

# **NATIONAL PHARMACEUTICALS PRICING POLICY, 2011**

## **(NPPP-2011)**

### **1. PREAMBLE AND BACKGROUND**

1.1 The Indian pharmaceutical Industry, driven by knowledge, skills, low production costs and international quality products, has witnessed a robust growth from the production turnover of about Rs. 5000 crores in 1990 to over Rs1 lakh crore in 2009-10 comprising about Rs, 62,055 crores of domestic market and Rs. 42,154 crores of exports. It is, globally, the 3<sup>rd</sup> largest producer of medicines by volume yet 14<sup>th</sup> in terms of value. The lower value is due to the fact that Indian medicines are amongst the lowest priced in the world. However, despite this medicine costs continue to be an important component in the overall medicare expenditure in the country.

1.2 Price control over drugs was first introduced in the country in the aftermath of the Chinese aggression with the promulgation of the Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 1963. These were promulgated under the Defence of India Act. With these orders, the prices of drugs were frozen w.e.f. the 1<sup>st</sup> April, 1963. Thereafter, a series of price control

regimes were notified through various Orders in the country from time to time based on different principles, in which the span of control of prices as well as the nature of control of prices varied from Order to Order as per the disposition of the respective Drug Policies. These were the Drugs Prices (Control) Order of 1966, the Drugs Prices (Control) Order of 1970 - issued under the "Essential Commodities Act 1955 by declaring drugs to be essential commodities under the EC Act, 1955. Thereafter the Drugs Prices (Control) Order of 1978, Drugs Prices (Control) Order, 1979 and Drugs Prices (Control) Order, 1987 were issued following the declaration of the Drug Policy, Drug Policy, 1979 and Drug Policy 1986. All these Policies were broadly based on the principle of effecting control over prices of essential drugs, and later bulk drugs, as well as availability of drugs while at the same time attending to the requirements of the indigenous industry for growth cost effective production, innovation and strengthening of capacity.

1.3 The present Drug Policy of 1994, as implemented through the Drugs Prices (Control) Order, 1995, was introduced in the context of the liberalization of economy and the abolishment of industrial licensing, as well as allowing of foreign investment in the country, including in the drug industry. The principle for price control broadly adopted in this policy represented a radical departure from the earlier policies. This envisaged control over prices on the basis of drugs on the

basis of economic criteria as represented in the market share of different companies in the context of total market sales turnover of various drugs. Thus, those drugs were brought under the ambit of price control, where the company turnover was of a particular level and where the market share of leading producers was beyond a particular level. The control over prices was to be on the basis of the cost of production with allowance being given for post production expenses. As per the criteria of 1994 Policy, a list of 74 bulk drugs was identified and these drugs as well as the formulations based on these drugs (currently about 1577 in number) were brought under the price control regime. Certain exceptions such as for small scale units, drugs produced through indigenous research and development, etc were envisaged for exemption under the Policy.

In the year 2000, further liberalization in the economy was effected, in light of which, Foreign Direct Investment (FDI) in the pharmaceutical sector was brought in the automatic route and the limit raised upto 100%. Following this, a new pharmaceutical pricing policy was introduced in the year 2002 which further liberalized the span of control over pricing. The turnover limit for purposes of price control was raised from Rs. 4.00 crores to Rs. 25.00 crores and the parameters of market share were also relaxed further. All drugs where unit price did not exceed Rs. 2.00 were also excluded from the ambit of price control. There were also exemptions given for drugs developed through indigenous R&D, New

Delivery Systems etc. The 2002 Drug Policy was, however, challenged in the Karnataka High Court, which by order dated 12.11.2002 issued stay on the implementation of this Policy. This order was challenged by the Government in the Supreme Court which vacated the stay vide its order dated 10.03.2002 but observed as under:

*“we suspend the operation of the order to the extent it directs that the Policy dated 15.2.2002 shall not be implemented. However we direct that the petitioner shall consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of the price control and further directed to review drugs, which are essential and life saving in nature till 2<sup>nd</sup> May, 2003”.*

In the light of the order of the Supreme Court, it was decided that a fresh Pharmaceutical Pricing Policy be formulated and accordingly, the 2002 Drug Policy was never implemented and the 1994 Drug Policy continued to be applicable and continues till date.

