

# **Indian Pharmaceutical Industry**

## **Understanding**

### **National Pharmaceutical Pricing Policy - 2012**

**And**

### **Drugs (Prices Control) Order, 2013**

# INDIAN PHARMACEUTICAL INDUSTRY

Today, Indian Pharmaceutical Industry is a world leader in international generics markets and has already begun making serious inroads in innovative drug discovery.

India is among the top five emerging pharma markets. By 2020, the country is expected to be within the top three pharmaceutical markets by incremental growth and sixth largest market globally in absolute size.

# INDIAN PHARMACEUTICAL INDUSTRY

India's pharma industry accounts for about 1.4 per cent of the global pharma industry in value terms and 10 per cent in volume terms.

It has grown at an estimated compound annual growth rate (CAGR) of 13 per cent during the period FY 2009–2013. Among the fastest growing pharma industries in the world, India's pharmaceutical sector is expected to expand at a compound annual growth rate (CAGR) of 12.1 per cent during 2012–2020.

# INDIAN PHARMACEUTICAL INDUSTRY

Therefore, It is very important that the citizens of India, particularly the common man, have access to affordable medicines for treating the most common and important disease conditions.

This is a core mission for any government.

# DRUG POLICY / NATIONAL PHARMACEUTICAL PRICING POLICY

Indian Pharmaceutical Industry has witnessed the first ever comprehensive drug policy in the year 1978.

Till date, the government has formulated following Drug Policies, Pharmaceutical Policy and National Pharmaceutical Pricing Policy:

1. Drug Policy 1978
2. Drug Policy 1986
3. New Drug Policy 1994 – Modifications in Drug Policy 1986
4. Pharmaceutical Policy 2002 – Not Implemented
5. National Pharmaceutical Pricing Policy 2012

# DRUG POLICY / NATIONAL PHARMACEUTICAL PRICING POLICY DEVELOPMENTS IN LAST 18 YEARS

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 (about 1577 in number) were brought under the price control.

Certain exceptions such as for small scale units, drugs produced through indigenous research and development, etc. were envisaged for exemption under the Policy.

# DRUG POLICY / NATIONAL PHARMACEUTICAL PRICING POLICY DEVELOPMENTS IN LAST 18 YEARS

- ✓ A new pharmaceutical pricing policy was introduced in the year 2002 which further liberalized the span of control over pricing.
- ✓ Was challenged in the Karnataka High Court.
- ✓ Court issued stay order on the implementation of this Policy.
- ✓ The stay order issued by the High Court was challenged by the Government in the Supreme Court.

# DRUG POLICY / NATIONAL PHARMACEUTICAL PRICING POLICY DEVELOPMENTS IN LAST 18 YEARS

Supreme Court vacated the stay order issued by the High Court 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 2nd May, 2003”*.



# DRUG POLICY / NATIONAL PHARMACEUTICAL PRICING POLICY DEVELOPMENTS IN LAST 18 YEARS

Meanwhile, in accordance with the guidelines of the Supreme Court, 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.

Based on the recommendations submitted by the Task Force set up by the Government, the Ministry of Health & Family Welfare revised the National List of Essential Medicines and notified the new NLEM, 2011.

# DRUG POLICY / NATIONAL PHARMACEUTICAL PRICING POLICY DEVELOPMENTS IN LAST 18 YEARS

On 7th December 2012, Government announced National Pharmaceuticals Pricing Policy 2012 with the central objective of transmitting the principles for pricing of Essential Drugs as laid down in the “National List of Essential Medicines – 2011 declared by the Ministry of Health and Family Welfare. It also aimed at a regulatory framework for pricing of drugs so as to ensure availability of required medicines – “essential medicines” – at reasonable prices, providing sufficient opportunity for innovation and competition to support the growth of industry.

# NATIONAL PHARMACEUTICAL PRICING POLICY 2012

## KEY PRINCIPLES:

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

# NATIONAL PHARMACEUTICAL PRICING POLICY 2012

## Reason For Adopting as Key Criteria:

### (1) Essentiality of Drugs

- ✓ Medicines specified in the list
- ✓ Significance of the list
- ✓ Priority health needs of the country's population
- ✓ Availability at all times in adequate quantities
- ✓ Supreme Court Directive

# NATIONAL PHARMACEUTICAL PRICING POLICY 2012

## Reason For Adopting as Key Criteria:

- (2) Control of Formulations prices only
  - ✓ Bulk Drug may not fully reflect the Essentiality of the actual drug formulation
  - ✓ Price Control on Bulk Drug was not creating positive effect on its production in the country
  - ✓ Pricing both Bulk Drug and Formulation was complicated and time consuming

