Public Policy and Economic Development Case Study of Indian Pharmaceutical Industry

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

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Preface

Professor Sachin Chaturvedi

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The pharmaceutical industry is a shining example of the way India can transform economic sectors through appropriate policy interventions for unleashing the power of entrepreneurship. In the case of pharmaceutical sector the amendment in Patent Acts in 2005, relaxations in FDI regulations, National Health Policy 2017, etc. have not only contributed immensely over the past years to India's efforts towards achieving universalisation of health care for the second largest population in the world, but have also helped significantly in the global efforts through the provision of affordable quality medicines in all the continents. Rightly, these initiatives help India to earn the sobriquet: the pharmacy of the world. In this context the present report, "Public Policy and Economic Development: Case Study of Indian Pharmaceutical Industry" captures the saga that made the Indian pharmaceutical industry a success.

The Report discusses and documents all major policy developments in the past that have impacted the development the pharmaceutical sector in India. It makes a critical evaluation of the policies and programmes and identifies areas wherever there are fault lines. It also examines in detail the trade data and analyses the products where the industry will have to lay focus in the future. The challenges and prospects in the field of the AYUSH industry are also discussed. The emphasis of the Report is on the importance of research and development in the pharmaceutical industry. Therefore, the study has great significance at a time when the country and the world are faced with an unprecedented pandemic. The crisis has brought out how India can conserve its resources and also walk the talk Vasudaivaka kudumbakam (the world is one family). It extended all possible cooperation to all countries, particularly the South in its fight against the epidemic.

This report is in fact part of the long series of publications on the Indian pharmaceutical industry that RIS brought out in recent years. These include reports and discussion papers on sub-sectors like medical devices, bulk drugs, trade in formulations and so on. This study has been made possible by a grant from the Ministry of Commerce & Industry, for which we are greatful to the Ministry.

We are also grateful to Shri Rajeev Kher, former Commerce Secretary and Distinguished Fellow with RIS who mentored the study and to Professor T C James; Dr Dinesh Kumar and Dr Deepika Chawla for carrying it out. We thank our colleagues in the RIS Publication Team, led by Shri Tish Malhotra and comprising of Shri Sanjay Sharma and Shri Sachin Singhal, who played an important role in bringing out this publication.

We are sure the Report would be found useful by policy makers, academics and pharmaceutical industry.

Sachin Chaturvedi

Abstract

As a result of the conscious efforts of the Indian government in the past, such as the Patents Act 1970, the Foreign Exchange Regulation Act (FERA) 1973, New Drug Policy (NDP), 1978, etc. the Indian pharmaceutical industry has been able to achieve remarkable success since the 1970s. Consequent on India joining the World Trade Organisation (WTO) in 1994, the sector has been facing serious competition from foreign pharmaceutical firms but has been able to do moderately well. However, the new economic model with global value chains impacting production and trade has posed special challenges for the sector in maintaining the flow of raw materials and goods. The disturbances in the domestic bulk drug manufacturing sector have been raising grave concerns about the vulnerability of the whole sector and in its ability to ensure an uninterrupted supply of affordable medicines to meet the public health challenges of India and the world. Technological developments in recent years have been at break-neck speed, with the onset of gene technology, artificial intelligence (AI), etc. The Organisation for Economic Cooperation and Development (OECD) countries and countries like China and Russia are investing heavily in research and development (R&D) and the advancement of technologies significantly. In this background, the present study was initiated to explore whether India is missing out on the new paradigm of development in the pharmaceutical sector and, if so, the reasons for the same and what should be done so that the strenuously built-up advantages of the sector are strengthened.

A narration of the experience of the last six or seven decades is expected to contribute to understanding what goes in favour of the growth of this sector, what comes as an impediment, and how domestic challenges and external opportunities can be converted in favour of the sector. The study, therefore, proposed to document and analyse past policy developments as contextual responses, industry performance in the past, current issues and challenges, and present a blueprint for future policy.

The present Report documents how the various phases of public policy mechanism have shaped the development of the Indian pharmaceutical industry from independence till the present. The pharmaceutical industry underwent different phases of its development trajectory marked by the dominance of foreign firms till the 1970s. Since then, it showed remarkable progress leading to a rise in domestic production as well as exports owing to policy interventions. Though the onset of liberalisation in 1991 provided the Indian pharmaceutical industry with access to cheap raw materials from other countries, it has adversely affected the domestic production capabilities and technological competitiveness, especially in the bulk drug industry at the same time. The competition from the other countries of the world points towards the need to make the industry more competitive in order to strengthen its position in the global economy. This Report extensively captures the working of different policies, bring to the forefront the areas where the policy failed and appropriately recommends what needs to be done to fully realise the strenuously built advantages of the pharmaceutical industry. It has analysed the policy areas of Patents, Investment, Health and Pharmaceuticals, Science, Technology, Innovation and Research & Development, and Trade Policies. Detailed data analysis has been made in all these areas. It also looks into issues of the AYUSH products and medicinal plants manufacturing and trade. Based on interaction with industry and research organisation representatives and government, a detailed list of challenges that the industry is facing, the opportunities they have and suggestions on way forward has been made. The report concludes with a broad view of the future of the Indian pharmaceutical industry, exploring the ways how it can contribute to *Atmanirbhar* India.

List of Abbreviations

AI	Artificial Intelligence
ANDA	Abbreviated New Drug Application
API	Active Pharmaceutical Ingredient
AYUSH	Ministry of Ayurveda, Yoga, Naturopathy, Unani, Siddha and Homeopathy
BIFR	Board for Industrial and Financial Reconstruction
CAGR	Compound Annual Growth Rate
CapEx	Capital Expenditure
CBD	Convention on Biological Diversity
CCEA	Cabinet Committee on Economic Affairs
CCI	Competition Commission of India
CDP-PS	Cluster Development Program for Pharma Sector
CDRI	Central Drug Research Institute
CIPLA	Chemical Industrial and Pharma Laboratories
COB	Carry on Business
CRAMS	Contract Research and Manufacturing Activities
CSIR	Council for Scientific and Industrial Research
CTRI	Clinical Trials Registry of India
D&C Act	Dugs and Cosmetics Act
D&P	Drugs and Pharmaceuticals
DALYs	Disability-adjusted Life Years
DBT	Department of Biotechnology
DDPB	Drug Development Promotion Board
DDT	Dividend Distribution Tax
DGTD	Directorate General of Trade and Development
DMF	Drug Master Files
DPCO	Drug Price Control Order
DPCRC	Drug Price Control Review Committee

DPRP	Drugs and Pharmaceutical Research Programme
DRPSCC	Department Related Parliamentary Standing Committee on Commerce
DSIR	Department of Scientific and Industrial Research
DST	Department of Science and Technology
EPZs	Export Processing Zones
ETDZs	Economic and Technology Development Zones
EXIM	Export Import Bank
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FERA	Foreign Exchange Regulation Act
FIBP	Foreign Investment Promotion Board
FICCI	Federation of Indian Chambers of Commerce & Industry
FTZs	Free Trade Zones
FYP	Five Year Plan
GCF	Gross Capital Formation
GMPs	Good Manufacturing Practices
GOI	Government of India
GVA	Gross Value Added
HAL	Hindustan Antibiotics Limited
HIDZs	High-Tech Industrial Development Zones
HS	Harmonized System
ICMR	Indian Council of Medical Research
IDPL	Indian Drugs and Pharmaceutical Limited
IDRA	Industrial Development and Regulation Act
ILO	International Labour Organisation
IPI	Indian Pharmaceutical Industry
IPRs	Intellectual Property Rights
ISM	Indian System of Medicine
ISM&H	Department of Indian Medicine and Homeopathy
LMZs	Large Manufacturing Zones
M&As	Mergers and Acquisitions
MAPE	Maximum Allowable Post-Manufacturing Expenses
MAT	Maximum Alternate Tax

MHRD	Ministry of Human Resource Development
MNCs	Multinational Corporations
MOH	Ministry of Health
MRTP	Monopolies and Restrictive Trade Practices Act
NBA	National Biodiversity Authority
NCEs	New Chemical Entities
NDA	National Drug Authority
NDA	National Drug Authority
NDDR	New Drug Discovery Research
nes	Not Elsewhere Stated
NLEM	National List of Essential Medicines
NMITLI	New Millennium Indian Technology Leadership Initiative
NPPA	National Pharmaceutical Pricing Authority
NTDs	Neglected Tropical Diseases
NTM	Non-Tariff Measures
OPPI	Organisation of Pharmaceutical Producers of India
OSDD	Open-Source Drug Discovery
PBT	Profit Before Tax
PCPIRs	Petroleum, Chemical and Petrochemical Investment Regions
PMP	Phased Manufacturing Programme
PMP	Phased Manufacturing Programme
PPP	Public-Private Partnership
PRDC	Pharmaceutical Research and Development Committee
PRDSF	Pharmaceutical Research and Development Support Fund
PSUs	Public Sector Units
R&D	Research and Development
S&T	Science and Technology
SAC	Standing Advisory Committee
SBB	State Biodiversity Boards
SBIRC	Small Business and Innovation Research Centre
SCM	Subsidies and Countervailing Measures
SDGs	Sustainable Development Goals
SEZ	Special Economic Zones

SITC	Standard International Trade Classification
SPS	Sanitary and Phytosanitary
STI	Science, Technology and Innovation
TBT	Technical Barriers to Trade
TFYP	Tenth Five Year Plan
TDB	Technology Development Board
TKDL	Traditional Knowledge Digital Library
TKRC	Traditional Knowledge Resource Classification
TRIPS	Trade Related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
UNICEF	United Nation's International Children's Emergency Fund.
UNIDO	United Nation Industrial Development Organisation.
WHO	World Health Organisation
WITS	World Integrated Trade Solution
WTO	World Trade Organisation

I
Introdution

1.1 Context

There are very few success stories of good policy making, which have resulted in measurable achievements in India since Independence. The pharmaceutical industry is generally perceived as a success story and an important one in that. Governance is a multi-sectoral activity and like in any other organisation, in government also it is axiomatic to say that a sectoral policy alone cannot achieve objectives without congenial policies in other sectors. A preliminary observation indicates that there exist many contributing factors from other sectoral policies and institutions which played a major role in the development of the pharmaceutical industry in India. Their contributions have not received due attention but need to be emphasised and highlighted. For example, policies on education have impacted the growth of the pharmaceutical industry. It was not possible for the industry to develop on its own if there were not enough universities. It was science education and later technology education through Indian Institutes of Technology (IITs) that provided appropriately qualified human resources, including skilled workforce from Industrial Training Institutes (ITIs), etc., for the sector.

Despite the growth of the Indian pharmaceutical industry and its present global leadership, a transformation in the context of global challenges is now overdue with the sector losing its grip on the world market. New technological challenges like the biotechnology revolution and Artificial Intelligence (AI) confronting the pharmaceutical industry necessitate the development of advance policy responses across different sectors, both in the medium-term and in the long-term, to maintain India's position as the pharmacy of the world. The recent problems faced by the Active Pharmaceutical Ingredient (API) industry with regard to key starting materials (KSMs) forebodes the kind of scenario unfolding. To take up the new challenges, we need to have a proper retrospect and reassessment of the past policies.

In this background, this study proposed to document and analyse past policy developments and contextual responses, industry performance in the past, current issues and challenges, and present a blueprint for future policy. The study will attempt to answer the questions of whether we are missing out on the new paradigm of development in the pharmaceutical sector; if so, what are the reasons for the same; and what should be done so that the strenuously built-up advantages of the sector are strengthened.

1.2 Scope

The scope of the study covers the growth of the Indian pharmaceutical industry, the impact of the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organisation (WTO), and the current challenges being faced by the industry. The study also explores the interaction between government policies and the development of the pharmaceutical industry. Based on the assessment of the emerging global challenges and present stress on liberalisation of the economy, the study aims to suggest policies and programmes for the healthy growth of the industry. It will keep in view the *Atmanirbhar* (self-reliance) strategy of the government, i.e. 'make in India; make for the world'.

1.3 Methodology

The methodology for the study is primarily desk research into government documents, reports, industry reports, literature, analysis of various data on the pharmaceutical industry, and consultations with industry, academia and government.

1.4 Literature Survey

There have been many academic papers and books assessing the impact of the WTO regime on India's pharmaceutical industry, from time to time. A brief narration of some of the important ones follows.

One of the early studies was by Dhar and Rao (2002) which analysed the impact of the new policy regime, introduced in 1991 on the development of the Indian pharmaceutical industry, covering the period 1991-2000. Findings of the study highlight that the Indian pharmaceutical sector not only expanded its production but has also emerged as a net trade surplus sector during this period. An interesting observation made in the paper is that though technology transfer policies were liberalised in the 1990s in the form of removal of restrictions on royalty payments, technical fees and also removal of restriction on the inclusion of restrictive clauses in arrangements, it has not resulted in increasing the technological collaborations in the pharmaceutical industry. The study also pointed out that despite easing of Foreign Exchange Regulation Act (FERA), 1973 restrictions on foreign enterprises which were allowed to increase foreign equity from 40 per cent to 51 per cent in 1994, it has not been able to attract a large inflow of foreign direct investment (FDI). Only 0.4 per cent (260 million US$)[1] of total FDI approvals during 1999-2000 was there in this sector. The study was limited to the first decade of liberalisation.

Mani (2006) maps the system of innovation in the Indian pharmaceutical industry, elaborating on its main components: (i) public policy regime, (ii) manufacturing enterprises primarily in the private sector and (iii) government research institutes (GRIs). According to the author, the pharmaceutical industry is one of the most innovative industries in the Indian manufacturing sector. The public policy regime endeavours to provide fiscal incentives for research and development (R&D) to industry, and also focuses on the promotion of R&D intensive companies, maintaining good product and standard regulations and development of orphan drugs. According to him, the private sector enterprises mainly dominate the manufacturing of drugs and the contribution of the public sector, i.e., Hindustan Antibiotics Limited (HAL) and Indian Drugs and Pharmaceuticals Limited (IDPL) is negligible (as both these public sector units were considered sick by the Board for Industrial and Financial Reconstruction [BIFR]). The author also observed that there has been an increasing number of mergers and acquisitions (M&As) in Indian pharmaceutical companies. These companies have been consistently expanding their operations overseas mainly due to an increase in their global competitiveness, moving up the value

chain, increasing their product offer, entering into new markets and consolidating their market share. He also found that out of the total pharmaceutical R&D, about two-third is contributed by the industry itself whereas the rest is managed by government research institutes mainly under the Council of Science and Technology (CSIR). Broadly, 20 laboratories under it are involved in pharmaceutical R&D. In addition, the Central Drug Research Institute (CDRI), a public sector organisation, is actively involved in new drug discovery research and has contributed about one-quarter of both Indian and foreign patents secured by CSIR. Industrial R&D in the pharmaceutical sector is mainly contributed by the private sector to the extent of 85 per cent whereas the share of public sector R&D is meagre owing to the financially weak position of HAL and IDPL. The firm-level analysis also indicated that the private sector has increased its R&D expenditure and is responding well to the challenges posed by TRIPS. These pharmaceutical companies have been actively engaged in patenting also in the US as pharmaceutical patents accounted for 20 per cent of all the patents granted during 2000-04, with most of the patents secured by the private sector. Still, these pharmaceuticals companies do not have adequate resources to become drug innovators as the estimated cost of developing the new drug is very high (around US$ 1 billion).

Contract research has been growing, on account of the increasing trend of outsourcing of R&D by Western companies, taking advantage of low-cost in developing countries and the growth of clinical trials. The study concluded that the TRIPS regime has not dampened the innovative efforts on the part of the pharmaceutical industry. Rather, their R&D efforts and patenting activity have been intensified. The activities of the domestic pharmaceutical companies are progressing in the area of new drug research. However, these companies lack the financial resources to work on all the stages of developing the molecules. They are licensing the molecules to MNCs. Thus, their R&D activities are biased towards the needs of the West and are ignoring the research for many neglected diseases like HIV/AIDS, dengue fever, leprosy, malaria, etc. This is an area where adequate support by a suitable public policy mechanism is required.

Kale and Little (2007) show how the Indian pharmaceutical industry has moved up the trajectory of the R&D value chain from duplicative imitation (reverse engineering) to advanced R&D capabilities or collaborative R&D, using the capability-creation model for different periods. The main findings of the study are as follows:

(i): In the 1960s, MNCs' market share in the pharmaceuticals was around 90 per cent and India was largely dependent on imports of medicines from the UK, France and Germany. The Government set up a network of research institutes under CSIR, and also with public sector units like HAL and IDPL. MNCs also started manufacturing in India due to increased pressure from the Indian government. The public and private sectors together built the knowledge base for the Indian pharmaceutical industry.

(ii)**:** Since the 1970s, the firms focused their efforts to adapt technologies to firm and country-specific needs and resorted to reverse engineering taking advantage of the new Patents Act, 1970. However, this phase is characterised by the development of capabilities in organic and synthetic chemistry only and not in medicinal chemistry and biology; publication and patenting activity were also negligible.

(iii): Since the 1990s, liberalisation in the pharmaceutical industry led to more exports mainly of generics to developed nations of the world. Thus, firms focused on developing creative imitation or intermediate R&D capabilities to develop patentable novel processes such as design copies, technological leapfrogging and creative adaptations through

non-infringement processes. As a result, firms succeeded in filing drug master files (DMF) for bulk[2] drugs and Abbreviated New Drug Application (ANDA) for formulations.

(iv): From 1995 onwards, the Indian pharmaceutical industry entered into the phase of collaborative or advanced R&D capabilities. It focused on developing new chemical entity research using analogue research or rational drug design or in terms of process R&D, and a new drug delivery system. Since Indian firms are not competent like MNCs in new chemical entity research, they are working on compounds whose structural activity is already known and are trying to make compounds with better efficacy and fewer side effects. Many firms also look at drug delivery system research as a risk-free strategy, which mainly involves improving the effectiveness of an existing drug in terms of dosage, length of treatment and biodegradability. In addition, Indian firms also collaborate with MNCs through licensing of molecules or drug delivery system technologies. The study highlights that the TRIPS regime has increased innovative R&D by Indian firms. The knowledge base developed through reverse engineering R&D in the 1970s helped build the absorptive capacity of the firms to build creative R&D capabilities and catalysing their movement from imitators to innovators.

Sahu (2007) analyses the impact of the TRIPS regime on the Indian pharmaceutical industry and the strategies evolved by the industry to meet the new challenges. The industry responded to this new patent regime in the following ways:

(i): There has been a rise in mergers and acquisitions within the domestic pharma sector which involved the acquisition of small firms by larger ones. Indian companies also acquired a large number of foreign companies as a part of their market expansion strategy. There have been acquisitions of Indian companies by foreign MNCs also and the pace of these acquisitions by foreign companies is expected to further increase. The foreign companies are increasing collaboration through strategic tie-ups with Indian and Chinese companies due to high drug discovery costs in the West and a shortage of new drugs in the pipeline.

(ii): The business model of the pharmaceutical industry underwent a change and the export of generic drugs to Europe, the United States and Russia became its main focus. They also aggressively engaged in challenging the patents of blockbuster drugs in European and American courts.

(iii): India has also become a hotspot for clinical trials on account of comparatively low cost.

Mani (2010) empirically analyses the effectiveness of R&D tax incentives for the pharmaceutical industry, covering the time-period 2004-5 to 2008-09. The study concludes that the R&D tax incentives have not been effective in raising the R&D expenditure of the firms for reasons such as the tax subsidy (6 per cent on average) being a very small proportion of their R&D expenditure, and the taxable income of the firms is not much. In order to make these R&D tax incentives beneficial for the firms, it is important that their profits before tax have to be large.

Abrol, Prajapati and Singh (2011) critically analyse the policy design in the post-TRIPS era. It found that the impact of TRIPS on Foreign Direct Investment (FDI), technology transfer and R&D was not encouraging and contrary to the positive expectations of the policymakers. The new investments by global MNCs in Indian companies confined to formulations, relegating investment flows into the bulk drug industry to a minor position. New investment inflows are mainly directed towards mergers, acquisitions and takeovers to gain more control over the operations of Indian firms. The pattern of activity-wise FDI shows that while it is mainly R&D projects accounting for the majority of

business activity (36 out of 86) by MNCs in India, the focus is mainly on phase III clinical trials which merely integrates Indian talent into MNCs objectives; hence, of little relevance to the Indian population. The evidence on technology transfer by MNCs also showed a high aversion to sharing technology related to bulk drugs. R&D expenditure of foreign firms is significantly lower than that of Indian companies. The study suggests that the policy mechanism should focus on the domestic market, information externalities arising due to a weak institutional research base and promotion of technology development. The private sector needs to coordinate with the public sector for the development of appropriate drugs for the poor. The policymakers should devise strategies in such a way that would enable Indian firms to focus on need-based innovation and, at the same time, reduce their dependency on foreign firms.

Chaudhuri (2012) has looked into the comparative performance of MNCs before and after 2005 amendments to the Patents Act, 1970 and observes that they are gaining a strong position in the Indian pharmaceutical industry. These firms, which had earlier focused on patented products and developed country markets are now manufacturing generics also. The share of MNCs in the domestic formulation market has significantly increased from less than 20 per cent in 2008 to around 28 per cent in 2010 mainly owing to the take-over of Indian companies in 2008-09. Additionally, these MNCs are gaining more control over Indian companies due to the abolition of FERA in the 1990s. Secondly, unlike the period from the 1970s till the 1990s the MNCs are now no longer required to produce bulk drugs and have started disinvesting in their manufacturing processes. The imports of high-priced finished formulations by MNCs are increasing. Their manufacturing and importing activities post TRIPS era resemble mostly those of the pre-1972 era now.

In a subsequent study, Chaudhuri (2014) notes that there has been a decline in R&D expenditure as a percentage of sales by MNCs. Around the early 1990s, the MNCs spent nearly one per cent of sales turnover on R&D, but it has consistently declined to merely 0.3 per cent of sales turnover spent on R&D in 2012-13. On the other hand, domestic pharmaceutical companies have now shown consistent progress in this regard from the mid-1990s and particularly from 2000 onwards. The study also shows that MNCs are importing the patented products from abroad and not manufacturing the same and a new patent regime is being used to launch infringement cases against Indian manufacturers.

Narayan and Thomas (2017) highlight the determinants of Industrial R&D in the Indian pharmaceutical industry, covering 173 firms for the period 1990-2015. The determinants which affect the R&D in pharmaceuticals are the size of the firms, technology imports (embodies and disembodies), exports, profits, age of the firm, ownership of the firms and outward investment. These are covered in the empirical analysis. The main findings highlight that there is a positive relationship between the size of the firms and their R&D activity as large size means more market share of the firm, which increases its R&D efforts.

The exports have a positive and significant relationship with the R&D of the firms as large exports by firms since liberalisation has led to an increase in the R&D efforts of the firms. The impact of technology imports on the R&D activity of the firms can be either substituting (if technology imports curb the R&D activity of the domestic firms) or it can be complementary if technology imports help the domestic firms in adopting and assimilating the technologies by increasing their R&D efforts. Thus, the impact of technology imports on the R&D activity of the firms has been found to be positive by the present study.

The rate of profit is another determinant of R&D as firms seem unwilling to depend on the borrowed funds due to the uncertain nature of the R&D activity. Thus, high-profit rates would lead to more R&D expenditure by the firms. Age of the firms (average age of the firms is 23 years), i.e. the accumulated experience and learning has also positive and significant influence on R&D. The foreign ownership of the firms usually has a negative impact on the R&D of the firms given the fact that these firms have access to technology from their parent company and are unwilling to invest in R&D in India. On the other hand, foreign equity participation can have a positive impact on R&D if the foreign technology is adapted to meet the local needs of the firms in India (the adaptations usually take place through joint ventures). In the present analysis, the foreign ownership of the firms has a negative impact on the R&D activity of the firms. The important policy implications of the study are that the R&D activity of the firms can be enhanced by increasing their exports, encouraging the small firms to undertake more R&D activities and by maintaining the competitive environment in the industry.

Dhar and Joseph (2019) also examine the performance of the Indian pharmaceutical industry in the TRIPS regime. Their findings suggest that (i): India's generic pharmaceuticals producers performed better in all three indicators, i.e. net worth, sales turnover and profits to sales ratio in the second half of the previous decade. (ii): But there has been a slowdown in the growth of these three indicators in the current decade. The growth in the sales turnover of the generic producers also led to a complete transformation in the composition of market leaders from affiliates of foreign companies in the 1990s to only the generic companies. Though Indian generic manufacturers have received a significant number of patents immediately after the introduction of the product patent regime during 2005-09, the numbers have fallen in the period 2010-2013. It is also observed that from 2000 onwards there has been a quantum jump in the number of FDA approvals granted to Indian generic manufacturers to market their products in the USA, leading to more market penetration.

What has come out from the survey of the above and other reports and papers is that the policy interventions of the pre-TRIPS period had significantly contributed to the rise of Indian generics. While in the post-TRIPS regime the domestic generic manufacturers continued to expand their market penetration globally, two significant developments took place. The first one was that the removal of the mandatory requirement of manufacture of APIs by all drug manufacturers has resulted in a decline in API manufacture and second, foreign pharma companies are now more focussed on marketing their generic and other formulations in India. The drug patent scenario has also not been showing a rosy picture for Indian innovation.

1.5 Committees

The pharmaceutical industry in the country has been the subject of a large number of expert committees. One of the early committees set up since independence was the Pharmaceutical Enquiry Committee set up by the Ministry of Commerce in 1953 under the chairmanship of Major General S. L. Bhatia, and which submitted a detailed report running into over 400 pages and containing 212 recommendations covering almost all aspects of the pharmaceutical industry. One of the major recommendations of the committee was that to continue to operate in India foreign firms should start manufacturing even if of basic chemicals.[3] The committees were not always to look into purely industrial issues; some studied other issues. For example, the Ayyangar Committee on the Revision of the Patents Law, set up in April 1957, which submitted its report in September 1959, was perhaps, the one that greatly influenced and transformed the development of the pharmaceutical industry in the country,

though the subject *per se* was not pharmaceutical industry. Its recommendation to take out medicinal products from the patent regime, which was done through the Patents Act, 1970, paved the way for generic manufacture in the country. Then there was the Hathi Committee, constituted in February 1974, to consider amendments to the policies concerning Drug Price Control Order (DPCO), 1970. Its remit also included a study of the status and progress of the pharmaceutical industry, the role of public sector units (PSUs), the growth of Indian companies including the small-scale units, and the quality control measures adopted by the industry. This Committee submitted its report in April 1975, highlighting the important role that the PSUs should perform.

After India joined the WTO (1994) also many committees have explored various aspects of the pharmaceutical industry in the country. The Pharmaceutical Research and Development Committee (PRDC) and Drug Price Control Review Committee (DPCRC) were set up in 1999. The recommendations of these committees influenced drug research and price control policies and the Pharmaceutical Policy, 2002. During the current century also, various expert committees have studied issues relating to the Indian pharmaceutical industry in the context of the WTO regime, the important ones of which are presented below.

1.5.1 Expert Committee on a Comprehensive Examination of Drug Regulatory Issues, Including the Problem of Spurious Drugs (2003)

The factors that led to the setting up of the committee were the concerns about spurious/counterfeit/substandard drugs and the weak enforcement of drug regulations in the country. The committee was to examine all aspects regarding the drug regulatory infrastructure in the country. The following are the main findings of the committee:

- Out of the information received from 31 States/UTs, only 17 drug-testing laboratories were found to be functioning. Out of 17 States having their testing laboratories, only seven were reasonably equipped/staffed, while the others were poorly staffed and did not even have the bare minimum equipment.
- The States had been repeatedly requested to set up intelligence cum legal cell but only 10 States had reported to have set up such cells. It was not clear as to how many of these are really functioning actively and effectively.
- The Committee was able to obtain detailed information regarding different categories of manufacturing units licenced by the State authorities. It was found that as against the frequently quoted figure of about 20,000 manufacturing units, the actual numbers of drug manufacturing licences issued were 1,333 for bulk drugs, 4,534 for formulations, 134 for large volume Parenterals and 56 for Vaccines. Thus, the total number of manufacturing units engaged in the production of bulk drugs and formulations is not more than 5,877. Besides, there are 199 medical devices units, 638 surgical dressings and 272 disinfectant units, 4,645 loan licences and 318 repacking units, 1,806 blood banks, 2,228 cosmetics units and 287other units not covered in the above categories.

The Committee found the following main reasons for the non-optimum performance of the industry, namely, inadequate or weak drug control infrastructure at the State and Central level; inadequate testing facilities; shortage of drug inspectors; non-uniformity of enforcement; lack of specially trained cadres for specific regulatory areas; non-existence of data bank; and non-availability of accurate information. Keeping that in view the Committee made the following important recommendations:

- Drugs and Cosmetics (D&C) Act, 1940 should be suitably amended and the

maximum penalty for sale and manufacture of spurious drugs causing grievous hurt or death should be enhanced from life imprisonment to death. Likewise, the Government should make the penalties more deterrent for other related offences. While the prevailing penalties are decided by the courts following normal legal procedures, it is imperative that there should be an effective deterrence against such offenders at the investigation level itself. The Committee, therefore, recommends a specific provision in the Drugs and Cosmetics Act that will allow persons indulging in spurious drug offences to be detained for a minimum period.

- Coordinate all stakeholders in the health care system such as medical and para-medical professionals, pharmaceutical companies, distributors and retail trade, patients, the media, the NGOs and the public at large.
- Establish a Central Drug Administration, which should be made into an independent office under the Ministry of Health and Family Welfare, as is the case in most countries. This helps to enforce the legal framework and licensing uniformly across the country.

1.5.2 Arun Maira Committee (High-level committee on FDI in Existing Indian Pharma Companies) (2011)

The background of the setting up of this committee was the activities of foreign pharmaceutical companies. Concerns were raised by many about their pressures on the government for amending the Patents Act, 1970, and also their moves to acquire Indian companies. To address these concerns, the Government appointed the Arun Maira Committee on 30 June 2011, which submitted its recommendations on 30 September 2011.

The committee was of the view that that the acquisitions by MNCs of Indian pharmaceutical companies might result in divergence of their (Indian companies) strategies to cater to western markets, thus depriving Indian consumers of essential drugs and may adversely affect the availability of necessary medicines and also increase their prices. There must be a proper institutional mechanism to scrutinize the activities of the foreign players coming to India.

With respect to the size of companies or combinations requiring approval from CCI for M&As, the Committee observed that the threshold for target companies requiring clearance from CCI is Rs. 750 crore based on turnover and Rs 250 crore based on assets respectively {*vide* notification S.O. 482(E) on 4 March 2011 and subsequently amended *vide* notification S.O. 1218(E)on 4 September 2011}. Most of the target companies in India have turnover significantly lower than what has been specified as a threshold for target companies, i.e. Rs 750 crore. The committee recommended that these target pharmaceutical companies must be exempted from the high threshold level specified by CCI, which would enable nearly two-third of target companies to come under the purview of CCI for merger review. Most MNCs undertake these acquisitions either through their subsidiaries or special purpose vehicles (SPVs), which also do not have high turnover as specified above (Rs 750 crore). Therefore, acquisitions by MNCs would fall under the group criterion for filing on a combined basis, both for acquired and acquiring companies.

In regard to the capacity of CCI to scrutinize acquisitions of Indian pharmaceutical companies by MNCs, the Committee opined that there are several aspects which place CCI in a far better position than the Foreign Investment Promotion Board (FIPB) to scrutinize the potential M&As and their likely impact on competition, prices and availability of medicines, such as the specialised knowledge of the industry along with knowledge of competition management that the CCI possesses. CCI has built-in internal processes for consulting and

obtaining requisite data/expert advice from concerned departments. The Committee also recommended the creation of the Standing Advisory Committee (SAC) on health and pharmaceutical issues to assist CCI. The SAC can be placed in an institutional set-up, i.e. with the Ministry of Health and would work on issues relating to affordability and accessibility of medicines in the country.

The Committee also suggested that CCI should perform the function of scrutinizing the potential impact of M&As on competition, consumer interests and availability of essential medicines by enlarging the scope of its activity through (i) lowering the threshold limit for target companies and (ii) through the assistance of SAC.

The Ministry of Health and Family Welfare (MoH&FW), however, held the view that FIPB is a better route to examine the impact of Foreign Direct Investment (FDI) entering into India taking into account the public health concerns, i.e. FDI should result in a rise in manufacturing capacity, retaining dominance of India as a manufacturer of generic medicines and adequate availability of generic medicines in India, involving the transfer of technology and enhancing R&D investments, whereas CCI should perform its function within its mandated legal role and that the capacity of CCI to scrutinize the impact of M&As taking into account public health concerns is not workable. MoH&FW was of the opinion that 100 per cent FDI through automatic route in Greenfield projects should be continued as before, whereas FDI with 51 per cent equity or more in Brownfield projects by foreign MNCs ought to be managed by the FIPB.CCI on the other hand can regulate the activities of the foreign MNCs within its legal mandate. Some other policy recommendations of the Committee are as follows:

Attracting more investments to expand and improve production capacities: There are several hurdles identified to attract Green field investment in India such as difficulty in acquiring land, complicated governmental procedures to obtain approval and environmental clearance. New Manufacturing Policy endeavours to make India an attractive destination for manufacturing and R&D and this must be pursued rigorously in light of the significance of Green-field investment for the pharmaceutical industry.

IPRs and Compulsory Licensing: Since patent protection is very essential for providing protection to inventors and boosting innovation and discovery of new drugs. On the other hand, patent protection may result in monopolies and exorbitant profits for some inventors. In this light, there is pressure from Western Governments on India to amend certain IPR provisions such as on data exclusivity, and deletion of section 3(d) and even compulsory licensing, which it must not.

Establishing a conducive environment for Drug Development: Currently, India is far short of facilities required for the preclinical phase of drug development and human resources required for it and Pharma companies may seek a favourable environment available elsewhere. To overcome the shortage of necessary infrastructure required for new drug development, India must develop itself as a preferred destination for attracting more Green-field investments in India compared to China and other competing developing countries.

Proper Check on anti-consumer practices in medicine prescription: Consumers in India are often made to pay much higher than the required price for the medicines due to asymmetry prevailing between prescriber and the patient, leading to monopoly power and anti-consumer practices in prescribing and retailing system. Improvements in the distribution system and provision of obtaining no-objection certificate from trade associations by stockist are necessary measures to be put in place immediately.

Redefining the Business Responsibility: The Committee further makes a plea to all companies whether Indian or foreign to ponder on the broader purpose of their enterprises, their business responsibilities and the business models rather than confining themselves to the discovery of new drugs. As the future success of companies (whether Indian or foreign) lies in catering to the broader needs of people through accessible and affordable medicines, they need to redefine the area of their business responsibility.

1.5.3 Katoch Committee 2015

A high-level committee, namely, the Katoch Committee for promoting the production of the bulk drug industry, under the chairmanship of Shri V. M. Katoch, the then secretary, Department of Health Research, was set up in February 2015. The main recommendations of this Committee are the following:

- For economising production of Active Pharmaceutical Ingredients (APIs), large manufacturing zones (LMZs) and mega parks need to be established. These zones/parks should be provided with common facilities like common effluent treatment plants, captive power plants/assured power supply by states and common utilities such as storage and testing laboratories. These zones should also be provided with solvent yards. These zones can be earmarked in National Manufacturing Investment Zones or Petroleum Chemical and Petrochemical Investment Regions (PCPIRs) in those states that possess the necessary facilities for setting up API units. In this regard, some states like Gujarat, Andhra Pradesh, Tamil Nadu and Odisha might be consulted and the states can provide land and other common facilities for setting up bulk drug parks. A central scheme for Development of Common Facility Centre for Bulk Drugs (DCFC-BD) with an allocation of Rs. 200 crore for 2018-2020 to provide grant-in-aid for creation of common facility centre to State Implementing Agencies (SIAs), be launched.
- Five to Six API clusters are necessary for the nation to become self-sustaining in API production. Two fully financed API clusters are urgently required to be set up keeping in view the huge and urgent demand for APIs. Each cluster would require 1000-2000 ha of land and Rs. 750-1,000 crore investments for common facilities.
- A Scheme to provide financial assistance to States for acquiring land and other common facilities, such as effective treatment plants, captive power plants, incubation facilities and advanced common testing centre, should also be launched.
- Revival of public sector units (PSUs) for production of the priority-based APIs such as Penicillin and Paracetamol should be considered. Apart from efficient use of the resources available with PSUs, infusion of capital around Rs. 500 crore be considered for PSUs such as IDPL and HAL to re-start manufacturing APIs.
- Proper synergy between the Department of Pharmaceuticals and other departments such as Ministry of Environment and Forests, Ministry of Coal, Department of Financial Services and Department of Revenue have to be built up through proper institutional mechanism.
- With regard to fiscal incentives, the committee made the following recommendations:
  - » Financial assistance from the government might be in the form of a professionally managed equity fund.
  - » All central and state duties, taxes and levies for the creation of API clusters should be zero.
  - » Soft loans and Capital Expenditure (CapEx) loans for high priority APIs and a moratorium of 10 years should be given.

» Faster clearances be granted to FDI proposals in bulk drug industry be provided but with relatively more encouragement to Brown-Field investment.

» Income Tax rebate on up-gradation of R&D facilities should be increased from 200 per cent to 400 per cent. Income tax benefits for manufacturers of APIs for ten years from the date of launch of a product should be given.

» Reduction of Service Tax for clinical trials for drugs developed in India should be considered.

The recommendations for promotion of the Research and Development are the following:

- Strong Industry-academia interaction by facilitation of movement of scientists.
- Proper Synergy between Ministry of Human Resource Development (MHRD) and various science departments like Department of Science and Technology (DST), Council of Scientific and Industrial Research (CSIR) and Indian Council of Medical Research (ICMR) on R&D relevant for best production practices of APIs.
- Rewarding scientists who contribute to developing improved processes for the production of bulk drugs.
- Import duty exemption on import of capital goods in respect of R&D.
- Tax Incentives/ subsidies and government support for R&D for improved strains and competitive technologies.

There are other committees, commissions and task forces also which have looked into the pharmaceutical industry issues during the last two decades and they have also made valuable recommendations. While efforts were made to implement most of the recommendations, newer issues keep emerging from time to time. At the same time, many of the recommendations of these committees are still relevant for the growth of the pharmaceutical industry. For example, the concluding recommendation of the Pharmaceutical Enquiry Committee, 1954 is that it is the duty of the government (a) to extend all possible help to pharmaceutical manufacturing firms to equip themselves with all necessary facilities such as modern plants and instruments and laboratories for research, (b) to coordinate the interests of manufacturers, traders and consumers, and (c) to ensure that the highest ethical standards are maintained in this industry and trade[4].

Endnotes

1. The dollar sign '$' is used throughout this report to refer to United States Dollar.
2. In this report the terms 'bulk drug' and 'API or Active Pharmaceutical Ingredients' are used interchangeably.
3. Pharmaceutical Enquiry Committee Report, 1954 (MoC).Accessed from http://cslrepository.nvli.in//handle/123456789/2136 on 28 February, 2021
4. Ibid. pg. 250.

II

Evolution of Indian Pharmaceutical Industry: A Brief Overview

2.1 Beginnings

The modern pharmaceutical industry in India is now more than a century old. Although allopathic medicines came to India with the arrival of the British and over the years, hospitals were set up on western lines, until the late 19th century medicines were being imported. The foundation for the manufacture of western medicine in India was laid by P. C. Ray on 12 April 1901 with the founding of the Bengal Chemicals and Pharmaceutical Limited (BCPL) in Kolkata. This was soon followed by a couple of other ventures like the Alembic Chemical Works in 1907 and the Bengal Immunity in 1919. The onset of World War II, however, turned out to be a boost for Indian pharma in view of increased demand for allopathic drugs. The period witnessed the establishment of a number of firms like Unichem, Chemo Pharma, Zandu Pharmaceuticals, Calcutta Pharmaceuticals, Standard Chemicals, Chemical Industrial and Pharma Laboratories (CIPLA), East India Pharmaceuticals, etc.

Towards the end of the war in 1943, India was producing almost 70 per cent of its drug requirements, though it was very limited, whereas in 1939 it was able to meet only 13 per cent of the requirement.[1] But the industry could not keep up with the rapid new developments in pharmaceuticals. The bulk drug production in 1947 was estimated as Rs. 10 crore.[2] In 1952, there were 1,643 (including 11 government) drug factories, with a capital investment of Rs. 23.64 crore in India. The sale value of the products made by them was Rs. 34.68 crore out of raw materials valued at Rs. 12.53 crore of which imports were of the value of Rs. 7.25 crore. The persons employed in the sector were 32,125 including 3,311 technical personnel.[3] The growth of the industry from such a small beginning to one of the estimated size of Rs. 3,01,000 crore industry with exports of Rs. 1,47,420 crore, of which 90 per cent are drugs, and imports of Rs. 72,800 crore, and reported employment of about 2.86 million persons in 20,053 units, is a veritable saga of the success of Indian economic policies.[4]

Four major policy shifts mark the evolution of the pharmaceutical industry in independent India. These are:

- Industrial Policy Resolution, 1948 and the Industries Development and Regulation Act, 1951
- The Patents Act, 1970
- New Industrial Policy, 1991
- The Patents (Amendment) Act, 2005.
- They account for four phases in the growth of the industry

2.2 Phase I- From Independence to 1972

The first major conscious intervention in the pharmaceutical industry by the government was with the Industries Development and Regulation Act (IDRA), 1951, which placed Drugs and Pharmaceuticals in the First Schedule of the Act whereby manufacturing, required specific authorisation. The Industrial Policy Resolution, 1956 was a comprehensive one covering all industries and led to certain amendments to the IDRA, 1951, which kept the sector open for both public and private sectors, but under regulations and permits. The objectives of the policy were to address the issues of lack of both investment and new technologies. The government in the next few years set up 5 PSUs, starting with the establishment of Hindustan Antibiotics Limited (HAL) in 1954 with World Health Organisation (WHO) and UNICEF assistance and collaboration and the Indian Drugs and Pharmaceuticals Limited (IDPL) in 1961 with the assistance of Soviet Union. It also made it mandatory for multi-national companies (MNCs) in India to manufacture drugs from the basic stage to formulations. Employees of PSUs with experience in drug manufacturing were allowed to move out. Dr Anji Reddy, ex-IDPL, founded Dr Reddy's Laboratories. By the 1970s, Indian pharma manufacturing reached around Rs. 450 crore (James 2020).

Some important features of Phase I are the following:

- Licences during 1962 -1965 favoured the expansion of foreign firms and certain large industrial houses by increasing their sales turnover through the production of 360 formulations and 4 bulk drugs (permission letters for 364 drugs in total) and by introducing specific new products. [5]
- Liberalisation of Industrial licensing policies in 1965 and the other policies during 1966 and 1967 permitted diversification of production to manufacture 'new drugs' and the expansion of 25 per cent of registered/ licensed capacities subject to certain conditions (Ghosh, 2019).
- After the withdrawal of the diversification policy in 1970, Carry-on-Business (COB) letters were granted for 215 formulations and 20 bulk drugs to continue with the diversification activities, which had taken place prior to the date of the notification. The share of Indian units in COB licences was very insignificant and no effective steps were taken by the foreign firms to get these COB licences.[6]
- These MNCs also had patent rights in various life-saving drugs and worked against the Indian units, which tried to produce these formulations, by importing bulk drugs[7].
- The MNCs initially flourished and expanded their capacities as these were mainly involved in importing bulk drugs and processing the same in India, for which no factories were initially set-up or major investments were done. Their initial investments were low compared to their sales turnover and they remitted huge profits abroad and, later on, these companies invested these profits to set up their own processing facilities.[8]
- Their technological competitiveness, the introduction of newer varieties of drugs, their trained medical personnel with the ability to explain the features of their products to medical practitioners, coupled with cost-effective management strategies contributed a lot for MNCs to establish their dominance.[9]
- MNCs were also favoured on two other accounts – they manufactured the bulk synthetic drug from late-stage intermediaries imported from abroad at a price dictated by the latter and sent their profits abroad by the sale of formulations.[10]

- They were mainly involved in production of formulations, which is profit-oriented and not showed much interest in the production of bulk drugs. On the insistence of Indian Government, when they started producing bulk drugs, their production activities confined to low-tonnage high priced bulk drugs only.[11]
- As per industry sources, 70 per cent of the market share belonged to MNCs in 1971.[12]

While the policies were intended to promote the growth of Indian pharmaceutical companies, they seemed to have not fully achieved their objectives. Some of the observations that one can make are the following:

- There was no legal backing for permission letters and COB licences granted to these foreign firms under the Industrial Development Regulation Act. (IDR Act, section11A-License for Producing and manufacturing new articles.)
- Before granting these permissions and COB licences, the competent authority should have verified the effective steps (rule 2 of IDR Act) under section 14 of IDR act.
- No effective steps had been taken by foreign firms to get COB licence as none of the firms had informed DGTD about the particulars of their revised manufacturing capacities, the new articles to be manufactured by them and the nature and value of minor balancing plant, if it has been added by them.

Source: Hathi Committee Report, 1976 ch-5, annexure-VIII.

An Assessment of Bulk Drug Manufacturing

- **Insufficient for Domestic Demand:** Though production increased during the period from 1951 to 1973, it was not sufficient to meet the market needs of the economy. The pharmaceutical industry could merely cater to the needs of 20 per cent of the population (Hathi Committee Report,1976 ch-2,para-17). The pattern of the production prevailing at that time confirmed to market needs of the country rather than existing social needs of the economy. Table 2.1 below shows the production of bulk drugs by the organized sector of the economy from 1951 to 1973. Keeping in view the broader objective of self-reliance as envisioned in the Fifth Five Year Plan (1974-79) and the targets set up by the Planning Commission Task Force, the production levels were really required to be geared up towards higher level to meet the increasing needs of the economy.
- **The level of production much below the approved capacities:** Most of the industrial units produced far below their approved licensed capacities mainly due to delay in the procurement of equipment/raw material, poor technology and uneconomic production.[13]
- **Research and Development**: R&D expenditure incurred by Indian pharmaceutical industry as a percentage of sales turnover was far below that of firms in developed countries. It was about Rs. 4.5 crore per annum and was only 1.1 per cent of the sales turnover.[14]
- **Low Level of Sales Capacity:** The Indian pharmaceutical units manufactured products from basic stage, which could not compete, well with the products of the MNCs which were made from penultimate stage or late-stage intermediaries. While some Indian units also brought into the market new range of products, these could not make much headway. Indian companies lacked professional management systems, marketing skills and financial resources to compete with the competition created by foreign firms at that time. The rapport between Indian units and medical profession was not too effective, and, as a result, the medical practitioners preferred to recommend the products/ drugs manufactured by foreign units.[15]

Table 2. 1: Production of Bulk Drugs by Organized Sector of Pharmaceutical Industry (1952-73)

Items	Units	1952	1957	1960	1965	1970	1973
1.Antibiotics	Tonnes	-	17.5	39.70	10.3	182	247
	MMU	-	3.43	6.39	151.17	249	316
	Kg	-	-	-	--	2308	3540
2.Anti-Dysentry Drugs	Tonnes	4.84	20.19	21.61	70.07	90	100
3. Anti-Diabetic Drugs	Tonnes	-	-	-	18.55	47	66
	MMU	-	-	-	513.75	807	
4. Anti-Leprosy drugs	Tonnes	0.83	2.49	7.41	3.55	8	8
5. Anti Pyretics&Anagestics	Tonnes	3.12	118.5	412.33	416.92	931	1315
	Kg	-	-	-	-	198	240
6.Anti TB Drugs	Tonnes	1.08	57.71	112.035	395.22	500	629
7. Anaesthetics	Tonnes	-	-	-	49.65	25.72	55
8. Synthetic Hormones	Kg	-	-	163	813	1997	25
9. Anti Malarial	Tonnes	-	0.06	-	13	40	26
10. Alkaloids and Allied Drugs	Tonnes	11.26	9.92	36.28	84.02	81.7	70.7
	Kg	1.18	89	211	3506	684	447
11.Sulphur Drugs	Tonnes	41.87	114.32	130.19	234.6	786	1211.78
12. Vitamins	Kg						
	Tonnes	0.94	0.18	0.213	151.26	280.841	393.7
	MMU	-	-	14.5	23.5	37	47.38
	Kg	-	-	5.22	43.7	141.40	180.80
13. Other Drugs	Tonnes	0.35	1354.24	82.66	173.10	207.34	257.68
	Kg	-	-	-	-	198	2.40

Source: Hathi Committee Report, 1976 Ch-2, pp. 42-43.

- **Lack of technological sophistication**: The Indian units did not possess advanced technology to manufacture drugs. It is mainly to enable Indian companies to obtain technological know-how from MNCs that the government allowed the operations of MNCs. But MNCs were always reluctant to share their novel technology with the Indian firms. The technology flow was allowed mainly through the overseas parent company only despite the availability of same technology at cheaper price in other countries of the world. New technology for basic drugs has not been transferred free of cost, rather large royalty payments/ technology fees have been paid by Indian companies despite foreign equity holding. Much of the technology imported at that time was such technology which had already established itself globally for the last 15-20 years.[16]
- **Production of bulk drugs was main activity:** The Indian pharmaceutical industry was mainly engaged in the production of bulk

drugs, which is more labour, technology and finance-intensive with a comparatively low turnover as compared to formulations. The Indian sector was mainly involved in the production of high-volume low-price bulk drugs.[17]

2.3 Phase-II- From 1972 till 1991

It is clear from the above discussion that the public policy mechanism in the first phase was such that it facilitated the continuance of the dominant position of MNCs in the Indian pharmaceutical industry and did not help growth of indigenous pharmaceutical units. The question of utmost importance in the 1970s was how the public policy mechanism should be set forth so that it may facilitate the development of domestic pharmaceutical units and also help to curb the monopolistic tendencies of MNCs. The Hathi Committee Report, 1974 gave some solid recommendations to set forth the development trajectory of pharmaceutical industry in the right direction. The Committee recommended that PSUs should take the leadership role in indigenous bulk drug production in the country, reducing the dominant role of foreign firms, and in developing technological and infrastructural capabilities in Indian pharmaceutical industry to help its growth in all dimensions.

The most significant change was the enactment of the Indian Patents Act, 1970 replacing the Indian Patents and Designs Act of 1911. The new law reduced the patent period of from 16 to 14 years and took out food items and drugs from the purview of product patents. These items were made eligible for process patents for seven years only. Removal of product patents opened the opportunities for Indian pharmaceutical firms to manufacture generic versions of new drugs at a comparatively low cost.

Other policy and legislative changes that impacted the growth of Indian pharmaceutical industry included the Foreign Exchange Regulation Act (FERA), 1973 which required, *inter alia*, pharmaceutical firms to reduce their foreign equity to not less than 26 per cent, and the registration scheme of Department of Science and Technology (DST) launched in 1973 for R&D Units to boost in-house R&D in private and public sector**.** This scheme of registration was taken over by Department of Science and Technology (DST) in 1984.

The Drug Policy of 1978 also played significant role in the growth of domestic pharmaceutical industry in the country. This policy reserved production of 25 drugs to public sector, 16 drugs to domestic pharmaceutical units and the rest were open for all but the FERA firms were required to sell 50 per cent of their bulk drug production to non-associated formulators. In contrast to this, it was found that small-scale pharmaceutical sector was selling the majority of its bulk drug production to other formulators. Another important provision of this policy was that the production of formulations was tied with the specific quantum of production of bulk drugs, the ratio of 1:5. If these companies produce bulk drugs worth Re 1, then the maximum formulations they can sell would be worth Rs 5 only.

The DPCO of 1979 provided a boost to the indigenous production of bulk drugs through its various provisions, such as setting up of retention price and selling price for bulk drugs (DPCO,1979). But despite adequate provisions, it could not provide much impetus to the bulk industry owing to relative decline in profitability of Indian companies *vis-a-vis* that of foreign companies around that time. (Ghosh, 2019.)

It is certainly true that the above policy measures taken in this phase, helped the Indian pharmaceutical industry in its manufacturing activity, with minor hiccups occasionally. Table 2.2 shows that there has been rise in production of bulk drugs and formulations during this period.

More detailed analysis of the policy impact on pharmaceutical industry during this period is made in Chapter 3.

Table 2. 2:Annual Production of Pharmaceuticals from1980-81 to 1989-90

	Year	Bulk Drugs (Value) (Rs. Million)	Formulations (Value) (Rs. million)	Total (Value) (Rs. million)
1	1980-81	2400	12000	14400
2	1981-82	2890	14340	17230
3	1982-83	3450	16600	20050
4	1983-84	3550	17600	21150
5	1984-85	3770	18270	22040
6	1985-86	4160	19450	23610
7	1986-87	4580	21400	25980
8	1987-88	4800	23500	28300
9	1988-89	5500	31500	37000
10	1989-90	6400	34200	40600

Source: OPPI, Organisation of Pharmaceutical Producers of India, 2001 as cited in Kale and Little (2007).

2.4 Phase-III-From 1991 till 2005

Economic development of the country till early 1990s was perceived to be pushed and guided by the government and private sector was to play a subservient role to the public sector. Economic liberalisation policies introduced in 1991 brought in momentous changes in the whole approach. It was aimed at giving more freedom to private capital and entrepreneurship. The broad liberalisation measures relating to pharma sector were the following:

- Industrial licensing for all bulk drugs was abolished initially except certain reservations for five bulk drugs, but later, in 1999, those reservations were also abolished.
- The ratio parameter where companies were required to manufacture specific quantities of bulk drugs before undertaking manufacturing of formulations no longer existed now.
- FDI inflows were liberally allowed in the post-liberalized phase. The FDI inflows upto 51 per cent were initially allowed which later got increased to 74 per cent in 2000 and 100 per cent in 2003.
- Drug Price Control Order (DPCO), 1995 relaxed the substantial price control on pharmaceutical industry and reduced the number of bulk drugs and formulations covered to 74 only, though the base of bulk drugs and formulations incorporated in DPCO, 1995 was not the essentiality of medicines but their market share.

Impact on Trade

Under the liberalised regime, international trade became a major tool for economic development. India had already achieved trade surplus in 1988-89 and it continued to have that till 2012 as evident from the studies of Dhar and Rao (2002) and Niranjan (2014). The export of bulk drugs increased by $ 236 million to $ 669 million during 1991-2000 showing the growth in exports of bulk drugs by 14 per cent. The export of formulations also showed rise by 18 per cent during 1991-2000, i.e. it rose from $ 212 million to $ 774 million. However, the imports of bulk drugs also increased in this period from $ 296 million to $ 641 million, and of formulations from $ 48.5 million) to $ 157 million during 1991-2000. Despite rise in imports, India continued to have trade surplus during this phase.

Imports of bulk drugs and formulations also rose but still India was able to have trade surplus during this phase.

The rise in India's exports has been possible due to increasing outreach of Indian pharmaceutical companies to world market, their adoption of Good Manufacturing Practices (GMPs) as per FDA (Food and Drug Administration, USA) norms. These companies have successfully evolved to meet the strict regulatory provisions of developed countries' markets by enhancing product quality and adopting the GMPs. The exports are mainly towards the markets of US, Europe Japan and Australia. India became successful in capturing the large export market as large number of drugs went off patent in 2007. A significant number of drugs again became off patent in 2012. The developed countries also shifted their priority towards low-cost generic medicine due to rise in manufacturing costs in their own countries, which further accelerated exports

Table 2. 3: Indian Pharmaceutical Industry: Exports (US$ million)

Year	Bulk drugs	Formulations	Total
1990/91	236.2	212.2	448.4
1991/92	317.7	245.6	563.3
1992/93	158.0	372.5	530.5
1993/94	174.1	429.9	603.9
1994/95	242.3	479.9	722.1
1995/96	349.4	630.6	980.0
1996/97	446.2	708.2	1154.4
1997/98	598.4	875.7	1474.1
1998/99	669.9	774.4	1444.3
1999/00	Na	Na	1540.1

***Source*:** Dhar and Rao (2012).

Table 2. 4: Indian Pharmaceutical Industry: Imports (US$ million)

Year	Intermediates and Bulk drugs	Formulations	Total
1990/91	296.5	48.5	345.0
1991/92	312.8	42.3	355.0
1992/93	392.7	46.1	438.8
1993/94	337.2	45.4	382.6
1994/95	381.1	55.1	436.3
1995/96	658.4	83.3	741.7
1996/97	638.0	97.4	735.3
1997/98	671.4	118.4	789.8
1998/99	627.3	130.9	758.1
1999/00	641.3	157.9	799.2

Source: Dhar and Rao (2002)

Table 2. 5: Production performance of the Indian pharmaceutical industry in the 1990s (US$ million)

Year	Bulk drugs	Formulations	Total
1990/91	417.0	2193.8	2610.8
1991/92	395.7	2110.6	2506.4
1992/93	443.7	2315.0	2758.7
1993/94	432.9	2262.8	2695.7
1994/95	483.8	2529.2	3013.0
1995/96	561.9	2814.0	3375.9
1996/97	616.9	2961.6	3578.6
1997/98	722.3	3323.3	4045.7
1998/99	763.0	3363.6	4126.6
1999/00	877.3	3706.9	4584.1

Source: Department of Chemicals and Pharmaceuticals, Annual Report (various years), Organisation of Pharmaceutical Producers of India (OPPI) and UNIDO, International Yearbook of Industrial Statistics. (Dhar and Rao2002)

from India to those developed countries. The compound annual rate of growth (CAGR) of exports in pharmaceuticals showed rise after the Patents (Amendment) Act, 2005 came into effect. The CAGR of exports was 9.5 per cent in 1995-1999, it was 19.31 per cent in 2000-2004 but it increased to 22.85 per cent in 2005-09 and further rose little more to 23.46 per cent in 2010-2012. (Tyagi, Mahajan, Nauriyal. 2014).

Impact on Production

The production of bulk drugs and formulations has also increased; bulk drugs increased from by 8.6 per cent from US$ 417 million in 1990-91 to US$ 877.3 million in 1999-2000 and formulations rose by 6 per cent during 1990-91 till 1999-2000 from US$ 2193 million to US$3706 million. It was mainly in the second half of this decade that production of both bulk drugs and formulations rose more sharply than in the past.

More detailed analysis of the policies and their impacts will be made in the next chapter.

2.5 Phase IV From 2005 to 2020

This was the period during which the pharmaceutical industry came under the full impact of the Agreement on Trade Related Aspects of Intellectual Property Rights, 1994 (TRIPS Agreement) and also of more liberalisation policies and measures. The Patents Act, 1970 was amended in 2005 to make all products and processes in all fields of technology, including pharmaceutical products and processes, eligible for a 20-year patent protection. Other developing countries also made necessary changes in their patent laws. Now Least Developed Countries (LDCs) only are left with the option whether or not to implement full patent obligations under TRIPS Agreement. This was also the period when India disinvested in most of the PSUs and further relaxations were made in domestic investment and FDI regulations. The policies and programmes and their impact on pharmaceutical industry during this period will be examined in detail in the subsequent chapters.

Endnotes

1 Ibid.Para 3.3 on pg. 18.

2 Hathi Committee Report, 1975. Pg. 89. Para13.

3 Ibid. pg. 21.

4 Department of Pharmaceuticals, Annual Report 2019-20.Pg 3,and ShuchiNahar_/ Articles, Industry & Sector Reports, Pharma / Pharmaceutical Industry In India at https://www.alphainvesco.com/blog/understanding-indian-pharmaceutical-industry-works-part-3. Accessed on 28 February, 2020.

5 Hathi Committee Report,1975,ch-5,pg-86 and Chaudhuri,2005,ch-4,pg-27.

6 Hathi Committee Report,1975, ch-5, pg-86.

7 *Ibid*.pg-90, para-13.

8 *Ibid*. pg-108-109.

9 *Ibid*.pg-87,para-8.

10 Chaudhuri, 2005, ch-2, pg-23.

11 Pharmaceutical Enquiry Committee, 1954,ch-2.

12 Dr Y K Hamied. Indian Pharmaceutical Industry. 2005. Pg. 18.

13 Hathi Committee Report 1975, ch-2, annexure-I,pg26-38.

14 Ibid. ch-2. Para 37.

15 Ibid. ch-5, Para 8.

16 Ibid. para.9

17 Chaudhuri,2005,ch-2,pg-40-41.

III

Patent Policies and Pharmaceutical Industry

3.1 Introduction

As seen from the brief overview of the industry in the previous chapter, government had made conscious policy shift in 1970 towards a liberal patent regime that would help in the development of Indian pharmaceutical industry. This shift was the result of a long process that started in the mid-1950s, with a move to draft a new patents law. Studies had shown that the previous patents and designs law, which was a copy of the old British law, had not contributed to the growth of an Indian pharmaceutical industry despite some impetus during the Second World War.

3.2 Impact of Indian Patents and Designs Act, 1911 on Pharmaceutical Industry

After the discovery of Penicillin in 1928 and sulphanilamide drugs in the 1930s, the pharmaceutical industry had attracted huge investment in the form of research and development (R&D) in developed countries, mainly EU and the USA. Despite growth in other industries such as steel industry, drugs and pharmaceutical industry in India remained comparatively less developed largely owing to Patents and Designs Act, 1911, which was used as a tool by the MNCs for the purpose of restricting the manufacturing of drugs invented abroad (Mueller, 2007).[1] Notwithstanding constituting more than 90 per cent share of Indian pharmaceutical industry by the MNCs (Ragavan, 2006),[2] indicating no competition and assuring of recouping return on investment, their contribution with respect to promoting domestic innovation in this industry, was negligible (Mueller, 2007). Therefore, the protected environment offered to MNCs *via* product patent, which continued until 1970s, hardly helped the Indian Drugs and Pharmaceutical industry in attracting FDI, technology and innovation. Despite controlling more than 99 per cent of the patents and 80 per cent of market concentration, between 1947 and 1957 in India,[3] the MNCs were largely concentrating on formulations and importing most active pharmaceutical ingredients (APIs)[4] and undertaking manufacturing from the penultimate stage only [Fifth FYP (Five Year Plan), chapter 5],[5] which requires relatively less investment. India was heavily dependent on foreign countries even for most essential drugs. The MNCs were also charging exorbitant prices[6] for most of the drugs. The growth of the Indian pharma industry remained stunted owing to negligible amount of manufacturing from basic stage by the MNCs on one hand and their strategy of patenting of large number of processes for a single product, on the other hand. Furthermore, domestic firms were not allowed

to manufacture and prepare formulations of patented drugs even using different process.

3.2.1 The Patents Act, 1970

It was in this background that Patents Act, 1970 was enacted. This Act laid down clear economic objectives in the following words in its Section 83:

> *"(a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay; (b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article; (c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;"*[7]

The main objective of the new law was to strike the right balance between the rights of a patent holder and social and economic welfare of Indian people.

As per the suggestions of the Ayyangar Committee, the Act treated food, medicine, and chemical inventions differently as only process patent was allowed in inventions under these areas:

Section 5. Inventions where only methods or processes of manufacture patentable.__(1) In the case of inventions __

> *"(a)claiming substances intended for use, or capable of being used, as food or as medicine or drug, or; (b) relating to substances prepared or produced by chemical processes(including alloys, optical glass, semi-conductors and inter-metallic compounds),*
>
> *no patent shall be granted in respect of claims for the substance themselves, but claims for the methods or processes of manufacture shall be patentable."*

Further, in these critical fields, the term of patent was reduced significantly to *"five years from the date of sealing of the patent, or seven years from the date of the patent, whichever is shorter."*[8]

Some of the other important changes that were introduced in the law include the following:

- Although the provisions related to issue of compulsory licences and revocation of patents were available in the Patents and Designs Act, 1911, their scope was extensively widened in Patents Act 1970.
- For the first time, complete accessibility was provided to the government for using patented inventions for its own purposes.
- Usage of patent inventions was permitted for carrying out experiment, research and teaching.
- In critical fields, the provision of "licences of rights" automatically allowed the use of process patent after a period of three years from the date of sealing of the patent for manufacturing which allowed the exploitation of the patented drugs after procuring licence from the patent holder.

3.2.2 Impact of Patents Act 1970 on Pharmaceutical Industry

a. Growth of manufacturing and exports

The provisions in the new law permitted domestic manufacturers to make generic versions of new drugs through a process of reverse engineering. This also reduced the cost of manufacturing leading to cheaper prices compared to the products of MNCs (Racherla, 2019). Consequently, the production of formulations increased from around $ 494 million in 1974-75 to $ 1030 million in 1977-78, i.e. more than double in four years and the production of bulk drugs increased from $ 111 million to $ 188 million during the same period (See Table 3.1). This trend continued until 1989-

90, except for a brief period between 1983-84 and 1986-87.

After 1978, the drug policies (1978 and 1986), FERA and other supportive policies also played key role in augmenting the production of the pharmaceutical industry. Further, the increase in the production of the pharmaceutical industry had also led to expansion of the exports and thereby contributed to foreign exchange earnings. The share of exports in production of pharmaceutical (formulations and bulk drugs) had increased from 17 per cent in 1990-91 to 34 per cent in 1999-00 (Dhar & Rao, 2002).

b. Development of Indigenous Technology for Bulk Drug Manufacture

The new law encouraged the development of indigenous technology for bulk drug production (Mehrotra, 1989).[9] Between 1965 and 1982, four Indian public sector companies pioneered manufacturing technology of 51 bulk drugs and top 10 private Indian companies introduced technology for 36 bulk drugs whereas top ten foreign companies launched technology for 9 bulk drugs only.[10] Most technologies developed by the Indian companies, both public and private, were from the basic stage while foreign companies evolved the technologies from intermediate stage. As a result of this technological development, the domestic production of the bulk drugs significantly grew and led to steep decline in the formulation prices.

c. Impact on Market share

As a result of cheaper prices of products of domestic companies, the market share of the MNCs also got reduced considerably.[11] In 1971, more than 70 per cent of the domestic market in pharmaceutical industry belonged to the

Table 3. 1: Category-wise Production of Indian pharmaceutical Industry after Patents Act, 1970 ($ million)

Year	Bulk drugs	Formulations	Total
1974-75	111.1	493.7	604.8
1975-76	155.2	668.6	823.8
1976-77	167.4	781.3	948.7
1977-78	187.7	1,029.9	1,217.6
1980-81	305.2	1,526.1	1,831.3
1981-82	333.8	1,656.1	1,989.9
1982-83	364.9	1,755.7	2,120.6
1983-84	351.5	1,742.7	2,094.2
1984-85	331.8	1,607.9	1,939.7
1985-86	336.3	1,572.5	1,908.8
1986-87	363.2	1,696.9	2,060.1
1987-88	370.3	1,813.0	2,183.3
1988-89	395.2	2,263.4	2,658.6
1989-90	394.4	2,107.7	2,502.1

Source: GOI, Ministry of Chemicals and Fertilizers, Annual Report and Organization of Pharmaceutical Producers of India (OPPI) as cited in Dhar & Rao (2002).

MNCs.[12] By 2005, however, domestic share held by the MNCs declined to 23 per cent. Over the same period, the number of MNCs in the list of leading 50 pharma companies declined from 33 to 13.

d. Enhancement of Efficiency and Capability of Domestic Manufacturers

Another significant impact of prohibiting product patent in the pharmaceutical industry was that it gradually enhanced the efficiency and capability of domestic firms in reverse engineering technology. They were progressively able to reduce the time lag (number of years) between launching of a new drug in the global market by the patent holder and introducing the generic version of same drug in the Indian market, as can be seen from Table 3.2.

e. Decline in the Number of foreign patent applications

One of the vital impacts of implementing the Patents Act, 1970 was that the number of patents applications filled by non-Indian had considerably fallen from 4,248 in 1968-69 to 1,010 in 1978-79 whereas applications filed by Indians remained unaffected, though quite less, during the same time period (Mueller, 2007).

f. Innovative Capabilities

The new law had also assisted, indirectly, in raising the innovative capabilities of Indian pharmaceutical industry as pointed out by Ballance *et al*. (1992). According to them, India became one of the 17 countries in innovative capabilities, although these 17 countries had modest research, production and distribution capabilities in pharmaceutical industry as compared to industries in ten developed countries.[13] their innovative companies had started competing vigorously in the export markets with these ten developed countries which had sophisticated pharmaceutical industry and a significant research base.

g. Impact on R&D

Notwithstanding India's major achievement with respect to production and export of generic drugs after the implementation of Patents Act, 1970, there was not much innovation of new molecules by Indian generic drug industry due to missing R&D expenditure on this front until TRIPS period (Mueller, 2007).[14] Similarly, the weakness of India's domestic pharmaceutical sector on this front was also highlighted by FICCI in a 2005 report[15] as a result of "low investments in innovative R&D and lack of resources to compete with MNCs for New Drug Discovery Research and to commercialize molecules on a worldwide basis". This was essentially due to minuscule R&D expenditure:

> *"Since independence, efforts of IPI[16] have mostly been directed towards the development of alternative cost effective manufacturing processes for molecules already invented and patented in other countries. Very little or no effort was invested in R&D towards development of new molecules/products. Over the last few decades, this contracted patent regime in India, recognising only process patent, has had a negative impact on the development of professional expertise in new chemical entity development as potential therapeutic agent. This in turn also gave lesser exposure to conducting advanced clinical trials and drafting patents and patent related litigation in the areas of new chemical entities, genetic engineering, combinatorial chemistry, natural products, agro-chemicals and agricultural products"*. (Chandran *et al*., (2005), p. 271.)

