

Draft

National Pharmaceuticals Policy, 2006

Part –A

(Contains issues other than statutory price control)

Department of Chemicals and Petrochemicals

Government of India

December 28, 2005

National Pharmaceuticals Policy 2006

PART – A (contains issues other than statutory price control)

1.0 Introduction

Driven by the knowledge skills, growing enterprise, low costs, improved quality and demand (domestic and international) the pharmaceuticals sector has witnessed a tremendous growth over the past few years - from a turnover of Rs 5000 crores in 1990 to over Rs 50,000 crores during 2004-05. Exports have also grown very significantly to over Rs 16700 crores during this period . India is today recognized as one of the leading global players in the manufacture of pharmaceuticals - it holds 4th position in terms of volume and 13th in terms of value of production. It is also recognized that the cost of drugs produced in India is amongst the lowest in the world. It is estimated that by the year 2010 industry has the potential to achieve Rs 1,00,000 crores in formulations with bulk drug production going up from Rs 8000 crores to Rs 25,000 crores. India's rich human capital is believed to be the strongest asset for this knowledge-led industry. Various studies show that the scientific talent pool of 4 million Indians is the second largest English speaking group worldwide, after the US.

However despite the impressive growth of the sector and low costs there are several concerns which need to be addressed. Some of these concerns pertain to accessibility and affordability of medicines by the common man particularly the vast segment of poor population, instituting standards of quality, particularly for units not conforming to standards of regulated markets, strengthening the fragmented regulatory system, sustaining growth of generics –the main forte of Indian industry , meeting the challenge of product patent regime and so on . Inorder to find the right solutions and the right balance between various viewpoints almost a continuous debate goes on regarding some of these issues both within and outside Government

In the year 2002 Government had formulated a new Drug Policy but the same could not be implemented due to litigation involving it , hence the policy of 1994 still continues to be in force.The present Policy known as the National Pharmaceuticals Policy, 2005 has been necessitated due to several developments that have taken place during the course of last few years as well as to address some of the major concerns as highlighted above. Price regulation of the essential medicines is an important component of this policy. However several other matters having a close bearing on the pharmaceuticals sector have also been included in the policy.

2.0 Past Approach

For meeting the requirements of medicines at reasonable prices as also for strengthening of the indigenous manufacturing capacity and capability, the Government has, over the years, formulated policies and issued drug price control orders from time to time. The first price control order was issued under the Defence of India Act in 1963 .Thereafter from 1970 onwards price control orders were issued under the Essential Commodities Act , 1955. Presently the Policy of 1994 is in existence and price control is being exercised through the Drugs Price Control Order,1995 under which prices of 74 bulk drugs and their formulations are controlled . Under the 2002 policy a new price control criteria was approved .However before the same could be implemented it was stayed by Karnataka High Court. An SLP was filed in the Supreme Court against the

order of Karnataka High Court .Supreme Court vide its interim order on 10th March, 2003 stayed the order of Karnataka High Court. However it also ordered that –“ --- the petitioner shall consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control and to review the drugs which are essential and life saving in nature till 2nd May,2003.” Accordingly the Central Government reviewed the National Essential Drug List , 1996 and brought out a new list called the National List of Essential Medicines ,2003 which was made available to the Supreme Court .Under this list as many as 354 drugs have been categorized as essential medicines.

Another important development that has recently taken place in India is the introduction of product patent regime in pharmaceuticals with effect from 1st January, 2005. Earlier with the enactment of The Patent Act ,1970 (which came into force in the year 1972) only process patent was made applicable for pharmaceuticals which played a very significant role in the development of the pharmaceutical industry in India . India emerged as a major producer and exporter of pharmaceuticals in the world .

After India became a signatory to the WTO and TRIPS agreements it was obliged to introduce product patent on pharmaceuticals with effect from 1st January , 2005 . Our patent law has now been made TRIPS compliant by fulfilling various commitments under the TRIPS agreement. This has brought a new challenge to the Indian pharmaceutical industry as it would no longer be able to freely continue with the production of generics of the new patented molecules without licence/payment of royalty to the innovator company.

With this paradigm shift the Indian industry would now be required to focus much more on research and development.

2.1 Experience Drawn from Past Pharmaceutical Policies

The first comprehensive Drug Policy of 1978 and thereafter the Drug Policy of 1986 together with the application of process patent under the Patent Act of 1970 successfully paved the way for development of indigenous pharmaceutical industry which went into the production of generic drugs in a big way . A conducive environment for success was provided by the then prevailing trade and economic policies . During the period from 1978 to 1990 indigenous industry acquired a respectable status in terms of product range and market share. R&D was confined to process development/innovation of existing molecules.

As regards pricing, the span of control, inclusion/exclusion of drugs under price control, methodologies adopted etc. continued to be debated. The Government developed principles of selectivity, from time to time, to keep the price control manageable and focused, as would be observed from declining trend in number of drugs under price control. In 1970, almost all bulk drugs and their formulations were under price control. In keeping with the economic policies of the country the number got reduced to 347 bulk drugs in 1979, 142 in 1987 and finally to 74 in 1995. It would have got reduced further under the criteria adopted in the Pharmaceutical Policy 2002, however, the same could not be implemented due to litigation involving it .

3.0 Important Developments after liberalization process in 1991

Following are some of the important developments that have taken place in pharmaceutical sector after the process of liberalization of the Indian economy was initiated by the Government in the year 1991---

1) Industrial Licensing: -

Industrial licensing for all kinds of drugs has been abolished (it has recently been done for the last remaining 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).

However the need for obtaining manufacturing licence under Drugs and Cosmetics Act,1940 continues for all units whether organized or small scale. The State Drug Controllers are authorized to issue such licences in most cases.

2. Foreign Direct Investment

FDI up to 100% is 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 the Drug Controller General (India), all their intermediates and formulations. Recently bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids as the active principles and special cell/tissue targeted formulations have also been allowed this facility.

3. Foreign Technology Agreement

Automatic approval for Foreign Technology Agreement (FTA) is already available in the case of all the bulk drugs cleared by Drug Controller General (India) , all their intermediates and formulations, except bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids as the active principles, and specific cell/tissue targeted formulations.

4. Imports

Imports of drugs and pharmaceuticals are regulated through EXIM Policy in force and presently all items except those requiring clearance under The Narcotics and Psychotropic Substances Act , 1985 are allowed under OGL. Further, a centralized system of registration has been introduced under the Drugs & Cosmetics Act and Rules made there under, administered by Ministry of Health and Family Welfare. These arrangements may continue to regulate imports of Drugs and Pharmaceuticals.

5. Exports

Exports are permitted in accordance with the EXIM Policy and relevant procedures/rules formulated for the purpose by the Directorate General of Foreign Trade. Exports are also subject to laws prevalent in importing countries. Also, the exporters are allowed imports of inputs on duty-free basis for export production. The industry has shown commendable export performance, the trade balance being positive. Over the last few years the compounded annual growth rate in exports has been 22.7 percent.

6. Constitution of Pharmaceutical Export Promotion Council (Pharmexil)

In order to provide a boost to pharma exports Government constituted a separate Export Promotion Council for Pharmaceuticals (Pharmexil) in the year 2004-05. This Council works closely with the Department of Commerce and the Export Promotion Cell in the Department of Chemicals and Petrochemicals to undertake activities such as promoting exports, preparing country-profiles, assessing export potential across the countries and to have greater degree of interaction internationally.

7. Research & Development

As recommended by the Mashelkar Committee in 1999 a Pharmaceutical Research and Development Support Fund (PRDSF) with a corpus of Rs. 150 crores has been set up under the administrative control of the Department of Science and Technology. A Drug Development Promotion Board (DDPB) to administer the utilization of PRDSF has also been set up .

8. Product Patent in Pharmaceuticals -

Product patent in pharmaceuticals has been introduced in the country with effect from 1st January , 2005 by amending the Patents Act , 1970 in conformity with the TRIPS agreement . The physical infrastructure in the four patent offices in the country (Kolkata, Delhi, Chennai and Mumbai) has been substantially strengthened and computerization has been introduced. Steps are now being taken to further augment and improve the software and human resources in these offices to enable them to deal with the new responsibilities .

9. Schedule M of Drugs and Cosmetics Act ,1940-

The revised Schedule M of the Drugs and Cosmetics Act, 1940 related to Good Manufacturing Practices (GMP) has come into effect from 1st July 2005. This would in the long run strengthen the pharma industry as a producer of quality medicines .

10. Introduction of Value Added Tax (VAT)

VAT has been introduced in India with effect from 1st April, 2005 . Already 22 States have implemented it . The remaining States are likely to implement it in the near future. VAT on medicines has been kept at 4%

11. Excise Duty payable on MRP (Maximum Retail Price)

A Notification was issued on 7th January, 2005 under which Excise duty became leviable on MRP with an abatement of 40% .