1.4 Meanwhile, in accordance with the guidelines of the Supreme Court above, the Ministry of Health revised the List of medicines in the National List of Essential Medicines (NLEM) earlier notified in 1996. The revised list was notified as NLEM, 2003. In November, 2004, the Government also set up a Task Force under the Chairmanship of Principal Advisor, Planning Commission, Dr. Pronab Sen to look into the issue of price control, options other than price control, and

other issues and to make recommendations for making available life saving drugs at reasonable prices. The basis of drugs to be considered was the NLEM, 2003, being the latest list at that time. The Pronab Sen Committee submitted its recommendations in September, 2005. The revision in the existing policy of pricing of pharmaceutical products has been under consideration at different levels. In the meanwhile, in 2011 the Ministry of Health revised the NLEM and notified the new NLEM, 2011. It may be noted that various drug policies adopted from time to time have tried to cope up with the challenge of striking a balance between the at times varying requirements of enabling industry to grow and at the same time ensuring affordable and reasonably priced to the consumers, particularly the poorer masses. This balancing of diverse and conflicting interests is indeed a difficult task, as is the reconciling of short term interests with long term goals and concerns.

1.5 The Government is therefore seized with the goal of enabling industry growth with attendant socio-economic benefits along with balancing the declared objective of providing better health care including making available essential medicines at reasonable prices to all. The Drug Policy, 1994 needs to be revised to meet the challenges brought about by the competitive international pharmaceutical industry in a globalised economic environment, as much as meeting the country's requirements for safe and quality medicines at reasonable

prices. Therefore, the Government hereby enunciates the National Pharmaceuticals Pricing Policy, 2011 (NPPP-2011) which seeks to replace the Drug Policy enunciated in September, 1994 as “Modifications in Drug Policy, 1986” (Drug Policy 1994). The NPPP-2011 is in continuation of the Policy announced earlier in 2002.

1.6 The National Pharmaceuticals Pricing Policy 2011 presently seeks to limit itself to the central objective of promulgating the principles for pricing of Essential Drugs as laid down in the “National List of Essential Medicines - 2011” as declared by the Ministry of Health and Family Welfare, Government of India vide communication No.12-01/essential medicines/08-DC/DFQC, dated 8<sup>th</sup> June, 2011 (Annexure-I). Other related and required steps for promoting growth of the Pharmaceutical Industry as well as development of new drugs including patented drugs, along with institutional mechanisms for better access to healthcare in the context of availability of medicines in general, would be formulated separately and thereafter adopted by the Government after due consultative process.

## **2. OBJECTIVES OF THE PRESENT POLICY**

As stated above in its present form, the Drug Policy of 1994 needs to be modified in the context of changed global environment for industry as well required changes in the mechanism to make available essential medicines to the masses. The objective is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – “essential medicines” – at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well being for all. The reasons are further elaborated later in the Policy Document.

### 3. KEY PRINCIPLES OF NATIONAL PHARMACEUTICALS PRICING POLICY 2011

The key principles for regulation of prices in the National Pharmaceuticals Pricing Policy 2011 are:

- (1) Essentiality of Drugs
- (2) Market Based Pricing
- (3) Control of Formulations prices only

3.1 The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2011 would be on the basis of **essentiality of drugs**. This is different

from the **economic criteria/market share principle** adopted in the Drug Policy of 1994. The reasons for the adoption of the principle of **“Essentiality”** as a key criteria are:

- (i) The “Essentiality” criteria for drugs under the NPPP-2011 is to be met by considering the List of medicines specified in the National List of Essential Medicines as revised from time to time and most recently declared by the Ministry of Health and Family Welfare, Government of India .
- (ii) The NLEM has been prepared by an Expert Core Committee constituted by the Director General of Health Services (DGHS) out of the WHO model list of essential medicines, Essential Drugs Lists of various States, medicines used in various National Health Programmes and Emergency Care Drugs.
- (iii) The NLEM contains such medicines that satisfy the priority health needs of the country’s population.
- (iv) The NLEM medicines are required to be made available within the context of a functioning health system at all times in adequate quantities in the appropriate dosage forms to serve large public masses.

