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Pharmaceutical Policy 2002

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INTRODUCTION

The basic objectives of Government's Policy relating to the drugs and pharmaceutical sector were enumerated in the Drug Policy of 1986. These basic objectives still remain largely valid. However, the drug and pharmaceutical industry in the country today faces new challenges on account of liberalization of the Indian economy, the globalization of the world economy and on account of new obligations undertaken by India under the WTO Agreements. These challenges require a change in emphasis in the current pharmaceutical policy and the need for new initiatives beyond those enumerated in the Drug Policy 1986, as modified in 1994, so that policy inputs are directed more towards promoting accelerated growth of the pharmaceutical industry and towards making it more internationally competitive. The need for radically improving the policy framework for knowledge-based industry has also been acknowledged by the Government. The Prime Minister's Advisory Council on Trade and Industry has made important recommendations regarding knowledge-based industry. The pharmaceutical industry has been identified as one of the most important knowledge based industries in which India has a comparative advantage.

2. The process of liberalization set in motion in 1991, has considerably reduced the scope of industrial licensing and demolished many non-tariff barriers to imports. Important steps already taken in this regard are: -

- Industrial licensing for the manufacture of all drugs and pharmaceuticals has been abolished except for bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids, and specific cell/tissue targeted formulations.
- Reservation of 5 drugs for manufacture by the public sector only was abolished in Feb.1999, thus opening them up for manufacture by the private sector also.
- Foreign investment through automatic route was raised from 51% to 74% in March, 2000 and the same has been raised to 100%.
- Automatic approval for Foreign Technology Agreements is being 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 procedure prescribed by the Government would be followed.
- Drugs and pharmaceuticals manufacturing units in the public sector are being allowed to face competition including competition from imports. Wherever possible, these units are being privatized.
- Extending the facility of weighted deductions of 150% of the expenditure on in-house research and development to cover as eligible expenditure, the expenditure on filing patents, obtaining regulatory approvals and clinical trials besides R&D in biotechnology.
- Introduction of the Patents (Second Amendment) bill in the Parliament. It, inter-alia, provides for the extension in the life of a patent to 20 years.

3. The impact of the policies enunciated, from time to time, by the Government has been salutary. It has enabled the pharmaceutical industry to meet almost entirely the country's demand for formulations and substantially for bulk drugs. In the process the pharmaceutical industry in India has achieved global recognition as a low cost producer and supplier of quality bulk drugs and formulations to the world. In 1999-2000, drugs and pharmaceutical exports were Rs.6631 crores out of a total production of Rs.19,737 crores. However, two major issues have surfaced on account of globalization and implementation of our obligations under TRIPs which impact on long-term competitiveness of Indian industry. These have been addressed in the Pharmaceutical Policy-2002. A reorientation of the objectives of the current policy has also become necessary on account of these issues:-

- a. The essentiality of improving incentives for research and development in the Indian pharmaceutical industry, to enable the industry to achieve sustainable growth particularly in view of anticipated changes in the Patent Law; and
- b. The need for reducing further the rigours of price control particularly in view of the ongoing process of liberalization.

4. It is against this backdrop, that Pharmaceutical Policy-2002 is being enunciated.

OBJECTIVES

5. The main objectives of this policy are:-

- a. Ensuring abundant availability at reasonable prices within the country of good quality essential pharmaceuticals of mass consumption.
- b. Strengthening the indigenous capability for cost effective quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector.
- c. Strengthening the system of quality control over drug and pharmaceutical production and distribution to make quality an essential attribute of the Indian pharmaceutical industry and promoting rational use of pharmaceuticals.
- d. Encouraging R&D in the pharmaceutical sector in a manner compatible with the country's needs and with particular focus on diseases endemic or relevant to India by creating an environment conducive to channelising a higher level of investment into R&D in pharmaceuticals in India.
- e. Creating an incentive framework for the pharmaceutical industry which promotes new investment into pharmaceutical industry and encourages the introduction of new technologies and new drugs.

APPROACH ADOPTED IN THE REVIEW

6. In order to strengthen the pharmaceutical industry's research and development capabilities and to identify the support required by Indian pharmaceutical companies to undertake domestic R&D, a Committee was set up in 1999 by this Department by the name of Pharmaceutical Research and Development Committee (PRDC) under the Chairmanship of Director General of CSIR.