# NATIONAL PHARMACEUTICAL PRICING POLICY 2012

## Reason For Adopting as Key Criteria:

### (3) Market Based Pricing

- ✓ Complex Cost Based Pricing with varied data
- ✓ Cost Based Pricing restrictive for New Entrant
- ✓ Market Based Pricing fair and transparent
- ✓ Market Driven Indian Economy

# DRUG ( PRICES CONTROL ) ORDER

Statutory controls on prices of drugs were imposed for the first time in India in the wake of Chinese aggression and declaration of emergency in 1962. The Drugs Order, 1962, was issued mainly to contain inflationary forces expected as a consequence of the war.

The Drugs (Control of Prices) Order, 1963, was notified, freezing sale prices of drugs.

Both these orders were issued under the Defence of India Act.

# DRUG ( PRICES CONTROL ) ORDER

Since then, the Government has issued following Orders under the Essential Commodities Act. Under the Essential Commodities Act, the government has power to control production, supply, distribution and pricing of essential commodities. Drugs are considered to be an essential commodity.

1. Drugs Prices (Display and Control) Order, 1966
2. Drugs (Prices Control) Order, 1970
3. Drugs (Prices Control) Order, 1979
4. Drugs (Prices Control) Order, 1987
5. Drugs (Prices Control) Order, 1995
6. Drugs (Prices Control) Order, 2013



# DRUG ( PRICES CONTROL ) ORDER

Year of Introduction of the Drug Price Control Order	No. of Drugs under Price Control
1970	18 Control On Profitability – Maximum 15%
1979	347
1987	142
1995	74
2013	348 – Medicines

# COMPARISION

## DRUG ( PRICES CONTROL ) ORDER, 1995

## DRUG ( PRICES CONTROL ) ORDER, 2013

	DPCO 1995	DPCO 2013
Coverage	Bulk Drugs and Formulations	Only Formulations
Price Control	74 Bulk Drugs and Its Formulations	348 Essential Medicines
Price Mechanism	Cost Price Based	Market Price Based
Methodology	RM + PM + CC + PC + 100% MAPE	Simple Average of Price of Products having Market Share of 1% or more
Exemption To Small Scale Industry Unit	From obtaining Prior Price Approval	Not Available

# DRUG ( PRICES CONTROL ) ORDER, 2013

- ✓ On 15-May-2013, the Government notified Drug (Prices Control) Order, 2013.
- ✓ National List of Essential Medicines 2011 being annexed as Schedule I to Drug (Prices Control) Order, 2013.
- ✓ National List of Essential Medicines 2011 contains 348 drugs / medicines adding up to 652 formulations.
- ✓ All strengths and dosages specified in the NLEM 2011 will be under price control;

# DRUG ( PRICES CONTROL ) ORDER, 2013

- ✓ Ceiling Price (CP) will be fixed on the basis of market-based data (MBD);
- ✓ Formula for computing Ceiling Price (CP) is simple average price of all products having Market Share of 1% or more;
- ✓ Manufacturers will be free to fix any price for their products equal to or below Ceiling Price (CP);
- ✓ Automatic annual price adjustment (up or down) linked to Wholesale Price Index (WPI) for NLEM 2011 products;

# DRUG ( PRICES CONTROL ) ORDER, 2013

- ✓ Ceiling Price (CP) will be revised every five-year or as and when the NLEM is updated/revised; However, if there is a significant change in the market structure of a product, the government will revise the Ceiling Price (CP) even earlier; Ceiling Price (CP) will also apply to imported drugs appearing under the NLEM 2011;
- ✓ Annual price increase of up to 10% for Non-NLEM products;
- ✓ Prices of DPCO 1995 products not in NLEM 2011 would be frozen for one year and thereafter will be allowed increase of up to 10% per annum;

# DRUG ( PRICES CONTROL ) ORDER, 2013

- ✓ Original research products having product/process patent and New Drug Delivery System (NDDS) products exempted from price control for 5 years;
- ✓ Any new combination of NLEM+NLEM or NLEM +Non-NLEM will require price approval by NPPA;
- ✓ Any addition to NLEM 2011 by ministry of health will come under price control;
- ✓ The department of pharmaceuticals will monitor production and availability of NLEM products;

