Draft Pharmaceutical Policy – 2017

1. Introduction:

1.1 The Pharmaceutical Industry in India is robust and thriving. The annual turnover of the Industry in 2015-16 was Rs. 2, 04, 627.15 Crores. Of these the exports constituted Rs. 110, 5, 342.20 Crores (Data source – CMIE – Economic Outlook) and the domestic consumption according to '*Pharma trac*' data was Rs. 98, 414.4 Crores [*Pharma trac* is the database of All India Organisation of Chemists & Druggists & Advanced Working, Action and Correction System (AWACS)]. The Indian Pharmaceutical sector is largely fuelled by exports and is the 3rd largest foreign exchange earner for India. According to the CMIE data, the industry has been growing at a Compound Annual Growth Rate (CAGR) of approximately 10% for the period 2010-11 to 2014-15. However the growth rate is coming down from 14.36% in 2010-11 to 8.68% in 2014-15 (based on sales data of CMIE Industry Outlook). It employs about 2 Million work force across the value chain.

1.2 It is a private enterprise driven industry and the contribution of the Public Sector Undertakings (PSU) are negligible.

1.3 Indian pharmaceutical industry has the largest number of U.S. Food and Drug Administration (USFDA) approved manufacturing facilities(262) outside USA. 253 plants are European Directorate for the Quality of Medicines (EDQM) approved and 1300 World Health Organisation (WHO) Good Manufacturing Practices (GMP) compliant plants. Top exporting destinations are North Americas (27%); European Union (18%); Africa (18%); Middle East (7%); ASEAN (6%); Latin America (6%); and CIS (6%). India is also called the 'pharmacy of the world' and renowned for very high quality drugs at very cost competitive prices.

1.4 However, there have been lately some concerns-Declining CAGR; Non-adherence to quality standards and norms; Growing competition from other countries; Dependence on imports for the Key starting materials as also of the APIs; Lack of R& D and discovery of new molecules;

1.5 The National Pharmaceutical Pricing Policy-2012 (NPPP-2012) had also envisaged that Department of Pharmaceuticals will take steps to initiate a holistic policy on the Pharmaceutical Sector in due Course. It is high time therefore for formulation of a comprehensive Pharmaceutical policy to guide and nurture the pharmaceutical industry of India to enable it to maintain and enhance its global competitive edge in quality and prices.

2. Background:

2.1 The first comprehensive pharmaceutical policy called Drug Policy was formulated in 1978. Prior to that *adhoc* orders given by the Government from time to time to meet the exigencies of the then prevalent situation guided and controlled the industry.

2.2 Thus for the first time due to the soaring prices of drugs and their large scale need of drugs during the Chinese aggression of 1962, The Drugs (Display of Prices) Order, 1962 under Defence Of India (DI) Act, 1915 was promulgated followed by The Drugs (Display of Prices) Order, 1963 under the same Defence of India Act. Vide these orders the government froze the prices of certain drugs as on 1st April 1963.

2.3 However, though the prices of drugs were frozen, the prices of raw material required to manufacture these drugs were not frozen. Realizing this difficulty (articulated by the industry) the government in 1966 vide another order, namely, The Drug Prices (Display & Control) Order 1966 introduced a system of selective increases. Under this order, it became obligatory for the manufacturers to obtain prior approval of the government before increasing the prices of the formulations. Simultaneously, the government identified 18 bulk drugs and tasked the Tariff Commission to examine the cost structure of formulations made therefrom and

recommend their fair (selling) prices. By an amendment in August 1968, drugs sold under pharmacopeial name were exempted from such price approval.

2.4 Meantime in 1968, the Tariff Commission submitted its report in August 1968 and the government after examining the recommendations promulgated Drugs (Price Control) Order 1970, this time under Essential Commodities (EC) Act, 1955. The prime objective of this order too was limited to rationalize the prices of drugs, though by this time (1966) there were about 2000 private manufacturing units producing formulations (Rs. 1500 million), production of Active Pharmaceutical Ingredient (Bulk Drug – raw material for producing formulation drugs) was picking up (Rs. 180 Million) and the PSUs had also been in existence (from 1954) and all this required a vision and guidance for the future.