Although Indian pharmaceutical industry has had allocated about 1.8 per cent, on average, of its sales on R&D between 1990 and 1999, which was greater than the average for Indian industry (around 0.7 per cent) (Dhar & Rao, 2002), the expenditure was insignificant in comparison to R&D expenditure carried out by the western pharmaceutical companies (Mueller, 2007).

Table 3.2: Time lag between launch of new drug and generic version in India

Drug	Year of Introduction in the World market by the Inventor	Year of Introduction in the Indian market by domestic companies	Time lag before introduction in India (years)
Ibuprofen	1967	1973	6
Salbutamol (anti-asthmatic)	1973	1977	4
Mebendazole (anti-helminthic)	1974	1978	4
Rifampicin (anti-TB)	1974	1980	6
Cimetidine	1976	1981	5
Bromhexin (anti-hypertensive)	1976	1982	6
Larazepam	1977	1978	1
Naproxen (anit-rheumatic)	1978	1982	4
Captopril (anti-hypertensive)	1981	1985	4
Ranitidine (anti-ulcer)	1981	1985	4
Norfloxacin (anti-bacterial)	1984	1988	4
Ciprofloxacin (anti-bacterial)	1985	1989	4
Acyclovix	1985	1988	3
Ciprofloxacin	1985	1989	4
Astemizole	1986	1988	2

Source: Keayla (1997) as cited in Dhar & Rao(2002).

h. Impact on FDI and technology transfer

Given that a weak patent regime was prevailing after the implementation of Patents Act, 1970, until 2005, there was virtually no incentive for the foreign investors to make investment in and transfer of technology to India. After the implementation of FERA, 1973, foreign firms had to reduce their stakes below 40 per cent in order to enjoy the privileges offered mainly to Indian pharmaceutical companies. Consequently, FDI inflow had remained quite low. It was only after allowing foreign equity up to 51 per cent under the drug policy 1994 that FDI increased.[17] The government eased the policies concerning transfer of technology during the 1990s through simplification of procedures, removal of restrictions on royalty or technical fee payments, removal of restrictions on inclusion of restrictive clauses in arrangements, and introduction of no scrutiny policy for repeated imports, etc. but it did not succeed in increasing the number of technical collaboration agreements between foreign companies, especially large MNCs, and the

Indian pharmaceutical industries (Dhar & Rao, 2002).

3.2.3 The Patents (Amendment) Act, 2005

Consequent on joining the WTO, India made various amendments to the patent law and finally through the 2005 amendment removed the exception granted to pharmaceutical and food products from patenting in the original act. How this amendment and other obligations under WTO affected the pharmaceutical industry is examined in this section.

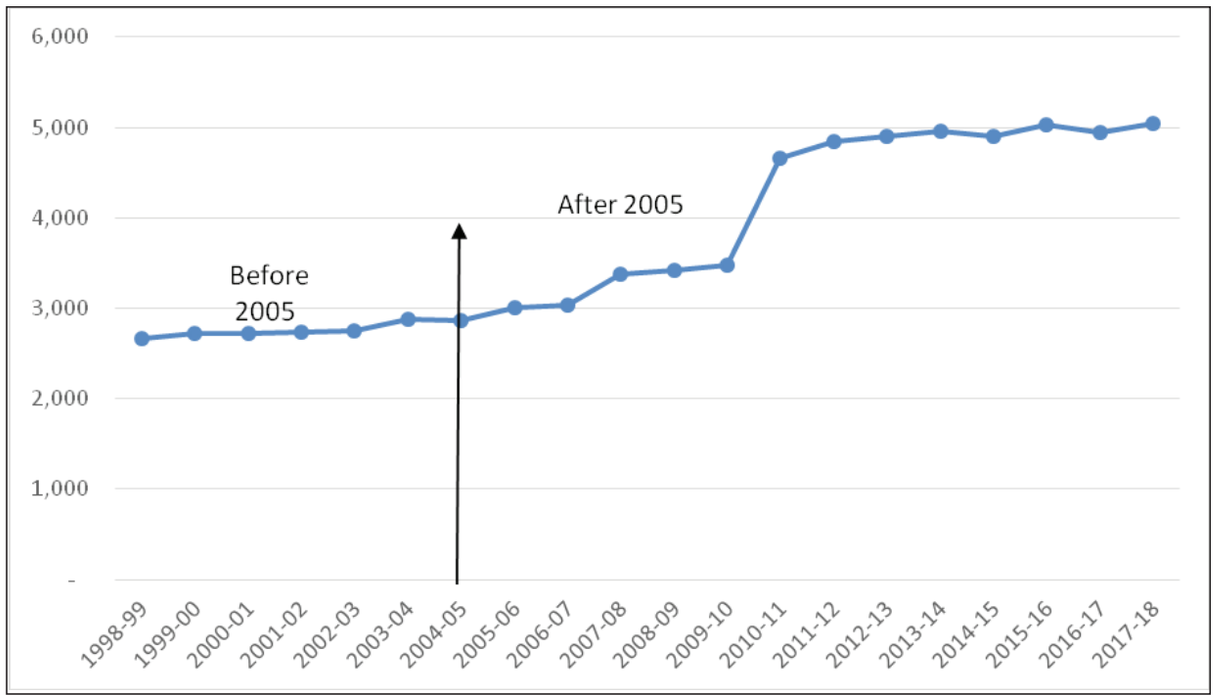
a. Impact on Production

A fear among many at the time of the 2005 amendment was that manufacturing of pharmaceutical products would decline, as Indian companies would not be allowed to produce patented drugs. However, the number of pharma manufacturing units has not recorded any negative impact, but rather has gone up as can be seen in Figure 3.1.

Similarly, with respect to value of output, gross value added (GVA), profits, the Indian pharmaceutical industry did not record any negative impact (Figure 3.2). In fact, post 2005, the industry grew at higher pace in comparison to pre-2005, particularly in relation to aforementioned variables (Table 3.3). However, with respect to gross capital formation (GCF), pharmaceutical manufacturing has underperformed in post-2005 compared to pre-2005.

By analysing trend of change in GCF, we have found that in post 2005, investment repeatedly fell every now and then (Figure 3.2). For three consecutive years, i.e. from 2007-08 to 2009-10, there was virtually no investment (GCF) in the pharmaceutical industry. In following two years, 2010-11 and 2011-12, there was notable increase in the investment, but it again went down significantly in the subsequent year 2012-13 (negative). Similarly, before falling once again below zero in 2015-16, the pharmaceutical

Figure 3. 1: Trend of Number of Factories in Manufacturing of pharmaceuticals, medicinal chemical and botanical products: 1998-99 to 2017-18 (absolute number)



Source: Authors' estimation using EPWRFITS[18]on line Database.

industry recorded an increase in investment in 2013-14 and 2014-15. In 2017-18, it fell over again after increasing in 2016-17.

Likewise, value of output, GVA and profits in pharmaceutical industry have fallen every so often after 2005. The years in which aforesaid variables significantly underperformed were 2007-08, 2009-10, 2012-13 and 2016-17. Among these four years, 2012-13 was significantly worse (See Figure 3.3).

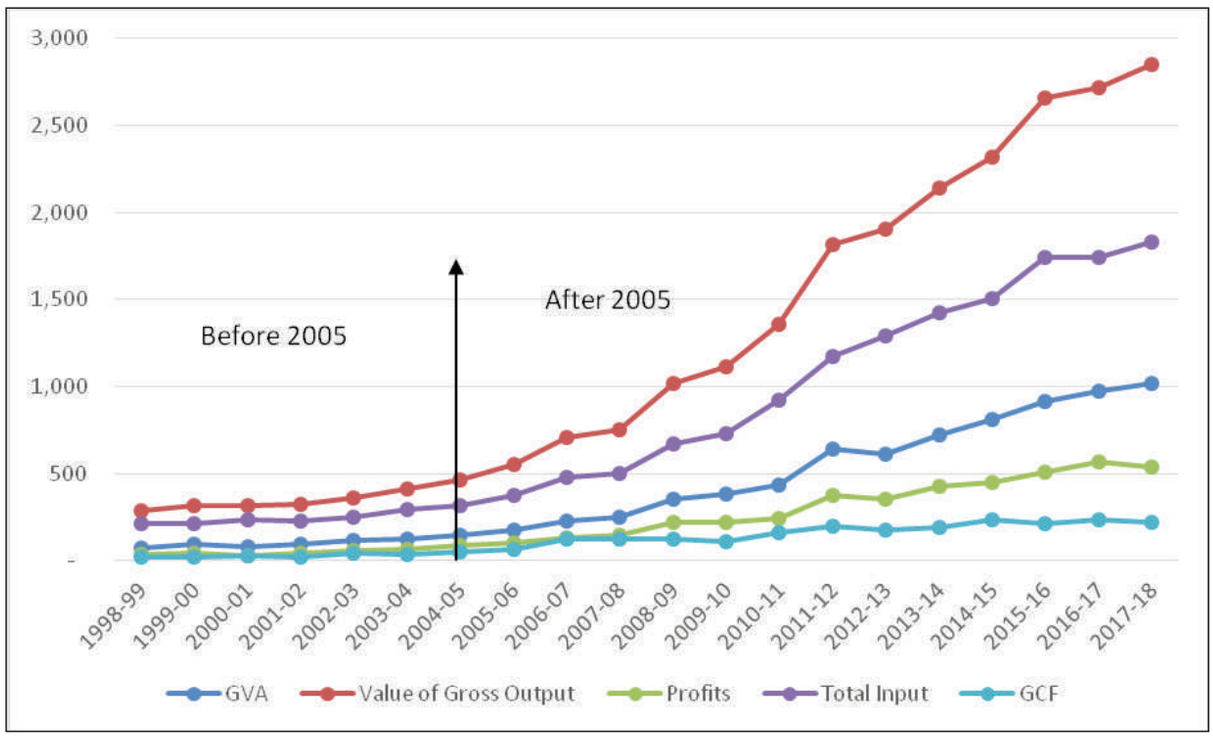
However, it is pertinent to note that at the aggregated level, the productivity per worker and profits per worker in the pharmaceutical industry did not record any effect of the patent

Table 3.3: Indicator-wise CAGR before and after 2005

S.No.	Period	GVA	Value of Output	Profits	GCF	Total Input
1	1999-00 to 2004-05	8.7	8.2	12.9	20.1	8.0
2	2004-05 to 2009-10	21.0	19.2	21.5	16.3	18.3
3	2004-05 to 2017-18	16.0	15.0	15.3	11.5	14.4
4	Entire Period (1998-99 to 2017-18)	14.7	12.9	15.8	12.5	12.1

Source: Authors' estimation using EPWRFITS[20] on line Database.

Figure 3.2: Trend of Value of Output, GVA, Profits, GCF and Total Input Cost in Manufacturing of Pharmaceuticals, Medicinal, Chemical and Botanical Products: 1998-99 to 2017-18 (in Rs billion)



Source: Authors' estimation using EPWRFITS[19] on line Database.

regime change, as they were kept on growing in post-TRIPS period as were growing in earlier phase (Figure 3.4).

b. Impact on Trade

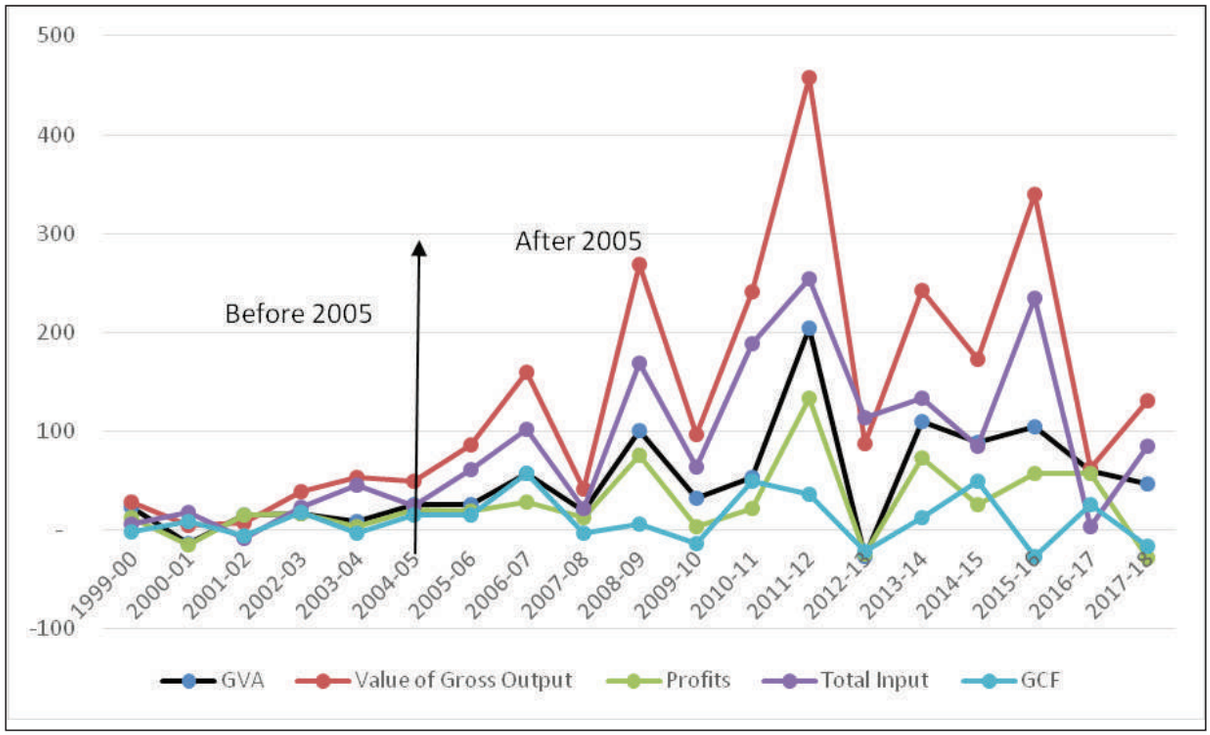
From the trend of India's export of formulations, it seems that there was no negative impact of patent amendment in 2005 as the exports were consistently increasing after 2005 as they were growing earlier (Figure 3.5).

However, there were few years, such as 2009, 2014 and 2017, in which exports of formulations went down significantly. Likewise, bulk drug industry had not recorded any negative impact on its exports (Figure 3.6**).** But, in 2009 exports of bulk drugs recorded a decline and, after 2012, the performance of bulk drugs exports has been remained significantly worse due to market factors and rising competition from other Asian nations[23]. For instance, between 2012 and 2014, exports of bulk drugs encountered steep decline in absolute terms; till 2017, its exports remained at around the level of year 2014; and finally recovered marginally in 2018. To large extent, the pattern of movement in exports of bulk drugs can be related with behaviour of production, GCF, and profits of the pharmaceutical industry, which we have observed earlier in the previous section and to some extent with formulation exports.

c. Impact on R&D Expenditure

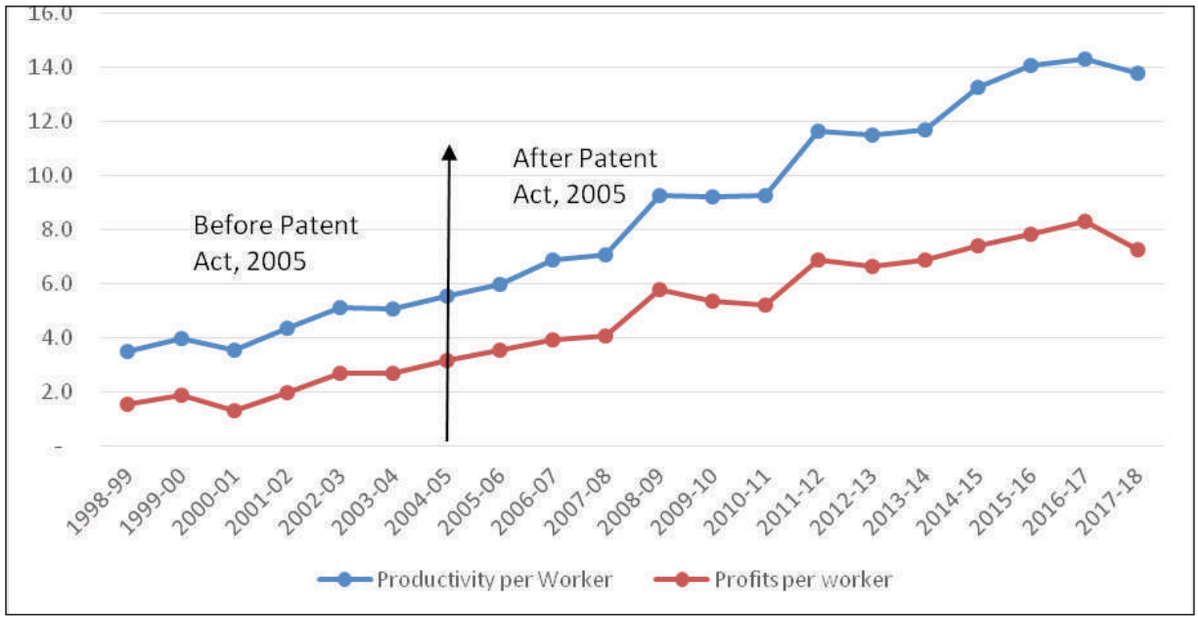
As in the case of production and trade, R&D expenditure too had not recorded any negative impact of patent law amendment in 2005 (Figure 3.7). In fact, in post-2005

Figure 3.3: Trend of Change (current minus previous) in Value of Output, GVA, Profits, GCF and Total Input Cost in Manufacturing of Pharmaceuticals, Medicinal, Chemical and Botanical Products: 1998-99 to 2017-18 (in Rs billion)



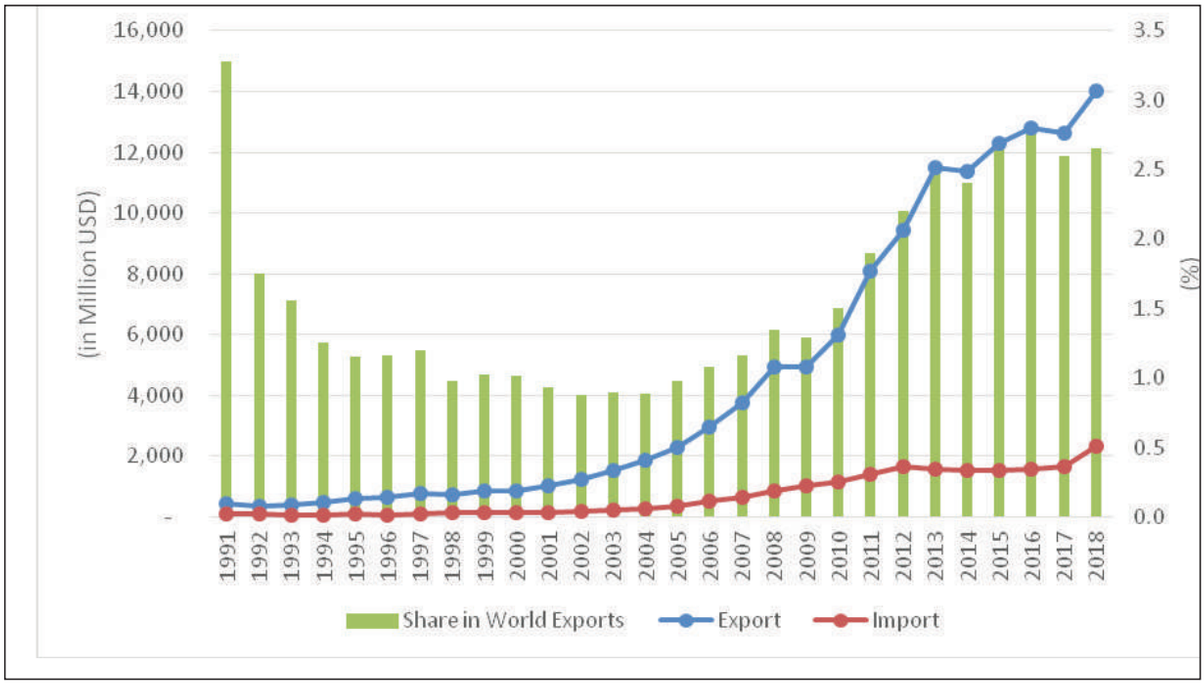
Source: Authors' estimation using EPWRFITS[21] on line Database.

Figure 3.4: Trend of Productivity per Worker and Profit per Worker (in Rs Lakh): 1998-99 to 2017-18



Source: Authors' estimation using EPWRFITS[22] on line Database.

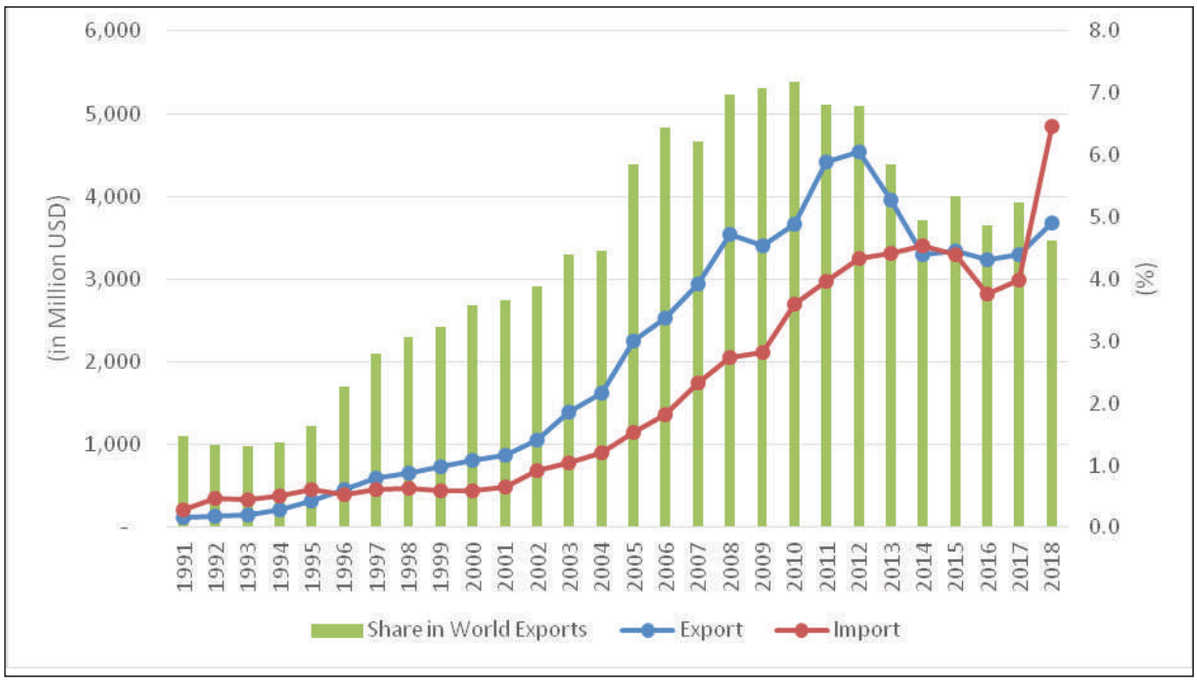
Figure 3.5: India's Global Trade in Formulation (Million USD) and Share in World Exports (%): 1991 to 2019



Source: Authors' Estimation using WITS, World Bank online database.

Note: Line-graphs are shown on Primary axis and Bar-chart on Right-hand axis

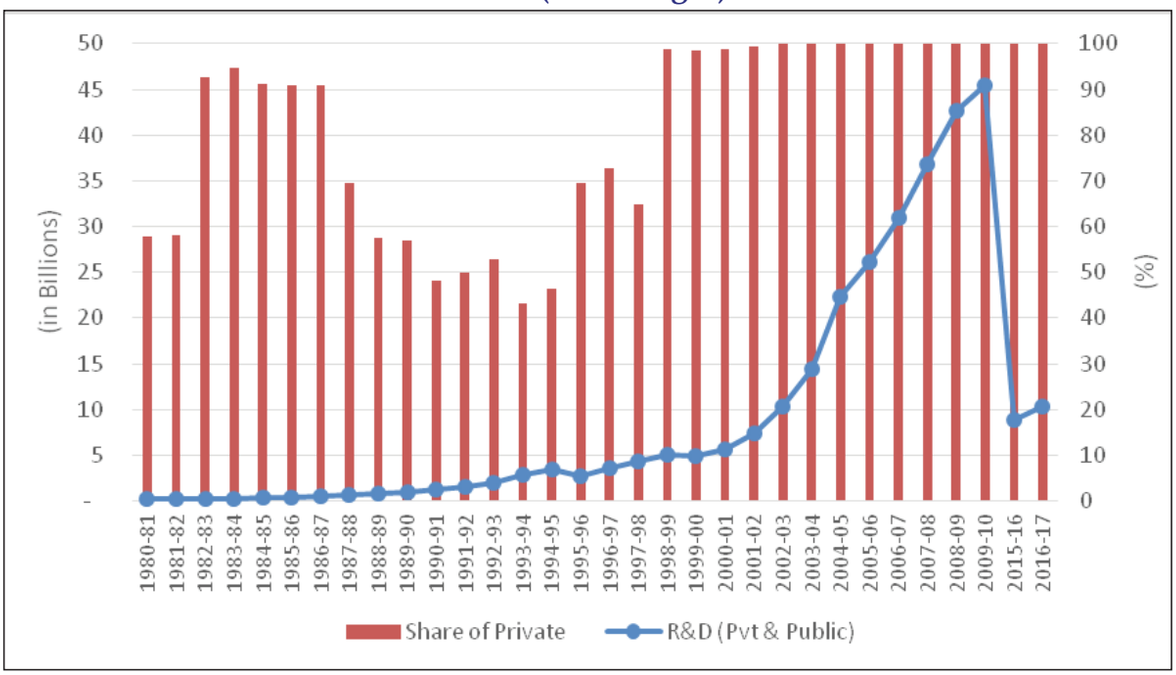
Figure 3.6: India's Global Trade in Bulk Drugs (Million USD) and Share in World Exports (Per cent): 1991 to 2018



Source: Authors' estimation using WITS, World Bank online database.

*Note: **Line-graphs*** are shown on Primary axis and Bar-chart on Right-hand axis.

Figure 3.7: Trend of R&D Expenditure (in Rs Billions) and Share of Private Sector in Total (Percentages)



Source: Authors' estimation based on Biennial Reports of NTSMIS, DST.

period, it has grown at a higher pace when compared to pre-2005 period, except in 2015-16 and 2016-17, as patent protection regime ordinarily encourages companies to enhance their expenditure on R&D to invent new and innovative products and processes. There were two main factors, which contributed to this growth in R&D expenditure, especially, by the Indian pharmaceutical companies even before the implementation the amendments. First, these companies would only be able to survive in the more competitive environment by raising R&D expenditure; second, incentives provided under drug policy order, such as, "production and development of innovative drugs and processes were exempted from price control for five years while new drugs were exempted for 10 years" (Bedi *et al*., 2013). In post- 2005 period, all major Indian pharmaceutical companies spent on R&D expenditure in the range of 5 to 10 per cent of their sales (Differding, 2017) which were spending maximally 2 per cent during pre-TRIPS period (Bedi *et al*., 2013 and Chaudhuri, 2007). In post-2005 period, there was notable shift in the composition of R&D expenditure by the Indian pharmaceutical companies (Chaudhuri, 2007). In post-2005 period, these companies carried out R&D expenditure on development of both new processes and NCEs while previously, they were mostly focussing on developing new processes for manufacturing drugs. Although, Indian pharmaceutical industry has been spending more money on R&D in post 2005, it is considerably lower when compared with MNC's expenditure on R&D (Banerji & Suri, 2017). As a result of this increase in expenditure on R&D, Indian pharmaceutical companies were able to increase number of product pipelines for the US market, but in relation to New Chemical Entity (NCE) development it has very limited impact. The larger part of this R&D expenditure spent on manufacturing cost effective generic products for US and European markets in key therapeutic segments.

d. Impact on Innovation, Technology Transfer and FDI Flows

Based on the assumption that MNCs own large resources, knowledge, patents, trademarks and technology (Bergman, 2006)[24], it is widely acknowledged among the fraternity of economists that Foreign Direct Investment (FDI) could play a pivotal role in industrial development and growth of the host country *via* supplying capital, technology through linkages with local players, and managerial skills and, thereby, may assist in raising domestic production, productivity, employment opportunities and improvement of the competitiveness of domestic firms globally (Arora & Lohani, 2017).

There are number of ways through which FDI inflows can take place, such as, licensing, joint ventures and goods trade (Blomstrom & Kokko, 1997). But, such increase of FDI and technology transfer could only be expected under a strong patent environment. There were number of researchers, largely in the global North, who had argued that TRIPS agreement would enhance FDI inflow, innovation and technology transfer to developing countries and, thereby, it would contribute to their economic growth (Ryan 1998).[25] However, this point of view was strongly challenged, especially in global South (Horner, 2014). There are number of examples of countries, which have procured significant amount of FDI, even under the environment of weak patent protection, such as, Brazil and Thailand in the 1970s and 1980s, and China (more recently). Brazil and Italy were able to attract considerable amount of FDI in the pharmaceutical industry even in the absence of product patent protection.[26] Therefore, it is pertinent to analyse the nature and impact of FDI inflows in Indian pharmaceutical industry in post-TRIPS period to find out that to what extent the FDI policy in India has been able to achieve the desired outcomes, sought by the government.

Over the years, there has been considerable change in the FDI policy for pharmaceutical industry in India. The seeds of opening up of drugs and pharmaceutical (D&P) sector for global economy were sown in the Drug Policy (1986). In 1991, government permitted FDI up to 51 per cent under the automatic approval route in D&P sector. As per the suggestion in the Drug Policy (1994), this sector was further liberalised, by allowing FDI up to 74 per cent under the automatic route. In 2001, the FDI liberalisation in the drugs and pharmaceutical sector was extended to its fullest level, i.e. 100 per cent, in those drugs, which were not attracting compulsory licensing or involving use of recombinant DNA technology and specific cell/ tissue, targeted formulations. The D&P industry was further liberalised in 2005 in relation to licensing requirement for drug manufacturing. These changes in FDI policy, especially in 2005, and other developments at global level (discussed in next paragraph), attracted many MNCs to acquire Indian pharmaceutical companies which troubled the Indian policy makers and resulted in setting-up parliamentary standing committee (PSC) in 2010 under the chairmanship of Shri Shanta Kumar[27] which submitted its report in 2013 [Department Related Parliamentary Standing Committee on Commerce (DRPSCC), 2013][28]. Before submission of the report by the PSC, there was one more significant development that took place in 2011 in relation to FDI policy. The GOI categorised FDI inflows into Brownfield investment and Greenfield investment.[29] In relation to Greenfield investment, the existing FDI policy remained the same, i.e. 100 per cent FDI permitted under the automatic route. In Brownfield projects also the GOI allowed 100 per cent FDI but under the government approval route.

DRPSCC (2013) made serious observations regarding the mergers and acquisition (M&A), which took place in D&P sector since 2005. According to DRPSCC (2013), out of 67 FDI investments, only one belonged to Greenfield projects while all the remaining were Brownfield. Further, it is important to note that out of a total US $ 9,174 million FDI inflows between April, 2000 and February, 2012, US $ 4,781 million came through acquisition route i.e. 52 per cent of the FDI in D&P sector belonged to M&A route. The following concerns or reasons were pointed out by the PSC for the FDI inflow, especially in the form of Brownfield projects, in D&P sector:

- According to the Committee, globally, there were sweeping changes taking place in D&P sector to maintain its growth level as patents on many blockbuster drugs were ending in 2011-13 (patents would end on 61 drugs worth US $ 80 billion). Consequently, MNCs were attempting to acquire Indian pharma companies which had strong generic manufacturing base (producing cheapest generic drugs in the world), well-oiled domestic marketing network, huge domestic market size, cheaper operating cost, English-speaking skilled manpower, predictability in business environment, efficient IT infrastructure, sound legal and IPR framework, broad base of scientists and R&D capabilities along with well-equipped laboratories. Further, developed countries were struggling to maintain their health budgets and, therefore, probing for generic drugs to reduce their health expenditure. Given the kind of advantage the Indian pharmaceutical industry was having, especially in generics, it would gain from the expiry of patents. In addition to this, India had the highest number of US-FDA approved plants outside the US and majority of these plants had multiple approvals from regulatory authorities in Canada, Australia and EU countries.
- Another disturbing point raised by the committee regarding the acquisition of the Indian pharmaceutical companies by the MNCs was that these companies were acquired at very high prices than their actual

value. For instance, Piramal Healthcare was acquired by Abbott at almost nine times the sales turnover. The Committee pointed out that these MNCs could only recoup such massive acquisition cost either through manufacturing more drugs and marketing of costly branded products or through raising the prices of generic drugs; possibly they might use both the options.

- The Committee was further concerned about the transfer of ownership of the generic companies to the MNCs which might alter the then existing business model and the marketing strategy of the acquired companies as per the requirement and objectives of the parent companies. Ranbaxy withdrawing all patent challenges filed on Pfizer's blockbuster medicine Lipitor in eight countries instantaneously after it was acquired by Daiichi-Sankyo is an example of altering business model. Additionally, the committee raised the apprehensions that these MNCs might either postpone the launch or not even launch generic versions of the patented drugs when the patents expire. The ability of the acquired firms to exercise the TRIPS flexibilities might also get affected.

Reportedly, in 2014, both the Health and Commerce & Industry ministries had recommended more controls for new entrants and reduction of FDI cap to 49 per cent in the Brownfield projects as FDI inflows had not contributed to value addition in terms of additional infrastructure or R&D segment and also had detrimental impact on the accessibility and affordability of drugs for the general public. But, the Ministry of Finance didn't immediately change the existing FDI policy and cited that it would hurt the FDI inflow in this industry.[30] It was only in 2016, the government altered the FDI policy in relation to Brownfield projects [Department of Industrial Policy and Promotion (DIPP), 2017]. In Brownfield projects, the government brought down the inflow of FDI under the automatic route from existing 100 per cent to up to 74 per cent and beyond 74 per cent is permitted through the government route while with respect to Greenfield projects FDI policy didn't record any change. However, it is important to note that FDI under Brownfield projects whether under automatic route or government route is further subject to fulfilment of following set of conditions:

> *"(a) The production level of National List of Essential Medicines (NLEM) drugs and/or consumables and their supply to the domestic market at the time of induction of FDI, being maintained over the next five years at an absolute quantitative level;*
>
> *(b) R&D expenses being maintained in value terms for 5 years at an absolute quantitative level at the time of induction of FDI. The benchmark for this level would be decided with reference to the highest level of R&D expenses, which has been incurred in any of the three financial years immediately preceding the year of induction of FDI;*
>
> *(c) The administrative Ministry will be provided complete information pertaining to the transfer of technology, if any, along with induction of foreign investment into the investee company; and*
>
> *(d) The administrative Ministry (s), i.e., Ministry of Health and Family Welfare, Department of Pharmaceuticals or any other regulatory Agency/Development as notified by Central Government from time to time, will monitor the compliance of conditionalities".*

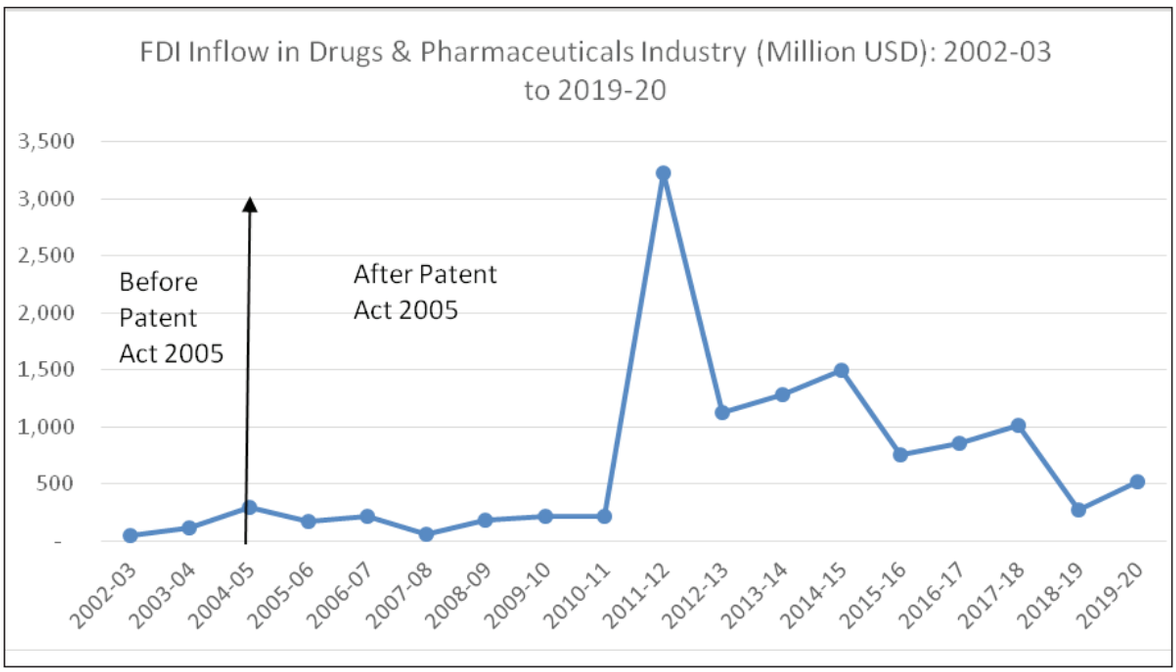
Recently, government of India (GOI) tweaked the FDI policy in April 2020, after observing few strategic takeovers during the precarious economic situation in that year, resulting from COVID-19. In relation to modification of the FDI policy (para 3.1.1),[31] the GOI permitted the inflow of FDI only through government route from the countries, which are sharing borders with India.

From 2002-03 onwards, the inflow of FDI in India in D&P industry is shown in Figure 3.8. It can be easily visualised from the figure that immediately after the implementation of patent law amendment in 2005, there was no change in the trend of the FDI inflow in D&P industry in India. Only in 2011-12, there was noticeable jump in the FDI inflow when it increased from an insignificant amount of $ 209 million in 2010-11 to $ 3,232 million. But, this increase in FDI inflow didn't persist and it gradually contracted overtime. The annual FDI inflow in this industry declined to $ 266 million in 2018-19 and marginally improved in 2019-20. As of March 2020, the D&P sector has attracted $ 16.5 billion of FDI inflow, accounting for 3.5 per cent of the total FDI inflows in the country and has been ranked ninth in relation to sector-wise FDI equity inflows (DIPP, March, 2020).[32] In post-TRIPS, the results are not encouraging with respect to technology transfer also(Abrol, *et al*., 2011).

It is pertinent to emphasize the contribution of MNCs to Greenfield projects. Sanofi has manufacturing facilities in Ankleshwar and Goa;[33] Abbott has two manufacturing facilities in Goa and Baddi (Mehta 2017); and while investing of Rs. 450 crore ($75 million), Abbott developed and launched Greenfield nutrition manufacturing plant in Jhagadia, Gujarat.[34] The existing and emerging manufacturing and R&D clusters in India are shown in Table 3.4.

The M&As offer positive synergies in the form of vertical or horizontal integration which could enhance efficiencies, trigger economies of scale (Mehta 2017), remove duplication and reduce costs (Lamattina, 2011). But, M&As could also have some negative impacts in the form of misusing of market power by reducing innovation efforts, increasing prices, creating artificial scarcity (Mehta 2017), reducing R&D, eliminating entire research sites and negative social consequences, especially with respect to employment (Lamattina, 2011). For

Figure 3.8: FDI Inflow in Drugs & Pharmaceuticals Industry (Million USD): 2002-03 to 2019-20



***Source*:** Author's estimation using DIPP database.

instance, during 2000s, Pfizer acquired three large companies — Warner-Lambert (in 2000), Pharmacia (in 2003) and Wyeth (in 2009) — and multiple smaller companies, such as Vicuron, Rinat and Esperion. But, it shut down its several research sites in "*the United States, including those at Kalamazoo, Michigan (formerly a site for Upjohn), Ann Arbor, Michigan (formerly a site for Warner-Lambert) and Skokie, Illinois (formerly a site for Searle) and Sandwich site in the UK*" to attain its business objectives (Lamattina, 2011). Another, two major troublesome features of the pharmaceutical companies that have been noticed in post-M&As phase, are the reduction in R&D expenditure and decrease in the number of NCE compounds in their pipeline (Lamattina, 2011). With respect to expenditure on R&D, it is observed that the R&D expenditure of the MNCs as a percentage of profit before tax (PBT) was consistently lower than that of Indian firms between 2004–2005 and 2011–2012 (Mehta, 2017). Further, it is important to note that significant number of foreign R&D investment projects are mainly focused on phase III clinical trials (Abrol,*et al*., 2011). So, to control these negative implications of M&As, the role of several regulatory bodies including Competition Commission of India (CCI), the National Pharmaceutical Pricing Authority (NPPA) and the Foreign Investment Promotion Board (FIPB), etc. become very crucial (Mehta 2017).

e. Impact on Market Share of Domestic Firms

In pre-TRIPS era, several researchers had predicted that the domestic market share of Indian pharmaceutical firms would decline while that of the MNCs would gain in Indian market since after 2005 Indian firms would not be allowed to manufacture those drugs, which were patented.[35] However, Indian pharmaceutical firms proved this prediction wrong. Indian firms have continued to dominate as they have around 80 per cent share of the Rs 1.36 trillion domestic pharmaceutical market in 2019[36] and also maintained its position of "the

Table 3.4: Key Manufacturing and R&D Clusters in India (2009)

Category	Number (absolute)	Name of the Place
Emerging Bulk Drug Cluster	1	Vishakhapatnam
Emerging Formulation Cluster	2	Baddi, Pantnagar,
Traditional Bulk Drug Cluster	14	Ahmedabad, Ankleshwar, Vapi, Vadodara, Mumbai, Tarapur, Aurangabad, Pune, Chennai, Pondicherry, Hyderabad, Mysore, Bengaluru, Panaji
Captive R&D Units	7	NCR, Ahmedabad, Mumbai, Aurangabad, Chennai, Bengaluru, Hyderabad-Medak
Contract R&D Units	5	Mumbai, Hyderabad-Medak, Bengaluru, Chennai, Ahmedabad
Traditional Formulation Cluster	4	Hyderabad-Medak, Goa, Mumbai, Pune

Source: https://www.ibef.org/download/Pharma_171109.pdf accessed on 24 September 2020.

pharmacy of the global south." (Mehta 2017). With respect to sales turnover in 2004-05 only three pharmaceutical firms were foreign, among the top 15 pharmaceutical companies in India (Table 3.5). Although, the same three foreign firms remained within the top 15 companies in 2019-20 as well, their domestic market share considerably declined.

Table 3. 5: Market Shares of Top 15 D&P Firms in 2004-05 and 2019-20

S. No.	Top 15 Companies in 2004-05	Sales Turnover in 2004-05 (in Rs Million)	Market Share in 2004-05 (%)	Top 15 Companies in 2019-20	Sales Turnover in 2019-20 (in Rs Million)	Market Share in 2019-20 (%)
1	Cipla Ltd.	24,012	12.1	Aurobindo Pharma Ltd.	1,32,665	10.32
2	Dr. Reddy's Laboratories Ltd.	16,380	8.3	Cipla Ltd.	1,26,867	9.87
3	Glaxosmithkline Pharmaceuticals Ltd.*	14,909	7.5	Sun Pharmaceutical Inds. Ltd.	1,25,361	9.75
4	Lupin Ltd.	12,186	6.1	Dr. Reddy's Laboratories Ltd.	1,18,504	9.22
5	Aurobindo Pharma Ltd.	11,618	5.9	Lupin Ltd.	1,10,252	8.58
6	Cadila Healthcare Ltd.	11,520	5.8	Alkem Laboratories Ltd.	68,620	5.34
7	Sun Pharmaceutical Inds. Ltd.	10,444	5.3	Cadila Healthcare Ltd.	63,292	4.92
8	Wockhardt Ltd.	8,816	4.4	Torrent Pharmaceuticals Ltd.	61,655	4.80
9	Sanofi India Ltd.*	7,936	4.0	Divi'S Laboratories Ltd.	53,106	4.13
10	Ipca Laboratories Ltd.	7,337	3.7	Ipca Laboratories Ltd.	43,843	3.41
11	Biocon Ltd.	6,884	3.5	Abbott India Ltd.*	40,934	3.18
12	Alkem Laboratories Ltd.	6,079	3.1	Glaxosmithkline PharmaceuticalsLtd.*	32,130	2.50
13	Torrent Pharmaceuticals Ltd.	5,403	2.7	Sanofi India Ltd.*	30,709	2.39
14	Abbott India Ltd.*	4,740	2.4	Nectar Lifesciences Ltd.	26,396	2.05
15	Unichem Laboratories Ltd.	4,220	2.1	Granules India Ltd.	23,099	1.80

Source: Authors' Calculations using Prowess database, accessed on 25 September, 2020.

The foreign firms gained significantly in market share in the late 2000s when some firms were takeover by them such as Ranbaxy by Daiichi Sankyo in 2008; Dabur Pharma by Fresenius Kabi Oncology in 2008; ShanthaBiotechs by Sanofi-Aventis in 2009; and Piramal Healthcare by Abbott in 2010 (Chaudhuri, 2013).[37] Further, it is important to note that when it comes to top 10 drug brands by sales in 2019, only three belonged to Indian firms.[38] Similarly, with respect to volume of sales in therapeutic segments, the MNCs had dominant market share in hormones (58.55 per cent), vaccines (56.26 per cent), and Parenterals (53.45 per cent) (Mehta 2017). While in Anti- Diabetic, Anti-parasitic and ophthal/ otologicals, foreign firms had 42.7 per cent, 34.53 per cent and 31.64 per cent share respectively.

f. Impact on Number of Patents

Under Article 27(1) of TRIPS Agreement, patents will have to be provided for inventions, which are 'new, involve and an inventive step and are capable of industrial application'. As the agreement does not define these terms, it provides some flexibility to member countries, especially developing countries. India has used these flexibilities efficiently, particularly in granting of secondary patents, patents that can be taken for new formulations, new combinations and new uses of existing New chemical entities (NCEs), through introducing a Section 3(d) in the Patents Act that stated that "salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy" and cannot be patented. For instance, the pharmaceutical company, Novartis, filed an application for a patent for Glivec (*imatinibmesylate*), a drug for Chronic Myeloid Leukaemia in India in 1997 under the then 'mailbox' provisions (Gabble & Kohler, 2014). However, in 2006, the Patent Office rejected the application under Section 3(d) of Patents Act on the ground that the drug was not innovative as it was an improved version of an existing drug, *Imatinib*. Novartis appealed against the decision up to Supreme Court of India where too, the verdict did not go in favour of the company. The Supreme Court stated that the drug had shown improvement only with respect to bioavailability but concerning efficacy, it had not exhibited any improvement, and, therefore, not patentable.

During the transition period (1995-2005), wherein, India introduced mailbox facility for accepting applications, the number of applications for product patent in pharmaceuticals saw significant jump, especially after 2002-03 (Figure 3.9). This significant rise in both the number of applications in drugs and number of patents granted continued even after the implementation of Patents (Amendment) Act, 2005. Between 1999 and 2004, majority of patent applications filed by top eleven pharmaceutical companies belonged to new or improved processes rather than product patents. The highest number of applications filed by Ranbaxy followed by GlaxoSmithKline (GSK), Dr Reddy's Laboratory (DRL), Cadila, Sun Pharma, Cipla, etc. (Bedi 2013). However, from 2005 to 2009, most of the applications pertained to product patents. After 2005, the sequence of patent filling by the pharmaceutical companies from top to bottom was GSK, Ranbaxy, Cadila, Abbott, DRL, etc. However, the number of applications for patents on drugs has been on the declining path after reaching its highest point in 2007-08. Similarly, the number of patents granted by India in drugs attained its climax point in 2008-09. But, after that it registered a significant decline until 2013-14 and, thereafter, it registered a continuous marginal improvement.

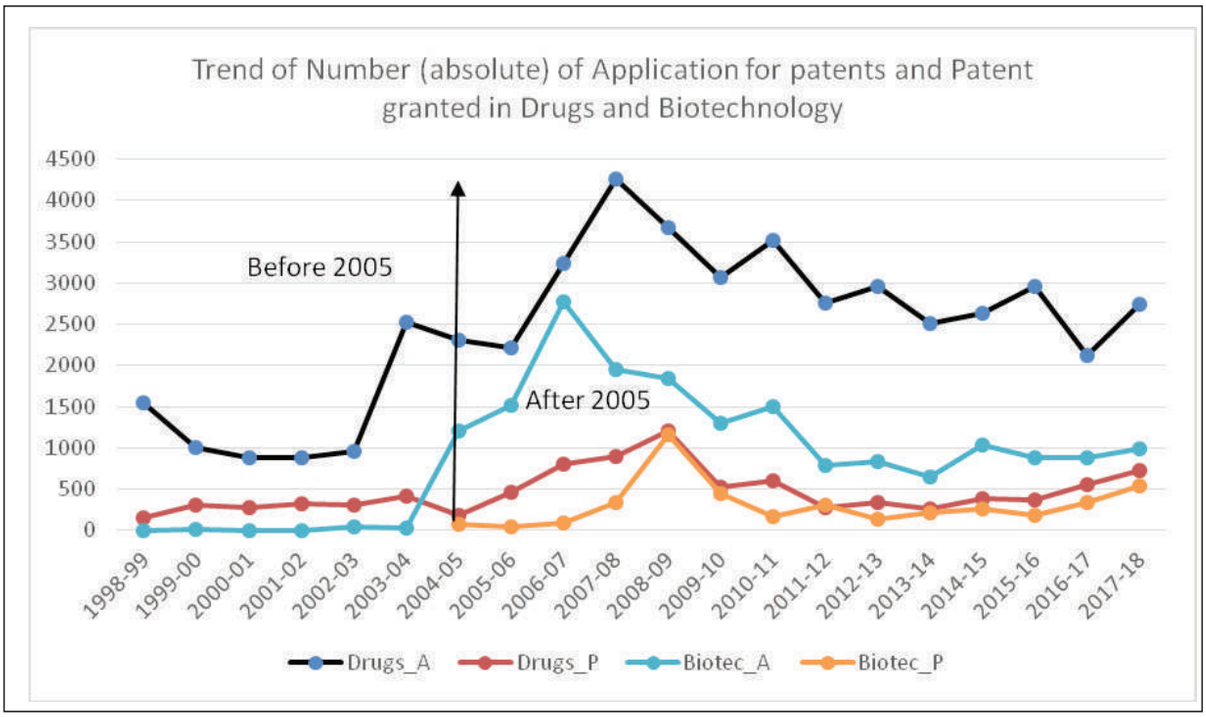
g. Impact on New Drug Discovery

Between 1994 and mid-2016, 28 major Indian pharmaceutical companies discovered 168 proprietary preclinical and clinical stage development compounds while 14 contract

research and biotech companies invented out 46 new compounds (Differding, 2017). Of these 214, however, only one compound, namely, ZydusCadila's saroglitazar, launched in 2013, has been entirely discovered and developed by an Indian company while the research is still (by mid- 2016) progressing on 83 compounds. Most of the major pharmaceutical companies have left or significantly reduced drug discovery activities after their R&D efforts didn't help them in realising the expected success. For instance, DRL and Piramal have almost quit activities related to new drug discovery whereas Zydus Cadila (from 13 in 2011 to 5 in 2016), Glenmark (from 8 in 2006 to 2 in 2016), and Sun (from 5 in 2012 to 3 in 2016) have significantly curtailed down activities in this area. Similarly, Dabur, Matrix, and Ranbaxy have quit the drug discovery after taken over by other companies. Only, Lupin Pharma is an exception to this, which commenced a range of new NCE projects after streamlining its R&D organization in 2010. On the other hand, Biotechnology and start-up companies have performed remarkably well in comparison to pharmaceutical companies, in terms of number, size and research output. For instance, the number of compounds from biotechnology companies increased from 2 per cent of the total pipeline in 2009 to 31 per cent in 2016 and even at preclinical stage, the number of compounds of bio-tech companies have increased from 4 per cent in 2008 to 71 per cent in 2016. It is worth noting that these new developed compounds of bio-tech companies are able to attract global partners, such as Rhizen Pharmaceuticals, Connexios, and Curadev.

Further, the Indian out-licensing model which resoundingly failed for pharmaceutical companies, in particular DRL, Ranbaxy and Glenmark, has actually worked for

Figure 3.9: Trend of Number (absolute) of Applications for Patents and Patents Granted in Drugs and Biotechnology



Source: http://www.ipindia.nic.in/, Compiled from various Annual reports.

Note: *_A* denotes for Applications and _P denotes of Patents granted.

biotech companies which have out-licensed 10 agreements since 2011, largely led by Aurigene. These bio-tech companies took advantage of existence of trained scientists which were having pertinent industrial experience; they also were able to bring out deftness in particular area through concentrating on specific disease as revealed by their licensing agreements.

All major Indian pharmaceutical companies, with notable discoveries of NCEs, made significant R&D expenditure, ranging from 5 to 10 per cent. But it is important to note that only very small proportion of this R&D expenditure (20-30 per cent) is spent on research related to NCEs (Differding, 2017 and Bedi *et al.*, 2013) and larger part of it is occupied by generics development, formulation and drug delivery technologies, or process R&D (Differding, 2017). The efficiency of R&D in pharmaceutical industry can be estimated using two parameters, namely, success rates[39] and time spent in development Phases (Table 3.6). The efficiency of the R&D expenditure of Indian pharmaceutical industry has remained significantly lower in comparison to industrial average with respect to both success rate and time spent across all the stages, except Phase 1. For instance, three major companies that almost abandoned drug discovery are DRL, Ranbaxy and Piramal with nine out of 11 compounds failing in Phase 2, and none completing successfully Phase 3 studies, where two out of two failed. These lower success rates are further aggravated by the increased time spent by phase, especially at the earlier stages.

There are various factors, which explain the trend of drug discovery development in India:

- *Skill gap*: There is no doubt that the Indian Patents Act of 1970 contributed significantly to the development of Indian pharmaceutical industry, particularly, generic manufacturing through permitting only process patent. It, thereby, on one hand made available good quality generic medicine affordable not only in India but also worldwide. On the other hand, it eliminated all the incentives to discover new drugs. As a result, level of research skill declined significantly because Western companies terminated their research departments and drug discovery-related disciplines, including medicinal chemistry, biology and pharmacology and things were further worsened by decline in the Indian science education system. Only with the efforts of the pioneer pharma companies these skills improved slowly and expedited with the rise of contract research companies. According to a 2014 survey[42], there is significant gap between industry requirement of the manpower and their academic training. The survey reported that about 66 per cent of the manpower is not as per requirements of the industry.

Table 3.6: Success rates[40] and timelines[41]

	Stage	Indian Companies	Industry Average
Success Rates (%)	Preclinical	50.3 (82/163)	63-69
	Phase 1	54.0 (34/63)	48-64
	Phase 2	17.4 (4/23)	29-34
	Phase 3	33.3 (1/3)	60-70
Timelines (years)	Preclinical	1.90	1.0
	Phase 1	2.50	1.5
	Phase 2	3.40	2.5
	Phase 3	3.00	2.5

Source: Reproduced from Differding, 2017, p. 806.

- There are some to internal issues, such as inadequate facilities and quality of teaching, bureaucracy and political influence. In addition to this, there is also deficiency of interactions between industry and academia or public research institutions, lack of interest among students for applied science, profound distrust or different priorities and key performance indicators in academia and industry, such as publications *versus* patents and commercialisation. Consequently, science is not being considered as an eye-catching career path and resulted in significant brain drain. For example, 40 per cent of India-born researchers were working in foreign countries in 2011.
- In Indian pharmaceutical industry, the R&D expenditure is significantly lower, particularly in NCE discovery in comparison to global industry average (Differding, 2017; Banerji & Suri, 2017 and Bedi *et al*., 2013). Likewise, the number of bio-tech companies are much lower in relation to US (1,700 biotech companies) (Differding, 2017).
- From smaller number of NCE compounds in the pipeline of major pharmaceutical companies in relation to earlier phase, and abandonment of new drug discovery projects by major pharmaceutical companies, and their small investment in R&D in this area compared to global industry average, it is emerging that new drug discovery is becoming less and less attractive among pharmaceutical companies in India. This low attractiveness towards new drug discovery is further aggravated by structural shortcomings present in this industry, such as much lesser awareness of "IP protection, regulatory uncertainty regarding clinical trials, unethical practices, or pricing uncertainties" (Differding, 2017). All these result in enhancement of barriers to new drug discovery, and should be properly handled at a policy level.

Endnotes

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4 According to First five year plan, Chapter 32, India had spentannuallymorethan Rs. 10 croresvalueof essential drugs and raw materials such as penicillin, streptomycin and other antibiotics, sulpha drugs, gland products, vitamins, anti-leprosy drugs and insecticide. Penicillin and streptomycin constituted nearly 35 per cent share in total value of imported drugs.

5 Fifth FYP: Chapter 5, note 75.

6 Concerning drugs prices "India was among the highest priced nations in the world" see SudipChaudhuri, The WTO and India's Pharmaceuticals Industry: Patent Protection, Trips, and Developing Countries (2005), pp. 132

7 The Patents Act, 1970 (39 of 1970). Universal Law Publishing Co. Pvt. Ltd., Delhi. Bare Act. 2006.

8 Ibid. Annexe.

9 The United Nations Industrial Development Organization (UNIDO) categorized India "as one of the most advanced amongst developing countries with respect to technological development (Mehrotra, 1989).

10 Ibid.

11 For instance, in 1998, the price of the Indian ranitidine, the active ingredient in Glaxo's Zantac antiulcer medicine, which was identical to Zantac, was over 100 times lower than the price in the U.S(Mueller, 2007).

12 Dr YK Hamied (2005), Indian Pharma Industry: Decades of Struggle and Achievements. http://www.arvindguptatoys.com/arvindgupta/avra-hamied.pdf

13 Belgium, France, Germany, Italy, Japan, Netherlands, Sweden, Switzerland, United Kingdom & United States.

14 Between 1956 and 1987, 13 new drugs (11 by Indian companies and 2 by foreign companies) were developed in India (Mehrotra, 1989).In the late 1990s, some new molecular discoveries were attained by the private sector firms, Ranbaxy and Dr. Reddy's (CRISIL, 2000 as cited in Dhar&Rao(2002).

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32 https://dipp.gov.in/sites/default/files/FDI_Factsheet_March20_28May_2020.pdf, accessed on 12, September, 2020.

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35 Patents are territorial rights and patents granted in other countries automatically do not apply to India.

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38 https://www.business-standard.com/article/companies/7-of-top-10-drug-brands-sold-in-india-are-from-multinational-companies-119102101293_1.html

39 Success rates by phase: the number of development compounds that advance to the next phase, divided by the number of compounds that entered the phase from which is subtracted the number of compounds of yet unknown fate (Differding, 2017)

40 Success rates are calculated using the information that the 214 compounds entered preclinical development, of which 82 progressed to Phase 1, 34 to Phase 2, and 4 to Phase 3, with 1 compound launched(Differding, 2017).

41 Due to very low number of drug candidates reaching Phase 3 and lack of accuracy in collecting timelines, author didn't find statistically significant values for all variables.

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IV
Industrial and Investment Policies

4.1 Introduction

As discussed earlier, economic policies of the government underwent a sweeping change in 1991. Its industrial policy was dictated till then more by the socialistic principles, with public sector remaining the mainstay of economic development; and many major industries were reserved for public sector only. The private sector, wherever allowed, was working under many restrictions. The regime was called derogatively as 'licence-permit raj' and the slow GDP growth rate of India came to be referred to as Hindu rate of growth. The whole economic policy was almost reversed in 1991 and that and other related polices affected pharmaceutical industry also like any other sector. This chapter explores that impact.

4.2 Changes in Industries (Development & Regulation) Act after 1990 and its impact on the Pharmaceutical industry

After Independence, the Government of India (GOI) had enacted its first Industries Development and Regulation Act (IDRA) 1951 to regulate the growth of industries listed in the First Schedule and D&Ps were one of them and listed at heading 22 of this Schedule (at p. 33). It is stated in the objectives of this Act that "it is expedient in the public interest that the Union should take under its control the industries specified in the First Schedule" (Department of Industrial Policy and Promotion) (DIPP), 1951 p. 4).

In the early 1990s, the government initiated a structural transformation in the Indian economy *via* a statement on industrial policy on July 24, 1991. This industrial policy statement made significant changes in the industrial policies pertaining to licensing, foreign investment, foreign technology agreements, public sector policy, and Monopolistic and Restrictive Trade Practice (MRTP) Act. The policy statement abrogated the provision of industrial licencing for all industries except those listed in Annex-II. The D&P industry was one of those listed industries that were kept under the purview of compulsory licensing and it would be regulated by the drug policy. Accordingly, the government brought about significant changes in the Drug Policy 1994 in line with the spirit and philosophy of the new industrial policy (examined in later section).

Before the introduction of the measures such as ratio parameter, fixed mandatory supply of a percentage of bulk drugs production to non-associated formulators, high technology bulk drugs to be produced by FERA MNCs, reservation of bulk drugs for public sector, etc., most of the MNCs were not undertaking

domestic production of bulk drugs from the basic stage and were involved in manufacturing of formulation from the penultimate stage, and, as a result, India became heavily dependent on imports of bulk drugs. The implementation of the aforesaid provisions resulted in a dramatic expansion of the domestic production of bulk drugs from basic stages which not only changed the status of India in this industry from a major importer to an exporter of low-cost bulk drugs but also contributed to the phenomenal growth of the formulation industry both at the domestic and global levels including in the highly regulated markets of Europe, United States, Japan and Australia. The Tenth Five-Year Plan (TFYP, 2002-07) report highlighted the achievements attained by the Indian pharmaceutical industry.

In 2000-01, the Indian drugs and pharmaceuticals had attained globally fourth rank as it accounted for 8 per cent of world production in terms of volume[1] and 1.5 per cent in terms of value. With respect to the export value of bulk actives and dosages, India achieved 17th rank globally. The domestic production of bulk drugs dramatically increased from Rs. 730 crore in 1990-91 to Rs. 4,533 crore in 2000-01 and production of dosage forms surged from Rs. 3,840 crore to over Rs. 15,000 crore during the same period.

After abolishing the aforementioned set of conditions in Drug Policy 1994, the government was only left with the provisions such as tariffs, negative list, etc. for keeping manufacturing from the basic stages and regulating regression towards manufacturing from the penultimate stage. As part of WTO rules, however, these available import controls had to be relaxed from time to time (TFYP). Consequently, according to TFYP report, imports of bulk drugs had kept on increasing and India was losing ground regularly in this industry. Further, TFYP report pointed out that this continuous downfall of the domestic bulk drug industry could not be protected through export-import policy and fiscal policy because of India's commitment towards relaxation of import controls in WTO.

Moreover, the contribution of the domestic bulk drug industry was further contracted because the public sector pharmaceutical units, that had contributed significantly in attaining momentous growth of the industry *via* establishing modern plants for the manufacture of bulk drugs at a reasonable cost, became sick to a certain extent owing to the government policy of allowing small formulators to take on a large part of the production, late revision of prices, and to some extent owing to the infrastructure and managerial problems (*ibid*).

By this time, China had emerged as a low-cost exporter of bulk drugs partly owing to relaxed environmental and pollution restrictions, cheaper electricity and partly owing to relatively late access to WTO membership (December 2001) which had given it ample time to develop its bulk drugs industry in the protected environment. From this, it cannot be denied that China's favourable policy measures and protected environment for its D&P industry, in comparison to India, led to growth of the industry there and contracting of Indian bulk drug industry, especially from basic stage.

4.3 FERA and FDI Policy

While formulating FDI policy, India had remained very watchful and selective in order to pursue its main strategy of 'import-substitution' to attain industrialisation. To become 'self-reliant', India adopted a dual FDI policy. In high technology and high priorities areas, India encouraged FDI *via* foreign collaboration to enhance capacity and capabilities of Indian industry while, in relation to low technology, it restrained the inflow of FDI to support and safeguard its industry. The GOI enacted Foreign Exchange Regulation Act (FERA), 1973 as a result of growing scarcity in the availability of foreign exchange and significant amount of foreign exchange remitted by MNCs

4.4 Special Economic Zones (SEZs) and Clusters

There is no doubt among the fraternity of economists that said rapid industrialisation is imperative for attaining economic growth and development (Aggarwal, 2011). It is also well established and acknowledged that industrialisation not only depends upon understanding of the drivers that propel this development but also on the implementation of well-designed policies to encourage these drivers. Since last few decades, one such policy instrument, that is turning out to be progressively prominent, particularly in developing countries, is the setting up of SEZs which is being considered as 'engines of industrialisation'. As per the estimates of ILO (2007),[2] the number of SEZs grew from barely 79 across 29 countries in 1975 to 3,500 across 130 countries in 2006.

The term Special Economic Zones (SEZs) encompasses a wide variety of clusters, such as Free Trade Zones (FTZs), Export Processing Zones (EPZs), Economic and Technological Development Zones (ETDZs) and High-tech Industrial Development Zones (HIDZs) (Mukherjee & Bhardwaj, 2016). Although these various zones can be defined differently but one salient feature of them is that their main objective is to encourage export for which they receive support from the government in terms of fiscal benefits, such as tax/duty reductions and subsidies and non-fiscal incentives, such as single-window clearances for setting up of units, government support in acquisition of contiguous land, training for employees and simplified procedures for custom clearances for certain period of time to attract domestic and foreign investment and global best management practices and technology. Further, it has been argued that productivity of the firms gets enhanced most when localised in an agglomeration from knowledge and information spill overs, labour pooling and backward and forward linkages by virtue of external economies of scale and increasing returns (Kamiike *et al*., 2012).

However, some of the fiscal incentives given to firms located in SEZs are prohibited under the World Trade Organization (WTO) Subsidies and Countervailing Measures (SCM) Agreement (Mukherjee & Bhardwaj, 2016). Consequently, the provision of fiscal incentives given to SEZs has been eliminated in developed countries while it is being encouraged in developing countries to attract private and foreign investment due to persistent fiscal constraints of the firms.

In 1965, Asia's first Export Processing Zone (EPZ) was built in Kandla, Gujarat.[3] After that seven more zones were developed but these zones would not be able to contribute much in encouraging exports due to 'multiplicity of controls and clearances, the absence of world-class infrastructure and an unstable fiscal regime'. These issues were corrected and new features were added while announcing SEZ policy in 2000. The success of China's policies in attaining considerable growth in exports *via* SEZs also influenced the new policy. The SEZ Act was notified on 23 June, 2005 and brought in force on 10 February, 2006. The main objectives of SEZs were generation of additional economic activity; promotion of exports of goods and services; promotion of investment from domestic and foreign sources; creation of employment opportunities; and development of infrastructure facilities.

In SEZ Act, 2005 major push was given to private sector participation in the development and promotion of SEZs *via* 'exemptions from taxes, duties and cess on goods and services exported out of, or imported into an SEZ, or procured from the DTA, exemptions from income tax for a certain time period, exemptions from minimum alternate tax (MAT) and dividend distribution tax (DDT), exemptions from central sales tax, and exemptions from services tax'(Mukherjee & Bhardwaj, 2016). As a result, the number of SEZs has

grown considerably and made contribution to exports, employment etc. For instance, Divi's Laboratories Limited, Andhra Pradesh, produced Rs 1967.51 crore worth of exports between 2007-08 and 2010-11, and provided employment to 1,434 persons.[4] During the same period, Serum Bio-Pharma Park, Maharashtra, manufactured Rs 1,959.97 crore worth of exports and employed 608 persons. Biocon Limited, Karnataka (Biotech SEZ) contributed to Rs 1,531.31 crore worth of exports during 2006-07 to 2010-11 and engaged 2,068 persons out of which 223 were women employees

The status of SEZs is as follows: number of operational SEZs was 240 as of 29 February 2020; 421 SEZs are granted formal approval; 354 are notified; and 33 are given in-principle approvals. In pharma sectors, total 15 SEZs are operational, 11 in pharmaceuticals and 4 in biotechnology (Table 4.1).

