National Drug Policy Face-off: Some Notes Justifying the Regulations and Drug Price Control Regime in India

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I Introduction

Pharmaceutical industry / sector consisting of firms involved in drug discovery, development and manufacturing along with marketing, is critical component of health care sector. The pharmaceutical products commonly known as medicines, medications or drugs are fundamental components of health care[1]. The advancements in the knowledge and innovations in respect of pharmacology and pharmacy along with technology and mobilization of required investment (public and private) leveraged the advancements in the human health care. The pharmaceutical industry producing the drugs / medicines and medical devices (patented, branded and generic), is crucial in ensuring availability of such life-saving drugs[2]. 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 predominant and playing a key role in growth of the pharmaceutical industry worldwide.

The pharmaceuticals industry has considerable economic impact as well for the economy at a macro and households at micro level. Its contribution to trade and economic growth and employment generation (directly and indirectly) is found to be significant. It is observed that significantly a large portion of health care expenditure (both the private and public) has been involved with drugs / medication (prescription or over-the-counter). Hence, the state policy and its performance of the pharmaceutical sector plays critical role in achieving universal health care through ensuring safety, quality and effectiveness of drugs and the access to life-saving drugs at affordable prices along with rational use of drugs (WHO, 2005; 2008; 2011; 2017). Pharmaceutical industry has been subject to a variety of regulations and laws governing the patents, testing, safety, efficacy and marketing of drugs along with price controls on certain drugs. One of the challenges that pharmaceutical industry across the globe wading through is these regulations along with price controls.

The polar opposite versions of arguments for and against such regulations and price controls are as follows. The argument against such regulations and price controls is they reduce the revenues of the firms of pharmaceutical industry and there by the further investment in drug discovery which deprives the future health care needs and generations. It places a discouragement effect that costs the future hence the apparent trade-off between present benefits and future risk or

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[1] According to the World Health Organisation (WHO) technology, pharmaceuticals and medical products are one of the key factors in health systems of a country (see WHO, 2016; IFPMA, 2017). According to the WHO, a health system is consists of six building blocks: service delivery; health workforce; information; medical products, vaccines, and technologies; financing; and leadership / governance (*ibid*).

[2] As it is well recognized that medicines / drugs are critical in protecting, maintaining and restoring health of human beings (WHO, 2011). Such pharmaceutical drugs are used to diagnose, cure, treat and prevent diseases.

costs (see Rand, 2008). The argument in favour of regulations and price controls is that while ensuring safety and efficacy of drugs they must be accessible and affordable to most of the population in need.

Also, by market economic principles, the demand for health care and drugs is observed to be price inelastic. Again, it is a well established fact that health care industry / sector consisting of pharmaceutical industry involved with the phenomenon of *induced-demand* which is influenced by the supply (Fuchs, 1996; Johnson, 2014). Patients' demand for health care and drugs is mediated through the physicians / surgeons who have a space, depending on their self-interest and expected benefits, to shoot up the demand beyond the patient's optimum leading to further cost burden on patients especially the poor ones. The induced demand indicates that drugs market is affected by supply chain strategies of the marketing and promotion beyond the optimum requirement of the patient. Pharmaceuticals is one of those industries where it may not work or prevail the price competition that brings down the prices of drugs. It is so given its 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 (see Centad, 2013; Bhattacharjea and Sindhwani, 2015; Mondal and Pingali, 2015; Gadre and Sardeshpande, 2017). Therefore, the regulations and price controls are viewed as correcting mechanism.

The discussion and debate on such an issue is a global phenomenon and across countries. Meanwhile, many of the countries have placed certain regulations in pharma industry and price controls on certain essential and life-saving drugs. In this regard, the Government of India as well has been implementing such regulations on its pharmaceutical industry and price controls on certain drugs and health products / services. However, the recent Drug Price Control Orders of 2013 (DPCO 2013) under the National Pharmaceutical Pricing Policy 2012 (NPPP 2012) being implemented by the National Pharmaceutical Pricing Authority (NPPA), Ministry of Chemicals and Fertilisers, Government of India, has come to scrutiny in the recent discussions (see Phadke *et al.*, 2013; EPW, 2014; Ahmed *et al.*, 2015; Gandhi, 2016; Rajagopal, 2016). Further, the NPPA's action on price capping particularly in respect of medical devices such as stents and knee implants has become a point of discussion on regulations and price control (see GOI, 2016, Khan, 2017; AdvaMed, 2017&2018). It is pointed out that the aim of recent price capping of medical devices is to improve access and affordability but as it observed to be failed, at least in the short-run, to improve the same and realizing its aim and hence the other alternative solutions surfaced (see AdvaMed, 2018). The undertones of the debate and discussion point out that these regulations and price control makes it difficult the 'ease of doing businesses' in India which is the central concern of Government of India's policy of making India. Hence, the health dilemma prevails in India where the required strategy is balancing one that facilitating serving the public needs with business sense (see Raghavan and Rajagopal, 2017; Khan, 2017).

