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Bulk Drug Industry in India: Challenges and Prospects

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Abstract: Pharmaceutical industry has been one of the sunshine sectors of Indian economy for the last many decades. Of late, the sector, particularly its bulk drug segment has come under serious challenges. The discussion paper reviews the growth of the industry, how policies and programmes in the past contributed to its development, its current status and challenges and concludes with recommendations on way forward.

Keywords: Investment, manufacturing, patent, pharmaceuticals, policy, regulation, trade.

I. Introduction

In this section a brief overview of the Indian pharmaceutical industry in general and the significance and role of the bulk drug industry is presented.

Indian Pharmaceutical Industry – an overview

Indian pharmaceutical industry is considered to be among the most dynamic and vibrant industries as it ranks third in the world by volume and tenth in terms of value [1] and continues to grow at a fast pace. The industry consists of the two sectors of drugs and medical devices. The drugs sector includes the segments of Active Pharmaceutical Ingredients (APIs) or Bulk Drugs,[2] Formulations, and Vaccines. This discussion paper focuses on the API segment. This has both patent protected drugs and generics. Indian pharmaceuticals' mainstay for many decades has been generics.

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The World Health Organization (WHO) defines generic medicines as "those produced without a licence from the innovator company when the patent or other market exclusivity rights on the innovator product has expired."[3] Generics would also include those medicines on which no patent exists in the countries of manufacture and sale. These drugs are bioequivalent to the innovator drug and are approved by drug controllers on satisfaction of proof of bioequivalence.[4] They are therapeutically equivalent to the original drug in that there is no significant difference in rate and extent to which the API or moiety becomes available at the site of drug action when administered in the same dose.[5] Therapeutic effectiveness of generic medicines is what facilitated Indian pharmaceutical industry to compete with well established large companies in the developed world and become the source for affordable medicines all over the world.

The pharmaceutical industry in India has gone through its fair share of structural and policy changes contributing to its growth and is now (2019-20) of the size of USD 43 billion (Rs. 3,01,000 crore) with a growth rate of 7-8 per cent in drug sector and 15-16 per cent in medical devices sector.[6] It has strong presence in India's trade with exports to the tune of USD 20 billion (Rs. 1,47,420 crore) of which 90 per cent is drugs and imports to the tune of USD 10.4 billion (Rs. 72,800 crore) of which 48 per cent is drugs, the rest being medical devices.[7] Ninety per cent of the exports are of medicinal drugs (formulations, APIs and medical devices) and India is now positioned as the largest provider of generic medicines globally[8] accounting for 20 per cent of the total global exports; it meets 50 per cent of the world's vaccine requirements too. WHO procures almost 70 per cent of its vaccine requirements from India.

India is home to over 60,000 generic brands across 60 different therapeutic areas. The number of pharma firms in the country is around 3,000 with a network of about 10,500 production units (TIFAC 2020). They manufacture more than 500 different APIs, making India the second largest contributor of global biotech and pharmaceutical workforce, creating around 2.7 million jobs directly and indirectly (IBEF 2020). The industry contributes around 1.72 per cent of India's GDP.[9] This is

one sector, which saw growth during the COVID-19 induced lockdown (in 2020), as per reports; the revenue of API sector grew 31 per cent year-on-year and 18 per cent sequentially during the first quarter of the current fiscal year.[10] At the same time, the sector faced many challenges seriously affecting its future, which will be explored later in this paper.

With the advances made by the Indian pharmaceutical sector over the years, and the several advantages that it enjoys, primarily its cost efficiency and a large pool of scientist workforce, the industry has been able to contribute significantly to global healthcare by providing high quality, affordable and accessible medicines. Not only has the disease burden in India reduced substantially, with the per-person Disability Adjusted Life Years (DALY) dropping by 36 per cent from 1990 to 2016, and life expectancy going up from 57.86 years to 68.90 years during the same period, this sector's growth has also been successful in bringing down the economic burden of several diseases in the country by providing highly economical alternatives (IPA 2019). Due to its large contributions in the total global drug and vaccine supply, the industry also enjoys an important position in the global healthcare sector spectrum. Indian pharma's health role is not limited to the countries of the South; almost 33 per cent and 25 per cent of all the medicines used in United States of America (USA or US) and United Kingdom (UK) respectively are produced by Indian manufacturers. Indian pharma firms supply over 80 per cent of the antiretroviral drugs used globally to combat AIDS.[11]

Indian pharmaceutical exports reach more than 200 countries and the product spectrum includes bulk drugs, intermediates, drug formulations, biologicals,[12] Ayush[13] & herbal products and surgicals. Indian pharmaceutical industry is estimated to be among the top five contributors of the India's trade balance, generating a trade surplus of around USD 10 billion. USA holds the position as the top importer of Indian pharmaceutical products while other regulated markets account for more than half of India's medicinal exports. The industry also shows a strong potential of penetrating other big markets such as China and Japan[14] (IBEF 2020).

It is also one of the top eight sectors attracting Foreign Direct Investment (FDI) in India, as FDI inflows worth USD 16,547 million (INR 88,165 crore) were cumulated in the during the period from April, 2000 to June 2020, which is 3 per cent the total FDI.[15]Policies such as allowing for 100 per cent FDI under automatic route for Greenfield pharma and 74 per cent in brown field pharma have also helped the cause (IBEF 2020). As per the Department of Pharmaceuticals, a total of 25 FDI proposals worth Rs. 2,496 crore have been approved in the pharmaceutical sector.[16]

Significance of APIs in Pharmaceutical industry

APIs form the core of pharmaceutical industry. They are the basic essential chemical compounds used in the manufacturing of any finished formulation drug product. API is the drug substance, i.e. the one with therapeutic effect, the other being excipients or inert materials. WHO defines API as "a substance used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings."[17] The definition being used by the US Food and Drug Administration (FDA) is more explanatory and brings out the substantive role of API in a drug. It reads: "Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body."[18]

APIs are the primary ingredients and the active component of a drug product. An API manufacturer uses raw materials or chemical products to produce API in reactor plants. The chemical product when it is in the process of becoming an API is termed as intermediate or intermediary. APIs can pass through several kinds of intermediaries in the process as it changes from raw material to an API. Drug manufacturers use these

APIs along with excipients (such as additives or binders, lubricants, disintegrants, colorants, sweeteners, preservatives, etc.) to produce the final medicines. Similarly, every vaccine also has an API which is used along other chemicals (suspending fluid, preservatives, stabilizers, adjuvants or enhancers etc.) to get the final product.[19]

Being a chemical industry and its results affecting animal or human life, the manufacturing process is very important. Pharmaceutical manufacturing is categorized in two parts: i) the production of bulk drug substances, and ii) manufacturing of dosage form products or formulations. Depending upon the original raw material, there are differences in the processes of making pharmacologically active substances.

For the biotech industry, APIs are biologically engineered protein and recombinant molecules made for the biotech medications. They are usually made from plants.[20] APIs are manufactured to different stages and using different processes. The preparation of an API is a multi-step organic synthesis. Critical steps of the manufacturing process may be purification, crystallisation, drying, milling and packing. Basic production of APIs may involve three processes: fermentation for micro-organic substances, synthesis for chemical substances, and biological and natural extraction from vegetable and animal tissues. Fermentation is usually applied to produce antibiotics, steroids and vitamins, while new substances are produced using organic synthesis. Fermentation is a biochemical process employing selected micro-organisms and microbiological technologies to produce a chemical product (Tait). Fermentation process produces huge amount of solid waste and hence can be a cause of environmental concerns for the countries. In some units, a combination of these processes is also employed. Both chemical and physical means are employed by the industry. Depending on the complexity of the molecule to be manufactured, APIs might need multi-step complex chemistry using a range of processing technologies that pose major technological challenges.

APIs represent 40-50 per cent of the total value of generic drugs and hence form a critical component of any pharmaceutical industry,

particularly setup in a competitive environment (Lofgren 2017). API supply chains spread across the globe. The APIs used in medicines prescribed either in the US or Europe are as likely to have been produced in an Asian country as to have been locally produced. Different producers and suppliers try to extend their dominance in the global market by attempting to manipulate drug industry demand mostly through price and regulatory compliance. Some suppliers target the low cost API market and produce large volumes of comparatively cheap APIs with high cost efficiency whereas some others focus on producing specialised and expensive active ingredients. In this competitive fast-paced global market, the efficiency of each of these strategies determines the market share that can be potentially captured by these suppliers.