(v) The Hon'ble Supreme Court in its Order dated 10.03.2003 in SLP No. 3668/2003 (Union of India Vs. K.S. Gopinath and others) has also emphasized the need to “..... consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control.....”

(vi) The current principle of economic/market share criteria needs to be changed now, given the fact that out of the 348 medicines listed in the NLEM-2011, only 34 drugs are included amongst the 74 drugs listed in the First Schedule of “The Drugs (Prices Control) Order, 1995 (DPCO 1995).

3.2 The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2011 would be **on the basis of regulating the prices of formulations only**. This is different from the earlier principle of regulating the prices of specified Bulk Drugs and their formulations adopted in the Drug Policy 1994. The reasons for adoption of this principle of price control of “**Formulations Only**” are:

- i. That the Bulk Drug - API (Active Pharmaceutical Ingredient) - may not fully reflect the ‘Essentiality’ of the actual drug formulation – now the subject of focus - due to the possible applicability of the API in

manufacture of various formulations which may or may not be considered “Essential” for the larger healthcare needs of the masses.

- ii. The emphasis on price control starting at the bulk drug stage itself has in recent times, resulted in amongst other reasons shifting of manufacture of drugs away from the notified bulk drugs under price control. In fact only 47 bulk drugs out of the 74 notified in the First Schedule of the DPCO, 1995 are now under production. This has had a cascading effect on the formulations manufactured from the concerned bulk drugs which in turn has affected the availability of such formulations. The consumer-patient has been adversely affected in the process.
- iii. The task of pricing both the bulk drug and the formulation makes it complicated and time consuming without commensurate direct benefits to the consumer who is actually affected only by the price of the final end product, i.e., the formulation - made from the bulk drug rather than its bulk constituents.
- iv. The price control in the form of formulations only ensures more specific pricing control of the required medicine which is in the interest of the consumer from the point of view of the actual

prescription by the Doctor. This aspect is more important for a country like India where there is large asymmetry in the information between the doctor and the patient.

- v. Since the bulk drug manufacturer is constrained to sell at a fixed price, the manufacturer is always likely to give preference to an existing buyer rather than to a potential new entrant. This constrains the emergence of new companies and formulations in the price-controlled segment and is inherently anti-competitive and also does not benefit the consumer-patient for the same reason.

3.3 The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2011 would be on the basis of regulating the prices of formulations through **Market Based Pricing (MBP)**. This is different from the earlier principle of regulating the prices through Cost Based Pricing (CBP) under the Drug Policy 1994. The reasons for adoption of this principle are:

- i. Under Cost Based Pricing, the prices of drugs have to be calculated in detail every year which requires a complex variety of data. For this, the manufacturers are required to provide their pricing data in an extremely detailed manner which is intrusive and so highly resisted by the individual manufacturers resulting in possible manipulation and

time delay of provision of the base costing data. This also makes it difficult to properly check the data provided by individual manufacturers in a timely and adequate manner. Additionally the data can vary in terms of production cost depending on technologies used for production.

- ii. Under Market Based Pricing, the pricing would be based on widely available information in the public domain as against individual manufacturer level production costing data which would result in more transparent and fair pricing.
- iii. Under Cost Based Pricing as the controlled prices of formulations of a particular API are determined on a “lowest common denominator” basis, they tend to be clustered within a narrow band. This allows virtually no space for a new entrant to come in at an uncovered price point. As a result, production activity and competition in the product segment tend to stagnate. This is neither good to the consumer-patient nor for industry growth.
- iv. The Indian economy is today largely market-driven and, particularly in the area of pricing of manufactured products, prices are determined by market conditions and market forces. Administered prices exist in

a few areas, such as pricing of petroleum products and procurement prices of food-grains but these are closely connected with a regime of subsidies paid by the Government. The Pharmaceutical Industry is a 1 lakh crore industry of which about Rs. 48,200.00 crores is the domestic market\*. The turnover of NLEM medicines is approximately Rs. 29,000.00 crores which is about 60% of the domestic