Concerned citizens and civil society[3] point of view is that change in span of control and method of setting drug prices in the recent orders is not in any way beneficial for the consumers. Even the Supreme Court of India convinced of the above view, lamented the concerned authorities on this issue. On the other hand the pharmaceutical industry especially the global firms who found market in India for their health care services and drugs are as affected by such regulations and

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[3] Including some non-governmental organizations (NGO) such as All India Drug Action Network and Jan Swasthya Abhiyan (JSA). The JSA formed in 2001 is part of the global People's Health Movement.

price controls, they raised their concern in this regard. One threatening consequence expected is that if they exit from producing and / or supplying for the Indian market, it may result in scarcity of supply of important drugs in meeting growing demand. Here comes how far it is right or justifiable each of the polar cases and if so is there any middle path resolving both the parties.

The epidemiological transition of disease burden in India indicates it is shifting from communicable, maternal, neo-natal and nutritional diseases (CMNNDs) to that of non-communicable diseases (NCDs) (see, ICMR/PHFI/IHMR, 2017, GOI, 2018). The increasing life expectancy at birth (LEB) along with a decline on the metric of Disability Adjusted Life Years (DALYs) over a period indicates the reduction in disease burden jeopardizing the potential and healthy human lives in India. Still such a disease burden (both the CMNNDs and NCDs) is very high when compared with any reference averages of the globe (see GOI, 2018). Along with such a high disease burden and the epidemiological transition has far reaching implications on the cost of health care. The shift is relatively less costly health care services attending the disease burden of CMNNDs nature to that of costlier NCDs (see, ICMR/PHFI/IHMR, 2017, GOI, 2018). The growth of pharmaceutical industry consisting of drugs and medical devices facilitated by balanced state policy regulating same are crucial in improving access and affordability to these drugs and devices.

In this backdrop, here is an attempt to examine the issue and discussion in the Indian context. It is to discuss and present both the perspectives of industry and affordability of the poor. The primary sources of material used are research studies, reports, and discussions and debate in the print media.

II Drug Industry: Discovery & Development, process of Production and Marketing

As the Census Bureau of United States of America (USA) defines the pharmaceutical / drug industry consists of companies or firms 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 biological are substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of diseases.

It is generally understood that *drug discovery* is a research or investigating process by which potential drug(s) are discovered or designed[4]. In the subsequent *drug development* process (after a compound is identified / discovered), it involves the activities undertaken to establish efficacy and safety of the potential drug candidate. 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.

Usually companies are categorized into large, medium and small by scale of operation and size of investment / capitalization / market revenue. In pharmaceutical industry all the companies /

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[4] Past experience indicates that drug discovery has been sometimes accidental (serendipitous) and other times it has been through a planned active research and investigation isolating active ingredient(s) from traditional remedies. Also, the growing knowledge systems understanding of metabolic pathways related to state of a disease or pathogen and ways manipulating these pathways using molecular science has been critical in these discoveries.

firms might not engage in all-through phases and activities beginning with researching and ending with marketing. As the Food and Drugs Administration (FDA) of USA categorized based on the activity and phase, the '***mainline(rs)***' category of companies, most of them are very large in scale, engage in all-through phases / activities as mentioned above. Another category of companies / firms restrict their engagement to ***research and development*** of new chemical entities (NCEs) or new drug candidates / compounds. The other category of companies / firms is of those engaged in manufacturing and marketing of only the ***generic drugs*** (branded or non-branded). One the other hand some firms are specialize in producing both or either of the bulk drug (API – active pharmaceutical ingredient) and / or the formulations.

In the drug market, one type of the product segmentation based on patent is in terms of *originator drug*, *branded-generic* and *commodity / generic - generic*[5]. Another type of segmentation of drug product market based on sales control is *prescription* drugs and *over-the-counter* (OTC) drugs. Drugs classes categorized based their chemical structure, mechanism of action, biological target and disease and mode of action. They are classified on their *therapeutic class or category*[6] which is based on diseases affecting different parts of human biological system (parts of body). A comprehensive system in this regard is ***Anatomical Therapeutic Chemical Classification System*** (ATC). It involves the classification by organ system and therapeutic, pharmacological, and chemical properties.

Some of the firms in the pharmaceutical industry do engage in activities that are overlapped into multi-therapeutic classes. The dosage form / unit dose of a drug (pill, tablet, capsule, syrup, solution etc.,) consisting of a mixture of active ingredient and inactive component (i.e. excipient), in each of the therapeutic class, depends 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 pricing 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, research and development (R&D) and innovation is the key to the success of the firms and industry in this sector. It incurs huge amounts of investment on its research and development (R&D) much more and before it incurs actual cost of production. Hence the capital employed in R&D and production along with the cost of such capital would form the basis for fixing the prices of product of a firm. The long process from drug discovery and development to testing, manufacturing and marketing involves a considerable gestation period for the return on investment. It takes a minimum of 10 years from drug discovery to launch of new drug candidate. It is one of the industries that require a long investment cycle and decisions made many years' ago have consequences on current financial performance. Similarly, the current performance may affect future investment.

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[5] The ***originator drugs*** are those developed and manufactured by a company and are under patent protection which provides virtual monopoly to that company. The ***branded generic*** drugs are those produced and marketed after expiry their patent protection period but they are marketed on a producing company's brand name. The ***commodity / generic – generic*** drugs same as above (those having expired their patent protection period but being manufactured and marketed) but without brand name, on the name of formulation (non-branded).

