NATIONAL PHARMACEUTICALS PRICING POLICY, 2012 (NPPP-2012)

1. PREAMBLE AND BACKGROUND

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 3rd largest producer of medicines by volume yet 14th 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 1st 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 1979 and Drugs (Prices Control) Order, 1987 were issued following the declaration of Drug Policy, 1978 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 at tending 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 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.

1.3.1 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 up to 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 10.03.2003 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 lifesaving drugs not to fall out of the price control and further directed to review drugs, which are essential and life saving in nature till 2nd May, 2003".

1.3.2 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 & Family Welfare 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 lifesaving 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 & Family Welfare 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 medicines 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, 2012 (NPPP-2012) which seeks to replace the Drug Policy enunciated in September, 1994 as "Modifications in Drug Policy, 1986" (Drug Policy 1994). The NPPP -2012 is in continuation of the Policy announced earlier in 1994.

1.6 The National Pharmaceuticals Pricing Policy 2012 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 –2011which was declared by the Ministry of Health and Family Welfare, Government of India vide communication No.12-01/essential medicines/08-DC/DFQC, dated 8th June, 2011.

1.7 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 through a wholistic policy 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 2012

The key principles for regulation of prices in the National Pharmaceuticals Pricing Policy 2012 are:

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

3.1 The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2012 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-2012 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 lifesaving 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 2012 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 2012 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 Marked 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. To determine the price 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. Further the resultant implications of this on the growth and innovation may also impact the industry's ability to invest in enhancing in 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 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) Since the prices fixed of all drugs (bulk & formulations) under the existing DPCO are envisaged to be frozen for one year in the policy with increases allowed up to WPI, the impact of the policy will be an additional impact.

4. PRINCIPLES FOR DRUGS PRICE CONTROL AND DETERMINATION IN NPPP -2012

(i) Price regulation would be on the basis of 'Essentiality' of the drug as laid down in the "National List of Essential Medicines -2011" declared by the Ministry of Health and Family Welfare, and modified time to time, in public interest under Drug Price Control Order.

(ii) 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.

(iii) The Span of Price Control shall be as per the dosages and strengths as listed in NLEM-2011.

(iv) The methodology of fixing a ceiling price of NLEM medicines, by adopting the Simple Average Price of all the brands having market share (on the basis of Moving Annual Turnover) more than and equal to 1% of the total market turnover of that medicine , will be as per the formula below:

(Sum of prices of all the brands of the medicine having market share more than and equal to 1% of the total market turnover of that medicine)/ (Total number of manufacturers producing such brands of the medicine)

(v) The formulations 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 as listed in NLEM-2011.

(vi) 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 (NPPA). As the IMS data gives price figures for stockist 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.

(vii) For drugs not in the IMS data, NPPA would collect data by commissioning the same.

(viii) For the medicines where there is no reduction of price due to absence of competition, the overall percentage reduction in the price of same molecule with other dosage and strength will be applied; otherwise the overall percentage reduction in the price of medicines in the same therapeutic category will be applied .

(ix) The CP for a drug listed in the NLEM would be the Simple Average of Prices 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 commission the data within a reasonable time for determining the Simple Average Prices also on the basis of prices prevailing six months prior to the Appointed Date. Thus the Simple Average Prices data date for the drugs available in IMS data and collected by NPPA would be same. Once the Simple Average Price is fixed, NPPA would monitor its implementation on a continuous basis through a proper methodology and system.

(x) The prices of these NLEM-2011 medicines will be allowed an annual increase as per the Wholesale Price Index as notified by the Department of Industrial Policy & Promotion. It is proposed to fix the 1st April of every year as the reference date for this.

Accordingly, on 1st April of every year, companies will be automatically authorized to revise their prices up to 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 1st 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.

(xi) The Simple Average Price of all the brands of the medicine having market share (on the basis of Moving Annual Turnover) more than and equal to 1% of the total market turnover of that medicine -the Reference Prices for calculation of Simple Average Price- 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 or as and when NLEM is updated/revised. However, the Government will revise the ceiling price of a medicine under NLEM, if there is a significant change in the market structure of the particular medicine even in between 5 years.

(xii) **Non-price Control Drugs** : Under the existing 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, subject to certain criteria, government fixes the prices of such medicines from time to time. 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 price increase at a rate of above 10% per annum is observed, the Government would be empowered to have the price of these drugs reduced to below this limit for next 12 months.

(xiii) **Imported Drugs**: The Ceiling Prices determined for drugs falling under the span of control as in 4(iv) 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.