*\*Note: The figure of Rs. 48,200.00 crores is on the basis of IMS-health data based on price to retailer. This does not include retail margin, hence the difference with the figure in para 1.1 above.*

market. To subject 60% of a Rs. 48,200.00 crore manufacturing industry to a regime of detailed administrative pricing, determined on the basis of costing, particularly where the inputs prices themselves are not subject to any form of price control and are determined in the open market by market forces, would indeed be anomalous and would, in the medium and long term, lead to severe distortions,

particularly in the product-mix and investment patterns in the industry, and there could be a serious possibility of production moving out of controlled drugs into non-controlled drugs. As indicated in para 3.2(ii) above, this has, amongst others, been a factor in the shifting of manufacture away from bulk drugs notified under the DPCO, 1995. This would have serious implications for the availability of NLEM medicines in the future and for the growth and structure of the pharmaceutical industry as a whole.

In the new policy, the span of control is likely to go up to 60%. If all these drugs come under cost-based control, the resultant implications of this on the growth and innovation may also impact the industry's ability to invest in enhancing its capabilities to capture the export potential likely to open up on account of the

almost US\$ 300 billion worth of drugs (including biological drugs) falling off patent in the US and other western countries upto 2015. In the proposed new policy, where Ceiling Prices will be fixed, there would be ample space for manufacturers to position themselves in an appropriate

- price band below the Ceiling Price thereby also retain competition in the market.
- v. The experience in recent years has been that circumventing price controls is not difficult through non-standard combinations, dosage strengths, and other such mechanisms. In addition, there is a tendency for prescriptions to move away from controlled drugs to non-controlled drugs in the same therapeutic class. The consequence on the quality of treatment may get affected and additionally lead to the consumers buying higher priced products.
  - vi. Since the prices fixed of all drugs (bulk & formulations) under the existing DPCO are envisaged to be frozen for two years in the proposed policy, with increases allowed up to WPI, the impact of the proposed policy will be an additional impact.

**4. PRINCIPLES FOR DRUGS PRICE CONTROL AND DETERMINATION IN NPPP-2011**

- (1) Price regulation would be on the basis of ‘Essentiality’ of the drug as laid down in the “National List of Essential Medicines - 2011” as declared by

the Ministry of Health and Family Welfare, and modified every five years or as required from time to time and mentioned hereinafter as “NLEM”.

- (2) Price regulation would be applied only to formulations, i.e. the medicine actually used by the consumers, and not to any upstream products such as bulk drugs and intermediates.
- (3) Span of Control: The following medicines will come under the span of price control:
  - a. Drugs with dosages as listed in the NLEM 2011.
  - b. Drugs with strengths and dosages not listed in the NLEM 2011 (non-standard dosages)
  - c. Formulations containing combination of drugs under NLEM 2011 with other drugs listed in the NLEM 2011
  - d. Formulations containing combination of drugs under NLEM 2011 with drugs not listed in the NLEM 2011

The NLEM-2011 above would be applicable as revised from time to time. It is envisaged that the NLEM will be revised after every 5 years.