[6] Namely, antibiotics for infections, those intended for respiratory, those of cardiovascular, that of oncologic etc.

As the schema of Food and Drugs Administration[7] (FDA) of US shows, from test tube to new compound approval for marketing the drug discovery and development consists of sequence of phases and activities beginning with basic and applied research initiating the process of discovery programme that would result in the synthesis or isolation of compounds. Then they are to be tested in assays and animal models in preclinical or pre-human development phase followed by the clinical (human) testing phase which is typically conducted in three successive phases. Meanwhile, a parallel process of indications on investigational new drugs (IND) begins with concerned national drug authorities permitting such trials. When successful in these phases, then for the new compound approval begins the process submitting marketing approval applications (i.e. new drug applications – NDAs or biologic license applications-BLAs) to the concerned National Drug Authorities[8] for review (see DiMasi *et al.*, 1991; 2016). Such approvals are to ensure the safety, quality and efficacy of the new drug candidate or compound. There starts the manufacturing for market, marketing and distribution activities. The *transition rates* along the sequence of different phases are volatile and reducing over a time. A study in this regard observed that success rate of the drug compound that enter testing phase and finally get through the marketing approval is only 12 per cent (DiMasi *et al.*, 2016).

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

Both advancements in human health care and growth of pharmaceutical industry depends on the drug discovery and development. It is understood that developing of 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 behavior 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(s)***, which are again subject to a new series of tests and non-clinical studies. There begins the *development phase* involving crucial preclinical and then clinical trials that determine the success of the drug candidate as a drug / medicine for use.

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[7] See at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm053131.htm.
[8] It is Food and Drugs Administration (FDA) in USA and its European Medicines Agency (EMA) for the European countries which are member states in Euro Commission (EU). The EMA works closely with the national competent authorities of the Member States of the EU and the European Economic Area (EEA) responsible for human medicines. The Pharmaceuticals and Medical Devices Agency (PMDA) is Japanese organization for the purpose. In India, the Central Drugs Standard Control Organization (CDSCO) is the national regulatory body for Indian pharmaceuticals and medical devices, and serves parallel function to EMA of Europe and FDA of USA and PMDA of Japan. Within the CDSCO, the Drug Controller General of India (DCGI) regulates pharmaceutical and medical devices, under the Ministry of Health and Family Welfare, Govt. of India.

It is obvious that more than any other sector, the growth of pharmaceuticals is highly dependent on the research and development (R&D). The drug discovery and development is capital intensive involving huge investments and it is risky and lengthy process. Also it is a gamble, chance factor, as out of the numerous trials there may be a few comes out as hit screens. Of which one or two may stand safe and effective. It is observed that for each of a successful new drug, there are number of trials in the range of 500 to 1000. Again, as mentioned above the transition rate of drug candidate through clinical trials is very low at 12 per cent (see DiMasi *et al.*, 2016).

According to an estimate the pharmaceutical industry at a global level spent nearly $157 billion on its R&D in 2016. According to a professional research services company estimate, R&D expenditure growth flattened during the 2008-2015 period wherein the compound annual growth rate of global R&D spending was 1.7 per cent (EvaluatePharma, 2017). According to some studies the cost of developing a successful medicine increased to US$ 2.6 billion when compared to US$ 179 million in 1970s (see IFPMA, 2017; DiMasi *et al.*, 2016).

There are various technical, regulatory and economic challenges in the R&D process of drug development. 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. The pharmaceutical R&D entails high failure rates. Many times R&D expenditures may not materialize in to a market-approved medicine. As a result companies / firms experience loses in their R&D investments. The lost in investments increase when a failure occurs in later R&D phases. It is observed that a phase III failure is significantly more costly than a preclinical failure because each phase is associated with a certain amount of required investment (see IFPMA, 2017).

Cost of Capital Employed / Invested: Costs of debt and returns to Investors

The drug discovery and development along with manufacturing and marketing involves multiple collaborates in terms of research and development (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). Given the opportunity cost and expected return on capital employed (ROCE), returns bearing risk premium of investors / shareholders and financiers is an incentive and a factor in mobilizing such a huge capital and investment into those firms and industry.

Along with business environment and conditions, the cost of capital is determinant factor in mobilizing the capital / investment required. In most of the research intensive industries / sectors 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 sector which is considered as highly variable (see DiMasi *et al.*, 2016). The Cost of Equity (COE) indicates the expected return while bearing the risk. Generally, the Cost of Equity (COE) is measured with two familiar approaches: the Dividend Capitalization Model which takes into account the equity appreciation and dividend growth; and the Capital Asset Pricing Model (CAPM) which accounts for market risk premium, the stock's historical borrowing

usually price changes compared to changes for the market as a whole (beta) and risk-free value. 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
Given the above long process and heavy investment the drug developing firms are granted with patents which ensures the exclusive market for the product. Usually the product / process patent duration varies between 10 to 20 years across countries. Evergreening is considered as one of the practices that firms sometimes engage in extending the 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, duration of market exclusivity through patent protection. It has to recover the total capital employed not only that involved with successful drug candidates but also the failure once in the process of discovering and developing the successful one.