(xiv) **Overlap drugs between DPCO 1995 and NLEM-2011**: The prices of medicines which are a part of DPCO 1995 but not in NLEM -2011 would be frozen for one year and thereafter a maximum increase of 10% per annum, as in case of other non-NLEM medicines will be allowed.

(xv) **Patented Drugs**: There is a separate Committee constituted by the Government order dated 1st February, 2007 for finalizing the pricing of Patented Drugs, and decisions on pricing of patented drugs would be taken based on the recommendations of the Committee.

(xvi) **Exemptions**: To promote innovation and R&D following drugs will be kept out of any type of price control:

(a) A manufacturer producing a new drug patented under the Indian Patent Act, 1970 (product patent) and not produced elsewhere, if developed through indigenous R&D, would be eligible for exemption from price control in respect of that drug for a period

of 5 years from the date of commencement of its commercial production in the country.

(b) A manufacturer producing a drug in the country by a new process developed through indigenous R&D and patented under the Indian patent Act, 1970, (process patent) would be eligible for exemption from price control in respect of that drug for a period of 5 years from the date of the commencement of its commercial production in the country.

(c) A formulation involving a new delivery system developed through indigenous R&D would be eligible for exemption from price control for a period of 5 years from the date of its market approval in India. The certification of innovation and R&D may be provided by the office of Drug Controller General of India (DCGI).

(xvii) The revision of NLEM for the purpose of price control is a dynamic process and any drug can be added in NLEM in public interest under Drug Price Control Order on the recommendation of Ministry of Health and Family Welfare.

(xviii) The production levels, availability and accessibility to the NLEM drugs and formulations should not fall after price control is introduced and the Department of Pharmaceuticals will ensure that production levels are maintained by an appropriate mechanism. If a manufacturer of a NLEM drug with dosages and strengths as specific in NLEM, launches a new drug by combining the NLEM drug with another NLEM drug or a non -NLEM drug or by changing the strength and dosages of the same NLEM drug, such manufacturers shall be required to seek price approval from the Government before launching the new drug.

(xix) Ministry of Health and Family Welfare will consider making prescription of drugs by generics names mandatory.

(xx) The distribution of quality affordable generics drugs through Jan Aushadhi Stores will be strengthened.

5. ESSENTIAL ISSUES FOR THE IMPLEMENTATION 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 programs of affordable healthcare to a majority of the population, either through direct Government healthcare programs or insurance linked programs, 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 and low cost drugs by creating a well spread out low-cost pharmacy chain through the Jan Aushadhi Program, so that the last mile reach of essential drugs are accessible and affordable to every village/town in the country.

(v) As per the recommendations of the High Level Expert Group Report on Universal Health Coverage for India submitted to the Planning Commission in October, 2011, strengthening of Pharmaceutical Central Public Sector Enterprises is essential to play a major role in benchmarking the prices and play a role in stabilizing the market forces and enable access to medicines. Further, the CPSUs may be mandated for producing such essential medicines as determined by the Government as per the requirement from time to time. The CPSUs need to be further strengthened by bringing them under the Drug Procurement System through preferential allocation of such requirement under the Public Healthcare System.

(vi) Education of the public in general as well as Medical fraternity, and making it obligatory for Doctors to also prescribe non-branded generics along with branded generics.

(vii) Implementation of special schemes for providing accessibility of drugs to low income families, especially BPL families.

(viii) Setting up of drug banks.

(ix) Taking up measures for strengthening of the pharmaceutical industry in the following areas:

(a) Strengthening and rationalizing the drug regulatory system.

(b) Bringing on a common platform all the regulatory authorities related to drug standards, bio-pharmaceuticals, clinical trials and Pharmacopeia.

(c) 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.

(d) Enablement of domestic pharmaceutical companies to achieve international GMP/GLP and GCP standards.

(e) Development of Human Resource, particularly in critical areas to meet the requirements of pharmaceutical industries.

(f) Rationalization of excise duties on pharmaceuticals.

(g) 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.

(h) Rationalization of pharma retail trade and strengthening of pharma supply chains.

5.1 All these issues require detailed consultation and cooperation of all other Departments of the Government, and the Department of Pharmaceuticals will take steps to initiate a wholistic policy on Pharmaceutical Sector in due course. To the present context, the National Pharmaceuticals Policy will be limited to the aspect of the Pricing within the domain of National Pharmaceuticals Pricing Policy-2012.

6. 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 (Prices 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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