Companies producing APIs either purchase intermediates from different producers and use them for producing a final API or produce the intermediates required as well and mix at their own. Such companies that are only involved in manufacturing APIs sell their finished APIs to formulation manufacturers who then process it to make the consumable drug.

The API market does not earn the players any substantial profits due to immense competition in the market (Nahar 2020), compared to formulation market. Of the three different streams of APIs, oncology, hormones and steroids, oncology APIs earn the maximum revenue as the cost for their manufacturing setups is significantly higher than the other streams, hence leading to strong barriers to entry of new firms leading to monopoly pricing.

The centralisation of the global supply for essential ingredients for drugs in China makes it vulnerable to interruption, whether by mistake or design. If disruptions occur for an essential ingredient made in China, US will wait in line along with Europe, India, and other countries to obtain it. If a global public health crisis occurs, China is likely to keep its domestically produced medicines at home and stockpile them to secure access for its citizens before seeing to the needs of other nations, like

most other governments whose primary duty is to their citizens. During the COVID-19 epidemic, we have seen the vulnerability of supply chains, which were disrupted due to undue dependence on a single country.

Many pharmaceutical firms manufacture from the raw material stage and end up marketing their final formulations. However, firms may find it more economical to buy APIs from another manufacturer and produce formulations. On the other hand, some firms may find it economical to specialise in an early stage like manufacturing basic chemicals or intermediates or APIs. With the emergence of global supply chains, manufacturers tend to diversify production process through concentrating on most cost-effective units in different countries leading to units specializing in certain segments of the manufacturing process. When global public health crises like the COVID-19 occur, this leads to supply chain disruptions and the industry has to rethink some of the earlier assumptions.

II. Indian Pharmaceuticals - A Growth Story

The eminent position that the Indian pharmaceutical industry has today is the result of a long and arduous struggle and the result of vision of many entrepreneurs. In this section, we, however, explore the role governmental policies and programmes played in this so that the same could be beacon lights for new interventions.[21]

Indian pharmaceutical industry, in so far as it relates to modern medicine and ancillary products, is not very old. Its history began with the establishment of Bengal Chemicals & Pharmaceutical Works by Acharya Prafulla Chandra Ray, an eminent scientist in 1901. Soon the Alembic Chemical Works was established in Baroda in 1907 and the Bengal Immunity in Kolkata in 1919. Prior to World War I, the industries that had developed in India were the cotton and jute textiles, which had historical groundings in the country. After the war, in 1922 the policy of discriminating protection was adopted by the British India government. There was no special treatment for the pharmaceutical sector and almost 87 per cent of medical requirements were met through imports. While the

World War II created enhanced demand for medicines, it did not translate itself into major increase in manufacturing. At the time of Independence, the pharmaceutical industry was worth around Rs. 10 crore only and almost all API requirements were met through imports from UK.

The Draft Outline Report of the Industries (Development and Control) Bill, 1949 provided suggestions, which were incorporated in the Industries (Development and Regulation) Act 1951. This legislation allowed for state intervention in case the performance of private sector is unsatisfactory. Pharmaceuticals and drugs are one of the 37 industries to which the Act applied.

The First Five Year Plan (FYP) (1951-1956) envisaged considerable investment in drugs and pharmaceuticals. An examination of the pattern of investment in industries in the public and private sectors during the period of the Plan shows that 8 per cent went into the manufacture of heavy chemicals, fertilizers and pharmaceuticals. It was felt that larger supplies of anti-malarials (benzene hexachloride and D.D.T.), antibiotics (penicillin, aureomycin, etc.) and other synthetic drugs (sulpha compounds, anti-T.B. drugs) from domestic sources would assist considerably the campaign against diseases and the protection of health in the country. Setting up of public sector for manufacture of affordable essential drugs was a major programme. This led to the establishment of five companies of which two, the Hindustan Antibiotics Limited (HAL) founded in 1954 and the Indian Drugs and Pharmaceuticals (IDPL) founded in 1961, played major roles in the development of Indian pharmaceutical industry.[22] HAL had a fermentation plant in Pune for manufacture of antibiotics and IDPL had a unit in Hyderabad for manufacture of APIs. The two new firms were set up with technical assistance from abroad; HAL with WHO and UNICEF assistance and IDPL with the erstwhile USSR assistance, and they, in turn, built up technical expertise in the country. They also laid foundation for a strong bulk drug industry. HAL started with an initial installed capacity of 4.8

million mega units of Penicillin. It was also the first one to produce bulk drugs of Streptomycin sulphate, 6-APA and Ampicillin. The following table presents the production of certain essential drugs at the end of the First FYP.

Table 1: Production of Select Drugs (1955-- 56)

Pharmaceutical	Unit	Production (1955-56)
Benzene hexachloride	Tons	500
Sulpha drugs	Lbs. 'ooo	400
Para-amino salicylic acid	Tons	48
Calcium lactate	Tons	50

The Plan also envisaged capacity building programme in pharmaceuticals and drugs in the private sector. Consequently many large transnational companies (TNCs) in the pharma sector expanded their units in India and new Indian companies also got established. Resultantly, the industry grew to the size of Rs.100 crore in 1962, a ten-fold rise in 15 years.

At the time of India's Independence the general perception both in India and outside was that the country lacked the capacity to manufacture APIs in a big way, that it was an activity which required huge investment, both financially and technically. But when HAL successfully started mass producing of penicillin and other antibiotics, it generated a new confidence in the minds of entrepreneurs that India has the capability. The objective of self-reliance in essential drugs became an achievable target. Incidentally, HAL is the only Indian company to invent two new molecules or new chemical entities (NCEs), namely, Hamycin and Aurofungin.

IDPL and HAL also contributed to the development of specialized human resources for the pharmaceutical industry. With very few technical job opportunities in the pharma sector, the universities were not into such programmes. But with increasing demand from the public sector and new units in the private sector, universities started offering such courses. The

undertakings also served as breeding grounds for new entrepreneurs in the pharmaceutical sector, leading to the establishment in later years of new private sector pharmaceutical firms like Dr Reddy's Laboratories Limited (DRL) in 1984.

There were other contributing factors. After the country became independent, there was great stress on development of the country's scientific and technological capability. This led to greater focus on research and development (R&D). The establishment of the Council of Scientific and Industrial Research (CSIR) in 1942 with many specialized research laboratories under it was a major effort in this direction. The CSIR had a number of pharma related laboratories such as the National Chemical Laboratory, Pune (1950), the Central Food Technological Research Institute, Mysore (1950) and the Central Drug Research Institute, Lucknow (1951). Other institutional level interventions by the government included the establishment of Defence Research and Development Organization (DRDO) (1958), the All India Institute of Medical Science (AIIMS) (1956) and various Indian Institutes of Technology (IITs), starting with IIT, Kharagpur in 1951. They were intended to create the scientific and technically skilled work force that was required for development of a self-reliant, *inter alia*, pharmaceutical industry in the country.

Simultaneously, Five Year Plans (FYPs) were focussing on development of the pharmaceutical industry as such. During the second FYP (1956-1961), the 1948 industrial policy resolution was revised and a new resolution of 1956 was adopted. Development Council for pharmaceuticals and drugs was set up. The manufacturing capacity, particularly in the HAL, for production of antibiotics like streptomycin was expanded besides increasing the capacity for the production of penicillin during this period. The question of the manufacture of other basic drugs from primary raw materials also received attention since short supplies of primary organic chemicals like benzene, toluene, xylene, naphthalene, phenol and anthracene were adversely affecting

development of pharmaceutical industry. In the case of synthetic pharmaceuticals like saccharin chloramine-T, ace-tyisalicylic acid and sulpha drugs the plan was development from basic primary organic chemicals and intermediate products in place of the operations based on penultimate products.

During the third FYP (1961-1966), production of basic chemicals and intermediates, and essential drugs continued to get attention and support. A major policy development was the delicensing of basic drug industry in the early 1970s. Consequently, by 1979-80, the contribution of the public sector amounted to 26 per cent in the case of bulk drugs and 6.3 per cent in the case of formulations only, the organised private sector accounting for 63.4 per cent and 67 per cent respectively with the balance being the output of the small industry sector, again in private sector.

During the 1960s and 1970s, government policy was of greater controls and establishment of public sector or joint sector units. This resulted in strict monitoring over the monopolistic policies of MNCs and consequently, while the sector got a boost, the contribution of the MNCs dropped to about half only of the total pharmaceutical production in the country, by 1980s.To promote private sector, government revised the policy in 1986 by relaxing many regulations as a result of which the number of private players increased in the sector but the competition among them adversely affected their profits.