III Pharmaceutical Industry and its Regulations in the Global Context

Pharmaceutical industry emerged as one of the fast growing ones at global level. The value of industry at a global level consists of several billion dollars. According to an estimate the pharmaceutical industry / market worldwide crossed a trillion US dollars in 2014 from about US$400 billion in 2001. Along with US and Europe, developing countries like China, India and others are emerging as key players in the industry. According to an estimate, the worldwide gross value added (GVA) of pharmaceutical industry touched US$452.8 billion in 2014 while accounting for 3.8 per cent share in the GVA of total manufacturing sector in the world and employed around 5.1 million workforce worldwide (see IFPMA, 2017).

A large portion of the industry earnings / revenue is comes from the branded and patented (originator) drugs sale / marketing. According to a market research services company (Hardman & Co.) estimates the worldwide prescription drug market had underlying growth of 4.9 per cent from $786 billion in 2015 to a reported level of US$816 billion in 2016.

It has been observed across countries that expenditure on drugs or medicine accounts of considerably major share of the total expenditure on the health care. In this regards, the global community and government of individual country committed to improve the access to and affordability to such life-saving drugs for needy. As a policy instrument in this regard many countries irrespective of their level of development have been implementing certain regulation and price controls on drugs.

The intuition and trial and error believing in medicinal properties of plants, animals and minerals that reigned for thousands of years gave way to modern pharmaceutical industry since mid-19th century. Advancements in science and technology in the 20th century further changed the system from crude drug to isolation and purification of active ingredients, chemical synthesis and computer-aided drug design. Industry also scaled up from small scale drug compounding with individual entrepreneurship at the local levels to large scale one involving discovery and

development of active ingredient molecules and mass production and distribution spanned across globe. In the process, different parts of the globe witnessed some tragedies related to pharmaceutical drugs (see Hooper, 2007). In order to mitigate unethical practices and ascertain the safety, quality and efficacy of the drug, certain regulations have come in to force. As early as in 1906 (The Pure Food and Drug Act), then the Drugs and Cosmetic Act in 1938 was passed in USA followed by Kefauver-Harris Drug Amendments passed in 1962 to ensure drug efficacy and greater drug safety and Food and Drug Administration (FDA) Act, 1988 officially established FDA as an agency 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[9] 2017. The UK Government made this Act in response the instances of extortionate prices charged (i.e. price gouging) for certain drugs (see 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". The previous Health Services Act[10] 2006 of UK prevented the Government from intervening and controlling the price of medicines of those companies which are voluntarily became part of the Governments' Pharmaceutical Price Regulation Scheme (PPRS). The PPRS is supposed monitor and control the prices of medicine in the country. Using loopholes in the PPRS, some of the pharmaceutical companies while imparting certain malpractices (de-branding, re-categorisation etc.,), they involve in shooting up the prices of drugs (Sweetman, 2017). Hence, the present Act is seen as a correcting mechanism.

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. A Rand study that examined the regulations in respect of pharmaceutical industry and their impact on industry revenue in 19 countries[11] (including OECD and other European countries and USA) for the period 1992-2004 shows that not only certain such regulations existed in these countries prior to 1992 but also some of them have adapted certain new regulations (see Sood *et al.*, 2009).

IV Pharmaceutical Industry, Domestic Drug Market and Regulations in India

In India, in contrast with its fast growing economy its health care situation is slowly advancing. Despite its advancement and achievements in healthcare since independence particularly the performance in this regard during the last two-and-half decades, it is falling short in many respects of required outcomes (see ICMR/PHFI/IHME, 2017). Although Indians are living longer, they are healthier at present than situation previously along with improvement in respect

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[9] That is the Health Service Medical Supplies (Costs) Act ('the Act') which received Royal Assent on 27th April, 2017 and the Act's provisions are now in 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.

[10] That is the National Health Service Act 2006 of United Kingdom (UK). See available at http://www.legislation.gov.uk/ukpga/2006/41/contents.

[11] The nineteen countries included in our analysis are Australia, Canada, Denmark, Finland, France, Germany, Greece, Hungary, Italy, Japan, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Turkey, the United Kingdom, and the United States.

of nutrition among children and adults, the high disease burden continue to persist (*ibid*). Along with age-old communicable and infectious diseases and malnutrition, the emerging non-communicable lifestyle disorders such as health and chronic pulmonary diseases, strokes and diabetes 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 is still not yet been ensured.

India has emerged as one of the largest in respect of volume and value of pharmaceutical industry in production / manufacturing as well as in marketing. While the Indian pharmaceutical industry has been succeeding in both the domestic and global markets including the Europe and USA, the global firms have been exploring the Indian market. The India's pharmaceutical industry strength in the global market is largely in respect generic drugs market, whereas the Indian market for pharmaceutical / drugs market is opened for both the branded (originator or otherwise) and generic drug by both the domestic and foreign firms. Given its growing size of Indian pharmaceutical industry and the country' domestic market, foreign direct investment (FDI) naturally attracted and country is opened its pharma sector for 100 per cent FDI in 2015. The advantages that India has in respect of pharmaceutical production are: competent and skilled workforce at cost-effective terms, its potential market with the growing demand for health care, legal framework and patent laws (see IBEF, 2017).