Highest number of SEZs was formally approved in IT/ITES/Electronic Hardware/ Semi-conductor/ Telecom equipment (276) while for pharmaceuticals/chemicals and biotechnology 17 and 23 SEZs have been approved respectively (Figure 4.1). Similarly, maximum number of SEZs is notified for IT/ ITES/Electronic Hardware/ Semi-conductor/ Telecom equipment (236) and the respective number of notified SEZs for pharmaceuticals/ chemicals and biotechnology are 17 and 16 (Figure 4.2).

In 2015-16, the Standing Committee on Chemicals and Fertilizers under the chairmanship of Shri Anandrao Adsul submitted its report on Cluster Development Programme for Pharma Sector (CDP-PS) with an objective to encouraging quality, productivity and innovation in pharmaceutical sector, especially for Small and Medium Enterprises (SMEs).[5] To attain it, Committee suggested setting up and advancement of 10 Pharma Growth Clusters under Public Private Partnership (PPP) model on which Rs. 125 Crore would be spent in various phases. Following were the main objectives of the CDP-PS:

- 'Increase the competitiveness, easy access to standard testing facilities and value addition in the domestic pharma industry especially to SMEs through creation of common world class facilities.
- Strengthening the existing infrastructure facilities in order to make Indian Pharma industry a global leader in pharma exports
- Reducing the cost of production by 20 per cent in the clusters leading to better availability and affordability medicines in domestic market.
- To help industry meet the requirements of standards of environment at a reduced cost through innovative methods of common waste management system.
- Exploit the benefits arising due to optimization of resources and economies of scale.
- To provide information of latest global developments in the sector related to regulations, IPR issues, new products, new markets etc.'

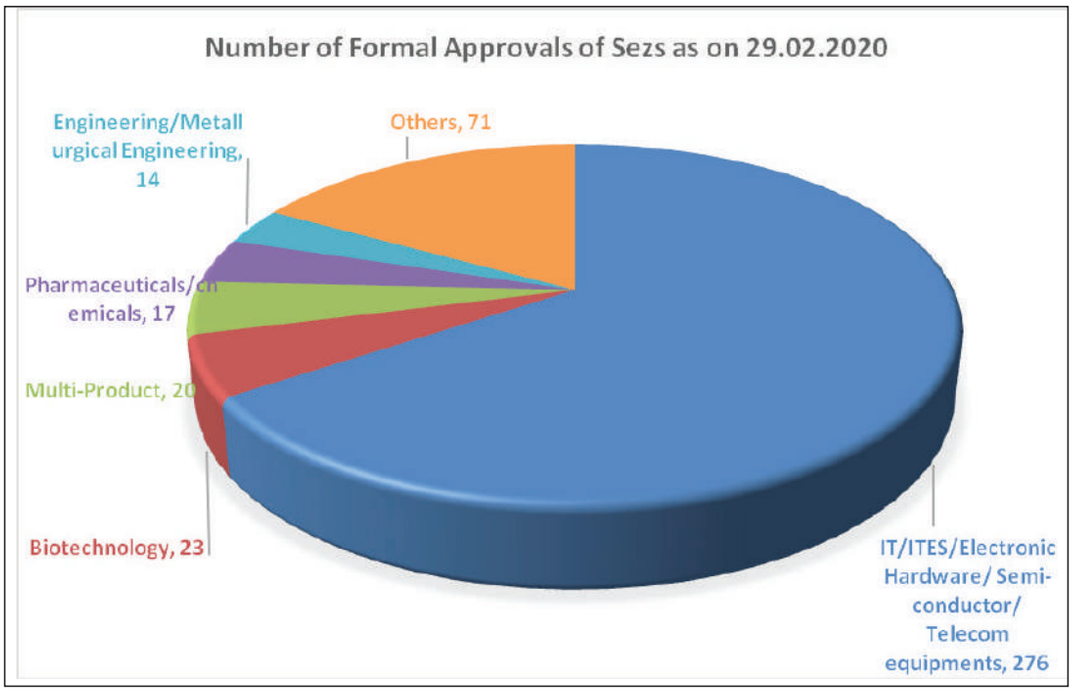
The government came up with a scheme costing Rs 460 crore on development of drugs and pharmaceutical industry in 2018. The main objective of this scheme was to reduce the cost of production of bulk drugs and medical devices *via* constructing of common facility centres and assisting SMEs in upgrading their technology[6]. There were five sub-schemes, namely, (a) For Bulk Drug Industry Rs 200 crore was allocated for setting-up Common Facility Centres which would include 'Effluent Treatment Plants, Captive Power Plants, Steam and Cooling Systems, Incubation Facilities, Common Logistic Facilities, Advance Common Testing Centre, Regulatory Awareness Facilitation Centre and Emergency Response Centre'; (b) for Medical Device Industry, Rs 100 crore was allocated of setting-up Common Facility Centre which would include 'Component Testing Centre,

Table 4.1: List of Operational SEZs in Pharmaceutical and Bio-Technology as on 20.02.2020

S. No.	SEZs	Place	Pharma/ Biotech
1	Divi's Laboratories Limited	Chippada Village, Visakhapatnam, Andhra Pradesh	Pharmaceuticals
2	Hetero Infrastructure Pvt. Ltd.	Nakkapalli Mandal, Visakhapatnam District, Andhra Pradesh	Pharmaceuticals
3	Ramky Pharma City (India) Pvt. Ltd.	E-Bonangi Villages, Parawada Mandal, Visakhapatnam District, Andhra Pradesh	Pharmaceuticals
4	Zydus Infrastructure Private Limited	Village - Matoda, Sari and ChachanvadiVasna on NH 8-A, Taluk - Sanand, District Ahmedabad, Gujarat	Pharmaceuticals
5	Karnataka Industrial Area Development Board (KIADB)	District Hassan, Karnataka	Pharmaceuticals
6	Maharashtra Industrial Development Corporation	Village Krushnoor, Taluka Naigaon, District Nanded, Maharashtra	Pharmaceuticals
7	Wockhardt BioPharma Limited (Formerly Wockhardt Infrastructure Development Limited)	Shendre Five Star Industrial Ares, Aurangabad District, Maharashtra	Pharmaceuticals
8	Sun Pharmaceutical Industries Ltd. (formerly Ranbaxy Laboratories Ltd.)	Plot No. A-41, Focal Point, Mohali, Punjab	Pharmaceuticals
9	Dr. Reddy's Laboratories Limited	Village Devunipalavalasa, Mandal Ranasthalam, District Srikakulam, Andhra Pradesh.	Pharmaceutical
10	Telangana State Industrial Infrastructural Corporation Ltd.(TSIIC) [Formerly Andhra Pradesh Industrial Infrastructural Corporation Ltd.(APIIC)]	Pollepally village, Jedcharla Mandal, Mahaboobnagar District, Telangana	Pharmaceuticals Formulation
11	Serum Bio-pharma Park	Pune, Maharashtra	Pharmaceuticals & Biotechnology
12	Biocon Limited.	Anekal Taluk, Banglore, Karnataka	Bio-technology
13	Frontier Lifeline Pvt. Ltd.	Edur Village, GummudipundiTaluk, Thiruvallur District, Tamil Nadu	Biotechnology
14	Telangana State Industrial Infrastructural Corporation Ltd.(TSIIC) [Formerly Andhra Pradesh Industrial Infrastructural Corporation Ltd.(APIIC)]	Genome Valley, Village Lalgadi Malakpet, Mandal Shameerpet, Ranga Reddy, Telangana	Biotechnology
15	Sanofi Healthcare India Pvt. Ltd. [formerly ShanthaBiotechnicsPvt. Ltd. (Formerly ShanthaBiotechnics Limited)]	Village Muppireddipally, Mandal Toopran, District Medak, Telangana	Biotech and related activities

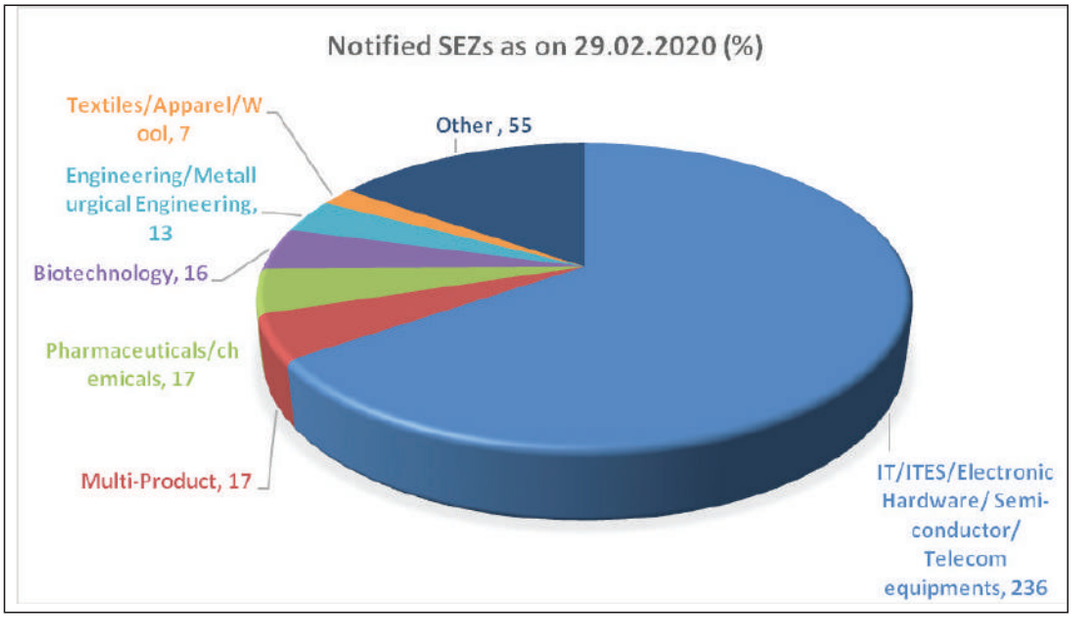
Source: www.sezindia.nic.in

Figure 4.1: Number of Formal approvals of SEZs as on 29.02.2020



Source: Authors' calculation using information available at www.sezindia.nic.in.

Figure 4.2: Notified SEZs as on 29.02.2020 (%)



Source: Authors' calculation using information available at www.sezindia.nic.in.

Electro-magnetic Interference Laboratory, Biomaterial / Biocompatibility Testing Centre, Medical Grade Low Vacuum Moulding, Cabinet Moulding Injection Moulding Centres, 2D designing and printing for medical grade products, Sterilization and Toxicity Testing Centre, and Radiation Testing Centre, etc'.; (c) Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) for assisting SMEs in upgrading their plant and machinery so that they become compliant with World Health Organization (WHO)/Good Manufacturing Practices (GMP) standards and enable them to participate and compete in global markets. For this scheme, Rs 144 crore was allocated; (d) Assistance for Cluster Development: under this scheme, earlier announced scheme in 2015-16, CDP-PS, was subsumed. Under the Scheme, financial assistance would be provided for creation of common facilities in any pharma clusters including Bulk Drug, Medical Device, Ayurvedic, Unani and Cosmetics Units; and (e) Pharmaceutical Promotion Development Scheme (PPDS): The scheme aims at the promotion, development and export promotion in Pharmaceutical sector by extending financial support for conducting seminars, conferences, exhibitions, mounting delegations to and from India for promotion of exports as well as investments, conducting studies/ consultancies, for facilitating growth, exports as well as critical issues affecting Pharma sector.".

In the wake of COVID-19, recently, in July 2020, the GOI has announced schemes for setting-up of two clusters, one for bulk drugs (Rs 3,000 crore)[7] and another for medical devices (Rs 3,420 crore).[8] In 2018-19, the share of bulk drugs in total pharmaceutical imports of India stayed at 63 per cent, according to the ministry. Further, it is worth pointing out that majority of bulk drugs are being imported from one country, namely, China. This enormous dependence on single country was highlighted by various reports and raised concern for the drug security of the country. So, this is exactly what has happened during COVID-19, which was predicted earlier.[9] Similarly, in medical devices, especially in high technology intensive ones, India is too much dependent on foreign countries. Therefore, in order to deal with similar situation in near future, government has announced schemes to raise the manufacturing of both, bulk drugs and medical devices; and to support the production of these, it announced establishment of clusters for them as well. Further, the provision of common infrastructure facilities would improve the competitiveness of bulk drug industry as well as medical devices through bringing down the manufacturing cost; it would assist the industry, particularly the bulk drug industry, in meeting the standards of environment through innovative methods of common waste management system; and would help both the industries in optimally utilizing the resources and economies of scale.

4.5. Contribution of Small and Medium Enterprises (SMEs) in Drugs and Pharmaceutical Industry

The SMEs are very crucial for drugs and pharmaceutical industry as they contribute 42 per cent of total pharmaceutical production, 62 per cent of total employment (Akhtar, 2014) and deliver life-saving drugs at affordable prices, especially in rural India (Iyer, 2008). However, these enterprises are highly fragmented and heterogeneous in relation to technological capability(Iyer, 2008). The majority of the firms are located in Maharashtra, Gujarat and Andhra Pradesh. Most of these firms produce anti-infective, anti-bacterial, nutritional supplements and anti-inflammatory drugs and some specialised drugs are manufactured by few medium scale firms. According to GOI (2012), there were 10,563 SME manufacturing units, containing 8,174 formulations and 2,389 bulk drugs (Niño-Amézquita *et al*., 2017). Further, it is noted that a bunch of high-tech SMEs are also involved in drug discovery and most of these are located in Bangalore region(Newton, 2007).

In order to raise the quality standards of the drugs manufactured by SMEs, GOI introduced Schedule M in 2001 by replacing local Good Manufacturing Practices (GMP) and deadline for adopting the same was extended to June 2005 (Iyer, 2008). However, most of the SMEs were finding it very difficult to upgrade quality standards in compliance with Schedule M of Drugs and Cosmetic Rules, 1945, as they are facing financial constraints. Further, for technical know-how, these pharmaceutical SMEs are too much dependent on their employed skilled chemists and common knowledge due to limited interaction with large domestic firms and R&D institutions. In addition to this, the major concerns of the pharmaceutical SMEs are: 'gradual reduction of list of drugs under DPCO; inability to generate investments for Schedule M requirements and automation, paucity of skilled labour; lack of consistency and standardisation in drug quality requirements; imitation not feasible (*sic*) under new patent regime; under-utilisation of plant capacity; and lack of adequate information about the new patent regime and its consequences' *(ibid*). Furthermore, the survival of the pharmaceutical SMEs in post-Patents Act, 2005, phase i.e. competitive era, has become difficult as most of these firms do not carry out R&D activity and those who undertake them, spend very meagre proportion of turnover on it (Bedi *et al*., 2013). In this regard Niño-Amézquita *et al* (2017) made very critical observation using regression analysis that the growth of the pharmaceutical SMEs are positively affected by exports, R&D expenditure, and past profits.

Endnotes

1 Chaudhuri (2005). P.51.

2 International Labor Organization (ILO) (2007). Export processing zones statistics, International Labor Organization, Geneva. Accessed on 6 October, 2020. https://www.ilo.org/public/libdoc/ilo/2007/107B09_80_engl.pdf

3 https://commerce.gov.in/publications/pdf/CHAPTER_5.pdf accessed on 9 October 2020.

4 https://commerce.gov.in/publications/pdf/CHAPTER_5.pdf accessed on 9 October 2020.

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6 https://pharmaceuticals.gov.in/sites/default/files/Scheme%20for%20Development%20of%20Pharmaceutical%20Industry_2.pdf

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V

Health and Drug Policies and Pharmaceutical Industry

5.1 Introduction

A third set of domestic and international policies that have great impact on manufacture and trade of drugs and pharmaceuticals is those relating to health and drugs. Health policies influence the market. When governments decide to extend health coverage of people or extend healthcare facilities to all, that is likely to increase the size of population who will require drugs and other pharmaceutical products. In the recent years, most governments have accepted universal health coverage as a goal to be achieved under Sustainable Development Goals. India is also moving towards that. How the health and drug policies in the past impacted the pharmaceutical industry in India is being examined in this chapter.

5.2 Drug and Pharmaceutical Policies and their Impact

5.2.1 Drug Policy, 1978

In line with the recommendations of the Hathi Committee, Government of India formulated its first drug policy in 1978. The main feature of this policy was that it outlined the roles to be played by public sector undertakings, private sector companies and foreign companies. Following are the set of broad objectives of the Drug Policy 1978 (Economic and Political Weekly [EPW], 1978):

- Achieving self-reliance in technology
- Attaining self-sufficiency in drugs
- Provision of adequate supply of quality drugs at reasonable prices
- Encourage the production, especially of bulk drugs,
- Promoting research
- Raise the standard of drugs through quality control

Under the Drug Policy, FERA companies were bound to produce high technology bulk drugs if they wanted to manufacture and sell formulations in India; otherwise, they had to reduce their equity share below 40 per cent. Further, FERA companies had to supply 50 per cent of the bulk drug production to non-associated formulators and, in addition to this, they had to maintain stipulated ratio of the value of bulk drugs consumed from own manufacture to the value of total formulation production which was set at 1:5 and corresponding ratio parameter for Indian pharmaceutical companies was fixed at 1:10. To encourage the production of bulk drugs from basic stage, the government provided incentive in the form of permitting a post-tax profit of 14 per cent on net worth (EPW, 1978). These policy measures encouraged the

development of indigenous technology for bulk drug production (Mehrotra, 1989).[1] With respect to technological capabilities, top 10 MNCs introduced technology for six bulk drugs during 1978 to 1982; four PSUs developed technology for 11 bulk drugs while top 10 Indian private companies introduced technology for only one bulk drug. During this time period, these top ten foreign sector companies had basic technology for 20 drugs and intermediate level technology for another 18 drugs; four PSUs had basic level technology for 39 drugs and top 10 Indian private companies had basic technology for 25 drugs. To encourage the research, the government provided incentive in terms of higher pre-tax return on sales turnover to those units which were involved in research (EPW, 1978). As a percentage of sales turnover, the R&D expenditure of Indian pharmaceutical companies increased from 1.4 per cent in 1978-79 to 2.2 per cent in 1983-84 (Mehrotra, 1989).

Consequently, under restrictive industrial policy environment Indian pharmaceutical industry flourished significantly and attained remarkable growth in manufacturing of both formulation and bulk drugs and led to steep decline in the formulation prices. The country has achieved self-sufficiency in formulations and also in a large number of bulk drugs (GOI, 1986).[2] In 1984-85, the imports of formulations were only about 0.5 per cent as a percentage of total formulations production while imports of 49 bulk drugs were insignificant. For numerous bulk drugs' production, technologies were indigenously developed including antibiotics like Ampicillin, Amoxicillin, Erythromycin, Anti-infectives like Sulphamethaxazole and Trimethoprim., anti-TB drugs like Ethambutol, Cardio Vascular drugs like Methyl Dopa; Analgesics like Ibuprofen and Isopropyl antipyrine; anti–amoebics like Metronidazole and Tinidazole, anti-cancer drugs like Vinblastine, Vincristire and Cisplatin. During that time, India was exporting diverse range of bulk drugs and formulations to many countries, including the U.S. and the West European countries and some Indian companies also established production facilities in foreign countries.

Although the production of the bulk drugs recorded significant growth after Drug Policy, 1978, it was quite lower in relation to target set to become self-reliant in production of bulk drugs (EPW, 1978). Also, the pattern of production was not in line with the requirements of the health care needs of the country (GOI, 1986). Another area of concern was expansion of formulations without adequate therapeutic rationale. In Drug Policy, 1978, the provision related to quality control on drugs continued to be kept under the charge of the Ministry of Health (MOH). However, without executive power to suspend or cancel the license of drug manufactures, provisions related to quality control on drugs were difficult to attain by the MOH (EPW, 1978). A large number of firms manufacturing formulations did not have requisite internal testing, quality control facilities and manufacturing practices (GOI, 1986). The 'institutional and statutory arrangements for enforcing quality control for registration of new formulations, for monitoring adverse reactions and for dissemination of unbiased information about the safety and efficacy of products marketed'[3]were not up to the mark.

5.2.2 Drug Policy 1986

The main objectives of the drug policy were "*ensuring abundant availability, at reasonable prices, of essential lifesaving and prophylactic medicines of good quality; strengthening the system of quality control over drug production and promoting the rational use of drugs in the country; creating an environment conducive to channelising new investment into the pharmaceutical industry, to encouraging cost-effective production with economic sizes and to introducing new technologies and new drugs, and strengthening the indigenous capability*

for production of drugs" GOI (1986). Four important policy thrust were on rational use of drugs, quality control, licensing and duty rationalisation. These are examined below:

- **Rational use of Drugs:** Only after the therapeutic efficacy and rationality of new formulations of the drugs, which were already approved, effectively, tested and proved, manufacturing would be permitted. The scrutiny over the registration of new drug would be enhanced through amendment of D&C Rules. Further, to make sure of proper dispensing and use of drugs, statutory guidelines for packaging would be suggested. In order to monitor adverse drug reactions, Central and peripheral units would be established. Setting up of a Central Information Bank for monitoring safety was also suggested. To enhance the coverage of health care schemes of the government, along with 'allopathic system of medicine', 'Ayurveda, Unani and Siddha systems of medicines' would be encouraged.
- **Quality Control:** To raise the standard of quality control, emphasis was given on 'Strengthening infrastructural facilities'; setting up of 'Internal Testing Facilities' by all manufactures; 'Good Manufacturing Practices'; discontinuing of 'Loan Licensing' system in phased manner; and certification scheme to encourage quality consciousness about drugs both among the manufacturers and user-agencies.
- **Licensing:** To attain the objective of better healthcare, FERA companies were allowed to manufacture 15 bulk drugs[4] and their related formulations under Phased Manufacturing Programme (PMP). However, the ratio parameter, value of production of bulk drugs to that of formulations, was reduced to 1:4. For others,[5] ratio parameter was set up in accordance with their value of ex-factory production of bulk drugs and formulations (Upto Rs.10 crore – 1:10, in excess of Rs. 10 crore and up to Rs. 25 crore – 1:7 and in excess of Rs. 25 crore – 1:5. The number bulk drugs reserved for PSUs was reduced from 17 to 15.[6] The two very important bulk drugs, namely, Penicillin and Polio Vaccines, were open to production for all sectors to attain self-sufficiency, as PSUs were not able to fulfil the domestic requirement of these two bulk drugs, which were being imported from other countries. Under the delicensing scheme, 94 bulk drugs including all anti-cancer drugs, all new bulk drugs developed through indigenous research, and related formulations were open to non-FERA and non-MRTP companies. To promote the 'cost-effective indigenisation' and to make sure that 'bulk drug production does not remain confined to processing of later intermediates only' PMP was introduced. To raise the manufacturing flexibility, 31 groups of bulk drugs[7] were brought under broad banding. To promote the production of bulk drugs, ratio of value of consumption of indigenously produced bulk drugs and that of imported bulk drugs was retained at 2:1. Similarly, the requirement of FERA and MRTP companies supplying 50 per cent of their bulk drug production to non-associated formulators remained while public sector companies had to supply 30 per cent of their bulk drug production to non-associated formulators.
- **Duty Rationalisation**: Under duty rationalisation, government brought down imports and excise duties in such a way so as to make sure that aggregated incidence of duty on bulk drugs was greater in comparison to that on the inputs and drug intermediates. This was done to promote cost efficient production of bulk drugs and high-quality formulation.
- As a result of aforementioned changes brought out in the Drug Policy, 1986, the situation of pharmaceutical industry improved significantly in relation to production of bulk drugs and formulation

and their respective exports (GOI, 1994).[8] The production of bulk drugs increased considerably from Rs. 240 crore in 1980-81 to Rs. 1,320 crore in 1993-94 and production of the formulations enlarged from Rs. 1,200 crore to Rs. 6,900 crore. The export performance of both bulk drugs and formulations were also noteworthy which resulted in trade surplus in D&P industry. Around 350 bulk drugs were having therapeutic value. Almost entire domestic demand for formulations was being fulfilled by domestic production during that time while, in relation to domestic demand for bulk drugs, about 70 per cent was satisfied by domestic production. It is worth mention here that small scale industries were contributing about 30 per cent of total production of bulk drugs.

5.2.3 Drug Policy 1994

Being the first drug policy in the liberalised era, the Policy proposed certain major changes in areas of licensing, investment, technology agreements, R&D, etc.

i. Licensing

- Licences' sanction by Drug Controller (India) for all bulk drugs and all their intermediates was abolished except in the case of
  - » Out of fifteen (in Drug Policy 1986), only five bulk drugs would continue to be reserved for public sector, namely, Vitamin BI, Vitamin B2, Folic Acid, Tetracycline and Oxytetracycline.
  - » Bulk drug production undertaken for the use of recombinant DNA technology
  - » Bulk drugs requiring *in-vivo* use of nucleic acids as the active principles.
- The binding conditions requiring a compulsory supply of 50 per cent of bulk drug production to non-associated formulators were abolished.
- For all formulations, also, the requirement of the licence was abolished except for specific cell/tissue targeted formulations.
- Ratio parameters relating to the production of bulk drugs to formulations were eliminated.
- Provisions related to broad banding, vocational restrictions and grant of COB licenses would be in line with the Industrial Policy.

ii. Restricting Bulk drugs Production to Basic Stage

- It was anticipated that policies related to liberalisation would result in regression of bulk drugs manufacturing from basic stage towards intermediate/penultimate stage. Therefore, to restrain this regression, use of tariff mechanism and also adding critical intermediates/penultimates to negative list was suggested.

iii. Foreign Investment

- FDI up to 51 per cent was allowed in all bulk drugs, their intermediates and formulations. However, in areas where inflow of the FDI has stopped, the government took the decision to raise the FDI above 51 per cent, on a case-by-case basis, mainly in the 'manufacture of bulk drugs from basic stage and their intermediates and bulk drugs produced by the use of recombinant DNA technology as well as the specific cell tissue targeted formulations'.

iv Foreign Technology Agreements

- Transfer of foreign technology agreements was permitted under automatic approval for all bulk drugs, their intermediates and formulations except those produced by the use of recombinant DNA technology.

v. Incentive to promote R&D Efforts

- A new drug invented through indigenous R&D would be kept outside the purview of price control for 10 years. In order to

galvanize the R&D efforts further, it was decided to set-up an inter-ministerial group and simplifying of the requisite *modus operandi* to prompt evaluation and clearance mechanism of new drug applications, especially those produced through indigenous R&D.

vi. National Drug Authority (NDA)

- It was proposed to establish a National Drug Authority (NDA), under the control of Ministry of Health and Family Welfare for quality control, rational use of drugs and related matters. It was also decided to impose a cess of 1 per cent on production of D&P to promote R&D and 'strengthening the drug control system'.

vii. Coordination Between various Ministries

- It was decided to set up a Coordination Committee under the chairmanship of Secretary (Chemicals and Petrochemicals) to assess key concerns every quarter and for undertaking timely and efficient action. Various Ministries/Departments, such as, Commerce, Revenue, Health, Biotechnology and Industrial Development and Bureau of Industrial Costs and Prices and National Pharmaceutical Pricing Authority were included in the Coordination Committee.

viii. AYUSH Department

- It was decided that a separate Department would be established to look after various prospects pertaining to encourage Ayurvedic, Unani, Siddha, Homeopathic and traditional systems of medicines.

As already stated, by 2000-01, the Indian D&P industry had made considerable progress. With respect to the export value of bulk actives and doses drugs, India achieved 17th rank world-wide. Further, Indian drugs and pharmaceutical industry came to be known all over as low-cost producer and supplier of formations and quality bulk drugs (GOI, 2002). The domestic production of bulk drugs dramatically increased from Rs. 730 crore in 1990-91 to Rs. 4,533 crore in 2000-01 and production of dosage forms surged from Rs. 3,840 crore to over Rs. 15,000 crore during the same period (TFYP, 2002-07). As a result, the domestic production fulfilled almost entire domestic demand for formulations and considerably for bulk drugs (GOI, 2002).

5.2.4 Pharmaceutical Policy 2002

As a result of liberalisation policy, globalisation of the world economy and implementation of obligations under TRIPS Agreement, Indian D&P industry was encountering new challenges (GOI, 2002).[9] In light of expected changes in patent law, the essential requirement at that time was to raise the incentives for R&D in pharmaceutical industry to make them more capable in attaining sustainable growth. In liberalised global economy, there was also requirement to lessen the stringency on price control in order to make D&P industry more competitive. To resolve these challenges, the government came up with Pharmaceutical Policy in 2002 under which following measures were taken:

- ***Industrial Licensing*:** For all the bulk drugs, their intermediaries and formulations industrial licensing was annulled except for 'bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids as the active principles, and specific cell/tissue targeted formulations'.
- ***Foreign Investment*:** For all the bulk drugs, their intermediaries and formulations FDI inflow up to 100 per cent was allowed under automatic route except for those mentioned in '(a) industrial licensing' above
- ***Foreign Technology Agreements*:** Transfer of foreign technology was permitted under automatic route for all bulk drugs, their intermediaries and formulations except for those mentioned in '(a) industrial licensing' above.
- ***Imports*:** Imports of drugs and pharmaceuticals were allowed in conformity

with EXIM policy. A centralized system of registration was to be setup under the Drugs and Cosmetics Act and Rules and Ministry of Health and Family Welfare was permitted to regulate imports of bulk drugs and formulations.

- ***Encouragement to Research and Development*:** Setting up of Pharmaceutical Research and Development Support Fund (PRDSF) and Drug Development Promotion Board (DDPB) under the administrative control of the Department of Science and Technology was approved. To promote R&D, government also made provisions for fiscal incentives. In 1999, the government had setup Pharmaceutical Research and Development Committee (PRDC) under the Chairmanship of Director General of CSIR to identify requirement of the support of pharmaceutical industry in relation to R&D and to raise their capabilities in R&D. According to PRDC a company could get qualified as R&D intensive company if it make an investment of 'at least 5 per cent of its turnover per annum in R&D; make investment of at least Rs. 10 crore per annum in innovative research including new drug development, new delivery systems, etc. in India; employ at least 100 research scientists in R&D in India: granted at least 10 patents for research done in India; and own and operate manufacturing facilities in India'.
- ***Quality Aspects*:** The government decided to establish 'a world class Central Drug Standard Control Organisation (CDSCO) by modernising, restructuring and reforming the existing system' to attain 'high standards of quality, safety and efficacy of drugs and pharmaceuticals. Further, the government was determined to improve gradually the quality of the drugs in conformity with international standards with respect to the regulatory standards, standards for clinical testing, simplifying steps and procedures for prompt assessment and clearance of new drug applications.
- ***Pharma Education and Training*:** To attain eminence in pharmaceutical sciences and technologies, education and training and to address the problems relating to human resources development as per requirement of both academia and industry, the government established National Institute of Pharmaceutical Education and Research (NIPER). Further, it was expected from the NIPER that it would strive to collaborate with industry and other technical institutes in the area of drug discovery and pharma technology development.

There is no doubt that Indian pharmaceutical industry has attained great heights not only in domestic economy but also in world economy as it is known for supplying high quality drugs at very cost competitive prices and recognised as 'pharmacy of the world' (GOI, 2017).[10] This is mainly driven by exports as about 52 per cent of total turnover of the industry was exported in 2015-16.

In the recent times, however, the D&P industry has been encountering a number of challenges, such as, falling compound annual growth rate (CAGR) (from 14.36 per cent in 2010-11 to 8.68 per cent in 2014-15); non-compliance with quality standards and norms[11]; time consuming registration process for new drugs (average time taken 2 years); facing increasing competition from foreign countries, especially from neighbouring countries like Vietnam, Korea, Sri Lanka and Bangladesh; weakening of comparative advantage due to mergers and acquisitions; depending significantly on one or two countries for its imports of APIs and Key Starting Materials (more than 60 per cent of APIs are sourced from other countries and in some specific APIs the dependence is 80 to 90 per cent);[12] insufficiency of R&D expenditure; and significant reduction in number of discovery of new molecules. Further, with respect to provision related to price control in the pharmaceutical policy (2002), the Supreme Court instructed the government to develop a criterion in such a way so that essential and

life-saving drugs do not fall outside the purview of price control (GOI, 2017).

5.2.5 Draft Pharmaceutical Policy 2017

In view of the aforementioned host of issues encountered by the D&P industry the government proposed a new draft Pharmaceutical Policy in 2017 with the objective of facilitating maintenance of its global competitive edge in prices of the formulations by India and augmenting quality standards. This draft contained the following policy prescriptions:

- In order to boost the domestic manufacturing of APIs and their precursor intermediates, government should largely procure those formulations which are manufactured using indigenously produced APIs and Intermediates. Also, these formulations should not be brought under price control for 5 years. Maximum tariff should be imposed on the imports of those APIs, which are being produced or can be produced domestically. The GOI should support the pharmaceutical industry in setting-up of mega bulk drug parks through public-private partnerships which would have common facilities for pollution control, effluent treatment, etc.
- For raising quality control standards, the government would make Bio-availability and Bio-equivalence Tests (BA/BE Tests) compulsory for drug manufacturing companies. For small scale industries (SSI), aforesaid compulsion should be made phase-wise so that their growth is not adversely affected. The government would make sure that all pharmaceutical manufacturing companies adhere to WHO's Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP). To attain this, both central and state governments should carry out procurement of drugs only from manufacturing units that fulfil minimum standards of WHO's GMP and GLP. On SSIs, however, government would impose this criterion phase-wise and they would be provided incentives to upgrade.
- The GOI would shorten and standardise the new drug approval process.
- The government would stimulate innovation in pharmaceuticals along with generic drugs. However, real innovation gets disrupt when generic drugs assigned with brands names, hence, these practices would not be permitted.
- The 'loan licensing' would not be continued except in biopharmaceuticals[13]. Similarly, the practice of P2P (product to product) manufacturing by which one manufacturer manufactures one pharmacopeial drug in multiple brand names and gives them to other manufacturers to market them at price chosen by the marketers, will be phased out. This will be achieved by following a principle of 'one manufacturer, one salt, one brand name and one price'
- The validated FDI in Brownfield would be subject to continuance if company, in which FDI inflows, manufactures NLEM drugs, carry out expenditure on R&D and transfer of technology. A mechanism would be placed by the government to keep an eye on post-acquisition activities of the company.
- To promote R&D, the GOI would permit the pharmaceutical companies to import goods and services required for R&D at concessional rate of customs duty of 0 to 5 per cent.

However, the Draft Pharmaceutical Policy, 2017 seems not to have been converted into a final policy possibly because of criticisms.[14] The draft suggested restraining the role of National Pharmaceutical Pricing Authority in relation to fixing the price of the drugs. Additionally, the DPCO amendment did not bring orphan drugs[15], like Myozyme and Fabrazyme, under the purview of price control, and the reason cited for the same in the draft was that it would upset the indigenous or generic production

of these. However, it may be pointed out that presently accessibility of these drugs is difficult as they are imported at exorbitant prices. The draft was, further, criticised for not bringing patented drugs under the purview of price control because some patented drugs are very vital, such as drugs used for cancer treatment, and so, would significantly raise cost of medicines.

5.3 Drug Price Control Orders (1970-2013) and their Impact on Pharmaceutical Industry

There was no statutory price control order existing prior to the year 1962. The prices of essential medicines soared badly during the Chinese aggression in 1962. As a result of which, government passed the Drugs (Display of Prices) Order 1962 and Drugs (Control of Prices) Order,1963 under the Defence of India Act. This order froze the prices of medicines from the 1 April, 1963. As a result, the pharmaceutical industry became critical mainly on two accounts: Firstly, the prices of raw materials used as inputs in medicines were not frozen. Secondly, the blanket freeze put on prices of medicines had adverse impact on the growth of small and marginal pharmaceutical companies. Government, therefore, introduced a system of selective increase of prices in 1966 and further, 17 essential drugs were refereed to Tariff Commission for investigating their cost structure and prices. Drug Price Control Order 1966 made it obligatory for the manufacturer of the medicines to take prior approval of the government if prices of these drugs are to be increased as on June 30, 1966. Through the amendment in 1968, the government exempted certain items from price approval, i.e. the items with pharmacopoeia properties were exempted from price approval and also, the new drugs that came into market as a result of indigenous research and marketed for the first time were also exempted from price approval. The manufacturers of these could fix the prices after submission of necessary data. The government in this case could fix/revise the prices within four months' time but no necessary guidelines were issued in this respect and also, the collection of large data during short period of four months was difficult. Thus, the manufacturers were free to fix the price of new drugs as there was no price control on them. In this regard, the MNCs producing new drugs stood in a favourable position whereas Indian firms which mainly introduce new processes for drugs could not gain much.

The DPCO-1970 resulted in general decline in profitability on sales. The Indian companies with no foreign equity participation found more decline in their profitability compared to the companies with foreign equity participation. The reason being that the companies with foreign equity participation were old and better organised. Even after the promulgation of the DPCO-1970, they had product range that had wide market acceptability and attractive profitability, whereas Indian companies which were latecomers in this field had to incur relatively more losses.

The profitability after tax measured, as return on capital employed did not decline. The manufacturers could suffer decline in terms of their profitability after tax due to sharp rise in manufacturing costs in 1972-73 (as the oil crisis in 1973 resulted in spiralling up of world prices and also high inflation rate of domestic economy). But the manufacturers were able to offset their decline in profitability by the rise in volume of sales of formulations during this period. The sales of companies with more than 50 per cent foreign equity increased by 69.2 per cent during this period whereas the sales of Indian companies could increase by only 32.9 per cent only. (Hathi Committee Report, 1976, chapter 8, page 178.)

Liberalisation of industrial licensing policies in 1966 also worked in favour of MNCs as these companies could now introduce new

drugs without an industrial licence. As a result, MNCs introduced 186 formulations in Indian pharmaceutical market during the period 1966 to 1972. Since the new drugs remained out of the purview of the price control, MNCs charged high prices for these formulations and continued to fetch more than 150 per cent mark up. (*Ibid.* page 177.)

The gross profit (profit before tax) on sales was allowed at 15 per cent on formulations. Profits earned in excess of this will not be used as dividends. These excess profits (with the prior approval of the government) will be used for R&D, adjustments against future profits or losses and other purposes specified by the government from time to time. On the other hand, the return on bulk drugs was calculated at 15 per cent on capital employed. The ratio of turnover to capital employed was 2.6:1 for formulations whereas it was 1:1 for the bulk drugs. This made the production of formulations more attractive compared to bulk drugs in DPCO-1970**.**

The uniform mark-up of 75 per cent was recommended in general scheme in DPCO-1970, but still significant price differentials continued to exist between MNCs and indigenous firms. The uniform mark-up of 75 per cent could lead to uniform prices among MNCs and indigenous firms, only if the standard process was followed for the calculation of material, packing and conversion costs. This did not happen as the formulations are made from bulk drugs and pharmaceutical aids. However, pharmaceutical aids used for producing formulations were out of the purview of DPCO-1970 and the prices paid by the manufacturers for the purchase of bulk drugs vary depending on the source of destination. MNCs by claiming the higher input costs got away with the higher prices. Thus, the MNCs like Glaxo, Pfizer, Merck Sharp and Dohme continued to charge their own higher prices violating the guidelines of DPCO and got stay orders from high courts (Chaudhuri 2005. Chapter 8). There was no provision in DPCO-1970 to tackle the higher prices charged by MNCs based on inflated costs and resultantly the MNCs continued charging higher prices for the products.

Under Drug Price Control Order-1979 (DPCO-1979), price-control was administered on 370 bulk drugs and formulations on 31 March 1979. These formulations covered around 80 per cent of the formulations in value terms, thus administering the price-control on the substantial part of the pharmaceutical industry. Based on the recommendation of Hathi Committee, the bulk drugs were classified into three categories based on their therapeutic properties and the three categories of formulations made from this, were each assigned different level of mark-ups mentioned below:

- 40 per cent mark-up for the most essential categories defined in the Category I of the third schedule of DPCO-1979;
- 55 per cent for the second most essential categories defined in the Category I of the third schedule of DPCO-1979; and
- 100 per cent for the third/last most essential categories defined in the Category I of the third schedule of DPCO-1979.

The DPCO-1979 order though took adequate steps to provide encouragement for bulk drugs production by establishing retention price and selling price for the bulk drugs. But despite providing adequate provisions, it could not create much positive environment due to general fall in profitability of companies at that time.

Though DPCO-1979 exempted the bulk drugs produced from original research from price controls, it could not encourage that high level of R&D in Indian pharmaceutical industry.

Overall, the aforementioned policy mechanism existing at that time thus failed to provide adequate encouragement to the MNCs as well as to the Indian companies due to low level of profitability levels experienced by these companies. This further hindered their spirit

to further capital investment in the economy as well their research and development expenditure. Production levels were also lower during this phase. This *not so encouraging* environment at that time pointed towards the needs to free the pharmaceutical industry from rigid price controls and move towards significant reduction in the price control.

The DPCO-1987 reduced the price control substantially from 347 drugs to 166 drugs. The categories for price controls were reduced from three (DPCO-1979) to two (DPCO-1987). The mark-ups were now changed to Maximum Allowable Post-Manufacturing Expenses (MAPE). The DPCO-1987 included 27 bulk drugs in Category-I and 139 bulk drugs in category-II. The price-controls have been substantially reduced from DPCO-1979 (370 bulk drugs and formulations, i.e. 80 per cent of the formulation market) to DPCO-1987 (166 bulk drugs and formulations, i.e. 60 per cent of the formulation market). Contrary to what Indian private industry along with MNCs propagated that the profits declined due to price controls the Table 5.1 below gives a completely different picture of rising prices during 1980-1995.

The Government of India appointed a standing committee in the Ministry of Chemicals and Fertilizers in 1990 for review of Drug Policy 1986 and DPCO-1987 (Ghosh. 2019). Consequent upon the recommendations of the Standing Committee, Government came with the revised Drug Control Order in 1995 (DPCO-1995). The salient features of this Order are the following:

- It reduced the number of drugs under price control. The bulk drugs were chosen on the basis of following criterion:
  - » A bulk drug with turnover of 40 million or more, provided that the number of bulk drug producers is less than five and the number of formulators using the bulk drug is less than 10. The market leader in the retail sale of the formulations has a share more than 40 per cent.
  - » A bulk drug with turnover of less than 40 million but more than 10 million. The market leader in the retail sale of the formulations using these bulk drugs has a share of more than 90 per cent.
- The DPCO-1995 created space for relatively more profits and more rate of return for pharmaceutical companies compared to previous price control orders.
- It provided for a post-tax return of 14 per cent on net worth or a return of 22 per cent on capital employed or in respect of new plant an internal rate of return of 12 per cent based on long-term marginal costing.
- If the production is from the basic stage, then the government will provide post-tax return of 18 per cent on net worth or a return of 26 per cent on capital employed.

The DPCO-1995 influenced the pharmaceutical industry in the following way:

- *Impact on Trade:* As exports were out of the purview of the DPCO-1995, so the manufacturers despite substantial reduction in price-control were still more inclined towards targeting foreign markets rather than catering to domestic market health requirements. The price control came as an opportunity for the companies to move towards those areas which are decontrolled to avoid the ceiling prices and provisions of DPCO-1995.This tendency to move to decontrolled areas is well-evident from the fact that some of the companies had very high percentage of exports as a percentage of sales, such as Strides Arcolab (93.7 per cent), Divi's Laboratories (89.3 per cent), Orchid Chemicals and Pharmaceuticals (82.5 per cent), Matrix Laboratories (70.6 per cent), Shashun Chemicals and Drugs (69.6 per cent), Ranbaxy (65.6 per cent), Dr. Reddy's (60.1 per cent).

Table 5.1: Prices of Pharmaceutical Products (Disaggregated Level) from 1980 to 1995

Alimentary System				
Ant-diarrhoeal				
Product	Pack	1980 prices (Rs)	1995 prices (Rs)	Percentage Rise
Salazopyrin 0.5mg	50T	29.39	255.00	767.64
Thalazole	10T	1.32	8.90	574.24
Antacids				
Disogel	175ml	5.40	18.55	243.52
Gelusil	170ml	6.10	13.19	117.87
Gastro-intestinal Sedatives				
Dimol	10T	1.16	5.00	331.03
Epidosin	20T	4 .16	19.06	358.17
Cardiovascular System				
Anti-congulants				
Acitrom 1mg	10T	1.45	22.00	1417.24
4mg	10T	1.83	45.00	2359.02
Unifarwin	25T	1.87	13.25	608.56
Antihypertensives				
Emdopa	10T	6.15	30.49	395.77
Melpoda	10T	6.37	24.14	278.96
Cardiac Disorders				
Paed elixir	30ml	2.69	18.27	579.18
Mephentine	20T	6.02	25.50	323.50
Netcardine	20T	10.63	37.32	251.08
Infections				
Antibiotics				
Bistrepen	vial	1.12	8.98	701.79
	5 doses	4.90	24.44	398.78
Erythrocin 100mg	10T	4.65	13.48	189.89
250mg	10T	10.69	33.10	209.64
Penidure LA6	Vial	2.17	7.00	222.58
LA12	Vial	3.80	11.82	211.05
LA24	Vial	6.70	19.94	197.61
Antituberculours				
Strepto-erbazide	Vial	22.46	5.96	142.28
Reduced (3)		244.28	147.48	

Table 5.1 continued...

Table 5.1 continued...

Antileprotics				
Hansipran 100	100T	184.50	180.00	reduced
Hormone				
Thyroid and antithyroid drugs				
Eltroxin	100T	2.74	20.40	644.53
Neo Mercazole	100T	15.97	73.24	358.61
Proloid	50T	8.14	76.00	833.66
Gonadal Hormones				
Aquaviron	1ml	1.48	14.75	896.62
Lynoral 0.01	20T	1.05	18.70	1680.95
Mixogen	20T	3.55	27.60	677.46

Source: Wishvas Rane (1996).

- I*mpact on Production:* The companies started shifting their focus from low profitability manufacturing activities towards high productivity or discontinuing production of some brands. For example, the *Diabinese* brand of chlorpropamide was withdrawn from the market (the production is closed as these are unprofitable). Other instance is where price-controlled drugs are replaced by decontrolled ones; for example, ibuprofen (Brufen 200mg for 10 tablets) which was price-controlled was replaced by its close-substitute Nimesulide (Nise, 100mg) which is not under price-control and sold at Rs.23.68 for 10 tablets. (Chaudhuri, 2005. Chapter 8. Pages 294-295).
- *Change the composition of the product in order to avoid DPCO-1995 provisions*: Para-9deals with the power to fix the ceiling price of scheduled drugs keeping in view the cost or efficiency or both and such price shall operate as the ceiling sale price of all such packs. This provides for applying the provisions of DPCO-1995 to standardized packs of formulations only. The manufacturers, therefore, resorted to changing the composition of the product to avoid the provisions of DPCO-1995. The manufacturers changed the product composition of Ibuprofen-Paracetamol tablets by adding 25 mg caffeine per tablet and sold ten tablets at rate of Rs. 12.94 per strip against the notified price of Rs.5.24 (thus charging Rs.7.70 extra per strip just by adding only 25 mg caffeine per tablet, the mere addition of which cannot increase the price by this large magnitude). Some other instances of change of product composition also include Corex- a brand of Pfizer - which used bulk drug ephedrine (price-controlled), the company reformulated the formulation without ephedrine, Ultragin (replacing Analgin and using Paracetamol in the production) and Disprin (replacing aspirin and using paracetamol). (*Ibid.* pp. 296-297).
- *Misuse of the exemption of small-scale units under para-25*: The government under DPCO-1995 has the power to exempt the small-scale units from provisions of the price order. Thus, many manufacturers started selling at a higher price while posing as small-scale industrialists. Johnson and Johnson was selling Rericap (a vitamin formulation for expectant mothers) at a price higher than that fixed by NPPA, which led to intervention by Delhi High Court. Later, the company posed as a small-scale industry under the name-NR Jet Enterprises for selling the drug at higher price. The CBI

investigation found that the Jet Enterprises was run by Johnson and Johnson in order to avoid the ceiling prices and provisions of DPCO-1995. (Chaudhuri, 2005. P. 298)

- *Impact on Prices*: The impact of DPCO-1995 on the prices of pharmaceutical products is mixed as some studies have reported high rise in the price of pharmaceutical products from 1995 to 2003 (Rane, W. 1996). However, the prices of medicine are not considered to be higher by NPPA, given the high inflation of economy during the same period. The findings of Chaudhuri (2005) also point towards differential response of controlled and decontrolled drugs, where the price of decontrolled drugs rose more sharply in comparison to the controlled ones during the period from 1995-2003.

The **Drug Price Control Order, 2013 (DPCO-2013**) was promulgated on 15 May, 2013 by the Ministry of Chemicals and Fertilizers. The formulations in Schedule-I of DPCO-2013 have been taken from 'National List of Essential Medicines (NLEM revised in 2015). NPPA is authorized to fix the ceiling price of the formulations (Schedule-I of DPCO-2013) using the *market-based approach* adopted in 2013. The ceiling price of scheduled formulation is determined by first working out the simple average of price to retailer (PTR) in respect of all branded-generic and generic versions of that particular formulations having a market share of one per cent and above and then adding the notional retailer margin of 16 per cent to it. The maximum retail price for that drug formulation should not exceed the notified-ceiling price plus applicable taxes. NPPA has fixed the ceiling price of 860 formulations under DPCO, 2013 till December, 2019. The details of reduction in ceiling prices of the scheduled formulations effected under DPCO-2013 compared to the highest price prevailing before the announcement of the DPCO-2013 is presented in Table 5.2 below.

Keeping in view the major objective of providing essential medicines at affordable prices to the masses, the government has invoked the provisions of para-19 of DPCO-2013- Fixation of ceiling prices under certain circumstances - broadly in three main areas listed below.

(i) *Coronary Stents*: Government included coronary stents in Schedule-I of DPCO-2013 in December, 2016. Then, the government notified

Table 5.2: Reduction in Ceiling price of Scheduled Formulations with respect to the highest price prevailing prior to the announcement of DPCO-2013

Percentage reduction w.r.t to the Max Price	Number of Formulations
0<=5%	236
5<=10%	138
10<=15%	98
15<=20%	100
20<=25%	92
25<=30%	65
30<=35%	46
35<=40%	26
Above 40%	59
Total Formulations in NLEM 2015	860

Source: NPPA, Department of Pharmaceuticals, Annual Report, 2019-2020.

the ceiling price (on 13 February, 2017) of these coronary stents for one year, the price of which was further re-fixed (on 13 February, 2018) for another one year. The fixation of ceiling price resulted in saving of Rs.4,547 crore annually. The fixation of ceiling prices of cardiac stents in the post price capping period (Ceiling prices w.e.f. 1-4-2017) has led to 26 per cent rise in the sales of cardiac stents in Indian market. The price capping has benefitted the indigenous manufacturers as their share in the production has increased by 10 per cent in the post price-capping period (i.e., from 1 February, 2017 onwards).

(ii) *Orthopaedic Knee Implant for Knee replacement System: Government* has fixed the ceiling prices of non-scheduled Orthopaedic Knees implants in August, 2017 which was extended till August, 2018 and then again for another one year till August, 2019. Revisiting the ceiling prices in August 2019, the government has ordered the rise in MRP of Knee Implant up to 10 per cent of the previous MRP. This led to saving of Rs.1,500 crore annually to the patients.

(iii) *Price revision of anti-cancer drugs on the basis of Trade Margin Rationalisation:* NPPA has also capped the trade margin of all non-scheduled formulations of 42 anti-cancer drugs under the Trade Rationalisation Approach. The decision for capping the trade margin was also taken by applying the provisions of para-19 of DPCO-2013, as a result of which 526 brands have registered reduction in the MRP.

The above aforementioned three cases of fixing ceiling prices were taken keeping in view the broader objective of providing essential medicines at affordable prices to the masses. Consequent on representations from the companies for the upward revision of the formulations on account of increase in API cost, increase in cost of production, exchange rate due to which the manufacturers are unable to go for feasible production and marketing of goods, etc., ceiling prices of 21 formulations were revised by allowing one-time price rise of 50 per cent from the present ceiling price in public interest. The formulations whose price are recently upwardly revised are BCG vaccine, Benzathine benzyl penicillin (powder for injection 12 lakh units and 6 lakh units), chloroquine 150 mg, dapsone 100 mg, Furosemide (tab 40 mg and injection 10 mg/ml), metronidazole (oral liquid 200mg and tab 200 mg and 400 mg), Ascorbic acid Vitamin C (500 mg), Co-trimoxazole+trimethoprim (Tab 400 mg, 800 mg and oral liquid 800mg(A)+160 mg(B), Pheniramine [injection 22.75 mg/ml(10ml), (2ml) and Drops (1%)], and Clofazimine (capsule 50 mg and 100 mg).

However, overall, DPCO-2013 has not resulted in keeping the prices of medicines low and patients are buying the medicines at much higher prices than what is being recommended in the DPCO-list from time to time, inter-brand price variation still exist at large scale in pharmaceutical industry and sales volume of the firms has reduced sharply due to decline in profitability of the firms (Sahay, A. and Jaikumar, 2016).

The broad impact of DPCO-2013 on pharmaceutical industry is as follows:

- *Higher Prices than the ceiling price of DPCO List are charged:* Kumar and Kumar (2019) shows this in case of hypertensive drugs by examining the prices of 30 formulations of 16 drugs (all covered in DPCO List of essential medicines). The study exhibited that out of 1,365 brands available for these hypertensive drugs, 831 brands (60.8 per cent) were charging price less than what is recommended in DPCO list-2017 whereas 534 (39.12 per cent) were charging more than recommended. It is found that around 50 per cent brands of 8 formulations, i.e., Spironolactone 25 mg, Sodium NitroprussideIng 1mg/ml, Telmisartan 20 mg, 40 mg and 80 mg, Methyldopa 250 mg, Metroprolol SR tab 25 mg and 50 mg, were selling at prices higher than the recommended ones. Similar findings in

case of antihypertensive drugs have been reported by Shah, Singh and Vacchani (2019) also which showed that maximum price variation exists in the case of Aspirin 100 mg where all 3 brands selling aspirin are charging higher prices than recommended in DPCO-2013, followed by Paracetamol where out of 19 brands, 12 brands are selling at higher than ceiling prices. The others covered are Metformin 500 mg (11 out of 25 brands), Losartan 25 mg (8 out of 32 brands) and Atorvastatin 10 mg (8 out of 59 brands), which are selling at much higher prices than the recommended ones. Since hypertensive drugs are supposed to be taken for long time, the prices charged higher than what is being recommended adversely affects the availability of these essential medicines at affordable costs to the masses for very long period of time. In order to check the availability of medicines at affordable prices, some action has been taken by NPPA where *prima facie* violations have been detected (161 cases from 2010-11 till 2019-20).

- *Inter-brand price variation in the same drug existent at large-scale:* Significant price-variations in the various brands of same drug are still existent even after promulgation of the DPCO-2013. The same drug is being sold under different brands at higher prices. Atal, Atal, Deshmankar and Nawaz(2016) highlight this issue of brand-price variation by examining the drug prices in six therapeutic areas, i.e. Cardiovascular Drugs, anti-bacterial, analgesics-anti-inflammatories, anti-diabetic, antiasthma, anticonvulsants and anti-arthritis(total 36 drugs and 60 different formulations prepared from all these six categories covered in the study). The maximum variation in cardiovascular area is found in Clopidrogel 75 mg tablet (maximum price being charged by brand Stromix), followed by Amlodipine 5 mg tab (maximum price charged by Amlogard brand). Other formulations showing substantial variation are Atorvastatin 10 mg tab (max price charged by Atorva) and Atorvastatin 5 mg tablet (max price being charged by brand Storvas). In anti-bacterial category, highest price variation is shown in Cefixime 200 mg tablet (it is sold under 57 brands and highest price is being charged by Taxim-O) and Ethambutol 400 mg tablet (sold under 5 brands and highest brand is charged by Mycobutol). In the miscellaneous category, Diclofenac tab 25 mg/ml is the one showing largest variation in its average price being set and the maximum price charged (sold by 22 brands and maximum price charged by Dicloran Rs. 24.85 against the average price of Rs. 5.66).
- *Decline in sales volume of drugs which impacted the availability of essential medicines:* There has been fall in the general level of social welfare as a result of DPCO-2013, as well indicated by the decline in the volume of sales of essential medicines reported by firms in the post DPCO-2013 period. The extensive study conducted by Arvind Sahay and Jaikumar 2016 on almost all the oral solid molecules incorporated in the Schedule-I of DPCO-2013 shows that this fall in sales volume has been reported by firms mainly on account of decline in the profitability levels, due to capped prices. The sales volume on average has declined by (-33,931,992 units), with the few molecules (37 molecules) registering rise in the sales volume whereas the majority of molecules (52 molecules, constituting large proportion of total sales volume) has registered decline.
- *Adoption of unfair practices by pharmaceutical companies to mitigate the impact of price-controls*: The pharmaceutical companies resorted to unfair practices *via* coordinating in order to increase the prices of regulated drugs prior to the implementation of the DPCO-2013. The case of Metformin 500 mg (oral anti-diabetic drug) points towards this

unfair practice where 16 out of 112 firms (each having at least 1 per cent market share) coordinated to raise the prices of the time release versions of the 500 mg Metformin which have high average price than plain version. The high average price before DPCO resulted in fixation of high ceiling price of Metformin (Bhaskarbhatla, Chatterjee, Anurag and Pennings, 2016).

- e. *Differential Impact on large Companies v/s Small-scale Companies*: The DPCO impacted large and small firms in different ways; it is mainly the small and medium firms that have relatively more benefitted from the DPCO-2013 compared to large firms. The underlying reasons for this is that the small and medium firms are already engaged in the production of low-cost generic medicines and they got impetus to increase their production and sales. The sales of generic and low-cost drugs increased by 20 per cent in case of Aurobindo whereas it declined by 40 per cent in case of Novartis.

5.4 National Health Policy 2017

Outside of industrial, pharmaceutical, intellectual property and STI policies, health policies are the ones that affect the growth of pharmaceutical industry the maximum. Hence a detailed examination of the same is warranted.

The National Health Policy of 1983 and the National Health Policy of 2002 have served well in guiding the health sectors in the five-year plans by the erstwhile Planning Commission. After the last health policy there are several changes in the health sector. First, the health priorities are changing. Although maternal and child mortality have rapidly declined still there is a growing burden on account of non-communicable diseases (NCDs) and some infectious diseases (IDs). The second important change is the emergence of a robust private health care industry estimated to be growing at double digit. The third change is the growing incidences of catastrophic expenditure due to health care costs, which are presently estimated to be one of the major contributors to poverty. Fourth, a rising economic growth enables enhanced fiscal capacity. Therefore, a new health policy responsive to these contextual changes was required.

The goal of the National Health Policy (NHP) 2017 is to "achieve the highest possible level of good health and well-being for all Indians through a preventive and promotive healthcare orientation in all developmental policies, and to achieve universal access to good quality health care services without anyone having to face financial hardship as a consequence." The key objectives of the policy are as follows:

Health Status and Programme Impact

Life Expectancy and healthy life

- Increase Life Expectancy at birth from 67.5 yrs. to 70 yrs. by 2025.
- Establish regular tracking of Disability Adjusted Life Years (DALY) Index as a measure of burden of disease and its trends by major categories by 2022.
- Reduction of TFR to 2.1 at national and sub-national level by 2025.

Mortality by Age and/ or cause

- Reduce Under Five Mortality rate to 23 by 2025 and MMR from current levels to 100 by 2020.
- Reduce infant mortality rate to 28 by 2019.
- Reduce neonatal mortality to 16 and still birth rate to "single digit" by 2025.

Reduction of disease prevalence/ incidence

- Achieve global target of 2020 which is also termed as target of 90:90:90, for HIV/AIDS, 90 per cent of all people living with HIV know their HIV status, - 90 per cent of all people diagnosed with HIV infection receive sustained antiretroviral therapy and 90 per cent of all people receiving antiretroviral therapy will have viral suppression.

- Achieve and maintain elimination status of Leprosy by 2018, Kala-Azar by 2017 and Lymphatic Filariasis in endemic pockets by 2017.
- To achieve and maintain a cure rate of >85 per cent in new sputum positive patients for TB and reduce incidence of new cases, to reach elimination status by 2025.
- To reduce the prevalence of blindness to 0.25/ 1000 by 2025 and disease burden by one third from current levels.
- To reduce premature mortality from cardiovascular diseases, cancer, diabetes or chronic respiratory diseases by 25 per cent by 2025.

Health Systems Performance

Coverage of Health Services

- Increase utilisation of public health facilities by 50 per cent from current levels by 2025.
- Antenatal care coverage to be sustained above 90 per cent and skilled attendance at birth above 90 per cent by 2025.
- More than 90 per cent of the new-born are fully immunised by one year of age by 2025.
- Meet the need of family planning above 90 per cent at national and sub national level by 2025.
- Eighty per cent of known hypertensive and diabetic individuals at household level maintain, "controlled disease status" by 2025.

Cross Sectoral goals related to health

- Relative reduction in prevalence of current tobacco uses by 15 per cent by 2020 and 30 per cent by 2025.
- Reduction of 40 per cent in prevalence of stunting of under-five children by 2025.
- Access to safe water and sanitation to all by 2020 (Swachh Bharat Mission).
- Reduction of occupational injury by half from current levels of 334 per lakh agricultural workers by 2020.
- National/ State level tracking of selected health behaviour.

Health Systems strengthening

Health Finance

- Increase health expenditure by Government as a percentage of GDP from the existing 1.15 per cent to 2.5 per cent by 2025.
- Increase State sector health spending to > 8 per cent of their budget by 2020.
- Decrease in proportion of households facing catastrophic health expenditure from the current levels by 25 per cent, by 2025.

Health Infrastructure and Human Resource

- Ensure availability of paramedics and doctors as per Indian Public Health Standard (IPHS) norms in high priority districts by 2020.
- Increase community health volunteers to population ratio as per IPHS norm, in high priority districts by 2025.
- Establish primary and secondary care facilities as per norms in high priority districts (population as well as time to reach norms) by 2025.

Health Management Information

- Ensure district-level electronic database of information on health system components by 2020.
- Strengthen the health surveillance system and establish registries for diseases of public health importance by 2020.
- Establish federated integrated health information architecture, Health Information Exchanges and National Health Information Network by 2025.

These national targets and vision set out in the NHP-2017 augur well for pharmaceutical industry. The industry is in an indirect way assured of a large domestic market and the industry can pep up for the same. It is too early to assess their actual impact.

Endnotes

1 The United Nations Industrial Development Organization (UNIDO) categorized India "as one of the most advanced amongst developing countries with respect to technological development (Mehrotra, 1989).

2 GOI (1986).Drug Policy of India, 1986.http://www.nppaindia.nic.in/en/drug-policies/drug-policy-1986/ accessed on 29, September, 2020.

3 *Ibid.*

4 http://www.nppaindia.nic.in/en/drug-policies/drug-policy-1986/annexure-irefer-to-paragraph-6-1/ accessed on 30 September, 2020.

5 However, activities such as Drug Intermediates, Empty hard gelating capsules, surgical ancillaries, Sera and Vaccines, Diagnostics of all types, AllerginsandTransfusion solutions were kept free from ratio parameter.

6 http://www.nppaindia.nic.in/en/drug-policies/drug-policy-1986/annexure-ii-refer-to-paragraph-6-3/ accessed on 30 September, 2020.

7 http://www.nppaindia.nic.in/en/drug-policies/drug-policy-1986/annexure-iii-refer-to-paragraph-6-8/ accessed on 30 September, 2020.

8 GOI (1994).Drug Policy of India, 1994.http://www.nppaindia.nic.in/en/drug-policies/modification-in-drug-policy-1986/ accessed on 30, September,

9 GOI (2002). Pharmaceutical policy (2002), https://pharmaceuticals.gov.in/policy/pharmaceutical-policy-2002 accessed on 1 October, 2020.

10 GOI (2017). Draft Pharmaceutical Policy 2017. Accessed on 1 October, 2020.

11 Although, the drugs exported by Indian pharmaceutical companies are quality products as they have to fulfil the strict quality standards which are imposed by the importing countries, the question concerning quality standards has been raised against the indigenously manufactured drugs which are meant domestic consumption because India does not has sufficient number of Nationally Accredited Laboratories (NABL) for conducting frequent regular tests; audit of these NABLs are not conducted regularly; even established drugs (already in market for more than 4 years) are given sanction for producing drugs by State Drug Administrators without any Bio-Availability and Bio-Equivalence test of the claimed products; and most of the manufacturing units are not in accordance with standards of World Health Organisation's (WHO) Good Manufacturing Practices (GMP) or the Good Laboratory Practices (GLP) (GOI, 2017).

12 As result of globalization and WTO regime, the Indian pharmaceutical companies resorted to foreign countries, especially, China, to obtain low cost imports of APIs and Intermediates because DPCO kept their profit margin lower through putting price cap on drugs prices (GOI, 2017).

13 The Indian pharmaceutical industry produces about 2500 pharmacopeial salts but the number of branded drugs are more than 60,000 with differential prices (GOI, 2017).

14 https://www.thehindubusinessline.com/economy/long-time-in-the-works-pharma-policy-may-get-a-quiet-burial/article25902067.ece. Accessed on 2 October, 2020.

15 According to Food and Drug Administration (FDA), the drugs which are used in the treatment for rare diseases are known as orphan drugs.https://rarediseases.info.nih.gov/diseases/fda-orphan-drugs

VI
Science, Technology, Innovation and R&D Policies

6.1 Introduction

An area where cross sectoral policies have significant bearing on the development of pharmaceutical industry is that of science, technology and R&D policies. Pharmaceutical products being the results of latest technologies and scientific advancements, policies in these fields have comparatively more impact particularly on R&D and innovation. While other policies may have more direct effect on manufacturing and trade, S&T policies affect the development of new products resulting in creation of intellectual property. This chapter explores the past and current developments in this area.

6.2 Science and Technology Policies (1958-2013)

6.2.1 Scientific Policy Resolution of 1958

The Scientific Policy Resolution of 1958 stressed that it is intense cultivation of science on a large scale, which is the most domineering feature of the contemporary world. It is only through application of science on a very large scale that high standard of living and cultural, social and household amenities have been provided to majority of population for the first time in the history of humankind, which was earlier being confined to very few people. The provision of these amenities has also given emergence to the concept of welfare state. Further progress of it depends on extent of industrialisation and the efforts made for strengthening the perusal of science. The early foundation of science and technology (S&T) base in the country can also lessen the burden on scarce-resource capital which is very much required for the import of technology, plant and machinery and technical consultations in the early stages of industrialisation of the country. The development of science at a fast pace has also widened the gap between the countries (developed and developing). It is through our rigorous efforts in development science that we can narrow this gap. The aims of scientific resolution are to (i) foster science and scientific research in all fields, i.e. basic, applied and educational, (ii) ensure adequate supply of research scientists in the country, (iii) provide adequate training facilities for the training of scientists in our country and ensure that they meet the national requirements in science and technology, industry, agriculture and defence, (iv) encourage the creative talent of men and women and ensure their adequate participation in scientific activity, (v) encourage the individual efforts for the acquisition and dissemination of knowledge and (vi) secure for the people of our country all the benefits accruing from the acquisition and application of science.

6.2.2 Technology Policy Statement, 1983

The Technology Policy Statement 1983 mainly focused on technological self-reliance in the country. The objective of the policy statement is in consonance with the objective of Sixth and Seventh Five Year Plans which also focused on the objective of self-reliance in the economy. The main objective of the policy is to be self-sufficient in technology and towards this, the importation and absorption of technologies from abroad are to be through a technological assessment and technology forecast team and this has to be in line with the local needs. The focus in this policy was on emerging areas of biotechnology and decreasing the incidence of communicable diseases like tuberculosis and leprosy. It also seeks to reduce the widespread blindness in the country as there are 45 million cases of blindness in the country during this time period (i.e. Sixth Five-Year Plan).

Following are the impacts of Technology Policy Statement 1983 on pharmaceutical industry:

- *Impact on Pharmaceutical R&D*: In order to build technological capabilities and become self-reliant, the Indian pharmaceutical companies enhanced their R&D activities during this period. The R&D expenditure on pharmaceuticals industry was around Rs. 234 crore in 1980, which rose to Rs. 1,015.94 crore in 1990. It further increased to Rs 4,861 crore in 2000.
- *Development of Reverse Engineering capabilities:* The Indian companies rigorously engaged in developing reverse engineering capabilities through non-infringement process during this period. Though the pharmaceutical companies initially succeeded in building basic technological capabilities during initial period, it was in the late 1990s that they could build in matured technological sophistication *via* engaging in infringement processes also. (Ray, S.A. 2008)
- *Import Substitution and Restriction on FDI:* There were restrictions on import substitution and FDI also during this period. As a result, the main focus was to develop adequate technological base in the country by developing infrastructure facilities, developing human resources and investing sufficiently in R&D
- *Impact on Communicable Diseases and Others*: There has been significant improvement in reducing the incidence of communicable diseases in the country like leprosy and Tuberculosis. In addition, the blindness cases which were around 45 million in the country have been reduced to a significant extent (Seventh Five Year Plan). There has been focus on the continuation of these programmes in the subsequent Eighth Five Year Plan also.
- *Fiscal Incentives for R&D:* It is during this policy regime that fiscal incentives for R&D to build the adequate technological base in the country in the form of tax-breaks and exemptions were discussed for the first time
- *Increase in the number of in-house R&D units in the country*: There has been rise in the number of in-house R&D units in the country thereafter. These in-house R&D units are great source of technological innovations in the economy (DSIR Annual Reports, Various Years).