The 6th FYP (1980-1985) continued most of the previous policies on drugs and launched programmes aimed at:

- Development of self-reliance in drug technology;
- Providing a leadership role to the public sector;
- Making drugs available at reasonable prices and in abundance to meet the health needs of the people; and
- Fostering and encouraging the growth of the Indian sector.

Apart from the industrial policy, other policies in science and technology and education fields also contributed to the development of

the pharmaceutical sector.

A major change in the pharma sector resulted from the new Patents Act that was enacted in 1970. Until this was brought into force in April 1972, the colonial Patents and Designs Act, 1911 was in force. The new Act was a consequence of a long process starting with the Report of the Patent Enquiry Committee (1948-1950) headed by Dr Bakshi Tek Chand which had recommended measures like compulsory licensing for counteracting the abuse of patent monopolies. These recommendations resulted in certain amendments to the Patents and Designs Act, 1911. Later, a bill for a new Patent law was introduced in the Parliament in 1953. Justice N Rajagopala Ayyangar was entrusted with scrutinizing the Bill and making suggestions. His report was submitted in 1959, but it took more than a decade to pass a new law. The most significant change that contributed to the development of the Indian pharmaceutical industry was the dropping of product patents for pharmaceuticals and food substances and restricting their process patents to a seven year period. This was a policy of momentous impact. It opened the field for Indian entrepreneurs to enter the field and start the production of generics. During the 1970s and to early 1990s, the policy of the government made it mandatory for private companies including the MNCs to manufacture APIs, a policy that led to the growth of bulk drug industry in India (Exim Bank 2020).

The next major change was in the year 1991 when the industrial licensing law was scrapped and the country opted for liberalization of economy with the abolition of the Industrial (Development and Regulation) Act, 1951 and change in industrial and economic policies. The constraints on private enterprises were removed. India also opted to join the global market by becoming a founding member of the World Trade Organization in 1994.

On the legislative side, this necessitated a change in the Patents Act, 1970. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement), 1994 mandated grant of product and process patents to inventions in all fields of technology without discrimination as

to the place of invention, the field of technology and whether products are imported or locally produced. Honouring the commitment, India through an amendment in the Patents Act in 2005 made all products and processes including in the pharmaceutical sector eligible for 20 year patent protection.

IDPL initiated the emergence of an API industry in the country. India was able to grow its technical knowledge base through reverse engineering in such a way that by 1990s, indigenous firms were able to meet 70 per cent of the API needs of the country. The adaptive and incremental innovation advancements made over all these years played a vital role in forming the basis of creation of several R&D departments with ample number of scientists. By 2005, India attained the status of the third largest API industry globally (after China and Italy) growing at an annual rate of 20 per cent. Currently, APIs represent about 20 per cent of the production value of the Indian pharmaceutical industry while formulations represent the remaining 80 per cent (Lofgren 2018). Bulk drugs production increased substantially from Rs. 18 crore in 1965-66 to Rs. 1518 crore in 1995 (Akhtar 2013).

The pharmaceutical industry is no longer able to rely on reverse engineering for making their generic products, which was the mainstay of Indian pharma industry. The protection guaranteed by the new Patent regime prompted MNC pharma companies to enter and play a more active role in Indian market. Further, the tariff and trade regimes underwent major change to fulfil the obligations under the new GATT being administered by WTO. The old self reliance doctrine was replaced by global trade based development doctrine, which generated space for global supply chains in pharmaceuticals including APIs. A natural expectation on the introduction of the new regime was that it would push Indian firms to engage more in R&D and bring out innovative drugs. This plan could not actualise fully since many firms found an easier way to thrive. A large number of drugs came off patent protection in the USA and that permitted Indian firms to continue to sell generics. Most Indian firms, who initially had comparable shares in the sale of global generic

formulations and APIs, grew on to have 4-5 times greater shares of sales in formulations as compared to APIs (Akhtar 2013).

The Pharmaceutical Policy, 2002, aims to ensure abundant and good quality essential pharmaceuticals at reasonable prices, strengthen indigenous capability for cost effective quality production, reduce trade barriers and encourage R&D. As per the new criteria, molecules with a turnover of less than Rs. 10 crore for the fiscal ended March 2001 will not come under DPCO, but a drug having a turnover between Rs. 10 and 25 crore and a single formulator having a market share of over 90 per cent will be covered by the price control order. Further, a drug with a turnover of over Rs. 25 crore and a single formulator and having a market share of over 50 per cent will be under price control. New drugs coming out of research from within the country would be off price control for the life of the patent. It has been decided to permit up to 100 per cent foreign equity under the automatic route so as to promote FDI.

During the WTO-TRIPS transition period between 1995 and 2006, most of the generic manufacturers consolidated their position in the industry and the larger ones registered very high growth rate. Also subsidiaries of foreign firms increased their stakes in the industry at a fast pace[23]. The other change in the industry was mergers and acquisitions of Indian firms. By 2010, 70 per cent of the country's demand for bulk drugs, chemicals, formulations, etc. was fulfilled by Indian pharmaceutical companies.

Indian pharmaceutical industry adapted to the new realities and continued to retain their share in the global market under the new regime. As of 2007, India had 10,563 manufacturing units, of which only 22.6 per cent units were involved in manufacturing bulk drugs while over 77 per cent units were involved in the manufacturing of formulations. Bulk drugs production in the country began 1970s onwards. From 2005-06 to 2008-09, while the growth rate of bulk drugs production was only 14 per cent, the share of bulk drugs in terms of value has shown to be rising. The most rapid growth rate was observed post 1990s where, bulk drug

production rose from USD 417.1 million in 1990-91 to USD 3503.2 million in 2008-09 (Akhtar 2013).

During the second half of last decade, however, concerns were expressed from various corners regarding the health of the API Industry. RIS in a Policy Brief in February, 2015 had drawn attention to the dangers of growing dependence on China and suggested several measures including cheap power, setting up of mega parks with common effluent treatment plants, special fiscal benefits for economies of scale, revival of PSUs, adequate provision of good quality biological strains, special purpose vehicle funding, rational use of anti-dumping law, simplification of procedures and single window system, and steps to re-activate innovation by domestic pharmaceutical industry (James, 2015). A High Level Committee headed by Dr V. M. Katoch, set up by the Department of Pharmaceuticals in 2015, also recommended a number of specific measures which, *inter alia*, include establishment of large manufacturing zones or Mega Parks for APIs with common facilities, setting up of six large API Intermediate clusters, revival of PSUs, institutional mechanism for single window clearance, and fiscal and financial incentives. The Committee also made specific recommendations for promoting R&D including industry-academia interaction[24].

III. API Industry – Current Status

Manufacturing

The Indian API industry is estimated at Rs. 798 billion (USD 106 million) and is expected to arrive at Rs. 1,307 billion (USD 1748 million) by 2026 at a CAGR of 8.57 per cent. It is the now biggest after China and US.[25] As per IBEF report for the month of August, 2020, domestic API consumption is expected to reach USD 18.8 billion by financial year 2022.[26]

There are about 1,500 plants manufacturing APIs. Among the firms, Dr Reddy's Laboratories, Mylan, Aurobindo, Sunpharma (including former Novartis and Ranbaxy), Divi's, Cipla, Cadilla Pharma or Zydus,

Pfizer, GSK and IPCA are the major ones. Many of them have API manufacturing facilities at multiple places. Sun Pharma has got API manufacturing facilities at Toansa, Khakhadi, Dewas, Dahej, Ankleshwar, Panoli, Ahmednagar, and Maduramthakam. Some of the firms specialising in APIs are Aarti Drugs, IOL Chemicals & Pharmaceuticals, Marksans Pharma, Granules India, Laurus Labs, Shilpa Medicare, Solara Active Pharma Sciences, JB Chemicals & Pharmaceuticals, Teva Active Pharmaceutical Ingredients (TAPI), Matrix, Mehta API Pvt. Ltd. Hikal, Leuland Labs, Lasa Supergenerics, BDR Pharmaceuticals International Ltd., Sreepathi Pharmaceuticals Ltd., Gujarat Themis, Wanbury Ltd., Wockhardt, Apollo Pharmaceuticals API Manufacturers India Pvt Ltd., and Ipca Laboratories.[27] There are also over 600 contract manufacturers in the API sector. These firms produce a wide range of products. For example, TAPI has more than 300 API products, Sun, Aurobindo and Cipla around 200 each and DRL 60 API products.[28]

The product range includes generics and complex APIs. Some of these products require even isolated manufacturing areas. Some of the large firms manufacture whole range of products from key starting materials, to intermediates to APIs to formulations to facilitate complete vertical integration. Indian firms produce anti-cancers, peptides, steroids, sex hormones, anti-diabetic, anti-depressants and so on.