According to the latest (October 2017) sectoral report of India Brand Equity Foundation (IBEF) the Indian pharmaceuticals market is the third largest in terms of volume and thirteenth largest in terms of value, and it accounts for 20 per cent in the volume terms and 1.4 per cent in value terms 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, 2017). As per the estimates of Business Monitor International, while the gross value added (GVA) of the pharmaceutical industry in India was US$17.77 billion in 2014, total sales value of pharmaceuticals in the country was US$15.63 billion and the industry employed around 6 lakh workforce of the country (see IFPMA, 2017). According to the Pharmaceuticals Export Promotion Council of India (PHARMEXCIL) India's pharmaceutical exports have stood at US$ 16.4 billion in 2016-17 (see IBEF, 2017). Of the total sale value pharmaceuticals in India in 2014 nearly 85.5 per cent is accounted for prescription drugs by mode of sale and around 76 per cent is accounted for generics category by the form of patent protection. The per capita sales value of pharmaceuticals in India was estimated to be US$12.4 which is 78 times lower than that of US$970.0 observed for USA (see IFPMA, 2017).

In terms of its structure, the Indian pharmaceutical industry consists of the presence of a category of Large firms of foreign (MNCs) and Indian origin involving in R&D activities developing drugs and production of originator / patented drugs; a category of Medium and Small Indian firms involving in production of patented and generic drugs, and contractual research and manufacturing services (CRAMs); and another category of small Indian firms involving in production of generic drugs (Centad, 2013). As is the case across the globe, chemical molecule based pharma industry has been predominant in India but the bio-technology based pharma (Bio-pharma) industry has been emerging in the country (IBEF, 2017).

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

To present brief history, the Independent India had inherited the two legislations the Drugs and Cosmetics Act 1940 and the Patents and Designs Act 1911 of the British Government in India. Post-independence, the Government of India made efforts in revising the 1911 Patents Act. After an unsuccessful attempt in 1953 in implementing a Bill based on recommendations Tek Chand Committee[12] of India and Swan Committee[13] of UK, it succeeded in 1970 while adopting the Ayyangar Committee[14] recommendations. The Government of India had enacted the India Patent Act (IPA) 1970. While the 1911 Act had made provision for patent protection for product, the 1970 Act changed it to patent protection on process. Compulsory Licensing (CL) was an important measure emerged in this policy (Centad, 2013). 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

The then new policy regime of Government of India during early 1970s (including MRTP Act[15] and FERA[16] along with IPA) facilitated the growth of pharmaceutical industry in the country (see Centad, 2013). While the MRTP Act 1970 restricted the monopolies and restrictive trade practices, the FERA 1973 curtailed imports and promoted production of bulk drugs (see 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 (see Centad, 2013). Prior to 1970, domestic pharmaceutical industry in India was a non-entity except a few public sector units with the help of WHO and UNICEF and producing cheaper bulk drugs[17]. The country was import-dependent and Indian drugs market was largely occupied by the multinational (MNCs) drug companies. During 1970-

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[12] 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.

[13] 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.

[14] 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.

[15] MRTP – Monopoly Regulations and Trade Practices Act 1969/1970.

[16] The Foreign Exchange Regulation Act (FERA) of 1973 restricted the foreign equity ownership to 40 per cent except for products involving high technology (Bhattacharjea and Sindhwani, 2002).

[17] The Hindustan Antibiotics Limited (HAL) was the first public sector undertaking in the Drugs & Pharmaceutical Sector in India 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. HAL is the first drug manufacturing unit in India to undertake commercial production of antibiotics like Penicillin, Streptomycin, Gentamicin, Ampicillin & Amoxycillin etc. Owing to continuous losses since mid-1990s, when referred to the BIFR, it was declared as sick and put under Rehabilitation scheme. The second one is Indian Drugs and Pharmaceuticals Limited (IDPL) incorporated in April 1961. Having multiple plans at different places (along with three plants at Rishikesh, Hyderabad and Gurgaon two subsidiary units at Chennai and Muzaffarpur), IDPL is the largest public sector undertaking in this field of production. While the Hyderabad and Rishkesh plants were commissioned in 1967, the Gurugaon unit was commissioned in 1969. The Hyderabad plant manufactured wide range of 47 bulk synthetic drugs like Vitamins, Sulphas, Chloroquine, Methyl Dopa, Analgesics etc., from basic stages. The Hyderabad plant operations are totally stopped since 1996 (Bulk) and 2003 (Formulations). Only Effluent Treatment Plant, (ETP) is being operated for treating effluents of other industries.

90, domestic industry in the private and public[18] sectors had been established and began growing in terms of production and export orientation, but the growth of pharma industry is observed to be little slow during this period. Still, by mid 1980s Indian drug exports crossed the value of such imports. It picked up in the post-reform period leveraging economic reforms of the country introduced in 1991. The law governing competition and patent protection in India was further revised in response to changing times and accordingly enacted the Competition Act 2002 and the Patent (Amendment) Act 2005. The Competition Act 2002 effectively came into force in 2009. These policies along with the growing domestic market for health care and pharmaceuticals further boosted the pharmaceutical industry in the country. The sector is opened for 100 per cent FDI (either Greenfield or Brownfield) in 2015. As a result, the Indian Pharmaceutical industry assumed considerable place in the global market (see Centad, 2013; Bhattacharjea and Sindhwani, 2014; IBEF, 2017).