2.5 In 1970, another development on the Ministry of Commerce side had a much more far reaching effect on the pharmaceutical industry than the limited and ad-hoc price control orders of the department looking after Pharmaceuticals. This was promulgation of Patent Act, 1970. It provided for process patent in case of Drugs and Pharmaceuticals as against the product patent that had hitherto existed. This allowed the same product to be manufactured by another (patented) process and the Indian pharmaceutical industry took off on an expansion path.

2.6 The expansion of the pharmaceutical industry necessitated a much more comprehensive look at the requirements of the industry and a guide map for drug industry than the limited focus on drug prices and drug price control orders. Hathi Committee was set up in 1974 which looked comprehensively at the drug industry and submitted its report in 1975.

2.7 For the first time, based on the report of the Hathi Committee, the government formulated a national policy called the Drug Policy, 1978. The policy delineated the role of public sector undertakings vis-a-vis the private sector. Role of units with foreign holdings was also defined. Recommendations on Price control were also made.

2.8 The Drug Policy was revised in 1986. Import duty on raw materials, drug intermediates and drugs were structured in a graded way so as to make indigenous production viable. Promotion of use of pharmacopeial (generic) names, strengthening of quality control measures etc. were part of this policy.

2.9 The policy was further revised in September 1994. Industrial licensing was abolished. Only 5 drugs were reserved for PSUs. Foreign investment limit was raised to 51%. To encourage R&D, new drugs were exempted from price control for 10 years. Task of price fixation/revision was entrusted to National Pharmaceutical Pricing Authority (NPPA). For quality control National Drug Authority (under Ministry of Health & Family Welfare) was provided etc.

2.10 In 1999, the government set up two committees – i) Pharmaceutical Research & Development Committee (PRDC) to identify the support required by Indian pharmaceutical companies, and ii) Drug Price Control Review Committee (DPCRC) to review the drug price control mechanism (NPPA) where it had become counter-productive.

2.11 The next pharmaceutical policy was formulated in 2002, based on the recommendations of these two committees – the DPCRC and the PRDC – and other feedback. It basically proposed a shift from "controlled" regime to "monitoring" regime, span of price control over drugs and pharmaceuticals to be reduced substantially and to cater to the interests of the weaker sections the government to retain the power to intervene comprehensively in cases where prices behave abnormally (therefore the suggestion to shift from control to monitoring regime).

2.12 The 2002 Policy went into litigation on its stand on price control and the Supreme Court while lifting the stay given by the Karnataka High court on that stand, has directed that the government evolve such criterion that essential and life-saving drugs do not fall outside price control.

2.13 In 2005 the Patent Act was amended to provide for product patent. In 2006, the government prepared a revised draft pharmaceutical policy which was referred by the Cabinet to a Group of Ministers (GoM) for examination. In 2012, the GoM after

detailed deliberations (and in view of the Supreme Court's directions on the 2002 policy) decided to recommend only a National Pharmaceutical Pricing Policy for the time being which was approved by the Cabinet in 2012. To meet the SC direction on pricing of drugs, the National Pharmaceutical Pricing Policy 2012 follows the National List of Essential medicines (NLEM) prepared by the Ministry of Health & Family Welfare for price control measures.

3 Need for a New Policy:

The National Pharmaceutical Pricing Policy, 2012 while limiting itself to the aspects of pricing of drugs had also announced that a (w)holistic policy for the Pharmaceutical sector will be initiated by the Department of Pharmaceuticals in due course. In the meantime the globalisation of economy has played out and impacted the Indian pharmaceutical industry in many different ways since the last effective policy of 1994. The World Trade Organisation (WTO) obligations and entitlements of member states too have led to quite a different milieu in which the Indian pharmaceutical industry has to compete and thrive. Added to all this is the experience of implementation of the Drug Price Control Order (DPCO) 1995 and more recently the DPCO 2013 as well as the working of the National Pharmaceutical Pricing Authority since 1998. Moreover, the Government has also come out with a National Health Policy 2017 that might have implications for the pharmaceutical sector. All these necessitate the formulation of a fresh comprehensive policy for the pharmaceutical sector.

