Discussion Papers

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Discussion Paper # 236

RIS
Research and Information System for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

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Government's Policies and Growth of Pharmaceutical Industry in India 1947-2018: A Review

Prasanta Kumar Ghosh *

Abstract: The Indian Government policies on the development and growth of pharmaceutical industry, since India's independence in 1947 to 2018 have registered a sea- change. The establishment of the public sector undertakings (PSUs) at the beginning was to reduce foreign dependence for active pharmaceutical ingredients (APIs) . The policies framed in late 1960s and early 1970s were built on perturbed economic situation and on experience of wars and on the observations that local multinational companies (MNCs) were not ready to invest on infrastructure for APIs unless compelled to. Indian industrial laws for manufacture and trade, abatement of monopoly, control of foreign exchange outflow as also protection of intellectual property rights on inventions were framed and modified to encourage manufacturing of APIs and formulations locally with the primary aim of import-substitution; the indigenous industry was 'protected' for a long period up to 1991 by administering 'cost-plus' prices on selected APIs and formulations made there from; their imports were regulated by levying heavy import duties. The prices of essential formulations were thus controlled. The drugs prices control orders (DPCOs) from 1970 to 1994 were for maneuvering the country through price-controlled regimen of diverse kinds, from more controls to lesser control measures over years. After India joined the World Trade Organization in 1991, the legal instruments changed fast, setting the process of liberalization into motion. Industrial licensing policies were liberalized. The drugs policies and pricing measures were altered, intending to gradually move towards price- monitoring regime, as was reflected in DPCO-2002 and 2013 and the draft Drug Policy 2017. Such measures led to price rise of several medicines in trade thereby raising out-of-pocket medical expenses of people. The local API industry was affected because of liberalization. The promulgation of future policies in 2019 and thereafter would have to be a judicial balancing between expectations of the consumers to have 'fair prices' of essential medicines and the concerns of the industry to remain financially healthy, and at the same time ensuring a strong API production base in India

Keywords: Essential Drugs, Drugs Price Control Order, DPCO, Drug Policy, Indian Pharmaceutical Industry, NPPA, Industrial Licensing Policy, I(D&R) Act, R& D Incentives, Pharma R&D.

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Introduction

In 1947, after India's independence, the pharmaceutical industry of the country was in the nascent stage. The multinational companies (MNCs) were enjoying the monopoly in the business, and were engaged essentially in the trade of finished formulations. Government policies during the initial years were encouraging both trading and manufacturing entrepreneurship. A large number of MNCs and their local collaborators came up and had establishment. Imported medicines were expensive. Pharmaceutical formulations production in India required access to modern research-based active pharmaceutical ingredients (APIs). And such APIs were not freely available; they were accessible through imports, and were expensive; most of them were protected by the intellectual property right (IPR) laws. Under such circumstances, it was crucial for the government to plan and invest in developing this sector locally. Therefore, initial government policies were framed in a public friendly manner.

Before various measures taken by the Indian Government from 1947 onwards are described, it is important to have an idea about the status of the industry during the pre-independence days. The history of the Indian pharmaceutical industry dates back to 12 April 1901 when Bengal Chemical and Pharmaceutical Works Pvt. Ltd, Kolkata, was started by Acharya Prafulla Chandra Ray[1] along with certain eminent medical practitioners. There is mention of at least of two other Indian companies ,which made significant contribution in the production of allopathic medicines , founded earlier than 1901 —B K Paul &Co, Kolkata, and N Powell & Co, Mumbai, which pioneered essentially in the imports and distribution[2] of allopathic medicines along with production of certain others local medicines; although details of the local production could not be authenticated. Setting -up of Bengal Chemical was followed by the establishment of Alembic Pharmaceutical Works [3,] Baroda, in 1907, Zandu Pharmaceutical Works Ltd[4], Kolkata, in 1910, Calcutta Chemical Company [5,6] **,** Kolkata, in 1916, and Bengal Immunity[7] , Kolkata, in 1919. These companies had started essentially with the zeal of patriotism to compete with the imported medicines of British companies and MNCs.

Indian companies were not yet technologically rich, and could not freely produce and supply "patented medicines" to the people of India because of legal barriers. But Indian entrepreneurs continued to show their enthusiasm to capture a part of the business, which grew. During 1930s and 1940s, several other Indian companies came up. Noteworthy among them were Cipla[8], Mumbai (established in 1935); Amrutanjan Health Care, Chennai (registered in 1935)[9]; East India Pharmaceuticals Ltd, Kolkata (formed in 1936)[10]; FDC Ltd, Mumbai (established in 1940)[11]; Dey's Medical Stores, Kolkata (started as a retail medical store in

1941 followed by factory in 1957)[12]; Indoco Remedies, Mumbai (incorporated in 1947)[13]; and IPCA Labs, Mumbai (established in 1949)[14]. Based on the scattered information left by these companies in their history-sheets as obtained from the sites of the companies on the net, it was observed that Indian entrepreneurs initially produced pharmaceuticals dispensed in various formulated forms such as tablets, dry powders, capsules, liquids, ointments and other forms, dispensed as alkalizers, digestives, immune boosters based on traditional herbal medicines, disinfectants- based on coal- tar products , plant-based astringents, balms for pain relief and alcoholic herbal extracts of different kinds.

The Second World War (1939-45) caused severe scarcity of modern medicines in India. At that time microbial diseases created considerable distress among people, and were the principal cause of death. The prevalent diseases included typhoid fever, tuberculosis, small -pox, malaria, measles, cholera, plague, dysentery and diarrheal diseases, a host of conditions of sepsis, respiratory diseases, including pneumonia and bronco-pneumonia, venereal diseases, kala-azar, leprosy, infection from hook- worm and other parasitic worms in the intestine, guinea-worm diseases and filariasis. Among non-microbial diseases, diabetes, mental disorders and certain types of cancer, were leading causes of disabilities and death. Modern medicines were not available in adequate quantities to treat these diseases[15]. Following the war, the modern medicines coming through imports brought by multinational companies were considerably expensive. The three countries — UK, Germany and Switzerland— among the West European countries were most advanced at that time in the pharmaceutical industry. These countries developed new APIs and formulations thereof; which were effective in treating wide range of ailments and more importantly deadly diseases caused by microbes (typhoid fever, dysentery, diarrheal diseases, malaria, tuberculosis and sepsis). Only the needy who could afford the cost used medicines; most people could not. There was, therefore, a national crisis to develop policies and methods to enable supply of life-saving medicines at affordable price. The pre-independence availability scenario of modern medicines through the Indian companies was not exciting by any standards.

The Indian pharmaceutical companies produced affordable cheaper drug formulations to meet the requirement of poor Indians. In the process, several spurious drug formulations were introduced in the market. Firstly, new chemical entities (NCEs) and APIs locally were scarcely available throughout the country, and secondly, most modern APIs used to be the patent-protected proprietary products of the multinational companies, and therefore use of such bulk drugs for turning out formulations and using foreign brand names for respective formulations by the Indian collaborators required payment of heavy royalties to foreign companies, which were often not affordable.

A few Indian companies ventured to manufacture patent-expired APIs from the basic stage. Such efforts were made mostly after the independence; though a few were manufactured earlier also from the available raw materials. East India Pharmaceuticals[16]was manufacturing iodochlorohydroxyquinoline since 1940s, and was using the API for its own formulation for treating dysentery and diarrhea.

The Indian petrochemical industry became more resourceful about a decade after independence and some of the companies produced and supplied certain basic chemicals for initiating synthesis of APIs. But during pre-independence days and shortly thereafter, raw materials were scarce locally. The available raw materials were largely inorganic; and the organic raw materials were mostly coal-tar based products as the petroleum- based industries were in infancy during early years of independence. Then ethyl alcohol was available produced by fermentation of molasses. Ethyl alcohol was extensively used by the Indian pharmaceutical companies as solvents and in manufacturing some liquid formulations. Certain pharmaceutically active ingredients were extracted from herbal sources and processed using ethyl alcohol. There were barriers in those days and even after independence, however, for free availability of ethyl alcohol. This hindered fast fructification of indianization.

The turnover[17]of the product value of all formulations in 1948, including local production and sale of imported medicines in India, was Rs100 million. It rose to Rs 1264 billion[18] (USD 20 billion) in 2015. Indian biopharmaceutical industry also achieved greater level with estimated turnover of Rs 120.5 billion[19] (USS2.14 billion) in 2012. The commitment of the government for the development of the whole spectra of pharmaceutical industry emerged out of compulsion and social commitments to eschew foreign dependence.

It is the endeavor of this paper to ascertain what major policies and legal instruments of the government enabled this phenomenal development of Indian pharmaceutical industry, what major amendments and changes were instituted over time and what had been the significant results from the enactment of changing legal instrument over time.

Indian Government actions and initiatives after independence

Initial developments were based on the philosophy of instituting public-friendly policies in socialistic pattern. Industrial developments were stewarded by the government with emphasis of development through public sector understandings (PSUs). Industrial infrastructure building in all sectors was through setting- up of PSUs.

A Committee was formed named, Pharmaceutical Inquiry Committee (PIC)[20] at the Ministry of Commerce & Industry of the then government to

prepare a Report to guide it on the path to be followed to develop industry in a public friendly manner. The PIC in its Report prepared in 1954, outlined its recommendations. M/s Hindustan Antibiotics Ltd (HAL), the first PSU was set up. Subsequently, the Indian Drugs &Pharmaceuticals Ltd (IDPL) was set up where recommendations of the PIC Report were the guiding document.

The intention of the government in establishing PSUs was to invest for the basic manufacturing facilities of those essential bulk drugs where the country was totally import dependent, and the investment-needs for setting them up were very large. In such selected areas at that time, neither multinational companies nor Indian private sector were ready to invest. Consequently, the HAL and IDPL were established by the government. HAL was conceived, constituted, established and inaugurated by the Prime Minister Jawaharlal Nehru on 10March 1954. HAL's Penicillin manufacturing technology came from United Nations International Children's Emergency Fund (UNICEF) and WHO[21]. And it employed highly qualified microbiologists, chemical engineers and other highly skilled technical personnel to adopt highly intricate and complex fermentation technology . HAL was one of the earliest developing country establishments to produce potassium penicillin G first crystals from the basic stage of fermentation. By using potassium penicillin G first crystals (produced by fermentation), HAL manufactured life-saving sterile injection vials of Sodium penicillin G; Procaine penicillin G; mixtures of Sodium penicillin G and Procaine penicillin G; as also Benzathine penicillin G. These medicines were made available at affordable price and this endeavor saved millions of lives.

In mid 1950s, the then Union of Soviet Socialist Republics (USSR) provided basic technologies for manufacturing certain other drugs. USSR also had supplied plant and machinery on a fast-track basis to enable India to move fast towards self-reliance in pharmaceutical industry sector. That time India was not ready to manufacture locally most of the equipment required for the purpose. India's decision to go with the Russian technologies was a wise decision even though they were not the best technologies. There were advantages of paying for the technology and equipment fees in Rupee and opportunities for utilizing Soviet Credit more rationally besides flexibilities in terms of payments. The Russian equipment were invariably over designed requiring more consumption of energy ; on the face of it, this was disadvantageous but considering that India did not have adequate trained manpower during, the over design could absorb much of the chances of " mishandling" . The Russian technologies provided great opportunities for learning in diverse areas to the Indian technologists, engineers, scientists and skilled labours. The IDPL was set up with the USSR technologies for manufacturing [22] antibiotics, such as tetracycline, oxytetracycline chlortetracycline, streptomycin, griseofulvin and nystatin

from the basic stage of fermentation at its plant at Rishikesh, Uttar Pradesh; the synthetic drugs such as sulphonamides , analgin , phenobarbitone, vitamin B1, vitamin B2 and a few others in comparatively small volumes in the category of diuretics, antihypertensive drugs and antimalarial drugs at its unit at Hyderabad, Telangana; and the surgical equipment plant at Madras, Tamil Nadu. Setting-up of these establishments and starting to run units, instilled and reinforced confidence among a large section of Indians at the highest level, including the politicians, the administrators, the technologists, the scientists and the common people regarding Indian capabilities to absorb such intricate processes in a very short time of a decade. IDPL was incorporated in April 1961 and soon thereafter all its units started production. India's first Prime Minister on the creation of IDPL said [23]: "… *the drug industry must be in the public sector…I think an industry of the nature of the drug industry should not be in the private sector anyhow. There are (is) far too much exploitation of the public in the industry".*

The vision of the then Prime Minister had set the mood of Indian political system and the people for the preference of the public sector units in the country. Socialism was extensively practised and there was seminal belief in much of the principles of communism as these were thought to profoundly take care of the interest of the common man.

Ministries and Attached Wings Regulating Indian Pharmaceutical Industry Development

(i) The ministries and departments empowered for governing the Indian laws for manufacture

All the laws enacted by the Indian Parliament are implemented through different ministries. Indian pharmaceutical industry development is possessed, held, authorized, regulated and implemented by the central government through its ministries. All aspects of industrial licensing is centrally controlled .The industrial policy includes principles, policies, rules and regulations as well as procedures in India controlling industrial manufacturing, trade and pattern of industrialization. The policy takes into consideration item of manufacture, capacity to be created, phases of manufacturing, raw materials and utilities to be used, employment generation potential, location of the unit, effluent management issues etc ; and examines proposals under the existing acts and instruments for issuing licensing authorization. The administrative ministry for all kinds of industrial licensing is the Ministry of Industry (MOI); industrial licensing for local manufacturing and expansion, imports, foreign collaboration, and research in different industrial activities are being implemented by this by authorizing administrative control to other ministries. Department of Pharmaceuticals (DOP)

of the Ministry of Chemicals and Fertilizers is presently the administrative ministry responsible for Indian pharmaceuticals industry to play a leading role in the global market for ensuring abundant availability of good quality pharmaceuticals for mass consumption in India at reasonable prices[24]. DOP is responsible for the promotion of pharma industry, fixation /revision of prices of pharmaceutical formulations, nurturing quality and excellence in pharma education and research, manufacturing strategic pharma products, taking citizen centric initiatives for making available essential medicines at affordable price and promoting domestic manufacturing of medical devices.

Licensing authorization of medicines for production requiring the deployment of biotechnology and modern biology including use of rDNA technologies is authorized by MOI after obtaining the opinion of the Department of Biotechnology (DBT) of the Ministry of Science &Technology is sought; DBT is mandated to promote biotechnology in the country[25]. On the basis of the comments, opinion and recommendations of DBT, licenses are issued where required, and these authorizations are then transferred to the DOP, which is the administrative ministry for drugs and pharmaceuticals industry.

The Ministry of Health and Family Welfare (MOH&FW) of the Government of India has two Departments — (a) Department of Health & Family Welfare and (b) Department of Health Research. The MOH&FW through its various activities and programmes is engaged primarily to provide accessible, affordable and quality health- care to urban and rural population, especially the vulnerable group. Activities relating to pharmaceutical industries are taken up by its attached offices[26].Directorate General of Health Services (DGHS) is the attached office of the Department of Health & Family Welfare, and has subordinate offices spread all over the country. The DGHS renders technical advice on all Medical and Public Health matters, and is involved in the implementation of various Health Services. The Central Drugs Standard Control Organization (CDSCO) of the DGHS is the Central Drug Authority for discharging functions assigned to the Central Government under the Indian Drugs and Cosmetics Act. The CDSCO through its six zonal offices, four sub-zonal offices, 13 port offices and seven laboratories implements its functions. Major functions of CDSCO include regulatory control over import of drugs, approval of new drugs and clinical trials, meetings of Drugs Consultative Committee and Drugs Technical Advisory Board, and approval for import of certain drugs as the Central Drug License Approving Authority[27].

