Drug Policy Amendment 1986

Introduction

1. The Drug Policy of 1986, which was titled "Measures for Rationalization, Quality Control and Growth of Drugs Pharmaceuticals Industry in India" was evolved under the dynamic guidance and leadership of late Shri Rajiv Gandhi. This was done after a detailed examination of the various issues. The main objectives of the Drug Policy, 1986 are as under :

- ensuring abundant availability, at reasonable prices of essential and life saving and prophylactic medicines of good quality;
- strengthening the system of quality control over drug production and promoting the rational use of drugs in the country;
- 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,
- strengthening the indigenous capability for production of drugs.

2. For meeting the requirements of medicines for health needs at reasonable prices and strengthening the indigenous base the Government has, over the years been guided by the above Policy. Implementation of the main policy provisions has been through the I(D&R) Act on Industrial Licensing aspects and through Drugs (Prices Control) Orders under the Essential Commodities Act in regard to the pricing mechanism. The Drug Policy has also given the policy framework in regard to Quality Control and Rational Use of Drugs. Enforcement of quality and standards in medicines is done through the provisions contained in the Drugs & Cosmetics Act, which is administered by the Ministry of Health and Family Welfare.

Present Status and Approach Adopted in Review

3. Over the last several years, policy inputs have been directed towards promoting the growth of the industry and in helping it to achieve a broad base in terms of the range of products and technologies needed to produce them from as basic a stage as possible. The results have been very encouraging. As on date there are about 250 large units and about 8,000 small scale units in operation, which form the core of the Industry (including 5 Central Public Sector Units). These units produce the complete range of formulations i.e. medicines ready for consumption by patients, and about 350 bulk drugs,i.e.chemicals having therapeutic value used for production of formulations. It is estimated that 70 per cent of the indigenous demand for bulk drugs and almost the entire demand for formulations are being met through domestic production.

4. During the last decade the production of bulk drugs has grown from Rs. 240 crores in 1980-81 to Rs. 1320 crores in 1993-94 and corresponding increase in production of formulations has been from Rs. 1200 crores to Rs. 6900 crores. The export performance of Industry has also been commendable. The trade balance has been positive for the last four consecutive years. During 1992-93 the trade balance was Rs. 560 crores (excluding exports of Medicinal Castor Oil).

5. Since 1986, the Drug Industry has grown significantly, as mentioned earlier, in terms of production of bulk drugs and formulations. In many cases manufacture of bulk drugs has also been established from the desired basic stage. It is estimated that in case of bulk drug production the contribution of small scale sector is approximately 30 per cent of the total

production in the country. It may also be mentioned that the pharmaceutical sector has been able to carve a special niche for itself in the international market as a dependable exporter of bulk drugs. As already mentioned, the industry has been a net exporter in the last four years.

Industrial Licensing

6. Import and Economic policies have undergone major changes like pruning of the Negative List for imports, doing away with the Actual User condition and full convertibility of Rupee on trade account. In this changed scenario, it is felt that there is no need to be more restrictive than before in granting industrial approvals, provided the two main concerns i.e., achieving basic stage manufacture and discouraging undue imports, are adequately taken care of. Under the circumstances, these objectives can be achieved only through the tariff mechanism and the EXIM Policy and as such Industrial Licensing and conditions stipulated therein have lost their relevance. It is also felt that, like in the other sectors of the economy, production would get the necessary impetus to meet any future demands as well as of ensuring adequate availability of drugs at reasonable prices if a more liberalised regime is operated in granting industrial approvals. Many of the drugs reserved for the Public Sector Undertakings have lost relevance vis-a-vis production programme of these units. Therefore, there is need to prune the list of items reserved for the Public Sector to only a few select items, where capacity in Public Sector is adequate to meet the country's demand and heavy public investment has been made.