7. To qualify as R&D intensive company in India, the PRDC has suggested following conditions (gold standards) :-

- Invest at least 5% of its turnover per annum in R&D,
- Invest at least Rs.10 Crore per annum in innovative research including new drug development, new delivery systems etc. in India,
- Employ at least 100 research scientists in R&D in India,
- Has been granted at least 10 patents for research done in India,
- Own and operate manufacturing facilities in India.

8. The recommendations of the PRDC in so far as they relate to the Pharmaceutical Policy have been taken into account while formulating the proposals on pricing aspects.

9. The Pharmaceutical Research & Development Committee has recommended in its report, submitted inter-alia, the setting up of a Drug Development Promotion Foundation (DDPF) and a Pharmaceutical Research & Development Support Fund (PRDSF). Necessary action in this regard has been initiated.

10. As far as the question of price control is concerned, the span of control has been gradually reduced since 1979. Presently, under DPCO, 1995 there are 74 bulk drugs and their formulations under price control covering approximately 40% of the total market. The functioning of the Drugs (Price Control) Order, 1995, has brought to light some problems in the administration of the price control mechanism for drugs and pharmaceuticals. In order to review the current drug price control mechanism, with the objective, inter-alia, of reducing the rigours of price

control, where they have become counter-productive, a committee, called the Drugs Price Control Review Committee (DPCRC), under the Chairmanship of Secretary, Department of Chemicals & Petrochemicals was set up in 1999, which has given its report. The recommendations of DPCRC have been examined and taken into account while formulating the "Pharmaceutical Policy - 2002".

11. It has emerged that the domestic drugs and pharmaceuticals industry needs reorientation in order to meet the challenges and harness opportunities arising out of the liberalisation of the economy and the impending advent of the product patent regime. It has been decided that the span of price control over drugs and pharmaceuticals would be reduced substantially. However, keeping in view the interest of the weaker sections of the society, it is proposed that the Government will retain the power to intervene comprehensively in cases where prices behave abnormally.

12. In view of the steps already taken and in the light of the approach indicated in the foregoing paragraphs, the decisions of the Government are detailed below :-

I. Industrial Licensing

Industrial licensing for all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations will be abolished, subject to stipulations laid down from time to time in the Industrial Policy, except in the cases of

- i. bulk drugs produced by the use of recombinant DNA technology,
- ii. bulk drugs requiring in-vivo use of nucleic acids as the active principles, and
- iii. specific cell/tissue targeted formulations.

II. Foreign Investment

Foreign investment up to 100% will be permitted, subject to stipulations laid down from time to time in the Industrial Policy, through the automatic route in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those, referred to in para 12.I above, kept under industrial licensing.

III. Foreign Technology Agreements

Automatic approval for Foreign Technology Agreements will be available in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those, referred to in para 12.I above, kept under industrial licensing for which a special procedure prescribed by the Government would be followed.

IV. Imports

Imports of drugs and pharmaceuticals will be as per EXIM policy in force. A centralized system of registration will be introduced under the Drugs and Cosmetics Act and Rules made thereunder. Ministry of Health and Family

Welfare will enforce strict regulatory processes for import of bulk drugs and formulations.

V. ENCOURAGEMENT TO RESEARCH AND DEVELOPMENT (R&D)

(a) In principle approval to the establishment of the Pharmaceutical Research and Development Support Fund (PRDSF) under the administrative control of the Department of Science and Technology, which will also constitute a Drug Development Promotion Board (DDPB) on the lines of the Technology Development Board to administer the utilization of the PRDSF.

(b) With a view to encouraging generation of intellectual property and facilitating indigenous endeavours in pharma R&D, appropriate fiscal incentives would be provided.

VI. PRICING

(a) Span of Price Control

The guiding principle for identification of specific bulk drugs for price regulation should continue, as per DPCRC's recommendation, to be: (a) mass consumption nature of the drug and (b) absence of sufficient competition in such drugs. However, the DPCRC's recommendation regarding the new criteria for ascertaining the mass consumption nature of a bulk drug on the basis of the top selling brand is not acceptable as it gives rise to anomalies.