The regulation of manufacturing, sale and distribution of Drugs, pertaining particularly, to quality, efficacy and safety is primarily the concern of the State Drugs Control Authorities. All the 31 States in India have its Drugs Control Authorities responsible for ensuring system of licensing for manufacturing, sale

and distribution of drugs and pharmaceuticals under the Drugs Act and Rules and for overseeing maintenance of quality of medicines in States. Manufacture of Drugs and Pharmaceuticals is governed in India by the country's Drug and Cosmetics Act and Rules[28]. Imposition of good manufacturing practices under the Rules as borne out in Schedule M of the Act[29]is overseen by the State Drug Controller under Act and Rules. The approval of New Drugs, conduct of Clinical Trials in the country, laying down standards for Drugs and Pharmaceuticals, import of drugs along with qualities thereof as well as coordination of the activities of State Drug Control Organizations with the Central Government besides providing expert advice are within the ambit of the Central Authorities. The Central Authorities provide expert advice to the State Authorities to bring about uniformity in the enforcement of the Drugs and Cosmetics Act and Rules in the country.

Production, imports, research and all kinds of use of rDNA drugs require clearance from the Genetic Engineering Appraisal Committee (GEAC) of the Ministry of Environment & Forests and Climate Change (MOEF & CC) from environmental safety angle, and therefore DGHS and CDSCO require clearance from GEAC of MOEF&CC before enacting authorization for use of any such drugs in the country.

While it was the expectation of the Indian government that GMOs and products thereof would play an important role in uplifting Indian economy, including in pharmaceuticals industry, it was also realized that unintended risks and hazards could emanate if techniques and technologies were not used with caution and adoption of precautionary principles. Indian government had therefore enacted[30]the Environment (Protection) Act in 1986 and thereafter notified Rules &Procedures [31](Rules) for handling GMOs and products thereof in 1989.

Certain executive powers[32]of the Genetic Engineering Approval Committee under the Rules were later curved and were taken up by the MOEF &CC directly without assigning such authority to other bodies. Applying the Rules, drugs and pharmaceuticals requiring the use of GMOs and rDNA technologies can be researched upon in Indian laboratories, institutions, universities and R&D establishments of manufacturing units for the generation of environmental and human safety information for the GMOs and products made there from following guidelines published by the Review Committee on Genetic Manipulation (RCGM) of the DBT. Guidelines[33]were framed by the RCGM of DBT; the latest was notified[34] in April 2018. Once the GMOs and products thereof are evaluated to be environmentally safe (including safety to human health), the RCGM and the GEAC would authorize their use in India, and thereafter the DGHS and the CDSCO would act upon under the Indian Drugs Act to authorize their use including manufacturing in the country.

All pharmaceutical manufacturing establishments require clearance for use of the premises for manufacturing from the Central Pollution Control Board (CPCB)[35]or its attached offices to ensure that the discharged solids, water and air from the factory conform to the standards laid down by the CPCB. CPCB is a statutory organization, and is an attached wing of the MOEF&CC. It provides technical services to MOEF&CC under the provisions of the Environment (Protection) Act, 1986. The main functions of the CPCB are — (a) promote cleanliness of streams and wells in different areas of the States by prevention, control and abatement of water pollution, and (b) to improve the quality of air and to prevent, control or abate air pollution in the country. The CPCB lays down, modify or annul in consultation with the concerned State Governments, the standards for streams or wells and lay down standards for air quality. All industries, including pharmaceutical industry, are required to satisfy CPCB that adequate measures have been undertaken for establishing infrastructure which shall be or would be utilized to discharge effluent water and air from the factory conforming to the standards laid down. Solid wastes are either to be segregated and safely preserved by generators at their premises or disposed of in accordance with procedures, which are to be approved by the CPCB on a case by case examination and assessment.

All manufacturing units require land and building where establishments are created. Since land is a subject matter of the state government under the Indian constitution, acquisition of land and construction of building requires compliance of local laws of the State Governments where establishments are created.

(ii) The ministries & departments promoting R&D in Pharmaceutical Industry and effect on industry

The research and development (R&D) in pharma industry was always a priority for promotion by the government. State of the art R&D units were set up in HAL and IDPL by the government when these PSUs were established. Later to promote R&D in private units too emphasis was laid on the subject matter by the government. Government created in the Ministry of Science & Technology, the Department of Scientific and Industrial Research (DSIR) through a Presidential Notification, dated January 4, 1985. DSIR is mandated to carry out activities relating to indigenous technology promotion, development, utilization and transfer for all kinds of industries and other legal entities in India. It is making efforts to promote R&D by industries to catalyze its faster commercialization of lab-scale, to support larger cross section of small and medium industrial units to develop globally competitive technologies, and to strengthen industrial consultancy and technology management capabilities. The DSIR also promotes association between scientific laboratories and industrial establishments for

transfer of technologies through the National Research Development Corporation (NRDC). Promotion of research in pharmaceutical industry is an important task for the DSIR.[36] It implements its programmes independently as well as through its other autonomous institutions such as Council of Scientific and Industrial Research, Consultancy Development Centre, National Research Development Corporation and Central Electronics Limited. The R&D expenditure of each of the units in the pharmaceutical industry is certified by the DSIR; based on which the company can have a claim for deduction of expenses for R&D u/s. 35(2AB) of the Income Tax Act. DSIR has evolved schemes and procedures for granting recognition and approval to in-house R&D Units of each company[37, 38].

Another government organization constituted in 1986, the DBT, supports drug development research in biotechnology through its different programmes, which include novel diagnostic methods as well as development of therapeutic products for diseases endemic to India. Certain diseases among others under sharp focus include MDR-TB, HIV, Chikungunya vaccines, respiratory syncytial virus (RSV) vaccine, rotavirus vaccine, dengue subunit vaccine and various malaria vaccines[39]. DBT has created several autonomous institutions[40] through which also research programs are pursued for the development of pharmaceutical substances. Notable among them are the National Institute of Immunology, Translational Health Science and Technology Institute, Centre for DNA Fingerprinting and Diagnostics, National Centre for Cell Sciences, National Brain Research Centre and Institute for Stem Cell Biology and Regenerative Medicine. An international research center in collaboration with Italy and other governments was also created in India. This is by the name International Centre for Genetic Engineering and Biotechnology (ICGEB) [41] and receives funding from DBT and conducts among others drug discovery research. As a large number of local and multinational bio-pharma companies have initiated their manufacturing operations in India, the demand of biotech incubators for catalyzing further research has increased. Keeping such initiatives in view, the DBT has started setting- up of biotechnology parks to facilitate innovation through the development of biotech industrial cluster and to produce biotechnologists and entrepreneurs having strong foundation in research and innovation activities. In such parks, facilities for technology incubation, technology demonstration and pilot plant studies have been set up. Presently, seven parks are constructed and are functional.[42.]

The combined effect of all these initiatives are anticipated to yield commendable results stewarding India towards developing deeper understanding in disease biology, new drug discovery, development of innovative biotech processes and creation of trained manpower .

Government's R&D promotional efforts on industry

The lead research initiative in Indian pharmaceutical industry from the time of Independence up to the end of the decade of 1970 was for development of technologies for producing already known molecules and upgrading of existing processes with a view to set up and improve local manufacturing facilities of APIs.

Developmental research was carried out in two PSUs — Hindustan Antibiotics Ltd (HAL), Pune, and Indian Drugs and Pharmaceuticals Ltd(IDPL) (at its facilities at Hyderabad and Rishikesh) —and several government funded research institutions such as the Central Drugs Research Institute, Lucknow, Indian Institute of Chemical Technology (earlier known as the Regional Research Laboratory; RRL), Hyderabad; Indian Institute of Integrative Medicine (earlier known as the Regional Research Laboratory; RRL), Jammu; Indian Institute of Chemical Biology(earlier known as Indian Institute of Experimental Medicine), Kolkata; National Chemical Laboratory, Pune; Haffkine Institute, Mumbai; Calcutta School of Tropical Medicine , Kolkata; All India Institute of Medical Sciences, Delhi ; Punjab University, Punjab; and a couple of private research establishments, such as Hindustan CIBA-GEIGY R&D Centre (CIBA-GEIGY), Mumbai; Hoechst Research Centre (Hoechst), Mumbai; Smith Kline and French Ltd, Bengaluru; Sarabhai Research Centre, Baroda; and Boots India R&D Unit, Mumbai. Most significant legislative initiative of the Government for promoting developmental research was the introduction of Indian Patents Act 1970, which allowed Indian establishments for working on patented molecules for developing newer and novel non-infringing processes.

During these periods, research for the development of new NCEs and new APIs was less intense in the industry; though besides PSUs, certain private sector initiatives of the above-mentioned establishments were significant. The public-funded Indian research institutions as above were also engaged in new drugs developmental research. New drug molecules developed in India from the time of Independence till today, and approved for sale under the Indian Drugs Act include Hamycin[43] by HAL, Pune; Enfenamic acid[44] by RRL, Hyderabad; Centimizone (INN-Mipnazole), Centbucridine (INN-Bucricaine) , Centbutandone (INN-Buriperone) , Bulaquin (marketed as a combination of Bulaquin and Chloroquin phosphate by the trade name Aablaquine), Centchroman (Ormeloxifene-INN) , alpha beta Arteether (INN-Arteether), Gugulipid (a fraction from gum of the tree of *Commiphora mukul* commonly known as "Gugglu") and Bacosides (a standardized fraction in terms of its contents of bacosides isolated from *B. monnieri*) by CDRI[45], Lucknow; Chandonium Iodide [46]by University Institute of Pharmaceutical Sciences of the Panjab University, Punjab ; Sintamil (INN-

Nitroxazepine), Satrogyl (INN-Satranidazole), Azabiperidol (INN-Nonaperone maleate) and Amoscanate at CIBA-GEIGY[47;] Flavopiridol (INN-Alvocidib) a flavonoid alkaloid isolated from the Indian plant *Desoxylum binectariferum,* and Consap (INN-Colforsin), a diterpenoid isolated from *Coleus forskohlii* by Hoechst[46], Mumbai; and Lipaglyn[46] (INN-Saroglitazar) at Zydus Research Centre of the Cadila Healthcare Limited, Ahmedabad. Methaqualone was discovered in India by RRL, Hyderabad, while searching for antimalarial[48]drugs, the actual development of the drug and marketing both were carried out abroad.

The country's legislative initiatives such as institution of Indian Patents Act, 1970 as also others such as eligibility of exemption from price control for new drugs invented through indigenous R&D as also new processes developed were not commensurate with ensuring higher returns from the deployment of success stories. New drugs developmental costs are exorbitantly high and often require almost a decade or more of continued efforts. The CDRI has made the largest contributions in this regard thus far in the country, and while the contributions have high visibility and impact, the technologies developed by it and transferred to industry did not fetch adequate returns commensurate with investments made and efforts put. The deployment of technologies developed by Hindustan CIBA-GEIGY R&D Centre was also not enough to recover the incurred costs. This was also the case with the other privately operating research outfits engaged in the development of new NCEs and new APIs. Consequently, several private research outfits engaged in the development of new NCEs and APIs were closed down before 1990. Government funded institutions, however, continued to operate though earnings from the sale/transfer of technologies from new APIs were meager and not commensurate with the investments made. Investments in Government funded institutions are however necessary for many reasons including social causes for addressing needs of medicines to treat diseases and also upgradation of human skills. To anticipate adequate returns on investments for new drug development in Government funded institutions are too myopic.

Following India's intent of joining global open economy from July 1991, new initiatives were taken by the government and the most significant among them for the promotion of efforts for the development of new NCEs and APIs was the enactment of the Indian Patents (Amendment) Act, 2005.This legislation was anticipated to promote research preferably in private setting; the efforts in the public- funded institutes did not have significant impact from this act except that patents from them in foreign countries may increase. One important aspect to be taken note of is that because of the PSUs not having any more to play a leadership role, benefits of success in the development of new NCEs and APIs would continue to be in private hands.

In 1980s onwards, a number of Indian companies performed exceedingly well. Most of them operated on the major pharmaceutical formulations, which were not price-controlled .Several of these units also had set- up their API production facilities, and therefore accrued advantage in manufacturing cost of APIs required for pharmaceutical formulations thereof. These companies were also engaged in exporting both patent -expired bulk APIs and pharmaceutical formulations thereof and substantially augmented their earnings. The Herfindahl index, which is a measure of competition in an industry and which also is an indicator of the turnover size-contribution of individual firm in the aggregate total number of firms, was determined for the Indian pharmaceutical industry from 1991 to 2005. It is indicative of the fact that only 25 companies in India could capture 85% of the market.[49] Presently, the top twenty-five companies[50] are Indian companies–Dr. Reddy's Lab., Hyderabad; Sun Pharma, Mumbai; Cipla, Mumbai; Ranbaxy, New Delhi (Presently taken over by Sun Pharma); Lupin Ltd, Mumbai; Cadila Healthcare Ltd, Ahmedabad; Aurobindo Pharma, Hyderabad; Wockhardt Ltd, Mumbai; Ipca Labs, Mumbai ; Orchid Pharma , Chennai; Biocon Ltd , Bangalore; Matrix Laboratories Ltd, Secundrabad (acquired by Mylon); Alembic Ltd, Baroda; Torrent Pharmaceuticals Ltd, Ahmedabad; Glenmark Pharmaceuticals, Mumbai; Intas Pharmaceuticals, Ahmedabad; Unichem Laboratories, Mumbai ; Nicholas Piramal India, Mumbai; and Cadila Pharmaceuticals ,Ahmedabad— and MNCs are GlaxoSmithKline Pharmaceuticals Ltd , Mumbai; Aventis Pharma Ltd, Mumbai ; Pfizer Ltd , Mumbai ;U S V Ltd, Mumbai; Novartis India Ltd, Mumbai; and Abbott India Ltd, Mumbai. Besides, there are several other medium, small and tiny pharmaceutical companies. R&D expenditure in large companies signifies intensity of research as these companies can allocate more funds for the purpose. The R&D expenditure in Indian pharma companies was small when compared with the expenditure incurred by international companies engaged in the search of NCEs; the expenditure by the Indian companies varied from less than 1% to up to 5% of the turnover from 1990-91 to 2009-10.Here also the overall percentage increase was especially on account of the contribution of R&D expenditure of two companies — Dr Reddy's Lab and Ranbaxy. If these expenditures are counted separately then the average expenditure of the all the other firms would work out to be less than 5%; although the trend over the years showed gradual but slow rise[51]. The enactment of the Indian Patents (Amendment) Act, 2005 was seen as a boon by many units, which intensified their R&D expenditure for the development of new APIs. The efforts of the industry resulted in the discovery[52] of more than 120 NCEs; which are being evaluated through stages of clinical experimentation in search of new APIs.