Research and Development

7. The Drug Industry is a highly R&D oriented sector in which there is a very high rate of obsolescence. This sector has also been identified as one of the thrust areas for exports. There is, therefore, need to ensure that the technologies used in the country are cost effective and efficient. It is necessary to attract greater investment into this sector in order to update the existing technologies and for bringing into the country technologies which are not currently available. At the same time it has to be noted that the Indian companies have achieved considerable stature in terms of production as well as in marketing ability and indigenous technology has also reached a commendable level in many cases. However, in view of GATT accord and impending changes in Patent Laws, the subject matter of Basic Research in drug sector has assumed greater importance and needs to be attended to on an urgent basis.

Investment

8. Keeping in view the need to encourage more investment in this important sector to achieve the future demands likely to be placed on it in order to meet the growing needs of the country as well as to promote exports. it is proposed to treat the entire drugs and pharmaceutical sector as a high priority industry for the purposes of permitting foreign investment in terms of Appendix-III of the New Industrial Policy. It is also proposed to treat companies with foreign equity upto 51 per cent on par with wholly Indian companies. It may also be mentioned that at present companies with foreign equity upto 40 percent are already enjoying this facility and in the circumstances mentioned above there is no need to place any fresh curbs on their activities. Similarly, it is felt that automatic approval for foreign technology agreements can be permitted for all items in the Drugs is and Pharmaceuticals sector to encourage the introduction of newer and more efficient technologies, subject to their fulfilling the standard conditions laid down in the Industrial Policy. However, keeping in mind the levels of technology already available in the country, it is necessary to consider proposals involving foreign equity participation above 51 percent on merits of each case.

Pricing

9. The aberrations which have come to notice, in the listing of drugs and their categorisation for the purpose of price control, need to be eliminated by the use of transparent criteria applied across the board on all the drugs with the minimum use of subjectivity. The high turnover of a drug is an index of its extent of usage and is considered to meet the requirements of objectivity justifiable on economic considerations. However, the monopoly situation in cases of drugs with comparatively lower turnover has also to be kept in view. Also as an experimental measure, drugs having adequate competition may not be kept under price control and if this proves successful it would pave the way for further liberalisation. In the event, however, of prices of these drugs not remaining within reasonable limits, the Government would reclamp price control.

10. The categorisation of drugs into two lists with different Maximum Allowable Post-manufacturing Expenses (MAPE) allows a lower MAPE of 75 per cent for the drugs required for National Health Programmes (Category 1 drugs) as against 100% for others (Category 11 drugs). To encourage the production and availability of these drugs, it is considered necessary to allow a uniform MAPE in all cases of drugs under price control. Further, to achieve uniformity in prices of widely used formulations, it is considered that there should be ceiling prices for commonly marketed standard pack sizes of price controlled formulations and it should be obligatory for all, including, small scale units, to follow the prices so fixed. Also, to give encouragement to manufacture of drugs from basic stage, it is considered necessary to allow higher return in such cases over the existing rates.

11. In the light of the apprehensions expressed in the Parliament on the likely spurt in the prices of medicines, it has been felt that it would not be desirable to allow automaticity in the pricing mechanism. The Government would set up an independent body of experts, to be called the National Pharmaceutical Pricing Authority, to do the work of price fixation. This expert body would also be entrusted with the task of updating the list of drugs under price control each year on the basis of the established criteria/guideline. Time limits would be provided for deciding the applications of price approvals and, to begin with, it is proposed to set a time limit of two months for formulations and four months for bulk drugs. This body would also monitor the prices of decontrolled drugs and formulations and oversee the implementation of the provisions of the Drugs (Prices Control) Order. The Government would have the power of review.

12. Government will keep a close watch on the prices of medicines which are taken out of price control. In case, the prices of these medicines rise unreasonably, the Government would take appropriate measures, including reclamping of price control.