4.0 Key Policy Objectives :

Following are the key objectives of the policy-

(a) To ensure availability at reasonable prices of good quality medicines within the country

(b) To improve accessibility of essential medicines for common man particularly the poorer sections of the population

(c) To facilitate higher investment for increased production of good quality medicines

(d) To promote greater research and development in the pharmaceuticals sector by providing suitable incentives in this regard.

(e) To enable domestic pharma companies to become internationally competitive by implementing cGMP, GLP, GCP and other established international guidelines

(f) To facilitate higher growth in exports of APIs and formulations by reducing the barriers to international trade in pharmaceuticals sector

To develop India as the preferred global destination for pharma R&D and manufacturing

To facilitate implementation of the Health Policy of the country

4.1 The National Common Minimum Programme, as adopted by the Government aims as follows:

a) UPA Government will raise public spending on health to at least 2-3% of GDP over the next five years with focus on primary health care.

b) A national scheme for health insurance for poor families will be introduced.

c) The UPA will step up public investment in programmes to control all communicable diseases and also provide leadership to the national AIDS control effort.

d) The UPA Government will take all steps to ensure availability of life saving drugs at reasonable prices.

e) Special attention will be paid to the poorer sections in the matter of health care.

f) The feasibility of reviving public sector units set up for the manufacture of critical bulk drugs will be re-examined so as to bring down and keep a check on prices of drugs.

An issue of paramount importance in the Indian context is to increase the accessibility of drugs to the common man and in particular to the vulnerable and poorer segments of the population. Even though the prices of drugs as compared to most other countries and particularly the neighbouring countries are one of the lowest yet these are important issues relevant to India. A Committee set up by Government under the chairmanship of Joint Secretary (Pharmaceuticals) popularly known as the Sandhu Committee had made several recommendations in this regard. Thereafter the Task Force headed by Dr Pronab Sen, Principal Adviser (PP), Planning Commission popularly known as the Sen Committee made several other wide ranging recommendations. Some important recommendations were made by the National Manufacturing Competitiveness Council (NMCC). National Commission on Macroeconomics and Health Constituted by the Ministry of Health and Family Welfare in its report on 'Access To Drugs and Medicine' also made some valuable recommendations on issues relevant to the drug industry. The

recommendations made by all these Committees have been examined by Government and there is a broad agreement on the implementation of several of the recommendations. Several suggestions were received from industry associations, voluntary bodies, States and other organizations. A Core Committee consisting of representatives of Department of Chemicals and Petrochemicals, NPPA, NIPER and Chief Executives of various public sector pharma undertakings was constituted to facilitate drafting of the policy based on the various / suggestions .

New Policy Initiatives

The new initiatives except for price control are enumerated in Part A of the report while Price control system is enumerated in Part B of the report (Part B has been prepared separately)

1. Strengthening of Drug Regulatory System

Drug regulatory system has a close bearing on the prices , availability and quality of drugs. Under the Drugs and Cosmetics Act,1940 there is dual regulatory control over the drugs by Central and State governments. While regulation of manufacture , sale and distribution of drugs is primarily the responsibility of the State Authorities , the Central Authorities are responsible for approval of new drugs , clinical trials, laying down standards for drugs , control over imported drugs , coordination of the activities of state drug control organizations

The Expert Committee set up by Government under the chairmanship of Dr R A Mashelkar, Director CSIR in its report submitted in 2003 has made comprehensive recommendations for strengthening the drug regulatory system including the problem of spurious drugs . It has made detailed recommendations to strengthen the existing regulatory organizations both at the Centre and the States.

The Task Force set up by Government to ‘ Explore Options other than Price control for achieving the objective of making available life saving drugs at reasonable level’ has recommended that in the long run both the functions of drug regulation and price control should be performed by the same agency and there should be an integrated regulatory system.

Keeping in view the recommendations of the two Committees it has been decided that –

a) As an immediate step an independent and autonomous body by the name of National Drug Authority would be constituted in place of the present Central Drugs Standard Control Organisation (CDSCO).

b) Several of the existing provisions of the Drugs and Cosmetics Act, 1940 would be amended to make the penalties more deterrent for various offences and in particular for spurious and sub-standard drugs . A bill in this regard has been introduced in the Parliament

c) In the long run the proposal of Task Force regarding merger of NPPA and NDA would be considered in the form of National Authority on Drugs and Therapeutics (NADT) which will lead to an integrated regulatory system in the country.

(Comments by Health)

2. Intellectual Property Rights including Data Protection

Government is committed to making the Indian laws and policies pertaining to Intellectual Property Rights fully compliant with the provisions of TRIPS . Significant progress has already been made in this regard. Product patent in case of pharmaceuticals has been introduced with effect from 1st April, 2005 by amending the Patents Act ,1970 . Under this Act both product as well as process patents can now be granted for pharmaceuticals .New Rules are being framed under this Act and would be notified soon. Under these

rules it would be the endeavour of the Government to simplify procedures and shorten the timelines for various approvals.

Modernisation of Patent Offices in the country has been undertaken and the number of patent examiners has been augmented in these offices. Following action is contemplated towards further improving the working of the patent offices –

- a) Proper training to be imparted to the personnel working in the four patent offices .Trainers from India and abroad would be utilized for this purpose.
- b) The number of patent examiners to be further increased to match the increased workload
- c) Full computerization would be undertaken so as to bring about greater transparency and convenience in the functioning of these offices.
- d) All the pending patent applications to be made available on the website of the patent office
- e) Electronic filing of patent applications to be introduced
- b) An IP Cell to be set up in the Department of Chemicals and Petrochemicals to support innovator pharma SMEs in the patenting process , training in documentation and other areas of intellectual property .This would enable them to take advantage of the patent regime and in the process encourage greater R&D in their enterprises
- c) A Technical Expert Group has been constituted under the chairmanship of Dr R. A. Mashelkar , Director General, Council of Scientific and Industrial Research with the following terms of reference-

- whether it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive steps,
- Whether it would be TRIPS compatible to exclude micro-organisms from patenting

As regards Data Protection various options are being examined by the Inter-Ministerial Committee headed by Secretary, Department of Chemicals and Petrochemicals . The Committee has heard various viewpoints on the subject and is likely to submit its report soon .Suitable policy decision/action would be taken after receipt of the report of the Committee on this matter.

(Comments by Health / DIPP/ Commerce)

4. Clinical Trials and Drug Development

Clinical Trials are essential for drug development . Schedule Y of the Drugs and Cosmetics Rules,1945 has been amended to allow for multicentric concurrent clinical trials in India. Under these rules clinical trials have been defined and it has been made mandatory to take approval for conducting any type of clinical trials in the country. Also Good Clinical Practices (GCP) guidelines have been published and made mandatory . It also addresses the protection of study subjects (patients/volunteers) and integration and quality of data . Following action is contemplated to facilitate and encourage clinical trials in India-

- a) An early decision on data protection
- b) As improved regulatory infrastructure and some form of protection to undisclosed test data will increase the activity in this field.
- c) In order to facilitate pre-clinical trials National Toxicology Centre set up in NIPER to be made fully compliant with GLP norms

- d) Tax benefits available to R&D to be made applicable for Clinical trials also
- e) Clinical trial samples being imported into India to be exempted from payment of import duty on the basis of authorization/licence issued by Drug Controller General of India
- f) To promote direct investment in the field of clinical development and data management exemption from service tax for a period of 10 years upto 2015

(Comments by Health /DST/Revenue)

5. Public-Private Partnership Programme for Anti-Cancer and Anti-HIV/AIDS Drugs

For making available anti-cancer and anti-HIV/AIDS drugs at reasonable prices to a much larger section of the population Government would evolve a public – private partnership programme with the concerned manufacturers and cancer hospitals in the country. All medicines pertaining to these categories whether under National List of Essential Medicines,2003 or outside would be brought under this programme . Some of the steps proposed to be taken are as under-

a) Anti Cancer Drugs—

At any given point of time there are about 20 to 25 lac people suffering from cancer in the country who are affected by various types of cancer (lung cancer , blood cancer etc.) It is estimated that every year about 7 lac people are detected with different types of cancer Most of them are unable to afford the cost of expensive anti-cancer medicines .Going by a conservative estimate of average cost of anti-cancer medicines per patient as Rs 25,000 it would require medicines worth Rs 5,000 crores . As against this, the present turnover of this segment of medicines in India is estimated to be only Rs 150 crores. The big gap indicates the near non-accessability of the medicines to a vast majority of the affected population mainly because of the high cost of these medicines .

In order to reach out to a larger number of cancer patients following steps would be taken –

1.Government would completely exempt anti-cancer drugs (bulk and formulations) from all types of Central taxes - excise duty, import duty etc and the benefit would be passed on to the consumers.