Global Trade

Bulk drugs and Intermediates form a sizable segment of India's pharmaceutical exports. As per Pharmexil Annual Report 2020, the export figures of APIs during the last three financial years are as below:

2017-18	USD	3525.65 million (Rs. 24,679.55 cr.)
2018-19	USD	3895.38 million (Rs. 27,267.66 cr.)
2019-20	USD	3867.11 million) (Rs. 27,069.77 cr.)

During last year, the export has declined by (-) 0.73 per cent, giving signals for need for immediate intervention at policy and strategy levels. China, US and Germany are the three countries to which the largest shares of Indian APIs are being exported, both in value and volume. The

ten countries to which major parts of the exports go and their shares are presented in the following Table 2.

Table 2: Major Destinations for Bulk Drugs in terms of Value and Quantity in 2018

S. No.	Country	Share in value (per cent)	Rank with respect of value	Share in quantity (per cent)	Rank with respect of quantity
1	China	9.2	1	8.2	1
2	United States	8.6	2	8.0	2
3	Germany	4.2	3	5.4	3
4	Brazil	3.9	4	2.7	10
5	Bangladesh	3.3	5	3.8	6
6	Netherlands	3.3	6	4.5	5
7	Turkey	3.2	7	0.9	32
8	Japan	3.1	8	1.5	20
9	Mexico	2.7	9	1.9	15
10	Belgium	2.6	10	5.0	4

Source: Author's calculation using WITS and World Bank online database.

Drug-wise and destination-wise of individual items, wide variety exists in export. The drugs being exported are ant-inflammatory medicines like Ibuprofen, antibiotics like Penicillin, Erythromycin, Cefadroxil, Rifampicin, and Ciproflaxacin, histamine-2 blockers like Ranitidine, amino-naphthols, certain vitamins and hormones, alkaloids like Nicotine, and Menthol. Percentage share-wise, the group of organic compounds like Cefadroxil, Ibuprofen, Nifedipine, Ranitidine, etc falling in HS code 294200 has a 30.6 per cent share and their top five destinations are US (9.2 per cent), Brazil (5.6 per cent), Germany (4.3 per cent), Ireland (4.1 per cent), and Spain (4.1 per cent. Antibiotics like Rifampicin, Cephalexin, Ciprofloxacin, etc. have a share of 14.3 per cent and their major destinations are Bangladesh (10.4 per cent), Turkey (7.2 per cent), Vietnam (6.6 per cent), Italy (5.4 per cent), and UK (5.4 per cent). Menthol has a share of 9.8 per cent in exports. China is the destination

of 58.7 per cent of its export. Other major importers of the same from India are US (10.2 per cent), Singapore (7.2 per cent), Netherlands (4.8 per cent), and Japan (3.7 per cent). Sulphonamides enjoy a share of 5.4 per cent with major destinations distributed among Germany (13.7 per cent), US (6.2 per cent), Brazil (6 per cent), China (5.1 per cent), and Nigeria (3.9 per cent). Penicillin forms 4.9 per cent of the bulk drug exports and is being exported to China (12.2 per cent), Thailand (8.6 per cent), Egypt(8.5 per cent), Vietnam (7.3 per cent), Indonesia (6.5 per cent), and 95 other countries. The shares of Amino-naphthols is 4.6 per cent, and of Erythromycin 3.8 per cent. Vitamins' share is around 2.8 per cent and out of which 15.8 per cent goes to the US followed by Belgium with 13 per cent). The major destinations of hormones (adrenal cortical) which have a share of 2.2 per cent, are Belgium and the Netherlands and of Nicotine (2.2 per cent), Switzerland (21.2 per cent), Turkey (18.6 per cent) and US (14.6 per cent)[29].

Despite being a major source of global generic drugs, India depends heavily on API imports. They accounted for 63 per cent of total pharmaceutical imports during the year 2019-20. India's API imports also showed its heavy reliance on one country, namely, China. The following are the ten major sources of APIs and their shares in the total during last year.

Table 3: Major Sources of APIs

Sl. No.	Country	Percentage share of import
1	China	68.04
2	USA	3.54
3	Italy	3.02
4	Singapore	2.88
5	Spain	2.17
6	Germany	1.85
7	France	1.56
8	Japan	1.53
9	Denmark	1.26
10	Hong Kong	1.25

Source: Reply to Lok Sabha Unstarred Question No. 251 dated 15 September 2020; DGCIS, Kolkata.

This presents a very uneven position from an economic angle. The heavy dependence on a single country is always a risk from the angle of a sustainable pharmaceutical industry. These lopsided imports by Indian firms were mainly for economic reasons. They include the lesser cost of the APIs from China and the higher profit margin in the case of formulations or Finished Pharmaceutical Products. Altogether 10 countries accounted for 87 per cent of India's total API imports last year.

The major bulk drugs imported are acetic acid (16.4 per cent of the total bulk drug import), Penicillin (16.1 per cent), Antibiotics like Rifampicin, etc. (13.9 per cent), and organic compounds like Ibuprofen (10.2 per cent). India also imports Amino-naphthols (5.7 per cent), Erythromycin (4 per cent), Enzymes (3.3 per cent) as well as Hormones (2.4 per cent). Compared to our export destinations, the number of countries from which imports are made is not very large. Acetic acid is sourced from 20 countries, Penicillin from 32 countries, Antibiotics from 52 countries and Erythromycin from 14 countries. However, in most of the leading items of import the major source is China like Amino napththols (96.9 per cent), Penicillin (90.6 per cent), Other Antibiotics (72.6 per cent), Organic compounds like Ibuprofen (70.1 per cent) and Erythromycin (63 per cent). Apart from these 5 sets, in another 3 major groups also China is the leading source like Hormones (46.5 per cent), Ascetic Acid (34.2 per cent), and Enzymes (28.5 per cent)[30].

This is in sharp contrast to the situation in 1992 when Germany, Italy, Netherlands and US were the major leading sources of India for bulk drugs (USD 355 million) as they were contributing 12 per cent, 11 per cent, 9 per cent and 7.3 per cent respectively. The contributions of Denmark, Japan and UK were in a range of 7 per cent to 5 per cent. However, in relation to volume, the leading contributors were Germany, UK and Japan with respective share 14 per cent, 12 per cent and 10 per cent.[31]

The status varies depending on the product category as per manufacturing stage, viz. key starting materials, catalysts, reagents, solvents and chemicals, intermediates, excipients, etc. In many of them India is dependent on imports and in a few like catalysts, mostly on

imports from China. But in most countries in the matter of APIs, the position is not much different. For example, Europe is dependent on Asia for most of their APIs; 2/3rd of the facilities which hold valid Certificates of Suitability (CEPs) mainly in China and India.

There are reasons for the shifting of global API manufacturing to developing countries. API units pose many environmental and pollution issues. They may produce large amount of hazardous waste, ranging from 3,000 to 5,000 tons annually, depending on the size of the plant. These and economic reasons have made outsourcing in APIs a very normal activity for big pharmaceutical companies located in the advanced countries of the West. India and China are the major centres of outsourcing. But the API units in these countries have to comply with the regulations of the countries to which the products have to be exported. India has a large number of FDA (USA) and EMA (EU) certified facilities.

Investment

Because of the complexity of the pharmaceutical manufacturing industry, the investment position has to be taken for the entire industry. The Bulk Drug Manufacturers Association (BDMA), based on the CMIE estimates, presents the investment status as in the Table 4 below:[32]

Table 4: Investments in Pharmaceuticals

Year	Cost of Projects completed (INR in million)
2011-12	65,448.90
2012-13	42,988.30
2013-14	19,205.90
2014-15	14,864.30
2015-16	27,099,60
2016-17	30,328.00
2017-18	24,600.00

The statistics do not present a consistent pattern. In fact, after a major spurt in 2011-12, it has been steadily declining till the year 2014-15; after wards it showed some improvements but no sanguine pattern of ascendency is visible. The cumulative total FDI in the sector is USD 16.39 billion from 2000 to 2020.[33]

Indian API Industry vis-a-vis World Industry

Fierce competition exists in the API sector with countries manufacturing highly cost efficient large quantity of output, constantly forcing the suppliers to invest in capacity building . API market is segmented as North America, Europe, Asia-Pacific and Rest of the world (ROW) by region and North America held the largest share in 2018. The size of the merchant demand for APIs stands at a value of USD 48 billion (in 2014), of which 29.1 per cent comes from North America, 27.5 per cent from Asia and 26.7 per cent from Europe (mainly UK and Germany) and 16.7 per cent from rest of the world (EFCG 2020).[34] The prominent players in the global market are Pfizer Inc. (US), Novartis International AG (Switzerland), Merck & Co. (US), Teva Pharmaceutical Ltd. (Israel), Mylan NV (US), Boehringer Ingelheim (Germany), F. Hoffmann – La Roche AG (Switzerland), Sanofi (France), Abbvie (US), and Eli Lily & Co. (US). The innovative pharma had the larger share than the generics in the API market by value in 2019.