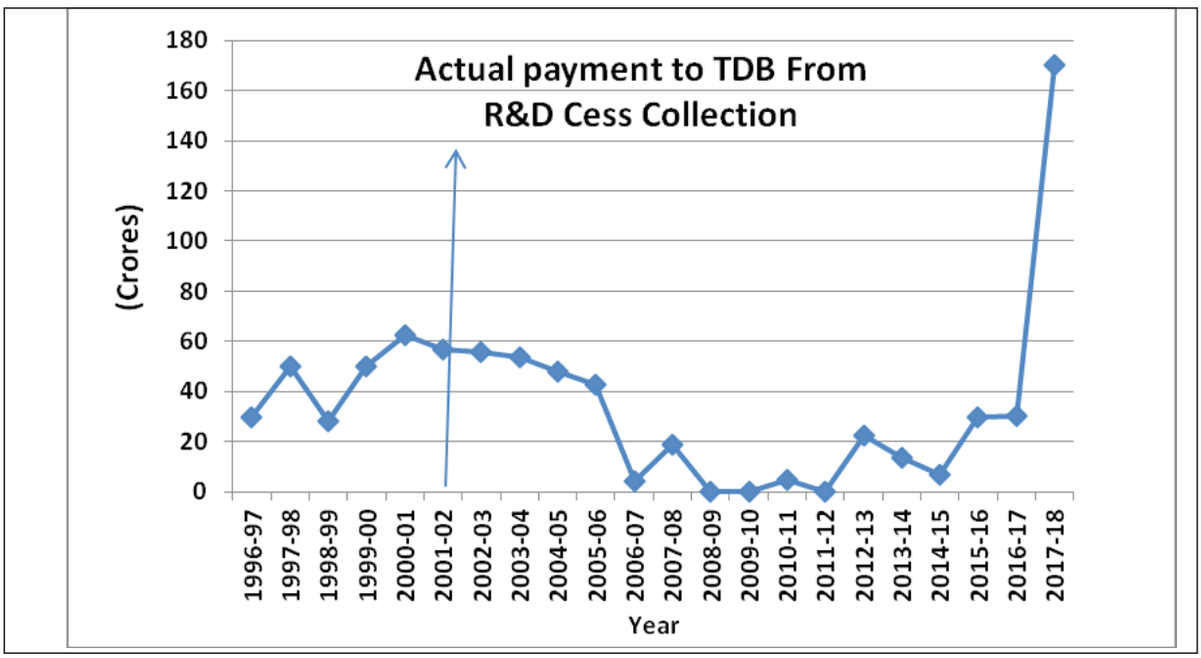
6.2.3 Science and Technology Policy 2003

The Science and Technology Policy 2003 came into existence almost two decades after the Technology Policy Statement 1983. In this policy, there has been paradigm shift in the focus from being self-reliant in technology and developing adequate technological capabilities for adoption and absorption of imported technologies towards commercialisation of indigenously developed technologies. "*The transformation of new ideas into commercial successes is of vital importance to the nation's ability to achieve high economic growth and global competitiveness.*" (Science and Technology Policy 2003). In this regard, Tenth Five Year Plan also put in place that though India has achieved robust S&T system, its lack of linkages with

industrial sector has resulted in R&D being academic in nature, leading to low level of commercialisation of indigenous technology and little patenting activities.[1] Consequently, the focus of the policy is not only on enhancing R&D activities but also on creating suitable social, institutional and market mechanism for transferring the technological know-how to productive sectors. In this regard, S&T policy highlights the need for autonomous technology transfer organisations in the country to transfer the know-how from universities and laboratories to industry. Industry should also come forward to provide adequate funding to these academic institutions in order to direct their scientific endeavours specifically towards industry needs (as R&D mainly being funded by public sector and the need for private sector to contribute more towards R&D funding in the economy). India's strengths and capabilities in R&D have not been translated to commensurate benefits due to lack of adequate scientific base in S&T.[2] The S&T Policy 2003 also highlighted the lack of qualitative human resources in S&T and endeavours to develop trained and high quality skilled human resource in science fields. The focus was on developing basic biology research in areas related to infectious diseases by providing adequate funding *via* science departments concerned and ensuring them flexible environment to work. The S&T Policy 2003 also directed towards putting substantial efforts for the development of traditional industry as this sector provides employment to large number of workers with relatively small investment levels and it also has fewer input requirements for its operations. The focus was relatively more on biotechnology R&D and providing suitable mechanism for encouraging basic research in biology and simplifying the procedures for commercialization of biological products and processes. The major impacts of S&T Policy 2003 on pharmaceutical industry were:

- *Commercialisation of indigenously developed technologies in pharmaceutical*

Figure 6.1: Actual payment to TDB from R&D Cess Collection (Rs Crore)



Source: *Annual Reports of Technology Development Board, Various Years.*

sector: The commercialisation of indigenously developed technologies in the pharmaceutical sector was given a push through Technology Development Programme. It is evident from the fact that the highest number of projects approved by the Technology Development Board (TDB) for commercialisation of technologies belongs to health and pharmaceutical sector. TDB has provided financial assistance to nearly 318 agreements, out of which 78 (nearly 25 per cent) agreements belonged to pharmaceutical sector till 31 March, 2016. The total financial assistance to pharmaceutical sector amounted to Rs. 356.96 crore till 31 March, 2016 (Annual Report of Technology Development Board, Various Years). However, overall commercialisation activities seemed not to have gone up significantly, as may be seen from Figure 6.1 below.

It is to be noted that in the above figure the contribution of R&D cess collection towards funding TDB fund declined after 2002-03, whereas it should have actually increased keeping in view the broader objective of S&T Policy 2003 to provide more support for the commercialisation of the technologies.

- *Human Resource Development:* Under the Integrated Programme of Human Resource Development in Biotechnology, the post-graduate programme, MSc in biotechnology, which was started in 1985-85 in five universities only, has now been extended to 63 courses with a total intake of around 1,000 students per annum. Out of these, 22 courses started in Tenth Five Year Plan 2002-07. (Eleventh Five Year Plan, 2007-12. Chapter 8).
- *Development of Biotechnology R&D:* The Department of Biotechnology (DBT) supported the biotechnology park at Lucknow and five biotechnology incubation centres at Hyderabad, Bengaluru, Kochi, Chandigarh and Solan. The DBT has also come up with Small Business Innovation Research Centre (SBIRC) to boost PPP efforts in the country (*Ibid.*)
- *Shift in the focus of Pharmaceutical R&D:* As a result of S&T policy, the focus of R&D in pharmaceutical industry had been shifted from basic technological capabilities *via* reverse engineering towards advanced technological capabilities or collaborative R&D. The focus of the Indian pharmaceutical companies was mainly on licensing their molecules to MNCs which fetch them huge royalty payments and also in the area of novel drug delivery system. (Kale and Little, 2007).
- *Redefining of the role of Research Institutions with more focus on collaborative approach towards industry*: In the post-2005 TRIPS regime, and in light of the S&T policy, research institutes were redefining and asserting their positions by development of expertise in drug discovery research, generics research and building the relations for their respective expertise. Earlier, academic research focused on publishing papers but not on bringing technologies in the market. Now, CSIR laboratories were becoming more market oriented and collaborating relatively much more to bring the technologies into the market (*Ibid.*).

6.2.4 Science Technology and Innovation Policy 2013

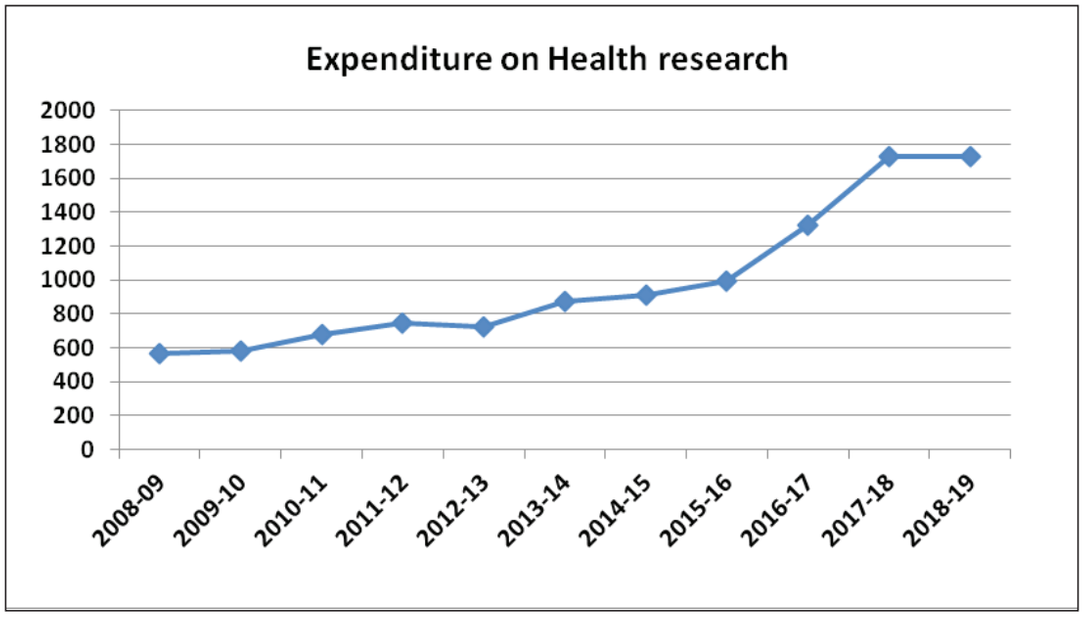
The Science Technology and Innovation (STI) Policy 2013 was envisioned in Twelfth Five Year Plan 2012-17. As S&T exist in their own disconnected spaces, the focus of the STI policy 2013 was on building the synergy between science, technology and innovation and also evolving a suitable mechanism to implement the interactions among these three in identified priority areas, i.e., health, nutrition and food. The implementation of the interactive synergy between science, technology and innovation in health sector would help to provide accessible

Table 6.1: Expenditure on Health Research (Annual Budget in Rs. Crore)

Year	Expenditure on health research (Rs crore)
2008-09	564.56
2009-10	583.97
2010-11	675.02
2011-12	746.43
2012-13	720.44
2013-14	874.08
2014-15	910.78
2015-16	992.77
2016-17	1323.60
2017-18	1731.68
2018-19	1727.88

Source: Union Budgets for various Years.

Figure 6.2: Expenditure on Health Research (2008-09-2019-20) (Rs crore)



Source: Union Budget for various years.

and affordable health care solutions to majority of the population of India. Thus, it is of utmost importance that national STI system should be evolved in a manner, which can consider the specific health requirements of the country and provide health facilities at lowest possible cost covering the major chunk of the population. The health innovation system of our country should be affordable, accessible and inclusive in its nature. It must take into account the specific health requirements of our country as communicable diseases like malaria, T.B., cholera, etc. are still widely prevalent despite huge efforts and significant success being

achieved in the past few years. The focus of the global health innovation system is mainly on the health requirements of the developed countries, thus often neglecting the critical diseases prevalent in developing countries. The focus of the STI policy 2013 was mainly on health, new drug discovery research, encouraging private sector investments in R&D and strengthening the PPP mode of investment in R&D. The impact of the STI Policy 2013 on pharmaceuticals is as follows:

Increase in the expenditure on health research: There has been rise in health research expenditure from Rs. 874.08 crore in 2013-14 to Rs. 1,727.88 crore in 2019-20. It is evident from Table 6.1 that out of the total budget of health research, only small proportion goes towards human resource development and infrastructure development for research.

Mismatch between prevalence of diseases and its public health research outputs: It is found that the public health research priorities are not commensurate with the prevalent disease burden in India. It is the infectious and parasitic diseases, which are ranked number one on the basis of disability-adjusted-life-years (DALYs),

Table 6.2: Scheme/Project-wise Expenditure in 2019-20 (Rs Crore)

S. No.	Scheme/Programme	Budget Head	Expenditure (Rs crore)
			2019-20
1	Secretariat-Social Services		14.53
2	Human Resource Development for Health Research	Advanced Training in research in medicine and health	24.27
		International cooperation in medical and health research	0.30
3	Grant-in-aid Scheme for inter-sectoral convergence & promotion and guidance on research governance issues	Inter-sectoral coordination in medical, biomedical and health research	28.13
		Promotion & guidance on research governance issues.	5.81
		Coordination with Governments/ organizations	0.00
4	Managing epidemics and national calamities		66.00
5	Development of infrastructure for promotion of health research	Promotion, coordination and development of basic, applied and clinical research	45.00
		Establishment of Model Rural Health Research Units.	8.12
6	ICMR		1413.60
7	Provisions for projects/ Schemes of North East areas.		120.94
	Total		**1731.68**

Source: Budget of Department of Health Research (2019-20).

but the clinical research trials in this area are ranked number seven. Highest clinical trials are being conducted in the area of cancer(first), cardiovascular diseases (second) followed by diabetes (third) but their disease burden is ranked as sixth, second and thirteenth respectively) (Chaturvedi and Thatte, 2017 and Clinical Trials Registry of India, CTRI).

Low level of indigenous research: The number of clinical trials in Phase-I is small, which shows there is very little indigenous research taking place in India. On the other hand, most of the clinical trials in Phase-I are related to developing vaccines, which shows our commendable efforts in vaccine development for the country and also the world.

Research efforts for Neglected Diseases more dependent on external factors: Some rise in research activities for neglected diseases are observed in recent years but much of the research activities in these neglected diseases are more influenced by external factors, i.e. Global Alliance for Tuberculosis Drug Development, WHO Special Programme for Research and Training in Tropical Diseases, and International AIDS vaccine initiative for HIV/AIDS vaccine (Abrol, Prajapati and Singh, 2011). Some initiative to deal with the type-III diseases is also taken under Jay Vigyan Programme.[3] Under this programme, the government entered into many technology transfer agreements with the above organisations which makes the innovation in the neglected diseases more dependent on these outside partners.

Contract research and manufacturing activities (CRAMS): The favourable environment supported through the Patents Act, 1970, as amended in 2005, has encouraged contract research activities in India. The changes in Indian Patents Act in consonance with the TRIPS Agreement have encouraged MNCs to outsource their manufacturing activities to India, taking advantage of low costs, large patient population and developed medical infrastructure. Thus, India has become favoured destination for clinical research trials (Sahu,2014).

Lessons to be learnt from developed countries for combating Neglected Diseases: Indian companies, though have increased their research activities, lack financial and infrastructural facilities to cover all the stages of drug development. As a result, they are licensing out molecules to MNCs for further development and consequently Indian companies focus on developing such molecules favoured by MNCs to cater to the health requirements of the developed countries. Here, public intervention policies of developed countries can be used as an example to combat this situation, i.e., USA's Orphan Drug Act, 1932 providing incentives for the treatment of orphan diseases affecting small number of people (Chaudhuri, 2005).

Public-Private Partnership Mode of investment in R&D: At present some initiatives by the government for PPP mode of investment in R&D is underway, i.e. Technology Development Board, New Millennium Indian Technology Leadership Initiative (NMITLI) and Small Business Innovative Research Initiative (SBIRI). Each of these programmes has its unique way to carry out its activities and has mixed outcomes in terms of their success. TDB has financed maximum number of pharmaceutical projects out of its total financed projects in different fields (Technology Development Board, annual reports). NMITLI has financed adequate number of pharmaceutical projects in TB, psoriasis and diagnostic kits but some projects have not been implemented properly due to lack of proper supervision and poor research outcome. (DSIR, annual reports). SBIRI shows that there is not much focus on disease pattern of India though there are some projects relating to malaria and typhoid (Abrol, Prajapati and Singh 2011). Overall, we may say that the R&D scenario of India need major improvements in the following areas:

- Though there are many modes of PPP carrying out their activities, there is a need

to evolve suitable mechanism to coordinate their activities in such a way that their research activities become directed more towards catering to the disease burden of India. Some projects are not properly supervised and no research outputs are shown which led to failure of the projects. The loan money taken for developing projects is not returned back in many cases (many projects of NMITLI where money taken as loan not repaid), which might discourage/dampen the spirit of the government to finance these projects on a long-term basis.

- Though rise in research activities of the neglected diseases is registered, much of the research is influenced from external factors, which makes the functioning of our health innovation system subject to the terms and conditions of our partners' activities abroad.
- The research activities are more in developing molecules and new drug delivery system (NDDS). The pharmaceutical industry lacks adequate research infrastructure to develop new chemical entities (NCEs), which require large financial resources and adequate laboratory infrastructure equipped with modern technologies.

6.3 Research and Development Expenditure and Its Impact

The above statistics present an image of reducing investment of public funds in industrial R&D in pharmaceuticals since 1980-81 from 42.15 per cent to 0.05 per cent in 2009-10. Figures 6.3, 6.4, 6.5 and 6.6 bring out this graphically.

Table-6.4 shows that the growth rate of R&D expenditure in pharmaceuticals industry during the period from 1980-81 to 2009-10 and also for three sub-periods, i.e. from 1980-81 to 1989-90, from 1990-91 to 1999-2000 and from 2000-01to 2009-10. Table depicts that the growth of total R&D expenditure is around 22.35 per cent during 1980-81 to 2009-10. It is mainly the private sector R&D growth, i.e. 22.35 per cent during 1980-81 to 2009-10, which has contributed towards the total R&D growth during this period, whereas the public sector R&D growth is only around 8.37 per cent during this period. The sub-period analysis shows that the growth of total R&D expenditure is 17.56 per cent during the first sub-period, i.e. from 1980-81 to 1989-1990. Table clearly highlights that it is both the private sector R&D, i.e. 15.11 per cent and public sector R&D, i.e., 18.26 per cent, which has contributed towards total R&D growth during this period. The second sub-period however shows that the total R&D growth has almost remained same as it is observed in the first sub-period also. However, it is private sector R&D growth, i.e. 27.63 per cent and small-scale sector R&D growth, i.e. 20.85 per cent, which has contributed towards total R&D growth during this period. The public sector R&D growth has turned out to be negative, i.e. minus 1.03 per cent during the liberalisation period (1990-91 to 1999-2000).

The third sub-period (2000-01 to 2009-10) shows that total R&D growth is even relatively more, i.e., 26.98 per cent as compared to first and second sub-periods. It is only the private sector R&D growth (27.17 per cent), which has contributed towards total R&D growth in the third sub-period.

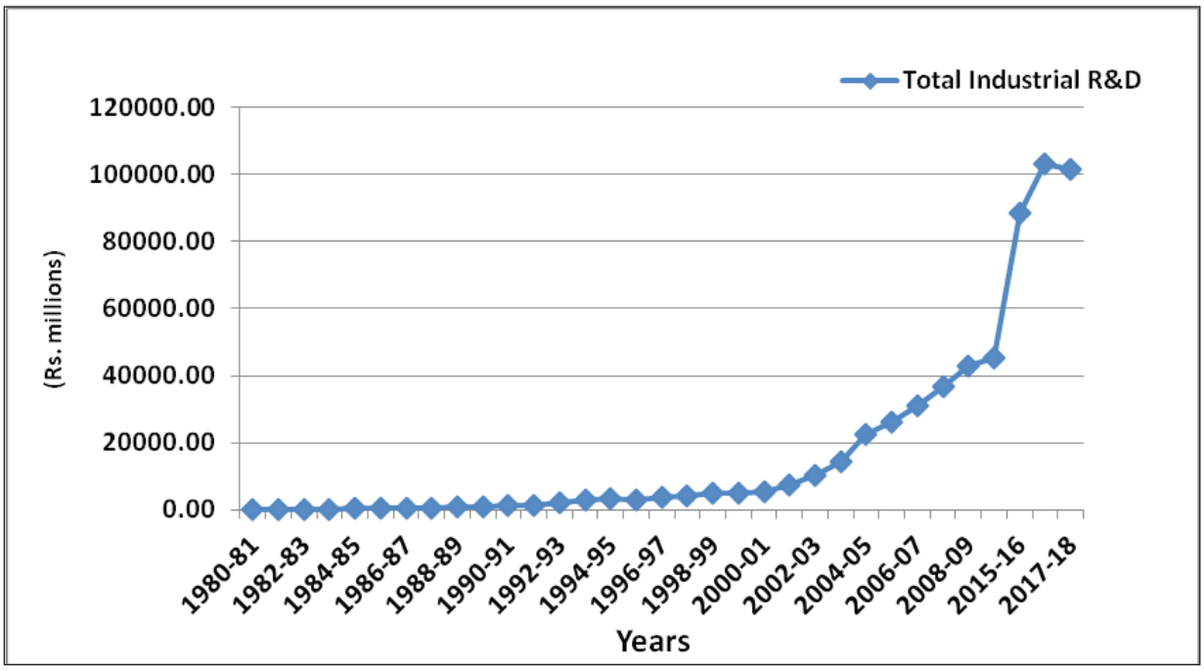
Public sector R&D growth is negative (-3.81 per cent) during the third sub-period. These findings are also corroborated from Table-6.1 *supra,* which shows that the share of private sector R&D in total R&D was around 50 per cent till 1993-94, though during the period from 1982-83 to 1986-87, it had been above 90 per cent. This, however, has a caveat that we do not have the figures for small scale industry (SSI) sector during that period and also from the period from 1998-99 onwards. At the same time, it may be noted that SSI sector is also private. It is from 1994-95 onwards that the share of private sector R&D in total R&D growth was around 98-99 per cent. This shows that the share of public sector R&D in total R&D has almost

Table 6.3: R&D Expenditure in Pharmaceutical Industry: Public, Private & SSS

Year	Private sector R&D expenditure (millions)	Public sector R&D expenditure (millions)	Small scale sector (SSS) R&D (millions)	Total Industrial R&D in Pharmaceuticals (millions)	Share of private R&D in total R&D	Annual growth rate of Total R&D
1980-81	174.2	22.107	104.82	301.13	57.85	-
1981-82	179.34	20.611	108.53	308.48	58.14	2.44
1982-83	185.210	14.87	..	200.08	92.57	-35.14
1983-84	221.767	12.533	..	234.30	94.65	17.10
1984-85	338.79	32.241	..	371.03	91.31	58.36
1985-86	355.106	35.572	..	390.68	90.89	5.30
1986-87	421.621	42.061		463.68	90.93	18.69
1987-88	471.917	38.27	167.33	677.52	69.65	46.12
1988-89	501.651	46.06	322.72	870.43	57.63	28.47
1989-90	579.674	54.158	382.11	1015.94	57.06	16.72
1990-91	598.727	118.934	527.63	1245.29	48.08	22.58
1991-92	756.592	168.312	586.53	1511.43	50.06	21.37
1992-93	1053.509	79.652	854.79	1987.95	52.99	31.53
1993-94	1217.206	71.416	1538.32	2826.94	43.06	42.20
1994-95	1600.268	57.813	1791.11	3449.19	46.40	22.01
1995-96	1938.869	48.432	802.87	2790.17	69.49	-19.11
1996-97	2618.954	44.402	940.16	3603.52	72.68	29.15
1997-98	2828.556	46.318	1486.01	4360.88	64.86	21.02
1998-99	4955.6	65.800	--	5021.40	98.69	15.15
1999-00	4789.8	72.000	..	4861.80	98.52	-3.18
2000-01	5542	73.6	..	5615.10	98.69	15.49
2001-02	7396	38.4	..	7434.70	99.48	32.41
2002-03	10268	15.912	..	10283.86	99.85	38.32
2003-04	14414	11.335	..	14425.67	99.92	40.27
2004-05	22371	20.327	..	22391.55	99.91	55.22
2005-06	26057	11.593	..	26068.39	99.96	16.42
2006-07	30935	15.431	..	30950.03	99.95	18.73
2007-08	36820	17.037	..	36836.84	99.95	19.02
2008-09	42683	17.622	..	42700.72	99.96	15.92
2009-10	45452	20.712	..	45472.71	99.95	6.49
2015-16	88329.6	20.9	--	88350.5	99.98	--
2016-17	102944.4	28.5	--	102972.9	99.97	16.55
2017-18	101591.1	31.5	--	101622.6	99.97	-1.31

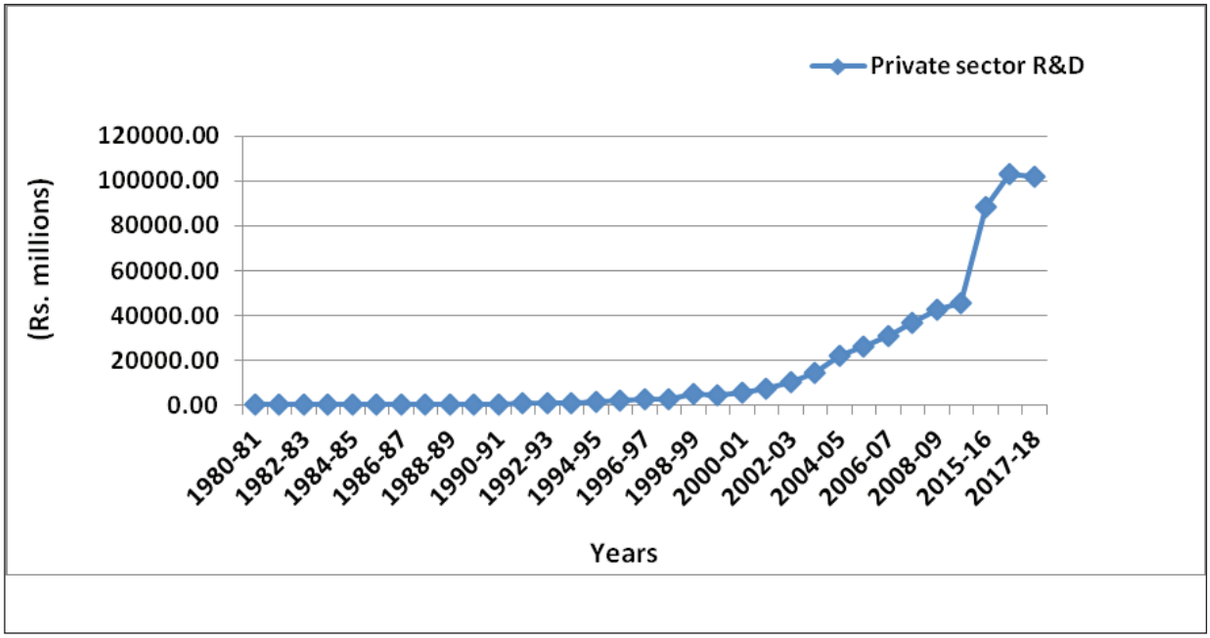
Source: Authors' compilation of data from R&D Statistics, NSTMIS, DST, Various years.

Figure 6.3: Total R&D Expenditure in Pharmaceuticals (Rs Million): 1980-81 to 2017-18



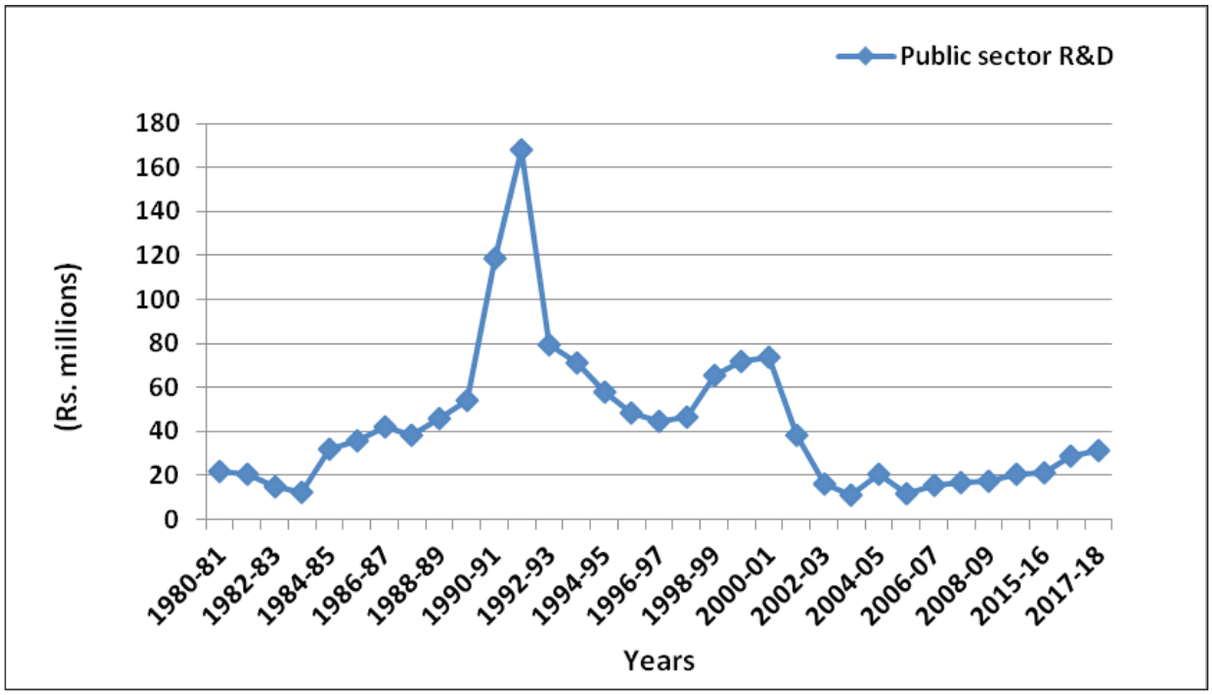
Source: Authors' calculation based on R&D Statistics, NISTMIS.

Figure 6.4: Private Sector R&D Expenditure in Pharmaceuticals-1980-81 to 2017-18 (Rs Million)



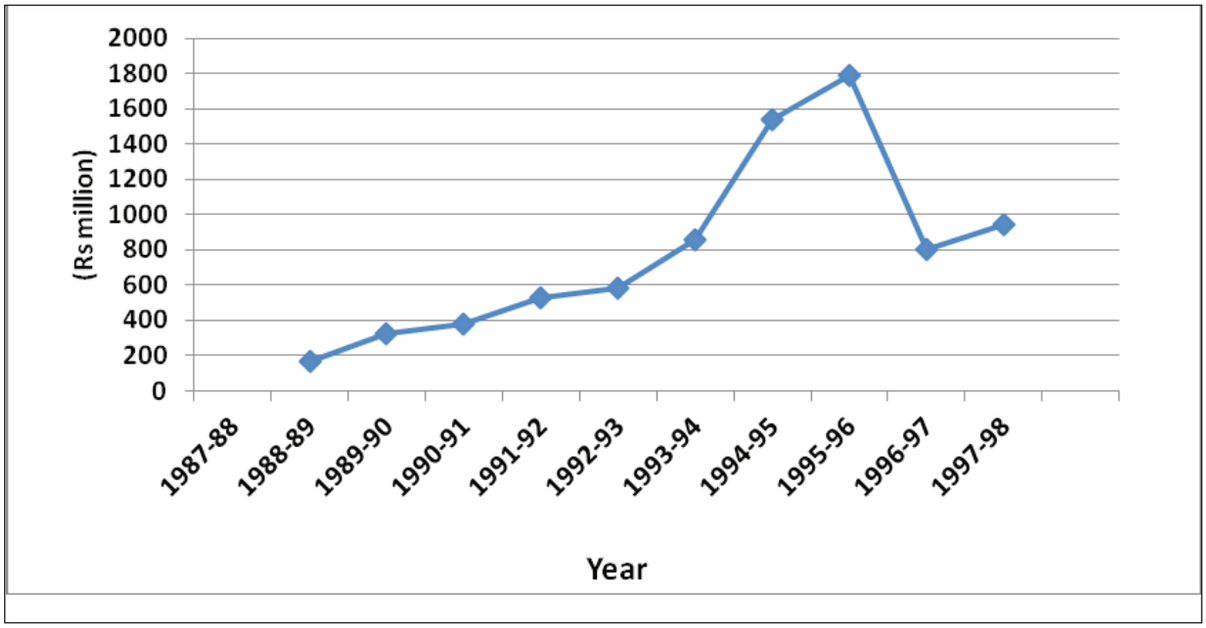
Source: Authors' calculation based on R&D Statistics, NISTMIS.

Figure 6.5: Public Sector R&D Expenditure in Pharmaceuticals-1980-81 to 2017-18 (Rs Million)



Source: Authors' calculation based on R&D Statistics, NISTMIS.

Figure 6.6: Small-Scale Sector R&D Expenditure in Pharmaceuticals: 1980-81-1997-98 (Rs Million)



Source: Authors' calculation based on R&D Statistics, NISTMIS.

become negligible. In fact, one does not find much change in the actual expenditure figures of public sector during the entire period from 1980-81, which mostly hovered around Rs. 20 million, except some sporadic increase in certain years. The general conclusion one can draw is that government has not been investing much in pharmaceutical R&D.

Table:6.5 shows that the total R&D as a percentage of sales turnover is around 4 per cent during the 1980-81 to 2009-10. However, there has been fall recorded in total R&D as a percentage of sales turn over from 1990-91 till 1996-97 and it is around 2 per cent only during this period. It is since 1997-98 onwards that total R&D as a percentage of sales turnover in pharmaceuticals industry has again picked up and now it is around more than 3 per cent till 2001-02 (slight fall is recorded for two years, i.e. 2002-2003 and 2003-04). There has been sharp rise in total R&D as percentage of sales turnover since 2004-2005 and it stays at this higher level throughout the period.

The R&D as percentage of sales turnover in private sector falls to less than 1 per cent during 1994-95 to 2000-01. It again picks up thereafter and increases from 2.5 per cent in 2000-01 to around 3.5 per cent till 2009-10. Contrarily, the R&D as a percentage of sales turnover in public sector has declined since 1998-99 and is less than 1 per cent throughout the first decade of 21st century. Though there has been some increase since then, it has not been significant. The share of public sector R&D in total R&D has also been relegated to very minor position and is around 16 per cent in 2002-03 and has declined thereafter and has become 11 per cent in 2009-10.

Table 6.6 presents the R&D as percentage of sales turnover for top 20 Indian pharmaceutical companies. Table clearly shows that all the Indian companies has shown a significant jump in their R&D as percentage of sales turnover except two, namely, Dr.Reddy's Laboratories (15.37 per cent in 2005 to 10.63 per cent in 2019) and Torrent Pharmaceuticals Ltd (10.34 per cent in 2005 to 6.94 per cent in 2019). Table also shows that six companies have R&D as a percentage of sales turnover more than 10 per cent in 2019. The remaining Indian pharmaceutical companies have R&D as a percentage of sales turnover between 5 per cent to 10 per cent in 2019 except one (i.e., Serum institute of India Pvt Ltd, which is at 2.50 per cent).

Table-6.7 presents the average annual growth rate of R&D expenditure in top 20 Indian companies for 2001-2019 and also for two sub-periods, i.e. 2006-2010 and 2011-2019 respectively. This clearly shows that all the Indian companies have registered high R&D expenditure growth during post-TRIPS regime to compete with the international patent regime now. However, a closer look at Table-6.7 shows that it is in the first sub-period, i.e. 2006-10 during which the companies registered higher R&D growth. In the second sub-period 13 out of

Table 6. 4: Average Annual Growth Rate (%) in pharmaceutical R&D- Total R&D (Private sector R&D, Public sector R&D and Small-scale sector R&D): 1980-81-2009-10

	1980-81-2009-10	1980-81-1989-90	1990-91-1999-00	2000-01-2009-10
Total R&D	20.66	17.56	17.79	26.98
Private sector R&D	22.35	15.11	27.63	27.17
Public sector R&D	8.37	18.26	-1.03	-3.81
Small scale sector R&D	-	-	20.85*	-

Source: Authors' Calculations based on data from R&D Statistics, NSTMIS.

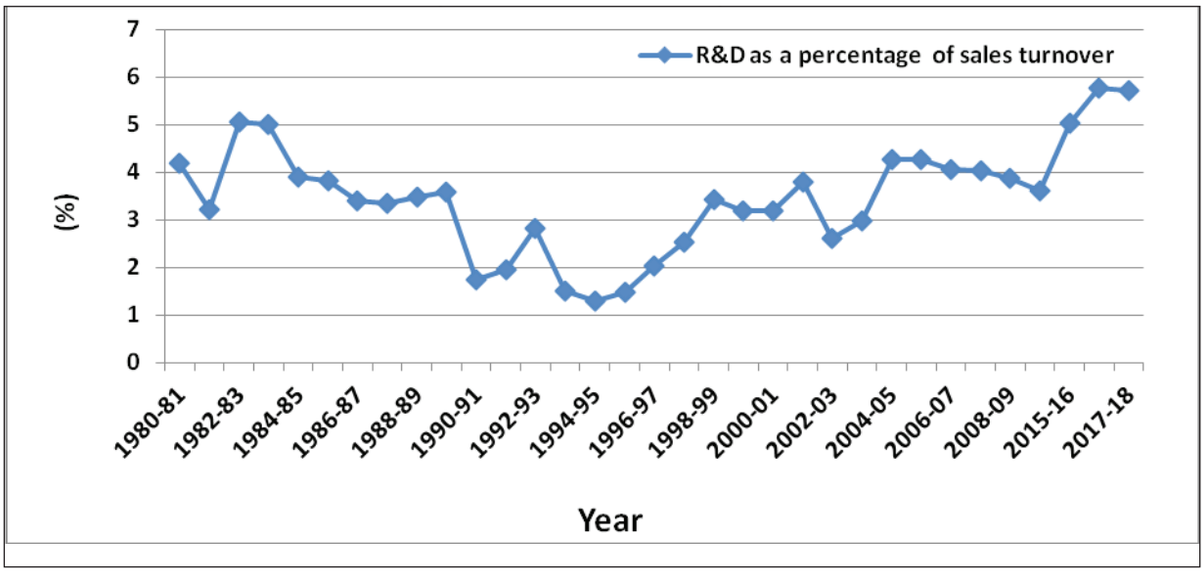
*Data for small-scale sector R&D refers to 1987-88 to 1997-98 only.

Table 6.5: R&D as a percentage of Sales Turn over in Pharmaceuticals Industry in India 1980-81 to 2017-18

Year	R&D as a %age of sales turnover in public sector	R&D as a %age of sales turnover in private sector	Total R&D as a percentage of sales turnover (%)	Share of public sector turnover in total R & D turnover (%)
1980-81	2.13	2.05	4.18	51.0
1981-82	1.51	1.72	3.23	46.7
1982-83	3.05	2.02	5.07	60.2
1983-84	2.74	2.26	5	54.8
1984-85	1.88	2.02	3.9	48.2
1985-86	2	1.82	3.82	52.4
1986-87	1.58	1.82	3.4	46.5
1987-88	1.6	1.76	3.36	47.6
1988-89	2.02	1.47	3.49	57.9
1989-90	2.18	1.41	3.59	60.7
1990-91	0.42	1.32	1.74	24.1
1991-92	0.61	1.35	1.96	31.1
1992-93	1.44	1.37	2.81	51.2
1993-94	0.14	1.37	1.51	9.3
1994-95	0.89	0.41	1.3	68.5
1995-96	1.07	0.4	1.47	72.8
1996-97	1.41	0.63	2.04	69.1
1997-98	1.9	0.62	2.52	75.4
1998-99	2.68	0.74	3.42	78.4
1999-00	2.52	0.68	3.2	78.8
2000-01	2.42	0.77	3.19	75.9
2001-02	1.47	2.32	3.79	38.8
2002-03	0.42	2.18	2.6	16.2
2003-04	0.36	2.62	2.98	12.1
2004-05	0.58	3.7	4.28	13.6
2005-06	0.65	3.62	4.27	15.2
2006-07	0.6	3.45	4.05	14.8
2007-08	0.43	3.61	4.04	10.6
2008-09	0.43	3.45	3.88	11.1
2009-10	0.4	3.22	3.62	11.0
2015-16	0.44	4.59	5.03	8.7
2016-17	0.55	5.21	5.76	9.5
2017-18	0.75	4.96	5.71	13.1

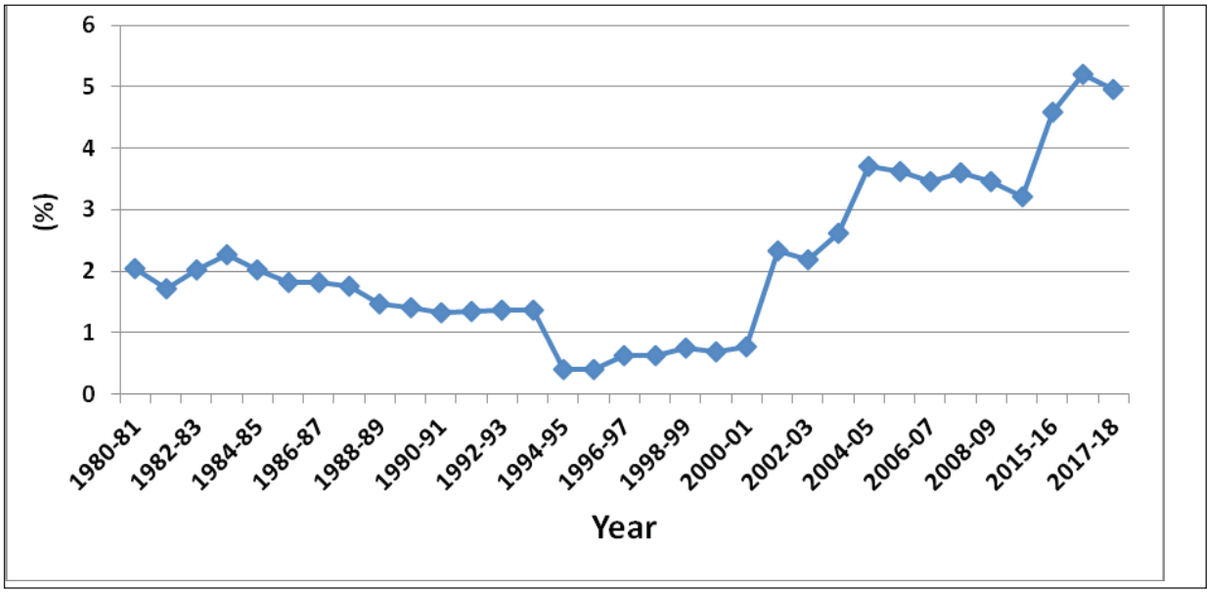
Source: Authors' compilation of data from R&D Statistics, NSTMIS, DST, New Delhi (various issues).

Figure 6.7: Total R&D as a percentage of sales turn over: 1980-81 to 2017-18



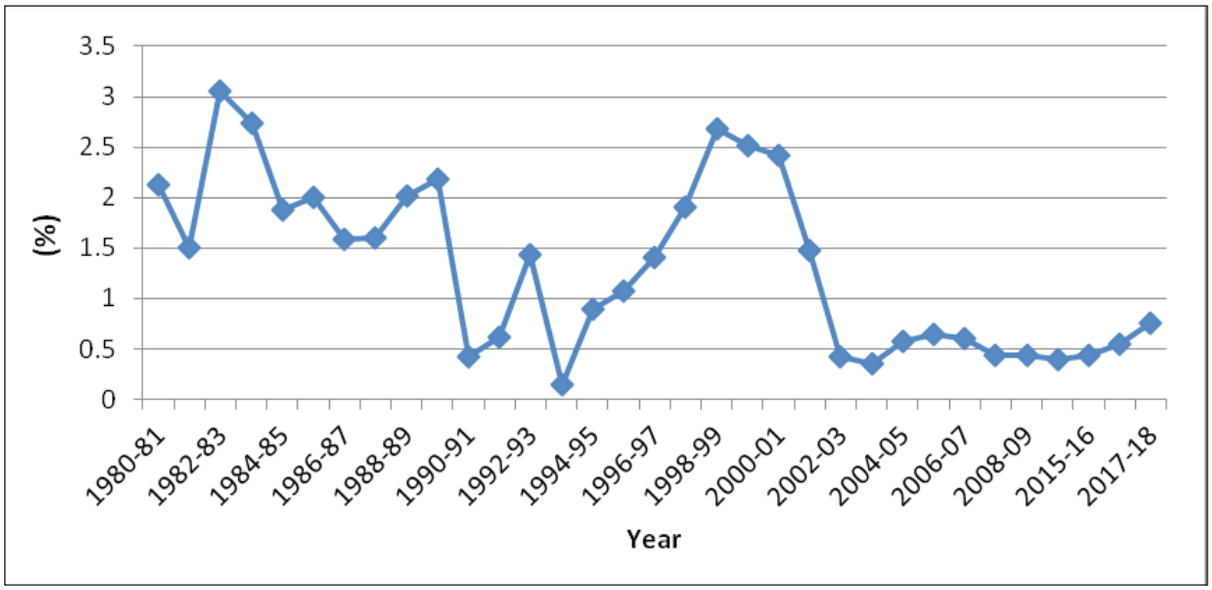
***Source*:** Authors' compilation of data from R&D Statistics, NSTMIS, DST, New Delhi (various issues).

Figure 6.8: R&D Expenditure as a percentage of sales Turn over in Private Sector: 1980-81 to 2017-18



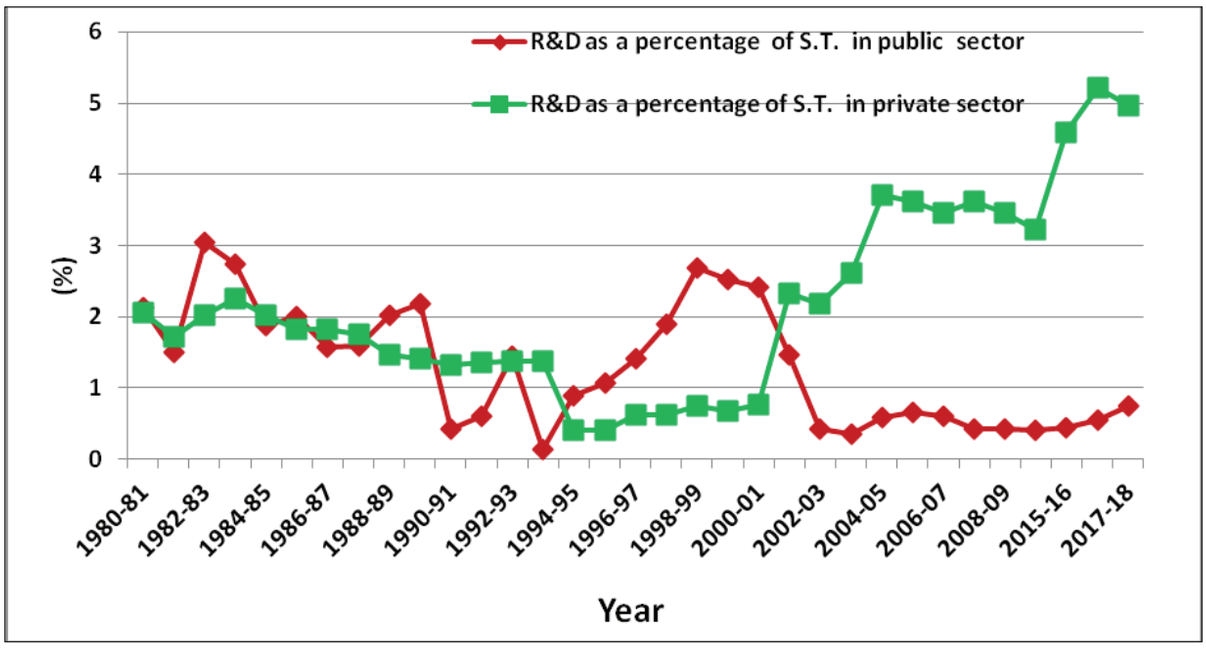
***Source*:** Authors' compilation of data from R&D Statistics, NSTMIS, DST, New Delhi (various issues).

Figure 6.9: R&D as a percentage of sales turnover in public sector (%) (1980-81 to 2017-18)



***Source*:** Authors' compilation of data from R&D Statistics, NSTMIS, DST, New Delhi (various issues).

Figure 6.10: R&D as percentage of Sales Turn over in Both Private and Public Sector R&D: Comparative Picture (1980-81to 2017-18)



***Source*:** Authors' compilation of data from R&D Statistics, NSTMIS, DST, New Delhi (various issues).

the 20 Indian companies have shown fall in the R&D growth as compared to first sub-period. Nine companies, i.e. Sun pharmaceuticals, Aurobindo Pharma, Alembic Labs., Glenmark Pharmaceuticals, Wockhardt, Natco Pharma, Lauras Labs, Serum Institute of India pvt Ltd and Strides Pharma Science have shown higher AAG in R&D expenditure during the third sub-period compared to the second. However, no company has shown consistent higher AAG in R&D expenditure in all three sub-periods compared to previous sub-period.

R&D as a percentage of sales turnover in MNCs has depicted the trend contrary to what is being observed in Indian pharmaceutical companies. Table 6.8 clearly indicates that R&D as a percentage of sales turnover in all these 8 MNCs mentioned in the Table has shown a fall from 2001 to 2015.These MNCs have rather decreased their R&D as a percentage of sales turn over in the post-TRIPS regime.

Table 6.9 presents the average annual growth rate of R&D expenditure in MNCs during 1993-2005 and 2006-19and how have these MNCs responded to new TRIPS regime in 2005. Table shows that the R&D expenditure of MNCs has declined in post-TRIPS regime. However, three MNCs, namely, Sanofi India, Merck and Wyeth, have recorded high R&D growth in the post-TRIPS regime.

Table 6.6: R&D as a percentage of sales turn over in Top 20 Pharmaceutical Companies: 2001-2019

Name of the Company	2001	2005	2010	2015	2019
Lupin	1.72	6.24	9.58	11.16	10.16
Dr. Reddy's Laboratories Ltd	4.17	15.37	8.23	11.13	10.63
Cipla Ltd	3.25	3.71	4.41	6.98	8.14
Sun Pharmaceuticals	1.68	7.10	7.71	10.04	9.26
Cadila Healthcare	2.69	6.16	8.97	10.54	10.95
Aurobindo Pharma	0.58	3.09	2.93	3.85	5.66
Alembic Laboratories	N.A.	N.A.	N.A.	5.36	13.34
Glenmark Pharmaceuticals Ltd	1.15	6.05	4.45	5.25	6.98
Intas Pharmaceuticals Ltd	1.00	3.49	4.77	5.94	4.98
Torrent Pharmaceuticals Ltd	5.16	10.34	8.95	4.76	6.94
Alkem Laboratories	N.A.	0.67	3.19	4.71	6.62
Macleods Laboratories	0.73	2.28	3.85	3.19	5.52
Biocon Ltd	2.20	2.07	5.24	4.45	11.28
Ajanta Pharma	0.73	0.42	5.26	5.12	9.93
Wockhardt Ltd	5.66	5.75	2.13	12.75	10.87
Natco Pharma Ltd	0.08	0.89	2.48	6.54	8.50
Emcure Pharmaceuticals Ltd	N.A.	1.75	3.71	7.27	6.66
Lauras Labs Ltd	N.A	N.A.	9.93	3.72	6.30
Serum Institute of India Pvt Ltd	N.A.	N.A.	1.80	1.87	2.50
Strides Pharma Science Ltd	N.A.	1.24	7.20	3.86	8.32

Source: Authors' Compilation based on Prowess database.

Table 6.7: Average Annual Growth rate of R&D expenditure in top 20 Indian Companies: 2001-2019 and 2006-10 and 2011 and 2019 (%)

Name of the Company	AAGR (2001-2019)	AAGR (2006-10)	AAGR (2011-2019)
Lupin	31.59	40.29	15.71
Dr.Reddy Laboratories Ltd	23.96	17.1	10.87
Cipla Ltd	22.09	20.68	19.4
Sun Pharmaceuticals	40.34	7.65	30.05
Cadila Healthcare	32.05	22.80	14.61
Aurobindo Pharma	502.1	13.88	22.34
Alembic Laboratories	N.A.	N.A	39.09
Glenmark Pharmaceuticals Ltd	43.28	9.79	34.15
Intas Pharmaceuticals Ltd	40.52	34.20	22.93
Torrent Pharmaceuticals Ltd	19.48	19.70	16.12
Alkem Laboratories	52.64	60.81	31.16
Macleods Laboratories	45.86	37.78	28.16
Biocon Ltd	32.00	40.2	11.37
Ajanta Pharma	43.68	122.9	29.47
Wockhardt Ltd	22.15	-6.53	46.6
Natco Pharma Ltd	90.16	40.27	43.09
Emcure Pharmaceuticals Ltd	39.12	30.91	30.07
Lauras Labs Ltd	24.36	N.A.	26.34
Serum Institute of India Pvt Ltd	25.18	-3.77	27.8
Strides Pharma Science Ltd	226.38	31.37	294.38

Source: Authors' own calculations based on Prowess database.

6.4 Publicly Supported Pharmaceutical R&D: A Case for Policy Intervention

6.4.1 *Rationale for the Government Support to Industrial R&D*

It is a widely known phenomenon that R&D activities are difficult to be totally financed by private sector in a competitive market for various reasons, including the high risk involved as well as the public interest lying underneath. Government support is needed for business-funded R&D to make the sector innovative and competitive. The well-known evidence in support of this view is found in the economic literature and probably begins from the seminal work of Nelson (1959). Nelson's classic study highlights the two main reasons for underinvestment in R&D by the private sector: (i) Large gap between private and social returns to R&D, i.e. external economies (ii) Results of basic research cannot be immediately patented. Hence, private sector investment in R&D is less than what is "socially-optimum level". Further, Arrow (1962) while discussing the issue of optimal resource allocation for invention cites three main reasons for the possible failure of competitive market to achieve optimality

in resource allocation, i.e. '*indivisibilities*', '*inappropriability*', and '*uncertainity*'. One of the main contributions of Arrow in 1960s was his exposure of the feature of "imperfect market for knowledge". The very interesting fact about the 'knowledge' or 'information' is that it is subject to all these three elements of market-failure. Consequently, it is expected that a free enterprise economy would underinvest in R&D as: (i) it is risky phenomenon; (ii) its returns cannot be fully appropriated and (iii) its use is independent of its scale or increasing returns. So, governments must come at forefront and should not be governed by profit-and-loss criteria while financing research and development (Arrow 1962).

Since the time this view was pioneered by Nelson and Arrow, it has further been developed, modified and tested by subsequent economists in many ways. Cohen and Levinthal (1989) provide evidence that assimilating a new technology is not without costs. 'Imitation' or 'learning' costs, although lower, still constitute 50 to 60 per cent of the original cost of invention. This fact can only partially mitigate the problem of underinvestment in R&D but does not fully resolve it. Empirical support for the basic theoretical argument of externalities or where social returns are higher than private returns of R&D is later on found in the work of Griliches (1979 &1992) also. Guellec and Potterie's (1997) study provides rationale for government

Table 6.8: R&D as a percentage of sales Turn over in MNCs (%): 1993-2015

MNCs	1993	2001	2005	2010	2015
Abott India Ltd	1.31	0.58	0.30	0.14	1.05
Astrazeneca pharmaceuticals Ltd	1.35	2.13	1.05	0.36	N.A.
Glaxosmithkline pharmaceuticals Ltd	0.76	0.39	0.29	0.19	0.06
Sanofi India Ltd	2.49	0.36	0.51	0.49	0.16
Pfizer Ltd	0.56	2.98	3.43	3.35	0.90
Merck	0.25	0.19	0.07	0.37	1.23
Novartis India Ltd	0.13	0.36	0.14	0.02	0.02
Wyeth Merged Ltd	0.52	0.39	0.10	0.27	0.20

Source: Authors' Compilation from prowess database.

Table 6.9: Growth of R&D expenditure in MNCs (%): (1993-2019, 2006-10 and 2011-2019)

MNCs	1993-2005	2006-2019	2006-10	2011-2019
Abott India Ltd	3.1	3.05	14.1	-8.63
Astrazeneca pharmaceuticals Ltd	18.71	-0.04	-0.04	N.A.
Glaxosmithkline pharmaceuticals Ltd	3.94	-3.46	2.46	20.09
Sanofi India Ltd	2.87	14.48	12.43	7.70
Pfizer Ltd	35.0	15.09	7.70	33.3
Merck	19.7	31.10	33.90	29.10
Novartis India Ltd	27.9	-16.4	-16.40	N.A
Wyeth Merged Ltd	1.16	23.80	12.43	20.9

***Source*:** Authors' calculations based on Prowess database.

support to R&D by identifying two aspects of market failure: (i) imperfect appropriability or 'diffusion of knowledge' due to which private sector underinvests in R&D and (ii) risk associated with research activities requires high risk premiums due to which external investors are reluctant to finance R&D projects, which in turn is detrimental to new entrants and small firms. Similar findings are reported in the study of Guellec and Ioannidis (1997), which shows that it is difficult for the firms to get external funding for R&D due to the difficulty of providing collateral and to the difficulty for external investors to assess the value of the R&D projects. So, asymmetric information and imperfect market for the 'knowledge' are the two main flaws that lead to under production of R&D. Hence, government intervention is required to reduce the risk of these market failures and further influence the generation of R&D *via* its policy tools.

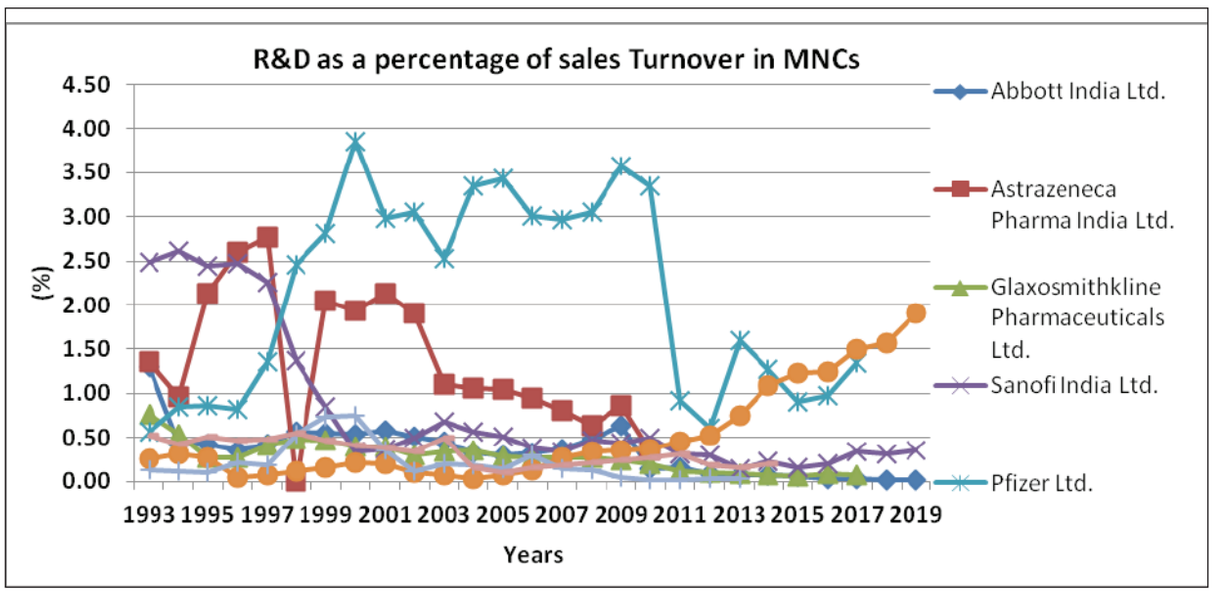
In light of the above framework, it is held that markets would fail to provide sufficient quantities of R&D in pharmaceuticals as it has some traits of public good. So, how can policy bridge the gap between social and private rates of return to R&D? What is the policy mechanism through which governments can help reduce this problem and generate sufficient incentives for private sector to stimulate R&D? Here, the role of governments is of utmost significance.

India has launched schemes and programmes to provide public funds to support pharmaceutical R&D, such as Technology Development Board (TDB), New Millennium Indian Technology Leadership Initiative (NMITLI), the Drugs and Pharmaceutical Research Programme (DPRP) and tax-incentive schemes (though the number of tax-incentives provided keep on changing). A brief review of the overall impact of these government support programmes on industrial R&D in pharmaceuticals is attempted below.

6.4.2 Direct Funding of R&D or Direct Subsidies

Government foster business research and development (R&D) with direct support *via* grants, subsidies and procurement. Other forms of support may also include loan guarantees, conditional loans and convertible loans. Government-funded R&D is 'vertical'

Figure 6.11: R&D as a percentage of sales Turnover in MNCs



***Source*:** Authors' Compilation based on prowess database.

as it is selective in nature and targeting those specific projects, which are selected by the governments for their own needs or to support industry (Guellec and Potterie 1997). The direct funding of industrial R&D either in the form of contracts or subsidies, has the advantage of allowing the governments to retain control over the nature of the research conducted. In addition, R&D subsidies help to ensure that industry must address some public needs like defence, health and energy sector. These subsidies will be primarily targeted towards those projects where significant gap persists between private and public returns to R&D. Subsidisation, therefore, reduces private cost and increases private marginal rate of return on investment in such activities (David 2000). Direct Government funding or R&D subsidies are mainly effective in the long-run as it requires sufficient time for the firms to adjust their own private R&D spending in response to change in conditions generated by rise in government funding. This clearly indicates that government funds are mainly concerned with the projects of long duration (Guellec and Ioannidis, 1997).

6.4.3: Tax Incentives for R&D

Tax incentives allow markets rather than governments to allocate R&D resources. The composition of R&D is also significantly affected by tax incentives. Unlike direct Government funding, tax mechanisms do not allow governments to direct business R&D into areas of high social return (technological areas of significant spill overs or basic research). As firms increase their R&D spending in response to linked tax offsets against earnings, they are more likely to favour projects, which will generate profits in the short-run. Consequently, projects with high social returns, long-term exploratory projects and research infrastructure investments would be less favoured by the expansion of private spending. In addition to it, weak spill over benefits to other firms and industries would be generated from these tax measures as compared to direct government funding (David, 2000).

R&D tax-incentives in India underwent changes many times as indicated in the different years of Union budget of Indian government. In the Union budget of 1999-2000, R&D tax incentives of 125 per cent was provided and later it was extended till the year 2004-05. In Union Budget 2000-01, the tax incentives on R&D were further raised to 150 per cent. Then in the Union Budget of 2010-11, R&D tax-incentives increased from 150 per cent to 200 per cent till 2016-17. However, the Union budget of 2016-17 decreased the tax-incentives from 200 per cent in 2016-17 to 150 per cent in the period 2017-18 and then to 100 per cent by 2020-2021(Union Budget, Various Years). This deduction in R&D tax-incentives is not justified given the nature of the pharmaceutical industry and secondly its significant share in total industrial R&D of India, i.e. 24.3 per cent. (R&D Statistics-2019-20, NSTMIS, DST).

6.4.4 Technology Development Board

The Technology Development Board (TDB) was set up by the Government of India on 1 September, 1996 through the Technology Development Board (TDB) Act 1995. The Board was established with the objective of accelerating the development and commercialisation of indigenous technology and adaptation of imported technologies for the wider domestic application. The TDB Act 1995 enabled the setting up of a Fund for Technology Development and Application. This Fund receives grants from the Government of India out of the R&D Cess collected by the government from the Indian concerns under the provisions of the Research and Development Act 1986 (which was further amended in 1995). This Act also enables TDB to build up the Fund by crediting all the sums received by TDB from any other source, recoveries made of the amounts granted from the Fund and any other income from the investment of the Fund. In the Budget of 2017-18, the union government abolished the R&D Cess Act with effect from 1 April, 2018.

Modes of Financial Assistance provided by TDB

TDB provides financial assistance through various channels, i.e. in the form of loans, grants, etc. The loan assistance is about 50 per cent of the cost of the approved project on 5 per cent simple rate of interest per annum (the loan amount is provided in instalments). The loan and interest is secured through collaterals and guarantees. The repayment of the loan and the payment of the interest starts only after the completion of the project and the moratorium period does not exceed one year. TDB also subscribes by way of equity capital and it is up to 25 per cent of the approved cost of the project. In addition to loans and equity, TDB also provides grants to some of the industrial concerns and R&D institutions, which are engaged in the projects of national importance. Since its inception in the year 1996, TDB has signed around 355 agreements with a project cost of Rs. 8,337.32 crore.TDB commitment for these projects is around 2,168.02 crore and out of this, TDB has disbursed around Rs.1,819.46 crore.

Table 6.11 and Figure 6.12 present the sector-wise financial assistance provided by the TDB since its inception in 1996. Table clearly reveals that it is the health and medical sector securing the largest share of financial assistance (94 agreements being provided financial assistance, worth Rs.563.94 crore), followed by Engineering and Information Technology.

Critical assessment of assistance by Technology Development Board Scheme on Pharmaceutical R&D:

- TDB has provided highest financial assistance to the pharmaceutical projects till 31 March 2019. Out of the 355 projects sponsored till that date, 94 projects are related to the pharmaceutical sector only. So, the assistance provided by TDB has resulted in large number of projects being technologically and commercially supported in the pharmaceutical industry as is evident from the list of Table 6.13. As a result, private pharmaceutical companies have increased R&D.
- TDB provides financial assistance through Technology Development Board Fund which is funded by R&D Cess collection. The fact that deserves attention here is that contribution of R&D cess Act towards TDB has sharply declined from 2003 onwards, as mentioned earlier. The contribution of R&D cess towards TDB fund has declined at a time when the commercialization of technologies was most emphasized in Science, Technology and Innovation Policy, 2003. Keeping this objective in mind, the contribution of R&D cess towards TDB fund should have actually increased but it rather declined, (Table 6.12) which is not in line with the broader objective of STI Policy 2003.
- Table 6.13 also presents that the financial assistance provided by TDB has gone into wide variety of pharmaceutical projects (covering broad range of diseases). The projects of Matrix laboratories (Sl. No 8),

Table 6.10: Financial Assistance provided by Technology Development Board Till 31 March, 2019 (Rs Crore)

Modes of Financial assistance	Amount sanctioned by TDB	Amount Disbursed by TDB
Loans	1699.30	1377.80
Equity	33.06	34.66
Grants	150.66	150.49
Venture Funds	285.00	252.51
Total financial assistance	2168.02	1819.46

Source: Technology Development Board Annual Reports.

Sequent Scientific, New Mangalore (Sl. No 15) and Ind-Swift laboratories (Sl. No 16) in Table 6.13 are the only ones providing financial assistance for R&D and commercialization of APIs (which is the most pressing need of our economy). Also, the projects financed in the direction of local disease burden are not large.

- Though the largest financial assistance by TDB goes to pharmaceutical sector, its efforts for R&D and commercialization of pharmaceutical technologies would be more helpful if it provides relatively more assistance to the projects like APIs, Medical Devices and local disease burden (i.e., tuberculosis and malaria).

6.4.5 New Millennium India Technology Initiative Leadership Programme (NMITLI)

The Union Budget 2000-01 made provision of Rs 50 crore in the budget of Department of Scientific and Industrial Technology (DSIR) for launching a New Millennium Indian Technology Leadership Initiative (NMITLI). It was to focus on areas, which fulfil national objectives and to be used on partnership between government and private sector (Union Budget 2000-01, para.36). It was approved by Cabinet Committee on Economic Affairs (CCEA) in 2003 for Tenth Plan programmes (Tenth Five Year Plan, page 1105). TNBD, carved out of R&D Planning & Business

Table 6.11: Sector-wise allocation of funds to approved agreements (Rs Crore)

Sl.No	Sector	Number of agreements	Total Cost (Rs Crore)	TDBs commitment (Rs. Crore)
1	Health & medical	94	1957.99	563.94
2	Engineering	69	699.96	256.98
3	Information technology	45	454.54	169.31
4	Chemical	26	236.80	84.69
5	Agriculture	26	212.53	67.52
6	Tele-communications	12	99.88	37.85
7	Road Transport	10	527.04	81.20
8	Energy & waste utilization	8	132.36	55.98
9	Electronics	4	52.56	17.75
10	Defence and civil aviation	10	648.83	229.95
11	Textile	1	689.00	250.00
	(a) Venture Funds	11	2463	285.00
	(b) STEP-TBI	35	35	35.00
	(C) CII	1	0.83	0.50
12	(d) Millennium Alliance	1	112	25.00
	(e) Global innovation &technology alliance	1	15	7.35
	(f) INVENT Programme	1		
	TOTAL	355	8337.32	2168.02

Source: Technology Development Report 2018-19.