- (4) The formulation will be priced only by fixing a **Ceiling Price (CP)**. Manufacturers would be free to fix any price for their products equal to

- or below the CP. The CP's would be fixed on the dosage basis, such as per tablet / capsule / standard injection volume and not on pack basis.
- (5) The Ceiling Price will be fixed on the basis of readily monitorable Market Based Data (MBD). To begin with, the basis for this readily monitorable market data would be the data available with the pharmaceuticals market data specializing company – IMS Health (IMS). Wherever required this data would be checked by appropriate survey/evaluation by the National Pharmaceutical Pricing Authority. As the IMS data gives price figures for stockiest level prices hence in order to arrive at ceiling Price (which will be the maximum retail price), the IMS price will be further increased by 16% as margin to the retailer so as to arrive at a reasonable ceiling price chargeable from the consumers.
- (6) For drugs not in the IMS data, NPPA would collect data through a special mechanism through appropriate survey and study of the market for the concerned formulation in terms of its price and total sales as reflected in the Moving Annual Turnover (MAT) for a given formulation, which is the standard criteria currently in the market for assessing the average sales, and therefore consumption, of a given drug formulation.
- (7) The Ceiling Price would be fixed on the basis of Weighted Average Price (WAP) of the top three brands by value (MAT value) of a single

ingredient formulation drug from the NLEM on per standard dosage basis. The WAP would be the Ceiling Price of the formulation fixed under the Policy, which would be calculated as follows:

- (8) In case there are less than three brands, the WAP would be taken for all the existing brands.
- (9) The Ceiling Prices of all strengths and dosages not mentioned in NLEM, but existing in the market on the Appointed date and six months before this (see para 4.12 below), would be determined as per para 4.7 above. However, in case of new strengths and dosages, which are being introduced for the first time, the Ceiling Price would be determined on the basis of a standard formula, which would be related to the Ceiling Price of the Reference Formulation (RF). The RF is the drug formulation listed in the NLEM. The suggested formula for the Ceiling Price of the new strength/dosage would be as follows:

$$P(s) = P^*.[1 + a.\{(s - s^*)/s^*\}]$$

Where:

$P(s)$  = price ceiling for strength  $s$

$P^*$  = price ceiling for reference strength  $s^*$

$s$  = strength in terms of API content

$s^*$  = reference strength

$a$  = constant such that  $0 < a < 1$

As the new policy (NLEM-2011) seeks to discourage non-standard strengths and dosages, the value of 'a' is to be chosen in a manner so that companies are discouraged from manufacturing non-standard strengths. Accordingly, the value of 'a' is **recommended as 0.5 for tablets and capsules and 0.6 for injectables.**

(10) As regards formulations with combination of more than one drugs within the NLEM, for those combinations in existence on the Appointed date and six months prior to that, the Ceiling Price will be determined as at Para 4.7 above. For other such combinations, including ones introduced after the coming into force of the new policy, the Ceiling Price would be determined as the WAP of its constituent drugs.

(11) In respect of drugs containing a combination a drug in NLEM and any other drug not listed in the NLEM for such combinations as are in existence on the Appointed date and six months prior to this, the Ceiling Price will be determined as per provisions of Para 4(7) above. For other such combinations including those introduced after the coming into force of the policy the CP would be calculated by applying the

applicable CP for the NLEM listed drug along with a Ceiling Price calculated for the drug not listed in the NLEM by appropriate survey and calculation by NPPA based on the same principles as applied for calculation of a drug listed in the NLEM and as mentioned in this Policy.

(12) The CP for a drug listed in the NLEM would be the WAP as calculated on the basis of IMS data six months prior to the date of announcement of the new National Pharmaceutical Pricing Policy i.e the “Appointed Date” for bringing the new Policy into effect. For a drug whose data is not available in IMS, the NPPA will collect the data within a reasonable time for determining the WAP also on the basis of prices prevailing six months prior to the Appointed Date. Thus the WAP data date for the drugs available in IMS data and collected by NPPA would be same. Once the WAP is fixed, NPPA would monitor its implementation on a continuous basis through a proper methodology and system.

(13) The Ceiling Prices of drugs would be allowed to be revised annually upto the limit of the change in the Wholesale Price Index for manufactured goods, as notified by the Department of Industrial Policy & Promotion, for the same period. It is proposed to fix the 1<sup>st</sup> April of every year as the reference date for this. Accordingly, on 1<sup>st</sup> April of every year, companies will be automatically authorized to revise their prices upto the limit of the increase

in the Wholesale Price Index for the previous year. In case of decline in Wholesale Price Index, a corresponding reduction in the ceiling price will be obligatory. The NPPA itself will also separately notify the revised ceiling prices as applicable as on the 1<sup>st</sup> of April each year, and in case any company has fixed the prices not consistent with the revised ceiling prices, the NPPA will take appropriate action to have these revised.