# DRUG ( PRICES CONTROL ) ORDER, 2013

- ✓ Ceiling Price notified up to 31-May-2012 of those Products currently covered under DPCO 1995 and NLEM will continue up to 30-May-2013 and thereafter price to be revised as per Annual WPI (Wholesale Price Index) of previous Calendar year. Ceiling Price will have to be followed as per DPCO 2013 once it is notified;
- ✓ Ceiling Price notified after 31-May-2012 of those Products currently covered under DPCO 1995 and NLEM will continue for 1 year. After 1 year price to be revised as per Annual WPI (Wholesale Price Index) as per previous Calendar year. Ceiling Price will have to be followed as per DPCO 2013 once it is notified;

# DRUG ( PRICES CONTROL ) ORDER, 2013

- ✓ Ceiling Price notified up to 31-May-2012 of those Products currently covered under DPCO 1995 only and not under NLEM will continue up to 30-May-2013 and thereafter price can be revised as any other Non Scheduled Formulations as per provisions of DPCO 2013;
- ✓ Ceiling Price notified after 31-May-2012 of those Products currently covered under DPCO 1995 only and not under NLEM will continue for 1 year. After 1 year price can be revised as any other Non Scheduled Formulations as per provisions of DPCO 2013;



# DRUG ( PRICES CONTROL ) ORDER, 2013

- ✓ 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 given formula i.e.  $(\text{Sum of prices of all the brands of the medicine having market share more than and equal to 1\% of the total market turnover of that medicine}) / (\text{Total number of manufacturers producing such brands of the medicine})$ ;
- ✓ Price Control will be for Formulations only and not on the Bulk Drugs;

# DRUG ( PRICES CONTROL ) ORDER, 2013

- ✓ All the existing manufactures selling scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price (plus local taxes as applicable) within a period of forty-five days of the date of such notification;
- ✓ All the existing manufactures selling scheduled formulations at a price lower than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government shall maintain their existing maximum retail price;

# DRUG ( PRICES CONTROL ) ORDER, 2013

- ✓ The basis for this readily monitorable market data would be the data available with the company – IMS Health (IMS). Wherever required this data would be checked by appropriate survey / evaluation by the National Pharmaceutical Pricing Authority (NPPA);
- ✓ The market based data, for fixing the ceiling price of scheduled formulations for the first time after the notification of this order, shall be the data of May, 2012;

# DRUG ( PRICES CONTROL ) ORDER, 2013

- ✓ The Government may in the due course of time come out with other appropriate mechanism of collecting or obtaining the market based data related to drugs and the decision of Government with respect to collection or obtaining of data shall be final;
- ✓ “New drug” means a formulation launched by existing manufacturer or importer of an NLEM drug with dosage and strength as specified in NLEM, BY combining the NLEM drug with another NLEM drug or non NLEM drug or by changing the strength and or dosage form of the same NLEM drug. Price approval for New Drug will be required if launched post DPCO 2013;

# DRUG ( PRICES CONTROL ) ORDER, 2013

- ✓ The market based data for fixing the retail price of new drugs available in the market, shall be the data available for the month ending immediately before six months of receipt of application for fixing the price of the new drug;
- ✓ The market based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six month of notification of revision in the first schedule;

# DRUG ( PRICES CONTROL ) ORDER, 2013

- ✓ 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;
- ✓ For drugs not in the IMS data, NPPA would collect data by commissioning the same. 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.

# DRUG ( PRICES CONTROL ) ORDER, 2013

Any manufacturer of scheduled formulation, intending to discontinue any scheduled formulation from the market shall issue a public notice and also intimate the Government at least six month prior to the intended date of discontinuation and the Government may, in public interest, direct the manufacturer of the scheduled formulation to continue with required level of production or import for a period not exceeding one year, from the intended date of such discontinuation within a period of sixty days of receipt of such intimation.

# DRUG ( PRICES CONTROL ) ORDER, 2013

- ✓ National Pharmaceutical Pricing Authority (NPPA) will be the implementation authority for the new Policy and the new Drugs (Prices Control) Order.
- ✓ Any manufacturer aggrieved by any notification issued, may apply to the Government for a review of the notification or order within a period of thirty days of the date of publication of the notification in the Official Gazette.



# DRUG ( PRICES CONTROL ) ORDER, 2013

## Forms To Be Submitted To The Government

1. Form I – For obtaining price approval of a New Drug
2. Form II – Price List of Scheduled Formulations After Revising Price as per Wholesale Price Index (WPI)
3. Form III – Quarterly Return Of Production / Import and Sales of NLEM Drugs
4. Form IV – For Discontinuation of the production and/or import of scheduled formulation
5. Form V – Price List of All Products i.e. Scheduled and Non-Scheduled Formulations

THANK YOU