Policy addressing Access and Affordability: Drugs Price Control Orders

Although the Drugs and Cosmetics Act 1940 and Rules 1945 is meant to regulate the import, manufacture, distribution and sale of drugs, it does not contain any provision for price controls. In respect of price controls the Essential Commodities Act 1955 included the drugs as one of the essential commodities to apply the price controls. Following that the first action on price control of drugs was promulgation of the Drugs Order (Display of Prices) 1962 and Drugs (Control of Prices) Order 1963. They were followed by the Drugs Prices (Control) Order of 1966 and that of 1970. Based on the Hathi Committee Report[19], a landmark, submitted in 1975, the Government of India made its Drug Policy in 1978 and set up the National Drug Authority in order to enforce the price control on selective drugs. It was followed by Drug Policy 1979 and that of 1986. Accordingly, the Drugs Prices (Control) Order 1978, 1979 and 1987 were promulgated.

In the context of 1991 economic reforms, the Drug Policy 1994 was introduced and subsequently issued and implemented the Drugs Prices (Control) Order 1995. The National Pharmaceutical Pricing Authority (NPPA) was established in 1997 regulating (monitoring and controlling) the drug prices of scheduled and non-scheduled drugs. The NPPA is made responsible for implementing NPPP and DPCOs. The drugs listed in National List of Essential

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[18] Two prominent ventures in Public sector prior to 1970 were Hindustan Antibiotics Limited (HAL) and Indian Drugs and Pharmaceuticals Limited (IDPL) and they continue to be so post-1970 with expanding capacity and production and research activity. Along with the HAL and IDPL there commissioned three more central public sector enterprises (CPSEs) under the administrative control of Department of Pharmaceuticals, Govt. of India. A private venture of the Bengal Chemicals and Pharmaceuticals Ltd. (BCPL of scientist Dr. Acharya P.C. Roy) established in 1901 was nationlised in 1980 and incorporated it as PSU in 1981. The company (BCPL) has four manufacturing units at Maniktala (Kolkata), Panihati in North 24 Parganas (West Bengal), Mumbai (Maharashtra) and Kanpur (UP). The Rajasthan Drugs and Pharmaceutical Ltd. (RDPL) at Jaipur was incorporated in 1978 started commercial production in 1981. The Karnataka Antibiotics and Pharmaceutical Ltd. (KAPL) at Bangalore was incorporated in 1981 and commissioned commercial production in 1984.

[19] The **Committee on Drugs and Pharmaceutical Industry** was set up in February 1974 by Ministry of Petroleum and Chemical, Government of India (Resolution No. 3 (26)/73-Ch.III, dated 08/02/1974). The Committee consisting of 15 members was chaired by *Shri Jaisukhlal Hathi*. It submitted its report in April 1975. It was to review functioning and growth of pharmaceutical industry in India and find ways and means to meet growing requirement in the context of social objectives of the country particularly focusing on promoting domestic and small scale sector in this regard, improving technological development, measures for quality control of drugs, reducing the prices of medicine while rationalizing the price structure, providing essential drugs, ensuring availability of raw materials to industry (see GOI, 1975).

Medicines (NLEM[20]) have been usually the basis of Scheduled I drugs mean for price control of DPCO in India during the last two decades. The first NLEM was released in 1996 and the list subsequently revised in 2003, 2011 and 2015. The DPCO 1995 was followed by the recent one, DPCO 2013 under the National Pharmaceutical Pricing Policy 2012 (NPPP 2012), and it is being implemented at present. Meanwhile, the Sandhu Committee[21] observed high trade margins while reviewing prices of drugs particularly that of life-saving ones. In continuation the Government of India's Taskforce[22] in 2005 explored the various options other than price control (GOI, 2005). The Task Force while recommending price regulation fixing ceiling prices on the basis of essentiality of drug (formulation) and de-branding the essential drugs, it emphasised that the NLEM 2003 that listed 354 drugs as essential ones should form the basis of drugs for price control / monitoring (see GOI, 2005). The NLEM 2011 consists of 348 drugs and the NLEM 2015 increased it to 376.

The earlier Drug Policy of erstwhile National Drug Authority and the recent NPPP of National Pharmaceutical Pricing Authority (NPPA) are under the Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers, Government of India. Therefore, the price controls fixing ceiling prices for certain essential drugs is under the same Ministry. The Ministry of Health and Family Welfare has nothing to do with the price control other than suggesting list of essential drugs.

Medical Devices Price Capping Policy

In respect of medical devices, the government of India has taken certain measures in order to expand access to safe and effective medical products and regularize the industry / sector. They include the recent introduction of globally harmonized rules (new Medical Device Rules) and classification system for medical devices, and establishing a Medical Technical Advisory Board (MTAB) in 2017. Besides, there is a regulation and price capping policy in respect of medical devices as well (see GOI, 2017; AdvaMed, 2018). In fact, coronary stents are considered essential drug and included in the NLEM in July 2016[23]. The Government of India's regulatory body, NPPA, capped the price of various models of stents and knee implants to reduce the cost of stents and knee replacement and revision surgeries. While the stent price capping was notified in February 2017 and that of knee implants was in August 2017. It resulted in more than six per cent reduction in price of knee implants.