3.1 One of the major areas of concern is a very high dependence on import from one or two countries for the raw material and intermediates needed for manufacturing drugs. It has a direct bearing on the drug security of the nation as a whole. From 1954 to 1966 the manufacturing of intermediates [the Active Pharmaceuticals Ingredients (APIs) and Key Starting Materials (KSMs)] for drug manufacturing had picked up and we were largely self-reliant in these areas. The PSUs were laying down a strong foundation and playing an important role in this. Then the Drug Price (Display & Control) Order 1966 put 18 APIs under price control. All subsequent Price control

orders modified the methodology but retained the basic idea of controlling the prices of APIs and Intermediates of drug manufacturing. From 1996 with the globalisation and a regime of WTO, the imported APIs and Intermediates started becoming hugely lucrative as a price cap on drugs forced the manufacturers who had to maintain the minimum profit margins to obtain the cheapest raw material with the basic minimum efficacy/quality. This started impacting the indigenous API and Intermediates manufacturing which though much better in terms of quality assurance were nonetheless not price competitive. Today overall more than 60% of APIs are sourced from other countries and in some specific APIs the dependence is 80 to 90%. The situation is more alarming in case of Intermediates of stages prior to APIs and Key Starting Materials (KSMs) which are the building blocks for the drugs. As a result, our competitiveness and capability in manufacturing some of these API has also dwindled. The new pharmaceutical policy therefore needs to address the ways and means to restore and revive the API and KSM (and other Intermediates) manufacturing capabilities indigenously.

3.2 The quality assurance of indigenously manufactured drugs is another area of concern. While the drugs that get exported have a stringent quality assurance system, put in place and insisted by the importing countries internal requirements; concerns have been raised on the quality surveillance of the indigenously manufactured drugs for domestic consumption. There are not enough Nationally Accredited Laboratories (NABL) for conducting frequent and regular tests. The record of regular audit of these NABLs itself is also not very encouraging. The manufacturing permission for established drugs (already in market for more than 4 years) is given by State Drug Administrators without any Bio-Availability and Bio-Equivalence test of the claimed products. The inspection of the manufacturing premise and processes are, many a times perfunctory or absent. Many manufacturing units are not compliant with the World Health Organisation's (WHO) Good Manufacturing Practices (GMP) or the Good Laboratory Practices (GLP). All these severally and in combination give rise to grave quality concerns in pharmaceutical industry.

3.3 Another major grievance of the industry is that the approval for a new drug (which is given by the Central Drug Regulator) is a long drawn process and the average time taken is 2 years. This has a huge economic implication for the pharmaceutical manufacturers and contrarian to the idea and concept of 'ease of doing business'.

3.4 There is disproportionate focus on generic formulations to the point of exclusion of lack of adequate R&D. Whatever R&D is there is also limited to new processes for the same product (Novel Drug Delivery System – NDDS). For a long-long time there has been no molecule discovery by indigenous manufacturers.

3.5 Even in generic formulations, tough competition has started to emerge from our neighbourhood like Vietnam, Korea, Sri Lanka and Bangladesh. Compounded Annual Rate of Growth in the pharmaceutical industry has started to decline. It has seen a decline from 14.36% in 2010-11 to 8.68% in 2014-15.

3.6 The competitive advantage is being undermined through another route – the acquisition of Indian companies by foreign companies. Countries that are traditionally not strong in manufacturing formulations have started acquiring formulation-manufacturing plants/companies through automatic and government approval route. While upto 74% acquisition by such countries can also facilitate technology transfer/ or give exposure to formulation manufacturing, 100% acquisition is much more amenable to technology transfer. Since the FDI in pharmaceutical sector was liberalised, investment in only one green field project has been received. Rest all have come in brown field projects.

