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Pharmaceuticals Industry and Regulation in India: A Note

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Abstract

An attempt is made in this paper to review the debates on the regulatory issues relating to the pharmaceutical industry in India. The paper presents the perspectives of both the industry and the advocates of health rights, especially of the poor. Research studies, official reports, and media reports form the sources of information. Given its critical role of protecting,maintaining and restoring health of human beings, regulations on pharmaceutical industry are necessary to ensure safety, quality and effectiveness of drugs they develop and produce. Characterised by the phenomenon of induced-demand and apparent lack of price competition, price controls oncertain essential and life-saving drugs are essential, particularly, in the Indian context.

Keywords : Pharmaceuticals, Drugs, Medicine, Drug Price Control, Drug Regulations

JEL Classification : I10, I11, I18

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1. Introduction

Pharmaceutical industry across the globe has been experiencing fast growth. The industry however, has also been witnessing several challenges arising mainly from a variety of regulations and laws governing patents, testing, safety, efficacy and marketing of drugs along with price controls on certain drugs (Sood *et al.*, 2009; Rand, 2008). State intervention is considered critical in universalising health care and ensuring safety, quality and effectiveness of drugs and access to life-saving drugs at affordable prices along with rational use of drugs (WHO, 2005; 2011). Many of the countries have introduced regulations in pharma industry and price control on certain essential and life-saving drugs (Rand, 2008; Hooper, 2007). The Government of India as well has been implementing such regulations and price controls on certain drugs and healthcare products.

There are divergent views on the need for regulations and price controls. Some argue that regulatory controls reduce the revenues of pharma firms and thereby disincentivise them to undertake further investment in discovering and developing new drugs, thus depriving future generations of better healthcare products. In other words, regulation has a discouraging effect on the apparent trade-off between present benefits and future risk or costs (Rand, 2008).

The argument in favour of regulations and price controls is that while ensuring safety and efficacy of drugs, they also help most of the population access necessary medicines at affordable cost. To go by market economic principle, the demand for health care and drugs is observed to be price inelastic. Again, it is established that pharmaceuticals industry is characterised

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by *induced-demand* or the phenomenon of consumption being influenced by supply rather than demand (Fuchs, 1996; Johnson, 2014). Several factors like patent protection monopoly, inelastic nature of demand, information asymmetry, skewed power relations between buyer and seller, and nexus between manufacturers / supply chain and the drug prescribing doctors contribute to this phenomenon (Centad, 2010; Bhattacharjea and Sindhwani, 2014; Mondal and Pingali, 2015; Gadre and Sardeshpande, 2017). Hence, competition within pharmaceutical industry may not result in declining drug prices. Regulations and price controls are hence essential as correcting mechanisms for the sector (*ibid*).

The Drug Price Control Orders of 2013 (DPCO 2013) along with price capping of medical devices (stents and knee implants) in 2017 has become a point of discussion on the debate on regulations and price control in India (EPW, 2014; Gandhi, 2016; GOI, 2016; AdvaMed, 2017 and 2018). It is pointed out that price capping of medical devices aims at improving access and affordability for common people, especially, those from weaker sections. But it is also observed that the intervention was not so successful, at least in the short-run, to achieve the desired objective. Hence, alternative solutions needed to be explored (AdvaMed, 2018). Moreover, such price control makes it difficult to promote business friendly atmosphere ('ease of doing businesses'). On the other hand, civil society organisations[1] argue that changes in the span of control and method of setting drug prices in DPCO 2013 are not in any way beneficial for the consumers. Even the Supreme Court of India was convinced of this view and lamented the authorities on the issue. In this context, the government needs to protect the interest of people at large in matters of access and availability to drugs/medicines and, at the same time, keep the sector attractive for private manufacturers, domestic as well as foreign. India requires a strategy to balance service of public welfare with business sense. Achieving such balance is crucial to the future of pharmaceutical sector in India.

In this backdrop, here is an attempt to examine the different perspectives and develop argument justifying reasonable regulation for pharma industry and drug price control in India based on existing research studies, reports, and discussions and debate that appeared in the print media. The paper is organized as follows. The second section presents the process of discovery,

[1] For instance, All India Drug Action Network and Jan Swasthya Abhiyan (JSA), formed in 2001 as part of the global People's Health Movement.

development, production and marketing of drugs along with overview of the drug industry in the global context. The third section presents the overview drug industry and its growth in India. The fourth section presents the discussion justifying the necessary regulations for pharma industry and price control for drugs. The final section concludes the discussion.

2. Drug Industry: Costs of Discovery and Development

The pharmaceutical products commonly known as medicines, medications or drugs are fundamental components of healthcare and saving lives from life-threatening diseases. Census Bureau of United States of America (USA) defines the pharmaceutical / drug industry as companies or firms that are engaged in researching (discovery), developing, manufacturing and marketing drugs including biologicals for humans or animals. By this definition it includes products derived of the chemical molecules (pharma) and those developed through bio-technology (bio-pharma). The drugs and biologicals are substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of diseases. Research and development (R&D) and innovation are the key to the success of the firms and industry in this sector. Along with the significant presence of public sector, private sector is playing a key role in growth of the pharmaceutical industry worldwide.

Usually companies are categorized into large, medium and small by scale of operation and size of investment / capitalization / market revenue. Food and Drugs Administration (FDA) of USA categorized the firms in the industry based on the activity undertaken and the phase in which the firm is placed. Companies in the 'mainline(r)' category are mostly very large firms in terms of operational scale and engage in all phases / activities. There is another category where the firms restrict their engagement to research and development of new chemical entities (NCEs) or new drug candidates/compounds. Some firms may engage in manufacturing and marketing of only the generic drugs (branded or non-branded). Yet another set of firms may be specialised in producing both or either of the bulk drug (API – active pharmaceutical ingredient) and / or the formulations. Some of the firms in the pharmaceutical industry do engage in activities that overlap multi-therapeutic classes.

In the drug market, product segmentation can be based on patent like originator drug, branded-generic and commodity / generic - generic, orbased

on sales control as in the case of prescription drugs and over-the-counter (OTC) drugs. Drugs are differentiated as therapeutic / drug class or category based on chemical structure, mechanism of action, biological target and disease and mode of action. A comprehensive drug classification system can be found in the Anatomical Therapeutic Chemical Classification System[2] (ATC) which divides active substances into different groups at five levels as per the organ or system on which they act in the therapeutic, pharmacological, and chemical properties. Drugs in each therapeutic/drug class differ by their dosage form / unit dose of a drug (pill, tablet, capsule, syrup, solution etc.), which consists of a mixture of active ingredient and inactive component (i.e. excipient), depending on the method or route of administration of drug (mouth, skin, blood) targeting the same disease.

In the context of debate and discussion on exorbitant drug prices and resultant price controls one would have thought that to determine whether drug prices are reasonable or not, prices must be compared to costs of production and mark ups. As mentioned above, R&D and innovation are key to the success of the pharma firms. It incurs huge amounts of investment on R&D of drugs. The amount that goes into R&D of new drugs is often larger than what is incurred on actual production. Hence, the price of the drug needs to account for not only the cost of the production, but also the cost that goes into development of the given drug. The long process from drug discovery and development to testing, manufacturing and marketing involves a considerable gestation period, at least 10 years, for the return on investment to be realised. Thus decisions made many years' ago have consequences on current financial performance of pharmaceutical firms. Similarly, the current performance of firms may affect future investment.