Table 6.12: Research and Development Cess and Its Disbursements to Technology Development Board (Rs Crore)

Year	R&D Cess collection (crore)	Allocation to TDB Budget Estimates Revised estimates		Actual Payment To TDB (crore)
1996-97	80.13	30.00	30.00	29.97
1997-98	81.42	70.00	70.00	49.93
1998-99	81.10	50.00	50.00	28.00
1999-00	88.93	70.00	70.00	50.00
2000-01	98.91	70.00	70.00	62.79
2001-02	95.30	63.00	63.00	57.00
2002-03	99.47	58.00	58.00	56.00
2003-04	119.51	55.00	55.00	53.65
2004-05	156.99	54.00	54.00	48.10
2005-06	176.61	43.50	43.50	42.66
2006-07	186.56	33.50	33.50	4.32
2007-08	254.09	63.00	20.80	19.00
2008-09	310.33	20.80	20.80	0.00
2009-10	418.22	50.00	10.00	0.00
2010-11	592.22	50.00	5.00	5.00
2011-12	702.54	50.00	25.00	0.00
2012-13	685.62	50.00	25.00	22.50
2013-14	737.54	211.06	15.00	13.50
2014-15	906.78	100.00	7.50	6.75
2015-16	914.81	100.00	38.79	30.00
2016-17	1187.24	20.00	10.30	30.30
2017-18		20.00	170.00	170.00
Total	7974.32			779.47

Source: Technology Development Board, Annual Reports, Various Issues.

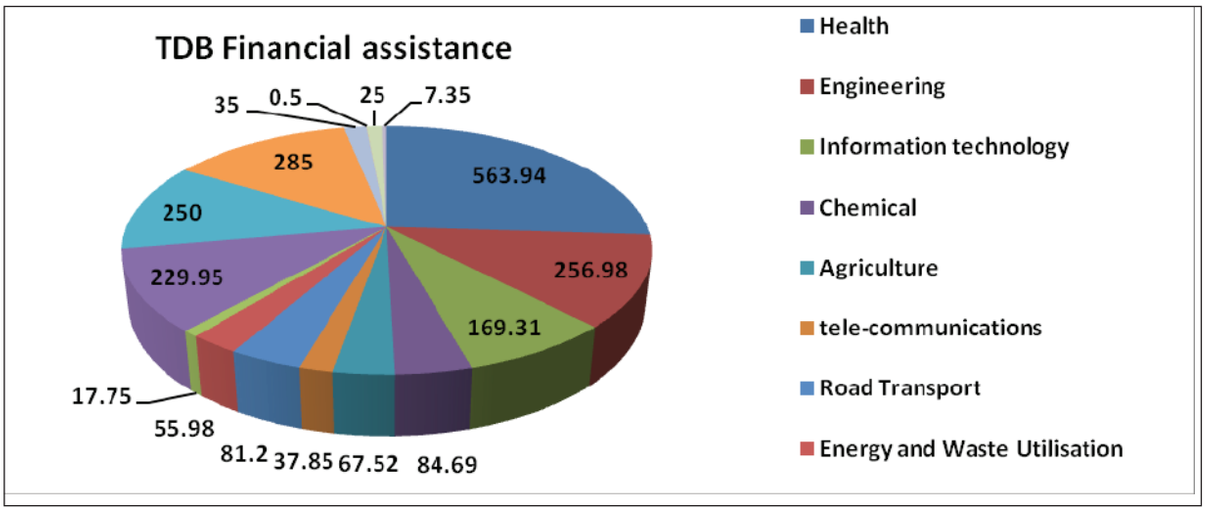
Development Division, has been mandated to support projects under NMITLI. In the first year of its inception, the division provided support for 25 ongoing NMITLI projects (Council of scientific and industrial Research, CSIR).

Some of the noted achievements in pharmaceutical sector under NMITLI Programme are the following:

- ***Tuberculosis therapeutic:*** A molecule named 'Sudoterb' has been developed for tuberculosis. This is the first molecule developed after rifampicin in 1963. This molecule when used in combination with other drugs can effectively reduce the duration of treatment from existing 6-8 months to 2-3 months. This molecule is presently undergoing phase-II clinical trial.

- ***Novel drug delivery system:*** The development of novel drug delivery system, based on dry powder inhalation of micro-particles containing rifampicin/ rifabutin and isoniazid.
- ***Lysotaphin, a novel biotherapeutic molecule for staphylococcus infections:*** The development of recombinant named Lysotaphin has taken place under NMITLI programme to check its efficacy against Staphylococcus aureasinfections. The IND application filed for Lysotaphin has been cleared and it is in phase-II of clinical trials.
- ***Oral herbal Formulation for the treatment***

Figure 6.12: TDB Financial Assistance to various sectors till 31st, March 2019 (Rs. Crore)



Source: Technology Development Report 2018-19.

Table 6.13: List of Projects Financed by the Technology Development Board for Commercialization and indigenous Development of Technology in pharmaceuticals since its inception (1st September, 1996) till present.

Sl. No	Name of pharmaceutical Company	Product invented	Field of application of invented product	Total project cost (lakhs)	TDB assistance (lakhs)
1.	M/S AxioBiosolutions Private Limited, Hyderabad	Axiostat –Emergency Hemostatic Dressings	For stopping profuse traumatic bleeding.	551	133
2.	M/s Robonik (India) Hyderabad	IN-Vitro Diagnostic (IVD) medical Diagnostic Products i.e. Ruralab, Autora automatic biochemistry analyser, Urine analyser, Multi strip and Elisa Analyser with Computer	Caters to wide spectrum of user requirements.	1700	850

Table 6.13 continued...

Table 6.13 continued...

3.	Shantha Biotechnics, Hyderabad	Shanvac-B, Hepatitis-B vaccine	Treatment of Hepatitis-B.	7000	1475
4.	M/s Bharat Biotech International, Hyderabad	Revac-B, (Recombinant Vaccine for Hepatitis B)	Treatment of Hepatitis-B	1221	325
5.	M/s Issar Pharmaceuticals, Hyderabad	Melgain i.e. peptide lotion/ gel/ointment	For treating vitiligo (white patches on the skin)	789	275
6.	Ranbaxy Laboratories, Ropar (Punjab)	Anti-bacterial i.e. Cefuroxime Axetil	Treatment of bone and joint infections, bronchitis, gonorrhea, meningitis and urinary tract infections	310	115
7.	Matrix Laboratories, Chennai	Manufacture of four APIs i.e. Fluconazole, Enarapril Maleate, Itraconazole and Omeprazole.	The first two used APIs for treatment of anti-fungal, the third one for hypertension and fourth one is anti-ulcer drug.	1700	450
8.	M/s Proalgen Biotech, Chennai	Production of Beta-carotene from algae, DunaliellaSp	It is a precursor to Vitamin-A	233	50
9.	M/s Biovet Bangalore	Foot and Mouth Disease (FMD) vaccine	For the treatment of foot and mouth diseases.	3531	1450
10.	M/s Biological E, Hyderabad	Two vaccines, i.e. Tetravalent-DTPw-r Hep-B and Monovalent-Heamophilusinfluenza type b conjugate vaccine	Hepatitis-B and for intramuscular use respectively.	9500	292
11.	OmnActive Health Technologies, Mumbai	Isolation and purification of Lutein from marigold flowers	Antioxidant used for reducing risk of age-related macular degeneration, cataract and several other forms of cancer.	1520	500
12.	Frontier Lifeline, Chennai	Tissue based products, i.e. Amniotic Membrane and Bovine Pericardium	Used as biological dressing for applications in post burn healing, cardiac surgery and the second one used as patch for various indications in cardiovascular surgery.	1553	500

Table 6.13 continued...

Table 6.13 continued...

13.	Neurosynaptic Communications, Bangalore	Telemedicine solution, i.e. ReMeDi	Used for recording physical and clinical parameters, i.e. ECG, Temperature, Oxygen Saturation for diagnosis of patient remotely by doctor.	417	128
14.	Sequent Scientific, New Mangalore	A key intermediate i.e. beta Thymidine	Used for manufacturing of anti-HIV/AIDS drugs, i.e. AZI(Zidovudine) and Zerit (Stavudine).		
15.	Ind-Swift Laboratories, Chandigarh	Manufacture of 9 APIs with modified processes-Quetiapine, Fumarate, Ropinirole HCI, Arip iprazole,Clopidogrel Besylate, Risedronate Sodium, Venlafaxine HCI, Donepezil, Nateglinide and Fluvastatin sodium.	The production of 9 APIs with modified process results in enhanced purity and yield.	2500	1000
16.	Gland Chemicals Hyderabad	Rocuronimum Bromide	Used as an adjunct to anaesthesia products in injectable formulations and also used in intra-abdominal surgeries.	770	350
17.	Hydrolina Biotech, Chennai	Extrcation of Lycopene from tomatoes	For preparing lycopene crystals, formulations and also powder form.	1913	800
18.	Lifecare Innovation, Gurgaon	Three Products, i.e. Fungisome, Fungisome gel and Psorisome gel	Used in the treatment of Psoriasis.	.490	200
19.	Alpha Corpuscles, New Delhi	endoXSTM, the laproscopytracor	Used for laproscopy surgery of abdominal diseases.	218	114
20.	i2iTelesolutions and Telemedicine, Bangalore	Product built on picture archiving and communication system technology for accessing and sharing healthcare resources between network hospitals and remote PHC	For access to expert diagnosis from rural un-served, access to targeted healthcare content and collaboration engine for second opinion and patient load balancing	751.17	250

Table 6.13 continued...

Table 6.13 continued...

21.	Sanzyme, Hyderabad	Manufacturing of Gonadotropins in non-dosage forms	For clinical applications in field of siabetes, Folliculogenesis and Spermatogenesis.	4000	500
22.	Sparsha Pharma International, Hyderabad	Manufacture of Rivastigmine Transdermal Patch i.e. the generic version of Exelon Patch.	For the treatment of Alzheimer disease.	2646	800
23.	Symmetrix Biotech, Mumbai	Clot Specific Streptokinase (CSSK), a therapeutic protein made by DNA recombinant technology	Used for animal toxicology and human clinical trials.	12057	1700
24.	Gland Pharma Hyderabad	Enoxaparin- a, ow molecular weight derivative of heparin	Used as an anti-coagulant in by-pass surgeries and also as preferred element in treating myocardial infarction.	770	350
25.	Virchow Biotech, Hyderabad	Tropical gel i.e. Recombinant Human Platelet Derived Growth Factor (rhPDGF)	Used for treatment of chronic non-healing diabetic ulcers.	500	250
26.	Biocon India, Bangalore	Production of MycophenolateMofetil	Used as an immuno-suppressant.	2550	970
27.	Ravindranath GE Medical Associates, Hyderabad	Creation of Facility for all important organ transplant i.e. liver,kidney,pancreas, small intestine .	For the purpose of providing all important facilities at one place.		
28.	M/S Panacea Biotech, New Delhi	PacliALL, a nano-based formulation of albumin-bound Paclitaxel particles	Used for treatment of breast cancer.	4947	475
29.	KhyathaAbhijith Pharma and Health Care systems, Visakhapatnam.	Manufacture of device called 'Diasense'	Detects the neuropathy at sub-clinical and pre asymptomatic level detects ultraprone zones to avoid ulcer formation.	2700	900

Source: Authors' compilation from various annual reports of Technology Development Board.

of Psoriasis (dermatological infection): Psoriasis is a dermatological disease affecting around 2 per cent of the world population. A single plant based oral herbal formulation has been developed under NMITLI using reverse pharmacology approach. It is currently under phase-II clinical trial.

- ***Novel molecular diagnostic for eye diseases and low vision enhancement devices:*** The project started in 2003 and ended in 2007.The technology was developed and commercialized also. However, the cost of the products developed affected the commercial viability of the project.
- ***Micro-PCR:*** A micro-PCR system for *in-situ* identification of Hepatitis-B virus.
- ***Ashwagandha:*** Five different types of chemotypes have been identified**.** The variety for best adaptogenic properties has been established.
- ***Development of drug Sepsiviac for treatment of gram-negative sepsis:*** Cadila pharmaceuticals under NMITLI programme has been receiving support since 2007 to develop Sepsiviac drug. This drug during its clinical trials has shown to reduce the mortality rate by more than half and faster recovery of patients.

Some pharmaceutical projects, which could not achieve their objectives, are the following:

- ***Oral Insulin capsule for treatment of diabetic patients:*** The desired formulation for the oral delivery of insulin could not be developed because of withdrawal of industrial partners (as formulation work did not progress). Other factors acted as hurdles were lack of product standardization and lack of positive clinical response.
- ***Development of process of 'Tamil-flu'- a drug to combat avian flu*****:** The process of development of Tamil-flu was patented. But the industrial partners failed to develop the process due to scientific hurdles. After the bird-flu menace abated, CSIR closed the project in October, 2007.
- ***Microbial conversion of erythromycin to Clarithromycin and other novel biologically active molecules*****:** The project could not achieve the envisaged objective as no positive leads could take place.
- ***Development of selected medical implants*****:** The monitoring committee felt that development of implants takes 8 to 10 years so no product was commercialised in the project. The objectives could not be achieved mainly due to disinterest shown by clinical partners in case of spinal plants and inadequate monitoring of project by committees of CSIR. Trials are going on in respect of dental implants only.

NMITLI has taken up some notable initiatives during the Covid-19 Pandemic, as indicated below:

- ***Novel therapy for management of covid-19*****:** CSIR-NMITLI in partnership with Cadila pharmaceuticals is initiating a clinical trial of Mycobacterium W drug for Covid-19 patients.
- ***Developing Human monoclonal antibodies.*** CSIR under its flagship programme of NMITLI has sanctioned a project to develop human monoclonal antibodies that neutralize the impact of SARS-COV2 virus. It will be led by Bharat Biotech Limited.
- Development of Ayurveda based botanical drugs for prophylaxis and for management of Covid-19.
- Development of an inactivated SARS-CoV2 vaccine for COVID-19 (ICoV2Vac)
- Design and Development of a portable personal Air purifying respiratory device.
- Overall, one can say that this is a programme that could be enlarged and implemented to improve the pharmaceutical research in the country.

6.4.6 Drugs and Pharmaceutical Research Programme

Drugs and Pharmaceutical Research Programme (DPRP) was initiated by the Department of Science and Technology, Government of India in 1994-95. It aims at synergizing the strengths of publicly funded R&D institutions and Indian pharmaceutical industry in order to create an enabling infrastructure for facilitation of new drug development in all systems of medicines. Some of the recent notable achievements of the programme broadly in the last ten years are presented in Table 6:14.

6.4.7 Open-Source Drug Discovery (OSDD)[4]

As part of the 11th FYP, in 2008, a novel initiative in drug research and discovery was launched under CSIR with the name Open-Source Drug Discovery (OSDD). It was aimed at developing

Table 6.14: Public-Private Partnership (PPP) Initiatives under DPRP

Sl. No	Public-private partners (PPP) in Projects	Product	Field of application
1.	Implemented at University of Hyderabad in collaboration with Dr. Reddy's Institute of Life Sciences	12R-L ipoxygenase	Psoriasis-inflammatory skin disease
2.	Implemented at National Institute of Animal Biotechnology, Hyderabad in collaboration with Chemical Life Sciences India Pvt, Ltd, Hyderabad	Development of peptide-based anti-inflammatory drug	Septicemia
3.	Initiated at Pondicherry University, Puducherry with M/s Arvind Remedies Ltd, Chennai	Evaluation of Polyherbal formulation (Pankare)	Diabetes
4.	Cadila Pharmaceuticals Pvt Ltd, Ahmedabad developed through PPP.	Innovative drug Mycidac-C (launched on Nov 21,2013).	Lung Cancer
5.	23 Public Private Partnership Collaborative Projects during Eleventh Five Year Plan.		Leprosy, tuberculosis, HIV/AIDS,Tetanus, measles,Hepatitis-B, Diarrhoea and many others
6.	Sri Ram Chandra University, Chennai, VisvaBharati University, Santiniketan and East India Pharmaceutical Works Ltd, Kolkata.	Product development of phyllanthusniruri and Glycine max(L)Merr. formulation	Diabetes and its complications (the product is in the stage of efficiency validation)
7.	SastraUniversity,Thanjavur and M/s Orchid Chemicals and Pharmaceuticals Ltd Chennai	Development of targeted stealth nanocarrier for dual delivery	In the treatment of oral cancer
8.	Tamil Nadu Veterinary and Animal Sciences, Chennai and M/s Neospark Drugs and Chemicals Pvt Ltd Hyderabad.	Development of novel mycotoxin binders	For management of mycotoxicosis in animals and humans.
9.	National Institute of Interdisciplinary Science and Technology (NIIST), Thiruvananthapuram/Arya Vaidyasala Nilayam, Kotakkal.	Replacement of herbal roots with other parts	Used in traditional Ayurvedic formulations.

Table 6.14 continued...

Table 6.14 continued...

10.	Sri Ramchandra University, Chennai and M/s Harshul Ayur Pharma, Ramnagar Uttarakhand.	Scientific validation of safety protective and curative efficacy of patented folklore medicine 'Savliv'.	Hepatitis Disorders
11.	M.S.University,Vadodara/ASHRAM,Eluru/ Sri Ramachandra University Chennai/M/s Laila Pharmaceuticals Ltd.,Chennai.	To identify genetic variations conferring risk in cardiovascular disease.	cardiovascular disease
12.	Jawaharlal Nehru University, New Delhi and Lal Path Labs Ltd.	Development of diagnostic kit.	For detection of mycobacterium tuberculosis complex.

Source: Annual Report, Various Issues, Department of Science and Technology.

Table 6.15: National Facilities set-up under Drugs and Pharmaceutical Research Programme (DPRP)

Sl. No	National Facilities	Location of National Facility
1.	Srengthening National facility for biopharmaceutical services for bioprocess training and biopharmaceutical characterization(PhaseIII)	Guru Nanak Khalsa College, Matunga, Mumbai
2.	National Facility for bioanalysis.	Dr. Babasaheb Ambedkar Marathwada University, Aurangabad, Maharashtra
3.	National facility for combinatorial Natural Products-Phase-II	Indian Institute of Chemical Technology, Chennai.
4.	National facility for Drug discovery and development therapeutics.	Rajiv Gandhi Centre for Biotechnology, Thiruvananthapuram.
5.	National Facility on community-based cancer tissue bio banks for drug targets.	Indian Institute of Technology, Chennai.
6.	Facility project entitled 'Strengthening of existing facilities with a special emphasis to bioequivalence study of drugs and metabolites in plasma'.	JadavpurUniversity,Kolkatta
7.	National Facility on Drug Development	SaurashtraUniversity,Rajkot
8.	The facility project on neurotoxicity research to assist drug development.	University of Madras Chennai.
9.	The facility for development of herbo-metallic preparations of Ayurveda, Unani& Siddha.	SASTRA University.
10.	Mechanism based screening and validation of herbal drugs using radiotractor technique	Hafkine Institute for Training Research and Testing, Mumbai.

Source: Annual Reports, Various Issues, Department of Science and Technology.

drugs for Neglected Tropical Diseases such as Tuberculosis and Malaria. It was a project involving thousands of scientists on a voluntary basis from around the world. The basic concept was crowdsourcing. By the year 2013-14, it had reached the stage of entering clinical trials of new TB drug combination for MDR-TB patients. However, later developments are not known. The programme points to the need for persistent and patient long-term investment in pharmaceutical R&D; it also highlights the risks that R&D in pharmaceuticals would face if policies change too soon.

There are also other policies such as the National Intellectual Property Right Policy, 2016 and the New Education Policy, 2020 which will have impact on the pharmaceutical sector R&D. The national policies on biological diversity and environment and climate control also will impact the sector. As the policies get translated into detailed field level action, the impact of the same on the industry and its R&D will have to be studied in detail. As for schemes and projects, what one finds is that there are good number of programmes, but the financial resources allocated for the same are generally very limited and the conditions very strict that the firms are not much forthcoming to avail of the benefits. In the schemes in the area of R&D and technology, the approach will have to be different from those in the purely economic or financial areas. They have to be liberal and support will have to be consistently extended for a long period.

Endnotes

1. Tenth Five Year Plan(2002-2007), chapter 10, pg 1095.
2. Ibid. chapter 10
3. Tenth Five Year Plan, chapter 10.
4. CSIR-OSDD Annual Report 2013-14, available at www.osdd.net accessed on 28 February, 2021.

VII
Trade in Pharmaceuticals

7.1 Introduction

International trade is an integral part of economic liberalisation policies initiated in 1991. The process got a big boost with India joining as a founder member of the World Trade Organisation (WTO) in 1994. This has hastened India's integration into global economy. In the decades following the establishment of the WTO, international trade has grown enormously averaging around 6 per cent per year, twice as fast as world output.[1] This has been made possible also because of technological developments, which increased connectivity enormously. India is considered as one of the successful models of economic liberalisation and new international trade regime. In this chapter we propose to examine how the new regime affected trade in drugs and pharmaceuticals, including medical devices.

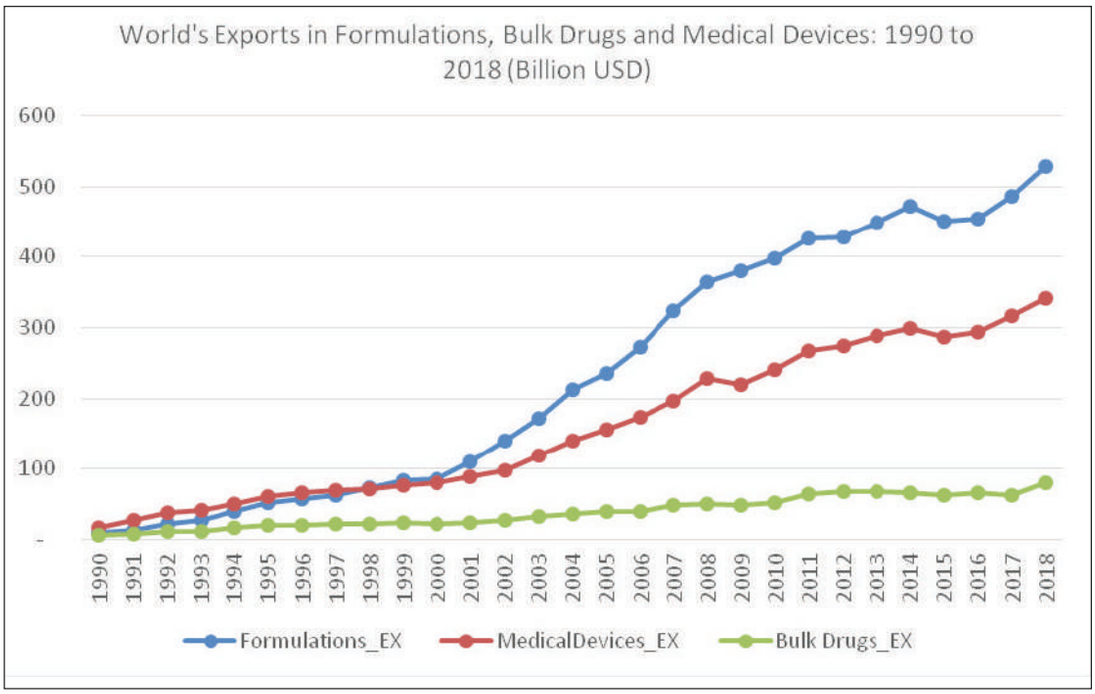
7.2 Global Scenario of Pharmaceutical Trade

In formulations, the global exports have increased from $ 10 billion in 1990 to $ 529 billion in 2018 (Figure 7.1). Between 2000 and 2008, the global formulation exports grew at significant pace, registering 20 per cent compound annual growth rate (CAGR). After that, it went on growing at just 4.4 per cent CAGR till 2014; declined in absolute terms in the following year (2015); and recovered in subsequent years. The pharmaceutical industry also, thus, had not remained immune from global financial crisis and European financial crisis. The global exports in medical devices have increased from $ 16 billion in 1990 to $ 342 billion in 2018. In bulk drugs, the growth of exports has remained much lower in comparison to what has been attained by formulations and medical devices industries. In 1990, world's exports in bulk drugs was at around $ 6 billion and it increased to $ 80 billion in 2018. It is important to note that global exports of both medical devices and bulk drugs recorded a decline in absolute terms in 2015 as has been the case with formulations and modest recovery took place in the following year.

7.2.1 Bulk Drugs

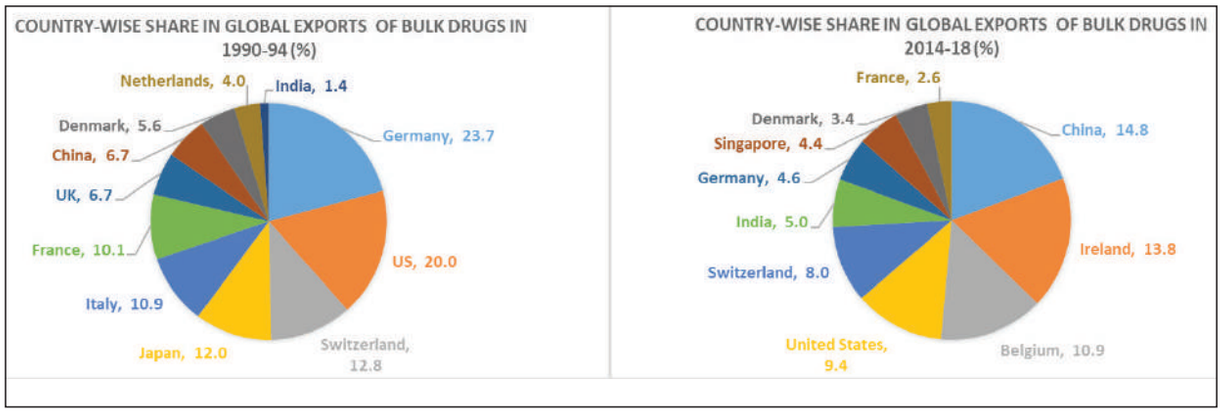
During the early 1990s, around $ 10 billion of bulk drugs were traded globally and around 90 per cent of that was exported by six countries, namely, Germany (24 per cent), USA (20 per cent), Switzerland (14 per cent), Japan (12 per cent), Italy (11 per cent) and France (10 per cent) (Figure 7.2). In this segment of pharmaceutical industry, the contribution of UK, China and Denmark was around 6.7 per cent, 6.7 per cent and 5.6 per cent, respectively. During the recent

Figure 7.1: Global Exports in Formulations, Bulk Drugs and Medical Devices: 1990 to 2018 (Billion USD)



Source: WITS, World Bank online database.

Figure 7.2: Country-wise Share in Global Exports of Bulk Drugs in 1990-94 & 2014-18



Source: WITS, World Bank online database.

years (2014-18), a significant change has taken place in the contribution of the countries in global exports of bulk drugs in comparison to what was existent during the early 1990s. Now, China (15 per cent) together with Ireland (14 per cent) and Belgium (11 per cent) exports around 40 per cent of $ 68 billion of global bulk drugs exports (2014-18). The contribution of Germany, US and Switzerland, which were major exporters during early 1990s, slumped to 4.6 per cent, 9.4 per cent and 8 per cent, respectively. Other countries, which have recorded a decline in contribution, are Denmark, France and Italy. Between 1990-94 and 2014-18, the contribution of India in global exports of bulks drugs has increased from merely 1.4 per cent to 5 per cent.

In relation to imports of bulk drugs, US and Germany have remained as significant importers since the early 1990s (Figure 7.3). During the early 1990s, France was the second largest importer of the bulk drugs with almost 18 per cent share but now (2014-18) its import share is around 8 per cent. In the recent years, Belgium has emerged as third highest importer of the bulk drugs, accounting for almost 9 per cent share. In bulk drugs, China accounts for 3.2 per cent share whereas India accounts for 4.6 per cent share of imports.

Table 7.1 depicts major exporters of bulk drugs with respect to share in value and share in quantity in 1992[2] and Table 7.2 presents similar analysis for 2018. In 1992, among the top 11 exporters of bulk drugs three countries, namely, Germany, China and India, had almost similar share in quantity as they had with respect to value (Table 7.1). However, Switzerland had 13 per cent share in value of global bulk drugs' exports whereas it had only 3.8 per cent share in quantity, reflecting higher prices of bulk drugs. Likewise, Japan, Denmark, Spain and Ireland had higher share in value in comparison to share in quantity whereas opposite was true for Korea and Netherlands. Switzerland had third position in world with respect to value of exports but concerning quantity it was at eighth position and its exports constituted around 4 per cent only.

Major differences were observed in global ranking among the principal exporters when compared with respect share in value and quantity in 2018 (Table 7.2). With respect to

Table 7.1: Major Bulk Drug Exporters and Their Shares in 1992

S.No.	Country	Share in value (per cent)	Global Rank with respect of value	Share in quantity (per cent)	Global Rank with respect of quantity
1	Germany	23.4	1	23.2	2
2	US	20.6	2	23.8	1
3	Switzerland	13.1	3	3.8	8
4	Japan	12.3	4	8.7	4
5	Denmark	6.0	5	5.0	6
6	China	5.3	6	5.8	5
7	Spain	3.9	7	1.2	13
8	Ireland	2.8	8	0.4	20
9	Netherlands	2.8	9	4.8	7
10	Korea, Rep.	1.7	10	10.5	3
11	India	1.3	11	1.4	11

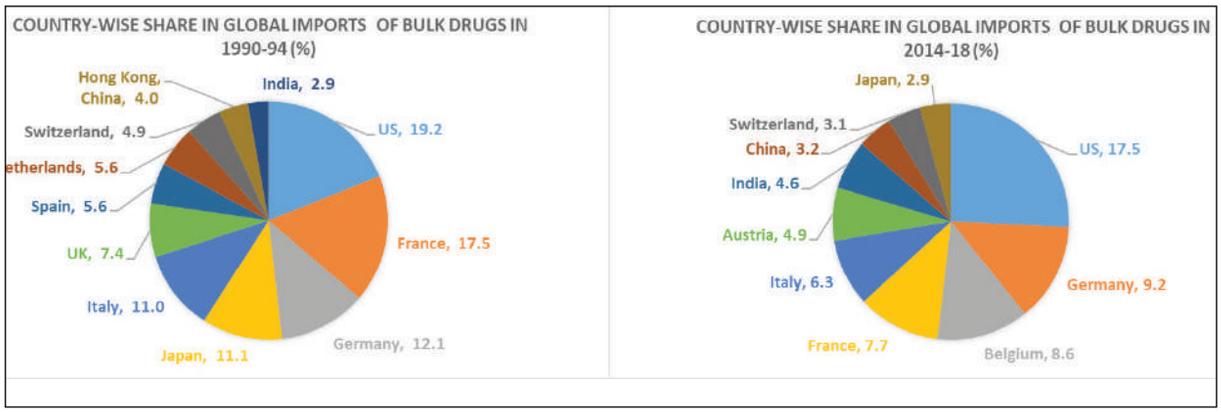
Source: Authors' estimation using WITS, World Bank online database.

share in value, Ireland and Switzerland attained rank 1 and 4, respectively. However, when compared with share in quantity, these two countries would not find place even among the top ten major exporters of bulk drugs as they were exporting less than one per cent of global exports. China has significant price advantage in bulk drugs as reflected by the enormous difference between share in value and share in quantity in 2018. It has also become leading exporter of bulk drugs with an almost one-fourth share in global exports. Similarly, Germany and Netherlands had higher share in quantity in comparison to their shares in value terms. However, opposite was the case with Ireland Belgium, Switzerland, US, India, Singapore and Denmark.

7.2.2 Formulations

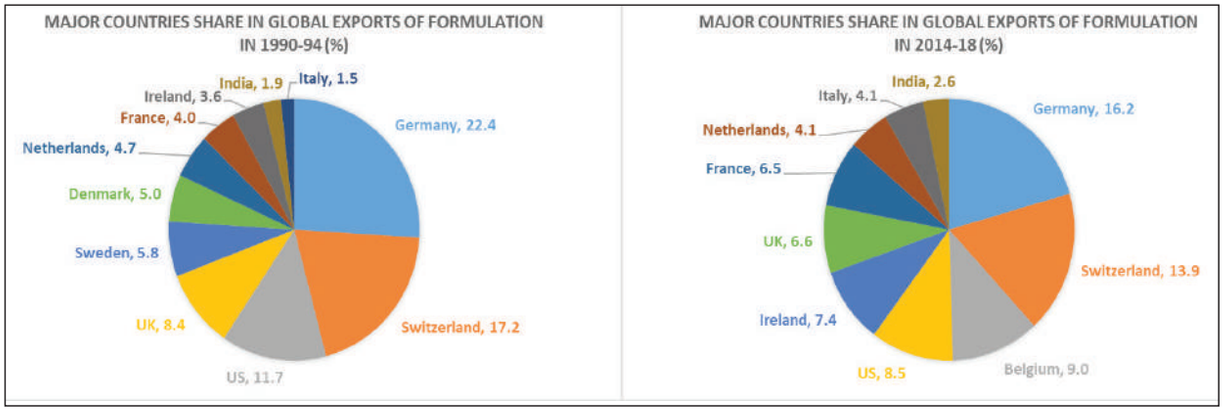
During the early 1990s, three countries, Germany (22.4 per cent), Switzerland (17.2 per cent) and US (12 per cent), were dominating the global exports in formulations as they together accounted for more than 50 per cent share global formulation exports. Other major exporters were United Kingdom (8.4 per cent), Sweden

Figure 7. 3: Country-wise Share in Global Imports of Bulk Drugs in 1990-94 & 2014-18



Source: WITS, World Bank online database.

Figure 7. 4: Country-wise Share in Global Exports of Formulations in 1990-94 & 2014-18



Source: WITS, World Bank online database.

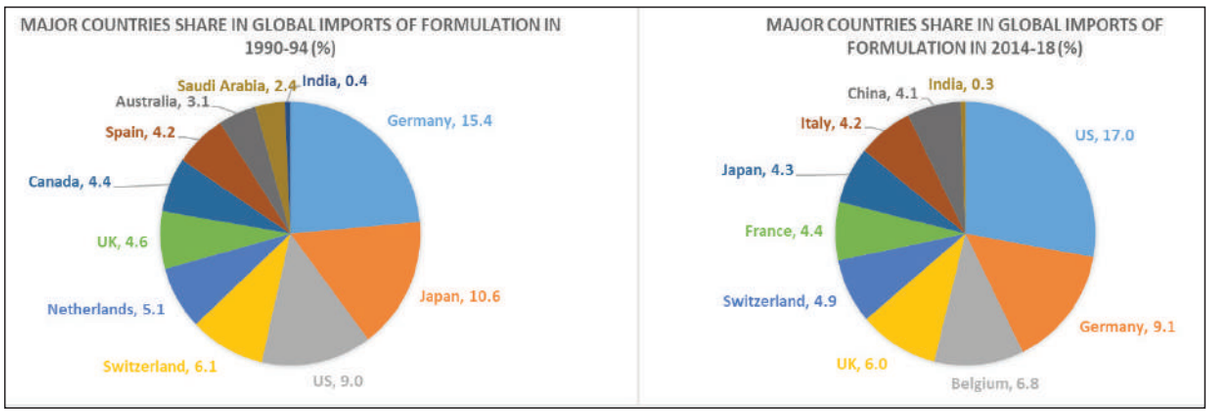
(5.8 per cent), Denmark (5 per cent), Netherlands (4.7 per cent), France (4 per cent) and Ireland (3.6 per cent), which together accounted for more than 31 per cent share while India had just 2.2 per cent share. However, during recent years (2014-18), the global picture with respect to formulation exports have changed significantly. The three countries, Germany, Switzerland and US, which were dominating the formulation exports during the 1990s, registered decline in their shares, which are now at 16 per cent, 14 per cent and 9 per cent respectively (Figure 7.4). Similarly, United Kingdom and Netherlands have recorded decline in share from 8.4 per cent and 4.7 per cent to 6.6 per cent and 4.1 per cent, respectively. Countries, which have recorded increase in shares, are Belgium (9 per cent), France (6.5 per cent), and India (2.6 per cent).

In relation to formulation imports, the share of US has recorded a noteworthy jump from around 9 per cent in 1990-94 to more than 17 per cent in 2014-18 whereas Germany and Japan have registered considerable decline from 15.4 per cent and 10.6 per cent to 9 per cent and 4.3 per cent respectively (Figure 7.5). The share of Switzerland has remained between 5 to 6 per cent while share of UK has increased by 1.4 per cent (from 4.6 per cent to 6 per cent). In recent years (2014-18), Belgium (6.8 per cent), France (4.4 per cent), Italy (4.2 per cent) and China (4.1 per cent) have also emerged as major importers of formulations as they together account for 18 per cent share.

As in the case of bulk drugs, in the case of formulations also there are differences in global ranking of the countries in both the years 1996 and 2018 in their shares in value and quantity terms (Tables 7.3 and 7.4). In 1996, Switzerland was the 3rd major exporter of formulations in terms of value as it was exporting around 11 per cent of $ 55.5 billion world's formulation exports (Table 7.3). However, with respect to quantity, its position was 9th only with about 3.6 per cent share in global quantity of formulation exports. Similarly, United Kingdom, Germany, Belgium-Luxembourg, Sweden and Netherlands had higher shares in the value of global formulation exports in comparison to their shares in volume. For US, Ireland and India, on the other hand, opposite was the case. Pertaining to quantity, India had attained 7th position in the world with around 5 per cent share in global quantity of formulation exports while its position in relation to value of formulation exports was 15th only, reflecting low prices of its formulations.

For Switzerland, significant difference was recorded in global ranking between value of formulation exports and volume in 2018 compared to that in 1992 (Table 7.4). In the

Figure 7. 5: Country-wise Share in Global Imports of Formulations in 1990-94 & 2014-18



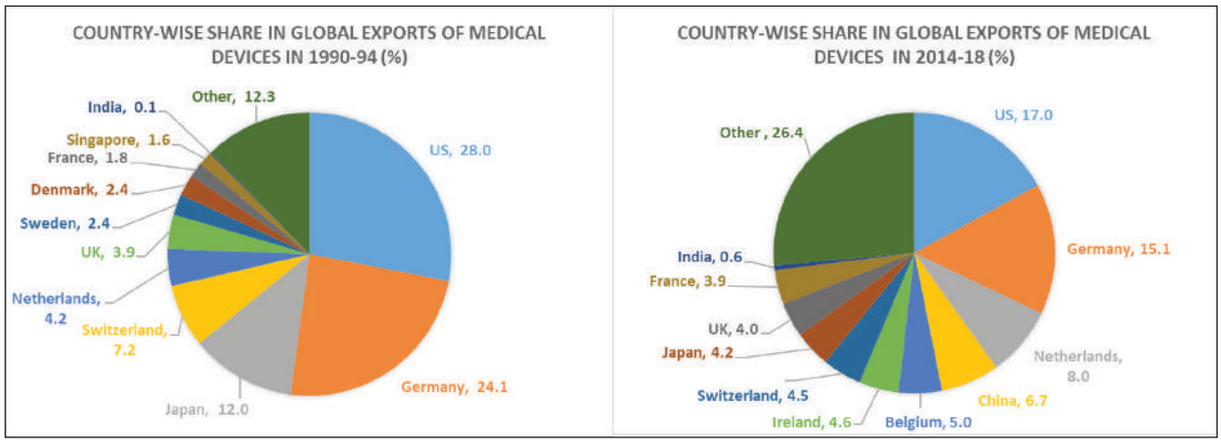
Source: WITS, World Bank online database.

same way, Germany, Ireland, Belgium, US, France, the United Kingdom and Netherlands had higher share in value of global formulations exports in comparison to share in volume while converse was the case with India, Italy and China. India while contributing 2.7 per cent in world's value of formulation exports had attained ninth position in 2018 but with respect to volume it achieved third position as it contributed around 8 per cent.

7.2.3 Medical Devices

This segment has been dominated by two countries, namely, US and Germany for quite long (Figure 7.6). However, major changes have taken place in the country standings between 1990 and 2018. Although US and Germany continued to dominate export market, the share of US has significantly slumped from 28 per cent (out of USD 34 billion) to 17 per cent (out of USD 304 billion) while share of

Figure 7.6: Country-wise Share in Global Exports of Medical Devices in 1990-94 & 2014-18



Source: WITS, World Bank online database.

Table 7.2: Major Bulk Drug Exporters and Their Shares in 2018

S. No.	Country	Share in value (per cent)	Global Rank with respect of value	Share in quantity (per cent)	Global Rank with respect of quantity
1	Ireland	18.2	1	0.1	42
2	China	15.8	2	24.3	1
3	Belgium	14.9	3	13.1	2
4	Switzerland	6.8	4	0.2	35
5	United States	6.5	5	2.3	9
6	India	4.6	6	1.9	11
7	Germany	4.0	7	7.3	4
8	Singapore	3.6	8	0.4	27
9	Denmark	3.5	9	1.6	13
10	Netherlands	2.8	10	5.8	5

Source: Authors' estimation using WITS, World Bank online database.

Germany has declined from around 24 per cent to 15 per cent. Likewise, the share of Japan significantly reduced from 12 per cent to 4.2 per cent and share of Switzerland shrunk by 2.7 per cent. However, the contributions of Netherlands, China, Belgium, and Ireland recorded significant surge. Although, India has less than 1 per cent share in global exports of medical devices, its share has increased from 0.1 per cent to 0.6 during this period.

During the early 1990s, the leading importers of medical devices were two countries, namely, UK (17 per cent) and Germany (15.5 per cent)

Table 7.3: Major Bulk Drug Exporters and Their Shares in 1996[3]

S.No.	Country	Share in value (per cent)	Global Rank with respect of value	Share in quantity (per cent)	Global Rank with respect of quantity
1	Germany	13.9	1.0	10.6	2.0
2	United Kingdom	12.9	2.0	9.3	4.0
3	Switzerland	11.3	3.0	3.6	9.0
4	France	10.9	4.0	11.7	1.0
5	United States	8.5	5.0	9.6	3.0
6	Belgium-Luxembourg	6.9	6.0	4.2	8.0
7	Italy	5.1	7.0	5.3	6.0
8	Sweden	5.0	8.0	2.3	13.0
9	Netherlands	4.3	9.0	2.7	12.0
10	Ireland	4.0	10.0	7.2	5.0
11	India	1.2	15.0	4.8	7.0

Source: Authors' estimation using WITS, World Bank online database.

Table 7.4: Major Bulk Drug Exporters and Their Shares in 2018[4]

S. No.	Country	Share in value (per cent)	Global Rank with respect of value	Share in quantity (per cent)	Global Rank with respect of quantity
1	Germany	17.7	1	14.6	1
2	Switzerland	14.3	2	2.1	12
3	Ireland	10.1	3	3.7	11
4	Belgium	8.8	4	4.7	7
5	United States	7.9	5	4.8	5
6	France	6.3	6	4.6	8
7	United Kingdom	5.5	7	4.4	9
8	Netherlands	4.0	8	1.7	13
9	India	2.7	9	6.3	3
10	Italy	2.6	10	4.8	6
11	China	1.3	16	7.7	2

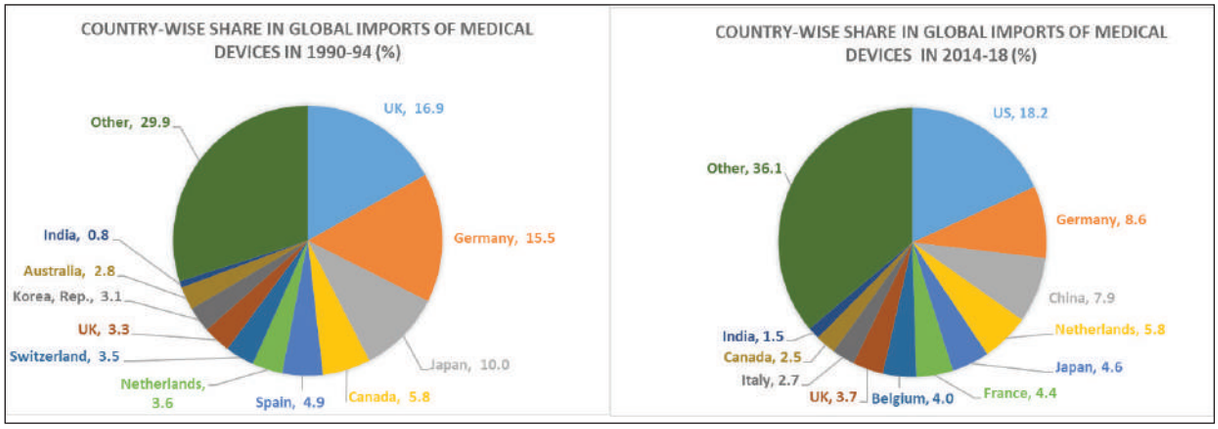
Source: Authors' estimation using WITS, World Bank online database.

as they together imported more than 32 per cent of USD 31 billion (Figure 7.7). In the recent years, however, UK has been replaced by US, which has imported more than 18 per cent of USD 328 billion in 2014-18. In terms of share, the dependence of Germany and Japan on other countries for medical devices declined enormously in the recent years whereas the dependency of China (8 per cent), France (4.4 per cent), Belgium (4 per cent), Italy (2.7 per cent) and India (1.5 per cent) increased.

7.3 Methodology of Trade Data Analysis

The exhaustive list of products pertaining to Formulations, Bulk Drugs and Medical Devices at HS six-digit level have been collected from several studies[5] and finally fine-tuned with the help of industry people.[6] Most of these studies have used Harmonized System (HS) 2002 product classification and reported products of aforesaid categories on that basis. But, use of this product classification (HS 2002) would only assist in constructing data series from 2002 onwards. Therefore, in order to have data for previous years, we have used concordance between Standard International Trade Classification (SITC) 1 and HS 2002, which enabled us to have the data series since 1962 for all three aforementioned categories. While compiling list of SITC pharmaceutical codes using the concordance, we confronted some technical issues. We observed that some identified SITC products include significant number of non-pharma HS products in comparison to pharma HS products. So, in order to avoid significant amount of overestimation, we excluded so identified SITC products from our list of pharmaceutical products. In addition to this, we have also found that few identified SITC products contained large number of pharma HS products besides some non-pharma HS products. In such cases, in order to avoid considerable amount of underestimation, we included such SITC products in our list. From 1988 onwards, we have used HS 1988 product classifications for constructing data series in order to resolve the aforementioned problems. Therefore, for developing long time series, we have used two product classifications, SITC1

Figure 7.7: Country-wise Share in Global Imports of Medical Devices in 1990-94 & 2014-18



Source: WITS, World Bank online database.

for data series from 1962 to 1987 SITC1 and HS 1988 for 1988 to 2018. Following is the list of 25 SITC products, which are categorised into formulations, bulk drugs and medical devices with the help of concordance (SITC 1 and HS 2002) (Table 7.5).

7.4 Trade Profile of Indian Pharmaceutical Industry

7.4.1 Formulations

Before 1970, the Indian pharmaceutical industry was 'underdeveloped' largely due to then

Table 7.5: Categorisation of Products into Formulations, Bulk Drugs and Medical Devices based on SITC1

S.No.	Category	SITC	SITC Description
1	Bulk Drugs	5411	Vitamins and provitamins
2	Bulk Drugs	5413	Penicillin streptom. Tyrocidine&oth. Antibiot
3	Bulk Drugs	5414	Alkaloids of opium, cocaine, caffeine, quinine etc.
4	Bulk Drugs	5415	Hormones
5	Bulk Drugs	51226	Glycerol and glycerol lyes
6	Bulk Drugs	51286	Sulphonamides
7	Bulk Drugs	51292	Sugars, chem. pure excl. sucrose glucose lactose
8	Bulk Drugs	54161	Glycosides and their derivatives
9	Formulations	5417	Medicaments
10	Formulations	51291	Enzymes
11	Formulations	54162	Organo therapeutic glands/organs & extracts
12	Formulations	54163	Bacterial products, sera, vaccines
13	Medical Devices	6293	Hygienic & pharmaceutical articles of rubber
14	Medical Devices	7261	Electro medical apparatus
15	Medical Devices	7262	X ray apparatus
16	Medical Devices	8416	Apparel & clothing acces., gloves, of rubber
17	Medical Devices	54191	Bandages, etc. impregnated/coated with pharm.pro.
18	Medical Devices	54199	Other pharmaceutical goods
19	Medical Devices	82102	Medical furniture, etc. parts thereof
20	Medical Devices	86171	Medical instruments &app.exc. electro medical
21	Medical Devices	86172	Mechano therapy appliances, etc
22	Medical Devices	86194	Technical models for demonstrating
23	Medical Devices	86196	Hydrometers, thermometers, etc.
24	Medical Devices	89961	Hearing aids
25	Medical Devices	89962	Orthopaedic appl. artificial parts of the body

Source: Authors' estimation using HS 1988 and SITC concordance.

prevailing product patent regime. Under this regime, India was heavily dependent on MNCs for its domestic requirement of formulations and bulk drugs. These MNCs, instead of manufacturing drugs domestically, were importing most of them. This is very well depicted in Figure 7.8. The import value of formulations stood at $ 12 million in 1966, which increased further close to $ 18 million in 1972. In comparison to imports, exports were significantly lower. The position changed significantly after 1972, with the new patent law coming into effect. The impact of the new regime on exports of formulations can easily be visualised from Figure 7.8. The formulation exports grew at around 21 per cent CAGR between 1973 and 1977, and since then they were increasing at a steady 33 per cent CAGR until 1984 and then declined in following two years (1985 and 1986). The main reason behind this sharp decline in formulation exports was the dramatic slump in exports to Russian Federation, which had been importing almost 50 per cent of India's formulation exports in 1984. Apart from this, formulation exports to Netherlands, US, France and Nigeria also declined in 1985.

The formulation exports recorded major turnaround after 1986 when it started to grow at much higher pace and reached $ 409 million in 1990 in just four years from $ 117 million in 1986, accounting for 37 per cent CAGR. As a result, India embarked on consistent and growing trade surplus in formulation since 1986. During this period, the share of Indian formulation exports in global exports registered a sharp jump from less than 1 per cent in 1986 to 5 per cent in 1989.

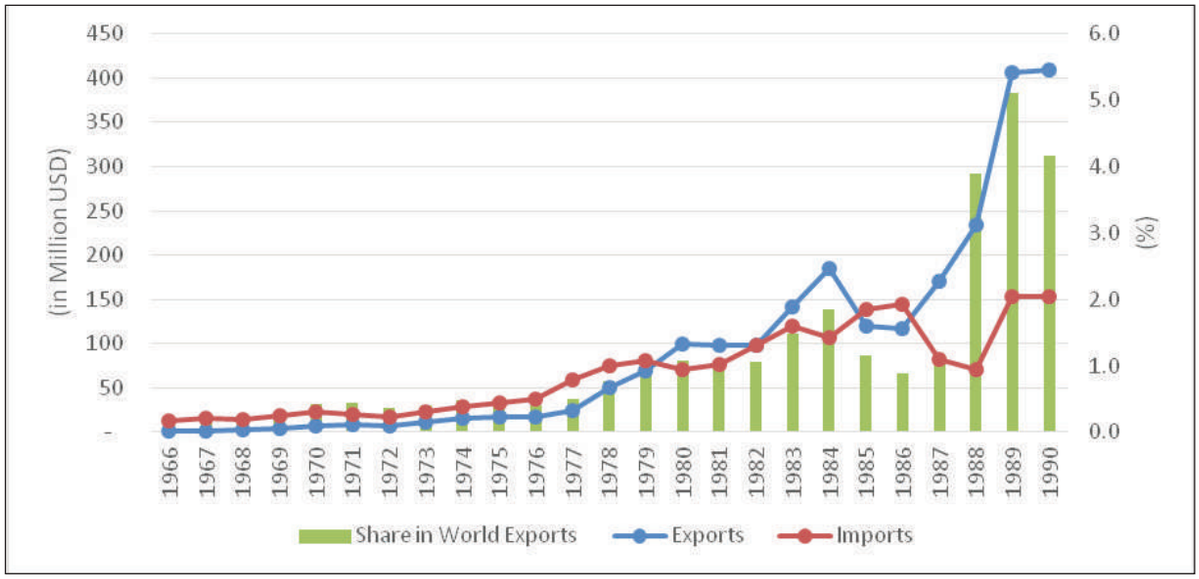
After 1972, the imports of formulations had remained much higher in comparison to its exports, till 1979. Since then, however exports were more than or equal to imports except in years 1985 and 1986. India's imports of formulations registered a sharp decline of $ 70 million in 1987 over previous year 1986 ($ 131 million) due to sharp drop in imports from Italy followed by Germany, US, Switzerland, UK, Japan, Spain and France. In 1989, India's imports of formulations reverted to the level of 1986.

Even after liberalisation (1991), Indian exports of formulations were growing remarkably as it had been growing in earlier phase (Figure 7.9). However, its share in global exports of formulations registered a significant decline and it kept on declining until 2004. Since then, though product patents regime for pharmaceuticals was introduced in 2005, India's share in formulations has grown consistently and increased from around one per cent in 2004 to 2.7 per cent in 2018. In this segment, India has attained distinct position in the world economy as its exports have increased enormously from less than $ 0.5 billion in the early 1990s to more than $ 14 billion in 2018. In formulation trade, India's trade surplus has increased from merely around $ 300 million in the early 1990s to more than $ 11.5 billion in 2018. However, it is important to note that Indian exports of formulations also did not remain unaffected by US financial crisis in 2009 and European Union crisis in 2013.

In 1996, Russian Federation was India's prime export destination both with respect to value (14.7 per cent) and volume (13.7 per cent) (Table 7.6). With respect to value, other important destinations were Germany (7.3 per cent), US (7.2 per cent), Hong Kong (5.4 per cent), and Nigeria (5 per cent). We observed significant difference in ranking of the major countries in relation to value and volume. For instance, Germany was third major export destination in terms of value whereas it was at fifth position with respect to volume. The sequence of major countries in descending order pertaining to volume was Nigeria (8.4 per cent), Nepal (7 per cent), Sri Lanka (6.6 per cent), Germany (6 per cent), and US (5.8 per cent).

In 2018, US has emerged as most important destination for India's formulation exports both

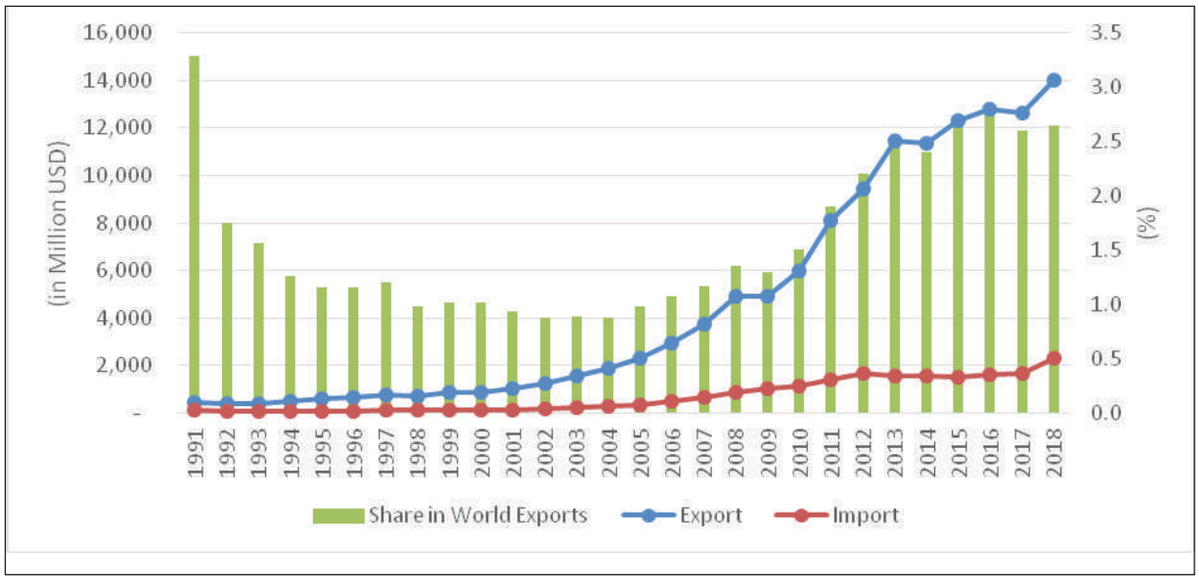
Figure 7.8: India's Global Trade in Formulations (Million USD) and Share in World Exports (%): 1966 to 1990



Source: Authors' Estimation using WITS, World Bank online database.

Note: Line-graphs are shown on Primary axis and Bar-chart on Right-hand axis.

Figure 7.9: India's Global Trade in Formulations (Million USD) and Share in World Exports (%): 1991 to 2019



Source: Authors' Estimation using WITS, World Bank online database.

Note: Line-graphs are shown on Primary axis and Bar-chart on Right-hand axis.

Table 7.6: Major Destinations for Formulation Exports in terms of Value and Quantity in 1996

S.No.	Country	Share in value (per cent)	Rank with respect of value	Share in quantity (per cent)	Rank with respect of quantity
1	Russian Federation	14.7	1	13.7	1
2	Germany	7.3	2	6.0	5
3	United States	7.2	3	5.8	6
4	Hong Kong, China	5.4	4	1.9	13
5	Nigeria	5.1	5	8.4	2
6	Netherlands	3.9	6	3.0	8
7	Vietnam	3.7	7	3.0	7
8	Nepal	3.2	8	7.0	3
9	United Kingdom	3.2	9	2.2	10
10	Sri Lanka	3.1	10	6.6	4
	Total in India's global exports (%)	**56.8**		**57.6**	

Source: Authors' estimation using WITS, World Bank, online database.

Table 7.7: Major Destinations for Formulations 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	United States	35.1	1	18.0	1
2	United Kingdom	3.9	2	4.4	3
3	South Africa	3.8	3	2.6	6
4	Nigeria	3.0	4	5.1	2
5	Russian Federation	2.9	5	2.2	10
6	Brazil	1.8	6	0.7	35
7	Australia	1.7	7	1.4	20
8	Canada	1.7	8	0.6	38
9	Kenya	1.6	9	2.5	8
10	Philippines	1.5	10	2.1	11
	Total	57.0		39.6	

Source: Authors' estimation using WITS, World Bank, online database.

with respect to value (35 per cent) and volume (18 per cent) (Table 7.7). Both United Kingdom and South Africa each accounted for almost 4 per cent share in value of formulation exports while Nigeria and Russian Federation each had about 3 per cent share. Major difference was observed in rankings of the major export destinations with respect to share in value and volume in India's exports of formulations in 2018, as had been the case in 1996. For instance, South Africa was 3rd major destination in relation to value of formulation exports but it was at 6th position with respect to volume.

Within formulations, HS 300490 (other medicaments of mixed or unmixed products) alone accounted for almost 46 per cent share in India's formulation exports (USD 659 million) in 1996 (Table 7.8). The major destinations for this product were Russian Federation (20.2per cent), Germany (7.5 per cent), United States (6.8 per cent), Nepal (5.1 per cent), and Nigeria (3.9 per cent). In India's export basket of formulations, the other important products were HS 300390, HS 300420 (Medicaments of other antibiotics) and HS 300410 (Medicaments of penicillin), which together constituted around 42 per cent share. These products were largely exported to US, Russian Federation, Germany, Hong Kong China, Vietnam, Nigeria, etc. Between 1 to 4 per cent share was captured by HS 300450 (Other medicaments of vitamins), HS 300439 (Medicaments of other hormones), HS 300220 (Vaccines for human medicine) and HS 300440 (Medicaments of alkaloids or derivatives).

US was a major export destination in most of the formulations in 2018 (Table 7.9). For instance, US has about 40 per cent share in 'other medicaments of mixed or unmixed products' (HS 300490); 35 per cent share in medicaments of other antibiotics (HS 300420) exports; 24 per cent in medicaments of penicillin (HS 300410); 23 per cent share in other medicaments (HS 300390), etc. As in 1996, HS 300490 (other medicaments of mixed or unmixed products) dominated India's exports of formulations also in 2018. This one product alone accounted for more than three-fourth share in India's global exports of formulations ($ 14 billion) and this product was exported to 203 countries, including US (39 per cent), UK (4 per cent), South Africa (4 per cent), Russian Federation (3 per cent) and Nigeria (2.4 per cent). Medicaments of other antibiotics (HS 300420), vaccines for human medicine (HS 300220) and medicaments of penicillin

Table 7.8: Major Formulations Exported in 1996, their Share and Main Destinations.

S. No.	HS code	Description	Share (per cent)	Count of Countries	Top Five Destinations and their shares (per cent in brackets)
1	300490	Other medicaments of mixed or unmixed products	45.9	147	Russian Federation (20.2), Germany (7.5), US (6.8), Nepal (5.1), Nigeria (3.9)
2	300390	Other medicaments with >=2 constituents, not fo	17.8	129	US (14.4), Russian Federation (12), Germany (6.1), UK (4.7), Nigeria (4.6)
3	300420	Medicaments of other antibiotics, for retail sa	12.4	112	Hong Kong, China (22.3), Iran Islamic Rep. (10.8), China (9.5), Vietnam (5.9), Russian Federation (5.7)

Table 7.8 continued...

Table 7.8 continued...

4	300410	Medicaments of penicillin... or streptomycin.	11.5	101	Germany (13.9), Nigeria (11.1), Vietnam (8.2), Russian Federation (4.9), Netherlands (4.6)
5	300450	Other medicaments of vitamins or other products	4.2	99	Nigeria (15.8), Russian Federation (10.5), Germany (9.6), UK (6.3), Sri Lanka (6.3)
6	300439	Medicaments of other hormones, for retail sale,	2.9	76	Netherlands (22), Russian Federation (11.2), South Africa (10.9), Vietnam (8.2), Sri Lanka (5.6)
7	300220	Vaccines for human medicine	1.7	76	Brazil (19.5), Bahrain (12.6), Egypt (8.6), Bangladesh (8.4), United States (6.7)
8	300440	Medicaments of alkaloids or derivatives thereof	0.9	50	Russian Federation (44.2), US (27.5), Hong Kong, China (3.5), Mexico (3.1), Ghana (1.6)
9	300290	Human and animal blood; microbial cultures; tox	0.8	75	Russian Federation (16), Italy (10.4), Netherlands (7.9), UK (7.2), US (4.5)
10	300431	Medicaments of insulin, for retail sale	0.4	5	Russian Federation (97.9), Uganda (1.4), Tanzania (0.4), Sri Lanka (0.1), Maldives (0.1)

Source: Authors' estimation using WITS, World Bank, online database.

(HS 300410) together constituted 16 per cent share and they were exported to 187, 172 and 181 countries respectively. For medicaments of other antibiotics (HS 300420), major destinations were US (36 per cent), South Africa (4 per cent), Belgium (3.4 per cent), Nigeria (3.3 per cent) and Russian Federation (3.3 per cent) while for vaccines for human medicine (HS 300220) key destination were Nigeria (8 per cent), Indonesia (7 per cent), Pakistan (5.4 per cent), Brazil (5.2 per cent) and Iraq (4 per cent).

In 1996, India's import of formulations costing $ 59 million was significantly lower in comparison to its exports (Table 7.10). HS 300490 (other medicaments of mixed or unmixed products) was the major import as it accounted for 37 per cent share in formulation imports. This product was largely sourced from two countries, namely, Nepal (37 per cent) and Switzerland (25 per cent). Two HS products, [300220 (Vaccines for human medicine) and 330390 (Other medicaments with >=2 constituents)] together accounted for more

Table 7.9: Major Formulations Exported in 2018, their shares and main destinations.

S. No.	HS code	Description	Share (per cent)	Count of Countries	Top Five Destination
1	300490	Other medicaments of mixed or unmixed products,	76.7	203	US (39.3), UK (4.2), South Africa (4.2), Russian Federation (3.2), Nigeria (2.4)
2	300420	Medicaments of other antibiotics, for retail sa	7.2	187	US (35.6), South Africa (3.9), Belgium (3.4), Nigeria (3.3), Russian Federation (3.3)
3	300220	Vaccines for human medicine	4.8	172	Nigeria (8.1), Indonesia (6.9), Pakistan (5.4), Brazil (5.2), Iraq (3.7)
4	300410	Medicaments of penicillins... or streptomycins.	3.5	181	US (24.1), UK (5.8), South Africa (5.4) Nigeria (4.9), Australia (3.9)
5	300390	Other medicaments with >=2 constituents, not fo	2.2	170	US (23), Netherlands (5.4), Germany (4.9), UK (4.2), Brazil (3.5)
6	300450	Other medicaments of vitamins or other products	1.7	162	Nigeria (11.5), Congo, Dem. Rep. (7.7), US (7.3), Myanmar (5.3), Ghana (5)
7	300290	Human and animal blood; microbial cultures; tox	1.4	169	US (11.9), Ethiopia(excludes Eritrea) (5.9), Canada (5.8), UK (5.4), Sri Lanka (4.5)
8	300431	Medicaments of insulin, for retail sale	0.9	162	US (26.5), Germany (7.3), South Africa (6), Malta (4.2), Thailand (3.2)
9	300439	Medicaments of other hormones, for retail sale,	0.6	168	US (20.5), UK (10), Singapore (6.1), Nigeria (5.4), Russian Federation (4)
10	300432	Medicaments of adrenal cortical hormones, for r	0.4	141	US (33.9), South Africa (6.2), Nepal (4.7), Algeria (4.5), Myanmar (2.9)

Source: Authors' estimation using WITS, World Bank, online database.

than 31 per cent share. India mainly imported HS 300220 (Vaccines for human medicine) from Germany (30 per cent), Belgium-Luxembourg (19.1 per cent), France (17.9 per cent) while HS 330390 (Other medicaments with >=2 constituents) mainly sourced from Switzerland (29 per cent) and Germany (18 per cent). HS 300290 (Human and animal blood; microbial cultures) constituted more than 10 per cent share in India's imports of formulation and it was mainly imported from Germany (42 per cent), Belgium-Luxembourg (19.3 per cent) and France (16.6 per cent). Other major HS products which India imported in 1996 were HS 300210 (Antisera and other blood fractions), HS 300439 (Medicaments of other hormones, for retail sale), and HS 300339 (Medicaments of other hormones, not for retail sale).

In 2018, India imported about $ 2.3 billion of formulations (Table 7.11). In $ 2.3 billion, 39 per cent share was captured by HS 300490 (other medicaments of mixed or unmixed products), 21 per cent by HS 300290 (Human and animal blood; microbial cultures), 16 per cent by HS 300220 (Vaccines for human medicine), 10 per cent by HS 300431 (Medicaments of insulin) while HS 300439 (Medicaments of other hormones), HS 300420 (Medicaments of other antibiotics), HS 300190 (Substances of human or animal origin), HS 300390 (Other medicaments with >=2 constituents) accounted shares between 2 per cent to 4per cent.

Potential Markets for Pharmaceutical Formulations

While India is perceived as a major exporter of pharmaceutical formulations, its reach is not optimum. The share of Indian formulation exports in the imports of 33 countries (Table 7.12) is below less than or around one per cent of their total drug imports. Indian pharmaceutical firms have the potential to compete with the companies already catering to these developed and developing markets as it has been doing in the US market. Africa and South America are also regions Indian generic pharma has not fully tapped.

7.4.2 Bulk Drugs

Although the exports of bulk drugs had registered inconsistent marginal improvement after implementation of Patents Act, 1970 in 1972 and FERA in 1973, notable increase took place only after 1987. From this, it can be assumed that various conditions stipulated in Drug Policy 1978 on FERA companies and Non-FERA companies to enhance the domestic production of bulk drugs were successful only in meeting domestic requirement of bulk drugs but not with respect to promoting exports. These conditions were made more stringent in Drug Policy 1986. In the absence of any other major policy intervention, one will have to study a whole host of issues such as international scenario, including domestic and international price differences, and gestation periods of new manufacturing capacities within the country to identify exact causes of the spurt in export growth. Be that as it may, the exports of bulk drugs increased from $ 7 million in 1987 to $ 81 million, 1990 which led to significant improvement in India's share in global exports of bulk drugs from 0.2 per cent to 1.4 per cent (Figure 7.10). At the same time, India's bulk drug imports had remained consistently higher in comparison to its exports leading to increased trade deficit since 1985.

Even after liberalisation, trade deficit in bulk drugs continued until 1996 although exports were also growing (Figure 7.11). A turnaround came in 1997, when exports over took imports in absolute terms and India had trade surplus in bulk drugs. The country continued to maintain this trade surplus until 2014. Consequently, India's share in global exports of bulk drugs increased from 1.3 per cent in the early 1990s to around 7 per cent in 2012. During the same period, India's bulk drug exports had increased

Table 7. 10: Major Formulations Imported in 1996, their share and main Sources.