3.7 While growth of pharmaceutical industry and concerns related thereto are important, more important is the overall objective of making quality drugs accessible to the poor patients at affordable prices. The generic medicines are low cost but some marketing practices deployed by the pharmaceutical manufacturing companies create doubts and negative perceptions about the truthfulness of the drug prices. For example, the same company manufactures the same salt (pharmacopeial name of the drug) on the same production line but sells it under different brand names at different

prices! The widely varying prices for the same drug and the mark ups thereon for retailers, distributors and the stockists has created a largely negative perception about the industry's drug pricing practice.

3.8 Another example is the practice of one company getting the approval for manufacturing one drug and manufacturing it under different brand names and then giving it under exclusive brand names to other companies to market it! Thus the other company without getting approval for manufacturing the drug starts marketing it in a brand name at a different price.

3.9 The practice of 'loan licensing' and 'contract licensing' also undermines the veracity of drug manufacturing and pricing practice.

3.10 In the pharmaceutical industry, about 2500 pharmacopeial salts are manufactured but there are more than 60,000 brand names with varying prices!

3.11 In the context of all these above listed pricing practices of the industry and to meet the overall objective of making quality drugs affordable and accessible to all, the pricing of drugs is an important and desirable intervention of the government. There is no country in the world, with the exception of USA, where the drug prices are not regulated in one way or the other, directly or indirectly. Almost all advanced societies have an oversight mechanism for drug pricing. While the drug pricing mechanism has been by and large successful and its fundamentals of price ceilings for medicines included in the NLEM are sound and proper, going by the experience of last almost 10 years, there is scope for improvement in Drug price regulator's structure and functioning. There is a need for the proposed new policy to address this aspect too.

3.12 An area of concern is unethical marketing practices deployed by the drug manufacturing and marketing companies. Doctors are lured to recommend a particular brand trough all expenses paid trips often disguised and called 'educational conventions' and such other incentives. While The Drugs & Magic Act prohibits any advertisement of a drug, such 'educational' conferences are used to circumvent and play the trick. These add to the overhead cost of the drugs. It is assuming menacing proportions and needs to be addressed through the new pharmaceutical policy.

3.13 The national IPR (Intellectual Property Rights) policy 2016 notes that India has robust IP laws and a strong IP jurisprudence. The legal framework does reflect the underlying policy orientation and national priorities which have evolved over time. In the pharmaceutical sector, government has to strike a balance between the economic and employment imperatives and ensuring affordable medicines accessible to the poorer sections of the society. The disease profile has been slowly shifting towards non-communicable diseases and latest treatments available are offered by costly patented medicines which more often than not are the reasons for economic and emotional distress which cannot be overlooked. Lately, apprehensions have been raised from certain quarters of the industry about compulsory licensing and governmental move to have price control over patented medicines.

3.14 The Public Sector Undertakings in the pharmaceutical sector have served their purpose. The robust formulation industry that has spawned and captured world's imagination is on the solders of the giant PSUs that gave the initial push in material manufacturing as well as provided the manpower in the initial phases. Today however their utility is very limited. They were very useful at the initial stages of the building up of pharmaceutical sector. The indigenous private industry is by now healthy and robust, very competitive and fully capable to meet serve the societal and the governmental needs. It is therefore an opportune moment to review their continuance and rationalise them.

4. Key Objectives of the Policy

4.1 Emerging from the analysis of pharmaceutical sector scenario the key objectives of the Policy would be to:

a. Making essential drugs accessible at affordable prices to the common masses;
b. Providing a longer term stable policy environment for the pharmaceutical sector;
c. Making India sufficiently self-reliant in end to end indigenous drug manufacturing;

d. Ensuring world class quality of drugs for domestic consumption & exports;
e. Creating an environment for R&D to produce innovator drugs;