The Evolution of various Acts and Legal Provisions

(a) Industries Development and Regulation Act 1951

Right from the beginning, Government of India had held full authority within itself for permitting licensing for local manufacturing, imports, collaboration, expansion and research in the country in all aspects of industrial activities. The first significant industrial policy statement was made in the Industrial policy Resolution [53, 54](IPR), 1948. This policy was the foundation of mixed economy, implying that the private and public sectors were accepted as important components of the industrial economy of the country. In 1951, the Industries Development and Regulation Act [I (D&R) Act] was enacted to regulate growth of all industries. The Act incorporated a declaration as to expediency of control by the Union Government, which read as under:

"It is hereby declared that it is expedient in the public interest that the Union should take under its control the industries specified in the First Schedule".

Drugs & Pharmaceuticals activities are listed in the First Schedule at Schedule 22 of the Act. The activities of all manufacturers of drugs & pharmaceuticals including the MNCs are to be authorized within the provisions of the act. Industrial licenses were issued by the central government to the existing as well as the new undertakings from time- to- time for conducting production activities of drugs & pharmaceuticals[55]. The provisions of the act have undergone a sea-change after India became Member of the World Trade Organization (WTO) on and from 01.01.1995 as has been discussed later.

Permission letters under I (D&R) Act and COB Licenses of early 1970s

Initially from 1952to 1965, the Government of India maximized domestic capabilities of production towards availability of life- saving medicines in abundance. "Permission Letters" were issues under I(D&R) Act for the production of various drugs and pharmaceutical items needed in the country. Authorization for taking up manufacturing through the issue of "Permission Letters" was required by manufacturers to produce and market new types of medicines. It was soon clear to the Government after enacting such policies that using such "Permission Letters", the MNCs and certain large houses were producing household remedies, and comparatively less important formulations such as cough syrups, gripe water, laxatives, digestive tablets, ointments, tonics, vitamins and minerals and likes. There were no substantial benefits to the country in terms of induction of basic technologies for the production of bulk drugs. The issuance of the "Permission Letters" was limited to creation of certain quantum of additional capacities. Several MNCs and certain large industrial houses grabbed sizable quantum of capacities that were available by

obtaining newer "Permission Letters" in their favor,and thereby harmed natural competitiveness in the marketplace as many newer units could not obtain any "Permission Letters" as the capacities up to which such "Permission Letters" could be issued exhausted already and filled up on paper.

Liberalization in the licensing policy was announced once again by the Government in 1966 and 1967 where manufacturers could diversify into production of "new articles" and expand their production capacities up to 25% more without any amendments in their licenses. The impact of these liberalization procedures was reviewed in 1970, and it was the conclusion of the government that concessions were utilized to expand capacities of pharmaceutical formulations- manufacture. Very little efforts were made by the companies to expand in their bulk drugs production capacities. These concessions were, therefore, withdrawn later in 1970s, and Government had to "allow" regularization of activities already instituted by companies from 1965 onwards in the form of "Carrying-on-business" (COB) licenses. The consequence of issuing COB licenses was seen in the form of authorization, which was to be provided to twelve foreign companies and five Indian companies to allow them to manufacture 215 formulations and 20 bulk drugs[56] for the period extended up to mid-1970s.

It was the learning of the Government that the MNCs and certain large companies were taking advantage of "licensing relaxations" allowed by the Government from time to time and expanded their business either in manufacturing of formulations or in the production of bulk drugs not requiring high technological inputs. Issuing of COB licenses under compulsions enabled the learnings that stricter policy options were required to be enacted to imbibe natural competitiveness in the market place to enable investment from more players for production, especially of bulk drugs required in the country.

(b) Monopolistic and Restrictive Trade Practices Act, 1969

Besides stopping the issuance of "COB" licenses for curbing further "expansion" by the MNCs and the large industrial houses, Government took another step to regulate sanction of industrial licensing. The action was to introduce an additional Act to restrict acquiring monopolistic situations in specific business activities. For understanding if monopolies were being created by industrial houses, Government instituted a study. In April 1964, it appointed the Monopolies Inquiry Commission under the Chairmanship of Justice K. C. Das Gupta[57]who was a judge of the Supreme Court. Inquiry was instituted to ascertain the effect and extent of economic power prevalent in the important sectors of industrial activities (other than agriculture) which were in private hands and private sectors. The Indian Drugs & Pharmaceutical industry was also investigated

to ascertain if any individual industry or house or connected group was in a dominant position to control market by regulating prices or outputs, and thus was able to eliminate competition and free trade. Such a situation would be able to deprive the community of the benefits of free competition. A report was submitted in 1965. On the basis of this report, the Monopolistic and Restrictive Trade Practices Act, 1969 was enacted[58] .The Soviet way of industrialization requiring extensive government intervention to institute free competition within the territory of India with the idea of rapid industrialization on an equitable basis was the driving force to institute MRTP-1969. This Act was utilized to review and rationalize the then industrial licensing policy of the country, and it made impact towards competitiveness.

(c-1) IPR Issues: Needs for Removal of Production Barriers on APIs

Hurdles of production barriers of APIs due to Intellectual Property Rights (IPRs) were increasingly perceived after Independence. Even though the HAL and IDPL were created by the government, the production of the number of APIs taken up in these two units was only a few, and these were not adequate to meet rising greater needs of the country. During 1950s up to the early 1970s, most of the APIs other than those manufactured by HAL and IDPL ,were protected by IPRs where the law provided "product parenting rights" which implied that up to the period of IPR protection no other entity is authorized to produce those APIs without the consent received from the holders of the IPR. In the meantime, the Indian petrochemical industry was getting established and developed from the early 1960s and onwards. As a result, many raw materials were becoming locally available. Further, a large number of agricultural and forest-based raw materials were available. India needed to utilize these resources for developing its pharmaceutical industry to produce APIs.

The then Patents Act 1911 and its subsequent modifications (Patents act-1911) became an impediment to taking up of manufacturing patent-protected drugs, and therefore indigenous production of any one of these by others not holding the rights or not having legal access to use the patent could not manufacture even by other new process not described even in the patent. The Patents Act-1911 allowed product patenting rights through the provisions of the Act which read as under:

Relevant portions of The Patents Act-1911[59]:

> ***"(8) "invention" means any manner of new manufacture and includes an improvement and an alleged invention:***
>
> ***(10) "manufacture" includes any art, process or manner or producing, preparing or making an article, and also any article prepared or produced***

by manufacture:

(11) "patent" means a patent granted under the provisions of this Act"

(12.1) A patent sealed with the seal of the Department of Patents, Designs and Trade Marks shall, subject to the other provisions of this Act, confer on the patentee the exclusive privilege of making, selling and using the invention....

Amendments made in Indian Patents Act, 1970 were as under[60]:

"5. In the case of inventions-

(a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or

(b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds),

no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable."

In 1970, the then Indian Patents Act was amended for allowing production of 'IPR-protected' bulk drugs to be produced by other "patentable innovative processes". In the said modified Act as above only "novel processes" could be patented for any NCE or API. New uses of known NCEs and APIs were not patentable as could be interpreted from the amendment. As the result of this amendment, many patent protected NCEs or APIs could be produced if they were produced by any "new" process/s which was/were not patented. Indian manufacturers developed new processes and started manufacturing products. In this process, there was tremendous development in the country and several Indian pharmaceutical companies started producing locally bulk drugs from basic chemicals as well as from drug intermediates.

Following the amendment of Indian Patents Act in 1970, a large number of Indian companies were set- up; many starting manufacturing bulk drugs using their own technologies. Concomitantly, several pharmaceutical units came up for manufacturing pharmaceutical formulations as such activities required lesser investment, the APIs were available from multiple local sources, and the business of manufacturing formulations by using local APIs became quite profitable. Such units operated first in small scale and soon many of them made so much of the progress that they turned into large- scale production units. This was because a sizeable number of APIs were available locally in abundant quantities, and further, a number of such units had set up their own manufacturing facilities too for a range of APIs. Most importantly, through administered prices of APIs

fixed by the government and through the imposition of higher import duties on them, a situation arose where local production was profitable and sustainable.

(c-2) Features of Indian Patents (Amendment) Act, 2005

Many years later after India joined WTO in 1995, the Indian Patents Act, 1970 was again amended to comply with the provisions of the trade- related intellectual property rights of WTO. Accordingly, therefore, the Indian Patent Act, 2005 was enacted[61]. In the revised Indian Patent Act, the 'product patenting rights' , where 'products' manufactured by any process described or not described in the patent specification document, were brought back again due to the compulsions of WTO. The author earlier discussed in 2001 in a paper, the freedom of space [62]from the minimum provisions for IPR protection under TRIPS of WTO. The provisions for a patent under the WTO were for inventions in all branches of technology; inventions meant that the products of invention were new, involved an inventive step (non-obvious) and were valuable for industrial applications (useful).Patents on microorganisms and microbiological processes were also made available. Flexibilities were provided for exclusion of patentability in (a) diagnostic, therapeutic and surgical methods for treatment of human and animals ;(b) plants;(c)animals; and(d) essentially biological processes for production of plants or animals. The patents were for a period of 20 years. Compulsory licensing was permitted on merits and for doing so, the holder of patent would have to be heard. These provisions were rightfully utilized by India in framing its amended Patents Act of 2005. The major changes made in the Indian Patents (Amendment) Act, 2005 were as under[61]:

(a)The Section 5 of Indian Patents Act, 1970 that was meant for providing limited conditions of "process patenting" for inventions relating to "substances intended for use, or capable of being used, as food or as medicine or drug, or substances prepared or produced by chemical processes", was omitted in the amended act of 2005

(b) Inventions for pharmaceuticals, food and chemicals will be available for a term of 20years. The subject matter of patentability of new inventions comprising of these substances are contained in Section 3(d); Sections 2(1)(ja);2 (1)(g)(l);2(1)(g)(m); and 2(1)(h)(ta)), all of which have been worded to take advantage of the flexibilities of the provisions of WTO. The Section 3(d) of the amended act does not allow the new uses of known substance for getting a patent.

(c) The scope for compulsory licensing has been expanded as can be seen from the wording of the new Section 92A. (1), which reads as follows: "92A. (1) Compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or nonmanufacturing capacity in the pharmaceutical sector for the concerned product to address

public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India". The scope for India to manufacture and export patented pharmaceutical substances in countries not having adequate manufacturing capabilities is opened up and enlarged by this clause to tackle situations of extreme conditions of human sufferings, requiring interventions.

In international scenario, the policy space available through the earlier Indian Patents Act of 1970 and the amended Indian Patents Act, 2005 enabled the Indian generic API manufacturers to supply low-cost, quality-assured generic medicines. Significant impact of the contributions was noticed especially in the supply of antiretroviral medicines to developing countries.[63]

In September 2001, when US was facing a major crisis from spores of anthrax bacteria, sent to USA through letters which killed five people and infected 17 others and some 12 million US citizens, and were of concern , there was suddenly a huge demand for antibacterial drug by the generic name ciprofloxacin. The drug was covered under the US Patents Act, and the patent right was held by the German pharmaceutical company Bayer. Then USA had to take a decision on whether to waive the Bayer patent as it was clear that Bayer would not be able to produce and supply to meet the huge demand that had arisen suddenly in the USA. The cost calculated for treatment of one individual for anthrax by using Buyers ciprofloxacin at USD350 against USD10, if treated by using Indian ciprofloxacin! Eventually although the USA government honored Bayer's patents right and did not purchase the generic version of ciprofloxacin from India or any other cheaper sources, but the USA cashed on the opportunity and negotiated with Bayer on one- to- one basis asking Bayer to reduce the price of ciprofloxacin tablets and was able to succeed. Bayer reduced their price of ciprofloxacin tablets substantially to meet USA requirements. The fact that cost-effective, but equally potent ciprofloxacin drugs from Indian companies were available allowed US to successfully negotiate with Bayer, and Bayer had to back down to reduce its price in the end[64, 65, 66].

Coming back to Indian scenario, in the meantime the provisions of open market economy were brought in place in the legal instruments which included among others, withdrawal of price protection of locally produced APIs and imposition of provisions for the reduction of import duties on such APIs. Effects of this new enactment in the Indian Patents act dried down the opportunity of working on IPR protected APIs. Further, the open-market provisions enacted earlier were being perceived strongly by the API manufacturers. In the new environment, the manner of conducting business in APIs shifted towards higher dependence on imports where APIs were either imported directly and sold or

produced from imported raw materials and drug-intermediates. These options were more cost-competitive to the API producers and consumers.

Soon local production of APIs became "uneconomical" for a large number of them. Many units closed down very fast including the ones producing antibiotics by fermentation technology using agricultural materials and a large number of manufacturers of synthetic drugs. Those operating (because of their having access to marginally better technologies and advantage of lower labor costs in India) are likely to lose their dominance soon as many developing countries have capacitated to improve their technological skills. Only those local API manufacturers would survive if their technologies are substantially superior. A broad list of such APIs has been drawn, and included in the text in the later portion.

(d) Foreign Exchange Regulation Act (FERA) of 1973 and Drug Policy-1978

Up to late 1960s, because of the monopolistic capture of the Indian pharmaceutical industry by the MNCs and because of growing scarcity in the availability of foreign exchange, Government studies were mooted towards the foreign exchange remittance by the MNCs. As a result of these studies, the Foreign Exchange Regulation Act of 1973 was instituted. Appendix-I[67] of this Act listed Drugs and Pharmaceuticals industry at serial no. 14. All MNCs were categorized as FERA companies. As the pharmaceutical industry was listed in the core sector of national economic development, meant that FERA companies would be participating in the growth of the industry.

However, as the MNCs were not taking adequate initiative to set up capacities for the production of bulk drugs in the country, the 1978 Drug Policy required[68]that foreign companies would have to dilute their foreign equity if they were not producing bulk drugs; FERA companies were to produce "high technology" bulk drugs if they wished to manufacture and sell formulations; further the production of bulk drugs was to be from the basic stage. The FERA companies were to maintain a ratio in value for the production of bulk drugs and their formulations as 1:5, meaning that if they produced bulk drugs worth Rs 1, they would be permitted to produce formulations worth up to Rs 5.

The Drug Policy 1978 was instrumental in causing dilution of all the MNCs in their equity capital to 40% or below because of these policy instruments.

Drugs Prices Control Measures

(a)The Chinese aggression in 1962 and thereafter up to 1970

There had been tremendous shortage of essential medicines in the country after

the Chinese aggression in 1962; extreme shortage of essential drugs was felt earlier also during the Second World War. During every war time, the prices of medicines increased substantially by the suppliers who were either distributors or agents of MNCs or MNCs themselves. Prices of formulations could be increased by the marketers as there were no laws to enforce maintenance of stable prices, say at the then existing levels.

To meet the indigenous needs, measures, such as promulgation of Drugs (Display of Prices) Order, 1962 and Drugs (Control of Prices) Order, 1963, under the Defense of India Act, were instituted to contain the situation of price increase[69]. However, it was increasingly felt by the government that these measures were inadequate. Indigenous capabilities were to be established and existing capabilities upgraded. The then legal instruments were also to be reviewed and modified to tackle the situation. One important consequence of such thinking was to amend the then Indian Patents Act as discussed.