As per market estimates, global API market is valued at USD 172.69 bn. in 2018 and is expected to reach USD 263.80 bn. By 2025 with the CAGR of 6.24 per cent.[35] Currently, API production is dominated by Asian countries (60.5 per cent), followed by 27.9 per cent of production from Western Europe, 4.6 per cent from North America and 7 per cent from the rest of the world (EFCG 2020). China's annual production capacity in APIs is more than 2 million tons. Despite several questions raised on the quality of its supplies, Chinese API industry continues to enjoy its dominance over the global API industry contributing about one fifth of the global production by volume. Chinese manufacturers, who have the reputation of producing high volume of APIs at extremely low cost, meet 40 per cent of the total global API needs. Many countries are hugely dependent on China for their bulk drug requirements. India has also been experiencing the issue of over-reliance on Chinese imports for its API needs (CII 2019). As per FDA data results, the number of registered facilities making APIs in China have more than doubled between 2010 and 2019.[36]

European API industry has always had a tough time competing with its Asian counterparts. As the difference in the cost of labour cannot be met across the two continents, European countries continue to push their API industries by enhancing their capacity to be able to produce specialised, highly potent APIs. Hence, European manufacturers are often sought after as far as high quality specialised APIs are considered.

US and Europe are the key target markets for all API manufacturers primarily due to potential for earning huge drug sales revenue from these markets. However, growing lifestyle diseases and hence increasing pharmaceutical sales across the world have started to dilute the dominance of the US and Europe as far as attractive API markets are concerned.

The CAGR of the domestic consumption of APIs in India is expected to be 10 per cent between 2015 and 2022 and the size of the industry is projected to reach USD 18.8 billion by 2022. The CAGR between 2016 and 2019 was 8.6 per cent when it reached the market size of Rs. 735 billion (USD 10.5 bn.). According to IBEF, India's API merchant market share was the third largest in the global market at 7.2 per cent in 2016 and this has been increasing thereafter. This is primarily due to an increase in the exports to all key markets, including China. Most of the neighbouring countries lack API manufacture capacity and hence rely on Indian API firms for their API requirements.

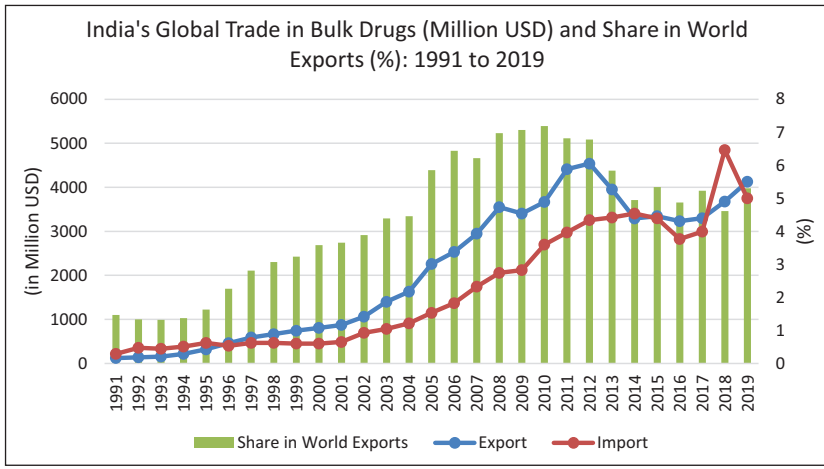
This growth observed in the API market also helps in forecasting the growth that can be foreseen in the excipients and intermediate market. India's excipients market is growing at a rate twice that of the global excipients market growth, at 10-12 per cent as in 2019. Countries like USA, Japan and the European region have strongly dominated the excipients market, comprising an 85 per cent share of the global market. India has risen to be an attractive destination, as domestic and global players go on expanding their footprint throughout the country, given its cheaper raw materials and labour.

From a historical perspective, the major change in India's position in bulk drug trade happened first around 1997 when for the first time it

became a trade surplus country in APIs and second around 2016 when it again became a trade deficit country. The decline in exports in two consecutive years (2013 and 2014) changed the position of India in the API segment from being a trade surplus industry to deficit making industry. Again, in next two years (2015 and 2016), exports of bulk drugs along with its imports fell but decline in imports were more sharp in comparison to exports, resulting in trade surplus. In 2016, India's imports of bulk durgs from world econonmy declined by USD 470 million. The significant part of this decline in imports was largely owing to decline in imports from China (USD 345 million) followed by Germany (USD 32 million) and US (USD 13.5 million). From China, the imports of 'Cefadroxil, Ibuprofane, Nifedipine, Ranitidine, etc.' declined by USD 216 million; Acetic acid by USD 68 million; and 'Other antibiotics', by USD 40 million. In caseof Germany, it is imports of 'Cefadroxil, Ibuprofane, Nifedipine, Ranitidine, etc.' that explained the slump whereas, for US, the imports of 'Erythromycin and its derivatives' went down. Since 2017, both exports and imports recovered but the rise in imports was significant. In 2018, India's imports of bulk drugs increased by USD 1.8 billion over previous the year and reached to USD 4.8 billion while its exports were slightly more than USD 3.6 billion. What has materially altered the position is that now India imports more APIs than it exports after having maintained higher exports than imports since 1995 (Figure 1).

In 1992, India exported USD 140 million of bulk drugs to the world economy. Massive difference existed in ranking of major destinations with respect share in value and quantity of bulk drugs exported. With respect to share in value Switzerland was fourth largest destination but twelfth in relation to volume of bulk drugs. Similary, United Kingdom was at ninth position in relation to value but it was ar fourth position with respect to volume. Volume-wise, US had the largest share (17 per cent) followed by Germany (9 per cent), Japan (7 per cent), and United Kingdom (6.2 per cent).

Figure 1: Bulk Drug Trade (1991-2018)



Source: Author's calculation using WITS and World Bank online database.

In 2018, however, China has emerged as a leading export destination as it has acquired more than 9 per cent share in India's global exports of bulk drugs (USD 3.67 billion). Likewise, Brazil, Netherlands, Turkey are also now major destinations, though US and Germany continue to remain leading export destinations. With respect to volume, the sequence of the leading destinations are China (8.2 per cent), US (8 per cent), Germany (5.4 per cent), Belgium (5 per cent), Netherlands (4.5 per cent), and Bangladesh (3.8 per cent), which is quite different from the leading destinations when measured in relation to value.

What the data reveals is that the items of bulk drug exports have not changed much in the last three decades, though the relative share of the products kept changing over the years. Out of USD 140 million exports of bulk drugs in 1992, almost 38 per cent was accounted by Other Organic Compounds such as Cefadroxil, Ibuprofen, Nifedipine, Ranitidine, etc. around 10 per cent by Penicillin and derivatives, 8 per cent by Menthol and Sulphonamides, etc. In 2018, while the share of Other Organic Compounds declined to around 31 per cent (USD 3.67 billion), but still remained leading item among the bulk drug exports of India. The share

of other antibiotics such as Rifampicin, Cephalexin, Ciprofloxacin, etc. and their salts increased significantly to more than 14 per cent but share of Penicillin and derivatives and Sulphonamides declined to around 5 per cent and the share of Amino-naphthols remained at around 5 per cent.

API industry is highly fragmented with about 1500 units (TIFAC 2020). India's share of bulk drugs and intermediates in the total pharmaceutical export has reduced from 42 per cent in 2008 to 20 per cent in 2018. The revenue earned from API export is only around one fourth of that from formulations. India has almost totally discontinued manufacturing of APIs for Ascorbic acid, Aspartame and antibiotics like Rifampicin, Doxycycline, Tazobactam acid, CoQ10, immunosuppressants and even steroids. Production of intermediates for atorvastatin, chloroquine, gabapentin, ciprofloxacin, cephalosporings, etc has also been effectively discontinued (TIFAC 2020).