2.States would also be asked to exempt these medicines from all types of state and local levies

3.Industry and trade would be asked to reduce their margins –both profit and trade margins to the barest minimum level and pass on the benefit to the consumers .

4 A subsidy scheme for making cancer drugs affordable to the common man would be worked out with the help of concerned manufacturers and the Cancer hospitals. Under this scheme a subsidy on the sale of anti-cancer drugs would be made available to all the cancer hospitals who register under the scheme .

5 Subsidized anti-cancer medicines would be provided to all the cancer patients from the retail outlets of the cancer hospitals on the recommendations of the doctors of such hospitals

In order to take advantage of lower rates from bulk purchase a Rate Contract for the anti-cancer drugs would be worked out with the manufacturers for all the hospitals which join this scheme . All Government run hospitals with facilities for treatment of cancer would be eligible to become members of the scheme as also the private cancer hospitals.

Efforts would be made to create drug banks in major cities where manufacturers would be encouraged to contribute to these drug banks which may be managed by hospitals and NGOs

(Comments by Revenue/ Health/States)

b) Anti-HIV/AIDS Medicines

India has the highest number of reported HIV/AIDS cases in the entire SOUTH Asian region. There are as many as 5.1 million people affected by HIV/AIDS in India , about 85% of the South Asian total. In the world India has the second highest reported cases of HIV/AIDS ,just below South Africa's total of 5.3 million

There are presently 39 Anti-Retroviral Therapy (ART) Centres in the country located mostly in the medical colleges and major tertiary hospitals. These are located mostly in the six high prevalence states namely Karnataka, Tamil Nadu, Andhra Pradesh, Maharashtra, Manipur and Nagaland.

100 new centres have been identified to be opened in the near future and the number would go to 188 by the year 2010. It would be the endeavour of the Government to open atleast one or two centers in each state .

The number of patients being provided free treatment through the ART centers is 16000 . (another 16000 patients are being treated by Railways and ESIC and 10000 by the private sector). The number of patients treated would be taken to 500,000 by the year 2010. Apart from the assistance available under the Global Fund for Aids, TB and Malaria-Round 4 , additional funds would be provided to cover the entire AIDS affected population.

Presently anti-HIV/AIDS drugs that are being manufactured in India are mostly first generation which have developed resistance in many cases. Production of second generation drugs would be ensured in the country so as to provide an effective treatment on a continuous basis.

Some of the measures envisaged to reduce the cost of ARV drugs and increase their availability are as follows –

a) Complete exemption of anti-HIV/AIDS drugs (bulk drugs as well as formulations) from the payment of excise duty, customs duty and other levies ,if any. This benefit would be passed on to the patients .

b) Manufacturers and Trade to charge lower profit and trade margins on these drugs.

c) Most of the first generation drugs and some of the second generation drugs are presently being manufactured in India . All efforts would be made to ensure production of second generation drugs in the country in consonance with the provisions of Patent Act ,1970

d) In case of second generation drugs which are not manufactured in India these would be procured at prices which are negotiated with the concerned manufacturers .

(Comments by Revenue / Health / NACO)

(In the case of AIDS cheaper and more easily available drugs have led to 80% decline in deaths between the period 1997 and 2003 –as reported by researchers from India and Rhode Island in the November 15 issue of Clinical Infectious Diseases.

Government is running 39 testing and treatment centers where over 14400 patients are being treated – only those with CD 4 count below 200 per cubic ml of blood are treated. Railways and industry is treating another about 30,000 patients. At the same time the fact is that there are over 5 million HIV-positive cases in India which is 10% of the world's population of people with HIV. Estimates of population affected by HIV varies between 5 million to 7 million. Presently NACO is purchasing medicines and distributing these free of cost through its Centers and State Aids Control Societies Government would allocate larger funds for the purchase of these medicines particularly anti -AIDS through a centralized system)

4.Prices of Drugs for Other Life Threatening Diseases

Drugs for other life threatening diseases requiring life long treatment ,whether part of National List of Essential Medicines,2003 or outside it , would also be identified and brought under the public-private partnership model

5. Patented Drugs –price negotiations

The patented drugs (formulations under product patent) that are launched in India after 1st January, 2005 would be subjected to mandatory price negotiations before granting them marketing approval. Department of Chemicals and Petrochemicals in consultation with Department of Health would lay down necessary guidelines for determining the negotiated prices. Practices adopted by some other countries particularly Canada, France and Australia and some of the Asian countries and their experience in this regard would be studied at the time of framing the guidelines. The norms for price negotiations would be made applicable from the date of notification of these.

After the norms are notified an Expert Committee would be constituted for carrying out the negotiations on case by case basis with the concerned companies.

(Comments by Health / NPPA)

6.Trade Margins

The issue of trade margins has been the subject of intense debate from time to time and different views have been expressed on this issue . Government appointed a Committee headed by Joint Secretary (Pharmaceuticals Industry) in the Department of Chemicals and Petrochemicals to examine this issue along with other issues relating to drug prices .Based on the recommendations of this Committee a suitable decision would be taken in the matter .

(Based on the recommendations of this Committee following can be the trade margins for different drugs—

Category A Drugs (drugs under cost based price control)-

Both Branded and Generics

- 8% wholesaler , 16% for retailer

These margins are already prescribed under the present system of price control

(2) Other Drugs(Not under cost based price control)

a)Branded – 10% wholesaler , 20 % for retailer

- these margins are prevailing as per an agreement between the industry and trade. Branded generics (5 to 7%) would also be put in this category

b)Generics – 15% wholesaler, 35% for retailer

These margins are not prescribed at present and vary largely across various drugs. Generics form account for 5 to 7 % of the total market

NOTE - All the above trade margins would be calculated on the MRP of the drug.

Comments
by NPPA

7.Excise duty relief

Excise duty on pharmaceuticals continues to be at the rate of 16%. With effect from 7th January,2005 excise duty was made applicable on MRP of drugs with an abatement of 40% . This means that the excise duty is now levied on 60% of the MRP as compared to the ex-factory price earlier. This has increased the burden on the industry particularly the small scale sector. The high rate of excise duty is particularly visible since the State governments reduced the applicable VAT rate to 4% in recognition of the essential nature of pharmaceutical products. At a time when there is a demand to make prices of medicines affordable and reasonable, particularly for the poor people, it becomes justified for government to reduce the excise duty from 16% to 8% on all medicines. Hence it has been decided to reduce the excise duty on all pharmaceutical products from 16% to 8%

In addition it has been decided to enhance the exemption limit of small scale units from excise duty from the present level of turnover of Rs.1 crores to Rs. 5 crores

Both these steps are likely to reduce prices of medicines and also provide the much needed relief to the small scale units leading to their survival, improved quality and better tax compliance which would have a positive effect on the revenues of Government

(Comments by SSI / Revenue)

8. Maximum Retail Price (MRP) inclusive of all taxes

Under the provisions of Packaged Commodities Rules, 1977, all commodities sold in prepackaged form are required to have a label declaration of retail sale price in the form of MRP inclusive of all taxes. This concept is well accepted and is being used for all packaged consumer goods in India except drugs .

DPCO requires 'Retail Price not to exceed Rslocal taxes extra ,” so that basic MRP is strictly followed and only actual taxes , which vary, are charged extra. However , in practice , this often leads to wrong calculations , extra charges and debate between the dealer and the consumer. From the consumer’s point of view it is most

desirable that the total price should be absolutely clear on the pack and uniform all over India.

It has now been decided that the concept of MRP inclusive of taxes would be made applicable to medicines sold in the packaged form.

(Comments by Consumer Affairs / Health/NPPA)

(With introduction of VAT in several states at the uniform rate of 4% (with remaining states to follow suit) and CST likely to be made 2% for the time being and soon to be abolished time has now come to introduce MRP inclusive of all taxes to drugs and medicines . Industry would be given time of three months to switch over to the new system.)