The other measures were to work on the price front of medicines. Since the prices of the medicines sold by the MNCs during 1960s and in the earlier times were felt high , it was considered that a price study should be made. Consequently, a price study was undertaken by the government through the then Tariff Commission in mid-sixties to ascertain if the multinational companies were charging high price of medicines in India.

The cost structure of 18 selected bulk drugs and their formulations were studied by the Commission and a Report was submitted to the government in August 1968. It emerged that the prices charged by the companies were on the higher side. It was, therefore, imperative for the Government to take steps to reduce and rationalize prices of medicines. In the meantime, Drugs Prices (Control) Order of 1966 was promulgated according to which it was obligatory for manufacturers of drugs to obtain prior approval of the Government if prices of such formulations as of 30th June 1966 were to be increased. After the Chinese aggression of India in 1962, prices of all the drugs and formulations were frozen at the level of April 1963 by a Government order, and such prices continued as frozen in most cases up to 1968.

This situation was not acceptable to the industry; the objections and grievances were because the prices of raw materials and packing materials were not frozen, and their prices started increasing. As a consequence, therefore, the Government order of Drugs Prices (Control) Order of 1966 was amended in August 1968. According to this Amendment, formulations sold under pharmacopoeia names were exempted from price approval. Prices of existing formulations were increased on a case-by case basis after studying the cost structure and appropriateness for the increases sought by manufacturers.

However, new drugs developed through original research and marketed for the first time were also exempted from price control[70].

It was another learning process for the government. The prices of the eighteen essential bulk drugs were fixed on a principle of "cost-plus" basis. The prices of the formulations manufactured there from were also fixed on "cost-plus" formula. The cost of manufacturing was considered to be "ex-factory cost" of medicines. On the ex-factory cost, some increase was allowed for factors such as marketing and distribution costs, allowing a "reasonable" profit. As the concept was new at that time and there was inadequate experience on what were "reasonable" marketing and distribution costs as well as "reasonable profits", a blanket mark-up of up to 150% on the ex-factory cost of formulations was considered as adoptable. The maximum retail prices (MRPs) which were approved and notified were based on a judicious selection of MRP of the applicant, which was again based on the comparison of the MRPs of other comparable brands in the market, and the figure worked out at 150% mark-up basis. MRPs of applicants were never approved above the figure worked out by the government using a formula as discussed in the following section.

For working out the ex-factory cost of formulations of applicants, there was need of adopting norms towards the cost of conversion of raw materials into dosage forms and the costs for packing the dosage forms into saleable packs. In addition, the costs incurred on raw materials and finally the costs of packing materials were to be aggregated. The four ingredients, the cost of raw materials, the cost of packing materials, the cost of conversion of raw materials into unpacked dosage forms of medicines, and the cost of packing of unpacked medicines into finished packs, when added, gave "ex-factory" cost.

To rationalize these four factors, Government in consultation with the then Development Council on Drugs and Pharmaceutical industry worked out the "norms" for conversion of raw materials into unpacked formulations (CC) or manufacturing cost of converting raw materials into unpacked dosage forms. For example, for manufacturing tablets of a particular size require, in operations, weighing of raw materials, shifting, mixing, slugging, drying, granulating, compressing and polishing. For coated tablets, a further coating operation was involved. The cost of labour, energies, consumables, factory overheads etc. spent on machines at annual operations on one shift basis for 280 to 300 days at capacity utilization of 60 to 80 % for calculating depreciations and interest cost were considered. The CC was then worked out for different sizes of tablets on an average basis for a lot. There were sufficient margins provided to accommodate operations of different types of industry sizes. Such norms were also worked for other kinds of dosage forms such as capsules, liquids, dry powder, syrups, liquids, ointments, injections in vials and ampoules etc. The conversion norms

were then presented in a tabular form for different formulations. The norms for the packing conversion (PC) for different saleable dosage forms of packs were also worked out in a similar manner. The (CC) and (PC) costs were notified. The cost of raw materials with appropriate overages (RM) for standard packing of various dosage forms as well as the cost of packing materials (PC) was based on actual costs incurred by the companies. These costs were certified by independent qualified Chartered Accountants.

The above four elements of costs were then aggregated. Mathematically represented, the ex-factory cost of formulations of each marketable pack was then worked out by adding up the above factors— RM + PM + PC +CC. On the ex-factory cost so derived for a marketable pack, a mark-up was allowed to determine selling price, to which the applicable excise duty was added to have final selling price per pack with excise duty. Such prices worked out and notified by the Government were to be printed by the manufacturers on their saleable packs as the authorized and approved prices.

For the determination of the above formula and the working out of the CC and PC costs, which were highly technical, the then technical organizations like the Drugs Directorate of the Directorate General of Technical Development (DGTD) and the office of the Drugs Controller of India (DCGI) made substantial contributions. These basic works thereafter formed the basis for the fixation of 'fair prices' as announced and promulgated by the government from time- to-time from 1970 to 2012. The CC and PC were also revised and notified by the government; as were required because of rising cost of labour, utilities, factory overheads, maintenance costs etc.

(b) Drugs Prices Control Orders (DPCOs) from 1970 to 2012

(i) DPCO-1970

Drugs (Prices Control) Order (DPCO-1970) was promulgated[71] on 16th May 1970. Drugs (medicines) were in the meantime brought under the Essential Commodities Act, 1955(ECA-1955) The DPCO-1970 was issued under Section-3 of the ECA-1955. This Order was promulgated with the primary intension of rationalizing prices of indigenously manufactured pharmaceutical formulations. The formulations sold by different manufacturers and suppliers before the promulgation of the Order were in considerable variance for the same or similar composition. Through this Order, a rational method of estimating the ex-factory manufacturing cost and a concept of 'mark-up' were brought in for manufactured formulations to account for the post manufacturing costs before the formulations reached buyers. While formulating the DPCO-1970, the policy formulators had drawn heavily from the concepts enumerated earlier for calculating theex-factory price of each formulation and the procedures for determining maximum retail prices (MRPs) of such formulations.

In this DPCO-1970 Order, there were two alternatives in pricing formulations— in the first alternative, companies could ask for price fixation of their formulations, where the prices were fixed by the Government by providing a "mark-up" of up to 150% on the ex-factory cost calculated as above. Such prices calculated required the authorization of the Government. In the second alternative, companies could fix their prices themselves by taking a mark-up of up to 75% on the ex-factory prices of formulations. It was the intention of the Government that the overall profitability of the companies should not exceed 15% of the 'capital employed' in the business which was to be net of excise duty and sales tax. The DPCO-70 was mooted to control profitability of pharmaceutical companies through control of prices of formulations. The pricing formula for the finished formulations was worked out essentially by adopting a procedure as described earlier; by adding together on "actual" basis, the costs of raw materials (RM) with overages, cost of packing materials (PM), the cost of manufacturing also designated as the conversion costs (CC) and the packing operations costs also designated as the packing conversion costs (PC). By adding four cost factors , RM+ PM + CC+PC, the aggregate was called as the "Ex-factory" cost per pack. The costs were worked out for the marketable packs of medicines. To the derived "Ex-factory" cost , a "mark-up" was allowed up to 150 % to arrive at the retail selling price to which was added applicable excise duty to arrive at the final retail selling price. This price was to be printed on the saleable pack.

The conversion costs (CC) and the packing conversion costs (PC) were determined in consultation with the then Development Council on Drugs and Pharmaceuticals Industry (DCDPI) and notified in the Official Gazette for different pharmaceutical finished packs. The MC and PM were obtained from the companies, where these 'costs' were certified by qualified Chartered Accountants.

There were extensive discussions on the extent of 'mark ups' up to which this was to be allowed on the 'ex-factory' costs so calculated, among the DGTD, the Directorate General of Health Services (DGHS) and the Ministry of Chemical &Fertilizers; DGTD was of the view that a mark-up of 75% on the 'ex-factory' prices were to be frozen, which was arrived at by DGTD by studying the Tariff Commission Report. As the industry represented to have an option of liberal mark-up up to 200% on the 'ex-factory' price and as the industry insisted through the DCDPI; two separate options were eventually arrived by the government as the best options to tackle the situation, which were then notified[72]. According to one option, "mark-up" up to 75% on the 'ex-factory' costs could be chosen by the companies and the MRPs of the formulations sold by them would not

attract government scrutiny; nor those companies were suppose to approach government for price fixation. They would have only to declare that they had adopted 75% option to submit their price-list to the government; if required, government could check prices of any of the formulated pack. According to the other option, a mark-up of up to 150% could be allowed to fix the prices of all of the formulations. However, they would have to apply to the government with cost sheets of each formulation and only after obtaining a clearance from the government; the price lists could be prepared and submitted to the government.

All the MNCs and most of the Indian companies opted for the "mark-up" of up to 150% on the ex-factory cost; only a few Indian companies, especially those from the eastern sector of India opted for 75% "mark- up".

By the enactment of the DPCO-1970, government anticipated that pharmaceutical formulators would be able to earn 'reasonable profits' on their net sale value even though the prices of most of the then existing formulations of the MNCs were reduced. It was the hope and expectation of the government that by the enactment of DPCO-1970, the profits would be brought down to reasonable levels. "Reasonable profits" were considered to be up to 15% return on capital employed.

After some period after the promulgation of the Order of DPCO-1970, an informal study carried out by the government indicated that most companies made profits of more than 15% of their 'capital employed' in the business. This situation was not taken with ease by a large section of vocal people of the country, including several Parliamentarians and therefore, there was a need to revise provisions of DPCO-1970.

HATHI Committee Report[56]

In the learning process, therefore, Government decided to make further amendment to its policies included in DPCO-1970, and a committee was constituted in February 1974 under the Chairmanship of Mr. Jaisukhlal Hathi, who was then a Member of Parliament (MP). Several other MPs as also some experts were inducted as Members. This Committee was popularly known as the Hathi Committee. The Committee was to study the status and the progress made by the pharmaceutical industry, the roles of public sector units, the growth of Indian industries and the capabilities developed by such industries including the small- scale industries, the pricing of drugs, the adequacy of and the also the quality control measures adopted by the industry etc. In April 1975, the Hathi Committee submitted its Report to the Government. The Hathi Committee made 224 recommendations in its Report! The recommendations highlighted once again that the public sector units should play a leading role in producing

bulk drugs in the country, which were needed in high tonnage quantities and where large -scale production would be economically preferable. The R&D units of public sector should be strengthened and such R&D laboratories should establish closest liaison with the National R&D institutes and other institutions including educational institutions so as to develop high scientific capabilities and competence in industrial projects. The Report also emphasized that the Indian private sector should be given preference for growth over foreign companies. Further, price control on drugs should be broader on wider basis where more essential drugs should be available at cheaper prices. The Hathi Committee also recommended that a National Drug Authority should be set up which would lay down and coordinate policies, which were to be implemented to strengthen pharmaceutical industry. In this context, the observations made by the Hathi Committee in its Chapter III on Public Sector needed to be flagged, which were as under:

> **"***2. The public sector has to play an important role in the industrial development of the country. Subject to the overall consideration of resources, the programme in the public sector envisages further expansion in the high priority field to fulfill the gap and correct existing imbalances in the industrial structure to meet the social needs of the country. The Industrial Policy Resolution, 1956, takes into account the need to prevent monopoly and concentration of economic power in the hands of a small number of individuals.*
>
> *3. The Committee notes that the public sector has achieved an overall production of substantial capacity particularly in the field of synthetic drugs, and has demonstrated the competence of this sector to handle the growing needs of the country in this highly technology-intensive area of drug production.*
>
> *4. In order that the public sector may enter the field of manufacture of basic drugs and formulations in a big way, as is recommended in this chapter, with a view to making essential medicines available to large masses of our people at reasonable prices, it will be necessary to remove some of the constraints and deficiencies in the public sector units.*
>
> *5. The Committee has suggested measures necessary to make the public sector more efficient, in respect of organizational set-up, and management patterns, taking into consideration the deficiencies, difficulties and disabilities from which the public sector units are suffering at present The Committee has also suggested the areas in which the public sector should expand so that it can effectively serve the objectives and attain a commanding height in the manufacture of*

bulk drugs and formulations. Measures have been suggested to bring about technological improvements and for appropriate organization of research and development in the field of drug industry. The importance of utilizing various public sector laboratories and institutions has also been dealt with. In view of the fact that this sector must grow in magnitude to fulfill national needs, the Committee has suggested the establishment of National Drug Authority (NDA), a central organization, which will lay down and coordinate the policies of manufacturing programmes, as well as the sale and distribution systems of the products produced in public sector units……

*6. Pattern of production of the dominating units in the private sector, which consists predominantly of multi-national subsidiaries or their branches or their equity partners in India indicates that the primary objective of these units were trade based almost entirely in the economically preferable area of formulations from bulk drugs, largely imported from their principals, rather than on the production of the bulk drugs themselves. Government, therefore, decided that, in the interests of the health and well-being of the people of this country, more units for the production of drugs be started in the public sector.***"**

It can be seen from the above that Hathi Committee anticipated the PSUs to steer production of bulk drugs in the country in all areas of requirement. However, in no part of the Report, there were recommendations on how to protect the PSUs from financial losses. It was also not been explicitly recommended as to how the PSUs could play a dominant role in entering into the trade sales of formulations where profitability margins were high.

Following the Hathi Committee Recommendations, the Drug Policy-1978 and Drugs (Prices Control) Order, 1979 (DPCO-79) were promulgated.

(ii) Drugs Policy -1978 and DPCO-1979

The Drug Policy-1978 and the DPCO-1979 were evolved by the Government essentially based on the recommendations of the Hathi Committee.

The Drugs Policy -1978 aimed at maximizing production of bulk drugs locally, providing leadership to the PSUs ,reduction of imports of bulk drugs , encouragement for growth of local industry and reduction in selling prices of essential drugs and their formulations. The Policy had an interesting feature of "production of bulk drugs by high technology" which compelled MNCs and large Indian companies to produce newer bulk drugs with the objective of marketing formulations thereof from the "basic" starting materials . The "basic "starting materials were either available locally or could be produced utilizing local materials.

Through DPCO-79[73]price control was imposed on 370 bulk drugs and formulations made therefrom. DPCO-1979 was promulgated on 31st March 1979.

For fixation of prices of formulations of different categories indicated to treat specific disease and ailment conditions of Indian people, the bulk drugs were required to be graded depending upon their relative usefulness to treat diseases. Consequently, based on the recommendations of the Hathi Committee, the bulk drugs were classified into three categories based on their therapeutic efficacies, and the three categories made there from were authorized three different levels of mark-ups for the fixation of prices of formulations manufactured there from, namely

- 40% for the most essential categories, which were sorted as Category I of the Third Schedule of DPCO-1979;
- 55% for the next most essential categories, placed at Category II of the Third Schedule;
- 100% for the third most essential categories as placed at Category III of the Third Schedule.

