery system remained unchanged.

• Urban areas continued to get over three-fourth of the medical care resources whereas rural areas received "special attention" under the Community Development Program (CDP). History stands in evidence to what this special attention meant.

• The CDP was failing even before the Second Five Year Plan began

MUDALIAR COMMITTEE, 1962

This committee known as the "**HEALTH SURVEY AND PLANNING COMMITTEE"**, headed by Dr. A.L. Mudaliar, was set up in 1959:

1. To assess the performance in health sector since the submission of Bhore Committee report.

2. To evaluate the progress made in the first 2 plans and

3. To make recommendation for the future path of development of health services. • The report of the committee recorded that the disease control programmes had some substantial achievements in controlling certain virulent epidemic diseases. • This committee found the conditions in PHCs to be unsatisfactory. – Most of the PHC's were understaffed, large numbers of them were being run by ANM's or public health nurses in charge.

Recommendations

1. Consolidation of advances made in the first two five years plans.

2. Strengthening of the district hospitals with specialists services to serve as central base of regional services.

3. Regional organizations in each state between the headquarters organization and the district in charge of a Regional Deputy or Assistant Directors – each to supervise 2 or 3 district medical or health officers.

4. Each PHC not to serve more that 40000 population.

5. To improve the quality of health care provided by PHC.

6. Integration of medical and health services.

7. Constitution of an All India Health service on the pattern of Indian Administrative Services.

• The third Five Year Plan launched in 1961 discussed the problems affecting the provision of PHCs, and directed attention to the shortage of health personnel, delays in the construction of PHCs, buildings and staff quarters and inadequate training facilities for the different categories of staff required in the rural areas.

• Ignoring the Mudaliar Committee's recommendation of consolidation of PHC's this plan period witnessed a rapid increase in their numbers but their condition was the same as the Committee had found at the end of the second plan period.

• In case of the disease programme due to their vertical nature there was a huge army of workers. – The delivery of services continued to be done by special uni-purpose health workers. Therefore in the same geographical area there was overlapping and duplication of work.