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

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[20] 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.

[21] The Indian Government Panel Chaired by Mr. 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.

[22] The Department of Chemicals and Petrochemicals, Government of India, had constituted in November 2004 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 life saving drugs at reasonable prices. It submitted its report in September 2005 (see GOI, 2005).

[23] The Union health ministry, following the recommendations of an expert sub-committee, notified the decision to include coronary stents under the National List of Essential Medicines (NLEM) in July 2016.

Points of Debate

The Drugs Price Control policy since its inception in 1962 has been attracting severe criticism from both the polar opposite groups: industry body as well as those concerned with consumers' access and affordability (see EPW, 1965; Nair, 1965). It is not only the method of price fixing that is being criticized, but also the list of essential drugs considered for brining it under price control and inclusions and exclusions of certain essential drugs in the list (see Rane, 1996 and 2002; Srinivasan, 2001; Josep, 2016). The point of debate and discussion 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 the recent order changes are observed for both the span of control and the method of fixing the ceiling price along with form of the drug to be brought under price control or fixation. The major change observed in the recent new order (DPCO 2013) is that its price control is applied to drug formulations not the drug as such (Bulk drug or API – Active Pharmaceutical Ingredient) it was the case in earlier orders. Secondly, the method of fixing price changed from a method of long-standing cost-based price (CBP) to that of market-based price (MBP). The method of CBP has been in practice for three decades since 1979.

In the CBP method the retail price fixing[24] is based on material and conversion costs, and packaging material costs and packaging charges along with maximum allowable post-manufacturing (MAPE) and the excise duty. But the MBP while taking into account current market conditions, based on the market share of drugs ($>=1\%$) a simple average of the prices of drugs of therapeutic class in the market is considered. In fact the Government of India's Task Force (led by Pronab Sen) in 2005 recommended a method of 'reference price' in each therapeutic class, a method different from CBM (see GOI, 2005). The MBP is even different from what the Task Force had recommended.

Eventually, the MBP method of NPPA in fixing ceiling price of drug encountered with severe criticism and was challenged in the Supreme Court of India. A civil society network, All India Drug Action Network, filed petition in the Supreme Court while showing the instance of NPPA's referential simple average price being higher than price of a market leader and in some case it is observed to be higher than procurement prices. According to the Network, the trade / profit margin of pharma firms and distributors is in the range between 10 to 1300 per cent. The Court[25] in 2015 pointed out the rationality of such a method and directed the Government of India to review the same. In this regard, an Inter-Ministerial Committee was formed to examine the matter.

Obliviously, the industry and those for it argue against any such price control (see Nair, 1965). If unavoidable, they argue for a very minimal list of drugs under the price control and a method of price fixing that is favourable for the industry. The polar opposite consisting of patient and the concerned civil society expects and argues for all or as many essential drugs as possible to be in the list and the method of price fixing that reduces the price of the drug as much as possible. Balancing between the polar sides is a knife-edge for any regulating / controlling authority.

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[24] The retail prices of formulations, as per the DPCO 1995, is derived as follows: RP = {(MC + CC + PM + PC) × (1+ MAPE / 100) + ED}; where RP - Retail price, MC - Material cost CC - Conversion cost, PM - Packaging material cost, PC - Packaging charges, MAPE - Maximum allowable post-manufacturing expenses, and ED - Excise duty.

[25] Verdict delivered on 15/07/2015.

There is a space for covert stand of the regulating authority depending on the influence / lobbying of either of the polar opposites. In most of the cases, as one can observe in real world, the industry-regulator nexus prevails more than that of the other way round (for instance see Mulinar, 2016).

The recent price orders fixing price of a formulation appear to have some leverage for industry. The very particular ingredient molecule of a therapeutic class targeted for certain disease can be administered in different drug dosage (eg. 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 herein is that bringing least demanded formulation (i.e. dosage form) under price control and all the others out of the net.

Emerging alternative to Price Control: Bulk Procurement through Negotiation

An emerging alternative to price control mechanism in order to bring down price of drugs ensuring the affordability, is negotiations and bulk procurement. In the developed countries such an alternative is evident (see Rand, 2008; Lakdawalla *et al.*, 2009). But the caveat is that it has a limited scope because it is possible for the state, large organization or insurance companies who have such a bargaining / negotiating capacity but not the individual patients.

Along with the price control mechanism, an exemplary cases observed in India in ensuring the accessibility to drugs at affordable prices is the cases of bulk procurement of state governments of Tamil Nadu and Rajasthan through negotiation with the drug manufacturers and dealers / distributors. 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 of 2004 and Taskforce of 2005 studied these two states. The Sandhu Committee in fact recommended the price negotiation at the launch of a new patented drug as one of the measures making drug prices reasonable (see GOI, 2005).