The Category I bulk drugs were identified with their names, and they were 23 in number;the Category II bulk drugs also identified with their names were 20. In case of the Category III bulk drugs, their names were to be collated from many specified therapeutic groups. The diverse curative groups included in the Third Schedule of Category III bulk drugs along with their respective counts (indicated in brackets) were as under: Anesthetics, General and Local (12); Analgesics and Antipyretics (12); Anthelmintics (7); Antiamebic drugs (10); Anti-asthmatic and Enteric Antiseptics (8); Antibiotics (30); Anti-Cancer Drugs (15); Anticoagulants (5); Anticonvulsants (3); Antidiabetics (6); Antihistaminics (31); Antileprotic Drug (1); Antimalarial Drugs (2); Antirheumatic (5); Antiseptics (8); Antispasmodics (5); Anti-tubercular(5); Cardiovascular drugs including Antihypertensive (8), Peripheral Vasodilators and Coronary (9), Cardiac Glycosides (3), Others (5); Vasodilator (9); Diuretics (13); Drugs used for Calcium therapy (4); Haematinics (6); Oral Contraceptives (6); Opthaimological Preparations (7); Oxytocies (2); Plasma Expanders and Transfusion Solution (6); Sera and Vaccines (12); Drugs used for treating UrinaryTract Infection (3); Vitamins (12); Antacids (11); Antigout drugs (2); Disinfectant (1); Antitussives and Expectorants (7); Dental products other than those containing local anaesthetics (2); Dermatological preparations not containing antibiotics, sulphonamides and cortiosteroids (14); Parasympathomimetics (5); Other Anti-infectives (14); and Central nervous system stimulants (1). The total number of bulk drugs aggregated to 327 in Category III.

All the bulk drugs included in the three Schedules (Category-I+II+III) cumulated to 370;the formulations of which were price controlled as per DPCO-1979. The formulations made from these 370 bulk drugs represented more than 80% of all formulations in value terms introduced in the Indian market. DPCO-1979 had thus put a price control on a substantial part of the turnover of the pharmaceutical industry.

The 'fair selling prices' of all the bulk drugs were fixed by the government. By using the fair selling prices of the bulk drugs, the retail prices of the formulations of the three categories mentioned above were fixed by using a formula similar to the ones used and discussed earlier—**R.P. = (M.C. +C.C. +P.M. +P.C.) X (MU+100)/100 + ED**: where **RP** meant retail price of the formulation pack; **MC** meant material cost and included the cost of drugs (APIs) and other pharmaceutical aids used including overages, if any, and process loss thereon in accordance with such norms as were specified by the Government ;**CC** meant conversion cost; **PM** meant the cost of packing material including process loss thereon ;**PC** meant packing charges and **MU** meant Mark-up in percentage for working out the 'fair selling' prices .**ED** meant excise duty. The retail prices of the formulations of all the three categories were inclusive of excise duty.

The rest of the bulk drugs other than the 370 mentioned above were kept out of the price control, and formulations thereof were also not under price control.

In the case of the imported formulations, the prices were fixed differently. In case of an imported formulation, the landed cost was to form the basis for fixing its price along with such margin as the Government would allow from time- to- time. Where an imported formulation was repacked, its landed cost plus the cost of additional packing material and packing charges incurred as worked out in accordance with such norms as were specified by the Government by notification in the official Gazette. Usually, a maximum margin of 50% on the landed costs was provided for fixing maximum retail prices (MRPs).

In addition to price fixation of the finished formulations of various kinds, the DPCO-1979 also brought in the following other major new concepts.

The concept of *fixing the retention price and pooled price* for selling a bulk drug which was either imported or produced in the country was introduced. When bulk drugs were imported, their prices were also fixed following a rational cost-accounting working method.

The concept of *fixation of leader prices* of formulations for all manufacturers of such packs of formulations was introduced so as to bring in more price competition and price efficiency.

A provision was introduced by the name and style *Drug Prices Equalization Account (DPEA)* for collecting excess amounts from companies if these had utilized bulk drugs produced at lower prices than the prices allowed/considered for price-fixation in their formulations. While DPEA was established to promote domestic production of bulk drugs through the system of retention price, its implementation created different kinds of administrative problems; the resolution of which was complex. This also created distrust and anguish among many of the industry members. The result was that after enactment, several court cases were to be settled by the government.

Provisions in DPCO-1979 were made for *encouraging R&D activity* by way of exempting the prices of locally conducted research and R&D-developed new products from control. However, such measures were not considered adequate by the industry to invest on R&D on a sustained manner, and therefore, the R&D investments were low in the industry when compared with the investments in the developed countries. Even then a large number of these bulk drugs were being produces/synthesized locally and consumed in manufacturing formulations in India, but as such the business was profitable. Production of already patented drug molecules was allowed in India if the process adopted was novel. Indian companies therefore developed innovative manufacturing processes and were satisfied with low profit margins; most such companies adequately made up in their profitability by producing and selling formulations manufactured from their own bulk APIs. This process is continuing up to the present time.

(iii) Decade of 1980: Drugs Policies & Price Control Measures

As mentioned previously, during the DPCO-1979 as many as 370 APIs and their formulations were under price control. The Indian pharmaceutical companies witnessed the lowest phase of profitability during following years of early 1980s. The PSUs had undergone losses or considerable reduction in profits. The MRTP provisions restricted large Indian companies to obtain license for the production of new bulk drugs and formulations thereof. The MNCs were also not in a position to introduce new drugs because of multiple and stricter regulatory hurdles. Further, as the profits of MNCs lowered, their interest to operate in India came down. Their interests further negated down because of restrictions in the sale of maximum volume of formulations in value terms, wherein maximum limits of the value of formulations sale were tied with the values of basic production of APIs through regulatory compulsions. A growing environment of dissatisfaction and frustration started to erupt and brew in the industry .The whole situation of the pharmaceutical industry needed a closer look by the Government and then the policies necessitated a review.

Drugs Policy 1986[74]

The National Drugs and Pharmaceuticals Development Council (NDPDC) undertook a study to review the Drug Policy 1978 and DPCO-1979 during 1983. A steering committee was set up to oversee policy changes and reporting to NDPDC. The recommendations of these studies were taken into consideration by the government while the New Drug Policy 1986 was formulated. The basic approach of the 1986 Policy, however, was borrowed from the Hathi Committee Report where the approach of selectivity in the system of licensing and pricing regulations was contemplated as is discussed briefly below.

For authorizing new business, the companies in different sectors were treated differently. FERA companies could choose to obtain licenses in respect of those bulk drugs which were required by the country from the objective of better health-care management, and a list of bulk drugs for licensing for FERA companies was brought out. A total of 65 bulk drugs[75] were enlisted in the policy, where the FERA companies would be eligible to seek new licenses; entry at serial no. 64 of the list mentioned "anew drug for which the company conducted clinical trials and obtained Drug Controller's approval" implying thereby that all new drugs that would be brought to India for usage would also be under price control. The policy also enumerated that the FERA companies would be eligible to take up manufacturing of bulk drugs in the list in a phased manner; ultimately requiring production of those from the basic stage. The related formulations when produced and marketed by FERA companies would have to conform to the ratio of 1:4; implying that if the production value of bulk drugs was rupee one then the formulation turnover could go up to four times in monetary values.

For companies other than FERA, these would be eligible for industrial approvals of all bulk drugs subject to sectoral reservations for public and small-scale sectors. There were certain other provisions of relaxation including broad banding in licensing policy. A list of 15 bulk drugs requiring heavy investment was reserved for the public sector[76;] at that time, no private company was willing to invest in this.

While government decided to bring in some relaxation in pricing structures of certain essential bulk drugs as well as their formulations, the local production of bulk drugs was to be increased and investment for production encouraged. For encouraging production of bulk drugs in the country by different sectors of companies, a ratio was announced between the ex-factory cost of production of bulk drugs to the ex-factory cost of formulations. As mentioned earlier, for FERA companies, the ratio parameter between the bulk drugs and formulations was 1: 4; for large Indian companies having turnover of more than Rs 25 crore

(Rs 250 million), it was 1:5; for Indian companies with turnover between Rs 10 crore to Rs 25 crore, it was 1:7; and for Indian companies having turnover of less than Rs 10 crore, it was 1:10. This policy provided encouragement for the development of bulk drugs by a large number of Indian companies.

The essence of the policy was to improve local skills in manufacturing and to make India move towards import substitution, and to use maximally locally available basic materials.

After the 1986 Drug Policy, Government promulgated the Drugs Price Control Order 1987 (DPCO 1987).

DPCO-1987

With the promulgation of the Drugs (Prices Control) Order, 1987, the earlier DPCO of 1979 was superseded. As per the DPCO 1987, two categories of formulations and bulk drugs (required to make such formulations) were promulgated to be price controlled, wherein Category I would consist of drugs required for the National Health Welfare Programs. For Category I formulations manufactured by using Category I bulk drugs, a mark-up of 75% of the "ex-factory cost of formulations" was contemplated. Another category designated as Category II drugs was announced where the formulations made from the list of Category II bulk Drugs, would be up to 100% of their "ex-factory cost".

The new regulations were drawn out so as to conform to the principles recommended by the Hathi Committee.

The terminology of "mark-ups" was changed to Maximum Allowable Post-manufacturing Expenses (MAPE). For identifying the Category II bulk drugs, Kelkar Committee was appointed in March 1987; the Committee took into consideration five "excluding principles" for selecting bulk drugs, which were to be included for price control. The excluding principles were (a) where the bulk drugs were not produced in India but the formulations were approved for sale, (b) where the turnover of the formulations assessed from available information was less than Rs 50 lakh, (c) exclusion of those new drugs and their formulations for which technologies have been developed indigenously, (d) identification of such life-saving drugs whose availability was more important than the price of their formulations and (e) the production structure of drugs was sufficiently competitive to prevent possibility of overcharging of formulations thereof. Based on the exclusion principles, the Committee prepared a list of bulk drugs to be price-controlled and submitted its Report in August 1987.The list of Category-II bulk drugs was notified thereafter based on Kelkar Committee report and included in the Drugs (Prices Control) Order 1987 (DPCO-1987). The DPCO-1987 was promulgated to have 27 bulk drugs in Category-I and 139 bulk drugs in Category-II; totalling to 166 bulk drugs[77].

One study indicated that DPCO-1979 covered 80% of the formulations sold in the market as price controlled while DPCO-1987 embracing 166 bulk drugs and their formulations constituted covering 60% of the formulation market under price control[78].DPCO-1987 was a 'relaxation' in controlling prices of pharmaceutical formulations from DPCO-1979.

(iv) Decade of 1990s: Drug Policies & Price Control Measures

In view of the growing dissatisfaction among the operators of the Indian pharmaceutical industry and the fast devaluation of rupee, Government of India appointed a Standing Committee in the Ministry of Chemicals and Fertilizers in February 1990 to review Drug Policy 1986 and DPCO-1987. Consequent on the study and recommendations of the Standing Committee, government came out with a revised policy.

Drugs Policy 1994 and DPCO-1995

The Government of India came out with a new policy, which was New Drug Policy-1994 and the Drugs (Price Control) Order, 1995 (DPCO-1995), the salient features of which were as under[79,80].

- in line with the liberalized industrial policy, the national drug policy was also restructured focusing on industrial and trade dimensions to promote competition, ease liberalization and protect intellectual property in a more comprehensive manner. A regime of intellectual property rights on patented products was introduced instead of the earlier process patent regime, which was to come into force from01.01.2006, in conformity with Trade Related aspects of Intellectual Property Rights (TRIPS) of World Trade Organization (WTO), to which India became a Member from 1st January 1995.
- the earlier years of price control on pharmaceutical formulations were substantially reduced and only the formulations of 74 bulk drugs were decided to be price controlled.
- the equity ownership of MNCs was substantially amended to enable holding of more portions of foreign equities in ownership of the business
- substantial relaxation was made in production, licensing, imports & exports and in retaining of higher profit margin of companies in all sectors
- prices of the formulations were to be calculated using a pricing formula, which was precisely similar to the one announced earlier— **R.P. = (M.C. + C.C. + P.M. + P.C.) x (1 + MAPE/100) + ED**.

In the above formula, the term **"MAPE"** was introduced, replacing **"MU"**. The term "MAPE**"** was defined as **'**Maximum Allowable Post-manufacturing Expenses'.

Study of the price change of certain medicines carried out[81] from 1994 to 2004 revealed that formulation prices which were under price control tended to be either stable or gone down . Certain formulations in the price controlled category had however registered price increase, and included formulations of streptomycin, sulphadoxine and framycetin sulphate. In the price decontrolled category, the price increase was sharp and upwards during the period. The price increase was registered in therapeutic category for anti-diuretics, cardio-vascular drugs, anti-allergic formulations, peripheral vasodilators and antileprotics. The study revealed that the price of essential decontrolled drugs in most cases moved upwards. In Indian context with private dominance of health services and financing of medical expenses done from private out-of-pocket savings, this situation was far from what common masses had contemplated.

In the meantime after the promulgation of the DPCO-1995 and assessment of the condition of the pharmaceutical industry, Government of India decided strengthening R&D base of the pharmaceutical industry and reviewed the current drug price control mechanism to assess if alternative models from the current procedures could be considered for price regulation of formulations. In this context, two separate committees were constituted in 1999.

1999: Pharmaceutical Research Policy & Price Control Policy Review Committees

In a radically new way of thinking, Government of India explored if the existing ways of determination of the fair selling prices could be done away with. In pursuance of such lines of thinking, two committees — the Pharmaceutical Research and Development Committee (PRDC)[82]and the Drug Price Control Review Committee (DPCRC)[83] —were set up by the government in 1999. PRDC was constituted to study and identify events and procedures which were required to strengthen R&D base of the pharmaceutical industry. The DPCRC was constituted to review the current drug price control mechanism and to suggest alternative models with a view to reduce rigors of price control. PRDC submitted its Report to the Government in 1999[84]. According to this report, the low level of profitability in the pharmaceutical industry combined with the comparatively small size was the reason for low investment in R&D. The Report identified certain priority areas for Indian R&D. It emphasized the need for upgrading the human resource in skill development and in acquisition of latest tools for R&D. It further cited opportunities for India for clinical trials because of population size and availability of more patients. It also emphasized the need for strengthening and modernizing Indian system of medicine. The PRDC also felt the need for maintaining higher levels of IPR management for strengthening IPR system with action points for the government, judiciary,

industry, S&T and educational system. The Committee also recommended creation of newer structures for the Central Drugs Standard Control Organization (CDSCO) to supplement its effort towards compliance with global regulatory requirement pertaining to quality, efficacy and safety of medicines. PRDC also suggested methods to generate funds for conducting R&D vigorously. PRDC did not, however, prepare any quantitative or semi-quantitative road map for the discovery of newer classes of APIs; starting from drug discovery to full drug development strategy to clinical research to introduction in the market. It is recognized globally that nearly 10-12years are needed to come to the stage of marketing a new drug, starting from the stage of developing newer concepts.