Discovery and Development: A Gamble involving heavy and risky investment, but a future

The drug discovery is a research or investigation process by which potential drug(s) are discovered or designed. The FDA[3] schema of the USA shows that from test tube to new compound approval for marketing the drug consists of sequence of phases and activities beginning with basic and

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[2] https://www.whocc.no/filearchive/publications/1_2013guidelines.pdf

[3] See at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm053131.htm.

applied research initiating the process of discovery programme that would result in the synthesis or isolation of compounds. Developing of a potential drug candidate begins with the discovery of a chemical compound consisting of a small molecule or molecule entity with strong therapeutic potential, through research (fundamental and academic). It involves identifying, characterising and validating the therapeutic targets containing particular diseases, through a series of biological tests and identifying the substances (compounds / molecule) capable of acting on the target appropriately. In a process of high-throughput screening (HTS) of large libraries of chemicals, active molecules are tested against the target through a chemical synthesis to identify successful ones (hit screens) and their dose-effect and physic-chemical properties are measured. The hit screens undergo several cycles of iterated optimization (observing molecule behaviour and activity on the target and surroundings) in order to identify and improve the selectivity (hitting the target without side effects), safety, efficacy, metabolic stability and bioavailability. With advancement of technology, the drug design is aided by computer modelling of the chemical structure of the hit screens and their interaction with the target. The successful substances (molecule/ compound) presenting optimal characteristics evolve as a drug candidate.

The subsequent drug development process (after a compound is identified or discovered) involves the activities undertaken to establish efficacy and safety of the potential drug candidate. They are to be tested in assays and animal models in pre-clinical or pre-human development phase followed by the clinical (human) testing phase which is typically conducted in three successive phases. These tests determine the success of the drug candidate as a drug/medicine for use. Meanwhile, a parallel process of indications on investigational new drugs (IND) begins with concerned national drug authorities permitting such trials. Once successful in these phases, the process of submitting applications for marketing approval for the new compound (i.e. new drug applications – NDAs or biologic license applications-BLAs) to the concerned National Drug Authorities for review begins (DiMasi *et al.*, 1991; 2016). When the successful compound or molecule synthesis while passing through these stages gets pre-market approval of the concerned national authorities, the manufacturing and marketing activities (consisting of promotion, sales and distribution) of the drug follows. There are various technical, regulatory and economic challenges in the R&D process of drug development.

Cost of Capital Employed/Invested: Costs of Debt and Returns to Investors

According to an estimate, the pharmaceutical industry at a global level spent nearly $157 billion on R&D alone in 2016 (IFPMA, 2017). However, R&D expenditure growth appears to be flattened during the 2008-15, wherein the compound annual growth rate of global R&D spending was 1.7 per cent (EvaluatePharma, 2017). Some studies found the cost of developing a successful medicine increased to US$ 2.6 billion when compared to US$ 179 million in 1970s (IFPMA, 2017; DiMasi et al., 2016). The drug discovery and development is capital intensive involving huge investments and it is a risky and lengthy process. The pharmaceutical R&D entails high failure rates. Many times R&D expenditures may not materialize in to a market-approved medicine. Even if an early-phase compound is promising, unless preclinical and clinical trials demonstrate its efficacy, quality, and safety such a compound may not be successful candidate for launch. It is observed that for each successful new drug, there are number of pre-clinical trials in the range of 500 to 1000. A study in this regard observed that success rate (transition rate) of the drug compound that enter testing phase and finally get through the marketing approval is only 12 per cent (*ibid*). The transition rates along the sequence of different phases are volatile and reducing over a time. The cost of investments increases when a failure occurs in later R&D phases wherein a phase III failure is costlier than a preclinical failure (IFPMA, 2017).

The drug discovery and development along with manufacturing and marketing involves multiple collaborators in terms of R&D and huge investments involving joint or multi ventures, partnerships and investment / capital contributing shareholders in respect of such investment. The important sources of capital are the investors, who purchase stock (equity) and debt holders, who buy bonds or issue loans (debt). Along with business environment and conditions, the cost of capital is one of the crucial determinants in mobilizing the capital/investment needed for introducing a new drug. In most of the research intensive industries such as pharmaceuticals with long gestation period *capital* mobilization is possible largely through equity rather than debt sources. It is so even when the cost of debt is lower than equity sources, because stable source of cash flow is required for servicing the debt that is not possible in this highly volatile sector (DiMasi *et al.*, 2016). The Cost of Equity (COE) indicates the expected return

against risk. As pharmaceutical industry is considered to be a highly risky one, it expects high rate of return as a risk premium.

Drug Patents and Pricing: Cost of Development, Manufacturing and Distribution

Patents as intellectual property right and as an incentive mechanism for development of product or process are accrued to originators/inventors, when governments grant them certain statutory privileges (monopoly of producing and marketing the product) for a definite period. While the product patent provides the inventor exclusive right on the product, the process patent is granted for particular manufacturing process of the product. Given the long process and heavy investment, the drug developing firms are granted with patents which ensure them exclusive market for their product(s). Usually the product patent duration varies between 10 to 20 years across countries (DiMasi *et al.*, 2016). The process patents are granted for a lesser duration. Evergreening of product or process is considered as one of the practices that firms sometimes engage in to extend patent protection for their product with certain modifications.

The pricing strategy of a firm takes into account the cost of the capital employed throughout the discovery and development stage, expected returns, size of market for its product and duration of market (exclusivity through patent protection). It has to recover the total capital employed on development of successful drug candidates as well as the capital that invested in those failed ones in the process (the failed drugs themselves might have contributed to discovery and development of the successful ones).

Pharmaceutical Industry and its Regulations in the Global Context

Pharmaceutical industry is growing fast globally. According to an estimate the global pharmaceutical industry market has crossed a trillion US dollars in 2014 from about US$400 billion in 2001 (IFPMA, 2017). Along with US and Europe, developing countries like China, India and others are key players in the industry. IFPMA (2017) estimates that gross value added (GVA) of global pharmaceutical industry accounting for 3.8 per cent share in the GVA of total manufacturing sector had employed around 5.1 million workforce worldwide. A large portion of the industry earnings/revenue comes from the branded and patented (originator) drugs sale.

As a policy instrument many countries irrespective of their level of development have been implementing certain regulation and price control on drugs. In order to mitigate unethical practices and ascertain the safety, quality and efficacy of the drug, certain regulations have come in to force. The beginning was with the Pure Food and Drug Act introduced in 1906, then the Drugs and Cosmetic Act in 1938 that was passed in USA followed by Kefauver-Harris Drug Amendments (passed in 1962) to ensure drug efficacy and greater drug safety. Food and Drug Administration (FDA) Act, 1988 officially established FDA as an agency under USA government for the purpose.

After the World War II, the Government of United Kingdom (UK) created the structured system of social health care by establishing National Health Services (NHS). It introduced price fixing scheme in 1957. Very recently, the UK Government has enacted Medical Costs Act[4] 2017. The UK Government made this Act in response to the instances of extortionate prices charged (i.e. price gouging) for certain drugs (Sweetman, 2017). In this Act certain provisions are made for controlling the costs of medicines and other medical supplies in the country. As per the Act the pharmaceutical companies can be compelled to reduce the price of a generic medicine or introduce other controls on branded products in cases where charges are "unreasonable".

In this regard, regulations on pharmaceutical industry are found to be normal rather than exception across countries, but the intensity and extent of such regulations varies. The Rand study (2008) referred above examined the regulations in respect of pharmaceutical industry and their impact on industry revenue in 19 countries (including OECD and other European countries including USA) for the period 1992-2004 to show that not only certain regulations existed in these countries prior to 1992, but some of them have adapted new regulations too (also see Sood et al, 2009).