In this context, it may be noted that there is no tailor made data available for the purpose of ascertaining the mass consumption nature and absence of sufficient competition with reference to a particular bulk drug. There is only one source namely, "Retail Store Audit for Pharmaceutical Market in India" published by ORG-MARG, which lists out all major brands and their sale estimates on All India basis. This publication contains data for single ingredient as well as multi-ingredient formulations. However, it does not give complete description of all the ingredients of the pharmaceutical product listed therein.

Hence, there is need to obtain information in regard to composition of each brand, dosage form wise and pack wise, from various other publications / sources, viz.,

(a) Indian Pharmaceutical Guide (IPG)

- a. Current Index of Medical Specialities (CIMS),
- b. Monthly Index of Medical Specialities (MIMS),
- c. Drug Today
- d. Information provided by some manufacturers
- e. Label composition as indicated on market samples.

Though none of these sources can be said to be exhaustive and comprehensive in regard to market information, yet under the given circumstances, these are the best available. It has also been noted that the sale value of any combination formulation is not directly relatable to a single particular bulk drug forming part of the combination formulation. Combination formulations involve too many variables, viz., strength of a particular bulk drug and its proportion with respect to other bulk drugs used in the combination formulation, price difference between bulk drugs used in combination formulation, pack sizes, dosage forms etc. In view of these facts, ORG-MARG sales data for combination formulations does not yield information in regard to mass consumption nature and absence of sufficient competition with reference to a particular bulk drug. Also, it is to be borne in mind that processing of such data, which requires cross-checking with other publications and sources of information in regard to composition of each brand, dosage form-wise and pack-wise may involve instances of omission / commission.

In view of above, it would be logical to conclude that although ORG-MARG sale estimates available in regard to all single-ingredient formulations of a particular bulk drug would not yield the sale value of that bulk drug in the form of all its formulations, yet it would adequately reflect the mass consumption nature of that bulk drug in the form of single ingredient formulations, which may be used as a practical indicator for formulating the policy.

The Department through NPPA, with the help of NIPER has developed the desired database for single ingredient formulations from the retail store audit data as published by ORG-MARG. On this basis, the Department proposes to undertake the exercise of identifying the bulk drugs of mass consumption nature and having absence of sufficient competition according to the following methodology: -

- i. The 279 items appearing in the alphabetical list of Essential Drugs in the National Essential Drug List (1996) of the Ministry of Health and Family Welfare and the 173 items, which are considered important by that Ministry from the point of view of their use in various Health Programmes, in emergency care etc., with the exclusion, as in the past, therefrom of sera & vaccines, blood products, combinations etc. should form the total basket out of which selection of bulk drugs be made for price regulation.
- ii. The ORG-MARG data of March 2001 would form the basis for determining the span of price control as suggested by DPCRC.
- iii. The Moving Annual Total (MAT) value for any formulator in respect of any bulk drug will be arrived at by adding the MAT values of all his single-ingredient formulations of that bulk drug, its salts, esters, stereoisomers and derivatives, covering all the strengths, dosage forms and pack sizes listed against that formulator in all groups / categories of the ORG-MARG (March 2001).
- iv. The MAT value for all the formulators, as defined in sub-para (iii) above, in respect of a particular bulk drug will be added to arrive at the total MAT value in the retail trade.
- v. The MAT value for an individual formulator, in respect of any bulk drug, as arrived at in sub-para (iii) above, will be the basis for calculating the percentage share of that formulator in the total MAT value arrived at as in sub-para (iv) above, in respect of that bulk drug.
- vi. Bulk Drugs will be kept under price regulation if:-

(a) The total MAT value, arrived at as in sub-para (iv) above, in respect of any particular bulk drug is more than Rs.2500 lakhs (Rs.25 Crore) and the percentage share, as defined in sub-para (v) above, of any of the formulators is 50% or more.

(b) The total MAT value, arrived at as in sub-para (iv) above, in respect of any particular bulk drug is less than Rs.2500 lakhs (Rs.25 Crore) but more than Rs.1000 lakhs (Rs.10 Crore) and the percentage share, as defined in sub-para (v) above, of any of the formulators is 90% or more.