(14) The WAP for top three selling brands of drugs / brands as required - the Reference Prices for calculation of WAP - may also change on an annual basis due to changes in the MAT value. However, there would be no annual revision of Ceiling Prices on the basis of MAT. Revision of Ceiling Prices on the basis of MAT value would be carried out only once in five years, which would likely coincide with the proposed five yearly revision in the NLEM.

(15) **Non-price Control Drugs:** Under the present price control regime, the prices of Non-Scheduled drugs are monitored, and in case the prices of such drugs increase by more than 10% in a year, the NPPA is empowered to fix the price of such drugs, subject to following criteria:

- (i) The turnover of that particular formulation pack is more than Rs. 1.00 crore
- (ii) The product is one of the top three brands or

(iii) The formulator has 20% market share in that segment of formulation

In the proposed policy, all essential drugs are under price control. It would follow that non-essential drugs should not be under a controlled regime and their prices should be fixed by market forces. However, in order to keep a check on overall drug prices, it is proposed that prices of such drugs be monitored on regular basis, and where such prices increase at a rate of 15% per annum or the increase in the WPI, whichever is higher, and certain conditions regarding turnover and market share, to be determined subsequently, are met, the NPPA would be empowered to have the price of these drugs reduced to below these limits for 12 months.

(16) **Imported Drugs:** The Ceiling Prices determined for drugs falling under the span of control as in 4.3 above shall also be applicable to such drugs that are imported. There will be no separate determination of Ceiling Prices for imported drugs falling under the span of control.

(17) **Overlap drugs between DPCO 1995 and NLEM-2011:** The prices of bulk drugs and their formulations under the ambit of the DPCO, 1995 will be held constant for two years from the Appointed date, and would be allowed changes only on the basis of the wholesale Price Index, as allowed for NLEM drugs under para 4.13 above. After two years the DPCO, 1995

drugs which are part of NLEM 2011 will come under the price control regime as stipulated in the New Policy, and the remaining drugs will come under the price monitoring as per the New Policy.

(18) **Patented Drugs:** There is a separate Committee constituted by the Government order dated 21<sup>st</sup> December, 2006 for finalizing the pricing of Patented Drugs, and decisions on pricing of patented drugs would be taken based on the recommendations of the Committee.

(19) **Exemptions:** The following drugs, although part of NLEM will be exempted from price control:

- a. Drugs which are part of Hospital Supply as maintained by M/o Health and Family Welfare.
- b. Drugs which are part of Public Health Products as maintained by M/o Health and Family Welfare.
- c. Drugs having weighted average price less than or equal to Rs3/- for each unit. For such drugs the Ceiling Price will be fixed at Rs.3/- and any such drug selling at a price higher than Rs.3/- will have to bring the price down to Rs.3/-. However, this limits of Rs. 3/- shall stand revised in accordance with the change in the WPI on an annual basis.

## **5. OTHER ASPECTS OF THE POLICY:**

Control over drug prices can be only one element of an overall strategy for provision of affordable healthcare. The existence of a vibrant, competitive, innovative drug industry would be an equally important part of such a strategy. In addition to this, such a strategy would have to incorporate programmes of affordable healthcare to a majority of the population, either through direct Government healthcare programmes or insurance linked programmes, and an overarching Pharma Control Policy, as part of the system of provision of affordable healthcare to the public at large, would also have to address several related issues. Some of these are:

- (i) Provision of direct healthcare to citizens by expanding healthcare cover through the State healthcare system, in combination with an insurance cover based healthcare system.
- (ii) Improvement of access to drugs for specialized treatment (anti-cancer, anti-HIV etc) through special assistance scheme for subsidizing the prices of such drugs, especially for BPL and APL families.
- (iii) Streamlining of the system of procurement of drugs by the Government for ensuring procurement of quality drugs at reasonable prices. This would apply in all Government procurement, both by the Central

Government, States, PSUs. In fact, a strong and transparent drug purchase policy for bulk procurement of drugs by the government would also help in determining reasonable Ceiling Prices for NLEM drugs under the Pharmaceutical Pricing Policy, in future.