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[4] The Health Service Medical Supplies (Costs) Act which received Royal Assent on 27th April, 2017 and the Act's provisions came to force as on 7th August, 2017. Available at: http://www.legislation.gov.uk/ukpga/2017/23/contents. Also see Sweetman (2017) available at: https://www.pharmaceutical-journal.com/opinion/comment/the-medical-costs-act-what-it-means-for-pharma-and-pharmacy/20203330.article.

The World Trade Organisation (WTO) and its Trade Related Intellectual Property Rights (TRIPS) agreement protecting intellectual property rights that came into force since 1995 has become a source of concern for the sovereign states of developing countries as they are deprived of access and affordability to life-saving drugs largely developed and produced by firms located in developed countries ('t Hoen, 2002; Subramanian, 2004). Most of those developing countries like India had process patents. As TRIPS agreement made strict compliance with product patent, they may lose opportunity to produce and access to certain lifesaving drugs. Concerted efforts and negotiations by a group of affected developing countries availed certain provisions like compulsory licensing and exports to prevent public health crisis, in Doha Declaration 2001. Despite such provisions, it is considered that developing countries are still in a disadvantageous position with respect to their access and affordability to essential drugs ('t Hoen, 2002).

3. Pharmaceutical Industry in India: Domestic Drug Market and Regulations

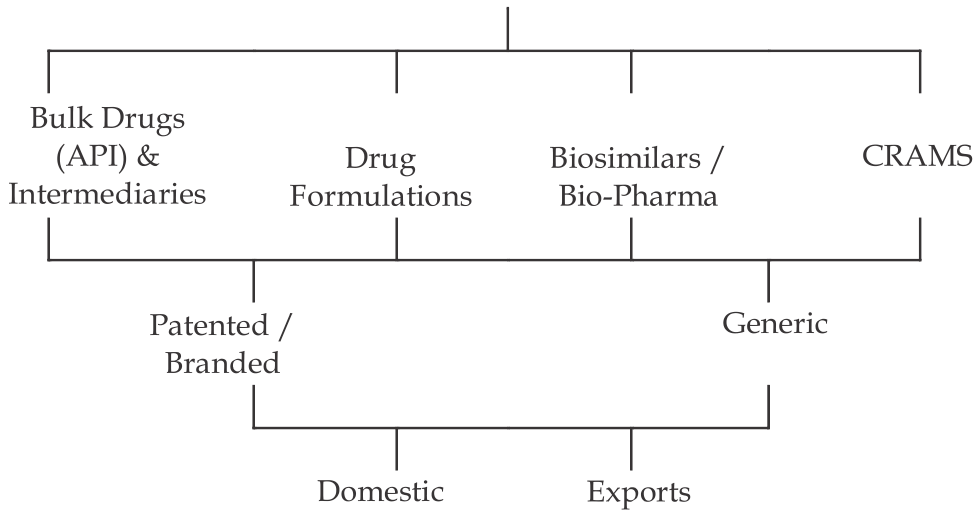
While healthcare situation is slowly improving in India, it is falling short of required outcomes in many fronts (ICMR/PHFI/IHME, 2017). Although Indians are living longer and are healthier than before, high disease burden continue to persist (*ibid*). The emerging non-communicable lifestyle disorders have been assuming the largest disease burden (*ibid*). Access to and availability of quality life-saving drugs for a majority of needy population in the country has not yet been ensured.

Nevertheless, India has emerged as one of the largest and self-reliant (less dependent on imports) producer of pharmaceuticals in the world. While Indian pharmaceutical industry has succeeded in both domestic and global markets including the Europe and USA, the global firms have been exploring the Indian market. The strength of the Indian industry in the global market is largely in generic drugs, whereas the Indian market itself is opened for both branded (originator or otherwise) and generic drugs. Given its growing size of country's domestic market, it has become attractive to foreign direct investment (FDI). The country has opened its pharma sector for 100 per cent FDI in 2015. One could observe that it is one among the top 10

sectors in India that attracts FDI. The advantages that India has in respect of pharmaceutical production are competent and skilled workforce at cost-effective terms, potential market with the growing demand for health care due to growing population and disposable income along with improving health infrastructure, legal framework and patent laws (IBEF, 2017).

Chart 1

Pharmaceuticals Industry In India



Notes: API – Active Pharmaceutical Ingredient; CRAMS – Contract Research and Manufacturing Services.
Source: Authors' Compilation.

In terms of its structure, the Indian pharmaceutical industry consists of the following: large firms of foreign (MNCs) as well as Indian origin involved in R&D activities developing drugs and production of originator/patented drugs; small and medium Indian firms involved in production of patented and generic drugs, and contractual research and manufacturing services (CRAMs); small Indian firms involved in the production of generic drugs (Centad, 2010; Das, 2003; Das and Nair 2004). As is the case across the globe, chemical molecule- based pharma industry has been predominant in India. However, pharma firms based on bio-technology based (Bio-pharma or Biosimilars) products have been emerging in the country (ibid). A large segment of the pharma industry including both the bulk drug (i.e. Active Pharmaceutical Ingredient-API) and drug formulations are export oriented.

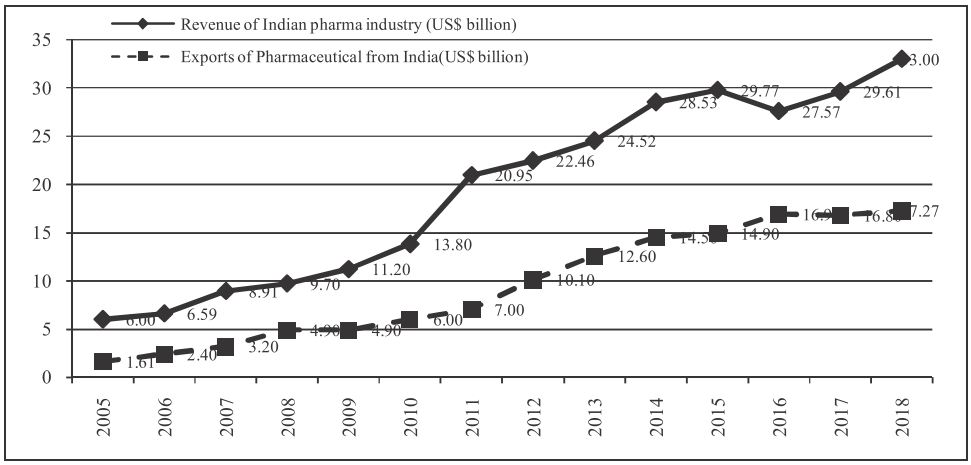
According to the sector reports of India Brand Equity Foundation (IBEF), the value of Indian pharmaceutical market (IPM), has grown five times from USD 6.0 billion to USD 33.0 billion between 2005 and 2018 (Figure 1). Indian pharmaceuticals market is the third largest in terms of volume and thirteenth largest in terms of value, and accounts for 20 per cent and 1.4 per cent respectively of volume and value of the global pharmaceutical industry. India is the largest provider of generic drugs globally with the Indian generics accounting for 20 per cent of global exports in terms of volume (IBEF, 2018). The Business Monitor International indicates that Indian pharma industry employed directly or indirectly around six lakh workers (IFMPA, 2017). By mode of sale in the domestic market, nearly 85.5 per cent was accounted for prescription drugs, of which 76 per cent of sales were of generics category. The per capita sales value of pharmaceuticals in India was estimated to be USD12.4 that is 78 times lower than that of USD 970 observed for USA (IFPMA, 2017). In 2017 Indian pharmaceutical companies received record 300 generic drug approvals in USA.