DPCRC[85] in its recommendations stated that the system of product-based price control which was in vogue should continue with simplified methodologies and procedures to take cognizance of the liberalization ushered into the Indian economy. The guiding factors to identify specific drugs were to be based on mass consumption, and even in the absence of adequate competition to include important drugs needed for national health programme. The committee also suggested that where 'per day' cost of treatment was not more than Rs 2/- be taken out of price control. It suggested that the turnover level of Rs 40 million stipulated in the Drugs Policy, 1994 be reviewed and updated. DPCRC also suggested an alternative method of instituting price control based on the brand-wise sales turnover of formulation in various categories as was available in the ORG-MARG[86,87] reports. In that case, the minimum moving annual total (MAT) sale value of a brand for determining the criteria of mass consumption should be considered as Rs 100 million. It also recommended exclusion of multi-ingredient based brands and Ayurvedic formulations from price control. The Committee further mentioned that for determining the price of bulk drugs, one has to have access to the confidential information of companies, and this needs to be avoided as the product patent regime has been reintroduced in the Indian patenting system. The Committee recommended that the prevailing market prices (MRP) of formulation packs could be taken into consideration, and price control may be instituted using the prices of brand leaders as the benchmark prices. In that case, there would be no need to go into the cost of production of bulk drugs. The Committee felt that market forces would be a better method for controlling maximum selling prices of formulations Also. It recommended that the Government policy should move away from the price-controlled regime to price-monitoring regime. The Committee further recommended that adequate health insurance cover should be instituted by both the public sector and the private sector so as to become less dependent on price control measures for obtaining medicines. The Committee in addition recommended for an expanded public health-care progressively by raising budgetary provisions and

by improving supply of essential medicines s to improve the public healthcare system of the country.

DPCRC method of determining prices of bulk drugs

The DPCRC suggested as an alternative method for determination of prices of bulk drugs; the price could be ascertained by consulting the **purchase documents/ information from the drug industry journals, purchase documents of the producers of formulations** etc. This method would avoid having exposure to the confidential information of *processes and operations data* of the production of bulk drugs, which at the earlier existing system of cost studies was exposed to investigators. For the imported bulk drugs, the import data available from the Directorate General of Health Services (DGHS), the Central Exercise authorities or the Annual Cost Audit Reports would have to be consulted.

DPCRC method of selecting list of bulk drugs to be price controlled

The DPCRC further mentioned that there existed in the ORG MARG Report approximately 180 groups/ categories of pharmaceutical formulations, and therefore, the 'mass consumption' formulations could be identified from groups/ categories. The groups/categories of formulations were worked out as per their clinical/therapeutic / chemical classification methods, and represented broad categories of pharmaceutical formulations that were to be used to treat different medical conditions. The DPCRC was of the opinion that to start with and to determine the annual sale value of the leader brand formulations, the data of the March 1999 issue of the ORG MARG Report, containing the MAT data for 1998-'99,should be taken into consideration. The DPCRC suggested that specific bulk drugs which were used for the manufacture of "mass consumption" formulations could be identified by the above manner, and such bulk drugs could be put under price control as they were also therefore of mass consumption nature. Once the list of bulk drugs was made out, the low cost drugs could be eliminated from price control on the basis of "per day cost of a medicine" worked out based on the MRP of the top selling pack of the brand, which enabled identification of bulk drug. For taking out the bulk drug from price control, the criterion should be that the 'per day cost' of the medicine should not exceed Rs 2. The DPCRC recommended that by this method of data generated from the ORG MARG Report, the **new list of bulk drugs,** if price controlled in future, could be worked out.

DPCRC suggestions of price control of pharmaceutical formulations

The DPCRC suggested that instead of the existing system of price control of pharmaceutical formulations, a new system could be introduced. In the alternative procedure, the DPCRC suggested to take into consideration prevailing

maximum retail prices (MRPs) of those formulations prevalent in the market as the 'bench mark-prices', where the formulations had registered a MAT sale value of Rs 10 crore (Rs 100million) or above with a market share of 10% or above in the group/category of formulations to be price controlled because such formulations represented, according to the DPCRC , to mass consumption category.

The DPCRC suggested that instead of carrying out price control on bulk drugs, the prevailing MRPs of the formulation packs containing any of the bulk drugs identified for price control be taken as the benchmark price and notified. The revisions of MRPs where required could be allowed linking notified prices with such other Government notified factors to be used as measures for inflation such as the Consumer Price Index (CPI) of the industrial workers/ agricultural labors etc. According to DPCRC, such a method would provide automaticity in the price fixation method formulations.

If the MRPs of the formulations thus selected were declared by the government then all the other manufacturers would fall in line and would fix prices of their formulations taking into consideration the MRPs of the identified formulations. This would be a simplified procedure for instituting price control methods by the government. This procedure would require only the identification of the leader brand of 'mass consumption'.

The DPCRC, however, cautioned that the price of new introductions of formulations with different pack sizes and with different compositions/strengths than those notified as benchmark formulations would need to be fixed afresh, thereby rendering system more complex. Therefore, the DPCRC cautioned that some new approach needed to be adopted to tackle such situations. The DPCRC was of the view that the suggestions made above, if implemented, could be re-examined for its feasibility before "the TRIPS provisions coming into existence".

The DPCRC therefore suggested the then existing method of price control as was described in Para 7 of DPCO-1995 could continue for the time being.

The DPCRC further recommended that an additional 8% cost be allowed for formulations manufactured under WHO GMP certification, and further, another additional 2% be allowed for improved packaging material usage. In addition, a further 3% of the ex-factory cost should be allowed for enabling companies to upgrade their manufacturing premises to meet the US FDA/MCA standards, which was considered to be the highest standard of manufacturing and documentation for pharmaceutical formulations.

Other DPCRC recommendations

The DPCRC also recommended that the price control method then existing in the

country should move away from the **"controlled regime"** to the **"monitoring regime"** over a period of time.

The DPCRC further recommended that good manufacturing practices (GMPs) prescribed under the rules needed to be established rigorously in all the manufacturing units over a period of two years so as to minimize manufacturing sub-standard and spurious drugs. The DPCRC recommended that the WHO-GMP standards should be made a basic criterion for granting a drug license to manufacture a drug in the country.

It further recommended that Government should develop a **data bank** on pharmaceutical sector and devise a simplified format in the DPCO to collect information. DPCRC also recommended that the availability and price situation of formulations in the market should be reviewed periodically with meetings with the consumers' interest group, industry and trade. Further, recommendations were that for import of formulations falling under the price-decontrol category to be monitored effectively according to a format prescribed in the existing DPCO.

Obviously, it was clear that the recommendations of the DPCRC were biased towards the interest of the industry.

The next pharmaceutical policy was formulated by the Government in 2002, which drew heavily from the PRDC and DPCRC reports and recommendations. This policy proposed a radical shift in the price control of pharmaceutical formulations from a price "controlled regime" to a price "monitoring regime". In this policy, the span of price control was to be reduced substantially even though the policy was to cater to the interest of the weaker sections of the Indian population in supply of medicines.

(v) 2002-Pharmaceutical Policy

The Pharmaceutical Policy 2002 was announced[88]on 15 February 2002. It was framed keeping in view the philosophy that the span of price control over drugs and pharmaceuticals would be substantially reduced. The earlier regime of rigors of price control, according to the policy, was required to be reduced in the back drop of global scenario of faster growth of capitalistic open-market economy. The process of liberalization set forth by the government in 1991 required reduction in the scope of enforcing non-tariff barrier to imports and substantial change in the then existing legal instruments; existing for industrial licensing, foreign investment and regulation of foreign technology agreements.

For identification of specific bulk drugs according to the policy for price regulation, the sale value of formulations requiring consumption of such bulk drugs were identified using information published by ORG-MARG on "Retail Store Audit for Pharmaceutical Market in India". The selection of bulk drugs

was made from the 279 Essential Drugs in the National Essential Drug List of 1996; another 173 medicines were picked up by the Ministry on the ground of their use in various health programmes. The ORG-MARG data of March 2001 was used as the basis for determining the span of price control. The procedure for utilizing MAT values of ORG-MARG data for formulations in respect of bulk drugs identified has been detailed. Bulk drugs would be kept under price control for the formulators if MAT value in respect of a particular bulk drug was more than Rs 25 crore and the percentage share of formulations (manufactured from the bulk drugs) was 50% or more; or the MAT value of bulk drugs was between Rupees 10-25 crore and the percentage share of any of the formulations (made from the bulk drugs) was 90% or more. All formulations containing a bulk drug, as identified through MAT value as above, would be under price control. There were pharmaceutical formulations where the costs incurred to the consumer (patient) did not exceed Rs. 2 per day. Such formulations were to be taken out of price control. The monitoring system would have to move away from the price "controlled regime" to a price "monitoring regime". The National Pharmaceutical Pricing Authority (NPPA) would be revamped and reoriented for monitoring. The NPPA would be entrusted with price fixation/ price revision and would be empowered to take final decision. In accordance with this policy, the list of "essential bulk drugs" was found to be less than 30 in number. All other bulk drugs were therefore not anymore 'price –regulated' or 'price –protected' as per this policy. The formulators could procure those for their own consumption from any source, local or imported. The import of bulk drugs was regulated through the government's EXIM policy in force.

As per the new Policy , the price of any "Scheduled formulation" as defined in Drugs (Prices Price) Control Order 1995 was to be determined, notified and controlled as per the then existing practices. The " Scheduled formulation" meant, as defined in the above Order of 1995 " the "formulation containing any bulk drug specified in the First Schedule either individually or in combination with other drugs, including one or more than one drug or drugs not specified in the First Schedule except single ingredient formulation based on bulk drugs specified in the First Schedule and sold under the generic name". There were 75 bulk drugs in the first schedule of the above Order of 1995.

Indian opinion-makers did not welcome the Pharmaceutical Policy 2002

A large section of the general Indian public did not like the policy. It was being perceived that the policy was becoming more industry-friendly, and was likely to result in drastic increase of prices of medicines required by the common man. A Public Interest Litigation (PIL) was filed in Karnataka High Court by Lt. Col. (Retired) K.S. Gopinath and B.V. Bhaskar, both from Bengaluru, against

Union of India through its Secretary, Department of Chemicals and Fertilizers and Others praying under Article 225 of the Constitution of India to produce all records of the Pharmaceutical Policy 2002 and quash the same on the ground that the policy had been framed like a business policy and on enforcement it would take away life-saving and essential medicines out of the ambit of the Drugs Price Control Order, which would be highly detrimental to public interest. Karnataka High Court, based on the PIL, issued a stay order directing Government not to implement the Pharmaceutical Policy 2002[89].

The Central Government challenged the stay and appealed to the Supreme Court of India against the stay, ordered by the Karnataka High Court. The Supreme Court on 10.03.2003 had lifted the stay but directed the Indian Government to evolve criterion such that the essential life-saving drugs do not fall out of price control[90]. While lifting the stay, the Supreme Court directed that Central Government may evolve such procedures and criteria that the essential life-saving drugs were not to fall outside the price control. Relevant portions of the Supreme Court order read as under:

> ***"Meanwhile, 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 price, control and further directed to review drugs which are essential and lifesaving in nature till 2nd May, 2003."***

In the environment of conflict between the control and availability of essential formulations at affordable prices to the Indian public and introduction of open market policy for enabling the prices of formulations to get fixed based on market competition, the Government of India came out with its latest Drug Policy of 2012 and DPCO 2013.

In the meantime, in April 2009 the government through the Pharma Advisory Forum of the Department of Pharmaceuticals had initiated creation of cheaper medicine shops for the sale of 'generic' drug formulations through its "JAN AUSHADHI CAMPAIN". The selling outlets created through this campaign are popularly known as the Pradhan Mantri Bharatiya Janushadhi Kendra, and have been set up in various parts of the country. An implementing agency had also been created for by the name 'Bureau of Pharma PSUs of India' in April 2010. This agency was to make quality 'generic' medicines available to the Pradhan Mantri Bharatiya Janaushadhi Kendra shops. Procurement of such medicines would be from the PSUs and private sector industries. Such Janaushadhi Kendras are already in operation, and the efforts are indeed praiseworthy[91,92,93] though such efforts have not yet made significant impact on the private out-of-pocket expenses

on medicines purchased by the common Indians. The number of Pradhan Mantri Bharatiya Janaushadhi Kendra shops in the country is not adequate, and often needed medicines, prescribed by the doctors, are not available.

(vi) National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012) and DPCO-2013

Government of India could not implement the Pharmaceutical Policy 2002 because of the directives of the Karnataka High Court, followed by the Supreme Court order as mentioned earlier. The Drug Policy 1994 and DPCO-1995 continued to be in vogue till a new policy made out in keeping with the directives of the Supreme Court Order was formulated. Up to that time, before a new policy was announced, the prices of the price-controlled formulations were calculated utilizing the formula of DPCO 1995 and using CCs and PCs as notified by the Government from time to time. The CCs and PCs were notified last time in 2011[94.]

The new National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012) was notified[95] on 07.12.2012. The key principles for regulating the prices of essential drugs were identification of 'essentiality' of medicines/formulations by certain criteria, intent to control the prices of essential pharmaceutical formulations only and not the bulk drugs used in the making of such formulations, and other non-essential formulations too; and that the prices of essential medicines were determined based on 'market based' information.

The NPPP-2012 was essentially the 'modified' concept of Drug Policy-2002 where the intention announced was to control the price of 'essential medicines' based on the market capture of such formulations as determined and published by reputed private organizations like the ORG-MARG utilizing the MAT values of essential formulations in each therapeutic category.

DPCO-2013

The DPCO-2013 was notified on 15May, 2013 by the Ministry of Chemicals & Fertilizers (MoC&F) [96]. The details for calculating the ceiling of maximum retail prices were spelt out in the DPCO. The formulations listed as 'essential medicines' in DPCO-2013 were chosen from the National List of Essential Medicines (NLEM)[97]. Such medicines were listed in Schedule-I of the notification. The DPCO 2013 in its Para 2(i) defined the term "formulation". According to the definition, "formulation" meant a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease and, but should not include– (i) any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines;

(ii) any medicine included in the Homeopathic system of medicine; and (iii) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) did not apply. All the prices to be fixed under DPCO 2013 would be implemented through the NPPA[98]. The details of how the prices of Schedule I formulations were to be calculated as per DPCO-2013 are complex and appended in Annexure-I.

In addition to the calculations of the prices of price-controlled formulations, two other aspects of the DPCO needs highlighting as enumerated below:

Para 7 of the notification defined the margin to be paid to the Retailer while Para 8 narrated the details about the maximum retail price that was to be fixed for each scheduled formulation.

The DPCO-2013 empowered NPPA to determine and fix prices of Non-Scheduled formulations also as per the procedures given below:

Pricing of non-scheduled formulations as per DPCO-2013

The NPPA was also empowered to monitor the Maximum Retail Prices (MRP) of all drugs, including the non-scheduled formulations. This ensured the Government that no manufacturer could increase the MRP of a drug formulation more than 10% of the MRP during the preceding twelve months. If the increase was beyond 10% of the MRP, the NPPA was empowered to reduce the price to the level of 10% of the MRP for the next twelve months. Overcharging was liable to deposition of additional amount along with interest thereon from the date of increase in the price to the government; besides the manufacturer was liable to penalty (Para 20 of the Order had the details).

Other important aspects of DPCO-2013

Besides the pricing aspects of DPCO 2013, there were other important features such as empowerment about deposition of amount resulting from overcharging of prices, requirement of displaying the maximum retail price inclusive of taxes etc. as described below:

Para 23 of DPCO-2013

Government was empowered to order the manufacturer, importer or distributor or as the case may be, to deposit an amount accrued due to overcharging, being the extent of prices higher than those fixed or notified by the Government under DPCO 1987, DPCO 1995 and the provisions of DPCO 2013(Para 23 of the Order had the details).