5. New Policy Initiatives

5.1 For encouraging end to end indigenous drug manufacturing including that of APIs and their precursor intermediates, it is proposed that the formulations produced from indigenously produced API and its Intermediates (end to end indigenous production) be given preference in government procurements. Such formulations be taken out of price control for 5 years and the price control be linked to the indigenous content of the formulations. WTO recognised principle of Rule of Origin may be used to give differential ceiling prices calibrated to the %age of indigenisation. All APIs which can be indigenously manufactured should be imported at peak customs duty. The structure of registration fee for import and manufacture along with the provisions of audit of foreign plants would be rationalised to match international standards being followed by the regulators of the larger pharmaceuticals producing countries. Additionally, an enabling environment will be created for setting up mega bulk drug parks where benefits of scale can be availed of by using common facilities for pollution control, effluent treatment or any such common activity provided by the central government in a Bulk Drug/Pharmaceutical parks which the state governments would be encouraged to set up in a Public Private Partnership mode. Such mega parks should provide for clearances for plants with minimum interface/single window clearance of various agencies by placing an official of the concerned department including the Department of Environment within the mega park itself.

5.2 For quality control, Bio-availability and Bio-equivalence tests (BA/BE Tests) will be mandatory for all drug manufacturing permissions accorded by the State Drug Regulator or by the Central Drug Regulator. This should be made compulsory even for the future renewals of manufacturing licenses for all

drugs. Phase wise implementation should be resorted to in order that Small Scale Industries do not get the brunt upfront. The Central Drug Regulator shall conduct regular annual audit of the laboratories which are accredited to conduct the BA/BE tests and certify the results thereof. A road map for BA/BE implementation will be prepared and implemented by Central Drug Regulator Provisions for self certification for BA/BE compliance by existing Licencees would also be introduced so that effective quality standards can be ensured without waiting till the time of future renewals. Besides the Central Drug Regulator shall also get all manufacturing units inspected at least once annually through an accredited network of third party inspectors/agencies (national/international) empanelled by it. Self-certification of manufacturing units can also be considered as an effective mechanism till such time that Central Drug Regulator develops capacity for annual inspections.

5.3 The government shall ensure to get the World Health Organisation's Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) adopted by all manufacturing units. Towards this, as the first step, all the national/central government level procurements as well as the state government level procurements done out of National Health Mission funds would be mandatorily from GMP and GLP compliant manufacturing units. In case of the Small Scale Industries this will be mandated phase-wise and they would be given incentives to upgrade.

5.4 The approval process of the Central or State drug regulator shall be shortened and standardised. The process for all approvals for which the organisation of Central or State Drug Regulator has the powers, shall be reengineered to ensure that a decision on applications are given within a period of 3 months – extendable by another 3 months by the Chief Drug Regulator for reasons to be recorded in writing and communicated to the applicant.

5.5 Innovation in pharmaceuticals will be encouraged along with generic drugs in generic (salt names). However, giving brand names to generic drugs hampers real innovation and shall be discouraged. Public procurement and dispensing of drugs will be of generic drugs in salt names. To facilitate this, the government will pursue the policy of sale of single ingredient drugs by their pharmacopeial name/salt name. To keep the identity of the manufacturer, the manufacturer would be allowed to stamp its name on the drug package. For patented drugs and Fixed Dose Combination (FDCs) drugs the brand names may be used. However here, the principle of 'one company – one drug – one brand name – one price' would be implemented.

5.6 To aid and assist the registered medical practitioners in prescribing medicines in the generic names, e-prescription will be put into operation whereby the prescriptions will be computerised and the medicine name will be picked up from a drop down menu of salt names.

5.7 The issue of unreasonable trade margins and bonus offers by various Stockists, Distributors and Retailers has been adversely affecting both the industry as well as consumer interest. After detailed stakeholder consultations, the level of trade margins will be prescribed to create a level playing field for the Industry and to bring down the prices. Institutions receiving supplies directly from manufacturers/distributors or retailers will also be covered under the trade margin reforms.