As mentioned above while a large proportion of pharmaceutical products produced in India are being exported, domestic market is supplemented with imports. According to Organisation of Pharmaceutical Producers of India (OPPI) and IBEF estimates more than 50 per cent of bulk drugs (API) and 90 per cent of formulation drugs are being exported[5]. As per the Government of India's Commerce Department, the value of India's drugs exports and imports in 2017-18 was Rs. 1,060,375.2 million[6] and Rs. 311,609 million respectively. In 2017-18 drug exports were 3.5 times of imports (Table 1).

[5] See, OPPI Annual Reports and IBEF Monthly Sectoral Report.

[6] According to the Pharmaceuticals Export Promotion Council of India (PHARMEXCIL) India's pharmaceutical exports have stood at US$ 17.27 billion in 2017-18 (IBEF, 2018).

Figure 1: Estimated Value of Indian Pharma Market and its Exports



Notes: Value of Indian pharma market includes domestic sales and imports; Years refer to end of the financial years; Values in nominal (current) prices and in US$ Billion.

Source: Authors' Compilation from IBEF's various Monthly Reports on pharma Sector.

A large proportion of drug exports are formulations and among imports they are bulk drugs (Table 1). Drug imports in the form bulk drugs cater drug formulation industry. In case of bulk drugs the value of exports is marginally higher than such imports. But, drug formulations exports are 7 times higher than there imports in 2017-18. During the last three and half decades the value of exports and imports of drugs has increased multiple times. The rate of growth in exports has been very high. In the early 1980s drugs exports were half of such imports. Since mid and late 1980s the value of drug exports from the country has crossed the value of drug imports. Trade performance indicates the strength and opportunities of Indian pharma industry.

Table 1: Exports and Imports of Indian Pharmaceutical Industry/Market (Rs. Millions)

Year	Drugs Exports		Drugs Imports		Ratio of Exports to Imports		
	Total Value	% of Drug Formulations	Total Value	% of Bulk Drugs	Bulk Drugs	Drug Formulations	Total
1980-81	464.0	75.6	969.0	90.0	0.1	3.7	0.5
1989-90	6647.0	47.3	4807.0	88.5	0.8	5.7	1.4
1998-99	53662.0	56.6	24580.0	78.0	1.2	5.6	2.2
2010-11	451923.4	63.5	170431.5	68.8	1.4	5.4	2.7
2017-18	1060375.2	78.5	311609.3	61.9	1.2	7.0	3.4

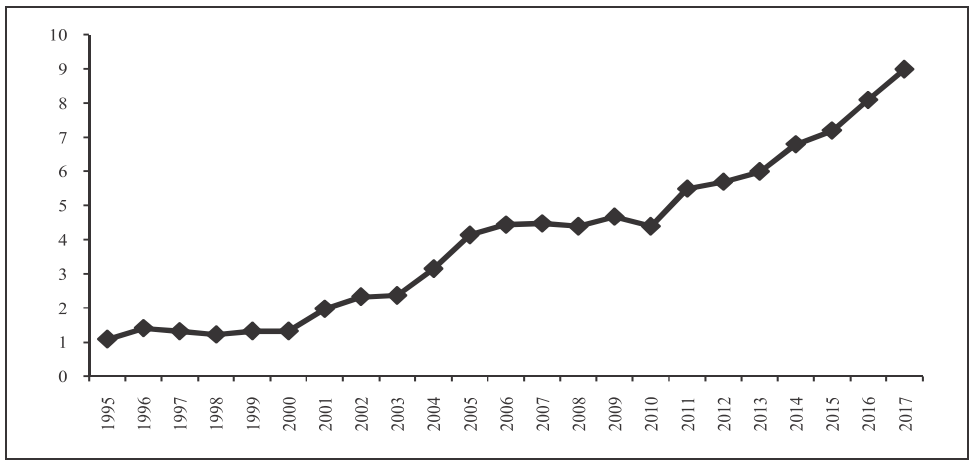
Notes: Values in Nominal (Current) Prices; Bulk Drugs – Active Pharmaceutical Ingredient (API).

Sources: Organisation of Pharmaceuticals Producers in India (OPPI); Directorate General of Commercial Intelligence and Statistics (DGCIS), Kolkata.

As of 2018, India is the largest provider of generic drugs in the international market and supplies over 50 per cent of global demand for various vaccines. Indian pharma producers cater to 40 per cent of the demand for generic drugs in the case of the US and 25 per cent of all medicines in the UK. Over 80 per cent of the antiretroviral drugs to fight AIDS (Acquired Immune Deficiency Syndrome) across the globe comes from Indian pharmaceutical firms (IBEF, 2018).

The industry's R&D expenditure began increasing during the post-reform period, especially since the turn of the 21st Century. The R&D-Sales ratio of pharma companies (R&D expenditure as a percentage of sales) was less than two per cent until the end of the 1990s and increased to nine per cent in 2017. The momentum in the ratio of R&D to sales had slowed down in the late-2000s and picked up since 2011. It is observed that the R&D profile of Indian pharmaceutical industry includes development of generics, new drug delivery systems and new drug development (Joseph, 2011). Also, the R&D intensity varies with size of the firms, where large pharma firms having relatively higher intensity than medium and small size firms (Mazumdar, 2013). There is a large scope for further growth of pharma industry in India, especially in the innovation and development side with the growing R&D investments, particularly, in the context of recent policy allowing 100 per cent FDI and the present patent regime.

Figure 2: Percentage of R&D Expenditure in Sales of Pharmaceutical Firms in India



Source: CMIE and CRISIL Research.

Patents and Prices of Drugs: Legislations, Laws and Regulations in India

Independent India had inherited the two legislations from the British Government - the Drugs and Cosmetics Act 1940, and the Patents and Designs Act 1911. Post-independence, the Government of India made unsuccessful attempt to revise the 1911 Patents Act, in 1953, based on recommendations of Tek Chand Committee of India[7] and Swan Committee[8] of UK. It succeeded in enacting the India Patent Act (IPA) 1970. The Act was based on recommendations of the Ayyangar Committee[9]. While the

[7] The Government of India had set up the Patent Enquiry Committee consisted of six others and presided over by Dr. Bakshi Tek Chand, a retired Judge of the High Court of Lahore. The Committee submitted an interim report in August, 1949 and final report in April 1950. The interim report suggested the immediate amendment of the Patents and Designs Act, 1911 with a view to counteract the misuse or abuse of patent monopolies in India by the enactment of provisions for compulsory licensing on the same lines as those suggested by the Swan Committee, of United Kingdom.

[8] A Departmental Committee led by Sir Kenneth R. Swan, a Patent Lawyer, was appointed by the Board of Trade, United Kingdom, in April 1944 that submitted two interim reports (in March 1945 and April 1946) along with final report in September 1947.

[9] The Government of India set up a one-man Committee led by Justice N. Rajagopala Ayyangar in April 1957 to revise the laws of Patents and Designs Act 1911 of British Government in India. The Committee submitted its report in September 1959.

1911 Act had made provision for patent protection for products, the 1970 Act changed it to patent protection on process. Compulsory Licensing (CL) was an important measure emerged in this policy (Centad, 2010). Further, the commitment of India to World Trade Organisation (WTO) and its Trade Related aspects of Intellectual Property Rights (TRIPS) resulted in India Patents (Amendment) Act 2005 that re-introduced the product patent in the country.