- (iv) Promotion of non-branded generic drugs, both through the Jan Aushadhi Programme as well as through education of the public as well as Doctors, and making it obligatory for Doctors to also prescribe non-branded generics alongwith branded generics.
- (v) Implementation of special schemes for providing accessibility of drugs to low income families, especially BPL families.
- (vi) Setting up of drug banks.
- (vii) Taking up measures for strengthening of the pharmaceutical industry in the following areas:
  - (a) Strengthening and rationalizing the drug regulatory system.
  - (b) Promotion of research and development in the pharmaceutical sector, directly through research institutions and universities, as well as through provision of

seed capital, venture capital funding and subsidies to innovative drug companies.

- (c) Enablement of domestic pharmaceutical companies to achieve international GMP/GLP and GCP standards.
- (d) Development of Human Resource Development, particularly in critical areas to meet the requirements of pharmaceutical industries.
- (e) Rationalization of excise duties on pharmaceuticals.
- (f) Setting up of common infrastructure through pharma development parks, pharma cluster schemes in order to strengthen and facilitate the smaller units in the pharmaceutical industries.
- (g) Rationalization of pharma retail trade and strengthening of pharma supply chains.

All these issues require detailed consultation and cooperation of all other Departments of the Government, and the Department of Pharmaceuticals is already taking steps in this regarding and shall continue to do so in due course.

**6. IMPACT ANALYSIS OF THE NEW PROPOSED POLICY:**

A detailed exercise for calculation of data relevant to the proposed has been undertaken. An analysis of this data indicates:

- i. The data available covers over 450 of the formulations under the new NLEM against a total of 663. Data in respect of the remaining will to be specially collected by NPPA after the Appointed day is determined.
- ii. As per the existing data, the total MAT of drugs coming under price control under the proposed policy is around Rs, 29000.00 crores (based on Price to Retailer data of IMS-Health). The span of control therefore increases to around 60% of the market. This percentage is likely to increase when data regarding the drugs which are not available in IMS-Health database is collected.
- iii. The reduction in prices from the highest price formulation in the market, and the WAP or ceiling price, ranges upto more than 80% which will be range of reduction in Ceiling Prices under the new Policy.
- iv. The distribution of the price reduction from highest priced brand is as follows:-

Range of Reduction in Ceiling Price	% of medicines related with NLEM 2011
Decrease in price of Highest Priced Brand between 0-5%	52%
Decrease in price of Highest Priced Brand between 5-10%	7%
Decrease in price of Highest Priced Brand between 10-15%	5%
Decrease in price of Highest Priced Brand between 15-20%	4%
Decrease in price of Highest Priced Brand between 20%	32%

Based on the above, with the implementation of present methodology of Price Control as stipulated in the Policy, the Ceiling Prices of formulations will be fixed below the current highest market prices by 0-5% for over 50% of the medicines of the NLEM-2011 and this reduction will be more than 20% for over 30% of such medicines. It is to be noted that different brands of formulations at **below the ceiling price** would continue to be available in the market.

## 7. IMPLEMENTATION:

A new Drugs (Price Control) Order would be notified as soon as possible after the Notification of the New Policy. The National Pharmaceuticals Pricing Authority will be the implementation authority for the new Policy and the new Drugs (Price Control) Order. The NPPA would be provided required organizational and financial support so as to enable it to implement the new Policy in an effective, speedy and transparent manner. In due course, however, the DPCO, which is presently mandated under the Essential Commodities Act, would be replaced by specific legislation covering the issue of price control and monitoring of drugs, which would be fine tuned to the requirements of the drugs regulatory regime.

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