9 New Drug Price (Control) Order

Immediately after the approval of the new pricing system under this policy a new Drug Price (Control) Order (DPCO) replacing the existing DPCO , 1995 ,would be issued under the Essential Commodities Act , 1955, incorporating the new system –as is decided in part B of the policy

10. Drugs and Therapeutics (Regulation) Act —

In order to give full effect to the new policy it is essential that a new law is enacted to exercise a more effective price control / monitoring of the prices of drugs . Therefore a new Act to replace the existing system of Drug Price (Control) Orders under the EC Act would be enacted by the name of Drugs and Therapeutics (Regulation) Act (DATA). The main features of this Act would be --

a) Empowering government or its designated authority to impose a price or limit the increase in the price or control the price in any other manner of any individual, class or category of drug or therapeutic product for any period of time it deems appropriate in public interest, irrespective of the fact whether a drug is manufactured in India or outside.

b) Requiring the government or its designated authority to clearly lay down the principles governing or the reasons leading to imposition of any such price control or any deviations permitted there from.

c) Authorizing the government or its designated authority to seek or compel disclosure of any information or data relevant to its functioning from all manufacturers, marketers, distributors or retailers of drugs and therapeutic products.

d) Requiring all companies involved in the manufacture or marketing of drugs and therapeutic products to submit authenticated price lists of all their products along with other relevant details to government or its designated authority on a regular basis with a frequency to be specified by the latter.

e) Granting the government or its designated authority the power to approve a brand name for a specific product, to prevent changes in the composition of a product marketed under an approved brand name and to determine the nomenclature under which a product can be marketed, if necessary, for all drugs and therapeutic products.

f) Providing penalties, for violation or non-compliance with the provisions of the Act or the Rules framed and orders issued under the Act. These penalties could be graded – fines, temporary withdrawal of marketing approval, withholding of marketing approval, sealing of production facilities, compounding of offences, etc.

g) Other relevant provisions with regard to production and prices as mentioned in the EC Act, 1955 would be incorporated in the Act to the extent possible.

h) Greater role and accountability of State Drug Controllers would be specifically provided for under the Act.

*(Comments by
Health/Consumer Affairs)*

11.0 National Pharmaceutical Pricing Authority (NPPA)—

National Pharmaceutical Pricing Authority was set up as envisaged in the Drug Policy of 1994 for fixation and monitoring of prices of various drugs as well as various related matters per the provisions of the Drugs (Prices Control) Order, 1995 and in accordance with the powers delegated to it.

Strengthening of NPPA

In order to enable NPPA discharge its responsibilities more effectively there is an immediate need to bring about some fundamental changes in its working. These are as follows :

Present structure and working of NPPA to be revamped to bring in greater transparency in the organization like making available information on the NPPA website pertaining to various norms, guidelines, details of ceiling prices of various drugs etc.

The tenure of Chairman to be minimum 2 years with maximum age limit as 62 years.

Strengthening of the monitoring system of NPPA through appropriate computerization and software. A system of online filing of prices on a six monthly/ annual basis and other information by industry to be developed

Establishment of a regular linkage between NPPA with the State Drug Controllers through a dedicated Drug Price Monitoring Cell in each of the major States and on-line electronic linkage. The full cost of these Cells and electronic hardware and connectivity would be funded by Central Government . (Health Department is already providing an all- India link with all States-this could be made use of for prices as well)

Review of all existing guidelines , norms and procedures followed by NPPA for fixing prices of bulk drugs and formulations by a Committee to be set up by Department of Chemicals and Petrochemicals. Among others this Committee would include representatives of pharmaceuticals industry also.

(Comments by Health / NPPA)

12.0 Bulk Procurement system for Drugs by Government--

The system of procurement in the Central Government must essentially ensure that quality drugs are purchased and that drugs have active ingredients at the maximum level throughout the shelf life period of the drug.

Following would be the main guiding factors for procurement of bulk purchase of medicines by various government agencies :

- (a) Procurement preferably in the form of generic drugs
- (b) Procurement only from pre-qualified manufacturers of drugs
- (c) Technical and price bids to be invited in separate envelopes. Bids /tenders to be invited through press and website of the concerned department .
- (d) Schedule M for GMP compliance of the manufacturer to be ensured.
- (e) Minimum three years of track record in sustained production and marketing of the concerned drug. Balance sheets for the previous three years be obtained to make an assessment of the manufacturing and financial capacity of the manufacturer.
- (f) Post-award inspection of manufacturing facilities to be carried out by the purchasing agency
- (g) Batch-wise sample testing of drugs from government run or government approved laboratories before the drugs are put to use. Incase of failure of a drug during testing suitable penalties to be imposed on the manufacturer
- h)Packaging specifications may be prescribed for better shelf life

Incase the price quoted by a manufacturer is lower than the price fixed by NPPA by more than 15% he should be asked to provide justification for the same. Incase he is unable to provide proper justification his / her bid should be liable to be rejected.

Third party quality assurance may be adopted as is being done by Health Department for World Bank funded drugs. It should be the responsibility of this agency to ensure supply of quality drugs.

Where a different criteria and methodology has been prescribed by any lending agency(World Bank,WHO , UNICEF etc) the same may be followed.

- l) Expired drugs must be destroyed by the hospitals as per the norms laid down by Pollution Control Board

In some of the Central Government Organisations and States a centralized purchase system for drugs is adopted. It would be in larger public interest that a similar system is adopted in all the organizations and the States

(Comments by Health / States)

13.0 Lower Prices for bulk purchases by Government –

For the bulk purchases made by Government for public health requirements (government hospitals/programmes , health insurance etc.) ceiling prices as follows would be fixed within which purchase prices would be charged by the manufacturers through open tenders –

For drugs under NPPA cost based price control –

-a ceiling price of 65% of the price fixed by NPPA

For drugs other than those under cost based price control and patented drugs

-a ceiling price of 50% of MRP of the drug

The above ceiling prices would apply to both branded as well as generic drugs. DPCO would be suitably amended to provide for these ceilings

14.0 Promotion of Generic Drugs –

It is seen that generally generic drugs are priced lower than the branded ones. Presently the branded drugs dominate the market in India and there is a very small presence of the generic drugs. One of the ways to make available cheaper drugs to people at large and to the public health system could be to promote the production of generic drugs in the country. This could be done in the following ways –

Public procurement and distribution of drugs through the public health system would preferably be for generic drugs.

Quality certification would be provided free of cost to generic drug manufacturers through an appropriate scheme

No control on prices of generic drugs (cost based or MRP based) would be specified. These would, however, be kept under price monitoring. Only those drugs would be exempted from price control which follow the prescribed norms

(Comments by Health / NPPA)

Note- Generic drugs would mean drugs popularly sold under their chemical names only (generic generic drugs)

15. Control on Pharmaceutical brands

The present system of brand approvals in the country appears inappropriate for the pharmaceutical sector. There are two kinds of problems that are commonly encountered. First, even a casual look at the list of brands existing in the Indian pharmaceutical sector reveals that a number of products have either the same brand name or names which are very similar both phonetically and written. Second, there are a number of recorded instances where the composition of a particular brand has been changed without any change in the brand name – a phenomenon termed as 'misbranding'. Both these have the potential to cause immense harm through mis-prescription and/or wrong dispensing.

At present, brand names of drug products are approved while granting manufacturing licenses by the State authorities, which is not a desirable practice when marketing is done at the national level. It is, therefore, suggested that branding of drugs and other therapeutics should be brought under the Central drug regulatory system. The drug regulator must be required to maintain a data base on brands and their compositions, and all brand registration of drugs must compulsorily be approved by the drug regulator. In particular, no change should be permitted in the composition of a given brand. Necessary changes would be made in the Drugs & Cosmetics Act, 1940 in this regard .

(Comments by Health)

16. Quality Certification of drugs

The prevailing system of drug certification is completely opaque as far as the therapeutic quality and effectiveness of different brands are concerned, certainly to the patient and also possibly for the doctors. The Indian Pharmacopeia (IP) certification or its equivalent in other countries , attests the quality of the API in most cases, and not to the quality of formulation, which is what the patient actually purchases. Different formulations of the same API are perceived to have different levels of effectiveness due to different bioequivalence of the APIs, differences in the excipients or the drug delivery technology. Lack of adequate information and awareness may lead to 'adverse selection' behaviour , whereby a higher price is associated with better 'quality'

Government would institute a method of widely publicizing GMP certification as a guarantor of quality of the certified drug. In addition a **quality mark like the ISI or Agmark** approvals would be evolved through industry involvement – BIS would be involved with the grant of these quality marks .These marks would be awarded only on submission of bioequivalence and bioavailability studies to the DCGI .

(Comments by Health /Consumer Affairs / BIS)

17.Strengthening of Pharma PSUs

Pharma PSUs have played an important role in producing and making available low cost essential drugs in the country. Also they help in carrying out important cost studies for drugs. Some of these PSUs are sick and need to be revived . Rehabilitation packages are being prepared to revive these units

A **Pharma Development Fund** would be created to help these units to conduct drug development including clinical trials ,patent filing and upgradation of technology

(Comments by Health/ DPE)

18.Purchase Preference to Pharma Public Sector Undertakings-

Public Sector Pharma enterprises have in the past served a very useful purpose in providing some of the essential drugs required in the country. They still continue to be relevant and have been at the forefront during times of calamities/emergencies. Under the product patent regime they can serve another useful purpose in terms of

manufacturing certain patented drugs required to meet emergencies through the grant of compulsory licence.