IV. Opportunities and Challenges

Pharmaceutical industry is the lifeline of healthcare. The expectations from the industry, therefore, stem from that perspective. Meeting the health care needs of the country and the world are the foremost task before the industry. All manufacturing, be it in agriculture or industry, is to meet individual needs and higher societal objectives. In the larger societal context, pharmaceutical industry is well placed as a producer of essential items for human wellbeing. Indian bulk drug industry has the challenges to meet the domestic requirement and the global demand for affordable medicines. From an industry perspective, it opens a big market for it.

India itself being the second most populous country is one of the largest markets for medicines in the world. Disease burden in the country is very high. It is the country with the largest number of tuberculosis patients. India has inherited burden of maternal, perinatal and childhood diseases (17 per cent), communicable diseases like Diarrhoeal diseases (8.2 per cent), TB (2.8 per cent), HIV/AIDS (2.1 per cent), Malaria and other vector-borne conditions (1.6 per cent), and also the growing burden

of non-communicable diseases like cardio-vascular diseases (10 per cent), and cancers (3.4 per cent), mental illness (8.5 per cent), injuries (16.7 per cent). Conditions like diabetes and hyper tension which require lifelong medication are growing (NCMH). This throws open a big domestic market for drug manufacturers. Meeting the growing demand of this huge patient population is the biggest challenge for Indian pharma/API industry. Currently, by revenue, anti-infectives (13.6 per cent), cardiac (12.4 per cent) and gastrointestinal (11.5 per cent) have the biggest market share domestically.

The world is also dependent on India for safe, quality and affordable medicines as is evident from the fact that Indian pharmaceutical industry including APIs is the third largest by volume and 10th by value. The lower rank by value shows that the drugs from Indian manufacturers are economical than others. But with higher consciousness among governments and international organisations about the need for ensuring the good health of people, the move towards achievement of Sustainable Development Goal 3, viz. Ensure healthy lives and promote well-being for all at all ages by 2030 and as more and more governments are declaring universal health care as a policy, the demand for medicines is steadily ascending. Considering that countries with proper manufacturing capability in medicines are limited, this throws challenges for pharmaceutical industry in countries like India to enhance their manufacturing.

The domestic and global market for pharmaceuticals is huge, but the industry is faced with several challenges in increasing production and export. They relate to regulations, both national and international, export policy measures, environmental regulations, tax regime, credit crunch, and inadequacy of R&D support. The early growth of Indian pharmaceutical industry was on the strong foundation of a robust indigenous API industry. However, the recent crisis caused by COVID-19 epidemic has brought out certain weaknesses in the sector

The domestic regulations that impinge on manufacturing are those relating to environment and access to biological resources. Environmental clearance for manufacturing is big hurdle for API plants since they generate large quantities of hazardous waste. As per existing environmental regulations there is need for approval for any change in product mix, capacity expansion even if there is no increase in pollution load. Industry has pleaded for ease of doing business during its presentation to the Task Force on APIs[37]. Industry's plea is that Ministry of Environment should be concerned with the pollution outside the unit and not what is being manufactured inside the plant. According to the industry this is the common practice followed by other countries. Industry has also offered to provide self certification to comply with the pollution norms. Despite the Common Effluent Treatment plants (CETPs), individual units are asked to treat their effluents before sending to CETPs.[38]

Setting up effluent treatment plants is expensive and beyond the capacity of most API manufacturers who are in the MSME sector. Another regulation that also raises hackles among the industrialists is the Biological Diversity Act (BDA). This affects those who require plants and plant based resources as raw materials. Firms with foreign participation are particularly hampered by this law since obtaining prior approval of the National Biodiversity Board is a time consuming process. A third law which affects the pharmaceutical firms is the Drug Price Control Regulations. The regulations have been introduced with the laudable objective of making essential drugs available to people at an affordable price, but has been creating an uncertain situation in most cases.

Environmental sensitivity has grown in recent years, particularly after the Paris Agreement on Climate Change. From pollution angle, pharmaceutical industries are highly vulnerable. The regulations require effluent treatment and other pollution control measures. They are costly and many old time MSME units are not even aware of the regulations. It is thus simultaneously a technological, financial and management issue. Upgradation of the industry to meet the present and future mandatory requirements is a challenge.

These issues also relate to meeting global manufacturing standards and quality regulations. Pharmaceuticals being an area directly affecting human and animal lives, these standards and regulations also are getting updated on a regular basis. The national quality control and safety of drug regulations of the importing countries prescribe many conditions which the Indian manufacturer has to fulfil. There are also periodic inspections of the units by the major importing countries. While these are unexceptional, meeting the global standards of quality and standardisation pose serious challenges to the industry, particularly the MSMEs. Although India is the country with the largest number of FDA approved drug units outside USA, it is necessary to ensure that all pharmaceutical manufacturing take place in the country as per global standards. The country cannot afford to have two standards for medicines for domestic use and export.

The industry also faces several obstacles in achieving its true potential. Inadequate infrastructure support in terms of lack of bulk drug clusters, accessible low cost utilities (waste management system, water, electricity) and R&D support are some of the concerns of the industry. Lack of large-scale fermentation capacity, low availability of feedstock and key starting materials, solvents (for which dependence on China is 60 per cent), chemicals used for reaction such as acid, base, reaction promoter, catalyst, etc., multiple regulatory bodies, high cost of finance, short repayment periods, and delays in land acquisitions and environmental clearances are other issues faced by the API industry (CII 2020 and TIFAC 2020).

Indian pharmaceutical industry is deemed to be a success story with strong trade dominance and a competitive edge over its other counterparts as far as generic drugs are concerned. However, one of the biggest challenges faced by the industry currently is its continued heavy dependence on imports for its API requirements, mostly on China followed by USA and Italy, and in case of certain crucial APIs over 90 per cent dependence on China alone, exposes India to the risk of disruptions in raw material supply and volatile price levels, which in turn can have strong adverse effects on the high riding generic formulation production

as well. Some of the reasons for this heavy dependence on imports are the cost advantages, leading to higher profitability in the formulation sector than if they had depended on domestic APIs. Even though India enjoys a lower cost labour force set-up, Indian bulk drug producers face a lot of competition from the Chinese counterparts in this area, who have higher cost efficiency as compared to India. The Katoch committee, which was set up to study this situation, has recommended creation of appropriate infrastructure, manufacturing clusters, and other policy reforms. Indian government understands the dire need of promoting domestic manufacturing of APIs as well as the intermediaries such that the competitive edge gained by the formulations industry is in no way jeopardized. Achievement of self reliance in API industry is itself a complex issue since India is currently almost totally dependent on China for Key Starting Materials and major Intermediates.

Indian pharmaceutical industry's global dominance is substantially dependent on its capacity to supply safe and affordable medicines without disruptions. That would necessitate near self-reliance in APIs and intermediates. It will not only facilitate Indian players to maintain competitiveness but also ensure undisrupted raw material supply to the local market. In a globalised economy, it may not always be possible to be fully self-reliant in such a vital sector. At the same time, high dependence on imports will be risky since supply chain disruptions may adversely affect availability of essential drugs in the country. The chances of such disruption are very high when dependence is primarily or overwhelmingly on one or two sources. In the case of a large number of APIs, India's dependence on China is very high. Strategies will have to be devised and implemented for emerging from this difficult situation. The two alternatives are (i) diversifying import sources, and (ii) enhancement of domestic manufacturing. The first one may enable to tide over immediate scarcities, but in the long run is not very dependable as it still will be subject to vagaries of international trade regime. In view of the WTO regime, it may not be easy to (i) to restrain imports from any particular country, and (ii) impose high tariff rates on items from one country, without valid reasons. The best way forward and which may stand in

the long run is to increase domestic production. This is easier said than done as there are many constraints and imponderables.

India's dependency on imported APIs is not only at the finished product level of APIs but all through the production chain, i.e. intermediates, key starting materials, excipients, raw materials and so on. Key Starting Materials for most API Intermediates are not currently produced in the country and are being imported. For about 60 per cent of the solvents India is dependent on China. Not only that, the chemicals used for reaction such as acid, base, reaction promoter, catalyst and so on are also imported mostly from China. This would necessitate development of manufacturing capability all through the process and that is a time consuming step. Formulation units will take time to set up and start production. Be that as it may, it will have to be done.