S.No.	HS code	Description	Share (per cent)	Count of Country	Top Five Sources
1	300490	Other medicaments of mixed or unmixed products,	37.0	32	Nepal (37), Switzerland (25.1), US(6.3), Germany (5.8), Sweden (3.9)
2	300220	Vaccines for human medicine	17.5	17	Germany (30.2), Belgium-Luxembourg (19.1), France (17.9), Italy (9.8), UK (9.2)
3	300390	Other medicaments with >=2 constituents, not fo	14.0	25	Switzerland (29.2), Germany (18.1), US (11), Italy (8.3), Sweden (7.7)
4	300290	Human and animal blood; microbial cultures; tox	10.4	17	Germany (41.5), Belgium-Luxembourg (19.3), France (16.6), US (8.8), Ireland (3.1)
5	300210	Antisera and other blood fractions	5.3	19	US (31), Netherlands (21.8), Italy (16), Korea, Rep. (11.1), Germany (5.8)
6	300439	Medicaments of other hormones, for retail sale,	4.7	15	Netherlands (42.1), Italy (38.3), Denmark (10.3), China (1.9), Hong Kong, China (1.9)
7	300339	Medicaments of other hormones, not for retail s	2.6	6	Italy (95per cent), UK (1.8), Germany (1.8), Netherlands (0.8), Korea, Rep. (0.7)
8	300420	Medicaments of other antibiotics, for retail sa	2.2	14	US (41.9), France (16), Switzerland (13.7), Belgium-Luxembourg (13.2), Italy (5.1)
9	300239	Other vaccines for veterinary medicine (excl. f	2.0	6	Netherlands (72.6), US (19.6), Germany (4.6), Italy (2.5), Russian Federation (0.4)
10	300190	Substances of human or animal origin.	1.0	9	Korea, Rep. (62.7), Malaysia (8.9), Germany (7.1), Korea, Dem. Rep. (5.2), Other Asia, nes (not elsewhere specified) (5.1)

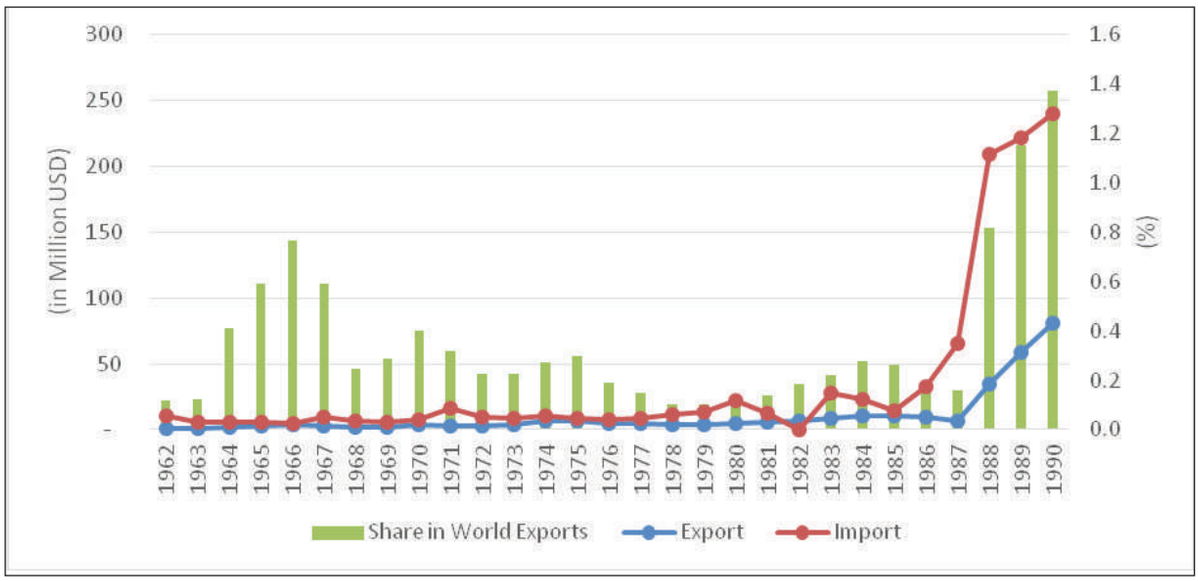
Source: Authors' estimation using WITS, World Bank, online database.

Table 7.11: Major Formulations Imported in 2018, their share and main Sources

S.No.	HS code	Description	Share (per cent)	Count of Countries	Top Five Sources
1	300490	Other medicaments of mixed or unmixed products,	39.1	81	US (22.8), Switzerland (18.9), Germany (13.5), UK (5.7), Singapore (4.8)
2	300290	Human and animal blood; microbial cultures; tox	21.2	62	US (21.2), Switzerland (17.4), Germany (14.9), France (8.3), Italy (6.3)
3	300220	Vaccines for human medicine	15.9	29	Belgium (32.1), Indonesia (22.1), France (21.2), UK (6.3), China (5.1)
4	300431	Medicaments of insulin, for retail sale	9.8	18	Brazil (32.4), Denmark (22.5), Italy (15.5), Germany (14.9), Belgium (8.8)
5	300439	Medicaments of other hormones, for retail sale,	3.4	17	Switzerland (33.7), US (11.7), Germany (11.3), Belgium (10.5), Netherlands (9.5)
6	300420	Medicaments of other antibiotics, for retail sale	2.5	29	Belgium (24), Switzerland (22.8), US (17.8), Netherlands (7.5), Other Asia, nes (6.6)
7	300190	Substances of human or animal origin	2.4	9	China (87.6), US (7.2), Belgium (4.7), Germany (0.3), Brazil (0.1)
8	300390	Other medicaments with >=2 constituents.	2.4	28	Germany (25.4), Canada (16), China (15.4), Belgium (14.3), Nepal (12.5)
9	300239	Other vaccines for veterinary medicine	1.2	14	Netherlands (27.7), Israel (24.4), US (13.8), Belgium (8.8), Brazil (6.8)
10	300410	Medicaments of penicillins... or streptomycins.	0.8	31	US (55.2), China (11.4), UK (8), Spain (7.5), Italy (6)

Source: Authors' estimation using WITS, World Bank, online database.

Figure 7.10: India's Global Trade in Bulk Drugs (Million USD) and Share in World Exports (%): 1962 to 1990



Source: Authors' Estimation using WITS, World Bank online database.

Note: Line-graphs are shown on Primary axis and Bar-chart on Right-hand axis.

from around $ 123 million to more than $ 4.5 billion whereas its imports increased from $ 217 million to more than $ 3.2 billion. However, India's exports of bulk drugs dramatically fell in absolute terms by around $ 586 million in 2013 and $ 660 million in 2014. In 2013, the US alone accounted for one-fourth share in total decline of India's global exports of bulk drugs followed by Israel (12 per cent), Singapore (8.3 per cent), Canada (6.7 per cent), and Turkey (3.6 per cent). It is mainly decline in exports of one product, namely, HS 294200 (Cefadroxil, Ibuprofen, Nifedipine, Ranitidine etc), which has caused this decline and to some extent fall in exports of HS 294190 (Other antibiotics, nes) also contributed to that decline.

Likewise, in 2014, India's exports of bulk drugs to both US (9.8 per cent) and China (10 per cent) declined by 20 per cent while exports to Germany, Turkey and Israel declined by 6 per cent, 5 per cent and 4.4 per cent respectively. India's exports of HS 294200 (Cefadroxil, Ibuprofen, Nifedipine, Ranitidine, etc) to US, Germany and Turkey further declined in 2014 while, to China, it was exports of HS 290611 (Menthol). The decline in exports of bulk drugs for two consecutive years changed India's position as a trade surplus country in bulk drugs to again a deficit country.

The decline in exports continued for two more years (2015 and 2016), but decline in imports was sharper in comparison to exports, resulting in trade surplus. In 2016, India's imports of bulk drugs declined by $ 470 million. The major part of this decline in imports was largely owing to decline in imports from China ($ 345 million) followed by Germany ($ 32 million) and US ($ 13.5 million). From China, the imports of HS 294200 (Cefadroxil, Ibuprofen, Nifedipine, Ranitidine,etc) declined by $ 216 million; HS 291521 (Acetic acid) by $ 68 million; and HS 294190 (Other antibiotics, nes) by $ 40 million. From Germany, it is the decline of HS 294200 (Cefadroxil, Ibuprofen, Nifedipine, Ranitidine, etc.) that largely explains slump in imports whereas, for US, it was fall in imports of HS 294150 (Erythromycin and its derivatives).

Table 7.12: Identified Potential Markets for India's formulation Exports

S. No.	Country	Country's Average Global Imports ($ million) (2015-19)	Country's Average Imports from India ($ million) (2015-19)	India's Share in Country's Global Imports (%)
1	Germany	49,393	336	0.68
2	Belgium	36,810	170	0.46
3	United Kingdom	30,403	488	1.60
4	Switzerland	27,001	20	0.07
5	China	24,454	33	0.14
6	Japan	23,679	55	0.23
7	Italy	23,112	34	0.15
8	France	22,233	133	0.60
9	Spain	14,230	81	0.57
10	Lebanon	8,570	15	0.17
11	Sweden	4,141	12	0.29
12	Denmark	3,434	12	0.34
13	Greece	3,014	4	0.14
14	Portugal	2,636	6	0.23
15	Israel	2,168	4	0.20
16	Slovak Republic	1,875	9	0.45
17	Kuwait	1,207	5	0.45
18	Lithuania	1,122	3	0.27
19	Panama	795	6	0.74
20	Latvia	626	3	0.56
21	Qatar	553	4	0.78
22	Estonia	453	2	0.39
23	Luxembourg	443	0.01	0.00
24	Bosnia and Herzegovina	313	2	0.58
25	Cyprus	243	1	0.53
26	Macao	187	1	0.33
27	Albania	102	0.5	0.45
28	Brunei	72	0.3	0.43
29	Montenegro	62	0.04	0.06
30	Aruba	28	-	0.00
31	Andorra	27	-	0.00
32	Bermuda	23	0.02	0.08
33	Greenland	12	-	0.00

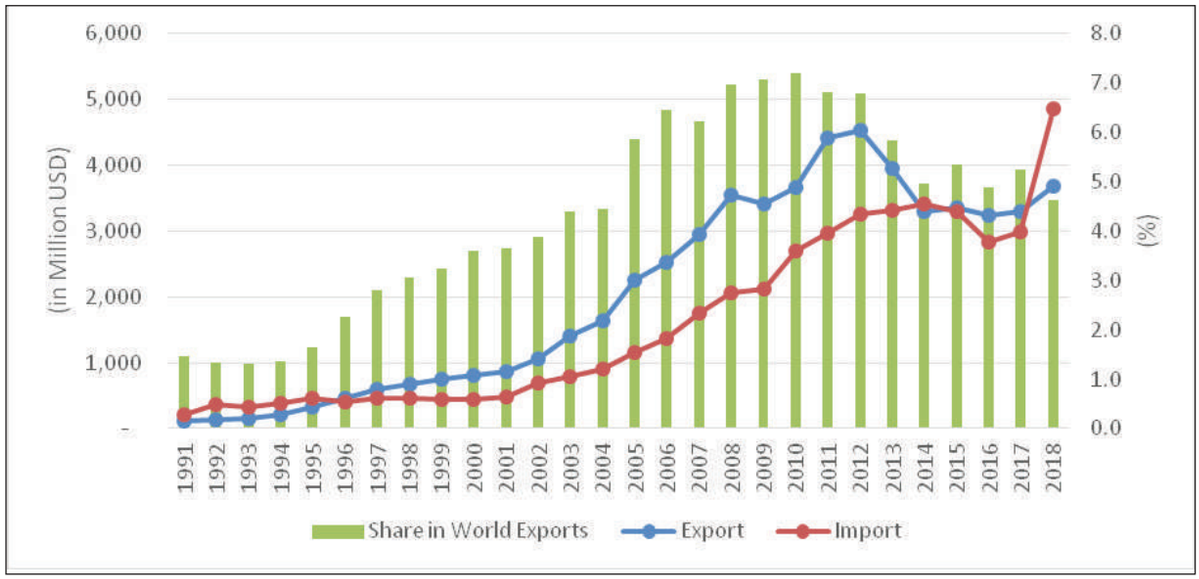
Source: Authors' Estimation using WITS, World Bank online database.

Since 2017, both exports and imports recovered but the increase in imports was significant. In 2018, India's imports of bulk drugs increased by $ 1.8 billion over previous year and reached $ 4.8 billion while its exports were slightly more than $ 3.6 billion, showing continued deficit trade in this industry segment.

In 1992, India exported $ 140 million of bulk drugs. Three countries, Germany (15 per cent), US (12 per cent) and Japan (9 per cent) had more than 34 per cent share in India's global exports of bulk drugs (Table 7.13). Of the remaining, four countries, namely, Switzerland, Singapore, Hong Kong, China and Italy, each had between 4 to 5 per cent share while Bangladesh, United Kingdom and Spain each had shares between 3 to 4 per cent. Massive difference is observed in ranking of major destinations with respect share in value and quantity of bulk drugs exported. With respect to share in value Switzerland was at 4th position in India's export, whereas volume-wise it was at 12th position. Similarly, United Kingdom was at 9th position in relation to value but was at 4th position with respect to volume. In volume terms, US had largest share (17 per cent) in India's exports of bulk drugs followed by Germany (9 per cent), Japan (7 per cent), United Kingdom (6.2 per cent), etc.

In 2018, however, China has emerged as a leading export destination with more than 9 per cent share in India's global exports of bulk drugs ($ 3.67 billion) (Table 7.14). Likewise, Brazil, Netherlands, and Turkey are also now among the leading destinations. In 1992, US and Germany were the two leading destinations, but in 2018 they are at positions 2 and 3. In 2018, we have also found difference in ranking of major destinations with respect to share in value and quantity of bulk drugs exported as observed previously in 1992. 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), Bangladesh (3.8 per cent), and so on which is quite different from the list in relation to value.

Figure 7. 11: India's Global Trade in Bulk Drugs (Million USD) and Share in World Exports (%): 1991 to 2018



Source: Authors' Estimation using WITS, World Bank online database.

Note: Line-graphs are shown on Primary axis and Bar-chart on Right-hand axis.

Table 7.13: Major Destinations for Bulk Drugs in terms of Value and Quantity in 1992

S. No.	Country	Share in value (per cent)	Rank with respect of value	Share in quantity (per cent)	Rank with respect of quantity
1	Germany	14.7	1	9.2	2
2	United States	11.7	2	17.0	1
3	Japan	8.5	3	7.2	3
4	Switzerland	4.9	4	2.3	12
5	Singapore	4.6	5	5.9	5
6	Hong Kong, China	4.4	6	2.9	9
7	Italy	4.2	7	2.3	11
8	Bangladesh	3.8	8	1.4	18
9	United Kingdom	3.1	9	6.2	4
10	Spain	3.1	10	1.4	17

Source: Authors' estimation using WITS, World Bank, online database.

Table 7.14: 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: WITS, World Bank, online database.

Out of $ 140 million exports of bulk drugs in 1992, almost 38 per cent was accounted by HS 294200 (Other organic compounds such as Cefadroxil, Ibuprofen, Nifedipine, Ranitidine, etc.), around 10 per cent by HS 294110 (Penicillin and derivatives), and 8 per cent by each HS 290611 (Menthol)& HS 293500 (Sulphonamides). (Table 7.15). While HS 294190 (Other antibiotics such as Rifampicin, Cephalexin, Ciprofloxacin, etc. and their salts), HS 293970 (Nicotine and its salts) and HS 292229 (Amino-naphthols) occupied around 5 per cent share. In 2018, while the share of HS 294200 (Other organic compounds such as Cefadroxil, Ibuprofen, Nifedipine, Ranitidine, etc) declined to around 31 per cent in India's bulk drug exports ($ 3.67 billion), it remained leading bulk drug among the major bulk drug exports of India (Table 7.16). The share of HS 294190 (Other antibiotics such as Rifampicin, Cephalexin, Ciprofloxacin, etc. and their salts) increased significantly to more than 14 per cent but share of HS 294110 (Penicillins and derivatives) and HS 293500 (Sulphonamides) declined to around 5 per cent and the share of HS 292229 (Amino-naphthols) remained at around 5 per cent.

With respect to value, Germany, Italy, Netherlands and United States were major leading sources of India for bulk drugs ($ 355 million) in 1992 as they were contributing 12 per cent, 11per cent, 9 per cent and 7.3 per cent respectively (Table 7.17**).** The contribution of Denmark, Japan and United Kingdom was in the range of 5 to 57 per cent. However, in relation to volume, the leading contributors were Germany, United Kingdom and Japan with shares 14 per cent, 12 per cent and 10 per cent, respectively.

Over time, however, India's dependence on developed countries for its bulk drugs requirement has declined and its reliance on China has significantly increased as India imported over 60 per cent of its value of bulk drugs ($ 4.8 billion) from China in 2018 and 39 per cent of its volume of imports (Table 7.18). Singapore and Malaysia are two other countries, which have emerged as important sources in India's bulk drug imports as they have supplied 22 per cent and 23 per cent of the total bulk drug imports in terms of volume respectively and their shares in relation to value are 5.6 per cent and 5.3 per cent, respectively. Among the developed countries, the share of US, Italy and Germany are in the range of 2 to 4 per cent while the contribution of Spain, Netherlands and Denmark are between 1.5 and 2 per cent.

In 1992, HS 294200 (Other organic compounds such as Cefadroxil, Ibuprofen, Nifedipine, Ranitidine etc.) (30 per cent), HS 294190 (Other antibiotics such as Rifampicin, Cephalexin, Ciprofloxacin, etc. and their salts) (23 per cent) and HS 294110 (Penicillin and derivatives) (23 per cent) together occupied three-fourth share in India's bulk drugs imports ($ 355 million) (Table 7.19). HS 294200 (Other organic compounds such as Cefadroxil, Ibuprofen, Nifedipine, Ranitidine, etc.) was mainly sourced from Japan (12.5 per cent), Germany (10.5 per cent), Netherlands (10.2 per cent), HS 294110 (Penicillin and derivatives) largely from Germany (24.4 per cent), Netherlands (23.8 per cent) and HS 294190 (Other antibiotics such as Rifampicin, Cephalexin, Ciprofloxacin, etc. and their salts) mainly from Italy (29.2 per cent), Korea, Rep. (12.5 per cent), and Thailand (9 per cent). However, in 2018, India imported huge proportion of almost all major bulk drugs from China such as HS 291521 (Acetic acid) (34 per cent), HS 294110 (Penicillin and derivatives) (91 per cent), HS 294190 (Other antibiotics such as Rifampicin, Cephalexin, Ciprofloxacin, etc. and their salts) (73 per cent), HS 294200 (Other organic compounds such as Cefadroxil, Ibuprofen, Nifedipine, Ranitidine etc) (70 per cent), HS 292229 (Amino-naphthols) (97per cent) (Table 7.20). The share of HS 291521 (Acetic acid) (16 per cent) in India's bulk drugs imports increased significantly in 2018 in comparison to 1992 while the share of HS 294110 (Penicillin and derivatives), HS

Table 7.15: Major Bulk Drugs Exported in 1992, their share and main destinations.

S. No.	HS code	Description	Share (per cent)	Count of Countries	Top Five Destinations
1	294200	Other organic compounds (Cefadroxil, Ibuprofen, Nifedipine, Ranitidine etc)	37.9	79	Germany (14.1), Italy (8.4), US (7.4), Bangladesh (7.1), Switzerland (6.5)
2	294110	Penicillins and derivatives with a penicillanic	9.9	33	Germany (14.3), Thailand (12.5), Canada (11.1), Hong Kong, China (7.2), Singapore (7.1)
3	290611	Menthol	8.0	30	Singapore (19.5), Germany (15.7), Hong Kong, China (13.9), US (12.8), Japan (11.8)
4	293500	Sulphonamides	8.0	36	Germany (22.4), Hong Kong, China (12.2), Singapore (9.2), Poland (7.9), US (6)
5	294190	Other antibiotics (Rifampicin, Cephalexin, Ciprofloxacin etc. and their salts)	5.0	32	Switzerland (20.3), Hong Kong, China (16), Indonesia (7.7), Nigeria (7.3), Bangladesh (6.9)
6	293970	Nicotine and its salts	5.0	10	Japan (71.7), Germany (15), United States (3.8), Russian Federation (3), France (2.8)
7	292229	Amino-naphthols and -phenols, etc... one oxygen	4.8	32	Japan (22.4), Korea, Rep. (9.6), US (9.3), Belgium-Luxembourg (7.5), France (5.7)
8	291461	Anthraquinone	4.2	4	US (90), Singapore (7.2), Italy (2.7), Japan (0.2)
9	293629	Other vitamins and their derivatives, unmixed,	3.7	30	Germany (26.4), Belgium-Luxembourg (20.5), Switzerland (8.4), Italy (8.3 per cent), US (7.5)
10	293910	Alkaloids of opium and their derivatives; salts	2.5	8	US (49.6), UK (22), Japan (16.1), France (9.8), Germany (1.7)

Source: WITS, World Bank, online database.

Table 7.16: Major Bulk Drugs Exported in 2018, their share and main destinations

S. No.	HS code	Description	Share (per cent)	Count of Countries	Top Five Destinations
1	294200	Other organic compounds (Cefadroxil, Ibuprofen, Nifedipine, Ranitidine etc)	30.6	151	US (9.2), Brazil (5.6), Germany (4.3), Ireland (4.16), Spain (4.1)
2	294190	Other antibiotics (Rifampicin, Cephalexin, Ciprofloxacin etc. and their salts)	14.3	118	Bangladesh (10.4), Turkey (7.2), Vietnam (6.6), Italy (5.4), UK (5.4)
3	290611	Menthol	9.8	82	China (58.7), US (10.2), Singapore (7.2), Netherlands (4.8), Japan (3.7)
4	293500	Sulphonamides	5.4	126	Germany (13.7), US (6.2), Brazil (6), China (5.1), Nigeria (3.9)
5	294110	Penicillins and derivatives with a penicillanic	4.9	100	China (12.2), Thailand (8.6), Egypt, Arab Rep. (8.5), Vietnam (7.3), Indonesia (6.5)
6	292229	Amino-naphthols and -phenols, etc... one oxygen	4.6	96	Nigeria (10.5), China (8.8), Ireland (7.6), Japan (6.4), Belgium (5.5)
7	294150	Erythromycin and its derivatives; salts thereof	3.8	91	US (11.9), Singapore (10.7), Brazil (9.1), Japan (7.7), Turkey (5.7)
8	293629	Other vitamins and their derivatives, unmixed,	2.8	108	US(15.8), Belgium (13), China (5.6), Korea, Rep. (5.3), Indonesia (4.5)
9	293729	Adrenal cortical hormones and their derivatives	2.2	89	Belgium (16), Netherlands (15.4), US (7.7), Brazil (7.1), Germany (6.2)
10	293970	Nicotine and its salts	2.2	77	Switzerland (21.2), Turkey (18.6), US (14.5), Italy (11.6), Greece (3.9)

Source: WITS, World Bank, online database.

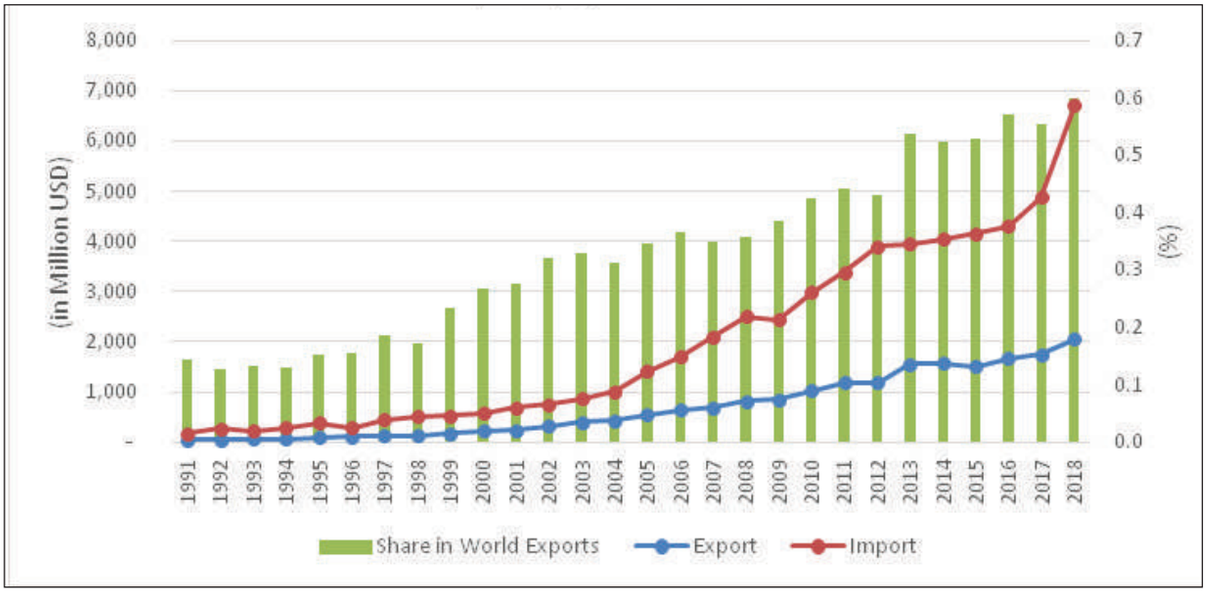
294190 (Other antibiotics such as Rifampicin, Cephalexin, Ciprofloxacin, etc. and their salts) and HS 294200 (Other organic compounds such as Cefadroxil, Ibuprofen, Nifedipine, Ranitidine, etc) declined significantly which were imported massively in 1992. The share of HS 294110 (Penicillin and derivatives) reduced to 16 per cent; HS 294190 (Other antibiotics such as Rifampicin, Cephalexin, Ciprofloxacin etc. and their salts) fell to 14 per cent and HS 294200 (Other organic compounds such as Cefadroxil, Ibuprofen, Nifedipine, Ranitidine, etc.) decreased to 10 per cent.

7.4.3 Medical Devices

In medical devices, India has been having trade deficit since 1962. In that year, India's exports of medical devices were $ 14,000 whereas its imports were $ 2.4 million (Figure 7.12). The performance with respect to exports had not remained consistent till the early 1980s. It is only after that year that exports improved steadily and increased from around $ 2 million in 1982 to around $ 70 million in 1989 but fell considerably to $ 50 million in 1990. As a result of this, India's share in global exports of medical devices improved marginally from less than 0.1 per cent to 0.5 per cent in 1989. However, imports of medical devices enlarged relatively at much higher pace in comparison to its exports. The imports of medical devices increased from around $ 28 million in 1982 to marginally higher than $ 260 million in 1990. Much of this increase in imports took place in the last four years.

Even after liberalisation, India continued to have persistent and enlarging trade deficit in medical devices as it was during previous phase, perhaps because of the sector's lack of competitiveness in the global market (Figure 7.12**).** India's imports in medical devices increased from $ 171 million in 1991 to around $ 6.7 billion in 2018 whereas exports grew from

Figure 7.12: India's Global Trade in Medical Devices (Million USD) and Share in World Exports (%): 1991 to 2018



Source: Authors' Estimation using WITS, World Bank online database.

Note: Line-graphs are shown on Primary axis and Bar-chart on Right-hand axis.

Table 7.17: Major Sources for Bulk Drugs in terms of Value and Quantity in 1992

S. No.	Country	Share in value (per cent)	Rank with respect of value	Share in quantity (per cent)	Rank with respect of quantity
1	Germany	11.9	1	14.0	1
2	Italy	11.0	2	4.4	8
3	Netherlands	9.0	3	7.9	4
4	United States	7.3	4	7.6	5
5	Denmark	6.6	5	1.8	14
6	Japan	5.7	6	9.9	3
7	United Kingdom	5.4	7	11.5	2
8	Spain	4.2	8	1.7	15
9	France	3.9	9	7.3	6
10	Switzerland	3.8	10	2.2	10

Source: WITS, World Bank, online database.

Table 7.18: Major Sources 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	60.9	1	38.8	1
2	Singapore	5.6	2	21.8	3
3	Malaysia	5.3	3	23.1	2
4	United States	4.3	4	3.2	4
5	Italy	2.8	5	0.5	12
6	Germany	1.9	6	0.6	10
7	Spain	1.6	7	0.2	20
8	Netherlands	1.6	8	0.4	16
9	Hong Kong, China	1.6	9	1.5	7
10	Denmark	1.5	10	0.3	18

Source: WITS, World Bank, online database.

just over $ 40 million to $ 2.1 billion only. This increase in exports of medical devices improved its share in world's exports from around 0.2 per cent in the early 1990s to more than 0.6 per cent in 2018, which cannot be considered a significant share.

In 1990, India had exported $ 50 million worth of medical devices. The prime destination was Soviet Union as it had around 28 per cent share in India's global exports of medical devices (Table 7.21). The United States (9.4 per cent), Poland (7.7 per cent) and German Democratic Republic (7.2 per cent) together accounted for slightly more than 25 per cent share while Zambia and United Kingdom each had around 5 per cent share. In 2018, however, United States has become a major destination as its share has increased to around 23 per cent in India's global exports of medical devices. Similarly, the share of Singapore registered an increase whereas Germany and United Kingdom recorded a decline. The new export destinations for India's medical devices exports are China, France, Brazil, Bangladesh and United Arab Emirates.

With respect to India's imports of medical devices, although the United States and Germany have remained major sources since 1990, the shares of these two have registered a decline. The shares of Japan and United Kingdom in India's imports of medical devices also considerably declined while the shares of Singapore and China recorded a significant jump.

Within medical devices exports of India, two products, HS 901890 **(**Instruments and appliances used in medical) and HS 300660 (Chemical contraceptive preparations) together captured around 45 per cent share in 1990 (Table 7.22). The major destinations for HS 901890 **(**Instruments and appliances used in medical) were Soviet Union (36.7 per cent), Poland (12.9 per cent), United States (10.1 per cent) and Zambia (8.6 per cent) and HS 300660 (Chemical contraceptive preparations) was largely exported to two countries, namely, German Democratic Republic (25.1 per cent) and Hong Kong, China (18.5 per cent). Around 6 per cent share each has been accounted for by HS 902511 (Thermometers & pyrometers) and HS 401410 (Sheath contraceptives) followed by HS 902690 (Parts of inst and app for measure/ checking) (4.5 per cent), HS 300610 (Materials for surgical sutures) (4 per cent), and HS 902219 (Apparatus based on the use of X-rays) (3.7 per cent).

However, in 2018, share of HS 901890 **(**Instruments and appliances used in medical) and HS 300660 (Chemical contraceptive preparations) in India's global exports of medical devices declined massively to 10 per cent and 7.4 per cent respectively whereas HS 901839 (Needles, catheters, cannulae) recorded significant increase in the share to 14 per cent (Table 7.23). HS 901890 and HS 300660 are primarily exported to US. The share of HS 901819 (Electro-diagnostic apparatus) increased from 2.7 per cent in 1990 to 7.7 per cent in 2018. The new major products which are being exported by India in 2018 are HS 902230 (X-ray tubes), HS 902290 (Parts and accessories for app based), HS 902610 (Instruments and apparatus for measure/checking), HS 902211 (Apparatus based on the use of X-rays for medical), HS 902620 (Instruments and apparatus for measuring or checking and HS 902130.

In 1990, India was mainly importing HS 901819 (Electro-diagnostic apparatus) (18.4 per cent), HS 901890 (Instruments and appliances used in medical) (13.3 per cent) and HS 902790 (Microtomes; parts & access of inst and app) (10.5 per cent) as they together comprised more than 42 per cent share in India's imports of medical devices (Table 7.23). HS 901819 was largely imported from Japan (27.5 per cent), German Democratic Republic (25.8 per cent) and United States (23.1 per cent); HS 901890 from United States (31 per cent), German Democratic Republic (20.3 per cent),

Table 7.19: Major Bulk Drugs Imported in 1992, their share and main Sources.

S. No.	HS code	Description	Share (per cent)	Count of Countries	Top Five Sources (Percentages in brackets)
1	294200	Other organic compounds (Cefadroxil, Ibuprofen, Nifedipine, Ranitidine etc)	29.8	46	Japan (12.5), Germany (10.5), Netherlands (10.2), Italy (7.5), US (6.6)
2	294190	Other antibiotics (Rifampicin, Cephalexin, Ciprofloxacin etc. and their salts)	22.9	39	Italy (29.2), Korea, Rep. (12.5), Thailand (9p), UK (5.7), Switzerland (5.4)
3	294110	Penicillins and derivatives with a penicillanic	22.8	30	Germany (24.4), Netherlands (23.8), UK (8) Denmark (5.6), Oman (4.7)
4	294150	Erythromycin and its derivatives; salts thereof	4.7	18	US (49.7), Italy (12.7), Brazil (11.4), Germany (10.7), Spain (7.2)
5	293791	Insulin and its salts	3.0	1	Denmark (100)
6	350790	Enzymes; prepared enzymes (not elsewhere specified)	2.7	19	Denmark (48.1), Germany (20.6), Italy (9.7), Japan (7.4), US (4.3)
7	294130	Tetracyclines and their derivatives; salts ther	1.6	6	China (25.9), Denmark (17.5), Hong Kong, China (8.3), Austria (4.9), US (2.5)
8	293799	Other hormones and derivatives, nes; other ster	1.1	17	US (44.1), Germany (15.8), Netherlands (10.9), Italy (9.8), France (4.8)
9	292229	Amino-naphthols and -phenols, etc... one oxygen	1.0	9	France (46), Japan (14.1), US (11.9), China (10.6), Germany (4.1)
10	294140	Chloramphenicol and its derivatives; salts ther	0.9	7	Spain (53.6), Hong Kong, China (20.6), Singapore (2.7), US (1.8), China (1.8)

Source: WITS, World Bank, online database.

Table 7.20: Major Bulk Drugs Imported in 2018, their share and main Sources

S. No.	HS code	Description	Share (per cent)	Count of Countries	Top Five Sources (Percentages in brackets)
1	291521	Acetic acid	16.4	20	China (34.2), Malaysia (29.1), Singapore (28.2), US (3.1), Saudi Arabia (2.1)
2	294110	Penicillins and derivatives with a penicillanic	16.1	32	China (90.6), UK (2), Austria (1.3), Mexico (1.1), Korea, Rep. (1.1)
3	294190	Other antibiotics (Rifampicin, Cephalexin, Ciprofloxacin etc. and their salts)	13.9	52	China (72.6), Hong Kong, China (4.7), Hungary (3.5), Spain (3.2), Italy (2.9)
4	294200	Other organic compounds (Cefadroxil, Ibuprofen, Nifedipine, Ranitidine etc	10.2	60	China (70.1), US (5.5), Italy (3.7), Spain (2.8), Other Asia, nes (2.6)
5	292229	Amino-naphthols and -phenols, etc... one oxygen	5.0	27	China (96.9), US (0.7), Brazil (0.7), Unspecified (0.3), Japan (0.2)
6	294150	Erythromycin and its derivatives; salts thereof	4.0	14	China (63), US (34.9), Unspecified (0.7), Thailand (0.5), Spain (0.4)
7	350790	Enzymes; prepared enzymes (not elsewhere specif	3.3	38	China (28.5), Denmark (15.2), US (14.4), Finland (10.4), Germany (7.4)
8	293799	Other hormones and derivatives, nes; other ster	2.4	31	China (46.5), Germany (10.8), Belgium (8.9), Netherlands (7.8), US(6.3)
9	293729	Adrenal cortical hormones and their derivatives	1.9	24	China (75.8), Italy (13.2), Netherlands (6.1), Singapore (0.9), UK (0.9)
10	294130	Tetracyclines and their derivatives; salts ther	1.7	19	China (37.8), Italy (30.3), Portugal (20), Hong Kong, China (4.9), Macao (4.5)
11	152090	Glycerol (excl. crude), including synthetic	1.7	25	Indonesia (46.8), Malaysia (22.8), Thailand (11.4), Argentina (7.9), Brazil (4.7)
12	293626	Vitamin B12 and its derivatives, unmixed	1.5	15	China (90.2), France (5), Hong Kong, China (2.5), Japan (0.6), UK (0.5)
13	293890	Glycosides and their salts, ethers, esters and	1.5	29	China (46.7), Spain (40.5), France (3.3), Malaysia (2.7), US (2)

Table 7.20 continued...

Table 7.20 continued...

14	293410	Compounds containing an unfused thiazole ring	1.5	18	Netherlands (40.5), Switzerland (32.3), China (23.7), Hong Kong, China (1), Japan (0.8)
15	291821	Salicylic acid and its salts	1.5	16	China (82.2), Italy (7.5), France (2.4), Brazil (2.2cent), Germany (2.1)
16	293500	Sulphonamides	1.3	28	China (55.1), Italy (15.7), Israel (9.2), Germany (7.9), France (3.3)
17	290722	Hydroquinone (quinol) and its salts	1.3	9	Italy (40.9), US (35), Japan (17.9), France (3.4), China (2.6)
18	290721	Resorcinol and its salts	1.3	11	China (63.7), Japan (35.5), Germany (0.5), US(0.2), United Arab Emirates (0.1)
19	291631	Benzoic acid, its salts and esters	1.2	30	China (76.3), France (10.4), Netherlands (5.2), Japan (2.4p), Other Asia, nes (1.7)
20	293721	Cortisone, hydrocortisone... and predisolone (d	1.0	14	China (68.3), France (18.5), Spain (6.7), US (4.4), Singapore (1.3)

Source: WITS, World Bank, online database.

Table 7.21: Major Destinations and Sources of Medical Devices in 1990 and 2018

	Major Destinations (Percentages in brackets		**Major Sources (Percentages in brackets)**	
S.No.	**1990**	**2018**	**1990**	**2018**
1	Soviet Union (27.5)	US (22.9)	US (27.2)	US (21.7)
2	US (9.4)	Singapore (6)	Japan (19.5)	Germany (13.5)
3	Poland (7.7)	Germany (5.4)	German Democratic Republic (17.7)	China (12.9)
4	German Democratic Republic (7.2)	China (5.3)	UK (9.1)	Singapore (9.2)
5	Zambia (5.1)	France (3.5)	Netherlands (4.2)	Japan (6)
6	UK (4.9)	Brazil (3)	Switzerland (4.1)	Netherlands (5.3)
7	Hong Kong China (3.7)	Japan (2.2)	Singapore (3.1)	Switzerland (3.7)
8	Singapore (2.8)	Bangladesh (2.1)	France (2.7)	UK (3.5)
9	Australia (1.8p)	UK (2)	Australia (2.4)	France (3.3)
10	Spain (1.7p)	United Arab Emirates (1.9)	Italy (1.9)	Korea Rep. (2.9)

Source: WITS, World Bank, online database.

Table 7.22: Major Medical Devices Exported in 1990, their share and main destinations

S. No.	HS code	Description	Share (per cent)	Count of Countries	Top Five Destinations (Percentages in brackets)
1	901890	Instruments and appliances used in medical or v	25.7	72	Soviet Union (36.7), Poland (12.9), US (10.1), Zambia (8.6), Kenya (3.6)
2	300660	Chemical contraceptive preparations based on ho	18.9	37	German Democratic Republic (25.1), Hong Kong, China (18.5), Spain (6.1), Poland (4.3), US (3.6)
3	902511	Thermometers & pyrometers, not combined with other	6.3	17	US (73.2), UK (24.4), Australia (0.7), Thailand (0.5), Japan (0.4)
4	401410	Sheath contraceptives	6.0	8	Soviet Union (98.1), Venezuela (1.2), US (0.5)
5	902690	Parts of inst and app for measure/ checking vari	4.5	22	Soviet Union (90.1), South Africa (3), Japan (2.7), Sri Lanka (1.3UK (0.7)
6	300610	Materials for surgical sutures; laminaria; abs	4.0	36	German Democratic Republic (20.3), Venezuela (7.7), Nigeria (6.8), Philippines (6), Zambia (5.9)
7	902219	Apparatus based on the use of X-rays for other	3.7	3	Poland (94.1), German Democratic Republic (5.6), United Arab Emirates (0.4),
8	300510	Adhesive dressings..., for medical... purposes	3.1	35	UK (35.1), Zambia (17), Sri Lanka (7.7), Afghanistan (4.2), Bangladesh (4p)
9	901819	Electro-diagnostic apparatus, nes	2.7	14	Soviet Union (37.8), Zambia (24.9), Singapore (15.2), US (7.3), UK (5.3)
10	401511	Surgical gloves	2.7	21	Zambia (26.7), Soviet Union (25.7), German Democratic Republic (10.1), Netherlands (6.3), Italy (4.9)

Source: WITS, World Bank, online database.

and Japan (17.1 per cent); and HS 902790 from United States (34.8 per cent), Japan (12.8 per cent), United Kingdom (11.9 per cent), German Democratic Republic (10.3 per cent), and Australia (9.5 per cent). Around six per cent share was accounted for by HS 902730 (Spectrometers, spectrophotometers), and HS 902780 (Instruments and apparatus for physical) and HS 902690 (Parts of inst and app for measure/checking) and HS 902190 (Orthopaedic and other appliances) each captured about 5.5 per cent share. From 2 per

Table 7.23: Major Medical Devices Exported in 2018, their share and main destinations.

S. No.	HS code	Description	Share (per cent)	Count of Countries	Top Five Destinations (Percentages in brackets)
1	901839	Needles, catheters, cannulae and the like, nes	14.2	177	US (10.1), Brazil (8), China (7.3), France (4.5), Iran, Islamic Rep. (4.4)
2	901890	Instruments and appliances used in medical or v	10.2	192	US (25.4), Germany (9.1), China (5.2), Belgium (3.3), Nepal (3.3)
3	901819	Electro-diagnostic apparatus, nes	7.7	136	US (65.9), China (9.1), Singapore (5.9), Germany (5.5), Japan (2.7)
4	300660	Chemical contraceptive preparations based on ho	7.4	153	US (62.4), Ethiopia(excludes Eritrea) (3.1), Canada (3), Zimbabwe (2.9), Myanmar (2.5)
5	902230	X-ray tubes	6.0	22	Singapore (53.9), China (20.7), Japan (15.9), US (5.6), Mexico (3)
6	902290	Parts and accessories for app based on the use	5.0	122	US (21), France (16), Singapore (14.4), China (13.3), Germany (12)
7	902610	Instruments and apparatus for measure/checking	4.2	153	US (24.8), South Africa (10.4), Australia (8.4), United Arab Emirates (5.7), Malaysia (5.3)
8	902211	Apparatus based on the use of X-rays for medica	3.4	109	US (16.3), Brazil (8), Netherlands (6.1), Japan (6), Germany (5.1)
9	902620	Instruments and apparatus for measuring or chec	2.9	139	Germany (16), US (10.5), United Arab Emirates (7.9), Australia (7.9Saudi Arabia (7.1)
10	902130	Artificial parts of the body, nes	2.3	159	US (11.9), Ecuador (5.9), Egypt, Arab Rep. (5.2), UK (4.2), Russian Federation (3.3)

Source: WITS, World Bank, online database.

cent to 3 per cent share was attained by HS 902290 (Parts and accessories for app), HS 382200 (Composite diagnostic or laboratory reagents) and HS 901839 (Needles, catheters, cannulae). India was importing these ten major medical devices mainly from four countries, namely, United States, German Democratic Republic, Japan and United Kingdom in 1990.

In 2018, the shares of HS 901819 (Electro-diagnostic apparatus), HS 902790 (Microtomes; parts & access of inst and app) and HS 902730 (Spectrometers, spectrophotometers) in India's imports of medical devices registered a significant decline and HS 901890 (Instruments and appliances used in medical) recorded marginal drop ( ). However, the shares HS 382200 (Composite diagnostic or laboratory reagents), HS 902780 (Instruments and apparatus for physical), HS 901839 (Needles, catheters, cannulae) and HS 902290 (Parts and accessories for app) have shown noticeable increase.

Overall, the picture that emerges in regard to trade in medical devices is that India has not emerged as a major exporter. It is mostly dependent on imports for high technology items and its exports are mostly in low-end products.

7.5 Trend of India's Tariffs in Pharmaceutical Industry

As a part of liberalisation package, India had to open its economy for the world economy by reducing its tariffs and pharmaceutical industry was no exception to it. The declining trend of average tariffs in the pharmaceutical industry is presented in Figure 7.13. Although India's average tariffs in formulations, bulk drugs and medical devices have followed the declining trend over time after the liberalisation (since 1990), some years have registered same pattern of increase or decrease in tariffs as well in all three sub-sectors of pharmaceutical industry (Figure 7.14). For instance, between 1997 and 2000, all three sub-sectors recorded increase in tariffs followed by a decline in the subsequent three years and then again, in 2004, surge in tariffs was observed in all three sub-sectors followed by decline in very next year, in 2005. The tariffs of formulations and bulk drugs overlapped after 1997 and remained same until 2007. Among the three, bulk drugs had highest average tariff (69 per cent) in 1990 followed by formulations (60 per cent) and medical devices (55 per cent). By 2018, these tariffs in bulk drugs, formulations and medical devices have come down to 8 per cent, 10 per cent and 7 per cent, respectively. It is important to mention here that India has reduced its tariffs on bulk drugs, formulations and medical devices until 2008 and thereafter the tariffs have remained same except on bulk drugs which recorded marginal reduction in years 2012 and 2015.

Further, average tariffs on formulations were slashed massively to 18 per cent in 1992 but raised to 41 per cent in 1996. In 1992, the tariffs of all formulations at HS 6-digit level were brought down to zero except for HS 300110 (Glands and other organs, dried), HS 300120 (Extracts of glands), HS 300190 (Other), HS 300210 (Antisera, other blood fraction), HS 300231(Vaccines against foot-and-mouth) and HS 300239 (Other) which registered increase in average tariffs by 5 per cent. However, the increase in average tariffs by 5 per cent was observed across all formulations at HS six level in 1999. Likewise, in 2000, average tariffs for all formulations were further increased by 3.5 per cent except for 300390 (Other) and 300490 (Other) which faced an increase in average tariffs by 3.2 per cent. In the subsequent three years (2001, 2002 and 2003), average tariff was cut down for all the formulations at HS six-digit level chronologically by 3.5 per cent, 5 per cent and 5 per cent except for HS 300440 (Containing alkaloids or derivatives) which recorded more than 8 per cent cut in tariffs in 2003. In the following year (2004), however, average tariffs for all the formulations raised to 30 per cent. On the other hand, the average tariffs for all the formulations were brought down to 15 per cent in 2005; then to 12.5 per cent in 2006; remained at 12.5 in 2007 also; and finally brought down

Table 7.24: Major Medical Devices Imported in 1990, their share and main Sources.

S. No.	HS code	Description	Share (per cent)	Count of Countries	Top Five Sources (percentages in brackets)
1	901819	Electro-diagnostic apparatus, nes	18.4	22	Japan (27.5), German Democratic Republic (25.8), US (23.1), Netherlands (8.3), Singapore (3)
2	901890	Instruments and appliances used in medical or v	13.3	28	US (31), German Democratic Republic (20.3), Japan (17.1), UK (6.1), Switzerland (4.6)
3	902790	Microtomes; parts & access of inst and app for	10.5	31	US (34.8), Japan (12.8), UK (11.9), German Democratic Republic (10.3), Australia (9.5)
4	902730	Spectrometers, spectrophotometers and spectrogram	6.2	15	US (25.1), Japan (22.2), German Democratic Republic (14.8), Switzerland (11.3), UK (10)
5	902780	Instruments and apparatus for physical or chemical	5.9	22	US (33.3), UK(16.7), German Democratic Republic (15.3), Japan (7.9), Switzerland (7.3)
6	902690	Parts of inst and app for measure/ checking vari	5.6	24	US (41.7), Japan (18.4), German Democratic Republic (12.5), UK (8.5), Switzerland (4.7)
7	902190	Orthopedic and other appliances,worn, carried or i	5.4	20	US (26.7), German Democratic Republic (25.9), Japan (10.6), Singapore (7.1), UK (6.5)
8	902290	Parts and accessories for app based on the use	3.2	23	German Democratic Republic (25.6), US (21.1), Japan (18.8), Australia (5.6), UK (4.8)
9	382200	Composite diagnostic or laboratory reagents, ne	2.4	25	US (28.6), German Democratic Republic (26.8), Netherlands (13), UK (8.9), Denmark (4.3)
10	901839	Needles, catheters, cannulae and the like, nes	2.1	18	Japan (26.7), Singapore (15.2), US (13.9), UK (13.6), German Democratic Republic (8.4)

Source: WITS, World Bank, online database.

Table 7.25: Major Medical Devices Imported in 2018, their share and main Sources.

S. No.	HS code	Description	Share (per cent)	Count of Countries	Top Five Sources (Percentages in brackets)
1	901890	Instruments and appliances used in medical or v	12.7	81	US (25), Germany (20.4), China (13.5), Japan (7.2), Singapore (5.1)
2	382200	Composite diagnostic or laboratory reagents, ne	8.2	79	US (34.9), Germany (14.6), Singapore (8.3), France (7.4), China (4.8)
3	902780	Instruments and apparatus for physical or chemi	6.7	63	US (23.5), Singapore (13.2), Germany (9.7), China (8.4), Japan (7.1)
4	901819	Electro-diagnostic apparatus, nes	6.3	52	China (27.1), US (23.2), Korea, Rep. (9.5), Germany (8.5), Netherlands (6.9)
5	902211	Apparatus based on the use of X-rays for medica	6.0	31	China (22), US (19.2), UK (11.5), Germany (11.4), Japan (9.2)
6	902790	Microtomes; parts & access of inst and app for	5.5	62	US (20.9), Singapore (20.3), Germany (18.4), Japan (8.3), UK (4.5)
7	901839	Needles, catheters, cannulae and the like, nes	5.1	49	US (16.6), Netherlands (15.2), China (9.8), Singapore (7.6), Japan (7.1)
8	902290	Parts and accessories for app based on the use	4.9	44	US (26.6), China (18.3), Germany (13.8), Japan (8.5), Netherlands (7.9)
9	902720	Chromatographs and electrophoresis instruments	3.8	31	Singapore (37.5), Germany (25.6), Japan (7.6), US (7.3), Austria (5.2)
10	902730	Spectrometers, spectrophotometers and spectrograms	3.2	44	Singapore (22.3), Germany (21.9), US (20.7), Switzerland (6.3), Japan (5.1)
11	901850	Ophthalmic instruments and appliances, nes	3.1	46	US (24.3), Germany (18.4), Switzerland (15.7), Japan (13.5), China (7.7)
12	902130	Artificial parts of the body, nes	2.6	35	US (41.7), Switzerland (13), Netherlands (10.5), Germany (8.1), Ireland (6.7)

Table 7.25 continued...

Table 7.25 continued...

S. No.	HS code	Description	Share (per cent)	Count of Countries	Top Five Sources (Percentages in brackets)
13	902750	Instruments and apparatus using optical radiate	2.4	47	US (23.1), Japan (16.5), Singapore (15.8), Germany (11.8), UK (7.5)
14	902190	Orthopaedic and other appliances, worn, carried or implanted	2.4	39	Netherlands (40.5), Australia (14.6), US (9.7), Switzerland (5.9), Ireland (5.5)
15	901920	Oxygen therapy, artificial respiration or oth	2.4	45	US (27.5), China (16.9), Germany (14.6), Netherlands (6.8), Australia (4.7)
16	902111	Artificial joints	2.0	29	Belgium (31.1), US (21.6), Singapore (16.8), Switzerland (16), Germany (9.9)
17	902219	Apparatus based on the use of X-rays for other	1.8	24	Germany (25.6), US (25.1), Malaysia (7.6), UK (7), China (6.6)
18	902690	Parts of inst and app for measure/checking vari	1.4	55	China (31.4), US (16.7), Germany (10.5), Japan (8.2), Italy (7.8)
19	902610	Instruments and apparatus for measure/checking	1.4	65	China (20.7), US (16.3), Germany (14.1), Japan (7.8), UK (4.7)
20	901849	Instruments and appliances, used in dental science	1.1	41	China (20.2), Switzerland (16.6), Korea, Rep. (13.7), Germany (7.4), US (7.1)

Source: WITS, World Bank, online database.

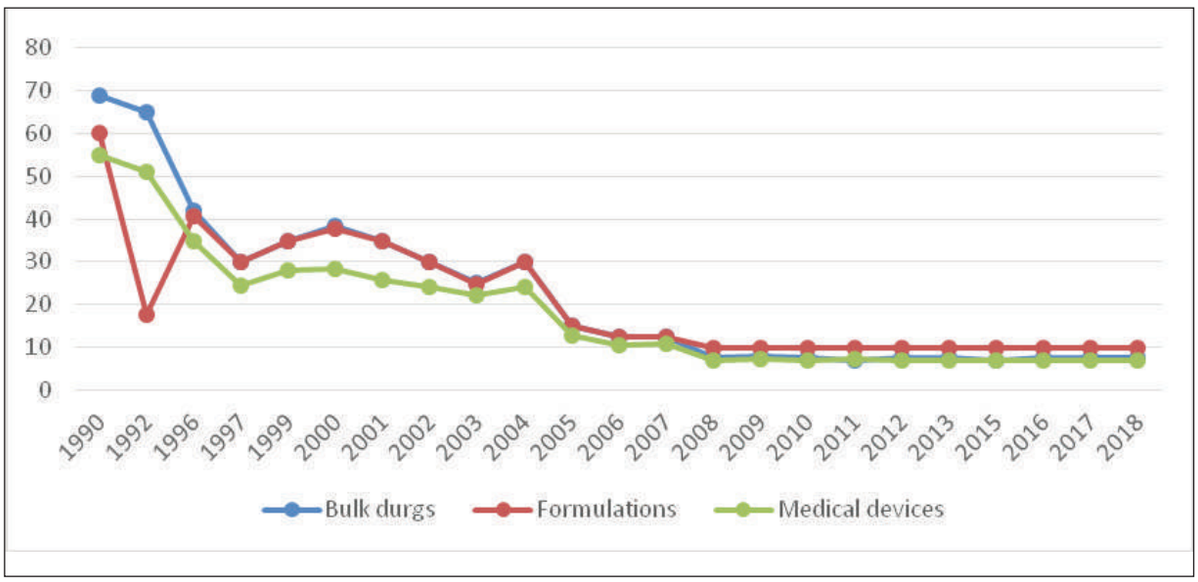
to 10 per cent in 2008 and stayed at 10 per cent until 2018.

Within the bulk drugs, out of 55 products at HS six-digit level, the average tariffs of 39 products were reduced by 5 per cent in 1992 over 1990; for two products, Formic acid (HS 291511) and Erythromycin and its derivatives (HS 294150), were cut down by 35per cent; and for one product, Penicillin and their derivatives (HS 294110), lowered by 10 per cent. For 12 products, however, an increase in average tariffs by 5 per cent was observed which included vitamins (for products of HS 2936). In 1996, an average tariff for all the bulk drugs at HS six-digit level was brought down to 42 per cent except for other organic compounds (HS 294200) and Acetic acid (HS 291521) for which tariffs were reduced to 52per cent and 27per cent respectively. India continued its tariff reduction policy in 1997 as well and tariffs of all the bulk drugs lowered down to 30 per cent except for acetic acid (HS 291521) for which tariffs were reduced to 25 per cent.

Contrary to the declining trend, the average tariffs for all the bulk drugs at HS six-digit level increased in subsequent year (1999) by 5 per cent and further increased by 3.5 per cent in 2000 except for acetic acid (HS 291521) for which tariffs were reduced by 7.5 per cent per cert. In the following three years, India again adopted the policy of tariff reduction and tariffs for all the bulk drugs cut down to 35 per cent in 2001; then 30 per in 2002; finally, 25 per cent in 2003. However, in 2004, tariffs for all the bulk drugs increased by 5 per cent whereas the reductions in an average tariff by 15 per cent was observed in 2005 and lowered down further by 2.5 per cent in 2006. The average tariffs for all the bulk drugs were kept at 2006 level in 2007 as well i.e., 12.5 per cent. In 2008, India cut down average tariffs for all the bulk drugs by 5 per cent except for concentrates of poppy straw (HS 293911) and HS 350790 (Other). The average tariffs of concentrates of poppy straw (HS 293911) were kept at the level of previous year, i.e., 12.5 per cent while tariff of HS 350790 (Other) reduced by 2.5 per cent. In the following year (2009), however, an increase in the tariffs by 0.5 per cent was witnessed for all the bulk drugs except for HS 350790 (Other) for which tariffs stayed at the level of previous year, i.e., 10 per cent. In 2010, tariffs for all the bulk drugs at HS six digit lowered by 0.5 per cent except for HS 350790 (Other) for which there was no change. From 2010 onwards, no change in the tariffs was seen for any of the bulk drugs except for HS 293729 (Other), HS 293911 (Concentrates of poppy straw), HS 293920 (Alkaloids of cinchona), HS 293959 (Other) and HS 293969 (Other) on which some changes were made.

In medical devices, out of 59 product lines at HS six digit, 32 products (such as HS 901811 Electrocardiographs, HS 901820 Ultraviolet or infrared ray apparatus, HS 901831 Syringes, with or without needles, HS 901841 Dental drill engines, whether or not, etc.) no change in tariffs over 1990 rates were made in 1992; for eight products (such as HS 401410 Sheath contraceptives, HS 401511 Surgical, HS 481850

Figure 7.13: India's Tariffs (simple average) in Formulations, Bulk Drugs and Medical Devices: 1990 to 2018



Source: Authors' Estimation using WITS, World Bank online database.

Articles of apparel and clothing accessories, HS 940210 Dentists', barbers' or similar chairs etc.) tariffs were reduced by 35 per cent; for four products (HS 902610 For measuring or checking the flow, HS 902620 For measuring or checking pressure, HS 902520 Barometers, not combined and HS 902680 Other instruments or apparatus) tariffs were reduced by 5 per cent; and for one product, (HS 902121 Artificial teeth) tariffs were lowered by 40 per cent. However, in case of 14 products tariffs were increased. For 11 products for which tariffs were increased by 5 per cent included HS 300510 Adhesive dressings and other articles, HS 300610 Sterile surgical catgut, HS 300620 Blood grouping reagents, HS 300650 First aid boxes and kits etc.); for two products tariffs (HS 902690 Parts and accessories & HS 902790 Microtomes; parts and accessories) were raised by 25 per cent and for one product (HS 902580 Other instruments) tariff was increased by 20 per cent. In 1996, the average tariffs for all medical devices at HS six level recorded a decline except for HS 902121 Artificial teeth, HS 902290 Other, including parts and accessories, HS 902300 Instruments, apparatus and models, HS 842390 Weighing machine weights of all kinds, HS 902219 For other uses, HS 902229 For other uses and HS 902230 Xray tubes which had registered increase in tariffs. The government of India continued its policy of reducing tariffs in 1997 as well. As a result, all the product lines of medical devices at HS 6-digit level recorded reduction in tariffs. Contrary to the declining trend, the average tariffs for most of the products of medical devices were enlarged in 1999 but for some product lines such as HS 401410 Sheath contraceptives, HS 401511 Surgical, HS 871420 of carriages for disabled persons, HS 902230 Xray tubes, HS 902720 Chromatographs and electrophoresis, HS 902730 Spectrometers, spectrophotometers, etc. it remained unaffected Although the reduction in tariffs for medical devices started again in 2000, 19 products such as HS 902150 Pacemakers for stimulating heart, HS 902212 Computed tomography apparatus, HS 902214 Other, for medical, surgical, HS 902111 Artificial joints, HS 902121 Artificial teeth, HS 901920 Ozone therapy, oxygen therapy, HS 901910 Mechanotherapy appliances; massage etc. registered an increase in tariffs. Similarly, in the subsequent three years, average tariffs for 19 products (such as HS 300510 Adhesive dressings and other articles, HS 300610 Sterile surgical catgut, HS 300630 Opacifying preparations for Xray, HS 300650 First aid boxes and kits, HS 300640 Dental cements and other dental filling etc. whereas 35 products observed no change in the tariffs; and for seven products, reduction in tariff only took place in 2003 such as HS 902720 Chromatographs and electrophoresis, HS 902730 Spectrometers, spectrophotometers and HS 902620 For measuring or checking pressure, HS902690 Parts and accessories etc. tariffs were reduced by 5 per cent every year.

Only in 2005, steep reduction in tariffs for all the medical devices took place and tariffs for most of the medical devices were brought down to 15 per cent except for eight products (such as HS 902720 Chromatographs and electrophoresis, HS902730 Spectrometers, spectrophotometers and HS 902620 For measuring or checking pressure, HS902690 Parts and accessories etc.) tariffs were cut down to zero. In 2006, tariffs were further lowered by 2.5 per cent for most of the medical devices whereas, in 2007, tariffs did not register any change. Further reduction in the tariffs for all the medical devices was noticed in 2008. In 2009, 39 products of medical devices such as HS 901811 –Electrocardiographs, HS 901812 Ultrasonic scanning apparatus, HS 901814 Scintigraphic apparatus, HS 901831 Syringes, with or without needles, HS 901841 Dental drill engines, whether or not, HS 902121 Artificial teeth, HS 902140 Hearing aids, excluding parts and accessories etc. recorded an increase in the tariffs by 0.5 per cent. But tariffs for other products had remained unaltered. In 2010, tariffs of those products recorded decline in tariffs by the same amount whose tariffs had

increased in 2009. From 2011 onwards, tariffs have mostly remained same for all medical devices.

Generally, the tariffs while showing a general declining trend also show lot of variations from time to time. In tariff measures while countries' latitudes are limited by the WTO regime, they can be used from time to time depending on sectors and products where the competitiveness of the domestic industry gets affected. At the same time, frequent changes are not welcome as that will create uncertainty among trade circles and also generate problems for financial management of the industries.

7.6 NTBs and India's Trade in Pharmaceutical Industry

The custom duties (tariffs) had been used as predominant mode of protection by several developed countries until the early 1970s. However, successive rounds of the General Agreement on Tariffs and Trade (GATT) negotiations significantly brought down the average tariffs of manufactured goods mainly in developed countries (R. Mehta, 2005).[7] As the tariffs were becoming more and more immaterial, the developed countries made use of administered protection known as Non-Tariff Measures (NTM) such as quantitative restrictions, tariff quota, voluntary export restraints, orderly marketing arrangements, export subsidy, export credit subsidy, government procurement, import licensing, antidumping/countervailing duties, Sanitary and Phytosanitary (SPS) measures, technical barriers to trade (TBT), Pre-shipment inspections and other formalities. The SPS, TBT and pre-shipment inspection requirements fall under the heading of technical measures whose objectives behind the imposition are not predominantly trade-related but to protect the human, plant and animal health, and the environment. These technical measures are applied to foreign producers as well as domestic producers and thereby regulate international trade and are thus considered NTMs (UNCTAD-World Bank, 2018).[8]

On the basis of country-wise exports of India, we have identified major destinations for formulations, bulk drugs and medical devices and the number of technical measures, comprise SPS, TBT measures and pre-shipment inspection requirements, imposed by these major destinations in the respective categories are shown and discussed in the following sections one by one.

7.6.1 Formulations

Highest number of technical measures are imposed by Canada (45) on its imports of formulations which includes 11SPS, 33 TBT and one Pre-shipment inspection related measures (Table 7.26). In the number of technical measures, the US is having the second highest number, comprising 5SPS and 38 TBT measures whereas Brazil is third highest with 42 technical measures followed by Philippines (27), European Union (18), and Myanmar (16). Nepal (4) and Nigeria (2) have imposed least numbers. The countries, such as European Union, Philippines, Myanmar and Brazil have brought most of the HS six-digit products of the formulations under the domain of technical measures. While product coverage is around 20 products at HS six digit lines for USA, Russia, Australia, Canada, and so on.

The USA and Canada are the two countries, which are imposing major technical measures on their imports of formulations from India (Table 7.27). The US is imposing three TBT measures (B33: Packaging requirements, B42: TBT regulations on transport and storage, B83: Certification requirement) and one Pre-shipment inspection (C9: Other formalities, n.e.s.) related measure. These four measures together cover 18 products of formulations at HS 6-digit level. Likewise, Canada is imposing two SPS (A41- Microbiological criteria of the final product and A83- Certification requirement) measures on one product (HS 300210 - Antisera, other blood fraction) imports from India.

7.6.2 Bulk Drugs

The greatest number of technical measures (72) are imposed by China on its global imports of 50 bulks drugs. These 72 technical measures comprise 23 SPS, 47 TBT and 2 Pre-shipment inspection related measures. The second largest number of technical measures is imposed by Europe (55), which is India's major destination of bulk drug exports. The USA imposes 25 technical measures, which include 11 SPS, 13 TBT and one pre-shipment inspection. Less than 20 technical measures are imposed by Bangladesh, Mexico and Singapore.

There are two countries, Turkey and USA, which are imposing technical measures on their imports of bulk drugs particularly from India. Turkey imposes 5 TBT (B31: Labelling requirements, B33: Packaging requirements, B83: Certification requirement, B84: Inspection requirement & B859: Traceability requirements, n.e.s.) measures which covers 56 HS six products of bulk drugs while the USA imposes three TBT (B33: Packaging requirements, B42: TBT regulations on transport and storage and B83: Certification requirement) and one pre-shipment inspection (C9: Other formalities, n.e.s.) related measures on one product (HS 350790: Enzymes; prepared enzymes).

7.6.3 Medical Devices

As in Bulk drugs, China is imposing significantly greater number of technical measures compared to other countries on its global imports of 62 products of medical devices (Table 7.30). China is imposing 73 technical measures, which mainly include TBT measures (65). The USA, which is a major export destination for India's exports of medical devices, imposes 28 technical measures, comprising only TBT measures. Europe, which constitutes 20 per cent share in India's exports of medical devices, imposes 38 technical measures on 62 products at HS six-digit level. The 38 measures include largely TBT measures (34) and 3 SPS & one pre-shipment inspection. In medical devices, United Arab Emirates is the only country, which imposes one technical measure (pre-shipment inspections) on India's exports of 41 products of medical devices (Table 7.30).

India on its formulation imports imposes 32 technical measures which mostly include 29 TBT measures, one SPS and two pre-shipment inspections (Table 7.32). These 32 technical measures cover 20 HS products at HS 6-digit level. Like-wise, India levies mainly TBT measures on its global imports of 19 products of medical devices. On the imports of 48 bulk drugs at HS 6-digit level, India imposes 43 technical measures, comprising 17 SPS, 23 TBT and 3 Pre-shipment inspections.

In this section, a general overview of the NTBs in the pharmaceutical sector has been presented. Some of them relate to quality and standards. By making improvements in both these fields, Indian manufacturers can take care of them. So far as bilateral measures are concerned, we may have to get into dialogues and assuage the grievances of the other party.

Endnotes

1 International Monetary Fund, 2001. Global Trade Liberalization and the Developing Countries. Available at https://www.imf.org/external/np/exr/ib/2001/110801.htm#i. Accessed on 16 February, 2021.

2 As we also wanted to bring China into the picture of data analysis of pharmaceutical but its data relating to bulk drugs exports are only available since 1992.

3 Since India's data relating to volume of formulations exports are available from 1996 onwards.

4 Since India's data relating to volume of formulation exports are available from 1996 onwards.

5 CWTO studies paper (2012), RIS (2020), Reji. K. Joshep (2010), Doha Text on Sectoral draft report 2008.

6 In this regard, we would like to thank Ashok Kumar Madan, Executive Director, Indian Drug Manufacturers' Association (IDMA), for assisting us in finalising the list for Bulk drugs.

7 Mehta, R. (2005), Non-tariff Barriers Affecting India's Exports, RIS Discussion papers, RIS-DP # 97.

8 UNCTAD-World Bank (2018), The Unseen Impact of Non-Tariff Measures: Insights from a new database.

Table 7.26: Number of MFN Technical Measures imposed by Major Destinations of Indian Formulation Exports

S. No.	Country	Latest Data Year	Country's share in India's Exports of Formulations (2018)	SPS	TBT	Pre-shipment inspections	Total	Number of HS lines at Six digit
1	USA	2018	35.1	5	38		43	20
2	Europe	2018	12.9	11	7		18	33
3	Nigeria	2013	3.0		1	1	2	20
4	Russian	2016	2.9	2	8		10	20
5	Brazil	2018	1.8	11	31		42	31
6	Australia	2016	1.7		11		11	20
7	Canada	2017	1.7	11	33	1	45	20
8	Philippines	2018	1.5	12	15		27	33
9	Myanmar	2018	1.4	1	14	1	16	33
10	Nepal	2012	1.4	3	1		4	20

Source: Authors' estimation using UNCTAD TRAINS online database.

Table 7.27: Number of Bilateral Technical Measures imposed on Indian Formulation Exports

S. No.	Country	Latest Data Year	Sanitary and Phytosanitary (SPS) measures	Technical barriers to trade (TBT)	Pre-shipment inspections and other formalities	Total	Affected HS Lines at six digit level
1	Canada	2017	2			2	1
2	USA	2018		3	1	4	18

Source: UNCTAD TRAINS online database.