- vii. All formulations containing a bulk drug as identified above, either individually or in combination with other bulk drugs, including those not identified for price control as bulk drug, will be under price control. The Government shall, however, retain the following over-riding power:-

In cases of drugs/formulations listed by the Ministry of Health and Family Welfare, mentioned in sub-para (i) above, and those presently under price control, having significant MAT value as per ORG-MARG but not covered under the criteria in sub-para (vi) above, as a result of this proposal, the NPPA would specially monitor intensively their price movement and consumption pattern. If any unusual movement of prices is observed or brought to the notice of the NPPA, the Authority would work out the price in accordance with the relevant provisions of the price control order.

(b) Maximum Allowable Post-manufacturing Expenses (MAPE)

Maximum Allowable Post-manufacturing Expenses (MAPE) will be 100% for indigenously manufactured formulations.

(c) Margin for Imported Formulations

For imported formulations, the margin to cover selling and distribution expenses including interest and importer's profit shall not exceed fifty percent of the landed cost.

(d) Pricing of Formulations

(i) For Scheduled formulations, prices shall be determined as per the present practice. The time frame for granting price approvals will be two months from the date of the receipt of the complete prescribed information.

(ii) The present stipulation that a manufacturer, distributor or wholesaler shall sell a formulation to a retailer, unless otherwise permitted under the provisions of Drugs (Prices Control) Order or any other order made thereunder, at a price equal to the retail price, as specified by an order or notified by the Government, (excluding excise duty, if any) minus sixteen percent thereof in case of Scheduled drugs, will continue.

(iii) The present provision of limiting profitability of pharmaceutical companies, as per the Third Schedule of the present Drugs (Prices Control) Order, 1995, would be done away with. However, if necessary so to do in public interest, price of any formulation including a non-Scheduled formulation would be fixed or revised by the Government.

(e) Ceiling prices

Ceiling prices may be fixed for any formulation, from time to time, and it would be obligatory for all, including small scale units or those marketing under generic name, to follow the price so fixed.

(f) Exemptions

(i) A manufacturer producing a new drug patented under the Indian Patent Act, 1970, and not produced elsewhere, if developed through indigenous R&D, would be eligible for exemption from price control in respect of that drug for a period of 15 years from the date of the commencement of its commercial production in the country.

(ii) A manufacturer producing a drug in the country by a process developed through indigenous R&D and patented under the Indian Patent Act, 1970, would be eligible for exemption from price control in respect of that drug till the expiry of the patent from the date of the commencement of its commercial production in the country by the new patented process.

(iii) A formulation involving a new delivery system developed through indigenous R&D and patented under the Indian Patent Act, 1970, for process patent for formulation involving new delivery system would be eligible for exemption from price control in favour of the patent holder formulator from the date of the commencement of its commercial production in the country till the expiry of the patent.

(iv) The DPCRC has suggested that the low cost drugs measured in terms of "cost per day per medicine" may be taken out of price control. Any formulator can represent to NPPA with proof of per day cost to consumer-patient. NPPA will be authorised to exempt such formulation from price control if its cost to consumer-patient does not exceed Rs. 2/- per day, under intimation to the Government. All orders passed by the NPPA will be prospective in operation. Whenever the concerned formulator wishes to revise the price, he, before effecting any change in

price, would be bound to inform NPPA and seek fresh exemption and in case the cost to consumer-patient, on the basis of the proposed revised price, exceeds beyond the limit of Rs. 2/- per day, obtain the necessary price approval.

(g) Pricing of Scheduled Bulk Drugs

(i) For a Scheduled bulk drug, 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. The time frame for granting price approvals will be 4 months from the date of the receipt of the complete prescribed information.

(ii) The present stipulation that a manufacturer, distributor or wholesaler shall sell a formulation to a retailer, unless otherwise permitted under the provisions of Drugs (Prices Control) Order or any other order made thereunder, at a price equal to the retail price, as specified by an order or notified by the Government, (excluding excise duty, if any) minus sixteen percent thereof in case of Scheduled drugs, will continue.