QUALITY CONTROL AND RATIONAL USE OF DRUGS

13. Quality Control and Rational Use of Drugs are important aspects of Pharmaceutical Industry. Steps have been taken for strengthening Drug Control Organization by sanctioning additional posts at various levels and by establishing subzonal offices at Hyderabad, Ahmedabad and Patna. The Bio-Laboratory at Madras has been upgraded to the level of National Laboratory. The Central Drugs Laboratory at Bombay, functioning from 1992 is in the process of being upgraded while Regional Laboratories at Guwahati, Chandigarh and Hyderabad are in the process of being set up. To improve the existing State Drugs Testing Laboratories and to set up new ones, wherever not established, funds have been sanctioned under a Centrally Sponsored Scheme, besides providing funds under this scheme for augmenting Drug Inspectorate Staff. For certain categories of drugs, which had caused adverse

effects due to the lack of drug control in one or the other State, the Central Government has taken upon itself the responsibility of granting license. These drugs are : (i) Large Volume Parenterals, (II) Sera and Vaccines and (III) whole Human Blood and Blood Products. Moreover, the Good Manufacturing Practices (GMP) have been made mandatory.

14. Screening of irrational or harmful drugs is an ongoing exercise and 44 categories of formulations have been banned so far and the definition of new drugs has been widened and guidelines issued on clinical trials. With a view to ensuring proper dispensing and rational use of drugs, packagings have been standardized. Five leading hospitals at Pondicherry, Chandigarh, New Delhi, Bombay and Lucknow have been identified as Adverse Drug Reaction Monitoring Centres.

15. While Ministry of Health and Family Welfare are taking some action on these matters, the general perception unfortunately is that this area is presently being neglected. In the interest of the consumers, there cannot be any compromise on quality aspects of medicines and the problem has assumed greater dimension in view of the large number of small scale drug manufacturing units which are estimated to be over 8000 in number.

NATIONAL DRUG AUTHORITY

16. In view of the above it is envisaged that a National Drug Authority may be set up by a separate Act of Parliament to perform the following functions:

1. Develop and define basic appropriate standards relating to the manufacture, import, supply, promotion and use of drugs.

2. To approve and register pharmaceutical products for use in the country only if

- it meets real medical need,
- it is therapeutically effective, and
- it is acceptably safe.

3. To enforce effectively appropriate quality standards of medicines and Good Manufacturing Practices, throughout the country, having full regard to the needs of public health and standardize dosage strengths and pack sizes of formulations with a view to check proliferation.

4. To monitor standard practices in drug promotion and use and to clearly identify those which are acceptable and prohibit those which are unethical and against the consumers' interest.

5. To monitor the prescribing practices and to evaluate their appropriateness for the purpose of guiding the medical profession and for achieving the aim of rational prescribing.

6. To ensure that appropriate information about registered pharmaceuticals is made available for the guidance of consumers having regard to:

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  - the adverse consequences of non-compliance by patients particularly in the case of antibiotics, steriods etc.,
  - dangers of self-medication, and
  - the need to involve consumers as full partners in the health care system.

7. To prepare and publish a national formulary and formularies relevant to various levels (like district hospital, community centre, primary health centre) for the guidance of consumers as well as doctors.

17. The functions mentioned above involve new responsibilities which will include:

Special focus on examining the technology of bulk drugs; capacity validation of machinery; assessing suitability of manpower for bulk drug production; undertaking scientific scrutiny of master formulae for manufacture of formulations; developing testing labs for cosmetics, diagnostics and devices; laying down standards for veterinary drugs; examination of labels and promotional claims and prescribing procedures for public hearing under the Drugs and Cosmetics Act; monitoring of clinical trials for the protection of human rights; quality control of herbal medicines; updating new drug approval process; weeding out of irrational combination formulations; and formation of expert committees for examination of new drugs.

18. In addition, screening promotional literature, monitoring ongoing clinical trials through an Institutional Review Board, unearthing sub-standard and spurious drugs with the help of Legal cum Intelligence Cells, centralizing all manufacturing licencees for inter-State commerce, updating Good Manufacturing Practices and education to achieve judicious use of drugs, setting up of new analytical testing labs, as well as imparting continuous education and skills for inspection and testing and setting up of Dispute Mechanism Cell are envisaged.