Table 7.28: Number of MFN Technical Measures imposed by India's Major destinations of Bulk Drugs Exports

S. No.	Country	Latest Data Year	Country's share in India's Exports of Bulk Drugs (2018)	SPS	TBT	Pre-shipment inspections	Total	Number of HS lines at Six digit
1	Europe	2018	26.8	44	11		55	60
2	China	2016	9.3	23	47	2	72	50
3	USA	2018	8.5	11	13	1	25	57
4	Brazil	2018	3.9	13	30		43	60
5	Bangladesh	2017	3.3	2	14	1	17	57
6	Japan	2016	3.1	10	35	2	47	57
7	Mexico	2018	2.7	5	8		13	15
8	Korea	2016	2.4	18	35	1	54	57
9	Singapore	2018	2.1	5	7		12	43
10	Vietnam	2018	2.0	13	19	1	33	60

Source: UNCTAD TRAINS online database.

Table 7.29: Number of Bilateral Technical Measures imposed on Indian Bulk Drugs Exports

S. No.	Country	Latest Data Year	Technical barriers to trade (TBT)	Pre-shipment inspections and other formalities	Total	Affected HS Lines at six digit level
1	Turkey	2016	5		5	56
2	USA	2018	3	1	4	1

Source: UNCTAD TRAINS online database.

Table 7.30: Number of MFN Technical Measures imposed by India's Major destinations of Medical Devices Exports

S. No.	Country	Latest Data Year	Country's share in India's Exports of Medical Devices (2018)	SPS	TBT	Pre-shipment inspections	Total	Number of HS lines at Six digit
1	USA	2018	22.9		28		28	54
2	Europe	2018	19.8	3	34	1	38	62
3	Singapore	2018	6.0		19		19	48
4	China	2016	5.3	4	65	4	73	62
5	Brazil	2018	3.0	8	28	1	37	62
6	Japan	2016	2.2	2	38	2	42	59
7	Bangladesh	2017	2.1	2	9		11	63
8	United Arab E.	2015	1.9	6	5	3	14	8
9	Nepal	2012	1.8	3	1		4	8

Source: UNCTAD TRAINS online database.

Table 7.31: Number of Bilateral Technical Measures imposed on Indian Medical Devices Exports

S. No.	Country	Latest Data Year	Pre-shipment inspections and other formalities	Total	Affected HS Lines at 6-digit level
1	United Arab Emirates	2015	1	1	41

Source: UNCTAD TRAINS online database.

Table 7.32: Number of Technical measures imposed by India on its imports of Formulations, Bulk Drugs and Medical Devices

S.No.	Category	SPS	TBT	Pre-shipment inspections and other formalities	Total	Affected HS Lines at six digit level
1	Formulations	1	29	2	32	20
2	Bulk Drugs	17	23	3	43	48
3	Medical Devices		17	4	21	19

Source: UNCTAD TRAINS online database.

VIII

Ayush System Drugs and Medicinal Plants

8.1 Introduction

AYUSH is the acronym for Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homeopathy (also Sowa Rigpa), the indigenous medicine systems. The policy development in this area took a long time from non-recognition to recognition as a viable and alternative system of health care to what has come to be known as modern medicine. Without proper recognition from the policy makers, the AYUSH pharmaceutical manufacturing industry did not make much progress. The following section on policy evolution will present how it has moved from positive discouragement to active encouragement in recent times.

8.2 Evolution of Policies and Programmes

Pre-Independence Days: While India has millennia old indigenous systems of medicine for long, the systems had not got much recognition or encouragement under the colonial regime. Consequent on the recommendations of Lord Macaulay in 1835, that the British administration should foster exclusively western knowledge, no indigenous system of knowledge including health systems was encouraged and as stated in the National Policy on ISM & H (2002), these were actively discouraged and Western medicine was recognized as the only legitimate system of medicine to be followed.[1] However, the subject of recognition of Indian medicine formed part of the freedom struggle agenda. The Nagpur session of the Indian National Congress in 1920 recommended that "there should be can Integrated System of Medicine and Research which should be combination of both our Ayurveda, Unani, Tibb, Siddha, and Modern medicine system choosing the best out of all and thus supporting one system by another to serve mankind to its best."[2] Report of the Committee on Indigenous Systems of Medicine, Madras (1923) commissioned by the Madras Government in 1921 is the first major government report on traditional medicine.[3] It recommend the synthesis and assimilation of western and indigenous medical systems. Later, in 1946, the Bhore Committee[4] also observed "services of persons trained in the indigenous systems of medicine should be freely utilized for developing medical relief and public health work in the country (minority view)."[5] The general thinking of Indian society in the pre-Independent days considered an integrated healthcare in the country inclusive of both traditional and modern systems.

Post-Independence Policies: The Health Survey and Planning Committee (Mudaliar Committee), 1961 recommended that "training of AYUSH in the (orthodox) traditions, chairs of Indian Systems of Medicine in all medical colleges, training in preventive medicine,

obstetrics and surgery for all 'AYUSH' graduates; research in indigenous medicine by separate central institutes of Medicine and in medical colleges; post graduate training to be available to medical men from both systems and so on."[6]

The Srivastava Report, 1975 recommended the "need to evolve a national system of medicine for the country by the development of an appropriate integrated relationship between modern and indigenous systems of medicine."[7] The National Health Policy, 1983 proposed initiating "organized measures to enable each of these systems – Ayurveda, Unani, Siddha, Homeopathy, Yoga and Naturopathy to develop in accordance with their own genius with planned efforts to dovetail the functioning of the practitioners."[8] The National Education Policy for Health Sciences (Bajaj Report 1989) noted that "a healthy and mutual respect for qualified practitioners of medicine, irrespective of the system is an essential re-requisite for effective health human resource utilisation and suggested that they be involved in disease prevention, health promotion, health education, drug distribution for national control programmes; motivation for family welfare and immunization and control of environment problems."[9]

The National Health Policy, 2002 also recommended that "under the overarching umbrella of the national health framework, the alternative systems of medicine, Ayurveda, Unani, Siddha, and Homeopathy, have a substantial untapped potential of India and build up credibility … by encouraging evidence-based research to determine their efficiency, safety and dosage and also encourage certification and quality marking of products to enable a wider popular acceptance of these systems of medicine."[10]

In the same year, the National Policy and Programmes on Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) also recommended strengthening the AYUSH systems and the infrastructure.[11] The current National Health Policy, 2017 made a strong recommendation for mainstreaming AYUSH and also recognizes the need to standardize and validate Ayurvedic medicines and establish a robust and effective quality control mechanism for AYUSH drugs. It also accepts that there is need to nurture AYUSH systems of medicine through development of infrastructural facilities of teaching institutions, improving quality control of drugs, capacity building of institutions and professionals. The Policy also recognizes the need for building research and public health skills for preventive and promotive healthcare. At a policy level now the AYUSH systems and AYUSH pharma are well placed.[12] Thus, in the post-Independence period, there has been a continuous policy stress on promotion and development of AYUSH systems. Greater acceptance of the systems naturally translates into growth of AYUSH pharmaceutical industry. Towards this a number of programmes were launched as part of the Five-Year Plans.

Five Year Plans and AYUSH: In the first FYP (1951-56), a paltry sum of Rs. 1.06 crore had only been earmarked for Indian Systems of Medicine (ISM) and Homeopathy hospitals and dispensaries.[13] It was then part of the Ministry of Health. The allocation for ISM&H got gradually increased but at a slow rate. It reached Rs. 15.63 crore during the 4th FYP.[14] During the 5th FYP, Central Council for Indian Medicine (CCIM) was formed in 1970 and Central Council for Homeopathy was formed in 1973.[15] During the 6th, 7th and 8th FYPs, there were efforts to employ ISM&H practitioners in management of communicable and non-communicable diseases, family welfare programmes (because they serve in far flung areas and have greater acceptability in rural areas.[16]) The 8th FYP envisioned integration of ISM&H with modern medicine in health care.[17] During this Plan period, a separate Department

of ISM&H was formed under Ministry of Health and FW in 1995. The 9th FYP proposed further mainstreaming of ISM&H.[18] The 10th FYP (2002-2007) marked a positive change with inclusion of ISM&H at all levels of healthcare. Accreditation system of ISM&H education was introduced during this Plan period.[19] The Department was renamed as Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) in November, 2003 with a view to providing focused attention for the development of education and research in Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy. The objectives of establishing a separate Department of AYUSH were the following:

- upgrade the educational standards of Indian Systems of Medicines and Homoeopathy colleges in the country;
- strengthen existing research institutions and to ensure a time-bound research programme on identified diseases for which these systems have an effective treatment;
- draw up schemes for promotion, cultivation and regeneration of medicinal plants used in these systems; and
- evolve pharmacopoeial standards for ISMs and Homoeopathy drugs.

Strengthening of the AYUSH systems continued during the 11th and 12th FYP period and a separate Ministry of AYUSH was formed on 9th November' 2014, giving further boost to the development of the systems. The outlay of the Department of AYUSH was increased from Rs. 775 crore in the 10th FYP to Rs. 3,988 crore in the 11th FYP.[20]

The 12th FYP (2012-17) Report[21] is a significant document in the evolution of the policies and programmes relating to AYUSH sector. In the Foreword to that document, the chairperson stated explicitly that "we must ensure that the ***Health care delivery system*** in the country is designed and developed in such a way that both AYUSH and allopathic systems are available to every patient and the **choice of system of treatment** is the ***patient's choice***…"[22] It also made a clear statement that the strength of the AYUSH system lies in promotive, preventive & rehabilitative health care, diseases and health conditions relating to women and children, mental health, stress management, old age problems, and non-communicable diseases and that the Department should retain its primary focus on these areas of core competencies.[23]

8.3 Patent Policies and AYUSH Systems

The relationship of AYUSH systems with Intellectual Property Rights like patents is totally different from the relationship between modern medicine and patents. Accordingly, the issues also differ. Most of the drugs in these systems have been developed long back and are not patentable. However, there have been attempts abroad to patent certain properties of the ingredients of these medicines such as the wound healing properties of Turmeric in the US in the 1990s. Since India considers such knowledge as part of its cultural heritage it took action against such misappropriation and got the patent revoked. Similar attempts were made in Europe also. A major cause of this was the absence of much published literature on the issues in the West and also almost total absence of data in the patent databases of the IP offices. India, therefore, in order to protect its traditional medicines, set up a Traditional Knowledge Digital Library to (TKDL) in 2001, the earliest and most comprehensive database globally.[24] It is arranged in a patent search friendly format; is accessible in five international languages; and is based on an innovative classification system Traditional Knowledge Resource Classification (TKRC). It serves as an important source of information on prior art on the Indian systems of medicine. Internationally, the TKDL is accessible to 12 patent offices[25] but other patent offices can seek access subject to the conditions laid down by the TKDL authority. Till date, in

225 cases the patent applications have either been withdrawn/cancelled/declared dead/ terminated or have had claims amended by applicants or rejected by the Examiner(s) on the basis of TKDL submissions.[26] The TKDL is considered a pioneer initiative to prevent misappropriation of the country's traditional medicinal knowledge.

Apart from TKDL, the Patents Act also has specific provisions to reject patent applications based on Traditional Medicine Systems. Applications for patents based on TK, "oral or otherwise, available within any local or indigenous community in India or elsewhere" and/or biological material contravening the provisions of law can be refused[27] during examination by the Patent Office or during pre-grant opposition[28] and granted patents can even be revoked as a result of post-grant opposition.[29,30] This provision enables protection of traditional medicinal knowledge (TMK) anywhere in the world from being granted patents in India. As per the Patents Rules, 2003, a patent applicant has to disclose the source of the biological resource used in the invention and permission of the competent authority to access the same. Nondisclosure or wrong mention of the source or geographical origin of biological material used in an invention in the complete specification also forms a ground for pre- and post- grant opposition as well as revocation of the patent.[31]

The issue is when the medicinal products of AYUSH systems are exported abroad, they do not enjoy any patent protection. That means once the market is developed, others will also be able to manufacture and sell it subject to other applicable laws of the country concerned.

8.4 Status

The AYUSH systems are quite widespread in the country giving positive hopes for the Ayush drug manufacturing industry. The Table 8.1 presents the status of the sector as on 11th December 2019.

Table 8.1: AYUSH System in India

Item	Number
Hospitals	3,986
Dispensaries	27,149
Colleges	914
Students	52,726
Practitioners	13,87,539
Patients	18,03,98,054
Manufacturing Units	8,954

Source: Ministry of AYUSH dashboard at https://dashboard.ayush.gov.in/#. Accessed on 27 February, 2021.

Table clearly indicates that AYUSH systems play a significant role in provision of healthcare in India. For many of these variables, the scale of AYUSH systems in India surpasses even that of TCM in China, even though the sector has not received the same honour as Western Medicine does in the country. For example, as of 2018, China had 3,695 TCM hospitals, compared to 3,986 AYUSH hospitals in India (James *et al.* 2020).

ISMs were not earlier commercially manufactured and, therefore, there was no ISM drugs and pharmaceutical industry in the country. The practitioners were manufacturing the products at a small level and supplying directly to the patients. Because of its very nature, large number of patients were making them at home as per the prescription of the local physician. There, certainly, was a medicinal plants market. It was towards the end of the 19th century and the beginning of the 20th century that many commercially producing firms got established.[32] Major players in the sector are Kottakkal Arya Vaidya Sala, Dabur, Himalaya, Zandu, Baidyanath, Hamdard, Sydler Remedies, Ganga Pharma, G.R. Herbals, Hootone Remedies. Patanjali Ayurveda, and Sri Sri Tattva are comparatively new comers but have made rapid progress.

8.5 AYUSH Product Manufacturing, Quality Control and R&D[33]

AYUSH, as medical products, includes players that are broadly organised. However, there are overlaps between the sector and other sectors, which make it difficult to estimate the size of the market. There is confusion regarding the description and differentiation between AYUSH, Natural, Organic and Herbal products. While they all are largely a part of the wellness industry, there are differences in their meaning and coverage. Ayurveda forms a major component of AYUSH. According to Confederation of Indian Industry (CII),[34] in the year 2016, domestic Ayurveda product market was $ 2.27 billion, but this comprised of classical, proprietary, over the counter (OTC), personal care and beauty products. The Traditional Knowledge Digital Library (TKDL) provides a list of around 82,900Ayurveda medical formulations. Official estimates of Ayurveda classical drug formulations market size are unavailable.

More than 75 per cent of the business today is in private sector. Most of these companies are small and medium sized and only around 50 companies have revenue above Rs. 100 crore in 2016-17. These 50 companies account for over 85 per cent of the revenue generated by this sector. According to Ayurvedic Drug Manufacturers Association (ADMA), which has around 9,000 members, 99 per cent of their members are MSMEs (micro, small and medium enterprises). As 100 per cent Foreign Direct Investment (FDI) is permitted in the AYUSH sector, it is attracting many domestic and international investors. With the growing potential of the AYUSH sector, several start-ups are also working on innovative ideas to tap this market and serve customers not only in Tier-1 and Tier-2 cities but also in the rural parts of India.

Efforts have been made to develop comprehensive guidelines and directives focusing on drug development (Standardisation and quality assurance), safety and toxicity and clinical evaluation for ready reference of stakeholders. Regulatory provisions are laid down prescribing conditions required to be fulfilled for grant of licence to manufacture Ayurvedic, Siddha, Unani and Homoeopathic (ASU&H) drugs, which include compliance to Good Manufacturing Practices (GMP) and proof of safety and effectiveness as prescribed under Drugs & Cosmetics Rules and adherence to quality standards of identity, purity and strength of drugs as prescribed in the respective pharmacopoeia. WHO-GMP and Certificate of Pharmaceutical Product (CoPP) Guidelines are applicable for quality certification of ASU herbal drugs intended for export and international trade. Quality standards of identity, purity and strength of about 2600 ASU&H drugs are published in the respective pharmacopoeias, which are mandatory for the industry to manufacture drugs under licence. Analytical techniques and equipment used for the testing of Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs and medical interventions are the same as applicable in modern system of medicine. Research Councils and Pharmacopoeia Committees of AYUSH undertake the work of standardisation and quality testing of drugs by adopting pharmacognostical and physico-chemical methods including macroscopic, microscopic and various instrumental techniques such as Thin Layer Chromatographic fingerprints. GCP Guidelines, ICMR's Ethical Guidelines and WHO Guidelines are followed, as and where required, for clinical validation of AYUSH interventions and evaluation of efficacy and safety of drugs.

Research and Development in the field of AYUSH system in different areas such as drug development including quality assurance, pre-clinical safety evaluation and clinical research are being conducted at different levels including Research Councils, academic institutions (both AYUSH and non AYUSH institutes such

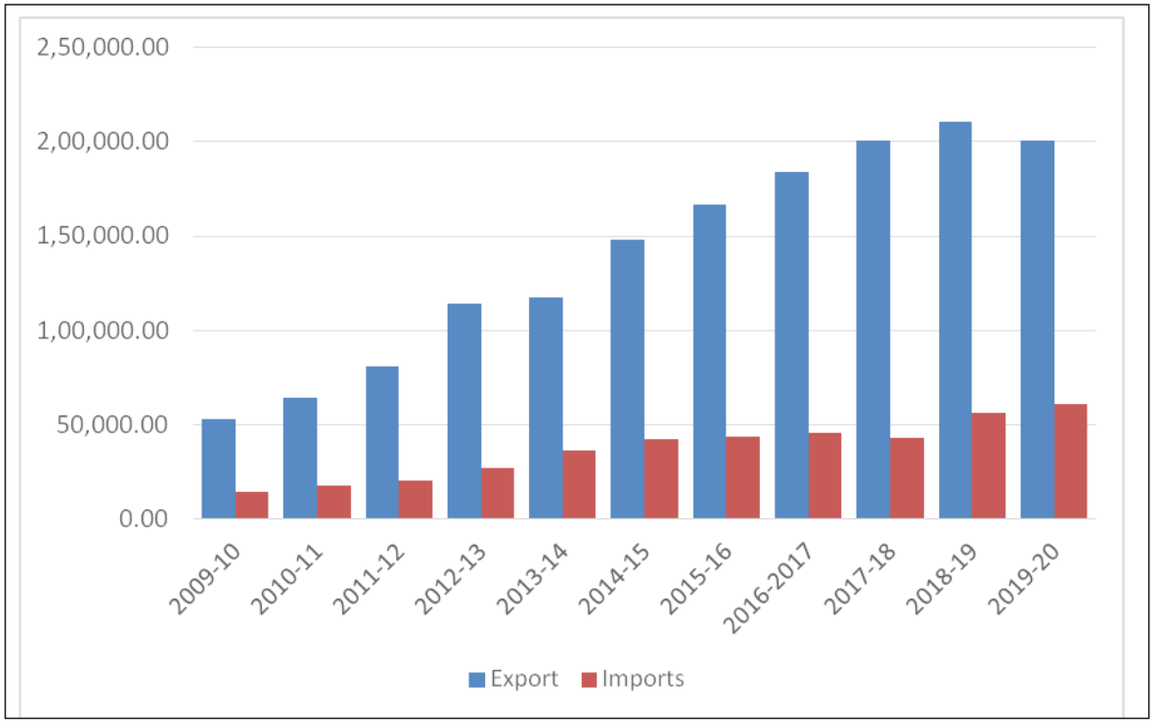
as Medical Colleges, Universities, etc.) and other research organizations such as ICMR, CSIR, etc. R&D interventions in AYUSH are by and large done on the basis of integrated protocols and methodologies involving both AYUSH and modern scientific parameters of analysis and assessment. In this direction, collaborative research activities in AYUSH are being promoted involving premier medical and scientific institutions and registration of clinical research studies for ASU&H drugs is done in Clinical Trials Registry of India (CTRI) maintained by the Indian Council for Medical Research (ICMR).

8.6 Trade[35]

During the last two decades or so, traditional medicine systems have been receiving increased international acceptance and promotion. Traditional Chinese Medicine products and services are now available in a good number of countries. India has also been making special efforts recently for promoting Indian Systems of Medicine abroad. It has been observed that "the immense untapped export potential for herbal products already existed and with COVID-19, the real demand for traditional products has witnessed a steep up stick."[36] There is great demand for herbal products and medicinal plants in countries like Korea and Japan who are currently importing them from China and Vietnam.[37] India has also been an important player in the traditional medicine products and medicinal plants global trade as may be seen from Figures 8.1, 8.2, 8.3., 8.4., and 8.5.

In terms of specific commodities under HS section 1211 Psyllium Husk (Isobgul Husk) remained the top exported medicinal plant from India in value terms. In 2018-19, the plant had an export value of Rs. 1,40,301 lakh. Other important herbs exported from India are Zedovary roots; Senna Leaves; Psyllium

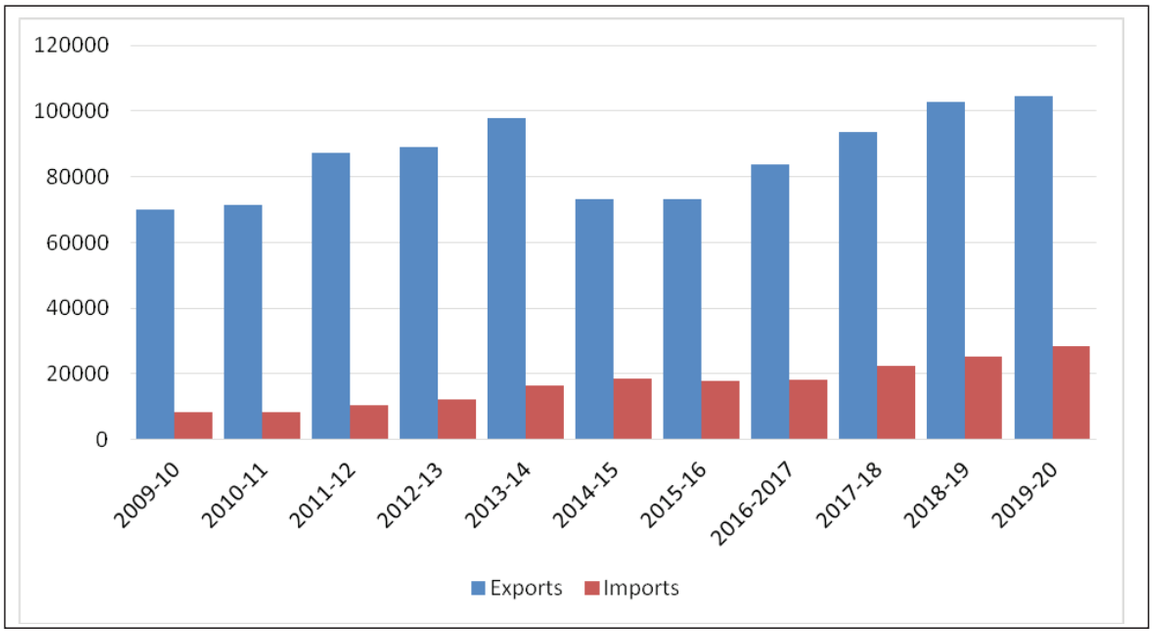
Figure 8.1: Exports and Imports of Herbal/Medicinal Plants from India



Note: Values in Rs. Lakh (Data from HS 1211).

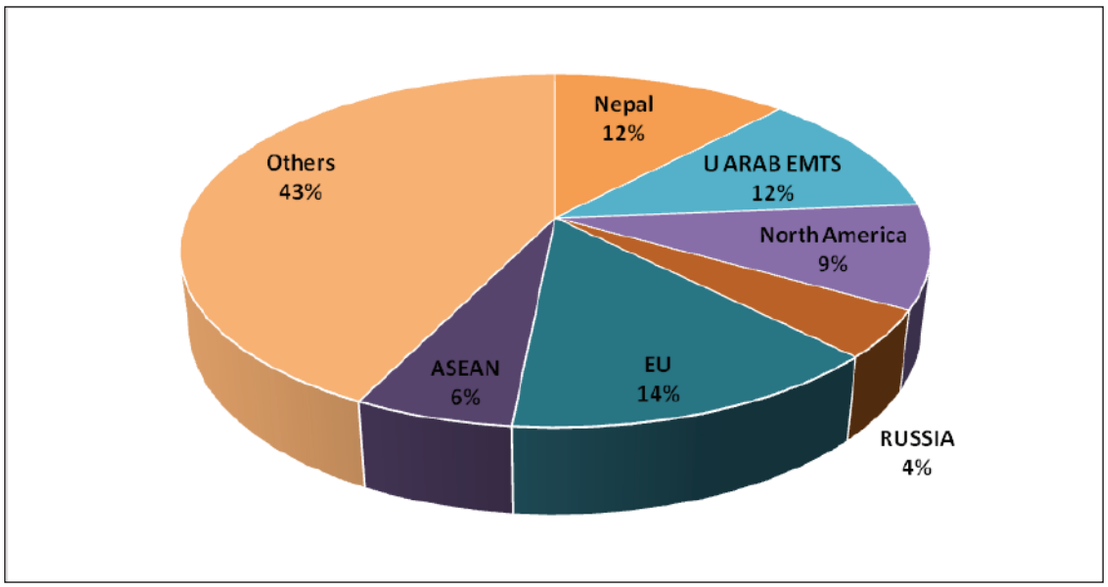
Source: Export Import Databank, Department of Commerce, Government of India.

Figure 8.2: Export and Import of Traditional Medicine Drugs



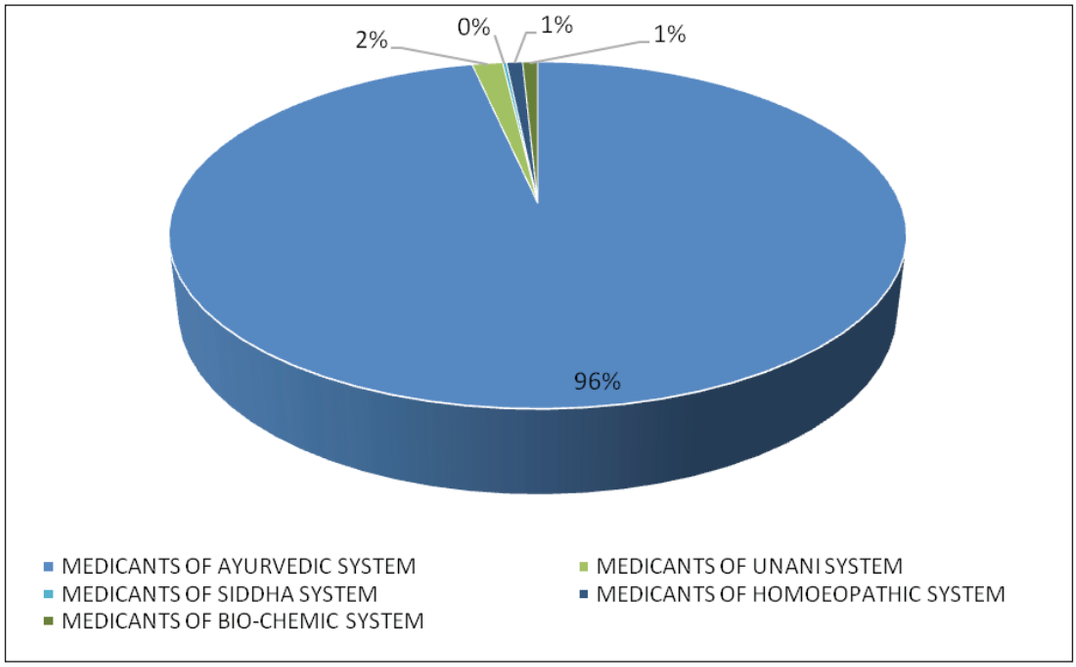
Note: Values in Rs. Lakh (Data for HS 30039011-15 and 30049011-15).
Source: Export Import Databank, Department of Commerce, Government of India.

Figure 8.3: Country and Region wise Exports of Ayurveda Medicaments, 2019-20



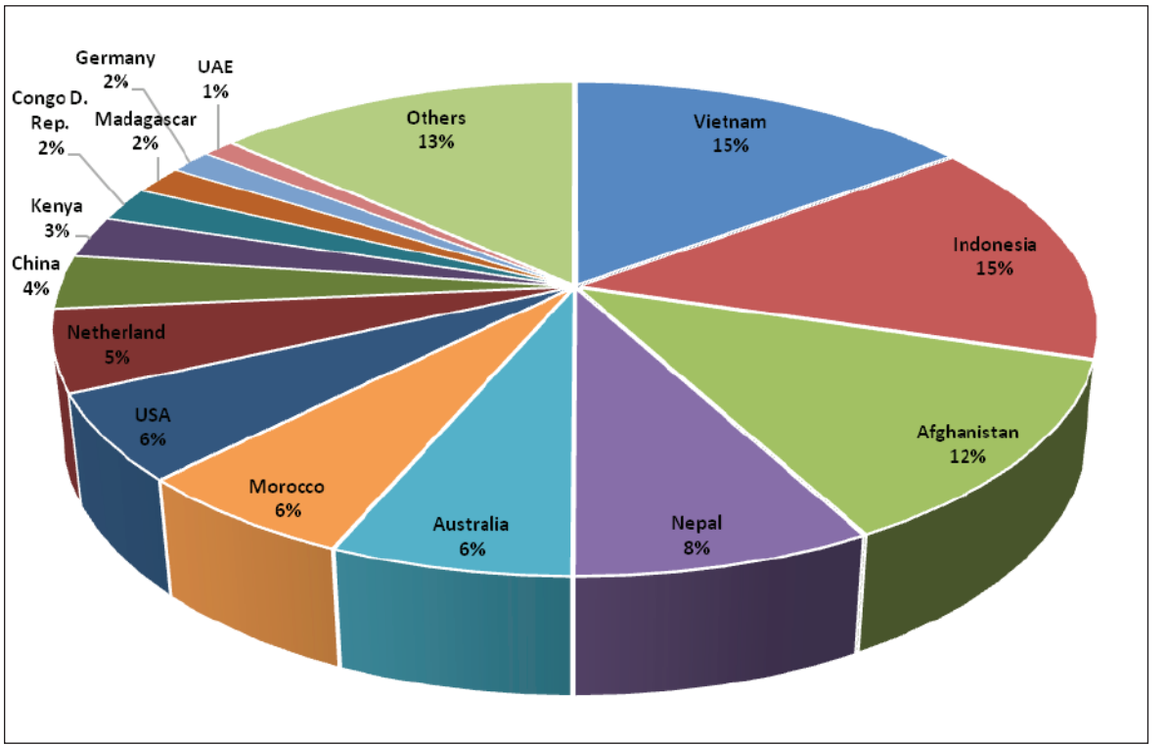
Source: Export Import Databank, Department of Commerce, Government of India.
Note that at the country level, Nepal imported the highest amount of Ayurveda medicaments from India in 2019-20.

Figure 8.4: System wise Export of traditional Medicines from India, 2019-20



Source: Export Import Databank, Department of Commerce, Government of India.

Figure 8.5: Imports of Medicinal and Aromatic Plants to India, 2019-20



Source: Export Import Databank, Department of Commerce, Government of India.

Seed (Isobgul); Basil, Hyasop, Rose Mary, Savory and; Tukmaria. Major medicinal plants imported in India include, Basil, Hyasop, Rose Mary Sage, Savory; Cubeb powder; and Sandal Wood chips and dust.

As seen in Figure 8.1, India also enjoys a trade surplus in the net exports of Traditional Medicine drugs. Figure 8.2 gives the nominal trade statistics for exports and imports of TM medicaments as reported by India between 2009-10 and 2019-20. The figure showed that the exports of TM medicaments from India suffered a decline 2013-13 and 2016-15. The exports, have since picked up again peaking at 2019-20

Medicament of Ayurvedic system takes up the majority of exports whereas medicaments of homeopathic system form the majority of imports in the country. Figure 8.4 shows the extent to which Ayurveda system dominates the exports of TM medicaments in India. In 2019-20, Ayurveda constituted nearly 96 per cent of total exports of TM medicaments from India. Figure 8.3 shows the major destinations of these Ayurvedic medicaments. Country wise, Nepal and UAE imports 12 per cent each of the total Ayurvedic medicaments exports from India. Although, the European Union region also imports a significant amount of Ayurvedic medicines from India, constituting 14 per cent of total Ayurvedic medicaments exports in 2019-20. A potential market for future can be ASEAN where TM sector is influenced heavily by the TCM sector (James *et al*, 2020). We would need significant push from the government in order to penetrate the ASEAN TM market.

It is important to note that the growth of TM sector in the country is constrained by sustainable supply of raw herbs and extracts of medicinal plants. In some cases it is important to source these herbs from other countries, provided the quality of raw material is not compromised. Currently India imports majority of its MaPs from Vietnam and Indonesia at 15 per cent each. Both of these South East Asian tropical countries have climate similar to that of Southern India and hence are ideal for imports of certain MaPs species. The next most important country from where we source our MaPs is Afghanistan. Although the majority of imports of MaPs from Afghanistan is recorded in the others category, it can be assumed that saffron would constitute a large extent of MaPs coming to India from Afghanistan, owning to the quality of saffron available in the country at very reasonable prices.

8.7 Policy Initiatives for Trade Promotion

The government has launched a number of initiatives for promotion of quality of the products, which is a pre-requisite for global trade. These include, *inter alia*, notifying Good Manufacturing Practices (GMPs) for Ayurvedic drugs and liberalising labelling provisions for export of products by amending Rule 61 of the D&C Rules. There is good scope for export of medicinal and aromatic plants. The major sources of these plants being sold in the EU market in 1999) were USA (32 per cent), China (31 per cent), and Germany (28 per cent).[38] The Exporting Indian Health Care report further observed that the products that were in high demand in Europe were that "give energy" in UK, France and Germany, that lowers cholesterol in UK and France, that promotes healthy bones in UK and Germany, and blood immune system in Germany and France. The sector is therefore full of potential for exports.

Endnotes

1 Janmejaya Samal, A Brief assessment of Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy health system based on Five Year Plans of India, in *International Journal of Green Pharmacy*. Jul-Sep 2016 (Suppl).10(3). 91-95.

2 Report of the Steering Committee on AYUSH for 12thFive Year Plan (2012-17). Planning Commission, Government of India. 2011. Quoted in Annexure III of the Report.

3 Usman Committee Report at Oro.open.ac.uk/71069

[4] The Health Survey and Development Committee set up by the Government of India in 1943 under the chairmanship of Sir Joseph Bhore made comprehensive recommendations for remodeling of health services in India and also laid emphasis on integration of preventive and curative medicine at all levels. (https://www.nhp.gov.in/bhore-committee-1946_pg).

[5] Supra. 2.

[6] Ibid.

[7] Ibid.

[8] Ibid.

[9] Ibid.

[10] Ibid.

[11] Ibid.

[12] https://www.nhp.gov.in/nhpfiles/national_health_policy_2017.pdf.

[13] Planning Commission Report (PCR) on 1st FYP. New Delhi.

[14] PCR on 4th FYP. New Delhi.

[15] PCR on 5th FYP. New Delhi.

[16] PCR on 7th FYP, New Delhi.

[17] PCR on 9th FYP, New Delhi.

[18] Ibid.

[19] PCR on 11th FYP, New Delhi.

[20] Report of the Steering Committee on AYUSH for 12thFive Year Plan (2012-17). Planning Commission, Government of India. 2011

[21] Ibid. Foreword.

[22] Ibid.

[23] Ibid. Chapter 1.

[24] James, T.C., Pathak. N. andYadav. D. 2017. Access and Expansion of Traditional Knowledge Digital Library and Incentivization of Innovations, *FITM Policy Brief*, p.1. Available at http://ris.org.in/fitm/sites/default/files/FITM%20Policy%20Brief_1.pdf

[25] *Ibid*, p 2.

[26] See http://www.csir.res.in/documents/tkdl (Last accessed on 18 February, 2021.)

[27] *Ibid* Section 15

[28] *Ibid* Subsections (d), (f) and (k) of Section 25 (1)

[29] *Ibid* Subsections (d), (f) and (k) of Section 25 (2)

[30] *Guidelines for Processing of Patents Applications Relating to Traditional Knowledge and Biological Material , Office of the Comptroller General of Patents, Designs and Trade Marks*.

[31] Patent Rules, 2003, Subsection (j) of Sections 25 (1) and 25 (2) and Section 64 (1)(p) respectively

[32] Exporting Indian Health Care, Exim Bank, 2013. P.6.

[33] We are grateful to Dr Namrata Pathak, Research Associate, RIS for contributing this Section.

[34] Ayurveda Industry Market Size, Strength and Way Forward , 2018 Confederation of Indian Industry (CII) http://ayurvedaindustry.com/pdf/ayurveda-industry-report.pdf

[35] The authors acknowledge with thanks the contribution of Mr Apurva Bhatnagar, Researcher, RIS for this section.

[36] Invest India Brief on AYUSH Roundtable: Global Promotion of AYUSH Products and Services, 26 February, 2021.

[37] Ibid.

[38] Exporting Indian Health Care. 2003. Export-Import Bank of India. Pp. 106-107.

IX
Challenges and Way Forward*

9.1 Introduction

Indian pharmaceutical industry has been on a growth path during the last almost five decades. This has been possible because of timely policy interventions to overcome particular challenges the industry was facing from time to time. The nature of the challenges varied periodically. There was a time when it was facing incipient troubles of an infant industry, but now Indian pharma has become a major global player. Its current challenges, therefore, relate to global competition. They include issues relating to regulations, quality standards, technology upgradation, and so on. The Indian companies are also encountering a challenge of acceptance of Indian pharmacopoeia which is quite comparable to the global best and has 2,996 monographs. However, it is accepted by Afghanistan and Ghana only, as of now. There are also issues relating to value chain integration and problems arising out of disruption of value chains. This chapter examines these and other challenges and proposes way forward, as emerging from the study as well as from interaction with industry and policymakers.

9.2 Challenges

The pharmaceutical industry consists of different sectors such as bulk drugs, formulations and medical devices, apart from AYUSH medicines. While there are some major firms [1] that are engaged in more than one segment, most, especially MSMEs, are concentrating on a limited number of products and also in one of the three sectors. Their problems also many a time differ. Hence, we propose to look at all three sectors separately first and then issue-wise.

9.2.1 Bulk Drug Industry

Due to conscious and consistent efforts of the Indian government in the past, like the establishment of public sector units such as the HAL and IDPL, introduction of statutory ratio parameter, compulsory supply of bulk drugs to non-associated formulators, the bulk drug industry got a significant boost. The exports of bulk drugs increased considerably, especially after the late 1990s while its imports remained comparatively lower. As a result, in 1996, India achieved a momentous position in this segment

* Many of the suggestions regarding way forward have emerged during the Round Table Consultation with policy and academic experts and industries on 20 January, 2021.

of the pharmaceutical industry, *i.e.* attaining trade surplus. The trade surplus increased from $ 60 million in 1996 to $ 1.4 billion in 2011 and its share in global exports reached close to 7 per cent. However, since 2012, the bulk drug exports have been mostly decreasing while imports have been continuously increasing which not only resulted in a considerable decline in India's share in global exports of bulk drugs (4.6 per cent in 2018) but also an increase in the trade deficit. The main challenge facing this sector is how to increase production and exports.

During the last three decades, the bulk drug industry in India has undergone many structural changes. The global value chain process has led to the closure of many uneconomical units, thereby leading to the loss of fermentation-based manufacturing facilities, over time. Several factors are responsible for this. Policy changes such as the requirement of production from the basic stage onwards, abolition of ratio parameters, etc. have led to a loss of market for domestic manufacturers and made the small ones uneconomical and non-competitive in the global market, leading to their closures. During the nineties when the country was facing a foreign exchange crunch, there was a shift in focus to more value-added formulations. This helped the growth of exports of formulations but at the same time, the API industry was left on its own to face the onslaught of competitively priced products from China. This wiped-out Penicillin G units[2] like HAL, and also the other API manufacturers of antibiotics and other needed drugs. We lost both in the domestic market as well in exports. Almost 35/40 per cent of existing capacities are lying unutilised. As per IDMA estimates,[3] out of the list of 41 APIs identified by the government,[4] at least 20 can be manufactured immediately with minor changes in existing plants and these are the lowest hanging fruits giving results in just six months to ward off Chinese dependence.[5]

Revival or setting up new fermentation units is a time-consuming process. Therefore, Brownfield units could also be considered for inclusion in the revival scheme. In the case of Greenfield units, it will take a minimum of two years time to commence production. Existing capital utilisation would have been prudent. For fermentation units, there is a huge investment needed. Industry was hesitant and wanted assurance from the Government to protect it from price war by firms from any country. The industry should also be designated as Infrastructure industry, with 5/25, i.e. five years moratorium period and twenty-five years to pay loans, etc.

Secondly, the contribution of the domestic API industry contracted because the public sector pharmaceutical units, that had added significantly in the past to the growth of the industry by establishing modern plants for the manufacture of bulk drugs at a reasonable cost, were adversely affected to a great extent owing to government policies, such as disinvestment in public sector units, closure of loss-making units[6], allowing small formulators to take on a large part of the production, delay in approvals for revision of prices, and, to some extent, due to infrastructure and managerial problems. Third, the policies related to pricing under DPCO have also played a key role in dismantling the API production base in India, as the price ceiling on formulations had put a lot of pressure on Indian companies to find cheap alternative sources of API to reduce the cost of production (GOI, 2020). Fourth, during the same period, a favourable policy environment was being offered in China, such as relatively relaxed environmental and pollution regulations and the availability of cheaper labour and electricity, etc. which supported it in emerging as a low-cost supplier of APIs. As a result of these developments, India's imports of bulk drugs kept on increasing significantly and it lost assured domestic supply chain in many significant pharmaceutical products. This is

particularly so in the fermentation-based APIs, many Key Starting Materials (KSMs), solvents, etc. For these products, India now relies on other countries, especially China, as brought out in the previous chapters. In the past few years, the industry's reliance on imports from China has gone up significantly and it has also encountered a decline in APIs exports, especially after 2011. Out of the total imports of APIs, 56 per cent was from China in 2018-19. In some of the products like Penicillin, Vitamin B12, Heparin, Rifampicin, Erythromycin, etc. the dependency is quite pronounced since the imports from China constitute more than 75 per cent of the total imports of those products.

Such an extreme dependence on a single country could become a major issue for domestic health security, especially in times of war, pandemics etc. During the ongoing COVID 19, the Indian government, like other governments, actually realised it and launched the Production Linked Incentive (PLI) Scheme for the promotion of domestic manufacturing of 41 products covering 53 identified APIs.[7] These products belong to four segments, namely, Key Fermentation based KSMs/Drug Intermediates; Niche Fermentation based KSMs /Drug Intermediates/APIs; Key Chemical Synthesis based KSMs/Drug Intermediates; Other Chemical Synthesis based KSMs/Drug Intermediates / APIs.[8] The main objective of the PLI scheme is to endeavour to create self-sufficiency and diminish import dependence in critical KSMs/DIs/APIs through giving financial incentives to designated companies based on threshold investment and increment domestic sales. For fermentation-based APIs, the provision of financial incentive kept on the higher side in comparison to chemical synthesis based APIs.

In addition to this, the GOI launched a scheme to promote "Bulk Drugs Parks" in the Indian economy.[9] The primary goals of this scheme are the provision of easy access to world-class Common Infrastructure Facilities (CIF) to manufacturing bulk drug units situated in the park in order to significantly reduce their manufacturing cost, thereby, improving their price competitiveness; assist bulk drug industry in fulfilling the environment standards at minimum cost *via* innovative methods of common waste management system; and help in reaping the benefits occurring from optimization of resources and economies of scale.[10] Implementation of the scheme, however, has to avoid the pitfalls of apportioning products among manufacturers that will lead to monopolies; competition among enterprises is the best way to ensure production and supply of quality products at competitive prices.

The availability of bulk drugs domestically would no doubt assist the Indian economy in attaining health security, particularly during an emergency, as it would not have to depend on foreign countries for its domestic requirements. At the same time, since the pharmaceutical industry's fortune is also dependent on the global market, and given the complexity of the products whose manufacturing is dependent on long supply chains, it cannot entirely disregard international trade. The industry should ensure that supply chains are agile to respond promptly to demand changes

The provision of common infrastructure facilities would improve the competitiveness of the bulk drug industry through optimally utilizing the resources and economies of scale. Further, it would assist the bulk drug industry in meeting the standards of the environment protection regulations *via* using innovative methods of a common waste management system. The challenge before the industry is not only one of revival and setting up of new units, but ensuring cost-effective, globally competitive production. The way forward involves investing in technology and management apart from attracting large scale investment.

The industry is also facing financial constraints, particularly in the fermentation-based ones, due to its highly capital-intensive

nature and huge time-lag in investment leading to profit. To rectify the financial issues, a suggestion made was to provide sovereign collaterals and moratoria for two years at zero or nominal rate of interest. API industry being basic to India's competitiveness in the pharmaceutical sector, this sector has to be nurtured with special care and ideological fixations on 'industrial activities are for private sector only' cannot be allowed to dictate terms. Strategic involvement of government in the sector will have to be considered. The public sector can contribute significantly in basic research, technology development and transfer, development of specialised human resources including skill development of workers. Health security, like food security, is fundamental to national security and targeted government action involving both public and private sectors, is required in this area. For attaining health security, the government may also think of reviving the PSUs,[11] which have stopped producing bulk drugs and could be given the responsibility of producing those bulk drugs, which are mainly required by the poor people. Unless the API industry is strong, the formulation industry will not be healthy and will not be a sustainable exporter.

9.2.2 Formulation Industry or Pharmaceutical products (HS chapters 3001 to 3004)

The global recognition of India as a source for affordable quality generic drugs is the result of key policies and regulations implemented in the past, viz. the Patents Act 1970, FERA 1973, Drug Policy, 1978, and Drug Policy 1986. In the last two decades, the Indian pharmaceutical industry has attained phenomenal growth as reflected by its continuous increasing share in global exports in terms of both value and volume. In terms of value, India's share in global exports has reached 2.8 per cent in 2019 and with respect to volume, it has accounted for 5.1 per cent. In the global generics market, India's share is around 20 per cent in relation to value.[12] By 2020, Indian pharmaceuticals has achieved almost 85 per cent share of the domestic market which was just 5 per cent in 1969.[13]

Despite this phenomenal growth and the bright prospects in near future, this industry is currently facing some major challenges, such as price competitiveness, efficiency, distribution of generics, quality and standard of the drugs (Kumar and James, 2021). From the empirical analysis, we observed that in 1996, India had price competitiveness in most of the pharmaceutical products over major exporters of pharmaceutical products and India was able to maintain this competitiveness until 2009.[14] In the last 10 years, however, India has lost the price competitiveness with almost all major exporters in a significant number of pharmaceutical products as brought out in Chapter 7.

When India's price competitiveness is compared with China, this loss is quite significant. Pharmaceutical products in five HS lines, [HS 300490 (77 per cent), HS 300420 (6.8 per cent), HS 300410 (3.4 per cent), HS 300390 (1.9 per cent) and HS 300450 (1.4 per cent)], accounted for more than 90 per cent share in India's global exports of formulation in 2019-20 in which India was found to be non-competitive in price *vis-à-vis* China. The draft of pharmaceutical policy [Government of India (GOI), 2017] made a similar observation. The Policy highlighted that the Indian pharmaceutical industry is facing increasing competition from foreign countries, especially from neighbouring and other Asian countries like Vietnam, Korea, Sri Lanka and Bangladesh. It further added that the comparative advantage of the Indian pharmaceutical companies got weak due to the takeover (mergers and acquisitions- M&A) of Indian pharmaceutical companies. The theoretical argument in support of the negative relationship between the increase in M&As and the decline in price competitiveness is that increase in M&As results in an increase

in prices due to shortages of the product and a decline in price competition (Gagnon & Volesky, 2017). The US economy experienced a significant increase in the prices of generic drugs during that period in which a substantial number of M&As took place.[15] Similarly, India, in the post-TRIPS period has experienced an increase in prices in a number of drugs in several therapeutic groups (Chaudhuri, 2019). Most of M&As took place between the late 2000s and early 2010s and Indian pharmaceutical companies have lost comparative advantage in the last ten years, as noted in earlier chapters.

Within India, the domestic market structure of the pharmaceutical industry is highly competitive or less concentrated[16] as the value of the Herfindahl Index (HI) estimated to be less than 0.15,[17] based on analysis of the top seven therapeutic categories from the molecules in India, with an annual sale of at least Rs. 100 crore.[18] One of the major advantages of having a competitive market structure is that prices of pharmaceutical products remain close to the market-clearing level, which, in turn, maximises consumer surplus as highlighted in the standard economic theories of the market economy. But, a major disadvantage of competitive market structure is that firms mainly concentrating in generics are reluctant to undertake R&D expenditure as there are very limited chances to recoup this expenditure (Danzon & Furukawa, 2003).

In addition to this, the loss of API production base, particularly the fermentation-based, and pricing policy under DPCO are other reasons for loss of price competitiveness, as discussed in the previous section.

The schemes launched for bulk drugs, i.e. PLI and bulk drugs parks, would assist the formulation industry in improving price competitiveness if bulk drugs would be produced in large volumes as in China. Due to economies of scale and efficient management practices, China has been able to produce lower-cost bulk drugs, and consequently low-cost formulations. Further, to improve its position in relation to competitiveness in the international market, the policies will have to be complemented with measures in the direction of new technological developments, such as biotechnology, gene-technology, bio-similar, Artificial Intelligence, 3D printers, Machine Learning, AR-VR, Digital Apps, Blockchain, Organ-on-Chips, etc.

9.2.3 Medical Devices

India never was a leader in this sector and was mainly dependent on imports for advanced instruments. India's imports of medical devices have increased from $ 171 million in 1991 to around $ 6.7 billion in 2018 whereas its exports grew from just over $ 40 million to $ 2.1 billion. As a consequence, the trade deficit has considerably increased from $ 131 million to $ 4.6 billion. Further, India's imports of medical devices are much more diversified in comparison to their exports. The major MD exports comprise low-tech items like needles, catheters, contraceptives and so on, while major imports include high technology instruments and appliances. This trade structure in medical devices is one of the reasons for the rising deficit as low-tech items have lower value in comparison to high-tech items. Additionally, the manufacturing cost of medical devices in India is found to be high due to inadequate infrastructure, issues with domestic supply chain and logistics; costly finance; the paucity of quality energy; the absence of capabilities in designing; and lack of focus on R&D and skill development. Overall, the challenges in this sector are of technology and precision manufacturing. Competitiveness has to be created through cutting edge technologies and efficient management of manufacturing units which adhere to GMPs.

In the pharmaceutical sector, like in other industrial sectors, a challenge is sudden changes in policies, particularly tax regimes. These changes affect both large and MSME units, but more the MSMEs. For example, the MSME-

dominated medical device manufacturing got severely affected by the imposition of GST, whereby imports became 11 per cent cheaper. The result was a sudden surge in imports by 24 per cent from Rs. 31,386 crore in 2017-18 to Rs. 38,837 crore in 2018-19.[19] This makes the MSME units unviable. Policy changes need to be nuanced from various angles. The sector was already facing an acute cash shortage because of certain other developments.

To improve the position in this sector, the GOI, recently, launched two schemes, namely, the PLI scheme for encouraging the production of technology-intensive medical devices through financial assistance and attracting foreign investment and building of four "Medical Devices Parks" for providing common testing and laboratory facilities at place.[20] Under the PLI scheme, the financial incentives would be given to designated companies on the basis of their threshold investment and incremental sales (5 per cent of incremental sales over Base Year) from 2020-21 to 2026-27 mainly in four segments *viz.* "Cancer care / Radiotherapy medical devices; Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging devices; Anaesthetics & Cardio-Respiratory medical devices including Catheters of Cardio-Respiratory Category and Renal Care medical devices; and All Implants including implantable electronic devices".[21]

The provision of common testing and infrastructure facilities under the scheme of 'Medical Devices Parks', would include "component testing centre/ESDM/PCB/ sensors facility, electro-magnetic interference & electromagnetic compatibility centre, biomaterial/ biocompatibility/accelerated ageing testing centre, medical-grade moulding/ milling/injection moulding/machining/ tooling centre, 3D designing and printing for medical-grade products, sterilization/ETO/ gamma centre, animal lab and toxicity testing centre, radiation testing centre etc."[22]

On one hand, these parks would assist the manufacturing companies in reducing their manufacturing cost greatly through reaping benefits arising from optimization of resources and economies of scale. On the other hand, these parks would help in improving India's price competitiveness internationally. Institutions like the National Institute of Pharmaceutical Education and Research (NIPER) have launched initiatives in the testing of medical devices, introduction of MTech. courses in this sector, etc. which should bring benefits in the long term.

The new schemes have been well-conceived, but there are issues like coverage of industries under PLI, etc. These will have to be addressed fast and rectified. At this point, it is too early to assess the impact of the schemes, especially when the general economy itself is recovering from the setbacks caused by the COVID-19 pandemic.

9.2.4 Gross Capital Formation (GCF)

In the period after India joining the WTO in 1994, the industry did not witness any negative impact on the value of output, gross value added (GVA) and profits. In fact, after the introduction of the product patent regime in 2005, it has done better in these variables. However, with respect to the gross capital formation (GCF), the performance of the pharmaceutical industry deteriorated in the post-TRIPS period despite an increase in the number of pharmaceutical industries from 2,868 in 2004-05 to 5,060 in 2017-18. In an analysis based on the Annual Survey of India (ASI) database, we have observed that the GCF was growing at 20 per cent CAGR during the period from, 1999-2000 to 2004-05, but it declined to 16.3 per cent between 2004-05 and 2009-10. During the entire post-TRIPS period (2004-05 to 2017-18), it has grown at 11.5 per cent CAGR.

A hundred per cent FDI is already allowed under the automatic route for Greenfield pharma; for Brownfield pharma,

74 per cent is allowed under the automatic route and thereafter through the government approval route. Drug price control is the only issue which according to industrialists makes the sector unattractive to investment, but how much that is a decisive factor is not clear. One way, the investment in the sector can go up is to enhance the domestic paying capacity of patients through schemes such as health insurance. On a more concrete level, the government can consider setting up a massive capital fund to provide support to pharmaceutical manufacturing in the country.

9.2.5 FDI, Technology Transfer and Innovation

Despite allowing 100 per cent FDI in the pharmaceutical industry *via* automatic route and, implementing all the provisions of the TRIPS agreement in 2005, there was no significant change in the trend of the FDI inflow in the drugs and pharmaceutical industry in India. In 2011-12 only, there was a noticeable jump in the FDI inflow when it increased from $ 209 million in 2010-11 to $ 3,232 million, but has been steadily declining since then, falling to 266 million USD in 2018-19; it improved in 2019-20 marginally. The remarkable feature of FDI inflow in the pharmaceutical industry is that a significant proportion of the investment came in the form of Brownfield through mergers and acquisitions (M&As). Further, there is no evidence of transfer of technologies pertaining to process improvement, drug discovery, operation management practices, IT system and quality control measures.

In addition to huge market size and well-developed pharmaceutical sector, the FDI inflow into the Indian pharmaceutical industry would depend upon acceleration in economic reforms, removal of barriers to foreign investment and technology transfer, provision of incentive for foreign investors to carry out R&D expenditure, improvement in the business environment (include both political stability and legal factors), protection of foreign investors' IP (Rai 2009). Further, FDI into a country is dependent on a conducive environment for the domestic industry also. Frequent policy changes, price controls and retrospective implementation of laws and rules act as deterrents (IPA 2019). There is a need for stable policies and no retrospective implementation including taxation.

9.2.6 Clinical Trials

Based on the WHO database, we have found that the cumulative total of the number of clinical trials in India has increased from 12,338 in 2015 to 27,638 in 2019. This increase is a significant one as it has resulted in a rise in India's share in global clinical trials from 3.8 per cent to 5.3 per cent during the same period. From the analysis of phase-wise clinical trials, it is emerging that the number of clinical trials in phase 1 is significantly lower in comparison to other phases, indicating that most of the research leading to the clinical trials conducted in India is from outside India. Further, the clinical trial profile is not commensurate with the disease burden in India. It is infectious and parasitic diseases, which rank number one on the basis of disability-adjusted-life years (DALYs) in India, but the clinical trials in this area are ranked at number seven. The largest number of clinical trials are being conducted in areas of life-style diseases like cancer, cardiovascular diseases and diabetes, in that order; their disease burden rankings are sixth, second and thirteenth respectively.

To promote clinical research and make the approval process faster and transparent, the GOI introduced notable changes in the regulatory landscape for the approval of new drugs and conduct of the clinical trials on 25 March 2019 which are called "New Drugs and Clinical Trials Rules, 2019".[23] These new rules are being applied to all new drugs, ethics committees and investigational drugs relevant for human use, bioequivalence study(ies) and clinical trials in India.[24]

One of the main features of these new rules is that "*any drug discovered/invented/synthesised in India, or research and development of the drug has been done in India, and which is proposed to be manufactured and marketed in the country, will be deemed approved for clinical trials within 30 working days by Central Licensing Authority (CLA)*".[25] If no communication is received from the CLA by the applicant within the specified time limit, the consent for conducting a clinical trial shall be assumed to have been granted.[26] Further, the drug companies would get additional benefits for conducting clinical trials in India if their drugs are already endorsed and marketed in specified countries, namely, European Union, the UK, Australia, Canada, Japan and the US. In addition, the application process for clinical trial would be easier and faster as the data generated outside India would now be accepted by the Drugs Controller General of India (DCGI).[27] As was observed during the current epidemic crisis, Indian regulatory authorities have been able to fast track vaccine and drug approvals.

However, there are concerns about the regulatory mechanism being followed before conducting clinical trials and experts opine that regulatory mechanism has to be maintained in such a way so that the cost of clinical trials is significantly reduced. This needs to be done extremely carefully without jeopardizing patient safety and compromising on quality, safety and efficiency standards.

9.2.7 Implementation of Key Policies and Schemes

While many good policy interventions and schemes have been proposed for the promotion of the sector, the implementation process has been quite slow. Some of the specific areas in which delays have occurred in implementation are policies related to cluster development programmes for SMEs, API units and medical devices. In addition to the above, EXIM Bank Report (2020)[28] highlighted the issues which have been long delayed, namely, regulatory issue,[29] export-import norm,[30] environmental clearance for API units,[31] Goods and Services Tax (GST), trade-related infrastructure,[32] and credit crunch.[33] Furthermore, there are some schemes for financing R&D and commercialising technologies like New Millennium Indian Technology Leadership Initiative (NMITLI) and Drugs and Pharmaceuticals Research Programme (DPRP) where only partial objectives have been achieved. Under the Technology Development Programme (TDP), very few API projects only got financial assistance. There are also schemes like SEZs, which have contributed to export growth and job creation. Some of the other schemes, which have performed well are Market Access Initiative Scheme (MAI) (introduced during 2002-07), Merchandise Exports from India Scheme (MEIS) (2015-20), Export Promotion of Capital Goods (EPCG) (2015-20), and Trade Infrastructure for Export Scheme (TIES) (2017-20). Remission of Duties and Taxes on Exported Products (RoDTEP)[34] has been launched with effect from 1 January 2021. The earlier PLI scheme did not generate much enthusiasm. Had the scheme been lucrative for the industry, there would have been much more interest. Therefore, a new PLI scheme was launched in March 2021 with an outlay of Rs. 15,000 crore. This has been well received by the industry. All these schemes are initiated to overcome certain challenges, which the industry was facing, and to boost exports. A detailed review of the performance of all schemes should be undertaken and based on the evaluation their continuance, strengthening and modification be considered.

9.2.8 R&D in Pharmaceutical Industry in India

The challenge faced in the pharmaceutical industry is that though the growth rate of industrial R&D has been increasing, this growth has been mainly registered through a rise in private R&D whereas the public sector R&D growth has become negative. The underlying reason for negative public R&D growth is the

weak financial position of PSUs like HAL and IDPL and their declining R&D expenditure over a significant period. The experts' opinion on the issue was that the reduction of R&D tax incentives from 200 per cent in 2016-17 to 150 per cent in 2017-18 and then further to 100 per cent till 2020-2021 has not gone well with the industry. The pharmaceutical industry has been worst hit by this reduction as this industry alone constitutes around 24.3 per cent share in total industrial R&D of India (R&D Statistics, 2019-20, DST). R&D in the pharmaceutical industry takes time and frequent changes adversely affect investor confidence, though the industry could achieve fast results in the case of COVID-19 vaccines, as is the case with Bharat Biotech International Limited (established in 1996 only) and Serum Institute of India. The same level of R&D tax incentives must be continued in order to give a push to the R&D efforts of the pharmaceutical industry in a consistent manner. Private equity investment should also be encouraged in the industry. The promised raise in the budget of the Department of Health Research by 26 per cent this year augurs well for R&D in healthcare.

Another issue faced by the industry is that R&D being an intangible asset is not considered as a fixed asset and, therefore, does not qualify for loans by the banks. The support provided by Technology Development Bank (TDB) is also not adequate enough and caters only to a small part of the financial requirement of the entire pharmaceutical sector. Industries feel that Special Purpose Vehicles (SPVs) must be formed by banks so that they can fund the industry. Venture-capital funds should also be given a boost. There is a need to set up many stand-alone centres for R&D. India has to become an innovation destination. The budget of 2021-22 has made a provision for incentivizing start-ups in the country in two broad ways: (i) extending the eligibility for claiming tax-holiday for start-ups by one more year, i.e. till 31st March 2022 and (ii) extending the capital gains exemption for investment in start-ups by one more year till 31 March 2022. The Budget has also earmarked Rs. 50,000 crore over five years for the National Research Foundation (NRF), an umbrella body which is expected to fund research across a wide range of disciplines in S&T and humanities.

Another challenge faced by the innovation system of the pharmaceutical industry is that after 2005, the R&D efforts of the Indian pharmaceutical industry have been increasing consistently to meet the competition brought by the implementation of TRIPS obligations, whereas MNCs are not positive towards enhancing their R&D efforts in the country, which is rather contrary to the expectations of the policy-makers; their R&D efforts are rather declining after 2005. This points towards the fact that the MNCs are not technologically contributing to the industry in India. MNCs had been reluctant to invest in the 1980s itself. A case in point is Astra Zeneca, which closed its unit in Bengaluru in 2014 and recently in 2017, commissioned a process R&D facility, and not a full-fledged R&D centre.[35] This leads to the oft-repeated criticism by many that the MNCs are aggressively asserting their patent rights not for getting genuine inventions patented but to prevent generic competition by filing infringement cases against Indian companies. This, of course, is a business strategy. From a policy angle, what is required is to create a conducive environment for both domestic and foreign firms to engage in R&D in India.

There has been a consistent demand of MNCs to CDSCO to display all the applications received for New Drugs on its Portal. This has been opposed by domestic pharmaceutical industry associations. The generic competition of Indian companies is impeded on the ground that Guidelines on Similar Biologics are not followed by the Indian companies and these Guidelines make it tougher for the generic companies to enter the global market. Taking note of the reduced R&D efforts of MNCs in India and their commercial strategies, it is worth exploring whether simplification of the *Guidelines on Similar Biologics* can pave the

way for Indian companies to enter the generic market for biologicals in a large way.

MSMEs cannot be ignored in policies relating to encouragement of R&D. In their case, a mindset change needs to be inculcated. They will be induced to enter research only when they are healthy. Innovations in drug delivery do not fetch any better prices for the firms. The tax incentive for R&D expenditure may be considered for restoration to the earlier 200 per cent to maintain the momentum

Industry-Academia Linkages: Research institutions like NIPER feel that there is a lack of interest by industry in academic activities. There are around 200 approved patents with NIPER, Mohali and the pharmaceutical industry has not yet got it assigned or licensed.[36] There are other technologies also available which need to be taken up by the industry for further development. The experts also highlighted that in drug discovery research, the industry has all components required to carry out good research. The only thing required in this area is coordination, cooperation and reliance. The needs of the industry are not reaching the academic institutions. They are working in isolation and with their own thought process. It has to be ensured that the academic institutions, industry and national level authorities work together. This is essential for research oriented to the needs of the people and market and for increased commercialisation of Indian academic research.

It is, however, encouraging to note that in the National Intellectual Property Right Policy, 2016 research in the pharmaceutical sector finds special mention when the Policy states "encouraging R&D including open source based research such as the Open Source Drug Discovery (OSDD) by CSIR for new inventions for prevention, diagnosis and treatment of diseases, especially those that are life threatening and those that have high incidence in India" as one of the objectives including through public R&D.[37]

9.2.9 Enhancing Quality Standards and Effectively Combating Spurious Drugs

Indian pharmaceutical industry has often been at the receiving end of criticisms on the quality and standards of its shipments, mainly from the USA, the UK and Europe. Out of 42 warning letters issued by the USFDA to global drug manufacturers last year, nine were sent to India alone, with major issues concerning 'data-integrity' and 'data reliability'. Criticisms also come from other places. Recently (on 9 October 2020) Gujarat-based pharma firm Mars Remedies had to face charges of exporting falsified packs of Ciprofloxacin 500 mg tablets to Nigeria from that country's drug regulator the National Agency for Food and Drug Administration Control) (NAFDAC). The Central Drugs Standard Control Organization (CDSCO) in its recent survey (January 2021) tested the quality of 1,001 drugs, out of which 985 were found to be of standard quality whereas the remaining 16 drugs were not declared of standard quality. The major issues faced in these drugs were related to dissolution, uniformity of weight and assay requirements of ethyl alcohol and glyceryl trinitrate (Drug Alert List, CDCSO, January 2021). The Indian companies such as Dr. Reddy's Lab, Sun Pharma, Lupin, Cipla and Zydus Cadila have formed quality forum with the Indian Pharmaceutical Alliance to combat the quality control issues. Pharmaceutical products affect the health of living beings and, therefore, there cannot be any laxity, even in a minor part, in the quality of these products. This is not only a question for exports but also for the domestic market. Further, even a limited number of cases can mar the general reputation of the Indian pharmaceutical industry. What is required is a rigorous implementation of the Drugs and Cosmetics Act and periodic revision of the law. Some suggestions are presented below:

As per section 17 of the Drugs and Cosmetics Act, 1940, the first incidence of offence is compoundable where the parties can settle the

dispute without reference or permission of the court and a subsequent attempt is made non-compoundable. It is, therefore, recommended that the very first instance of offence should also be made non-compoundable. This would help better combating the instances of the spuriousness of drugs.

In accordance with Section 32 of the Drugs and Cosmetics Act, 1940 the authorities, which are empowered to take action against the culprits, are drug inspectors, officers authorised by the state government and central governments, the aggrieved parties and voluntary organisations. When any of these parties approach the courts, the cases are filed under 'complaint cases' (case other than police report). Police officers do not have the power to arrest or move the court in respect of cognizable offences under this section. The procedure adopted needs to be made simpler. Drug inspectors should approach the police officers concerned on the completion of the inquiry to lodge an FIR under Section 154 of CRPC. The police should investigate and file the challan in the court of law under section 173 of CRPC. This would improve the process, as now the police would come into action directly on the report submitted by the drug inspector. This would avoid the time-lapse occurring in filing the compliant case and the required action.[38]

Apart from amendments to the D&C Act, there is also a need for having new legislation, given increasing concern about patient safety and patient rights. The domestic medical devices industry has already suggested the need to "regulate all Medical Devices under a Patient's Safety Medical Devices Law to protect patients and aid-responsible manufacturing".[39]

Improvement of quality of drugs marketed domestically will indirectly contribute to export performance, since it will change the perception of the Indian pharmaceutical industry into that of a highly quality conscious drug maker.

9.2.10 Quality of Human Resources

A major challenge being faced by the Indian pharmaceutical industry is that of quality of the workforce. As per a 2014 survey (KPMG, BioAsia, 2014), there is a significant gap between industry requirement of the manpower and their academic training; about 66 per cent of the manpower is not as per requirements of the industry. One reason for this is the education system. The pharmaceutical industry is largely chemistry-based and the country needs a large number of chemistry graduates, post-graduates and PhDs to meet the need of a growing industry, but India lacks an adequate number of chemistry graduates, etc. As per a report by the Department of Science and Technology (R&D Statistics, (2019-20) the percentage share of doctoral degrees awarded in the field of science out of the degrees awarded in all S&T disciplines has declined sharply from 63 per cent in 2010-11 to 41.1 per cent in 2017-18. The research output (scientific papers) in the field of Chemistry is 91,605 which is only 7.1 per cent of world output and in Biochemistry, Genetics and Molecular Biology it is 84,456, which is 4.9 per cent of world output during 2011-16. Ensuring a suitable pipeline of talented youth in the field of science is a big challenge and this requires reforms in school science education, science curricula and adoption of new teaching methods as has been well highlighted by Science, Technology and Innovation Policy, 2013. Institutions like the Indian Institutes of Science Education and Research (not examined in this report) are good beginnings in this regard.