Change in Policy and Growth of Domestic Industry

According to the existing literature, the evolution of Indian pharma sector is broadly divided in to four phases. The first phase started in 1901 when Bengal Chemical and Pharmaceutical Work (BCPW) Limited was set up in Kolkata by Acharya P.C. Ray. In the same decade, in year 1907, The Alembic Chemical Works Co. Ltd. was established in Vadodara by T.K. Gajjar, Rajmitra and B.D. Amin. Both the companies lay the foundation for scientific approach in discovery, development and manufacture of pharmaceuticals in India. Also, a few public sector undertakings (PSU) were set up in independent India since the mid-1950s. The Hindustan Antibiotics Limited (HAL) was the first public sector undertaking set up with the cooperation of the WHO and UNICEF. The HAL Plant / unit set up at Pimpri, Pune in 1954 was commissioned during 1955-56 producing Penicillin. The second one was the Indian Drugs and Pharmaceuticals Limited (IDPL) incorporated in April 1961. Having multiple plants at Rishikesh, Hyderabad (both commissioned in 1967) and Gurgaon (commissioned in 1969) and two subsidiary units in Chennai and Muzaffarpur, IDPL has emerged as the largest public sector pharma undertakings. However, in this phase from 1901 to 1970 India was heavily dependent on imports of pharmaceutical products to take care of domestic needs.

The second phase between 1970 and 1990 is a turnaround. A few Indian companies entered the sector with a view to tap its growing potential. The government also introduced price cap on drugs to help domestic consumers. The Indian Patent Act, 1970 was introduced in this setting. The then policy regime of Government of India (including the Monopoly and Restrictive Trade Practices (MRTP) Act, 1970 and the Foreign Exchange Regulation Act (FERA), 1973 along with IPA) facilitated the growth of the domestic pharmaceutical industry (Centad, 2010). While the MRTP Act 1970

restricted monopolies and restrictive trade practices, the FERA 1973 curtailed imports and promoted production of bulk drugs (Bhattacharjea and Sindhwani, 2014). The change in patent regime (IPA 1970) facilitated development of reverse engineering in India and established to some extent the competitiveness of Indian firms in the global market (Centad, 2010). During this phase the Bengal Chemicals and Pharmaceuticals Ltd. was nationalised and incorporated as PSU in 1981. BCPL has two manufacturing units in West Bengal (Maniktala and Panihati) and one each in Maharashtra (Mumbai) and UP (Kanpur). The Rajasthan Drugs and Pharmaceutical Ltd. (RDPL), Jaipur, was made an PSU in 1978 and started commercial production in 1981. The Karnataka Antibiotics and Pharmaceutical Ltd. (KAPL), Bangalore was incorporated in 1981 and commissioned commercial production in 1984. The growth of domestic industry in terms of production and export orientation began during the period 1970-90. By the mid-eighties Indian drug exports crossed the value of imports. It picked up momentum in the post-reform period leveraging economic reforms introduced in 1991.

During the third phase, spanning 1990 to 2010, the Indian pharma sector saw a revolution in manufacturing of generic drugs. Liberalization facilitated more foreign investments flowing into the sector. Indian pharma majors started exporting their products to other countries and give more emphasis on R&D and getting patents for their innovations. More domestic companies came in to the sector to tap its potential. The country could achieve near self-sufficiency both in the technology and production of pharma products thanks to large scale reverse engineering and process innovations. The Indian companies became self-reliant in production of bulk drugs as well as formulations (tablets, capsules, liquids, orals and injectables). Due to low cost of production the Indian manufacturers got competitive edge in both national and global markets over foreign counterparts.

The laws governing competition and patent protection in India were further revised in response to changing times. The Competition Act 2002 and the Patent (Amendment) Act 2005 came into force. These along with the growing domestic market for health care and pharmaceuticals further boosted the pharmaceutical industry in the country. The sector is opened up for 100 per cent FDI (either Greenfield or Brownfield) in 2015. As a result, the Indian pharmaceutical industry came to occupy a creditable place in the global market (Centad, 2010; Bhattacharjea and Sindhwani, 2014; IBEF, 2017). After the introduction of product patent regime in 2005 the pharma

sector in India got opportunity to get linked with global pharmaceutical market. It also helps India to get established in the export market for pharmaceuticals, especially in innovatively-engineered generic drugs and active pharmaceutical ingredients. It is also becoming a preferred destination for outsourced clinical research and the contract research and manufacturing services (CRAMS) segments. Currently the country has 332 sites for CRAMS manufacturing facilities approved by the US FDA. Further, in 2011, one-third of all Abbreviated New Drug Applications (ANDA) approved by the US FDA, belonged to Indian companies. India is one of the leading countries in Drug Master Files (DMF).

However, in recent years the sector is facing new challenges as pharma sector is changing at global stage. Brands like Dr. Reddy, Sun Pharma, Cipla, Lubin, Ranbaxy, Cadila and Aurobindo were getting recognized in the global market as well for their innovation and quality of products. In 110 years the country became one of the three largest pharmaceutical markets globally. Given the increase in income and growth of tertiary care providers in urban and peri-urban areas, the Indian pharma sector witnessed a growth of 10-15 per cent per annum and it has emerged as the fifth largest source of FDI in the country. The slowdown of the pharma sector in the USA has forced many pharma companies to look for opportunity in growing markets like India[10].

The debate is on how the government can balance WTO's TRIPS guidelines, which prohibit excessive protective measures, and welfare of people for providing cheaper medicines. Kapczynski and Kesselheim (2016) argue that the state can procure generic versions of patented drugs and in exchange pay the patent-holding companies reasonable royalties to compensate them for research and development as is the case in USA. It is to avoid being at loggerhead with many of the WTO provisions and ensure that the pharmaceutical companies are not disincentivised to discover new drugs. This policy of compensating private firms for the research and development of new drugs may be a boost to private pharmaceutical farms. The public sector undertakings can produce cheaper generic drugs for schemes like the Pradhan Mantri Bharatiya Janaushadhi Pariyojana (PMBJP). Puranik *et al.* (2010) argue that developed countries like the USA have relatively easier patent standards. Patents are granted not only for new chemical entities or

[10] https://www.thepharmaletter.com/article/india-s-nppa-slashes-more-drug-prices.

formulations (NCEs) but also for new formulations and combinations, and new uses of existing NCEs. The latter are known as secondary patents that help in keeping drug prices at affordable level for patients. It has recommended a similar patent system for India especially the secondary type which benefits the small and medium enterprises in the sector. India needs to improve drug control administration to ensure all the products available in the market as equally good.

Kumar and Pradhan argue that WTO provisions allow experimentation on a patented invention to understand the invented product better (Article 30). This provision can be used by Indian pharma to do further research on already patented drugs and develop substitute or new drugs. The authors cite another exception called the Early Working Exception or 'Bolar' Provision that allows manufacturers of generic drugs to use the patented invention to obtain marketing approval without patent owner's permission and before the expiration of patent (Bolar provision under Article 8). This provision may be very helpful to Indian pharma industries to expand their innovation and research activities.

Lalitha (2011) emphasises the role of the state to regulate pharma sector in India and ensuring medicines accessible to the common people. She argues for mandatory licensing clause of 'government use' to ensure access to medicine. It is essential to sustain interventions like Janaushadhi stores for the benefit of common people. Similarly collective action in terms of 'joint business promotion' is necessary for the marginal, small and medium firms (MSMEs) in the pharmaceutical sector in India to economise the expense on research, development and marketing of new drugs by the smaller players. The collective approach will help small players to survive the onslaught of industry majors and keep the sector competitive and the price of drugs reasonable. The Janaushadhi scheme of the government can play major role to strengthen MSMEs in pharmaceutical sector in India.