19. There is an imperative need to undertake upgradation of the drug testing facilities under the Central and State organizations as well as augmentation of the Drug Control and enforcement staff to enable statutory inspections to be undertaken as provided for under the Act. Therefore, there is need for establishing more zonal and sub-zonal offices under the Central Drug Standards Control Organization as well as additional Regional Drug Testing Laboratories.

20. The implementation of the above proposals would require additional funds, which are proposed to be mobilized by levying a cess of 1 % on production of drugs and pharmaceuticals, by a special legislation to be piloted by the Ministry of Health and Family Welfare. The funds mobilized through the cess would be utilized also for encouraging Research and Development in the drug sector.

Indigenous and Other Systems of Medicines

21. Various aspects relating to development and promotion of Ayurvedic, Unani, Sidha, Homeopathic and traditional systems of medicines would be actively pursued and the machinery for carrying out these tasks would be adequately strengthened. To provide better focus to this important work it is felt that there is need to create a separate Department, to look after all matters relating to development and promotion of these systems of medicines.

Decisions in Regard to Modifications in Drug Policy '86

22. In the above background, the Government have decided to modify the Drug Policy, 1986 as follows

22.1 Licensing

22.1.1 Industrial Licensing for all bulk drugs cleared by Drug Controller (India) and all their intermediates will be abolished, except in the cases of

- 5 identified bulk drugs which are to continue to be exclusively reserved for the Public Sector as mentioned in Para 22.3 below,
- bulk drugs produced by the use of recombinant DNA technology, and
- bulk drugs requiring in-vivo use of nucleic acids as the active principles.

22.1.2 Conditions stipulating mandatory supply of a percentage of bulk drug production to Non-associated Formulators will be abolished.

22.1.3 Licensing shall be abolished for formulations except in cases of specific cell/tissue targeted formulations.

22.1.4 Ratio parameters linking bulk drugs and formulations production and limiting the use of imported bulk drugs will stand abolished.

22.1.5 Broad-banding, Vocational restrictions and grant of COB licenses will be in accordance with the Industrial Policy.

(The Memorandum of Information prescribed by the Department of Industrial Development shall include an Addendum, to meet the additional requirement of the Drugs & Pharmaceuticals industry, as would be devised by the Department of Chemicals and Petrochemicals.)

22.2 Basic Stage Production

For achieving manufacture from the basic stages and arresting the regression towards manufacturing from later stage intermediates/penultimates, the tariff mechanism would be utilized. Imports of critical intermediates/penultimates may also be put in the negative list so as to arrest regression from basic stage manufacturing.

22.3 Review of Items Reserved for the Public Sector

Out of the fifteen drugs currently reserved, only five drugs namely Vitamin BI, Vitamin B2, Folic Acid, Tetracycline and Oxytetracycline, shall continue to be reserved for public sector units. The position will be reviewed after a period of three years.

22.4 Foreign Investment

22.4.1 Investment upto 51 per cent will be permitted in the case of all bulk drugs, their intermediates and formulations.

22.4.2 Investment above 51 per cent will be considered on a case by case basis in areas where investment is otherwise not forthcoming, particularly in the manufacture of bulk drugs from basic stages and their intermediates, and bulk drugs produced by the use of recombinant DNA technology as well as the specific cell tissue targeted formulations.

22.5 Foreign Technology Agreements

Automatic approval for foreign technology agreements shall be given in the case of all bulk drugs, their intermediates and formulations except those produced by the use of recombinant DNA technology, for which the existing procedure would continue.

22.6 Encouragement to Research & Development (R&D) Efforts

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

22.6.2 The Department of Chemicals Petrochemicals would set up an Inter-Ministerial group to decide, within a set time frame, on measures to give further impetus to R&D in the Drug Sector.