Expansion of manufacturing capacity also is hampered by other issues. MSMEs form about 50 per cent of Indian pharma. They particularly face many hurdles including lack of proper industrial infrastructure and capital, besides issues of non-compliance with environmental and regulatory laws. Technological obsolescence is quite high among them and most do not have access to the latest technologies. Development of infrastructure is a capital intensive activity and the units do not have the capacity to raise that much capital. Many of them are finding it difficult even to have working capital. Though pharmaceuticals are a high dividend sector at a large corporate level, at the MSME level, there is a lack of venture capital investments, probably because of risk aversion in the context of tough competition from China. Affordability and availability of land for expansion and for setting up new units, high physical infrastructure cost, low profit margins, and lack of fermentation capacity, low availability of feedstock and key starting materials, solvents (for which dependence on China is 60 per cent), chemicals used for reaction such as acid, base, reaction promoter, catalyst, etc., multiple regulatory bodies, high cost of finance, short repayment periods, and delays in land acquisitions and environmental clearances are other issues faced by the API industry. (CII 2020 and TIFAC 2020).

Another challenge for API industry in India relates to technology. Pharmaceuticals is an area where competition is fierce. Consequently, drugs supposed to be being at the cutting edge technology level, the industry has to be on its toes at all times and everywhere from a technological angle. One of the problems that the Indian API industry is facing is that of high rate of obsolescence due to fast technological developments. Processes are ever getting updated. Upgradation of technology also requires capital expenditure in machinery besides payment of royalties for new technologies. They would also require skill upgradation by the employees.

To attain success in a competitive setup, firms need to exploit either a cost advantage, or a value advantage or a combination of both. Measure such as coalition of different firms to lower the market risks and ensure each can enhance their pool of resources providing them an edge in the market to increase business effectiveness and stress on innovation. (Mahajan 2010). As observed in the US and Chinese pharmaceutical industry, human resource management index (a measure of high performance work practices such as extensive training, participation, detailed job definition, result-oriented performance appraisal, internal career opportunities, and profit sharing) is related significantly to firm's market performance. A positive association is observed between high performance work practices and firm's overall performance (Zhang 2009). Management of the working capital affects the profitability of firms directly. Working capital management requires "planning and controlling current assets and liabilities in such a way that it eradicates the threat to meet short term liabilities and evade excess investment in these assets" (Haresh 2012). Some firms tend to outsource several processes of the manufacturing and R&D to centres where the labour cost is considerably low. However, a report by PA consultancy suggests that firms should be very cautious while moving R&D to other countries as a part of cost cutting as it poses significant risks. Innovation is best centred at home.[39]

Not enough emphasis is laid on how pharma companies can improve the efficiency by developing a process for improvement, standardisation and automation of technology. Eliminating manual tasks, hence, reducing the probability of errors, can free up work force to participate and contribute in tasks related to innovation and research. Mckinsey reports suggest the importance of big data and how it can help firms in identifying the factors where costs can be brought down without compromising on patient safety.

The involvement of inter-industry linkages can help in streamlining as well as improving various operations that an individual firm cannot process in isolation. This approach has the potential to be beneficial specially for conducting clinical trials.

To meet those challenges huge investment in technology and quality control measures is required. Coupled with the same is the challenge of R&D. Cyber security, employment of digital technologies and Artificial Intelligence (AI) in drug discovery create new concerns. Fully automated medical science literature monitoring process may soon become the norm. Technology and R&D also raise the challenges of IPRs. Indian pharma came up of age on the favourable conditions created by the Patents Act, 1970, but since 2005, it is to abide with the TRIPS regime. While, so far it has been able to meet with those challenges, continued expansion without a strong foundation in R&D and with a large patent portfolio is a major challenge. This would necessitate huge investment in R&D and technology. Currently India's public investment in R&D does not create confidence in the area. Massive public investment over many years leading to invention of new chemical entities is required for development of new drugs.

As part of the investment challenge, the FDI question also the Indian pharma has to face. With good amount of FDI happening through mergers and acquisitions (brown field) it does not automatically lead to expansion of capacities. In some cases, on account of avoidance of duplication, and the strength of their existing R&D units in the advanced countries

by multi-national drug firms, the local R&D may not be receiving due attention.

Recent Government Initiatives

The Government of India announced in March, 2020, a package of about INR 10,000 cr) ($1428.5 mn) solely targeting at boosting production as well as exports of the bulk drug industry. Steps in terms of promoting bulk drug parks and financing these parks with common infrastructure facilities have also been planned for by the government, as it approved an amount of INR 3,000 crore ($ 428. 57 mn) for the next five years. Further, a Production Linked Incentive (PLI) scheme was announced on 27th July, 2020 with a sum of INR 6,490 cr. ($ 927.14 mn.) for active promotion of domestic production of critical key starting material, drug intermediates a well as APIs. Financial incentive on the incremental sale over the base year of 2019-2020 has been promised for the next six years to eligible manufacturers who will be identified in due course. The initially proposed minimum capital has since been done away with, thus making small firms eligible. These policies promise a better future of the Indian API industry; however, their efficient and effective implementation will be vital (CII 2020).

Industry, however, has requested to delink the investment open to brown field and remove the restriction for exports. Indian Drug Manufacturers' Association (IDMA) has pleaded that across the API industry, almost 35-40 per cent capacities are lying unutilised. These idle capacities should be tapped. These are the low hanging fruits. Out of the 27 molecules to be manufactured by synthetic chemistry route, twenty can be produced by these units with minor changes in plants within two / three months time. Industry is also reluctant to invest huge amounts (minimum of Rs. 400 crore) in fermentation fearing the predatory pricing by China. Industry has requested the government assurance on this count. Entire guidelines are at present under reconsideration.

The foreign direct investment in the pharmaceutical sector has seen a rise in the last few years, with more and more MNCs interested in taking

over shares of the local firms in India. With a global trend of an increase in FDI in the pharmaceutical industry, India has also seen a rise in this sector due to the liberalised policies, such as restricted/no involvement of the government, ease of investment, and protection of intellectual property rights. Many MNCs have set foot in the pharmaceutical industry of India by taking over the local companies which have had the following impact on the industry. Based on a report by a pharma market research company (AIOCD AWACS), the growth rate of the Indian pharma market was observed to be 9.5 per cent in March 2018, a considerable increase from 7.1 per cent in February 2018. The growth observed in terms of volume was in double digits with the pricing caps placed on the NLEM listed drugs. The impact of the mergers and acquisitions could be observed as growth rate was skewed towards the MNCs which grew at 11.2 per cent yoy in March 2018 whereas their Indian counterparts grew only at 9.1 per cent. A similar trend was observed in the non-NLEM category as well where MNC pharma companies grew faster than domestic pharma companies.[40]

V. Way Forward: Convergence of Trade and Other Policies

Industry associations have been recommending several policy changes to meet with current challenges of API industry. It has been suggested that a single window clearance for establishing an API manufacturing unit and to obtain all kinds of licences related to testing, imports, development etc. should be set up. Priority environmental clearances for APIs with definite timeline should be in place and soft loans should be provided with long repayment periods (CII 2020).

Ministry of Environment should provide blanket permission subject to compliance with pollution load for all these 53 priority molecules of PLI scheme. Brown field Fermentation units will need minimum 3/4 years time and good quality strains with huge investments. The Green (new) units would also need minimum two years time. The country's needs are immediate. Hence it is of utmost importance that existing Brown Units

may be incentivised for production of these molecules with the condition that their existing molecules production will not be stopped. MSMEs need handholding both in terms of technology and finance to upgrade to WHO GMP. So the proposed Pharma Technology Upgradation Scheme with interest subvention of 6 per cent should be operationalised on priority.

As long term policy reforms, integrated large-scale clusters (chemical and pharma) to encourage private sector participation should be set-up by the government along with providing common infrastructure facilities (Effluent Treatment Plants (ETPs), testing facilities, captive power plants, boilers, chilled water plants, cooling towers etc.) where the industry can pay based on their use. There is a strong need to promote collaboration between the industry and academic and research institutions to encourage R&D and subsidies and incentives can also be provided as part of government support for technology modernisation and for adoption of green technology (CII 2020).