Policy addressing Access and Affordability: Drugs Price Control Orders

Although the Drugs and Cosmetics Act 1940 and Rules 1945 are meant to regulate import, manufacture, distribution and sale of drugs, these do not contain any provision for price controls. The Essential Commodities Act 1955 included drugs as one of the essential commodities to apply price controls. Drug price controls in India began with promulgation of the Drugs

Order (Display of Prices) 1962 and it was followed by Drugs (Control of Prices) Order 1963 and that of 1966 and 1970. Based on the report of the Committee on Drugs and Pharmaceutical Industry (Chairman: Jaisukhlal Hathi), submitted in 1975, the Government of India set up the National Drug Authority (NDA) and made its Drug Policy of 1978 in order to enforce price control on selective drugs. It was followed by Drug Policy 1979 and that of 1986. Accordingly, the Drugs Prices (Control) Orders of 1978, 1979 and 1987 were promulgated. Following 1991 economic reforms, the Drug Policy 1994 was introduced and subsequently promulgated the Drugs Prices (Control) Order 1995. The National Pharmaceutical Pricing Authority (NPPA) was established in 1997 to regulate (monitoring and controlling) drug prices of scheduled and non-scheduled drugs and began implementing National Pharmaceutical Pricing Policy (NPPP). The DPCO 2013 under the NPPP 2012 is currently being implemented. Meanwhile, efforts were also made by the central government to explore[11] options other than price control for achieving the objective of making life saving drugs available at reasonable prices.

It may be noted that the earlier Drug Policy of erstwhile NDA and the recent policy of the NPPA are under the Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers. The Ministry of Health and Family Welfare has nothing to do with price control other than suggesting/preparing a list of essential drugs i.e. National List of Essential Medicines (NLEM[12]). The drugs listed in NLEM or drugs considered adequate to meet the common contemporary health needs of the general population, are usually subject to price control of DPCO in India. The first NLEM was released in 1996, and revised subsequently in 2003, 2011 and 2015. The Task Force constituted by the Department of Chemicals and Petrochemicals (Chairman: Pronab Sen) in its interim report (2005) recommended fixing ceiling prices on the basis of essentiality of drug (formulation) and de-branding the essential

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[11] Government of India, in November 2004, constituted a Taskforce chaired by Dr. Pronab Sen, Principal Adviser, Planning Commission, to explore the various options other than price control for achieving the objective of making available lifesaving drugs at reasonable prices. It submitted its report in September 2005 (see GOI, 2005).

[12] The drugs included in the NLEM are considered to be adequate to meet the common contemporary health needs of the general population of the country (see GOI press note 15/03/2013 at http://pib.nic.in/newsite/PrintRelease.aspx?relid=93719.

drugs. It emphasised that the NLEM 2003 which had listed 354 drugs as essential ones should form the basis of drugs for price control/monitoring (GOI, 2005). The NLEM 2011 consists of 348 drugs and the NLEM 2015 increased it to 376.

Medical Devices Price Capping Policy

In respect of medical devices, the government of India has taken certain measures to regulate the sector as also to expand access to safe and effective medical products. These include the recent introduction of globally harmonized rules (new Medical Device Rules), the classification system for medical devices, and establishing a Medical Technical Advisory Board (MTAB) in 2017. Besides, there is a regulation and price capping policy with respect to medical devices as well (GOI, 2017; AdvaMed, 2018). In fact, in 2016 the Union Health Ministry notified its decision to include coronary stents under NLEM. The NPPA has capped the price of various models of stents and knee implants in 2017 to reduce the cost of surgeries. This has resulted in more than six per cent reduction in price of knee implants.

The medical device sector in India prior to the 1990s was dominated by multinational companies (MNCS) and advent of Indian players began since the 1990s. But there has not been any regulatory mechanism in India specific to medical devices, and which used to be part of drugs list (AdvaMed, 2018). The recent step is a move towards establishing such a regulatory system.

Pointers for DPCOs

The DPCO since its inception in 1962 has been attracting severe criticism both from industry bodies as well as those concerned with consumers' access and affordability (EPW, 1965; Nair, 1965). It is not only criticised for the method adopted in fixing the price of the drugs, but also for the preparation of the list of drugs to be brought under price control. The inclusions and exclusions of certain essential drugs in the list have become controversial (Rane, 1996 and 2002; Srinivasan, 2001; Joseph, 2016). The point of debate for all the earlier price control orders was the span of control, i.e., coverage or number of drugs in the scheduled list of essential drugs considered for price control. In DPCO 2013 changes are observed for

both the span of control and the method of fixing the ceiling price along with the form of the drug to be brought under price control or fixation.

The major change observed in this order is that price control is applied to drug formulations, and not to drug as such (Bulk drug or API). Secondly, the method of fixing price changed from cost-based pricing model (CBP) to market-based pricing model (MBP). The method of CBP has been in practice for three decades since 1979. In the market-based mechanism, the ceiling price or the maximum selling price is decided by taking the simple average of prices of brands with more than one per cent market share. In the case of each bulk drug, which is under price control a single maximum selling price is fixed that is applicable throughout the country and that is called as ceiling price.

Reference pricing', differential pricing and price negotiation are the other major drug pricing models. In reference pricing people in India will pay what people in other countries pay for a given drug for a given cure. However, it is difficult to determine the paying parity in case of products that are similar, but not the same. The differential pricing model suggests that government procurement and private market have different prices as the former purchases drugs in bulk and may enter into a long term contract for procuring drugs. This will help drugs available in the government system to be cheaper. It helps both the rich and the poor to access lifesaving drugs. It is, however, likely that the cheaper drugs came back to the market through profiteering from black marketing. The price negotiation model ensures a pre-determined price for the drug manufacturer. But one does not know the cost of research and development of the drug, time to produce the drug on industrial scale and amount of the drug to be produced. So the private manufacturer will not have an incentive to join such a venture. Given the reality that a substantial proportion of Indians do not have money to buy drugs at market prices, the Committee on Price Negotiations for Patent Drugs (2007-13)[13] recommended reference pricing as the method to price fixing. In fact the Government of India's Task Force (2005) also recommended the method of reference pricing in each therapeutic class.

[13] http://pharmaceuticals.gov.in/sites/default/files/Report%20of%20Committee%20on%20Patented%20drugs.pdf

Eventually, the MBP method of NPPA in fixing ceiling price of drug encountered with severe criticism and was challenged in the Supreme Court (SC) of India by a civil society organisation 'All India Drug Action Network' by demonstrating the instance of NPPA's referential simple average price being higher than price of a market leader and in some cases, higher than the procurement prices too. According to the Network, the trade/profit margin of pharma firms and distributors is in the range between 10 to 1300 per cent. In its verdict delivered in July 2015 the SC pointed out the irrationality of such a method and directed the Government to review the same. An Inter-Ministerial Committee has since been formed to examine the matter.

It is obvious that there is strong advocacy against price control in the pharma sector (Nair, 1965). If unavoidable, they argue for a minimal list of drugs under price control and a method of price fixing that is favourable for the industry. At the other end, there are constituencies that advocate right to health and favour expansion of the list of essential drugs and a method of price fixing that reduces the price of the drug as much as possible. Balancing these extreme positions is a knife-edge walk for any regulatory agency. There is of course the space for a covert stand for the regulator depending on the lobbying power of the interest groups. In most of the cases, as one observes in the real world, the industry-regulator nexus tends to prevail upon the rights based movements rather than the other way around (Mulinar, 2016).

The recent price control orders fixing price of a formulation appears to provide some leverage for the industry. The very particular ingredient molecule of a therapeutic class targeted at a certain disease can be administered in different drug dosages (i.e., 200mg or 300mg) and forms of dosage (pill, tablet, capsule syrup, solution etc.) and routes (mouth, blood and skin) with varying in-active ingredient (i.e., excipients). The formulation involves these dosages, forms and routes of administration. The leverage lies in bringing the least demanded formulation (i.e., dosage form) under price control, keeping all others out of the net.