(iii) The Government shall, however, retain the overriding power of fixing the maximum sale price of any bulk drug, in public interest.

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Ceiling prices may be fixed for any formulation, from time to time, and it would be obligatory for all, including small scale units or those marketing under generic name, to follow the price so fixed.

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(i) A manufacturer producing a new drug patented under the Indian Patent Act, 1970, and not produced elsewhere, if developed through indigenous R&D, would be eligible for exemption from price control in respect of that drug for a period of 15 years from the date of the commencement of its commercial production in the country.

(ii) A manufacturer producing a drug in the country by a process developed through indigenous R&D and patented under the Indian Patent Act, 1970, would be eligible for exemption from price control in respect of that drug till the expiry of the patent from the date of the commencement of its commercial production in the country by the new patented process.

(iii) A formulation involving a new delivery system developed through indigenous R&D and patented under the Indian Patent Act, 1970, for process patent for formulation involving new delivery system would be eligible for exemption from price control in favour of the patent holder formulator from the date of the commencement of its commercial production in the country till the expiry of the patent.

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- ii. The Government shall, however, retain the overriding power of fixing the maximum sale price of any bulk drug, in public interest.

(h) Monitoring

(i) The DPCRC's recommendations to have effective monitoring and enforcement system and to move away from the "controlled regime" to a "monitoring regime" is in the present context an extremely important recommendation as imports will increasingly compete with local drugs and pharmaceuticals in the domestic market. A new system based on solely market prices data is required to be evolved and controls applied selectively only to cases where, either profiteering or monopoly profit seeking is noticed. The National Pharmaceutical Pricing Authority, set up in August, 1997, would need to be revamped and reoriented for this purpose. It will continue to be entrusted with the task of price fixation / price revision and other related matters, and would be empowered to take final decisions. It would also monitor the prices of decontrolled drugs and formulations and over-see the implementation of the drug prices control orders. The Government would have the power of review of the price fixation/and price revision orders/notifications of NPPA.

(ii) Although the prices of some bulk drugs have been steadily decreasing, yet the same do not get reflected in the retail price of non-Scheduled formulations. Also, there is need to check high margin/commission offered to the trade by printing high prices on the labels of medicines to the detriment of the consumers. It is, therefore, proposed to strengthen the National Pharmaceutical Pricing Authority by providing appropriate powers under the DPCO which would make it mandatory for the manufacturer to furnish all information as called for by NPPA and also to regulate such prices, wherever, required.

(iii) The other recommendations of DPCRC like giving powers to drug control authorities to dispose of small and petty offences etc., will require an amendment to the Essential Commodities Act. This suggestion is considered not practicable. Monitoring price movement of drugs sold in the country as well as that of imported formulations will require developing appropriate mechanism in the NPPA.

(i) Drug Price Equalization Account (DPEA)

Provision would be made in the new Drugs (Prices Control) Order (DPCO) to ensure that amounts which have already accrued to the DPEA and those which are likely to accrue as a result of action in the past, are protected and used for the purpose stipulated in the existing DPCO.

VII. QUALITY ASPECTS

The Ministry of Health & Family Welfare would

(i) progressively benchmark the regulatory standards against the international standards for manufacturing,

(ii) progressively harmonize standards for clinical testing with international practices,

(iii) streamline the procedures and steps for quick evaluation and clearance of new drug applications, developed in India through indigenous R&D, and

(iv) set up a world class Central Drug Standard Control Organisation (CDSCO) by modernizing, restructuring and reforming the existing system and establish an effective net work of drugs standards enforcement administrations in the States with the CDSCO as a nodal center, to ensure high standards of quality, safety and efficacy of drugs and pharmaceuticals.

VIII. PHARMA EDUCATION AND TRAINING

The National Institute of Pharmaceutical Education and Research (NIPER) has been set up by the Government of India as an institute of "national importance" to achieve excellence in pharmaceutical sciences and technologies, education and training. Through this institute, Government's endeavor will be to upgrade the standards of pharmacy education and R&D. Besides tackling problems of human resources development for academia and the indigenous pharmaceutical industry, the institute will make efforts to maximize collaborative research with the industry and other technical institutes in the area of drug discovery and pharma technology development.

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