In drawing up policies, one should retrospect on past policies and their impact as well as study successful models abroad. In Section II, we have seen how India has developed a globally competitive API and formulation industry with a strong base on generics. China's rapid growth in the past several decades can be attributed to two factors: a) market-oriented policy reforms and strengthening property rights, reducing trade and FDI barriers; and b) economic fundamentals, including a favourable demographic structure and a low initial level of labour cost (Wei et al. 2017). 'Economies of scale' and 'continuous innovation' are also factors that helped China to acquire predominance in APIs. China has invested heavily in the next generation drugs- mainly in biologics and biosimilars along with constant investment in new technologies like installing cold chain storage and continuous processing (ET 2019). Productivity enhancement was a crucial part of the proximate drivers of growth in China. With the reallocation of resources from the lower to the higher-productivity sectors, making innovations to increase productivity was an essential requirement. (Wei et al. 2017). A survey conducted in China in the year 2000 reported that technology improvement was a major driver and 78 per cent of the technology development was done within China,

20 percent was budgeted by importing and digesting foreign technology, and 2 per cent was done by buying technologies from other domestic sources (Wei 2017).

Patent applications also followed the rising trend and escalated from 83,045 in 1995 to more than 2.3 million in 2014. A major fraction of the patents was dedicated to invention patents (others being utility model and design) as these patents rose from 8 per cent to 18 per cent (1995 to 2014) (Wei et al. 2017). Medical and pharmaceuticals firms ranked ninth with new product sales, that too, with a very high growth rate (Dobson 2008).

In China, the 11th Five-Year Programme for "scientific development" laid emphasis to promote "an innovation-oriented nation". Chinese pharmaceutical industry stood to the plan and the US patents by Chinese nationals increased from 150 in 1978–1995 to 217 in 2000 and further doubled to 414 in 2005 (Wang 2007). A study conducted to analyze the innovation efficiency of Chinese pharmaceutical sector over the period of 2006-2014, reported that a low efficiency was observed, with average comprehensive technical efficiency, pure technical inefficiency and scale inefficiency. The contribution of knowledge innovation to the innovation efficiency of pharmaceutical manufacturing in each province and region was observed to be smaller than that of commercialisation (Liu 2020).

The introduction of product patents was an important transition for both Indian and Chinese economies, as the industries in both countries feared the potential destruction of their global suppliers, leading to increased drug prices. The revenue options for Indian firms reduced as the generic copies of the newer drugs became illegal. There was a shift in the focus to exporting products to more regulated and profitable markets in an attempt to compensate for the revenue lost. Increased expenditure and emphasis was also observed in the R&D sector to promote innovation. (Grace 2004). With the introduction of product patents, a clear change in the focus of Chinese pharmaceutical industry was observed. The industry which enjoyed the position as the 'lowest-

cost' source of APIs and generics started taking steps to enter the market of innovated products. The long term goal of most of the local suppliers shifted to take advantage of the opportunities arising in the innovative products category, mainly biotech and traditional medicine to slide away from the market which was the area of expertise of other competitive industries, such as of India (Grace 2004).

Post-TRIPS situation is the vigour with which the MNCs are trying to expand not only in the patented markets, but also in the generic markets. The most obvious reflection of such changes in strategy is the takeover of Indian companies by MNCs and strategic alliances between MNCs and Indian companies. Global supply chain manufacturing process may have certain advantages of economy but also certain risks such as disruption of supplies as many countries faced during the COVID-19 pandemic. At least certain vital sectors of industry such as pharmaceuticals, self sustainability of production process will have to be explored. It need not necessarily be in all the products, but in some essential life saving drugs such as penicillin, aspirins, certain antibiotics and so on.

Two most important issues that the industry and government have to tackle in this are achieving the economies of scale and reduction of cost. Setting up of industrial parks is one means. But, perhaps, the way to achieve is through development of infrastructure including road and rail transport, water, electricity, etc. and making them available to the industry at a low cost. Pharmaceutical industry is one of the most polluting industries. This necessitates pollution control measures including affluent treatment plants. Common facilities for these can also reduce the cost.

Technological challenge will perhaps be the most important challenge in the future. Information and communication technologies are very powerful tools that can be used in every component of manufacturing and marketing. To take few examples, they can contribute to avoidance of waste by monitoring and linking demand and supply, most economic use of storage space by ensuring just-in time delivery of raw materials, factory floor activities, shipping and so on. Artificial Intelligence is now altering the manufacturing processes and delivery mechanisms all

across various economic sectors and pharmaceuticals is no exception. Companies are in the process of acquiring AI capability. As per a 2019 report the top ten pharmaceutical companies who have either entered into partnerships or acquisitions for AI space are Roche, Johnson and Johnson, Novartis, Pfizer, Merck, Sanofi, AstraZeneca, GSK, AbbVie, and Bristol Myers Squibb. They are leveraging AI for drug discovery. In the long run, AI will reduce cost of drug discovery and supply. The Indian companies will have to take active steps to changeover to this new phase of technology. Amgen has started employing AI to identify manufacturing deviations and Dr Reddy's in its manufacturing process and quality assessment (FICCI 2019).

VI. Conclusion

A wrong policy decision or a disaster can lead to the rapid fall of an industry, but its growth will take time, as in the case of organic life. The policy approach to the current crisis in API industry has to bear this in mind. The policies adopted will take time to really result in robust growth. There are also always the risks of the imponderables. One cannot visualise what they will be and how will they affect the economy and society. What is required is avoidance of knee jerk reactions and adoption of well considered policies with a long term perspective. The current disaster caused by a pandemic may raise in the minds of many doubts about the wisdom of globalisation. This process has created perhaps the largest market ever in history and it is a market where competency, efficiency and quality rule, by and large. There may be infirmities in the system, but they are remediable. One must find ways to exploit the advantages of globalisation of production and trade maximally.

Another observation is that all economic and social sectors are related. If policies in one sector, for example education or health, are not conducive, the industrial sectors will suffer for want of well qualified scientists and managers and healthy and skilled workforce. Similarly, productivity is linked with factors like availability of easy, quick and economical transport, safe environment and water, peaceful society and so many other conditions.

A third important point is the need for integration of local MSMEs as primary suppliers to large manufacturers. This can become possible only if they are able to produce and supply materials and products in required quantity and with quality but in a globally competitive price. That would require certain facilitations in provision of basic infrastructure like road and railways, energy and so on, referred to in earlier sections.

The essentiality of greater focus on innovation cannot be overstated. Innovation is really successful exploitation of novel ideas, but a conducive environment for generation of ideas and their experimentation will have to be created. This necessitates much higher public investment in R&D. Policy has to provide for large number of failures of ideas, but failures are what will push science. Policies should encourage widespread teaching of basic and theoretical science in schools and colleges in such a way that scientific temper should become a national trait. Government should share the risk of development inherent in pharmaceutical technologies, as the world is currently seeing in the efforts to develop effective vaccine for COVID-19.

In policy making in the API sector, all these will have to be factored in for the best result in the long run. At the same time, a number of immediate measures may have to be taken. These, among others, include:

- Expeditious regulatory clearances,
- Ensuring easy availability of finances at low interest rates,
- Prescribing liberal eligibility conditions for government schemes,
- Setting up of large number of common facilities for MSMEs,
- Subsidised and priority movement of APIs from production units in view of role in public health,
- Simplification and restructuring of GST for APIs, and
- Identification of high potential API markets and special trade agreements with them.

These measures may be needed to ensure that the industry does not collapse in the future and make India *Atmanirbhar* in its domestic

medicine requirements, as well as promote India's status as the pharmacy of the world, supplying affordable quality medicines.

Endnotes

1 Department of Pharmaceuticals Annual Report 2019-20. P.3.

2 In this paper, the two terms 'API' and 'bulk drug' are used synonymously.

3 Generic Medicines in WHO Drug Information Vol. 30, No. 3, 2016. P. 370.

4 As per Merriam-Webster dictionary, bioequivalence is "the property wherein two drugs with identical active ingredients or two different dosage forms of the same drug possesses similar bioavailability and produce the same effect at the site of physiological activity." Bioavailability is the degree and rate at which the drug is absorbed into a living system or is made available at the site of physiological activity.

5 *Ibid.*

6 *Supra* 1.

7 *Ibid*.

8 *Ibid*.

9 *Ibid*.

10 Sesa Sen in the New Indian Express published on 29 August, 2020. https://www.newindianexpress.com/business/2020/aug/29/indian-pharma-sector-sales-to-rise-after-cost-cuts-support-margins-in-pandemic-hit-q1-2020-2189947.html.

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12 They are substances of biological origin used as drugs, vaccines, pesticides, etc.

13 Ayurveda, Yoga & Naturopathy, Unani and Siddha; now includes Homeopathy also.

14 IBEF. *Supra* 11.

15 Factsheet on FDI - April 2000 to June 2020, Department for Promotion of Industry and Internal Trade, https://dipp.gov.in/sites/default/files/FDI_Factsheet_June20_23Sept2020.pdf

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19 *Supra* 17.

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