Emerging Alternatives: Price Negotiation and Trade Margin Rationalisation

Bulk procurement negotiation is an emerging alternative to price control mechanism in order to bring down drug prices. In the developed countries

such an alternative is evident (Rand, 2008; Lakdawalla *et al.*, 2009). But the ability to engage in such negotiations is limited only to the state, large organizations or insurance companies.

In India bulk procurement has been tried by state governments of Tamil Nadu and Rajasthan through negotiation with the drug manufacturers and dealers / distributors (Lalitha, 2008). The drug procurement of Tamil Nadu Medical Service Corporation is considered to be the time-tested and successful model based on the principles of centralised procurement and decentralised distribution. The Sandhu Committee (2004) and the Taskforce (2005) both studied the two states. The former recommended price negotiation at the launch of a new patented drug as one of the measures to make drug prices reasonable (GOI, 2005).

The scope of the method is limited. The percentage of patient population in India getting health care services from public hospitals varies across states. A large portion of them approach private sector, because of poor facilities in government premises and absence of such health facilities altogether. According to NFHS-4 (2015-16) findings, private health sector is the primary source of health care in urban (56 %) and rural areas (49 %). There has not been any organizational back up for the patient population, to negotiate price of drugs that are prescribed to them. With limited coverage, the insurance companies of the country have also not made any attempt to negotiate drug prices for their clients. Only 29 per cent households in India have at least one person covered under health insurance or health scheme as per NFHS-4, and findings mostly under state provided schemes like Rashtriya Swasthya Bima Yojana (RSBY).

Another alternative suggested in recent years is rationalization of trade margin (AdvaMed, 2018); its feasibility is a matter of debate. Such a trade margin in generics is number of times higher than the production cost. However, unless there is a proper mechanism to assess the cost of innovation and drug production for the originator drugs under patent protection and cost of production of patent expired drug formulations, fixing the trade margin would be arbitrary.

Bulk procurement and distribution or sale of generic and/or branded medicines at subsidized prices through public sector outlets is an option in making affordability of life saving drugs to all especially the poor. Certain policy measure like the 'Pradhan Mantri Jan Ausadhi Pariyojana (PMJAP)'

initially launched in 2008 intends to ensure quality medicines available at affordable prices for all to help the poor and disadvantaged, through exclusive outlets Jan Aushadhi (Medical) Store[14]. The Public Health Foundation of India (PHFI) in its report in 2012 has outlined several bottlenecks in the implementation of the scheme and concluded that only 50 per cent of the prescribed basket of medicine is available for the public in any given time in Jan Aushadhi stores in public hospitals. The aim of the Jan Aushadhi scheme to reduce out of pocket expenses in healthcare remains a distant goal. Recently the Government of India took measures in supplying generic drugs through Pradhan Mantri Bharatiya Jan Aushadhi Kendras (PMBJAK). At present 3100 such stores working across the country. The government encourages the reputed NGOs and person with credentials to open Jan Aushadhi stores. The report on the business plan for Jan Aushadhi model shows medicines available in open market could be higher between 2.5 times to 10 times compared to Jan Aushadhi stores[15]. But still, there are not enough number of stores to serve the needy poor who are widely spread across the country. Further, as most of the doctors especially the private ones given their own business interests may prescribe those branded drugs which may not be available in these stores.

Menace of Spurious Drugs

The quality of the drugs produced in India is another major issue. It is observed that India could be one of the leading countries in the world for the production of spurious or low quality drugs (Khan and Kahr, 2015). WHO observed that India accounts for nearly 35 per cent of world's spurious drugs market. In a recent study by National Institute of Biologicals, for Ministry of Health and Family Welfare in year 2014-16, it was found that more drugs of poor standards were found in the government hospitals as compared to the pharmacies in the market. While pharmacies in the market had 3 per cent of the poor quality drugs, government hospitals had 10 per cent. In this regard NITI Ayog suggests using Block Chain technique to deal with the menace of counterfeit drugs in India[16].

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[14] See at: http://janaushadhi.gov.in/pmbjp.html. Under the scheme all the commonly used generic medicines covering all the therapeutic groups and other related health care products are provided at cheaper than market prices. Currently it covers 700 medicines and 154 surgical items.

[15] See at: http://janaushadhi.gov.in/pmbjp-book.html.

[16] See https://factordaily.com/niti-aayog-blockchain-for-drugs-in-india/

All the above discussion indicates that these all these issues are related and affecting the access to and affordability of healthcare especially the needy poor. As observed above, considerable portion of household health expenditure is on drugs and hence drug price policy affects the access to affordable life-saving drugs.

National Health Policy (NHP) 2017

The new NHP 2017 of Ministry of Health and Family Welfare (MoHFW), Government of India states that *any regulatory environment around pricing requires a balance between the patient's concern for affordability and Industry's concern for adequate return on investment.* The NHP also envisages that public sector companies producing drugs, vaccines and surgical implements would act as catalysts to ensure better quality and price in the private sector. The government of India has made it clear that it is bound to revise the NLEM for generic drugs from time to time to help patients who depend on private care. Similar interventions in regulating price will also be made in case of diagnostics and equipments. The policy document acknowledges the catastrophic health expenditure as one of the major contributors of poverty. How far the Government of India materializes the same is to be seen.

Draft Pharmaceutical Policy 2017

The Draft Pharmaceutical Policy 2017 of Government of India aims to 'guide and nurture pharmaceutical industry of India to enable it to maintain and enhance its global competitive edge in quality and prices' and to make essential medicines affordable to common people. It aims to achieve self-reliance through indigenous production of drugs, research and development and ensure quality of medicines for export and domestic markets. The pricing mechanism in this policy is sale of medicines in pharmacopeial name. The focus is shifted 'from price control to monitoring of drug prices, their availability and accessibility'. But the Government of India does not seem to have much resource to achieve its desired goal through implementing compulsory licensing and other mechanisms (Joseph, 2017). Moreover, critiques of new policy say that it dilutes the authority of NPPA and DPCO and is advantageous to the pharma industry (Srinivasan, 2017).

4. The Debate and Discussion on Price Controls

In this section we examine the major arguments in the literature for and against price control in general and in India in particular.

Future-Present Trade-off and AMR factor

The Rand study that examined the pharma industry regulations and their impact on industry revenue in 19 countries (including OECD and other European countries and USA) for the period 1992-2004 observed that such regulations had impact on reducing the revenues of the pharma firms (Sood *et al.*, 2009; Lakadawalla *et al.*, 2009). From Rand research studies it is observed that regulatory approaches that reduce pharmaceutical revenues may generate modest consumer savings in the best cases, but they risk much larger costs as decreased innovation leads to reductions in life expectancy (Rand, 2008; Lakadawalla *et al.*, 2009). In the Rand studies, they have estimated based on a modelling and simulation the potential effects of drug price regulation in the USA. Based on their estimates they observed that price controls reduced life expectancy over time. The price control scenario simulated the effect of a 20 per cent reduction in manufacturer revenue while holding consumers' out-of-pocket prices constant. Price controls would have small negative effects on life expectancy for current cohorts, but more significant negative effects in the future (Rand, 2008; Lakadawalla *et al.*, 2009). Herein, if one believes in the methodology and estimates of these studies, there is a valid point for consideration.