For strategic reasons it is essential that these PSUs continue to play an important role in future. Their continued survival can be ensured incase some kind of purchase preference based on the NPPA approved prices is accorded to them.

A list of drugs manufactured by the PSUs alongwith prices (to be certified by NPPA) would be prepared for supply to Government. . All departments/hospitals of Central Government purchasing these drugs from the market would be required to first procure these from the PSUs at prices approved by NPPA .

A Coordination Committee in the Department of Chemicals and Petrochemicals would be constituted to sort out various issues pertaining to the pharma PSUs.

*(Comments by
Health/NPPA/ESIC/Railways/Defence)*

19. Consumer Awareness

Consumer Awareness Campaigns through print and electronic media on price fixation , revision , use of generics including consumer education and empowerment will be carried out on a sustained basis for which Government will provide adequate budgetary resources to NPPA.

A **dedicated website** will also be created which would all possible information about drug prices and related matters. In addition to English language publicity would also be carried out in other Indian languages. State governments would also be involved with this work.

Inorder to address various grievances and public complaints about overcharging , quality , availability etc the **Helpline set up by Consumer Affairs Department would be made use of .**

(Comments by Health / Consumer Affairs)

20.Schemes for Providing accessibility of drugs to the Poor (BPL families)

About 26% of India's population is estimated to live below poverty line .There is very poor accessibility of drugs to this population and even low priced medicines become unaffordable for them. Some schemes by Central Government and State Governments are already in existence for these people but these have had limited impact due to lack of resources and seriousness on the part of different players. National Common Minimum Programme clearly stipulates that 'Special attention would be paid to the poorer sections in the matter of health care' . Apart from addressing the general issue of healthcare it is essential to ensure that essential drugs are made available to these people free of cost. No single scheme can address this subject . There have to be a host of schemes at the Central and State levels for the achievement of this objective. Some of the schemes are as under-

a) Rashtriya Swasthya Bima Yojna for BPL families-

Public health system in India has a limited reach. Existing health insurance schemes have not become popular in India for various reasons and are estimated to cover only 3% to 5% of the population and much less of the BPL segment. As a result of this a vast majority of the population have to bear expenditure which is out of pocket on health and purchase of medicines. Some of the reasons for non popularity of the health insurance schemes are the unregulated environment, unaffordable premiums ,non promotion of schemes, inadequate supply of health services in the rural areas etc. This is a peculiar problem (and a serious one)in India as population in most other countries is largely covered by a public health system or a health insurance policy. The National Common Minimum Programme of the Government envisages a National Health Insurance scheme for the poor families. **Universal Health Insurance Scheme** was announced by Government in 2003 .BPL families were given a subsidy of Rs 200 , Rs 300 and Rs 400 per annum depending on the size of the family. However the scheme remained a non starter and as per the **report of National Commission on Macroeconomics and Health only about 34000 BPL families were covered upto 31st January, 2005**

A **new scheme** by the name of '**Rashtriya Swasthya Bima Yojana**' is proposed to be launched in the country for the BPL families.

Some of the important features of this scheme would be as follows:-

- i. Scheme to be implemented in a phased manner. Initially scheme to be launched on a pilot basis in some districts of the country (2 in each state). Based on the experience gained it would be extended to all families below poverty line throughout the country.
- ii. Government of India to pay full cost of the premium amount for all BPL beneficiaries
- iii. Scheme to be implemented by the four public sector insurance companies in the country.
- iv. Beneficiaries to be extended benefits on the basis of BPL/Health cards issued to them by the States
- v. Benefit of hospitalization (upto Rs 15000) and for medicines as outpatient (Rs 5000) per annum per family to be made available
- vi. Each Insurance company would shortlist chemist shops upto PHC level/ taluka level. A certain number of BPL families would be assigned to each selected chemist shop
- vii. f) Chemist shop will maintain complete account of the medicines taken by the BPL persons and send the same to insurance companies from time to time.Computerised statements should be prepared for transparency in the account.
- viii. g) BPL family can approach any government doctor in the area . Based on the prescription of the government doctor the BPL card holder can approach the authorized chemist shop for obtaining medicines. He would be supplied medicines free of cost .

- ix. The chemist would send the bill to the concerned insurance company which would reimburse him for the amount of the medicines purchased by the BPL family
- x. The entire insurance premium on account of the BPL families would be paid by Government to the insurance companies Medicines to be provided based on prescription by government doctors.
- xi. From the 3^d year of operation of the scheme it would be suitably revised and extended to all parts of the country.

(26% of population is considered to comprise of the BPL segment , which is over 5 crore families. Insurance cover would be for each family irrespective of the size of family , premium would be also per family basis – indicative amount indicated by the insurance companies is Rs 550 per family per annum . This come to approx. Rs 2750 crs per annum when the scheme is fully implemented after the first two years of trial period. During this period only 60 of the 600 districts would be covered which may be taken as 10% coverage, hence the cost during the first two years may be taken as approx. Rs 200 crs .The source of funding would be the health cess)

(Comments by Revenue/Health/Insurance/States)

b) National Illness Assistance Fund, State Illness Assistance Funds & District Illness Assistance Funds (for people below poverty line)

The Central Government under the Ministry of Health and Family Welfare operates **the National Illness Assistance Fund (NIAF)** through which financial assistance is provided to states for the medical treatment of people living below poverty line and other poor families. Out of this fund assistance is provided to States upto 50% of their share in the **State Illness Assistance Fund (SIAF)**.Also revolving funds have been set up in some of the leading Government Hospitals for providing financial assistance to BPL families upto Rs 50,000. A Rashtriya Arogya Nidhi has been set up for this purpose. Some states are making good use of these schemes for the BPL families while some have not yet set up the State Illness Assistance Funds.

Inorder to ensure that the benefit of these funds is passed on to a larger section of the poor people, following steps would be taken:

- i. Larger allocation would be made towards National Illness Assistance Fund (NIAF).
- ii. State Illness Assistance Funds (SIAFs) would be set up in all states with financial assistance from Central Government.
- iii. Revolving Funds for BPL families would be set up in all the Central Government hospitals .
- iv. States would also be asked to set up revolving funds in all the government hospitals for free treatment of BPL families.
- v. Inorder to increase the reach of poor people to these funds **District Level Revolving Fund** would also be maintained The quantum of the District Level Revolving Fund would be **Rs 1.00 crore**. Initial amount of Rs 1.00 crore would be provided by the Central Government , thereafter it would be shared on 50:50 basis between the Centre and the States. .The fund would be replenished as soon as

the level of fund in a district falls below Rs 50 lacs. This fund would be managed by a Committee headed by the District Collector with Chief Medical Officer of the district as the Member Secretary . Some public representatives may also be coopted on the Committee. Detailed guidelines with simplified procedures for operating the fund would be issued by the Health Department .

- vi. Wide publicity would be given to the availability of funds at the district , State and Central levels.

Proposed allocation –Rs 1000 crs (source of funding- health cess)

(Comments by Health /Planning Commission /Expenditure/States)

c) Rajasthan Model of Medicare Relief Societies to be replicated

In Rajasthan Medicare Relief Societies have been set up in all the government hospitals at State, Divisional, District and sub–division level for the purpose of -

- i. better maintenance and upkeep of the hospitals;
- ii. providing cheaper medicines to the common man through outlets known as life-line fluid stores opened within the hospital premises.
- iii. providing medicines free of cost to BPL families.

These Medicare Societies mainly comprise of the doctors in the hospitals Their source of income is primarily the user charges levied by them for the services provided in the hospitals. Through these medicare societies several critical medicines, injections, antibiotics, IV Fluids etc. are purchased in bulk through open tender from the manufacturing companies and sold through the lifeline fluid stores in the hospital premises. As a result the prices are reduced considerably and some of the medicines are sold at prices as low as or even lower than 50% of the prevailing market rates. An example is the Intra Veinous(I V) fluid , a bottle of which is being sold to patients between Rs.10 to Rs.11 as against its ceiling price of Rs.17/-. Running of the Stores is contracted out and these are generally open all the 24 hours.

All states would be advised to replicate this model which would help make available critical drugs at affordable prices to the common man and to provide medicines free of cost to BPL families.

Comments by Health/States

d)District level Drug Banks

In-order to increase accessability of medicines to the BPL families efforts would be made to establish a District Drug Bank at each District level . Considering that there are 600 districts in the country an equal number of drug banks would be set up in a phased bank. These banks could be managed by Red–Cross Societies , Medicare Societies or such other charitable bodies having linkage with the District Administration/ district level hospital .Various manufacturers would be encouraged to donate generously to these drug banks- efforts would be made that they adopt one or two districts for this purpose . Such drug donations would be made eligible for tax exemption under the corporate tax.