In consonance with caveat mentioned above, the percentage of patient population in India getting health care services from public hospitals varies across states but it is not so great. A large portion of them approach private sector. There has not been any organizational back up for patient population approaching private sector, to negotiate for price of drugs which were prescribed to them. Insurance coverage is very minimal in India and insurance companies of the country have so far not made any attempt in having such negotiated drug prices for their clients. But there is a scope for the same.

Rationalization of Trade Margin

Another alternative suggested by the body closely associated the pharmaceutical industry, in the wake of recent debate on Government of India's price fixation for certain medical devices, is rationalization of trade margin (AdvaMed, 2018).

V The Debate and Discussion on Price Controls

Here we examine the debate and discussion on case for and against the price control in India based on research studies showing evidences.

Future-Present Trade-off and AMR factor

A Rand study that examined the regulations in respect of pharmaceutical industry 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 companies / firms (see 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 (see Rand, 2008; Lakadawalla *et al.*, 2009). In the Rand studies, they have estimated based on a modeling and simulation the potential effects of drug price regulation in the United States. Based on their estimates they observed that price controls reduced life expectancy over time. The price control scenario simulated the effect of a 20 percent 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 (see 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 (see Ranganathan, 2017). But, when due to sheer callousness of Pharma and Bio-pharma firms and Hospitals while dumping the pharma / bio and hospital waste in the neighbourhoods, is polluting the environment and spreading the AMR. It is also considered as an important factor in spreading the AMR (WHO, 2005). A recent report commissioned by Nordia[26] through Changing Markets Foundation[27] investigating the polluting wastes from pharmaceutical firms in and around Hyderabad highlighted the prevalence of such a phenomenon polluting the neighbourhood environment[28] (see Nordia, 2016).

Market Economy and Price Competition Vs Information Asymmetry and Power Relations

In the theory of market economics, usually the consumer choice resulting in price competition in turn result in price reduction of goods and services. Such a theoretical construction is based on assumption such 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 it may not work or prevail

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[26] Nordia is a Sweedish Wealth / Asset Management Company.
[27] The Changing Markets Foundation is an NGO based in Netherlands with operational office at London. It was formed by Joakim Bergman and Paul Gilding – life long campaigners on environmental and social issues. It is also having bases in USA and UK. The Foundation was formed to accelerate and scale up solutions to sustainability challenges by leveraging the power of markets. See at: https://changingmarkets.org
[28] See at: http://changingmarkets.org/wp-content/uploads/2018/01/Changing-Markets-Nordea-report-January-2018.pdf

the price competition in drugs / pharmaceuticals market that brings 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 (see Centad, 2013; Bhattacharjea and Sindhwani, 2015; Mondal and Pingali, 2015). The demand for pharmaceutical drugs is not direct emerging from the end consumers (i.e. patients) but is mediated through doctors (physicians and surgeons) and pharmacists.

Induced-Demand

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 private health service agencies in India are well acknowledged (see Centad, 2013). A very recent study has shown certain evidence in the form of 'cut practices' in the state of Maharashtra (see Gadre and Sardeshpande, 2017).

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 (see Raghavan and Rajagopal, 2017; Gadre and Sardeshpande, 2017).

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

It is also observed that pharmaceuticals industry one of those industries which has a high trade margins and super-profits. In fact the Sandhu Committee of Government India came out with such an observation of high trade margins. Also there are some research studies as well have observed such a case (see 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 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 (see Mudur, 2017).

In fact the sociological research in the fields of pharmaceutical marketing and its regulation and that studying socio-political relations of pharmaceutical production, development and consumption brought out the concept of pharmaceuticalisation (see 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.

Regulations and Price Control: Is it throwing Baby with Bath Water and Future lost?

Despite certain anomalies prevailed in the pharmaceutical industry and market, imposing regulation and price controls as pro-business / industry observed, is considered as throwing baby with bath water and it constrain the future generation. But the question arises is whether healthcare and pharmaceutical industry can serve the purpose rightly with an in-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 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 as well as in order to promote furthering their private investments in these domains, it must be facilitated they recover their capital invested in development of drug as well as the cost of such capital along with production and distribution or dispensing costs. When a drug developed for the rare diseases which contain very limited market, the average cost of development and production of the drug would very higher than that of drugs for more general or widespread diseases. In the later case, the cost can spread over but is limited in case of drug for rare disease. But the very high costs on drug promotion (advertisement or otherwise) is something which is how far it is socially relevant 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 (see Mulinari, 2016).

Socially Responsible?

Most of the domestic industry especially that of private sector in India, 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 and financial resource, state procurement etc. They are also benefiting directly or indirectly from the R&D in public sector.

How far the health care and pharmaceutical industry is socially responsible? When Adam Smith, the first advocate economist of free market, originally advocated free market guided by certain moral values and social responsibility, but the later descendent economists have absorbed the principle of market and left out the guiding principles (Woolcock, 1998). The demand for health care and education are certainly the special cases where the concerned industry may have to serve these demands going beyond market principles. But the industry that serving these sectors / domains because of given their inelastic nature of demand for the price of services they render and creating their high trade margins and making supernormal profits, are definitely be regulated.

VI 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 being, 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 especially in the Indian context.

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