Another argument against the price control is that cheaper price of certain drugs especially the antibiotic may cause the wide spreading phenomenon of Anti-Microbial Resistance (AMR) which is considered as a threat and disastrous for public health and health care sector. The misuse and overuse of the drugs such as antibiotic may result in AMR (WHO, 2005). In fact a recent study as observed such trend of misuse and overuse of antibiotics (Ranganathan, 2017). There is also pollution of environment due to sheer callousness of pharma and Bio-pharma firms and hospitals while dumping the pharma / bio and hospital waste in the neighbourhood, which causes AMR to spread (WHO, 2005). A recent report commissioned by Nordia[17]

[17] Nordia is a Swedish Wealth / Asset Management Company.

through Changing Markets Foundation[18] investigating the polluting wastes from pharmaceutical firms in and around Hyderabad, highlighted the prevalence of such a phenomenon polluting the neighbourhood environment[19] (Nordia, 2016). Moreover, irrational fixed dose combinations (FDCs) of drugs are also major cause of antibiotic resistance in India (Srinivasan *et al.*, 2016: 21).

Market Economy and Price Competition Vs. Information Asymmetry and Power Relations

In the theory of market economics, usually the consumer choices result in price competition which in turn brings down the prices of goods and services. Such a theoretical construction is based on assumptions such as perfect competition, no information asymmetry, and availability of effective substitutes in the market. But, in case of pharmaceutical products, many of these assumptions may not be applicable. Pharmaceuticals is one of the industries where competition in drugs / pharmaceuticals may not bring down the prices of drugs given patent protection monopoly, information asymmetry, skewed power relations between buyer and seller, and nexus between manufacturers / supply chain and the drug prescribing doctors (Centad, 2010; Bhattacharjea and Sindhwani, 2014; Mondal and Pingali, 2015). The demand for pharmaceuticals / drugs is not emerging from the end consumers (i.e. patients) but is mediated through doctors (physicians and surgeons) and pharmacists. Moreover, as it is observed, the players in pharmaceutical market are far from competitive and more of concentrated ones (Mehta *et al.*, 2016).

When Adam Smith, the first economist advocating free market, expected the 'free market' will follow certain moral values and social responsibility, but the later it is noticed theemphasis was more on market than its guiding principles (Woolcock, 1998). The demand for health care certainly a special cases where the concerned industry may have to serve these demands going beyond market principles.

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[18] The ***Changing Markets Foundation*** is an NGO based at London. The Foundation was formed to accelerate and scale up solutions to sustainability challenges by leveraging the power of markets. See at: https://changingmarkets.org.

[19] See at: http://changingmarkets.org/wp-content/uploads/2018/01/Changing-Markets-Nordea-report-January-2018.pdf

Induced-Demand and Missing Standard Therapeutic Procedures

The concept of induced-demand is well observed in the market for health care services including the prescription drugs (see Fuchs, 1996; Johnson, 2014). Such a demand prevails '…when the physician influences a patient's demand for care against the physician's interpretation of the best interest of the patient' (as quoted in Johnson, 2014). Although treatment varies with patients characteristics and hence the physician has to accordingly tailor the care services and it is the moral and ethical responsibility of the physician ensuring patient's optimum requirement. Certain mechanisms (incentives) and physician own interests move the demand for health care beyond the best interest of patient (see Fuchs, 1996; Johnson, 2014). In case of prescription drugs there is always a space for such induced-demand. Such practices, particularly in private health service agencies in India are well acknowledged (see Centad, 2010). A very recent study has shown certain evidence in the form of 'cut practices' in the state of Maharashtra (Gadre and Sardeshpande, 2017). There is a 'missing' in the standard therapeutic procedures, either lack of guidelines or regulations to implement the same.

In order to control such malpractice in the healthcare, some of the concerned state Governments such as Karnataka and Maharashtra, have made certain moves regulating the private health care industry through legislative action (ibid).

Drugs Market: Higher Prices, Higher Margins and Super-profits

It is also observed that pharmaceuticals industry is one of those industries which has a high trade margins and super-profits. In fact the Sandhu Committee[20] observed high trade margins while reviewing prices of drugs particularly that of life-saving ones. Also there are some research studies as well which have observed such a case (see Mazumdar, 2013; Selvaraj, 2007). Price of patented drugs in any particular therapeutic classes, are number of times higher than their counterpart generics. Soon after expiry of patent protection of a drug, price of the same drug drastically declines. There are

[20] The Indian Government Panel Chaired by G.S. Sandhu, Joint Secretary, Department of Pharmaceutical, Ministry of Chemicals and Fertilisers, Government of India, was set up in August 2004 to report on drug prices and recommend ways to rationalizing drug prices. It submitted its interim report in November 2004.

huge variations in prices of drugs and medical devices in each of therapeutic categories / classes. The pharmacies attached to hospitals their dispensing price when compared to their procurement price, is set to earn for them huge margins (Mudur, 2017).

In fact the sociological research in the fields of pharmaceutical marketing and its regulation and studying socio-political relations of pharmaceutical production, development and consumption brought out the concept of *pharmaceuticalisation* (Mulinari, 2016). The concept is defined as 'the translation or transformation of human conditions, capabilities, and capacities into opportunities for pharmaceutical intervention' (*ibid*). It is observed that the marketing-regulators nexus in respect of pharmaceuticals industry is concerned with the socio-political mechanisms underlying development and enforcement of marketing rules, and impact of these rules and enforcement scheme on marketing practices (*ibid*). All they are crucial in shaping the pharmaceutical markets and healthcare.

5. Concluding Remarks

This is an attempt in examining and carrying out the discussion and debate on regulations and prince control in pharmaceutical industry in the Indian context. Herein the above discussion presented the perspectives of the industry and the welfare of the poor population along with alternative options. Given its critical nature in existence of human race while protecting, maintaining and restoring health of human beings, regulations on pharmaceutical industry are needed to ensure safety, quality and effectiveness of drugs they develop and produce. As pharmaceutical industry involved with the phenomenon of Induced-demand and it is one of the industries where the price competition may not be prevailing, hence price controls on certain essential and life-saving drugs are needed in the Indian context.

Despite certain anomalies prevailed in the pharmaceutical industry and market, imposing regulation and price controls as pro-business/industry lobbies observed, are considered as obstacle for the growth of Industry and affects the future generation. But the question arises is, whether healthcare and pharmaceutical industry can serve the purpose rightly with anin-built mechanism of self-regulation without any of these external regulations and price controls of the state. When an industry consists of in-built feature of market failure characterized in criticality of information asymmetry, absence

of price competition and induced demand, market mechanism may not be the right one directing its market transactions.

One must agree that unlike the public sector, for the survival of the private firms and encourage private investments in these domains, the pharma sector must be facilitated to recover their capital invested in development, production and marketing of new drugs. When a drug developed for the rare diseases which contain very limited market, the average cost of development and production of the drug would be very high than that of drugs for more general or widespread diseases. In the latter case, the cost can spread over but is limited in case of the former. But the justification for very high costs made on promotion of drugs (advertisement or otherwise) is something which need to be debated, particularly in case of life-saving drugs. This is where the incentive mechanism tailored in the drug promotion creates induced demand in case of aggressively promoted drug over and above the optimum demand (need or requirement) of the patients and against the demand for its substitute, especially the cheaper counterpart in a therapeutic category. Here comes, as mentioned above, the issue of what the research in the discipline of sociology call it pharmaceuticalisation.

A free market should be guided by certain moral values and social responsibility. The demand for health care and education are certainly the special cases where the concerned industry may have to serve these demands going beyond core market principles. The industry that serves these sectors / domains, given their inelastic nature of demand for their services and products often fell for high trade margins and making supernormal profits. So these needed to be regulated. Since most of the domestic industry especially those in private sector in India, including pharma industry, has been one or the other way thriving on the state patronage and social investment such as tax incentives or levy exemptions, land acquisition, physical infrastructure, facilitating raw material, easy access to financial resources and access to research output from R&D in public sector, they have an obligation to make available their products and services at affordable prices to the masses in the country. It is right time to reflect upon how far the health care providers and pharmaceutical industry are socially responsible in present times.

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