21. Health Cess for funding Schemes for Poor-

A **health cess of 2%** would be levied on various central taxes on the lines of education cess which is likely to provide approx. Rs 6500 crores to the Government . This amount is proposed to be spent primarily on **schemes meant for the poor people** . In order to ensure that the money collected from the cess is not diverted to other areas it shall be kept in a separate **non- lapsable fund** . This fund may be **managed by an independent body** specially designated for this purpose . It may be called the National Public Health Board . The broad areas on which this amount may be spent are -

- i. to fund supply of medicines through the Rashtriya Swasthya Bima Yojana .
- ii. to fund the subsidy scheme for anti-cancer drugs .
- iii. to fund the expansion of ART centres for additional AIDS patients throughout the country . (through NACO)
- iv. to provide additional funds for National Illness Assistance Fund / State Illness Assistance Funds / District Illness Assistance Funds and revolving funds .
- v. provide funds for technology upgradation for implementation of schedule M for GMP in pharma SMEs .
- vi. to start a scheme for awareness generation for drug prices and related aspects .

OR

In case there is difficulty in levying of health cess, Government may provide funds amounting to Rs 6500 crores which is equivalent to 0.02 % of the GDP out of the general budget .(present spend on health only 0.9 % of GDP –as per NCMP it is to be raised to 2 to 3 % of GDP) .

(Comments by Revenue/Health)

22. Encouragement to Community based organisations in the Health Sector

Certain community based organizations like LOCOST and SEWA (Self Employed Women's Associations, Ahmedabad) are engaged in providing medicines to the needy at low prices , preventive health care, health insurance etc. Encouragement would be provided to more such bodies to function in the area of healthcare services.

23.0 Human Resource Development in Pharmaceutical Sciences-

National Institute of Pharmaceutical Education and Research (NIPER), under the aegis of Ministry of Chemicals and Fertilizers, Government of India is an Institute of National importance by the act of Parliament is engaged in training the human resources in the field of Pharmaceutical sciences. In a short span of time, NIPER has created a brand name for itself. The post-graduate students of pharmaceutical sciences and pharmaceutical management of NIPER are in great demand and till now there is hundred percent employment. On several forums there are demands for more NIPER-like institutes in different regions of the country. Indian Pharmaceutical Alliance predicted that to double the pharmaceutical exports by 2010, there is need for highly trained manpower of one thousand per annum for the next five years and demanded the GOI

should start at least ten more NIPER like Institutes. In 57th Indian Pharmaceutical Congress held recently at Hyderabad a demand for more NIPER-like Institutes was made. Government of India has received requests from some State Governments showing their interest in setting up of such institutes. Some of the probable sites for setting up these Institutes could be Ahmedabad, Hyderabad, Kolkata, Bangalore, and Guahati (Assam). These institutes would be started on the lines similar to the Indian Institutes of Technology.(IITs)

World over, pharmaceutical scientists are working on how to decrease the cost of drug discovery and development, increase the safety and efficacy of drugs. The aim of pharmaceutical research is to reduce the duration of the pre-clinical phase of drug discovery and development, decrease the attrition rate and cost of the clinical trials.

To achieve this, India needs to strengthen the areas viz., in silico drug design, computation and simulation of biological systems (normal and pathological) for better understanding of drug and macromolecule interactions, early prediction of pharmacokinetics and toxicity, pharmacogenomics, stringent quality control and impurity profiling solid state characterization of APIs and newer drug delivery systems.

To be front runner in pharmaceuticals R&D which is knowledge based, India needs highly trained human resources in the area of medicinal chemistry, computational biology in silico drug design, in vivo pharmacology, regulatory toxicology, pharmaceutical analysis, formulation, clinical trials, intellectual property protection, drug regulatory affairs and pharmaceutical care.

Simultaneously, scientific validation and standardization of the procedure followed in the traditional medicine of India need to be undertaken on priority base.

(Comments by DST/DBT/CSIR/Health/Planning Commission)

24.0 Research and Development – A Fiscal Incentives

India is emerging as the most favoured destinations for collaborative R&D bioinformatics, contract research and manufacturing and clinical research as a result of growing compliance with internationally harmonized standards such as Good Laboratory Practices (GLP), current Good Manufacturing Practices (cGMP) and Good Clinical Practices (GCP)

With the application of product patent in the case of pharmaceuticals it is imperative for the Indian industry to accelerate its efforts in R&D in this sector. The present level of spend on R&D (about 5% of turnover) is much lower as compared to most of the developed countries (15 to 20%)

With a view to encourage R&D in this sector it is essential to provide suitable incentives to industry. At the same time it is also necessary that the incentives are made use of by those units which are genuinely engaged in R&D. As such the required incentives would be made available with some safeguards to ensure that these are available to the deserving cases only. The incentives available would be as under –

a)The benefit of 150% weighted exemption under section 35(2AB) to be continued till 31st March, 2015

b) Section 35(2AB) to be extended to depreciation on investment made in land and building for dedicated research facilities, expenditure incurred for obtaining regulatory approvals and filling of patents abroad and expenditure incurred on clinical trials in India .

c) Reference Standard (sample under test) would be exempted from import duty

e) Reference books to be imported for R&D would be exempted from import duty.

f) Presently there are 101 specified instruments (list 28) required for R&D purposes which are exempt from import duty. With the ever changing requirements new instruments are required to be imported .These instruments based on the certification of DSIR would also be exempt from import duty.

The fiscal incentives are at present only available up to 31st March, 2007. Since R&D activity has to be carried over long periods of time, fiscal incentives would be granted over a longer period of time extending upto 10 years ie upto 31st March, 2015.

The above incentives would be available to such units which fulfill the following conditions-

a)The unit should be prequalified and registered with Department & Scientific and Industrial Research (DSIR) as R&D centre..

b)The unit should submit a statement certified by the Auditors showing the total expenses incurred on R&D.

c)In case of claims for clinical trials, the unit should submit approval obtained from the Drug Regulatory Authority for carrying out the trials and certificate by the CEO or the Auditor for completion of trials.

d)In case of claims for patent filing abroad, the unit should submit relevant documents (official receipt, etc) showing the filing expenses duly certified by the CEO or the Auditor.

e)In case of claims related to land and buildings, the unit should submit a letter signed by the CEO confirming that the claims pertain to facilities used exclusively for R & D.

B .R&D Intensive Companies (Gold Standard Companies)

The Pharmaceutical Research and Development Committee headed by Dr R A Mashelkar in its report submitted to Government in November,1999 recommended that R&D intensive companies fulfilling certain conditions should be given price benefits for the drugs under DPCO . It specified certain norms in this regard and termed these as the gold standards.Since six years have elapsed since this report was submitted it has been considered proper to revise these norms

The revised norms are as under –

a) Invest at least 3% of the annual sales turnover on R&D or Rs 50 crores per annum, (average of last 3 years)whichever is higher on research facilities .

b) Employment of at least 200 scientists in India (MScs or Phds employed at least for one year).

- c) Own and operate manufacturing facilities in India which have been approved by at least two reputed foreign regulatory agencies (US, Europe, Japan, Canada, Australia, Israel, South Africa etc)
- d) Have filed at least 10 patent applications in India based on research done in India

Companies fulfilling the above norms would be eligible for the benefit of 200% weighted deduction under 35(2AB) till 31st March, 2015. Additional incentives under price control measures may also be considered to such companies by Department of Chemicals and Petrochemicals.

However in order to be eligible for any of the additional incentives such companies would be expected to fulfill the following norms –

a. The unit should submit a statement signed by HRD/R&D chief or CEO certifying the number of scientists employed through the year.

b. The unit should submit a statement certified by the CEO and the Auditor that it has invested at least 3 per cent of the annual sales turnover or Rs 50 cr (average of the last three years) whichever is higher, on R & D.

c. The unit should submit certified true copy of the approval granted by the Drug Regulatory Authority of the specified countries approving the manufacturing facility for export to their country.

d. The unit should submit particulars/documents evidencing patents filed in India

The inter-departmental Screening Committee constituted by DSIR may further recommend additional safeguards to be taken for making available fiscal incentives to various companies.

(Comments by DST/ CSIR/DBT/DSIR)

C Pharmaceutical Research and Development Support Fund (PRDSF)

At present, the Pharmaceutical Research and Development Support Fund (PRDSF) has a corpus of Rs. 150 crores (where only interest income is available for spending) is utilized for funding R&D projects of Research Institutions and industry in the country. It is not adequate to meet the present day and the emerging requirements of this sector. It needs to be sufficiently augmented over the next five years. It has been decided to convert it into an annual grant of Rs. 150 crores, and thereafter it would be suitably increased further in a phased manner over a period of next five years. Priority would be given for R&D in case of diseases which are endemic to India like malaria, tuberculosis, hepatitis-B, leishmania (kala-azar), HIV/AIDS etc.