Para 24, 25 and 26 of DPCO-2013

According to these, every manufacturer of a scheduled or a non-scheduled formulation should on the label of the container display the MRP with the words

"Maximum Retail Price" and should succeed it with the words "inclusive of all taxes". No one was allowed to sell any formulation to any customer at any price above that which was indicated on the label of the container or on the pack.

The DPCO-2013 did not elaborate on how the new method of price control of selected formulations termed as "essential" was better than the earlier cost-based price determination of selected bulk drugs and determination of the price of formulations thereof. It also did not discuss on whether government was going to establish its own information base instead of relying continuously on the ORG MARG data for selecting market leaders.

The Government in the meantime circulated a draft pharmaceutical policy 2017 to obtain the views of a diverse cross-section of interested parties.

(v)) Draft Pharmaceutical Policy 2017

In August 2017, a draft pharmaceutical policy[99] (Draft Policy Paper) of 18 pages was circulated by the Department of Pharmaceuticals (DOP) to different organizations working in the pharmaceutical industry. Certain civil societies were also included.

The Draft Policy Paper within its contents had narrated the role which the government would like to play for easing objectives of providing health- care to all. The document emphasized the need 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'*. The policy formulation area covered was wide and included pricing of drug formulations, selection of additional formulations for price control, distribution of formulations, quality control aspects of marketed formulations as well as patenting issues. The existing NPPA according to the Draft Policy Paper would have an advisory board in which NGOs, medical doctors, pharmacists etc would be members, who would provide assistance to NPPA. On the issues of present marketing strategies of certain companies manufacturing the same drug and selling them with different brand names with different prices, the policy recommended to have "one company–one drug–one brand name–one price." The Draft Policy Paper discussed India's concern of heavy dependence for several raw materials and drug intermediates on certain countries, including China. The paper finally intended to intensify 'ease of doing businesses' in the country and in contributing strongly to the momentum of 'Make in India' dream.

Since following the announcement of the Draft Policy Paper, Government has not yet notified any Executive Order, the Drug Policy 2012 and DPCO 2013 continue to remain in vogue and the industry as well as the general consumers of pharmaceutical formulations would be steered by these orders.

Discussion

The instruments of industrial licensing policy, abetment of monopolistic and restrictive trade practices, regulation of outflow of foreign exchanges, removal of production barrier of bulk drugs by amendment of the Indian Patents act and price control on selected bulk drugs as well as formulations pursued from 1947 up to 1991 enabled development of a strong local API as well as pharmaceutical formulation production base. The creation of the PSUs with emphasis on the production of investment-oriented APIs contributed substantially to the establishment of a culture of Indianization during the earlier years. The shadows of the wars in 1960s and the observation of paltry interest of the MNCs towards setting up of basic establishments for APIs drove conceptualization of earlier instruments.

In a systematic manner for the first time from 1963 onwards, through the promulgation of executive orders for freezing prizes of formulations sold in the market, following the Chinese aggression and later the enactment of the DPCO-1970, the endeavor of the Government was to impose a check on the MRPs of essential pharmaceutical formulations and also a check on the overall profitability of pharmaceutical companies, including e MNCs to curb their profits to "rational extents". The DPCO-1970 was also directed towards rationalizing the prices of formulations. Rationalization of prices meant narrowing down the differences between and among the prices of formulations (MRPs) of the same or of similar composition, marketed in the country. The policies up to this period to up to mid- 1970s could not reduce the profitability of the manufacturers of formulations below the higher end of "rational extent" envisaged by the government. As a result, new efforts and initiatives were taken to enable the Government to curb the profitability, especially of the multinational companies. Hathi Committee Report was the basis for formulating the Drug Policy 1978 and the DPCO-1979. Through this DPCO-1979, price control was imposed on 370 bulk drugs and their formulations, which constituted 80% of the turnover of the whole pharmaceutical industry. The MRPs of all the formulations produced from these 370 drugs were fixed by the government. The 'fair selling prices' of all these were determined by conducting an elaborate technical evaluation and cost studies of bulk drugs manufacturing units, and a fair return was provided to the 'capital employed' for manufacturing each bulk drug by the announcement and the notification of "administered prices" of each of them by the government. This process brought down the prices of the 'price controlled' bulk drugs and their formulations. The overall prices of the pharmaceutical formulations sold in the Indian market were substantially brought down resulting in decreased overall profitability of the entire pharmaceutical industry, including the MNCs.

The effect of profitability reduction could be felt from the later ends of 1970s up to mid-1980s.The "low profitability" of the industry brewed dissatisfaction, and, therefore. on pressures from all corners, including the industry, the move of the Government had been towards modifying legal instrument gradually, moving out towards a gradual less-controlled regime. Price fixation of essential bulk drugs and their formulations continued although their number came down. The DPCO-1987 was promulgated to have initially 166 bulk drugs and their formulations under price control. Subsequently, the number was reduced to 142. The prices of these bulk drugs and their formulations were controlled. The DPCO-1995 brought down the number of essential bulk drugs further to 74. The prices of these bulk drugs and their formulations were controlled through this order. In the meantime, because of India's announcement to adopt the market -driven economy in 1991, the process of liberalization was set in motion, and most of the instruments of the government were being reworked moving towards abolition of industrial licensing, unwillingness for reservation of production of a bulk drug for manufacturing by any specific sector, willingness to allow foreign investment gradually going up to 100%, ease in approval of foreign technology agreement, pushing PSUs to face competition in production of APIs with the imported sources and introduction of amendments in the Indian Patents Law/ Act of 1970.

It is clear that while announcing the Pharmaceutical Policy 2002 on 15February 2002, the Government of India was convinced that the pricing policies adopted thus far required corrections by extending and elaborating policies of lesser controls and more of decontrols. Indeed, these were costly realities to be faced by most common people of the country. Common men looked backward at the outcome of DPCO-1979 and expected the future to emerge on the lines with the past. This did not happen on one hand and on the other hand government used discretionary policy in choosing the APIs and their formulations to be price controlled, which made the general public dissatisfied as the prices of the several medicines increased. The rationality in the formulation of the new policy and DPCOs were not based on comprehensive reports such as the earlier Hathi Committee Report. In framing the newer DPCOs from 2002 onwards, government paid less attention to the recommendations of the Hathi Committee Report and reduced its intent for investing in PSUs either in their expansion or in the creation of newer PSUs. On the top of it, government brought in stringent criteria for efficient performance in the sector requiring increased capacity utilization as well as increased efficiencies in the consumption of material and utilities through the Bureau of Industrial Costs and Prices; a wing created by the Ministry of Industry. To improve upon the efficiencies, the PSUs required investing for procuring better technologies and

conducting much increased level of research and developmental activities; for which adequate funds were not available. The enforcement of efficient criteria for determining the fair selling prices of APIs resulted in substantial shrinkage in the profitability of PSUs in particular while the effect was across the whole industry. Thus , the well-built Indian pharmaceutical industry with its reasonably strong API infrastructure started to show signs of instability as inputs for the production of bulk APIs were rising; thereby pushing costs of APIs being up and in the process most affected were the PSUs. The formulations producing sector survived and indeed some outperformed because of various reasons; important among them were lesser price controls on their products, deployment of cheap labour, both skilled and unskilled, and somewhat cheap cost of infrastructure including pharmaceutical machinery (with less of automation) and lesser cost of ancillaries. However, the pressure on the industry remained high to perform efficiently in the manufacturing of formulations as there existed a fierce competition in the market place.

The enumerated policy of the DPCO-2013 fixing prices of "essential medicines", was a concept borrowed[100]from the World Health Organization (WHO) "to satisfy the priority health -care needs of the population". This concept of "essential medicines" was different from the concept of the "essential drugs" of the earlier Indian concept; as enumerated in the DPCO-1979 and thereafter, where during the earlier times "essentiality" meant a list of bulk drugs and the formulations made there from based on the economic impact/ contributions effected by the bulk drugs in comparison with the total bulk drugs approved and used in the country. The DPCO-2013 identified a basket of "essential medicines" appended in Schedule I of the DPCO 2013 and later amended in 2016, containing a basket of 430 medicines(formulations), covering 74 *therapeutic categories* of products. As assessed by the author, the baskets of 430 numbers of formulations required 371 bulk drugs for their manufacturing. A large number of other formulations including single-ingredient formulations of composition not mentioned in the list of "essential medicines" or multi-ingredient combinations of "essential medicines",which were combination of these 371 bulk drugs not considered as "essential" according to DPCO-2013. For example paracetamol tablets containing 500mg of paracetamol per tablet was "essential" but not 650 mg per tablet; a combination of diclofenac 50 mg plus paracetamol 500mg was not considered as "essential" though each of the single ingredient formulation tablet of these drugs were " essential". It was further ascertained that within these 74 therapeutic categories of products, there existed in total 766 bulk drugs (which were approved by the government for use and sale under the Indian Drugs act) and that their formulations were also approved for marketing in India. Thus, formulations of 395 bulk drugs(*766 minus 371*) falling within

the 74 therapeutic categories were not considered " essential" in DPCO-2013. This resulted in considerable price rise of almost all formulations sold in the open market ,which fell under the "essential" therapeutic category but were not in the list of Schedule-I. Indeed, the basket of 430 essential formulations of DPCO-2013 constituted only 20% of all the formulations marketed[101]in trade and therefore the remaining 80% remained almost out of price control.

The JAN AUSHADHI CAMPAIGN for selling medicines in generic names for providing medicines at cheaper prices by the government to the people was a praiseworthy move but it lacked elaborate efforts. The Pradhan Mantri BharatiyaJanaushadhi Kendra shops could have been expanded, and such shops could be established alongside the post offices all over the country and private medical doctors residing in the vicinity could be teamed up for easing in the writing of prescriptions. Well-designed room with refrigerators and minimum staff of two to three operating in the private sector could be established, who would liaise with the main medicine distribution centers for procurement and teaming up with the medical doctors for facilitating prescription writing and easing treatment. This would however require huge initial investment. If this issue is taken up with whole-hearted sincerity then the use of allopathic medicines in the rural areas is anticipated to increase and people's health in rural areas may improve.

The bulk drugs production industry in India started to have hard time on the promulgation of the policies from 1991 onwards. The Drug Policy of 2002 had made the most severe adverse impact on the bulk drug industry. This policy was a radical departure from the earlier drug policies. This time instead of relying on the fixation of the prices of the bulk drugs by techno-economic-cum-cost studies, it was decided not to 'regulate' the prices of bulk drugs at all but to allow the Indian bulk drugs producing industry to compete freely with the global players. The only protection for a while was by way of regulating free imports of each such bulk drugs produced locally by levying "import duties" on the imported stuff. Here also because of the country becoming a Member of the WTO, India was committed to provide 'equal' level playing ground to international trade and was handicapped to impose excessive duties unless there were compelling reasons. Indeed, the import duties were gradually brought down over years.

From 1991 onwards, the import restrictions and duties levied gradually came down. Concomitantly, the regime of "withdrawal of administered" prices of bulk drugs produced indigenously was getting introduced which was a big blow to the API manufacturers, and this resulted in the close down of several bulk drugs manufacturing units in the country. The earlier vision of pursuing socialistic policies evaporated completely from the political scenario,

and market-driven economy was taking roots. As a result, several bulk drug manufacturing units had to close down as they could not compete with the prices of foreign manufacturers, especially from China. Almost all *antibiotics* produced from the basic stage such as penicillin first crystals, streptomycin, tetracyclines including chlortetracycline, tetracycline and oxytetracycline, demethylchlorotetracycline and doxycycline , gentamycin, and griseofulvin ; *analgesic and antipyretic drugs* such as paracetamol, analgin, ibuprofen and naproxen; *steroids* such as prednisolone, dexamethasone and betamethasone ; *vitamins* such vitamin B1, B-2, B-6, B-12 and vitamin-C ; and a host of other *synthetic bulk drugs* were to be discontinued. According to the author, this was primarily because of increased costs of input materials, including raw materials, petrochemicals, agricultural materials and packing materials in India as also the energy costs (especially the unit costs of power) compared to such costs in many other countries including China though the technologies for manufacturing several of these were comparable with the international standards in terms of input consumption efficiencies. In a few instances, the smaller plants set up in India could not take advantage of reducing costs on the 'overheads' expenses. In addition, the stringent compulsions from the environment protection agencies to follow the regulations on the factory-discharged materials namely the air, effluent water and solid wastes required considerable investments to make the discharged materials to conform to accepted safety standards. The cost to be incurred to comply with the regulation was high, and therefore added considerably to manufacturing cost of bulk drugs.

Many of the bulk drugs in the country were consumed in very large quantities to meet local demand. These included several antibiotics, analgesics and antipyretics, certain other synthetic drugs . A feature of the high consumption bulk drugs is that they became a kind of "commodity chemicals and commodity substances" and international trade on them occurred on high price competition with lower profit margins. Moreover, because of "highly polluting nature" of several of these products, many developed nations have shown preference to setting -up their own units for such products in developing countries or outsourcing from cheaper sources of third parties. While these factors are opportunities for India for setting- up of competitive alternate manufacturing establishments, without government intervention for access to cheaper input materials and energies, these opportunities cannot be fructified. Indeed, India's growing dependence on imports of bulk drugs as well as drug intermediates, the API industry is going to get into more financial and economic difficulties[102].