22.6.3 The Ministry of Health and Family Welfare would further streamline the required procedures and steps for the quick evaluation and clearance of new drug applications, specially those developed through indigenous R&D.

22.7 Pricing

22..7.1 Single List of Price Controlled Drugs & "Mape"

The system of price control may be operated through a Single list of price controlled drugs and formulations based thereon with a MAPE of 100 per cent.

22.7.2 Span of Control

- The criterion of including drugs under price control will be the minimum annual turnover of Rs.400 lakhs.
- Drugs of popular use, in which there is a monopoly situation will be kept under price control. For this purpose if for any bulk drug, having an annual turnover of Rs. 100 lakhs or more there is a single formulator having 90% or more market share in the Retail Trade (as per ORG) a monopoly situation would be considered as existing.
- Drugs in which there is sufficient market competition viz. at least 5 bulk drug producers and at least 10 formulators and none having more than the 40% market share in the Retail Trade (as per ORG) may be kept outside the price control. However, a strict watch would be kept on the movement of prices as it is expected that their prices would forces of market competition. The Government may determine the ceiling levels beyond which would not be permissible.
- Government will keep a close watch on the prices of medicines which are taken out of price control. In case, the prices of these medicines rise unreasonably, the Government would take appropriate measures, including reclamping of price control.
- For applying the above criteria, to start with, the basis would be the data upto 31st March, 1990 collected for the exercise of the Review of the Drug Policy. The updating of the data will be done by the National Pharmaceutical Pricing Authority as detailed in para 22.7.4 (i).
- Genetically engineered drugs produced by recombinant DNA technology and specific cell/tissue targeted drug formulations will not be under price control for 5 years from the date of manufacture in India.

22.7.3 Ceiling Prices

Ceiling prices would be fixed for commonly marketed standard pack sizes of price-controlled formulations and it would be obligatory for all, including small scale units, to follow the price so fixed.

22.7.4 Simplified Procedure

- An independent body of experts, to be called the National Pharmaceutical Pricing Authority, will be entrusted with the task of price-fixation/revision and other related matters such as updating the list of drugs under price control by inclusion and exclusion on the basis of the established criteria/guidelines and would be empowered to take final decisions. The Government would have the power of review. It would also monitor the prices of decontrolled drugs and formulations and oversee the implementation of the provisions of the Drugs (Prices Control) Order.
- The time-frame for granting price approvals will be 2 months for formulations and 4 months for bulk drugs from the date of receipt of the complete prescribed information.

22.7.5 Encouragement to Production from Basic Stage

The rate of return in case of basic, manufacture would be higher by 4 per cent over the existing 14 per cent on net worth or 22 per cent on capital employed.

22.8 Setting Up of National Drug Authority

22.8.1 A National Drug Authority would be set up by an Act of the Parliament, to be steered by the Ministry of Health and Family Welfare, to look after the Quality Control aspects, Rational Use of Drugs and related matters as outlined in Paras 16-19 above.

22.8.2 For strengthening the drug control system including GMP and for encouraging R&D, a cess of 1% would be levied on production of drugs and pharmaceuticals through legislation, details of which would be worked out by the Ministry of Health and Family Welfare.

22.9 Coordination Between Ministries

A Coordination Committee consisting of Secretaries of the Ministries/Departments of Commerce, Revenue, Health, Biotechnology and Industrial Development and Chairman, Bureau of Industrial Costs and Prices will be set up under the chairmanship of Secretary (Chemicals and Petrochemicals) for monitoring the areas of key concern every quarter and for taking effective and timely action. The Chairman of the proposed National Pharmaceutical Pricing Authority would also be co-opted on this committee, as and when it is constituted.

22.10 Other Matters

The various aspects relating to promotion of Ayurvedic, Unani, Sidha, Homeopathic and traditional systems of medicines would be actively pursued and the machinery for carrying out these tasks would be adequately strengthened. To provide better focus to this important work, a separate Department, to look after all matters relating to development and promotion of these systems of medicines, would be created.