(Comments by Health/DST/DBT/Expenditure/Revenue/Planning Commission)

25. Development of Orphaned Drugs

Several drugs have been discovered and developed by Central Drug Research Institute (CDRI) and other organizations in the past which were granted marketing approval by the Drug Controller General of India. However some of these could not be

marketed due to one reason or the other . Such drugs would be identified and efforts made to further develop and launch these in the market.

(Comments by DST/Health/CDRI/NIPER)

26.Scheme of Interest Subsidy for implementation of Schedule M of Drugs and Cosmetics Rules for Good Manufacturing Practices

A dedicated fund would be created for providing **interest subsidy (5 percent) on borrowings to small scale/medium pharma units going in for** Schedule M implementation for GMP for Drugs and Cosmetics Rules. This assistance would be in addition to any other financial assistance that may be available to the SSI pharma units from Central or State Governments. While SIDBI would be the nodal agency for this scheme , other banks / financial institutions would also be involved in this work. Promotional activity to motivate industry to adopt schedule M would also be undertaken from this fund with the active involvement of Ministry of Health and Family Welfare and the States. A plan scheme would be prepared in this regard

(Comments by Health/SSI/Finance/Planning Commission)

27. Regulation of Drugs under Narcotics and Psychotropic Substances Act ,1985

In order to effectively control the abuse of narcotic drugs and psychotropic drugs in the country the Narcotics and Psychotropic Substances Act, 1985 was enacted . There is lack of clarity about regulating the sale and use of certain drugs which contain regulated quantities of narcotic drugs and psychotropic substances as legally permitted. Through a notification issued on 14th November , 1985 such drugs were exempted from the applicability of the NDPS Act. However such drugs are manufactured and regulated under the provisions of the Drugs and Cosmetics Act ,1940 and the Drugs and Cosmetics Rules ,1945. Several instances of misuse of these drugs taking advantage of the loopholes in the existing regulations have been noticed in the past. In order to prevent misuse of such drugs as intoxicants **Department of Health and Family Welfare would evolve an effective mechanism under the provisions of Drugs and Cosmetics Act ,1940.**

(Comments by Health/ Revenue/Home)

28.0 Settlement Commission --

A large number of cases of overcharging incase of drugs are detected where the overcharged amount is recovered from the concerned companies. Often recovery of the amount is contested by the companies leading to protracted litigation and court stays. This holds up recovery of substantial dues and long drawn court cases. There is need to work out a mechanism under which this issue can be tackled.

In case of some other recoveries of government dues like Income-tax arrears , Government have constituted a Settlement Commission which is authorized to decide the contested recoverable amount in a summary manner after hearing both sides. This helps in faster recovery of the dues and avoids unnecessary litigation.

A similar system needs to be put in place in the recovery of disputed overcharged amount of cases which are under litigation . All ongoing court cases would also be

brought before the Settlement Commission and effort made to arrive at some workable settlement.

Amount so recovered would be put in a special fund to be created for this purpose to be called the **Price Monitoring and Public Awareness Fund**.

Most of the cases of old dues of **Drug Price Equalization Account (DPEA) under DPCO, 1979** are being disputed by industry and these are under litigation in various courts in the country .Efforts would be made to settle these complicated cases through a **One-Time Settlement scheme** on the lines of Amnesty schemes under Income tax .

While framing the Terms of reference for the Settlement Commission suggestions of industry would be kept in view.

(Comments by Revenue/Health/NPPA)

29. Drug Price Monitoring and Awareness Fund (DPMA Fund)

A fund under DPCO,1979 has been set up by the name of Drug Price Equalisation Account (DPEA) wherein amount recovered on account of overcharging on the formulations / bulk drugs sold by companies prior to the DPCO of 1987 as per the assessment of the Department of Chemicals and Petrochemicals is deposited . This fund is administered as a public account by the Department of Chemicals and Petrochemicals . With the formation of the Settlement Commission the scope of this fund would be enlarged so as to accommodate overcharged amount recovered by NPPA under the DPCO, 1995 and any subsequent cases under the DPCO/ Act to be enforced under the new policy.

NPPA would also be authorised to levy such user charges , fees etc that may be permitted by the Government for the services rendered by NPPA.

This fund would be housed in NPPA but it would be operated by an Empowered Committee headed by Secretary, Chemicals and Petrochemicals.

Sources of Fund-

a) Any amount by way of overcharging or otherwise recovered under any DPCO by Department or NPPA

(NPPA on an average recovers Rs 15 crores of overcharged amount from drug companies per year . Most of this amount is in litigation and there is uncertainty about its quantum and final recovery .Settlement Commission can help finalisation of the amount and enable it to be spent on certain drug related activities.This amount is presently deposited in the Consolidated Fund of India)

b) User charges , fees etc levied and recovered by NPPA on the services rendered by it

Application of Fund-

This fund would be utilized for -

a)Expenditure on public awareness about drug prices of generics, comparative drug prices , banned drugs ,misbranding , facilities given by government for different categories of patients or any other aspect of public interest through the use of print and electronic media

b)Expenditure for operating and strengthening of the price monitoring mechanism of NPPA on a continuous basis

c)Computerisation of NPPA and offices of State Drug Controllers

d)Online electronic data filing system by the State Drug Controllers and industry

- e) Fund studies on the drug prices ,production and availability of drugs , impact of patents on drug prices ,studies/data required(in India or abroad) for negotiation of prices of patented drugs and various other aspects pertaining to drugs and drug prices
- f)Funding such incidental activities which may be instrumental in achieving the broader objectives of this policy.

(Comments by
NPPA)

(Based on the Drug Policy announced by the Central Government on 29.03.1978 “The Drugs (Prices Control) Order, 1979” was issued on 31.3.1979 superseding the then existing DPCO, 1970. Under DPCO, 1979, with a view to regulating the equitable distribution of an indigenously manufactured bulk drug specified in the First schedule or the Second schedule and making it available at fair price, maximum sale price of the bulk drugs were fixed and promulgated by the Government during the period 1980-1987. The Government had also powers to fix the retention price and the pooled price/common sale price for the sale of individual bulk drugs, and imported bulk drugs specified in the First Schedule or the Second Schedule. The Government during the period 1980-1987 also promulgated retail Prices/leader prices of a number of formulations in the Third schedule. As per the provisions of Para 17 of DPCO, 1979; the manufacturers, importers or distributors were required to deposit the excess of the common selling price or, as the case may be, the pooled price over his retention price and also the amount determined under sub-paragraph (2) of para 7 into the Drug Prices Equalisation Account. As per the provisions of the Para 7(2) of DPCO, 1979, where a manufacturer of a formulation utilized in his formulations any bulk drug either from his own production or procured by him from any other source, the price of such bulk drug being lower than the price allowed to him in the price of his formulations, the manufacturer was required, on demand, to deposit into the DPEA the difference between the price of bulk drug allowed in his formulations and the actual procurement price of the bulk drug.

Out of the 345 bulk drugs under price control under this DPCO, the Government computed liabilities in respect of 47 bulk drugs only covering 172 cases and communicated the same to companies concerned by way of demand notices till the Interim Stay dated 30.6.1997 granted by the Hon’ble Bombay High Court restraining the Government from issuing fresh notices to the drug companies calling for information required for determining liabilities. However, most of these companies filed writ petitions in the different High Courts and did not bother to deposit the DPEA liability. A very limited part of the DPEA liability could be recovered and that too in most of the cases on the directions of the various Courts. The DPEA liability cases pertain to the period wef 1.4.1979 to 25.8.1987 and thus are very old. It is understood that as per existing accounting procedures, the companies are required to maintain records for a period of 15 years only. It is, therefore, doubtful whether the companies would be having records for this old period. Considering the prolonged litigations, and the Government stake in DPEA under DPCO 1979 being very large, it would be worthwhile to announce a one time settlement scheme to be implemented through a Settlement Commission)

30.0 Pharma Parks/SEZs for Pharma industry-

In order to enable India to achieve a leading position as the **Drug Maker of the World** it is essential that a **World class infrastructure** is provided for the accelerated growth of the industry. Added to this are the environmental concerns due to difficulties in hazardous waste disposal by some of the bulk drug units. In order to provide the required infrastructure it is essential to have a scheme where Central Government, State Governments and industry are participants. A special scheme for setting up

pharmaceutical parks in the country (separate for bulk and for formulations) in the next 5 years is proposed. This would be broadly on the lines of Scheme for Integrated Textile Parks.

a) This scheme would be based on public-private partnership model

b) Each park would be set up in a minimum area of 250 acres for bulk and 100 acres for formulations . It would be expected to have about 50 to 100 units, investment of 1000 crs to Rs 2000 crs and likely employment of about 20,000 persons.

c) Scheme to be implemented through SPVs (Special Purpose Vehicles) with Industry Associations to be the main promoters

d) An MOU will be signed with a leading professional body/ consultant to act as Project Management Consultant

e) Where an SEZ is to be set up the minimum size criterion for pharma SEZs would be 50 hectares for the next 3 years . This would encourage quick setting up of such parks and for demonstration effect. After a successful take-off of the scheme minimum size may be increased suitably

All environmental approvals in the case of pharma parks would be granted at the State level only

*(Comments by
Health/DIPP/Commerce/Environment)*

(Government has recently passed an Act to facilitate setting up of Special Economic Zones in the country. Some SEZs for pharma have been sanctioned in a few states . There is need to have more of such economic zones in the country. It is estimated that an SEZ in an area of 50 hectares would require an investment of Rs 100-120 crores on land and development . It would be able to attract an investment of Rs 1000 crores and would be able to generate exports worth Rs 2000 crores and employment of about 6000 people .Looking to the attractive tax concessions and good infrastructure available in these parks these are becoming popular with the industry).