5.8 Loan licensing was decided to be discontinued in phased manner in the drug policy 1986. Loan licensing has served a useful purpose in the past when the MNCs wanted to get their drugs manufactured in India and market it. There was indigenous manufacturing capacity which was utilized by them. It helped the indigenous manufacturers gain in expertise and experience as well as in acquiring technology. However in the present context, when India is saturated

with formulation manufacturing, 'loan licensing' is not of overwhelming benefit. Instead, it raises many quality maintenance and assurance issues. Therefore, except in biopharmaceuticals where our stage of development is similar to what formulations were in 80s, in other pharmaceutical formulations, 'loan licensing' will not be allowed. (Plan B include (i) phasing out over 3 years (ii) loan licensing to be allowed only for WHO GMP approved facility (iii) loan licensing to be allowed upto only 10% of the total production of the Company).

5.9 Similarly, another variant of loan licensing i.e. the practice of P2P (product to product) manufacturing by which one manufacturer manufactures one pharmacopeial drug in multiple brand names and gives them to other manufacturers to market them at price chosen by the marketers, will be phased out. This will be achieved by following a principle of one manufacturer, one salt, one brand name and one price.

5.10 The marketing practices of several pharmaceutical companies create an unfair advantage. To provide a level playing field, the regulation for marketing practices which is at present voluntary will be made mandatory. Penalty for violations and an agency for implementation would also be assigned

5.11 Like other sectors, it is time for the Pharmaceutical sector also to move away from only the brick and mortar retail outlets into the e-pharmacy space. Detailed guidelines for encouraging e-pharmacy with adequate safeguards will be operationalized and e-pharmacy would be encouraged in larger consumer interest. The opportunities in the e-Pharmacy Sector can also be a potential area for attracting Foreign Direct Investment (FDI).

5.12 There is no authentic database on pharmaceutical sector. A database will be created by the Department of Pharmaceuticals alongwith the Drug Control

General of India (DCGI) on manufacturer wise, brand wise products and product wise, brand wise manufacturers.

5.13 Compulsory provision of static bar code containing price information on drugs will be enforced. Bar code reading and computerized billing will be introduced in pharmaceutical distribution and retailing.

5.14 Skilling Programme for Pharmacists will be designed to meet the modern day requirements of drug dispensing. Skill set of the Chemists and Drug Stores will be improved keeping in mind the emerging requirements and challenges of proper and efficient dispensing of drugs.

5.15 As far as FDI in brownfield pharmaceutical companies is concerned, the FDI approvals would be subject to continuance of (i) manufacturing of NLEM drugs by the entity in which the FDI is being made; (ii) expenditure on R&D; and (iii) transfer of technology. At present there is no mechanism or system to monitor the post-acquisition (FDI) activities of the company. A system would be developed to monitor the adherence to these conditions.

5.16 Instead of opening new National Institutes of Pharmaceutical Education and Research (NIPERs), the existing NIPERs will be expanded and strengthened. New NIPERs will be located on the basis of completion and parameters like the one followed in selection of 'Smart Cities'.

5.17 R&D for drug discovery involves identifying the gene that needs to be worked upon, zeroing on, through painstaking research, on the efficacy of one particular molecule from a large number (thousands) of molecules that could finally work on that gene in a desired manner, researching its efficacy, testing them first on animals and subsequently on humans. All these stages require in depth research which in turn needs human resource, time and money.

For the initial research on identification of gene and the molecules, the Government shall bring together the industry and the institutes of higher learning and research in Chemistry, Biology and Pharmacy for creating synergy and more efficient allocation of tasks. For the clinical trial stage, the Government has already brought in some clarity by publishing and mandating Good Clinical Practices (GCP) guidelines for conducting clinical trials.

To further encourage the R&D agenda the Government would allow a concessional rate of customs duty of 0 to 5% on import of specified goods and services required for R&D in pharmaceutical industry. All Novel Drug Delivery Systems should be considered as 'new drugs', unless certified otherwise by the licensing authority. This will also encourage innovations.