It is considered prudent in this context to present that even under the existing circumstances, several bulk drugs are being produced in the country, which are locally consumed as well as exported. The bulk drugs industry that survived in the

era of new government instruments were mostly those of being comparatively "high-value" bulk drugs, where prices were high, implying increased margins to producers and further their manufacturing required deployment of complex, closely guarded technologies. In certain instances, the APIs survived because the production costs were favorable to the local industry because of extremely low value products, where imports were not economical e.g. ferrous fumerate, ferrous sulphate, and sodium chloride injectable. Examples of a few 'high value' bulk drugs which are being produced presently in India and being consumed locally as also being exported[103,104]are , in alphabetical order as abacavir sulphate, alendronate sodium, allantoin, ambazone, amodiaquine , ampicillin sodium /sterile, amoxicillin sodium sterile, amylmetacresol, atenolol ,atorvastatin calcium, ascorbyl palmitate, azithromycin, amiodarone hydrochloride, albuterol sulphate/salbutamol, apomorphine hydrochloride, amlodipine besylate/maleate, acetyldigoxin , alprazolam, aluminum hydroxide gel/powder, anagrelide hydrochloride monohydrate, acyclovir , albendazole, azelastine hydrochloride, benazepril ,benzethonium chloride, bromhexine, bifonazole ,bupivacaine, bisacodyl, calcitriol,capecitabine, carvedilol,cefixime trihydrate,cefuroxime axetil, cetrimide, cetirizine hydrochloride,cetalkonium chloride , chlorzoxazone, cilazapril , cilostazol,cinitapride hydrogen tartrate, cisapride monohydrate ,clopidogrel bisulfate,clobetasol propionate, colchicine, cyclosporine , cyclandelate, cyproheptadine hydrochloride, desl oratadine,diacerein,domperidone,domiphen bromide, donepezil hydrochloride , dorzolamide hydrochloride, diphenhydramine hydrochloride, dioctyl sodium sulfosuccinate, doxylamine succinate, ebastine, eprosartan mesylate, ethopabate, ethambutol hydrochloride, esomeprazole magnesium, ezetimibe, erythromycin estolate/stearate,felodipine,fenoprofen calcium ,fexofenadine hydrochloride, fluticasone propionate, fluconazole, finasteride, formoterol fumerate, fosinopril, gabapectin, gefitinib, gemcitabine, glibenclamide, glimepiride, glipizide, glucosamine sulphate, glycopyrrolate, granisetron, halquinol, imatinib mesylate , ipratropium bromide ,irbesartan, irinotecan hydrochloride,isosorbide-5-mononitrate,isoxsuprine hydrochloride, itraconazole, itopride hydrochloride, ketoconazole,lacosamide,latanoprost,lamotrigine,lansoprazole, lenalidomide, levomepromazine maleate, levosalbutamol, lercanidipine, lidocaine base/ hydrochloride, lisinopril, loperamide hydrochloride, losartan potassium, loratadine, lovastatin, lumefantrine, mebeverine, mebendazole, mefenamic acid, mepivacaine hydrochloride, methocarbamol , metoprolol, metoclopramide hydrochloride, metformin hydrochloride, meloxicam, miconazole nitrate, mometasone furoate, montelukast sodium , moxifloxacin, mycophenolate mofitin/ sodium, nalidixic acid ,nateglinide, nebivolol hydrochloride, nevirapine, octenidine hydrochloride, olmesartan, ondansetron hydrochloride, omeprazole, ,

orlistat ,ornidazole, oxyclozanide, pantaprazole sodium, pamidronate disodium, perindopril, phenytoin sodium, pioglitazone hydrochloride, piroxicam, pralidoxime chloride/ iodide, prasugrel, pravastatin,pregabaline, progesterone, proguanil, pyrazinamide, quinine, rabeprazole sodium, rafoxanide, ramipril,rizatr iptan,ropivacaine hydrochloride , rosiglitazone maleate, rifampicin ,rosurvastatin calcium,salmeterol xinafoate, sesamo l(methylene dioxy phenol),sildenafil citrate, simvastatin, sirolimus, simethicone, sodium picosulphate,sodium cromoglycate,solifenacin succcinate, sumatriptan succinate, tacrolimus/ tacrolimus premix, tadalafil, tamoxifen citrate , tamsulosin hydrochloride, tazarotene, telmisartan , temozolomide, terbinafine hydrochloride, thioridazine hydrochloride ,timolol maleate, topiramate,trandolapril, tramadol hydrochloride , terbutaline, triamcinolone acetonide, triclosan, trimetazidine, trioxsalen, triprolidine, tolnaftate, valacyclovir, valsartan,vancomycin,venlafaxine, vinblasyin, vincristin, voriconazole, warfarin, xipamide, zonisamide, zileutonetc .The phenomenon of production of a large number of bulk drugs in India in an environment of open market economy, facing severe international competition, has established beyond doubt that skills and capabilities do not get nurtured or remain entirely only on strong IPR regimen, an argument often brought out by the MNCs for not investing for the local development and manufacturing of APIs. It is however prudent to study and understand what strategies were responsible for the entrepreneurs to manufacture and sell these bulk drugs locally and internationally. Such strategies must be strengthened further by the government by every means. A study is called for, and a Report needs to be prepared for enabling the government to act further.

During the period from 2002 to 2017, the pharmaceutical formulation industry of the country witnessed several eye-catching events such as public interest litigation, government move challenging the litigation, pronouncement of DPCO-2013 and the Draft Policy Paper-2017.The latest one, the Draft Policy Paper-2017, did not have an easy sail. The most important aspect of any pharmaceutical formulation (medicine) for the consumer is its quality, which implies that the medicine is effective as per its stated claim. That the Draft Policy Paper-2017 recognized that medicines manufactured and sold in India for domestic consumption had issues of quality problems and that there were needs for fixing the problem was a paradigm shift in the government attitude and it was a welcome move [105]. Government announcement of its intent to dismantle the NPPA and its intention of keeping the powers to itself and to take control over NLEM for deciding which pharmaceutical formulations government would control price of were seen as moves to push up the prices of “essential medicines”, thereby affecting the ordinary people and unduly benefitting the industry. Though the government had not come up with any firm policy on this

very important issue, the move was seen to be not in line with the government policy objective of appropriately balancing between the aims of ensuring access to medicines by the people at the affordable price on one hand and on the other hand keeping the interests of the industry secured adequately. Indeed, the move was seen to ensure that the industry carried out business more effortlessly and smoothly [106,107]. On other issues, it had been stated in the Draft Policy-2017 that it was the aim of the government to guide and nurture the industry to enable it to maintain and enhance its competitiveness in quality and price on a global context. For achieving these objectives, the proposal was to move away from price control of medicines to price monitoring. An important feature of achieving this was to enforce the dispensation of single ingredient medicine in generic names so as to promote competition in the market place. However, this enforcement was not to be imposed on multi-ingredient formulations as well as on patented medicines. Doubts have been raised as to how enforcement of a policy to allow the sale of single-ingredient formulation in generic names would promote competition as the sale of medicines is executed by the chemists at the chemists' shops and their selling behavior could be modulated by the manufacturers/ suppliers; and the government yet do not have methods to control the selling behavior of chemists nor government have had issued any executive order on this. As regards the other categories of formulations, the manufacturers would use their brand names for sale and would promote their brands; which would not promote the sought objectives of the Draft Policy [108].

On the R&D front, India has done excellent innovative work on the development of non-infringing newer processes for manufacturing a wide range of patent-expired APIs, and have been able to produce for sale, both for local consumption as well as for exports. The present Patents Act 2005 enables companies to protect their innovations. The R&D expenditure can have a claim for deduction of expenses incurred for R&D u/s. 35(2AB) of the Income Tax Act. The average R&D of all companies is, however, low, below 5% of sales .As the size of the companies is not large, the fund allocated by each individual company is considerably small to work for the NCEs and new APIs. Yet more than 120 numbers of NCEs have been invented, which is commendable, and they are being evaluated through various stages of clinical experimentation.

It is however felt that it would not be easy to come out with new APIs for global use; firstly because individual monetary strength of each company for such an aim is low; and secondly, the number of NCEs for new API development for global use, which has been invented, is considered small in number. The new APIs already discovered in India thus far could not make any major global impact and none of the discoveries have been a jack-pot discovery. Almost all the new APIs discoveries are registered for use under the Drugs Act only in

India. Some of the relatively recent initiatives taken by the government from various scientific departments such as through the Biotechnology Industry Research Assistance Council (BIRAC)[109] and the Biotechnology Industry Partnership Programme (BIPP)[110] of the DBT as also the New Millennium Indian Technology Leadership Initiative (NMITLI)[111] and the Open Source Drug Discovery (OSDD)[112] of CSIR shall certainly promote developmental skills of a large number of individuals. These would also contribute to the development of certain innovative processes, techniques and technologies of already known products and substances. New diagnostics, novel drug delivery methods and more efficient production techniques are anticipated to be evolved. But yet the fund allocated individually for each program and on each project is considered smaller, not enough for discovery of *jack pot new drugs*. Further, there is yet no strong national mechanism to integrate the major leads that would accrue for further pursuing towards fruition to create global impact.

A 2006 publication[113] had estimated a new drug developmental costs to vary between USD 500 million and USD 2000 million; the costs incurred had been thought to vary depending upon the intended therapy as also on the firms developing. These cost-estimates in 2019 must have escalated further. While it is believed that the developmental costs in India for new drugs could be lesser, it would certainly be much more than what were currently available for deployment per each project.

In the present situation and existing social Indian context, it would perhaps be wiser to negotiate for sale of the innovative research results wherever generated for new drugs, either in the public sector setting or in the Indian private establishments, to large international giants to recover the costs or to strongly team up with the international companies for joint development so that more resources and avenues can be made available for clinical and end-stage developments. End-stage developments of new drugs are extremely expensive. New government policies enumerated towards these directions would assist the country towards achieving greater heights.

Concluding Remarks

While announcing the newer drug policies and DPCOs in 2019 and later, government of India would have to have a fine balance between the expectations of the general public to have the essential medicines at the affordable prices on the one hand and the concern of the pharmaceutical industry to remain financially healthy at the other hand. The newer policies to move away from the price controlled regime to price monitoring regime of pharmaceutical formulations would require not only to be ensuring availability of “essential medicines” through the trade channel at “affordable prices” but also should be substantially

strengthening health infrastructure of the country, a feat which is most difficult to achieve in another two to three decades, according to the author.

It had been surmised scientifically that every single-ingredient medicine has its highest score and advantage over others for which it is indicated for treating specific disease conditions in a therapeutic group as well as the patients treated. While the essentiality of a medicine for a disease condition is determined based on the multiple clinical conditions and parameters, and in several situations use of multi-ingredient formulations would be more advantageous, the selection of essential medicines from the national point of view is dependent on the country's health priority concerns, disease burden and availability of finances. India has not yet been able to accrue enough finances for deployment into its health budget. Therefore, to live with the regime of price control of "essential medicines" is perhaps a better option for the foreseeable future. However, the supply of such "essential medicines" need to be abundant and have easier access to the products for purchase/ procurement by a common man.

The existing policies required to be more 'friendly' to enable development of a more strong local industry for manufacturing APIs that form the core of the industrial strength for India in the global context. Dependence on certain countries only, for a large number of APIs and drug intermediates, needs to be minimized and if possible be done away with. An exercise can be attempted by the government for implementation to select and produce APIs locally with advantage by encouraging procurement of key input materials and energies at more "competitive" prices within the provisions of WTO from within the country itself. A case-by-case analysis is, however, required. The advantage of the country's low cost scientists, technologists and engineers along with strong linkage created among Indian institutes with the industry through structured government policies can also go a long way. Public discussions on these issues need to be initiated along with the entire stakeholders for evolving an innovative future government policy. Therefore, along with the implementation of the existing "Pharma Policy", the induction and implementation of other innovative policies to promote the development of selected high-tech "essential bulk drugs" locally utilizing local materials, local talents and capabilities of local institutions would be the strategically important move to be globally more competitive .It needs to be seen how the country collectively takes the challenge and what policies get evolved to strengthen local capabilities further.

Acknowledgements

The author acknowledges Ms. Deepali Ghosh, the other partner of Sompradip Publishers and Consultants, New Delhi, for encouraging and providing all the financial support to complete the manuscript. The author has no conflict of interest regarding the content of this article.

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Annexure-I

(The details of how the prices of **Schedule I** formulations were to be calculated as per the DPCO-2013).

PRICING OF SCHEDULE I FORMULATIONS AS PER DPCO-2013

The DPCO 2013 in its Para 4 states as under:

"Calculation of ceiling price of a scheduled formulation

(1) The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule shall be calculated as under:

Step 1. First the Average Price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below:

Average Price to Retailer, P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.)

Step 2. Thereafter, the ceiling price of the scheduled formulation i.e. **P(c)** shall be calculated as below:

P(c) = P(s).(1+M/100), where

P(s) = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step 1 above.

M = % Margin to retailer and its value =16

(2) The ceiling price calculated as per sub-paragraph (1) and notified by the Government shall be applicable to scheduled imported formulations also.**"**

The Ceiling prices calculation-methodologies have been provided in the Order. Further it has been directed that

"(1) where the average price to retailer of a scheduled formulation, arrived at as per the formula specified in sub-paragraph (1) of paragraph 4, has the effect of -

(a) no reduction in average price to retailer with respect to the prices to retailer of the schedule formulation; and

(b) there are less than five manufacturers for that formulation having one percent or more market share, the ceiling price shall be calculated as under:-

(i) in the event of other strengths or dosage forms of the same scheduled formulation is available in the list of scheduled formulation, the average price to retailer shall be calculated as under:

Step 1: First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under:

P(s) = Pm{1-(Pi1+Pi2+…)/(N*100)}

where

Pm = Price to Retailer of highest priced scheduled formulation under consideration.

Pi = % reduction in Average Price to Retailer of other strengths and dosage forms (calculated as in step1 of sub-paragraph (1) of paragraph 4) in the list of schedule formulations w.r.t the highest priced formulation taken for calculating the average price to retailer of such strengths and dosage forms.

N = Number of such other strengths or dosage forms or both in the list of schedule formulations

Step 2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under:

P(c) = P(s).(1+M/100)

where

P(s) = Average Price to Retailer of the scheduled formulation as calculated in step 1 hereinabove and

M = % Margin to retailer and its value=16

(ii) in the event of other strengths or dosage forms of the scheduled formulation is not available in the schedule but there are other scheduled formulations in same sub-therapeutic category as that of the scheduled formulation, then the

Ceiling Price shall be calculated as under:

Step 1: First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under:

P(s) = Pm{1-(Pi1+Pi2+…)/(N*100)}

where

Pm = Price of highest priced formulation taken for calculating the average price to retailer of the formulation under consideration..

Pi = % reduction in Average Price to Retailer of other schedule formulations (calculated as in step1 of sub-paragraph (1) of paragraph 4) in same sub-therapeutic category as that of the scheduled formulation under consideration w.r.t the highest priced formulation taken for calculating the average price to retailer.

N = Number of such other schedule formulations in same sub therapeutic category as that of the scheduled formulation under consideration.

Step 2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under:

P(c) = P(s)*(1+M/100)

where

P(s) = Average Price to Retailer of the scheduled formulation as calculated in step 1 above and

M = % Margin to retailer and its value=16

Explanation: *where the scheduled formulation under consideration is coming under more than one sub-therapeutic category, the Average Price to Retailer of the scheduled formulation shall be calculated after taking into consideration the percentage reduction in Average Price to Retailer of other schedule formulations under all such sub-therapeutic categories and the lowest average price to retailer shall be taken for calculating the ceiling price of the scheduled formulation under consideration;*

(iii)in case the other strengths or dosage forms of the scheduled formulation are not available in the schedule and there is no sub therapeutic category of the scheduled under consideration, the ceiling price shall be calculated as under:

Step 1: First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under:

P(s) = Pm{1-(Pi1+Pi2+…)/(N*100)}

where

Pm = Price of highest priced formulation taken for calculating the average price to retailer of the formulation under consideration.

Pi = % reduction in Average Price to Retailer of other schedule formulations (calculated as in step 1 sub-paragraph (1) of paragraph

4) in same therapeutic category as that of the scheduled formulation under consideration w.r.t the highest priced formulation taken for calculating the average price to retailer, N = Number of such other schedule formulations in same therapeutic category as that of the scheduled formulation under consideration.

Step 2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under:

P(c) = P(s).(1+M/100)

where

P(s) = Average Price to Retailer of the scheduled formulation as calculated in step 1 above and

M = % Margin to retailer and its value=16

Explanation: *where the scheduled formulation under consideration is coming under more than one therapeutic category, the Average Price to Retailer of the scheduled formulation shall be calculated after taking into consideration the percentage reduction in Average Price to Retailer of other schedule formulations under all such therapeutic categories and the lowest average price to retailer shall be taken for calculating the ceiling price of the scheduled formulation under consideration.*

(2) notwithstanding anything contained in this paragraph, where the price has been fixed and notified by the Government under the Drugs (Prices Control) Order, 1995 the provisions of sub-paragraph (1) shall not apply.**"**

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