31.Greater Thrust on Pharma Exports

Pharmaceutical Export Promotion Council (Pharmexcil) is the sole agency authorized for issuance of Registration-cum-Membership Certificate to exporters of Drugs and Pharmaceuticals. Pharmexcil, during the last over one year of its formation, has successfully completed various projects, particularly sponsoring full-fledged trade delegations to various countries

Future growth of pharma sector would be largely driven by exports to other countries. Although exports of pharma products from India are growing at a healthy rate there is need to accelerate this further in view of the vast potential existing in some of the countries

Following steps are envisaged to be taken in this regard-

a) Suitable measures would be taken to **tackle the non tariff barriers to exports of pharma products** in various countries through consistent efforts and greater interaction with the concerned agencies of the focus countries

b) **Africa , Latin America , ASEAN and CIS** countries have been put in the category of **focus countries** by Commerce department. These would continue to get special attention for the purpose of exports.

c) The **South Asian Free Trade Area (SAFTA)** , an agreement between Saarc countries comprising of India , Pakistan , SRI LANKA, Bangladesh , Nepal, Bhutan , and Maldives is scheduled to come into force **on January 1, 2006**. It will be fully operational by 2016. The pact holds huge potential for intra-regional trade growth which is presently only US\$7 billion (only 6% of the total external trade in the region which is US\$350 billion)

Pharmaceuticals has a substantial potential in the intra-regional trade of the area. A detailed study would be undertaken of this potential

A study to determine the market potential for pharma products in these countries and their registration procedures /requirements would be carried out soon.

d) Some more countries with good potential **namely GCC, European Union , Japan and Korea** would also be paid special attention looking to the big potential for pharma exports in these. An action plan including a study of the pharma export potential in these countries would be carried out to improve exports of pharma products to these countries

e) **International meets/conferences/seminars** with potential countries would be organized on a regular basis in India and abroad

f) Apart from the existing formal arrangements for export of drugs there is an urgent need to have a **government-industry standing forum** for each of the high potential markets comprising of the key industry players active in that area and concerned government departments.

g) Quality is an important issue with the importers from India . It would be worthwhile to lay down guidelines regarding the consignments of pharma products being exported outside India. A system of registration for quality products would be worked out in consultation with industry.

h) Exports may be exempted from service tax.

i) **Pharmexil** would be suitably strengthened to meet the future challenges of export market . It would be assisted financially and otherwise for **opening warehouses/offices** in some of the countries to help the Indian entrepreneurs there , for an **online library, organization of exhibitions in various countries, and brand building activity**

(Comments by Commerce/Pharmexil)

32. Pharmaceutical Distribution –Retailing

Pharmaceutical distribution system in India needs much to be desired as retailing in India is highly unorganized . With increasing concern for healthcare and to ensure quality of medicines a good retailing system can play an important role. Proper storage , cold chain and organized retailing would be encouraged .

*(Comments by
Health/States)*

33.Pharmaceutical Advisory Forum

In order to have a meaningful dialogue amongst all stakeholders on various issues concerning policy the Pharmaceutical Advisory Forum constituted under the chairmanship of Minister , Chemicals and Fertilisers would play an important role.

Summary of proposed Revenue and Expenditure (Tentative Estimates)

OPTION 1 (health cess 2%- to be kept in a separate non- lapsable public account to be managed by a separate body)

Revenue items

a)Health Cess of 2% on Central Taxes (like Education Cess) - Rs 6500 crs (assumed to grow at 10% per year)

Less Loss due to reduction in Excise duty from 16% to 8% - Rs 1000 crs.approx.

Net Revenue -Rs 5500 crs approx.

Over 5 year period - 5500×5 (with 10% increase) = Rs33,300crs

b)Overcharged amount recovered by NPPA –approx. Rs 15 crs. per year (to be put in a separate public account fund with NPPA)

Expenditure items-

a)Free medicines for poor through health insurance or otherwise - estimated as Rs200crs.in the first two years of trial run in about 60 districts in the country – 2 per state –to increase subsequently to approx. Rs 3000 crs per year when scheme is fully implemented.

b)Public Private partnership for cancer drugs including subsidy -- Rs 100 crs approx in the first year , to increase in the subsequent years as the scheme picks up..

c)Contribution to National Illness Assistance Fund(NIAF), State Illness Assistance Fund(SIAFs) and District Illness Assistance Funds(DIAFs) —Rs 1000 crs per year

d)Anti HIV/AIDS drugs(through NACO) - Rs 1000 crs approx per annum.

e)State Monitoring Cells (50 lacs per state, for 20 states) - Rs 10 crs

f)Public Awareness Programme - Rs 25 crs per year

g)Additional NIPERs - Rs 50 crs in first year (total exp. Likely –Rs 500 crs for 5 NIPERS to be spent in 5 years)

h)Computerisation of NPPA – Rs 5 crs in 2 years.

- i) R&D Fund - Rs 150 crs per year (in place the existing corpus fund of Rs150 crs under DST)
- k) Interest Subsidy for Implementation of Schedule M for GMP – Rs 10 crs in first year ,Rs 560 crs over a period of 8 years.
- l) Pharma Parks -Rs 100 crs in first year, (1000 crs for 25 parks in 5 years @ Rs 40 crs per park on the lines of Textile Parks)
- m) Drug Development Fund for Pharma PSUs – Rs 10 crs in first year , (Rs 100 crs in 5 years).

Since the expenditure on some of the items would pick up over a period of few years savings in any year should be put in a non-lapsable account to be managed by a separate body so as to utilize the savings in subsequent years

OPTION 2 (Health Cess of 1%- to be kept in a separate nonlapsable fund)

Expected Revenue per year assumed)	---Rs 3200 crs.(10% growth in revenue
Revenue over a period of 5 years-	Rs 20220 crs.

Expenditure Items

- a) Free medicines for poor through health insurance or otherwise - estimated as Rs 200crs. In the first two years of trial run –to increase subsequently to approx Rs 3000 crs per year when scheme is fully implemented.
- b) Public Private partnership for cancer drugs including subsidy -- Rs 100 crs approx. in the first year to be increase in subsequent years as the scheme picks up
- c) Contribution to National Illness Assistance Fund(NIAF), State Illness Assistance Fund(SIAFs) and District Illness Assistance Funds(DIAFs) —Rs 1000 crs per year
- d) Anti HIV/AIDS drugs(through NACO) - Rs 150 crs.
- e) State Monitoring Cells (50 lacs per state, for 20 states) - Rs 10 crs
- f) Public Awareness programme - Rs 25 crs per year
- g) Additional NIPERs (total exp. Likely –Rs 50 crs in first year (total of Rs 500 crs for 5 NIPERS spread over 5 years)
- h) Computerisation of NPPA – Rs 5 crs in 2 years
- i) R&D Fund - Rs 150 crs per year (in place of existing corpus fund of Rs 150 crs under DST)
- k) Interest subsidy for Implementation of Schedule M for GMP– Rs 10 crs first year (560 crs over a period of 8 years)
- l) New Pharma Parks (for bulk as well as formulations) -Rs 100 crs first year (1000 crs for 25 parks in 5 years @ Rs 40 crs per park as GOI investment –on the lines of Textile Parks)
- m) Drug Development Fund for Pharma PSUs – Rs 10 crs first year (Rs 100 crs in 5 years)

The full text of this policy is also available at

<http://chemicals.nic.in>

Response/comments can be e-mailed at :

pareshjohri@gmail.com

Postal Address

Sh. Paresh Johri,
Deputy Secretary(PI)
Ministry of Chemicals & Fertilizers,
Department of Chemicals & Petrochemicals,
Room#228, A-Wing, Shastri Bhawan,
Dr. Rajendra Prasad Road,
New Delhi 110001.