5.18 Every country in the world with one or two major exceptions has a price regulation mechanism for drugs. For social safety, it is necessary that drugs are available at reasonable prices to the common populace. It is more so for India because 65% of the medical costs are on drugs which are out of pocket expenses. Therefore the drug pricing will be made more poor oriented while retaining at the same time its industry friendliness. The following is proposed:

a. National List of Essential Medicines will remain the basis of the medicines to be brought under price regulation. Government in the Department of Pharmaceuticals will prepare the list of medicines for price regulation and transmit them to the NPPA for fixing the price ceilings.
b. The Regulator and the Government would be two distinct agencies. The Government shall not be the Regulator and the Regulator shall not be the Government.
c. For ensuring accessibility and affordability of drugs, ease of doing business and more coordinated synergies, all the regulators/commissions pertaining to Pharmaceutical industries/sector will be brought within the ambit of one Department.

d. NPPA will be strengthened. It will be assisted by an advisory body for pricing, nominated by the Government in the NPPA. The body will consist of doctors, pharmacists, other experts, civil society representatives, industry representatives and government representatives. The advice of this body will be recommendatory and the NPPA may accept or modify the advice rendered. While modifying/rejecting its advice, the NPPA will assign reasons in writing for doing so.

e. Prices once fixed by the NPPA shall not be revised by NPPA unless directed specifically by the government or a higher court to do so.

f. NPPA will be a multi-member body of full time Members – a Chairman, Member (Enforcement) and a Member (Pricing). The Members will be notified by the Government. The decision of the Authority will be by consensus.

g. The Authority shall be assisted by a Member Secretary who shall be a Government official and head the secretariat of the Authority. The Authority shall have a permanent secretariat with adequate staffing. Government shall provide the necessary staff on deputation to the secretariat. These, being sensitive positions, shall be strictly regulated by enforcing the rotational transfer policy of the DoPT and the CVC and no one should be allowed to continue for more than 3 years.

h. The appeal against the decisions of Authority shall lie with the government and against the decisions of the government, with the higher judiciary.

i. NPPA shall be responsible for laying down the price ceilings of selected medicines; enforcing those price ceilings; and ensuring that the medicines are available in the market in adequate quantities. NPPA shall also be responsible for maintaining a database of information required for fixation of price ceilings. For all these functions, the Authority shall announce and publish its compendium of standard processes and procedures for dealing with every aspect of its work.

j. Drugs (Prices Control) Order, (DPCO) which is implemented by the NPPA will be modified to the following extent:

i. The Schedule I of DPCO shall contain only the medicine's name in the NLEM without referring to their strength and dosage forms. All strengths and dosage forms of that medicine shall be liable for price cap. This will make some entries in DPCO related to 'new drug' redundant.

ii. DPCO will include only 'off-patent' medicines in its schedule. 'In-Patent' medicines will not be subjected to price ceiling by NPPA. They can be regulated through compulsory licensing under the Patents Act or by use of emergency powers under paragraph 19 of DPCO-2013, that too, only when expressly directed by the government in the Department of Pharmaceuticals to do so.

iii. DPCO schedule will be amended only through 'additions' & 'deletions' list.

iv. Paragraph 16 of DPCO shall be amended to clarify that any change in the WPI shall be reflected by adjusting the ceiling price in accordance with the change in WPI. Individual brands will thereafter adjust to the thus revised ceiling price.

v. The revised price ceilings should be effective immediately by means of bar- coding

vi. Overcharging provisions would be expressly provided in the DPCO. 'Overcharge' will be realised from the actual defaulting agency – manufacturer, distributor, retailer etc.

vii. Instead of an unrealistic 60 day time frame for deciding the price ceilings, flexibility should be provided to NPPA to complete its job;

viii. Language of DPCO should be made more definitive. There should not be much scope for different interpretations.

ix. Anomalies in the pricing of certain medicines in the present DPCO will be removed by making necessary amendments.

x. DPCO will be reoriented to move from price-control to monitoring of drug prices, their availability and accessibility.

5.19 This Policy would significantly contribute to the Ease of Doing Business in the Pharmaceutical Sector by the interventions at Para 5.1, 5.4, 5.5, 5.6, 5.7, 5.10, 5.11, 5.12, 5.13, 5.14 and 5.18 of this Policy.

5.20 The 'Make-in-India' programme would also get an impetus by the actions at Para 5.1 and 5.14 of this Policy.

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