9.2.11 Reduction of Compliance Burden in Pharmaceutical Industry

The industry has been voicing concern about the 'compliance burden.' It takes around 6-8 months for companies to comply with all requirements for starting a business in India, whereas in Vietnam it takes only 1-2 weeks. Consequently,

as per industry sources, companies, which were shifting from China, were moving to other countries, where the ease of doing business is better than in India. In recent years, there has been much improvement in India in the matter of ease of doing business. As per the 17th annual report on ease of doing business by the World Bank, India has significantly improved its rank from 130 in 2016 to 63 (out of 190 countries) in 2020. The relative ranks of some other countries are China (31), Russia (28), Vietnam (70), Brazil (124) and the USA (6). India is lagging in six indicators out of ten (i.e. starting a business (rank 136), registering property (rank 154), paying taxes (rank 115), enforcing contracts (rank 163), trading across borders (rank 68) and resolving insolvency (rank 52). Improvement in these indicators can help in reducing the compliance burden in India. This has become more important given the current pandemic situation where many US and UK production facilities are in China, India and South Asian countries. Any rise in demand coupled with political tension can lead to a search for more conducive regions and shifting/moving away of supply chains to other preferred destinations.

There are other issues connected with ease of doing business. Though the 'Make-in-India' initiative and national manufacturing policy envision making India a manufacturing hub but setting up of a manufacturing plant requires dealing with complex regulatory mechanisms, clearances at every step such as purchasing of land, getting electricity, environmental clearance and clearance nod from factory inspector, etc., and filing of returns. The broad issues which companies are presently confronted with are:

- Companies are managing their compliances through an outdated manual tracking system.
- Companies lack trained human resources to understand the complex regulatory mechanism.
- Some companies do not have updates regarding which compliances they need to comply with.
- Though the government wants to encourage the start-ups it treats them on par with large business houses and they are also required to adhere to complex regulations/ mechanism in the initial period of their business which acts as a deterrent for expanding the business.[40]

Taking note of the above complex regulatory mechanism prevailing in India, it is recommended that improvements are required in the following broad areas:[41]

- **Rationalising**: Rationalising the various provisions of the Companies Act and a large number of compliances which business ventures are required to comply with.
- **Procedural simplification**: Simplifying the number of filings/returns and the changes within it.
- **Digitalisation**: The companies need to adopt digital mode for their compliances and do away with the manual tracking system to ensure transparency and efficiency in their day-to-day transactions.
- **Trained Human Resources**: A large number of companies in the survey (Deolitte, 2014) mentioned the paucity of trained/skilled human resource as the main factor for non-adherence to compliances. It is thus recommended that the companies should equip their staff with adequate technical skills so that they can handle the complex regulations in a more effective and digital mode, which is the need of the hour. Periodic skill upgradation should be built into human resource policies by the firms.

9.2.12 Role of PSUs

From the early 1950s till 1980, PSUs like HAL and IDPL were involved in the manufacturing of Penicillin, streptomycin, tetracycline, Oxytetracycline and Dimethyl, etc. The role of PSUs assumes significance specifically in the production of fermentation-based APIs

(which are more capital-intensive and require environment-related regulatory approval and R&D) and where the private sector is not willing to come forward. Earlier the government had also recognised that the production of some critical APIs should be reserved for the PSUs (Drug Policy, 1994). In the light of the present COVID-19 situation where India faced a shortage of critical APIs and their Key Starting Materials (KSMs), and wanted to reduce its dependency on China, the manufacturing of these critical APIs and KSMs can at least be resumed in PSUs, considering their existing infrastructural potentialities, if the government comes forward to support them financially. The indigenous manufacturing of bulk drugs by these PSUs would also complement the 'Make in India' initiative. Recently, HAL has planned up-gradation of facilities for the manufacture of certain bulk drugs, namely, Telmisartan (capacity of 100 M.T per annum), Morepenam (24 M.T per annum) and Gabapentin (24 M.T per annum) and also for the supply of COVID-19 related products, i.e. PPE kits, face shields, hand gloves, N-95 respirator, infrared thermometer and Hydroxychloroquine (obtained license for its production recently). These objectives can be achieved if the strategic sale tag of these PSUs and the associated uncertainty about their future plans is removed through required and timely government support. Further, it is recommended that R&D activities of PSUs must be encouraged by the government as these are the only institutions which can undertake both basic and development research. Though the results of basic research are fruitful only after a long gestation period and have large spillovers/benefits to other institutions without any effort, the same should not act as a deterrent for the continuing basic R&D efforts of these institutions. HAL is also involved in the production of some formulations which meet with the domestic requirements (anti-inflammatory, anti-histamine and anti-infective drugs) of our economy. It is thus strongly recommended that the production activities of the PSU like HAL must be given impetus *via* adequate government support in view of its current production activities catering to domestic needs on a priority basis (Committee on Public Undertakings, Fourth Report, 2021).

9.2.13 AYUSH Sector[42]

The AYUSH sector comprises more than 9,000 manufacturing units across the country.[43] A 2018 industry report by the Confederation of Indian Industries (CII) estimated the Gross Market Size of just the Ayurveda sector to be Rs. 30,000 crore. Though the sector, especially the Ayurveda industry, is expected to reach US$ 9 billion by 2022,[44] as yet it constitutes a disproportionate share in India's export basket. According to data available from the Ministry of Commerce, Export-Import Databank, India's export of medicaments in AYUSH constitute less than 1 per cent of India's total export of pharmaceuticals in value terms. Moreover, the exports of Medicaments of AYUSH registered a Compounded Annual Growth Rate (CAGR) of just around 1 per cent between 2013-14 and 2019-20 compared to CAGR of 7.99 per cent registered for the total pharmaceutical sector.

Key challenges pertaining to AYUSH product manufacturing and export include:

- ***Standards and quality assurance*:** Stability, safety and standardisation of Indian Systems of Medicine (ISM) drugs and their formulations are essential requirements for building confidence in export destinations. Good Manufacturing Practices (GMP) guidelines and quality certification schemes have been introduced by the Ministry of AYUSH. Key issues in quality and standard-setting include the following:
  - » *Pharmacopoeia:* For reference standards of drugs and formulations several pharmacopoeias are in existence. Along with the Pharmacopoeia Commission of Indian Medicine and Homeopathy,[45] there is the Indian Pharmacopoeia Commission (IPC), an Autonomous

Institution of the Ministry of Health and Family Welfare. Pharmacopoeias are also developed by agencies like the Indian Council of Medical Research (ICMR). With different references and standards prescribed, the industry uses these as per provisions that provide ease of business. This, in turn, creates challenges of uniformity.

» *Lack of controlled usage of ISM*: An often-repeated complaint from export destinations is about toxicity in ISMs, associated with heavy metals. Sold as OTC, diet supplements and by unqualified pharmacists, uncontrolled usage of ISM products requires urgent intervention. Efforts should also be taken to develop norms for medicine, which have minerals and animal by-products as ingredients.

» *Lack of International Standards in ISMs:* Voluntary certification schemes are implemented by the Quality Council of India (QCI) for grant of AYUSH Standards. The AYUSH Premium Mark, which is based on World Health Organisation (WHO) Guidelines on Good Manufacturing Practices (WHO GMP) for herbal medicines, is for both international and domestic use. These export-related certifications should be encouraged to be used domestically also to support a culture of higher standard subscription to be used by the industry for greater quality assurance. Convincing target groups in export destinations through an international standard would be more advisable. Development of International Standard Organisation (ISO) standard in ISMs is underway to provide quality assurance to the global market.

- ***Recognition of AYUSH abroad***: European Union (EU) and the United States of America (USA) are the major international markets for AYUSH. In herbal products, they have a market share of 41 per cent and 20 per cent, respectively.[46] Hence the regulations in these two trade zones are material to any consideration of international trade barriers. Europe regulates herbal medicinal products under the European Directive 2001/83/EC. The European Union Directive 2004/24/EC on traditional herbal medicinal products amended the provisions of the 2001 Directive to provide for a simplified regulatory approval process for herbal products.
- There are still many regulatory barriers where ISM products may not be able to get the registration. Some of the ISM products may contain mineral components or animal products or herbal constituents, which will debar them from registration as traditional herbal medicinal products. The requirement for registration is that the products are to be taken without supervision by a medical practitioner. Most ISM drugs are to be used under the supervision of a medical practitioner of that branch. The US has introduced GMP regulations, covering herbal medicines through the Drug Amendments of 1962. In 2007, FDA issued mandatory current good manufacturing practices (cGMP) for dietary supplement manufacturers and distributors also. Most of the developed countries prefer to have standardisation for quality, efficacy and safety which exporters from India find challenging. An important reason further is the lack of standard and quality subscription and capacity building in the sector. Lack of traceability is another reason, more specifically about raw materials used, i.e. medicinal plants.
- *Legal and Regulatory:* The Drugs and Cosmetics Act, 1940 (D&CA), requires several amendments for the growth of the sector. While Schedule (T), D&CA prescribes GMP standards for ISMs based on Indian Pharmacopoeia, upgrading

standards based on WHO Guidelines is desirable. 'Extracts' and 'intermediates', etc. used in Ayurveda, Siddha and Unani (ASU) are not clearly defined in the D&CA. Portability of drug licence is required as this gives uniformity and credibility in export destinations. This measure can be implemented by a suitable amendment of Rule 157 of the Drugs and Cosmetics Rules, 1945, namely: "Approval of a drug in any state is valid in any other state provided that the licensee has the required facility and capacity for manufacture of the drug." Regarding regulatory challenges, a single licensing authority for all standards and quality inspection of ISM products and ingle-window clearance for AYUSH exports has been felt necessary to facilitate the faster movement of products.

- *Sustained supply of raw materials:* AYUSH industry at present is heavily dependent on forest and other biological resources for raw materials. More than 70 per cent of raw materials in the form of medicinal plants is sourced from forests. To control unsustainable use of these resources and in keeping with obligations under the Convention on Biological Diversity (CBD) 1992, India enacted the Biological Diversity Act 2002 and Rules 2004. Regulating access to these resources and establishing benefit-sharing arrangements in compliance with the CBD is the key mandate of the Act. The Guidelines on access and benefit-sharing (ABS) were issued in 2014 to give greater clarity to the process.[47] The Act establishes a three-tier system including the National Biodiversity Authority (NBA) at the Centre, State Biodiversity Boards (SBBs) at the state level and Biodiversity Management Committees (BMCs) at the local level for effective implementation of ABS provisions. However, ABS provisions in the Act and Rules and the functioning of the above-mentioned regulatory bodies have been felt to be constraining the AYUSH industry.
- As per Section 7 of the Act, Indian entities are allowed access to biological resources after prior intimation to the SBBs. While this interpretation has not been challenged, the role of the SBBs with regard to determining terms of ABS has been contested. Procedural difficulties of filing prior intimations in case of jurisdictions of more than one SBB, lack of clarity on issues of calculation of ABS fees and point of access to determine BS, etc. persist. Following several petitions filed against the show cause notice by SBBs to Indian companies, and also owing to court cases, the latest being Uttarakhand High Court judgement in the case of *Divya Pharmacy vs Union of India and others,*[48] it has been felt by the industry that due to lack of clarity in the Act and Guidelines (2014), a review of the same is required. Further, product exemptions as provided under Section 40[49] and Section 2(c),[50] 2(p),[51] have been facing interpretational and operational challenges. These include, for example, conflicting interpretations of what constitutes 'value-added product' by regulatory bodies and inadequate listing of normally traded products by the NBA. Encouraging cultivation as a solution to reduce dependence on forests and limited supply of specific/endangered plant species has been undertaken by the NMPB. Even then, it accounts for only 22 per cent of the medicinal plants procured for the industry.

To sum up, the challenges faced by the Indian pharmaceutical industry are quite varied and may even differ from sub-sector to sub-sector and even units. In general, these are: loss of domestic value-chain in key ingredients, lack of adequate ease of doing business, laxity in enforcing quality standards in some critical areas, lack of economy of scale and application of modern management techniques to ensure competitiveness, inadequate investment, whether from domestic sources or through FDI, and most importantly lack of adequate R&D and application of latest technologies all

through supply chains and in all categories including MSMEs. Policy measures will have to be reviewed and monitored from time to time and immediate remedial measures need to be taken. After the launch of a new scheme or programme, there has to be a close follow-up to ensure that the objectives are achieved. Considering the 'essential' nature of the pharmaceutical industry, it is also necessary to have a public sector presence there, given India's current economic level, while encouraging new entrepreneurs and ensuring competition in the market.

9.3 Opportunities

While there are many challenges for the industry, there is a whole basket of opportunities also. The industry itself has been fully conscious of these prospects. Indian Pharmaceutical Alliance (IPA) has already pointed out these in a 2019 forward-looking document (IPA 2019). The important ones are the following:

- ***Universalisation of Health Care*:** The international community has already set the target of ensuring healthy lives and promoting well-being for all at all ages as Sustainable Development Goal (SDG) No. 3 by 2030 and India is also party to the Declaration. India on its own has set various targets in the National Health Policy, 2017. It has also launched a number of state-sponsored programmes for the same. These include Ayushman Bharat Yojana which has been given a big push in the Budget 2021-22. Upgradation of all Primary Health Centres as Wellness Centres is also a target. These and already existing schemes and projects (mentioned in previous chapters) are likely to massively hike the demand for drugs and medical equipment in the country. The recent COVID-19 pandemic has shown how there can be a sudden spurt in demand for pharmaceutical products, including vaccines. This is a grand opportunity, an assured market when the industry can enhance its manufacturing capability to meet the increasing demand in the coming years. However, the opportunity depends a lot on high investment in the health care sector, both public and private.
- ***New Product classes such as biosimilars, gene therapy and speciality drugs*:** As already mentioned the future of pharmaceuticals are in these new technology-intensive product classes such as biotechnology, gene-technology, bio-similar, Artificial Intelligence, 3D printers, Machine Learning, AR-VR, Digital Apps, Blockchain, Organ-on-Chips, etc. As observed by IPA, while India has shown its ability in these areas with the launch of the first biosimilar to Rituximab, Reditux, in 2007 by Dr Reddy's Lab., further successes, especially in gene therapy and speciality drugs, are limited. The report has estimated the biosimilar market to be of the size of $ 60 billion by 2030. However, to remain a leader in this industry, India will have to undertake investment on these technological fronts along with increased expenditure on R&D.
- ***New Technologies:*** Technologies are now spanning across different sectors and contribute to the saving of time and other resources. India has rich resources in technological areas like ICT. Cloud computing offers an opportunity to innovate faster. ICT can be leveraged to enhance the delivery mechanisms of pharmaceutical products to the market. Artificial Intelligence can reduce time in drug discovery and also reduce the risks. The Indian pharmaceutical industry must build on the technological strengths already available within the country and create capabilities in the new areas.
- ***Skilled Workforce:*** According to the All-India Survey on Higher Education 2017-18, the number of graduate-level pharmacy students in India in 2017 is 2,25,000, way above the US number which is 17,000. The IPA report highlights the following points

on this: "The workforce includes highly-skilled medical practitioners and specialists who bring significant expertise and actively contribute to clinical research. This is boosted by an astute and highly skilled team of people working in the field of clinical research across the industry and academia. Moreover, availability of a diverse patient pool makes India as one of the most potential destinations for clinical research. Additionally, labour cost efficiencies provide a significant competitive advantage to the Indian companies. Their manpower costs are about 33 per cent lower than their western counterparts, on average." This rich demographic dividend is such an opportunity for Indian pharma.

- ***Patent cliff:*** The world is now on a patent cliff with quite a number of important patents either having already expired or expiring soon. Twenty-four drugs have already gone off-patent in 2020 which include Atrovent HFA, BydureonBCISE, Chantix, Dexilant, Inlyta and so on. In 2021, 19 drugs will be off-patent, such as Bystolic, Crixivan, Emtriva, Hysingla ER, etc. while, in 2022, 12 drugs will be off-patent, namely, Januvia, Pristiq, Vimovo, Vimpat and so forth.[52] On the basis of 'World Preview 2018, Outlook to 2024' by EvaluatePharma, IPA has estimated that patents for branded molecules with cumulative global sales of over $ 251 billion are expected to expire between 2018 and 2024. This is also a grand opportunity for Indian generics to encash on a global scale, without attracting patent infringement complaint.
- ***New or Under tapped Markets:*** An examination of global drug trade establishes the pointers in chapter 7 that India has remained a minor player in the imports of a large number of countries including many in Europe, Japan and China (See Table 7.11 *ante*). These are potential high return markets for India. It should also increase its presence in Africa and South America, the regions which are facing issues of access to affordable quality drugs.

9.4 Way Forward

To avail of these and other opportunities, and to overcome the challenges, besides what is already stated above, the following steps are also required:

- *Higher allocation for Health Care*: Central government should immediately provide the two per cent GDP committed in the National Health Policy 2017 to the health sector. This should prompt state governments and the private sector also to raise their contributions. India requires one of the largest healthcare systems in the world. The government's approach should be that our people's health is our wealth.
- *Public Health Care and Health Insurance*: While the principle each one pays for what one gets may be good economics, it has to be implemented keeping in view the paying capacities of the people of a developing country. India will have to take a two-pronged strategy: One of enlarging its public health care system and another of enhancing the capacity of the people to bear medical expenditure through public or private health insurance schemes. This will be a step on the part of the government to ensure a big market.
- *Investment Regulations*: There is a great need for streamlining regulations regarding investment, both domestic and FDI, in the sector.
- *Ease of Doing Business:* In policy and programme-making, both at the Central and State levels, and even at the local self-government level, greater focus should be laid on enhancing the ease of doing business.
- *Domestic Supply Chains*: In the years immediately after the establishment of the WTO, many countries ignored sustaining and maintaining domestic

supply chains in many industries, including in pharmaceuticals; and India was no exception. The creation of sustainable domestic supply chains for APIs and Intermediates is an immediate need, as already brought out in the previous chapters. Setting up API parks, hubs, SEZs, etc. can go a long way in this regard.

- *Allocation for R&D*: To survive in a competitive international market, the pharmaceutical industry has to be backed solidly by a large R&D base. For this, as already stated in the previous chapters, there is a need for drastic enhancement of public allocation for R&D.
- *Technological Upgradation*: This is an area that decides the competitive edge of the pharmaceutical industry. It is also one where different sectors like ICT, AI, Gene technology, etc. mesh with the chemical and pharmaceutical industry. While large industries may have certain capabilities and financial resources to do regular technology upgradation, the MSME sector will have to be assisted significantly and schemes like Pharmaceutical Technology Upgradation Assistance Scheme will have to be considerably expanded and in a more liberal way than hitherto.
- *Quality Standards*: Upgradation of Indian quality standards for the manufacture, storage and transport of pharmaceutical products to global best levels is a must for Indian pharmaceutical industries to maintain its position as the pharmacy of the world.
- *Indian pharmacopoeia*: Interaction and collaboration with foreign drug regulatory authorities and making serious efforts to get Indian pharmacopoeia accepted in the developed countries will go a long way in boosting the international trade of Indian pharmaceutical products.
- *Awareness generation*: Conducting public awareness programmes abroad about the quality of Indian pharmaceutical products is necessary to change some of the wrong perceptions about Indian products. Both government and industry should join hands in this.
- *Public Relations:* The industry associations should undertake high-level public relations exercise with governments, regulatory authorities and pharma bodies abroad, as is being done by industry associations of developed countries. They have to take a more pro-active role in this than being merely reactive.
- *Health Diplomacy*: India has always been a votary of healthcare partnerships and has engaged in a large number of initiatives in this regard. The recent cooperation that India displayed through the supply of drugs and vaccines for COVID-19 manufactured in India, is an example of this. While continuing this, it should also engage diplomatic efforts such as easing regulations for meeting needs of less developed countries to meet health emergencies like the one it has taken up recently in international fora such as WTO and WHO, with South Africa.
- *MSMEs*: Special funds for MSMEs with easy loan terms be established, considering their distinct problems, as brought out in previous chapters.
- *APIs*: There is also a need for long term easy funding of private API start-ups. Special funds can be created for this either with the government or with banks.
- *AYUSH Systems:* Special efforts to get recognition of Indian Systems of Medicine abroad should be given top priority for promoting the export of AYUSH system services and products.
- *Databases:* Successful policy-making depends on the availability of up-to-date reliable data regularly. While trade data is made readily available it is also necessary to have manufacturing and domestic consumption data of pharmaceutical products. A system

needs to be devised for this, which will have to take into consideration of confidentiality of firm-wise data.

In the light of the preceding discussion, it is underscored that the Indian pharmaceutical industry has the basic strength to overcome the challenges and avail of the opportunities; with some policy and programme support, including financial from the government, it can achieve the desired goal.

Endnotes

1 Johnson & Johnson, Novartis AG, Abbot Laboratories, etc. produce both drugs and medical devices. Lupin Labs.,Aurobindo Pharma, Dr Reddy's Lab., Torrent, Zydus, etc. are into both APIs and Formulations.

2. "When the prices increased firms like Alembic, IDPL, KJ Pharma, Spic, Hindustan Max GB and Torrent entered the field."

3 Shri A.K. Madan, IDMA.

4 Government of India, Department of Pharmaceuticals 'Guidelines for the Production Linked Insurance Scheme for promotion of domestic manufacturing of key starting materials. Drug intermediates/ Active Pharmaceutical Ingredients in India' No. 31026/16/2020/Policy dated 29th October, 2020. A Note to Appendix A of the document states: "The 41 eligible products for which the scheme is proposed covers the 53 APIs which have been approved by the Government."

5 As per a news report dated 14th February 2021, government has approved 14 projects under the scheme. (https://www.thehindubusinessline.com/economy/policy/govt-approves-14-projects-under-pli-scheme-for-bulk-drugs/article33943027.ece)

6 The decision to close three pharmaceutical units, namely BCG Vaccine Laboratory (Chennai), Pasteur Institute of India (Coonoor) and Central Research Institute (Kasauli), in 2008 was later in 2012 reversed consequent on court intervention. The decision to disinvest in HAL and IDPL is still standing.

7 For more details see https://plibulkdrugs.ifciltd.com/docs/Gazettee%20notification%20of%20bulk%20drug%20schemes.pdf

8 For more detail see, https://plibulkdrugs.ifciltd.com/

9 For more detail see, https://pharmaceuticals.gov.in/sites/default/files/Guidelines%20of%20the%20Scheme%20Promotion%20of%20Bulk%20Drug%20Parks_1.pdf

10 Ibid.

11 However, the future of of the two pharma PSUs i.e. IDPL and Rajasthan Drugs and Pharmaceuticals Limited (RDPL) is bleak as per recent reports about their proposed closure as announced by Minister of Chemicals and Fertilizers (Economic Times,9th Feb,2021).

12 ArvindSahay. 'India Can Become the Pharmacy of the World' in the Hindu Businessline. Accessed at https://www.thehindubusinessline.com/opinion/india-can-become-the-pharmacy-of-the-world/article31516558.ece# on 28 February, 2021.

13 *ibid*and P K Ramachandran and B V Rangarao.*The Pharmaceutical Industry in India* in EPW Vol. 7 No. 9 dated 26 February 1972. Accessed at http://www.jstor.org/stable/4361074 on 28 February, 2021.

14 *ibid*

15 *ibid*

16 However, if we look the pharmaceutical industry as whole, this industry is found to be highly concentrated as twenty-five out of 3,000 companies contribute 85% of the total industry output. For more details see https://economictimes.indiatimes.com/markets/expert-view/how-indian-pharma-can-grow-to-be-a-100-bn-industry/printarticle/78056703.cms

17 If the value of HI is less than 0.15 makert is said to be unconcentrated or highly competitive. On the other hand, the highly concentrated or less competitive markets, generally, have HI values greater than 0.25.

18 https://www.thehindubusinessline.com/opinion/india-can-become-the-pharmacy-of-the-world/article31516558.ece#

19 https://www.biospectrumindia.com/reports-whitepapers/59/14035/import-of - medical devices-up-by-record-24.html.

20 For more detail see https://plimedicaldevices.ifciltd.com/docs/Gazette%20notification%20of%20Medical%20Device%20schemes.pdf

21 For more detail see, https://plimedicaldevices.ifciltd.com/

22 For more detail see https://plimedicaldevices.ifciltd.com/docs/Gazette%20notification%20of%20Medical%20Device%20schemes.pdf

23 For more detail see https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

24 https://www.expresspharma.in/guest-blogs/the-golden-days-are-here-again-clinical-trial-market-of-india-in-2019-and-onwards/

25 ibid.

26 Ibid.

27 ibid

28 Export-Import Bank of India (EXIM Bank) (2020), Domestic Policy Constraints for Exports in Select Sectors.

[29] Regulatory control mechanism cost-unfriendly and unpredictable as these are being imposed by multiple authorities and also changed frequently.

[30] It accounts issues related to fixation of Standard Input Output Norms (SION).

[31] In India, Enviornment clearance for establishing manufacturing unit generally requires 2-3 years

[32] Lack of quality Energy and trade infrastructure.

[33] Current practice of credit support is not suitable for industry requirement.

[34] The scheme is being implemented frm 1 January, 2021., as per government press release. (https://content.dgft.gov.in/Website/dgftprod/6d28c659-c6d7-43d9-a3ea-bd76ab4c71d9/Press%20Note%20on%20RoDTEP%20by%20CBIC.pdf).

[35] https://www.siliconindia.com/shownews/astra-zeneca-opens-prd-unit-in-bangalore-nid-35373-cid-3.html.

[36] As stated by Director, NIPER during the round table, referred to earlier.

[37] National Intellectual Property Right Policy 2016 accessed at http://dipp.nic.in/English/Schemes/Intellectual_Property_Rights/National_IPR_Policy_08.08.2016.pdf on 28 February, 2021.

[38] *Union of India vs. Ashok Kumar Sharma* (SC. Criminal Appeal No. 200 of 2020)

[39] https://biospectrumindia.com/reports-white-papers/59/14035/imports-of-medical-devices-up-by-record-24.html.

[40] https://www.avantis.co.in/blogs/17/break-the-compliance-burden/2019

[41] The small companies may get some relief from compliance burden as government has proposed to revise the definition of small firms (The Economic Times, February 1, 2021). The government has also launched a regulatory compliance portal, a central on line repository of central and all states compliances.

[42] The authors acknowledge with thanks the contribution of DrNamrataPathak, Research Associate, RIS in this section.

[43] https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1663989.

[44] https://www.ibef.org/download/Healthcare-July-2019.pdf

[45] It serves as an umbrella organization for Ayurvedic Pharmacopoeia Committee (APC), Siddha Pharmacopoeia Committee (SPC), Unani Pharmacopoeia Committee (UPC)] under the Ministry of AYUSH.

[46] Deshpande, Suvarna M. 2015. "Study of Current Market Scenario & Marketing Prospects against Changing Attitude of Consumers towards Buying of Ayurvedic Medicines in India." International Journal of Business and Management Invention, Vol. 4(6): 48-54.

[47] Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014

[48] https://sbb.uk.gov.in/pages/display/143-court-cases

[49] Section 40 , excludes biological resources normally traded as commodities from the purview of the Act

[50] Section 2 (c), excludes 'value added products' from the purview of the Act

[51] Section 2 (p) defines "value added products'

[52] https://www.greyb.com/drug-patents-expiring-2020-2021-2022/

X
Epilogue

10.1 The preceding chapters have brought out how the Indian pharmaceutical industry evolved from a very insignificant role in India's economic and social development to become a key player not only in the country's industrial, commercial and health spheres but also a major provider of affordable quality medicines to the world, as well as a major export sector with much more inherent potential. Pharmaceuticals are not merely industrial or consumer goods; they, like food items, are essentials for the health of human and animal life; they are global non-excludable but limited goods. Public policies and programmes for promotion of this sector have to keep this important factor in mind.

10.2 The uniqueness of medicinal products is that the market demand is dictated not by the ultimate consumers, who are the patients, but a third party, namely, medical professionals. The latter sometimes may take into account the paying capacity of the patient, but being a matter of life and death, there is deficit financing by the patient consumer many a time. Another significant fallout of this position is that, being a third party who may face certain liabilities, the medical professionals have to opt for advising the latest and best products. This leads to a situation of monopoly for the manufacturers, at least for a period after a new product is launched, because of the intellectual property right protection.

10.3 The competition in the pharmaceutical industry is for developing a new product, before others so that the developer can enjoy the benefits of a non-competitive market for a limited time. The pharmaceutical companies, therefore, have to be highly innovative or be able to get the latest innovations before anyone else. In the latter, big firms have a natural advantage over their small rivals, in a bidders-market. The small companies, therefore, required protection from the monopolistic practices of the big players. The Patents Act, 1970 and some other policies in the early years of the Indian republic were based on this rationale. As a consequence, over a couple of decades following 1970, the Indian pharmaceutical industry came of age.

10.4 At the same time, policies in other sectors were not encouraging private entrepreneurship. For long the policies

were based on the assumption that the public sector was to be the mainstay of development. While at an incipient stage of the economy and with the mindset of a population with lots of idealism and nationalism nurtured during a long and arduous freedom struggle this could lead to growth, however the licence-permit raj resulted in slow growth in most sectors. Being an essential item, pharmaceuticals were not affected like other sectors such as automobiles. Still, one would dare to think that the pharmaceutical sector would have grown much faster had private players been allowed more freedom.

10.5 This conjecture gets proved when we examined the growth of the sector during and after the 1990s, i.e. after the economic liberalization in 1991. Its manufacturing and trade increased. During the period up to 2005, the sector had carried on the advantages of the absence of a product patent regime for pharmaceuticals. But from 2005, domestic pharmaceuticals which were dependent mostly on generic products had to compete with firms which had advantages of innovative drug monopoly. While we claim to be the pharmacy of the world, the almost total generic dependence by the domestic industry does not augur well for the future. Rather, we have to get into large molecules. Of course, Biogenerics and Biosimilars require more time and investment. Making generic versions of biological drugs is not easy since large molecules that are manufactured using living cells cannot easily be replicated. Making biosimilars is also complicated and costly. Added to these technological and economic challenges are the legal issue posed by the practices of multiple patenting. For example, Humira (a medicine [a recombinant protein] to treat Crohn's disease is protected by 257 patent applications, of which 130 have already been granted, may enjoy 39 years monopoly from granted patents, as per a report by iMak in 2020. Interestingly, 89 per cent of the applications were filed after FDA approved the drug, a clear case of ever-greening.[1] But there is no alternative to developing technological capabilities by Indian pharma in the area of biologicals in the coming years.

10.6 The global value chains that emerged consequent on the new WTO regime led most of the domestic firms to look for the cheapest APIs and Key Starting Materials, leading to the slow death of the API industry in the country. Another factor that contributed to this was the across sector policy decision of the government to close PSUs. In the pharma sector, these public units were contributors of not only APIs but also of trained human resources and conduits of technology. Another feature of private capital also worked not in the best interest of the sector. This was the route adopted by FDIs, not the Greenfield one but the Brownfield of Mergers and Acquisitions. From a long-term perspective, the industry seems to be falling into the trap of remaining producers of generic versions of old medical products, leaving the lucrative and sustainable sector of new drugs to outside players. In such a scenario, innovation is likely to be snuffed out, except for minor ones. This is seen in the low number of domestic patents in pharmaceuticals.

10.7 As mentioned above, the pharmaceutical industry's sustainability is dependent on major innovations through R&D. It has to come out with innovative products continuously because of the nature of evolution of the microbes that cause the diseases. Many diseases like

Neglected Tropical Diseases (NTDs) are still awaiting medicines or vaccines. R&D in modern pharma requires huge investment, both in basic research and also at the stages of development, which involves clinical trials. In a global pandemic situation, the regulators may allow certain relaxations, as in the case of the current epidemic, but that kind of exception only proves the law. The very nature of private capital is that it cannot be locked down for long periods with uncertain prospects. Therefore, at the fundamental research stage, the investment has to be mostly led by public funds. In the long-term interest of the pharmaceutical industry in the country, the government should invest heavily in basic research leading to new drug and vaccine discoveries. Various committees in the past have recommended the proportion of GDP that should go into R&D. Instead of clubbing the figures of the private sector, the government should allocate in a sustainable way huge funds for the same. The Science, Technology and Innovation Policy contains many suggestions in this regard. Investment in scientific research ultimately will get translated into the growth of the economy and society.

10.8 At the same time, many ancillary policies have to follow suit. As already mentioned in the previous chapter, there is a need for strong linkage between universities, which are the places with young minds with massive creativity, and industries where production takes place. Mostly such connectivity will develop when the research reaches certain stages, which will give hints of possible marketable products. Such linkages will turn possibilities into high probabilities. Secondly, the researchers will have to have total autonomy in their areas of work. Collaborations will have to be established with international bodies, universities abroad and other research and academic institutions from other countries. Material, data, information, knowledge and personnel exchanges will have to be encouraged, of course within universally accepted values and ethical norms. The policies on the commercialisation of public-funded research also have to be conducive to the growth of R&D. Adequate incentives, both monetary and non-monetary, will have to be provided to researchers at all stages, the institutions and the industrial establishments who take the product to the marketplace. The procedural and other matters relating to IP laws also will have to be continuously upgraded and simplified for this. The country also should develop policies for lighting up the entrepreneurial spirit of academics too, as in the case with many developed countries. Thirdly, in the context of India having limited financial resources, and in order to avoid duplication or repetition of the same research, a central R&D portal can be set up. Each laboratory can then decide what to pursue. Industry can also assign particular laboratories with specified research. In order to encourage applied industrial research stand-alone R&D centres also be given incentives. The syllabi of such institutions can be suitably tailored for such research.

10.9 In the commercialisation of pharmaceutical products, as in the case of any other product, the market has a very significant role. For the private capital, it is the return that matters. High paying markets are, therefore, at an advantage in this. Economic growth that raises the capacity of individuals to pay dear takes time, but meanwhile, policies can be in place to ensure that the just profit expectations of firms are not adversely affected. This is

a very ticklish area where constant monitoring and evaluation is required, both domestically and internationally. A fine balance between the right of access to medicine and private profit will have to be maintained. Complex policy measures will include, among others, free access to quality primary healthcare and financial protection of patients through health insurance, etc. A universal prescription is not easy to make. The policies would have to be mostly contextual, many a time locally. The price fixation mechanism has not been well accepted by the industry as has been brought out in this report. Larger markets are one way out that means promoting global trade. While Indian pharma has been focussing greatly on the developed markets, which certainly fetch more return per investment, for various reasons including diplomatic and other reasons, it should also focus on unexplored markets beyond the developed ones. Deep penetration into Africa and South America is needed. The industry should be encouraged by the government on this. In the long run, it will fetch rich dividends both to the country and the industry.

10.10 It is now more than two and a half decades since the WTO was set up with the objectives of promoting international trade. It has a whole bunch of rules and agreements, including on IPRs, tariffs, non-tariff barriers, investments, etc. for boosting global trade. The organisation is also supposed to help developing countries benefit fully from the global trading system. In enforcing its trade measures or for countering trade measures by other countries, particularly by the developed ones, which have highly profitable markets for pharmaceutical products, the country will have to take recourse to the WTO objectives. Trade policies, including parallel imports, will have to be modulated depending on the products and domestic requirements.

10.11 At the same time, the country cannot depend purely on the WTO mechanism, as there is an increasing trend among nations to get into bilateral or regional free trade agreements. It is time India moves into this field. The inclusion of items in such agreements will have to be based on detailed research analysis as to the advantages and disadvantages for the country. Recognition of Indian pharmacopoeia, Indian Systems of Medicine, etc. will have to be considered in such bilateral agreements. The inter-sectoral linkages also will have to be studied to find how a change in policy in one sector affects products from another sector.

10.12 The most decisive factor in international trade, as in the domestic market, is also the competitiveness of the product. In the previous chapter, this challenge has been examined in detail. While manufacturing firms feel that the global supply chain is the best way to reduce the cost of raw material and labour, there are many issues linked with that when it comes to an essential good like medicines. In this, the policy modulations may have to be product-specific and also from a long-term perspective. The sustainability of the production has to be a criterion. The report has suggested two other possible ways forward. These relate to technology infusion into manufacturing and supply processes and improvements in management, from procuring raw materials to floor management and delivery mechanisms. Modern technology now enables quicker deliveries and reduction of storage spaces. Technology-led health

surveillance can also help in production and delivery management.

10.13 An aspect on which there can be no compromise is about the quality of the medicines, irrespective of whether they are for domestic consumption or international market, as already mentioned. It is on this aspect that, apart from the IPR angle, the Indian pharmaceutical products receive much criticism abroad. Some way forward for improving the situation has already been suggested in the last chapter. This is one area where individual firms, industry bodies and the government will have to invest more. Industry associations, while enabling their players to maintain the quality of their products, also should effectively counter the use of few cases as a stick to beat the domestic industry in general. Media and other means will have to be used for it. Industry associations should also ensure that there should be more coordination, within allowed limits by WTO, among the companies, such as not resorting to price undercutting.

10.14 Quality improvement of products will involve the use of Global Manufacturing Practices (GMPs). In the field of pharmaceuticals, this is now becoming a technology-intensive area. The infrastructure and machinery will have to be most modern. It requires huge investments and most of the MSME sector will find it beyond their means to do so. Separate funds for infrastructure and technology upgradation, which can advance easy loans on a long term basis will have to be considered for this.

10.15 For a country of the size and diversity as India, sector focussed growth will not bring rich dividends. All sectors of economy are interrelated and growth has to impact all. While all economists now agree on the fact that the development of basic infrastructures like energy, water and transport is important for the development of industry in any sector, connectivity has now achieved new dimensions. Digital connectivity is a major factor. The health and education of people are also equally important and basic. Environmental protection and sustainable use of natural resources (Sustainable Development Goals [SDGs] numbers 13, 14 and 15) are factors that will now have to be built into all policies. Factors like the promotion of a peaceful and inclusive society (SDG No. 16) also will affect the manufacturing and trade of the pharmaceutical products. It is because of these that this report has been looking into past policies in different sectors to assess their impact on pharmaceutical industry and is suggesting formulation of new policies, both at government and industry levels, in a horizontal way to carry all sectors simultaneously.

10.16 The country also has to ensure a stable policy environment favourable for long-term investments. Frequent and unexpected changes in policies, including on monetary matters, create an uncertain environment for investment and innovations. (IPA-2019). As already mentioned, policy changes should be made with detailed study and taking the stakeholders, including the industry, into confidence. Governance is the art of making things possible and not of miracles.

Endnote

[1] Humira. Available at https://www.i-mak.org/humira/. Accessed last on 28 February 2021.

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Annexure-I

Bilateral Investment Treaties and Pharmaceutical Industry in India*

Introduction

Bilateral Investment Treaties (BITs) are treaties between two countries aimed at promoting and protecting private investments in each other's territories. (Ranjan. 2019). They establish a system that guarantees national treatment, fair and equitable treatment, and protection from expropriation. They provide an option to private foreign investors to take legal recourse against the State where public policies and actions adversely affect their normal profit prospects, if necessary, through international arbitration systems. The underlying rationale for countries signing the BITs is to attract foreign direct investment (FDI). Investment policies followed by India and their impact on FDI in the drugs and pharmaceutical sector has been assessed in detail in chapter 3 of the main report.

This paper examines how the policies on BITs impact the pharmaceutical industry. This industry is considered as a high dividend paying one, but the global pharmaceutical trade is dominated by limited number of global firms. Ownership of patents on most of the breakthrough pharmaceutical inventions are with such Transnational Corporations (TNCs). The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (1994) ensured that patent laws in all World Trade Organisation (WTO) member countries become harmonised with minimum levels of protection everywhere and also with provisions of national treatment and most favoured nation treatment (MFN). In all those countries new inventions in all fields of technology, whether products or processes, get patent protection for 20 years now. The other protection that big TNCs sought was against expropriation of their investments. But capital investments are outside the purview of the WTO.

The background to the BIT phenomenon extends to the period of times of the demise of colonialism. The newly independent countries of Asia, Africa and South America in the 1950s faced major challenges for economic development. While rapid industrialisation was touted as the panacea for fast economic development, they faced problems in attracting technology and capital from the countries of the

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North. Many of the developing countries like India opted for a socialist pattern of economy and there were nationalisations of private enterprises. This raised concerns among private capital in the industrialised countries of the West about the safety and security of their technological and capital investment in the South. IPR laws were the main concern of the pharmaceutical TNCs. IPR laws in the newly independent countries were at an infant stage and their enforcements were very lax. Some countries like India even opted for a non-patent regime in pharmaceutical patents.[1] So far as capital investment is concerned, the TNCs had much apprehensions. They desired assurance against government appropriation of their investment. That was the background of the Bilateral Investment Treaties.

The Treaty between the Federal Republic of Germany and Pakistan for the Promotion and Protection of Investments (1959) signed on 25 November 1959 and which entered into force on 28 April 1962 is the first such BIT[2] (Vandevelde:2010), though the roots of modern treaty rules to protect foreign investment can be traced back to 1796, when the United States negotiated the first Treaty of Friendship, Commerce, and Navigation with France.

Other European nations, including the UK, Belgium, France, the Netherlands, Switzerland, and Austria, began finalising BITs with other countries, following Germany. A total of 385 BITs were signed between 1959 and 1989. Many (260) were between developed nations, which commonly export capital, and developing nations, which commonly import capital. Between the beginning of the 1990s and the end of 1999, there was an exponential increase of about 380 per cent in the number of BITs signed, which increased to 1,857, with 40 per cent being signed between developing and developed nations. In just ten years, the number of BITs signed has increased not only between developed and developing countries but also between developing countries, also known as "South-South BITs." In the 2000s, this figure kept rising, though at a slower rate than in the 1990s, and by the end of 2017, more than 3,322 BITs had been signed, according to Ranjan. 2019. As per UNCTAD estimate, the total number of BITs was 2846, of which 2235 were in force. There are also Treaties with Investment Provisions (TIPs), the total number of which is 439 of which 362 are in force.[3] They followed a template of the European partner developing a model negotiating text for discussion with the potential developing country partner.

Evolution of India's BITs/BIPAs/ BIPPs

From the early years of independence until the end of the 1960s, India's policy toward foreign investment was receptive but its approach was cautious and need-based, such as enhancing foreign exchange reserves or plugging the domestic savings gap. This attitude toward foreign investment began to shift in the 1970s, when there was a conscious shift towards adopting protectionist and inward-looking economic policies to protect India's infant industries, which had developed in the 1950s and 1960s. Overall, foreign investment didn't figure prominently in India's economic policy in this phase, but this changed dramatically in the 1990s. As part of its wider economic liberalisation, India started entering into BITs with the clear objective of attracting foreign investment (Ranjan. 2014). Post-1991 economic reforms and up to 2015, India has entered into Bilateral Investment Treaties (BITs) and Free Trade Agreements (FTAs) containing a chapter on investment protection with 83 countries, out of which 74 were enforced. These BITs were mostly negotiated on the basis of the 1993 Indian Model BIT Text (Lok Sabha. 2021). In 1994, India signed its first BIT with the United Kingdom (UK). Between 1994 and 2000, India signed BITs with nearly every major European country, including France, Germany, Italy, the Netherlands, Belgium, Denmark, Poland, Switzerland, and Sweden. From 2000 onwards,

India entered into BITs with many developing countries also, including Argentina, Mexico, China, Thailand, Indonesia, and Saudi Arabia, as well as with least-developed countries (LDCs) such as Bangladesh, Sudan, and Mozambique (Ranjan. 2014).

Since around 2005, India has signed Comprehensive Economic Cooperation Agreements (CECAs or FTAs) covering trade and investment liberalisation, compensation policy, trade facilitation, origin rules, and IPRs. India has signed such FTAs containing investment treaties with Singapore, Japan, Malaysia, and Korea. India has signed an investment agreement with the Association of Southeast Asian Nations (ASEAN). India's BITs with African countries after 2005, as well as with other developing and least developed countries where India has capital-exporting interests, demonstrated that India began to view BITs as key instruments not only to attract and protect foreign investment in India, but also to protect Indian investments abroad (Ranjan. 2019).

India adopted the "exporting-country" model BIT throughout the period from 1991 to 2010 and was effectively a "rule-taker" in international investment law. In addition, the general consensus in India during the initial phase was that BITs primarily increased foreign investment and interacted little with the country's regulatory authority. According to Ranjan, India followed a BIT template based on laissez-faire liberalism. Rarely did foreign investors used BITs to sue India in international courts in the early phase. As a result, the broad and vague nature of BITs signed by India, as well as the implications of BITs on India's right to regulate, received little attention (Ranjan. 2019). India's involvement with Investment Treaty Arbitration (ITA), the dispute resolution procedure available under BITs, was minimal up to the end of 2010. During this period, India was involved in only one investment treaty dispute, the Dhabol case, and even this dispute did not result in an arbitral award as mutual settlement was reached. However, towards the end of 2011, in the case of White Industries Australia Limited v. Republic of India, India got its first Adverse Award from an ITA tribunal in relation to the India-Australia BIT. The tribunal found that India had violated its obligations under the India-Australia BIT. As a result of the adverse award in the *White Industries case* and the substantial increase in international arbitration cases arising out of these investment treaties, India's earlier Model BIT text was revisited with the objective of balancing investment protection with India's regulatory power.

After inter-ministerial discussions, the new Model BIT of 2015 was created while keeping in mind the shortcomings of the preceding BITs. The Model has a number of built-in safeguards to deal with disputes, based on experiences in India and other cases around the world. These safeguards include a more comprehensive Dispute Settlement provision to regulate arbitration proceedings and a number of exceptions in the Scope and Definition of Investment to preserve policy flexibility. Additionally, there are a number of measures to reject baseless lawsuits and avoid a broad interpretation of the treaty's substantive requirements. The Model BIT, 2015, employs an enterprise-based definition of investment in contrast to the older BITs' open-ended asset-based definition, aligning the BIT regime with the Indian FDI policy. This definition also clarifies the types of assets of the enterprise that are entitled to the protection of the treaty. Additionally, in order for an investment to be eligible for protection under the treaty, it must exhibit certain minimal characteristics, such as the commitment of capital, the expectation of profit or gain, the assumption of risk, and significance for the development of the host state. The definition of "investment" and its qualities have been connected. The ICSID tribunal's ruling in *Salini Costruttori SpA v. Kingdom of Morocco*; ICSID Case No. ARB/00/4,

para. 46 ("Salini"), has had the most significant impact in this regard. *Salini* is frequently cited as the leading instance supporting the goal, which stipulates five criteria to be met in order to identify such an investment under the ICSID convention: 1) a definite term; 2) regularity of profit and return; 3) risk assumption; 4) a significant commitment; and 5) importance for the growth of the host State The "Salini test" has also been adopted by India. As a result, the objective Salini requirements must also be met by the new Model BIT's definition of an investment. Using an enterprise-based approach enables a government to provide enhanced treaty protections to those companies that have actually made a commitment to pursue economic activity in the host country (Lok Sabha. 2022).

Additionally, it lacks a "Fair and Equitable Treatment" (FET) clause and instead contains a clause on how foreign investments are treated. This clause forbids the host nation from taking any action that would violate customary international law, including depriving foreign investors of justice (judicial and administrative), violating their right to due process, discriminating against them on grounds that are manifestly unjustified, or treating them manifestly abusively, such as through coercion, duress, or harassment. While the MFN (most favoured nation) clause is absent from the new model BIT (a clause that went against India in the White Industries case), it includes a provision for national treatment, which states that a party shall not apply policies that treat foreign investors less favourably than it does its own investors in comparable situations when it comes to the management, conduct, operation, sale, or other disposition of investments within its borders. According to the Ministry of External Affairs, the new model BIT's dispute resolution clauses place strong emphasis on domestic remedies, and investors must first exhaust all local and domestic remedies, including resorting to the domestic courts of the host country for at least five years, before turning to arbitration under the terms of the treaty. However, if the investor has no domestic remedies available and the BIT is the sole option, this requirement is exempt. The new model treaty also describes the procedures and standards for appointing arbitrators and makes an effort to describe potential conflicts of interest. The new model BIT also makes an effort to embrace the concept of transparency by containing clauses that demand that the procedures under the BIT be made public, subject to any existing laws governing the protection of sensitive information (Lok Sabha, 2021).

Current Status

Based on the new model BIT, the MEA has issued termination notices to 77 countries since 2016, the most recent being the Latvia BIT, and older BITs are still in force in 06 countries, out of which Joint Interpretative Statements have been signed with Bangladesh and Columbia. India has signed BITs/ Investment Agreements based on the Model BIT only with Belarus, Kyrgyzstan, Taiwan, and Brazil, and negotiations of various BITs/International Investment Agreements (IIAs) are in the various stages with 37 countries/blocks (Ministry of External Affairs [MEA]. 2021). Old BITs are still in force with six countries, namely the UAE, Colombia, Bangladesh, Senegal, Lithuania, and Libya, out of which, a Joint Interpretative Declaration (JID) was signed with Colombia on October 4, 2018 and a Joint Interpretative Note (JIN) was signed with Bangladesh on October 4, 2017. The India-UAE BIT was signed with the understanding that both countries would commence negotiations no later than January 1st, 2016, as per Article 18 of the India-UAE BIPA. The negotiations are ongoing. The date of expiry of the BIPA agreement is on 12, September 2024 (Lok Sabha. 2021). The India-UAE Comprehensive Economic Partnership Agreement (CEPA), which was signed between the two countries on February 18, 2022, officially entered into force on May 1, 2022. The Agreement

is a comprehensive agreement that will cover trade in goods, rules of origin, trade in services, technical barriers to trade (TBT), sanitary and phytosanitary (SPS) measures, dispute settlement, movement of natural persons, telecom, customs procedures, pharmaceutical products, government procurement, IPR, investment, digital trade, and cooperation in other areas (MoCI, 2022). The date of expiry of the India-Senegal BIPA agreement is October 16, 2024, and notice of termination has been proposed to be issued in 2024 if no response is received on JIS. The date of expiry of the India-Lithuania BIPA agreement is November 30, 2026, and notice of termination has been proposed to be issued in 2026 if no response is received on JIS. The date of expiry of the India-Libya BIPA agreement was March 24, 2019, but a termination notice could not be conveyed due to the lack of a credible institutional counterpart. Presently, India is negotiating BITs with 37 states and/or blocs, which include several key economies like Switzerland, the USA, and Canada. India's negotiations with 17 states / blocs—which include key economies such as the European Union, Hong Kong, and Australia—remain stuck at the preliminary stage. This slow progress contrasts sharply with the initial period from 1994 to 2011, during which India signed multiple BITs almost every year (Lok Sabha. 2021).

The negotiations with the USA, which have been ongoing since 2009, have stalled since 2016 because "both sides had different positions on issues related to market access, the definition of investments, dispute settlement, taxation issues, etc." (Kumar, A. and Anchayil, A. 2022). The Investment Incentive Agreement (IIA) was signed in 1997 with the US Development Finance Corporation. The total investment support till date has been USD 2.88 billion, comprising a loan of USD 0.99 billion, an investment guarantee of USD 1.5 billion, insurance of USD 13 million, and equity support only of USD 100 million. The India-USA IIA has been extended until December 2021, and India received the request for the negotiation of a new agreement from the USA in June 2020. This proposal was examined, and it was decided to terminate the 1997 Agreement and renegotiate a replacement agreement in light of the possibility of limiting the country's policy space and the possibility of bringing a claim under the dispute arbitration mechanism under the said agreement. The most recent text of the agreement under negotiation is to provide investment protection to investments supported by a US organization, i.e. the US Development Finance Corporation (USDFC). Regarding the India-EU BIT, both India and the EU have agreed to a standalone investment protection agreement (Lok Sabha. 2022).

Taking cues from international trends in the BIT system, the Department of Economic Affairs (DEA), Department of Legal Affairs (DoLA), and MEA are considering adding new ideas and amending some existing provisions in the ongoing BIT negotiations. The ongoing BIT discussions place a strong emphasis on both the investor's right to protection and the state's and the nation's right to self-regulate. The negotiations also focus on the type of dispute settlement mechanism to avoid later interpretations by the tribunals. For example, the recently signed India-Brazil Investment Cooperation and Facilitation Treaty (ICFT) only has State to State Dispute Settlement (SSDS) and no Investor-State Dispute Settlement (ISDS) mechanism. A Joint Committee made up of government members from both state parties is established by the India-Brazil ICFT to oversee the resolution of disputes, followed by arbitration. It clearly states that a tribunal established to resolve a State-State dispute cannot grant compensation, unlike the majority of investment agreements. Instead, it only permits a tribunal to interpret the BIT without awarding compensation. The government in its submission to the Parliamentary committee stated that efforts will be made on the Model BIT to produce a balanced and thorough BIT. The BITs are in an evolving state since the adoption of the Model BIT. Indian BITs aim to include the

pertinent and appropriate clauses from other BITs signed globally and have adapted the Joint Committee for Dispute Resolution process from the Brazilian model BIT. The model BIT deviates from other international BITs' customary "fork in the road" clause by requiring the parties to exhaust all domestic remedies before domestic courts for a period of five years before resorting to international arbitration. However, it should be remembered that BITs only come to an end with the approval of both parties, and both parties must concur on all suggestions that will be incorporated into the BIT (Lok Sabha, 2022).

On the state of India's BITs dispute the JPC observed that under various BITs, there have been 37 notices of dispute or letters intended to raise a dispute by claimants or investors against the Republic of India. Of these, India has only so far won in four arbitrations, lost in two, and received adverse awards in three. All three of these cases are still pending a challenge to the arbitral award at the place of arbitration. One dispute saw the investors withdraw their claim; three disputes were settled amicably; and in fourteen disputes, the claimants did not pursue the matter after the initial request under BIPA. Two fresh notices have been received, and eight cases are still in various phases of arbitration. Out of the nine disputes that have been resolved thus far, according to the Ministry, only the White Industries case has resulted in India paying the claimant the arbitral award (Lok Sabha. 2022).

Pharmaceutical Industry and BITs

One of India's top ten industries for foreign investment is pharmaceuticals. Under the automated approach, 100 per cent foreign investment is permitted in medical devices. With a few exceptions, 100 per cent FDI was previously approved for the manufacture of drugs and pharmaceuticals through the automatic method (i.e., without needing prior government approval). The FDI policy was revised in 2011 to make a distinction between FDI in greenfield and brownfield investment in response to a wave of takeovers of domestic pharmaceutical industries and sector concerns regarding the availability of essential medicines, research and development, and technology availability. For greenfield projects, 100% FDI was permitted under the new regime's automatic route, facilitating the establishment of new manufacturing capacity, R&D, and technology acquisition. Hundred per cent FDI was permitted for brownfield investments under the approval method (i.e. with prior government approval). In 2014, amid rumours that FDI in brownfield pharmaceutical companies would be prohibited, the FDI policy was updated to include a new requirement that non-compete clauses in inter-se agreements would only be permitted in exceptional instances with government permission. Investments in both greenfield and brownfield sites are subject to this requirement. In addition, the Indian government eased its FDI policy for brownfield pharmaceuticals in 2016, allowing up to 74 per cent of FDI by the automatic route into the industry, in contrast to the previous requirement that such investments be subject to government approval. Investments above 74 per cent, however, remained subject to approval. FDI up to 100 per cent through the automatic method was still allowed for greenfield investments at the same time (Shah *et. al.*, 2020).

As regards, the impact of the revised model BIT of 2015, it is too early to make an assessment since very few BITs have been signed since then and they are with countries who are not major exporters of capital. The following sections review the developments of FDI in the pharmaceutical sector by some of the major foreign pharma investors.[4]

The USA

The Governments of India and the USA has signed an Investment Incentive Agreement (IIA) on May 23rd 2022. This IIA supersedes the IIA signed between the two countries in the

year 1997. According to this new agreement either party may terminate the agreement at any time by providing six months written notice to the other party. Six months after receiving the notification, the agreement will be terminated. In any such event, the provisions of the agreement shall, with respect to investment support provided prior to or while the agreement was in force, continue to apply so long as such investment support remains outstanding, but in no case longer than twelve years after the termination on the agreement (Development Finance Corporation (DFC), 2022). The Agreement is the legal requirement for DFC to continue providing investment support in India. Since 1974, DFC or its predecessor organisations have operated in India, and to date, they have supported investments totalling $5.8 billion, of which $2.9 billion is still outstanding. DFC is considering proposals for offering investment support in India totalling $4 billion. DFC has offered investment support in industries critical to development, including those that produce COVID-19 vaccines, finance healthcare, finance renewable energy, finance SME financing, finance financial inclusion, finance infrastructure, etc (PIB Delhi, 2022).

US is home to major pharm firms like Johnson & Johnson, Eli Lilly & Co., Pfizer Inc., AbbVie Inc., Merck & Co., Bristol-Myers Squibb Co., Amgen Inc., Gilead Sciences Inc., Regeneron Pharmaceuticals Inc., and Vertex Pharmaceuticals Inc.,

As per the DPII factsheet on FDI inflow updated till September 2022, USA is third among the share of countries in FDI equity inflows. For the FY 21 total inflows from USA was USD 13,823 million, for FY22, it was USD 10,549 million, from April 2022 to September 2022, it was USD 2,602 million and from April 2000 to September 2022 cumulative FDI inflows from USA has been USD 56,753.1450 million. USA has been top export destination in pharmaceutical sector with total exports worth USD 600.01 million for the year 2020-21 and USA has been the second top import destination with total imports worth USD 984.1 million for the year 2020-21 (Department of Pharmaceuticals, 2021).

Growing interest from several large pharmaceutical MNCs and 100% FDI under automatic route have resulted in some significant acquisitions in the pharmaceutical sector since 2006. In August 2006, Matrix Lab was acquired by the US-based company Mylan Inc for USD 736 million. Followed by acquisition of Orchid Chemicals by Hospira in December 2009 for USD 400 million and Piramal Healthcare in May 2010 for USD 3720 million (Sekhon & Mangla, 2013). Two facilities in India are owned by Hospira through its subsidiary Hospira Healthcare India Pvt Ltd, which it purchased from Chennai-based Orchid Chemicals and Pharmaceuticals. For around $400 million, Hospira purchased the generic injectables division of Orchid Pharma in December 2009. It had previously announced in 2012 that, through its Indian subsidiary, it would purchase Orchid Pharma's penicillin and penem active pharmaceutical ingredient (API) business, the API facility in Aurangabad, Maharashtra, as well as related research and development infrastructure in Chennai, for about $200 million. The deal was concluded in 2014. It is setting up another facility in Visakhapatnam, Andhra Pradesh. The plant, which will manufacture speciality injectables, is being set up at a cost of $375-450 million. As a part of US pharmaceutical major Pfizer's $17-billion acquisition of Hospira, its manufacturing capacity in India is set to get a boost as it is likely to get three manufacturing facilities from Hospira in the country (Babu, 2015).

On November 21, 1950, Pfizer Limited entered the Indian market via Dumex Limited. At Darukhanna in Mumbai, the first production facility was established. Pfizer built a sizable, cutting-edge facility in Thane, close to Mumbai, in 1960, housing manufacturing quality control and product research operations. The

company and Pfizer Corporation had entered into a licence agreement in November 1965 to continue the royalty-free licence for the use of Pfizer processes, technological know-how, etc. that had previously been granted to the Company. It also has a manufacturing plant in Goa. The stock exchanges were notified by Pfizer Limited (India) on May 31, 2017, that the company had reached an agreement with AstraZeneca AB Sweden to purchase the "Neksium" brand in India for a sum of Rs 75 crore (Business Standard, n.d.). With an initial investment of about $20 million, pharmaceutical giant Pfizer opened a global drug research and development centre at the IIT Madras research park in Chennai on May 4, 2022. (Rs. 150 crore) (The Times of India, 2022).

A leader in pharmaceutical, consumer healthcare, and animal health products, Wyeth Limited (Wyeth) is the Indian division of the US-based pharmaceutical corporation Wyeth and is now a member of the Pfizer group. Under the name Lederle Laboratories (India) Ltd., a private limited corporation was created in 1947. A direct, wholly-owned subsidiary of Pfizer Inc., Wagner Acquisition Corp., and Wyeth of USA combined in 2009. Pfizer Inc. is now Wyeth's parent company as a result of the merger, making it the ultimate parent of the Indian business. Wyeth was purchased by Pfizer for $68 billion. A proposal to merge Wyeth India with Pfizer India was agreed at a meeting of the boards of directors of Pfizer India and Wyeth India on November 23, 2013 (NDTV).

Abbott has two manufacturing facilities in Goa and Baddi and while investing of Rs. 450 crore ($75 million), Abbott launched its greenfield nutrition manufacturing plant in Jhagadia, Gujarat in October 2014 (Palmer, 2014). Amneal Pharmaceuticals, the drugmaker with headquarters in New Jersey and supported by NRI brothers Chirag and Chintu Patel, set up a greenfield biologics manufacturing facility in Ahmedabad that will export goods all over the world. Amneal has spent $350 million on capital projects in India throughout the years. The company has eight production facilities across the US that create injectables, oral solids, and APIs. In 2015, Amneal acquired Epsilon India followed by acquisition of WHO-certified injectables manufacturing facility in Gujarat, Kashiv Specialty Pharma and Puniska Healthcare in Ahmedabad in 2021 (Amneal, n.d.)

Advent International agreed to buy 50.1 per cent of Suven Pharmaceuticals Ltd for Rs 6,313 crore on December 26th, 2022, as part of the private equity firm's plan to build an Indian contract drug manufacturing powerhouse. Advent will also launch an open offer to minority shareholders for an additional 26 per cent of the company, a listed contract research and manufacturing services (CRAMS) business, at the same Rs 495 per share. If fully subscribed to, Advent could pay a total of 9,589 crore, making it the company's largest takeover in India to date (Dhanjal, 2022).

France

BITs agreement was signed between the India and France on 2nd September 1997 in Paris and it was stated in the agreement that the Agreement shall be in force for an initial period of ten years and it came into force on May 17, 2000 and got terminated on April 7, 2017 (Department of Economic Affairs).

In 2009 Shantha Biotech was taken over by the French major Sanofi Aventis. Sanofi, the French pharmaceutical giant, has a significant presence in the country. Sanofi has contributed to greenfield project and has invested about 1330 million in new assets creation. Further it has manufacturing facilities in Ankleshwar, Hyderabad, and Goa where APIs and formulations are manufactured (Mehta *et. al.*, 2017). Sanofi India Limited's (SIL) Board of Directors has approved a transaction for the slump sale and transfer of its manufacturing facility in Ankleshwar, Gujarat, to Zentiva and

its legal entity in India, Zentiva Private Limited, for a consideration of Rs. 2,617 million, subject to customary working capital adjustments. Zentiva, Sanofi's European generics business, was sold to Advent International in 2018 as part of a global transaction. Sanofi India's oldest manufacturing facility, Ankleshwar, produces brands such as Combiflam, Allegra, and Amarylare. These iconic brands' production has been moved to the Company's Goa site as well as external manufacturing sites (Sanofi India, 2019). Other well-known French pharmaceutical companies with a presence in India include Boiron, a manufacturer of homoeopathic medicines, and Bioderma (Briefing, 2018).

From January 2021 to December 2021, the trade in goods (excluding military equipment) between India and France was € 12.58 billion which was a 39.17 per cent increase compared to the previous year. Indian exports to France were worth € 6.70 billion and had risen by 39.36 per cent. Indian imports from France also rose by 38.98 per cent to € 5.88 billion. France has become a major source of FDI for India, with over 1,000 French establishments in the country. France is the 11th largest foreign investor in India with a cumulative amount of USD 10.31 billion from April 2000 to June 2022, representing 1.70 per cent of the total FDI inflows into India, according to the Department for Promotion of Industry and Internal Trade (DPIIT) (Embassy of India in Paris, 2022).

Switzerland

BITs agreement was signed between the India and Switzerland on 4th April 1997 and it was stated in the agreement that the Agreement shall be in force for an initial period of ten years and it came into force on February 16, 2000 but got terminated on March 22, 2017 (Department of Economic Affairs).

The Swiss pharma giant Novartis has had a significant presence in India since 1947, with a focus on drug development, manufacturing, commercial, and social business services. It employs over 10,000 people across three legal entities: Novartis Healthcare Private Limited (NHPL), Novartis India Limited (NIL), and Sandoz Private Limited (SPL). Novartis has invested more than $300 million in developing an R&D support centre and services in India over the past five years. The Drug Development Centre in Hyderabad, one of Novartis' three main international development centres, offers strong operational capabilities and integrated development capabilities (Novartis). In November 2008, Novartis has tied up with leading healthcare company of USA, USV Ltd. to market its anti-diabetic product Galvus (Sekhon & Mangla, 2013).

Germany

As per DPIIT factsheet on FDI inflow updated till September 2022, Germany ranks ninth in terms of FDI equity inflows. Total inflows from Germany were USD 667 million in FY21, USD 728 million in FY22, USD 222 million from April 2022 to September 2022, and USD 13,813 million cumulatively from April 2000 to September 2022, respectively.

Bayer HealthCare, a subgroup of German chemical and pharma major Bayer AG, and the Indian company Zydus Cadila signed an agreement in Mumbai, India, on January 28, 2011, to form the Joint Venture Company Bayer Zydus Pharma. On June 21, 2021, Bayer and Cadila Healthcare Limited announced an extension of their Joint Venture for a period of three additional years, commencing June 2021. During the joint venture's term, the company also launched some of Bayer's global innovative assets in India, including Xarelto, EyleaTM, and Visanne. With new products in the pipeline, Bayer Zydus Pharma will continue to operate in core therapies such as cardiovascular diseases, diabetes, women's health, ophthalmology, and oncology. Among the company's key pharmaceutical products are Xarelto, Glucobay, EyleaTM, Yaz, Mirena, and Visanne (Gonsalves & Rajesh, 2021).

In 2008, German company Schott AG and Indian company Kaisha Manufacturers formed a joint venture for pharmaceutical glass packaging. Schott Kasha inaugurated its new pharmaceutical packaging plant in Jambusar, Gujarat, on February 8, 2013. This 20 million Euro greenfield investment increases the company's production capacity in India by 50 per cent to around 2.0 billion ampoules and vials per year. The addition of India's first fully automated pharmaceutical packaging plant to an existing Daman production facility significantly boosts Schott Kaisha's competitive advantage (Orient Publication, 2013).

Following several million in investments over the last few years, in September 2021, Schott stated that it will invest 70 million euros to expand its tubing facility in Jambusar, Gujarat. With the help of the global pharma tubing and packaging market, the development in Jambusar will leverage Schott's more than $1 billion strategic investment programme through 2025 and add about 225 new employments. The expansion of melting capacities in India is part of Schott's commitment to invest over 100 million euros in its Indian tubing facilities and triple production capacity to produce FIOLAX® glass tubing for domestic and export demands (SCHOTT, 2021).

On August 17, 2021, Indian biopharmaceutical company Serum Institute of India (SII), acquired 50 per cent stake of SCHOTT Kaisha to become SCHOTT's joint venture partner and secure pharma packaging supply. Furthermore, Schott's managing director, Eric L'Heureux, stated that the company has invested 600 crores in the last three years to establish two new plants in Umarsadi, Gujarat, and Baddi, Himachal Pradesh (ANI, 2021).

BITs agreement was signed between the India and Germany on December 10, 1995 in Bonn and it was stated in the agreement that the Agreement shall be in force for an initial period of ten years and it came into force on July 13, 1998 and got terminated on March 23, 2017 (Department of Economic Affairs).

The first case involving a compulsory licence in India involved Bayer Corp. Natco Pharma Limited, a generic manufacturer with headquarters in Hyderabad, filed a compulsory licencing request against Bayer's patent on Sorafenib under Section 84(1) of the Indian Patent Act, 1970. It was granted but conditions stipulated included payment of royalty at 7 per cent of the medicine's net sales. (Kumar, 2021).

The Netherlands

BITs agreement was signed between the India and Netherland on November 6, 1995 and it was stated in the agreement that the Agreement shall be in force for an initial period of ten years and it came into force on December 1, 1996 and got terminated on December 1, 2016. Survival/ sunset clause length in the agreement is for 15 years (Department of Economic Affairs).

The Netherlands is a case with investments by both parties in each other's territory. It is the fourth largest foreign investor in India during fiscal year 2021-2022, with USD 4.62 billion in FDI equity inflows (INR 34,442 crore). During the period from April 2000 to September 2022, their investment accounted for 7 per cent of overall investment with cumulative FDI equity inflow of USD 43.022 billion (INR 2,77,387 crore). From April 2000 to November 2022, it accounted for 9 per cent of total overseas investments. With USD 1.02 billion in investments in fiscal year 2021-2022, the Netherlands was the fifth largest destination for ODIs from India (Embassy of India in the Hague).

In recent years, the Netherlands exported 80 million euros (Avrg. 2011-2017) worth of pharmaceutical and medical products to India. In contrast, India exported 99 million Euros worth of medicinal and pharmaceutical products to the Netherlands between 2011 and 2017. Several Indian companies, including Piramal, Dr. Reddy's, Serum Institute, Sun Pharma, Bharat

Biotech, Bharat Immunologicals, Gennova, and Aurobindo, have partnered with or acquired Dutch companies in the Netherlands (Kedar, 2018). Some of the major acquisitions in the Netherlands made by Indian companies includes the purchase of the Dutch company Bilthoven Biologicals by the Serum Institute of India for total consideration of over Rs 550 crore (Jyothi, 2012) and also the acquisition of dutch drug firm OctoPlus by Dr. Reddy's Laboratories for about €27.4 million (about 193 crore) (Pilla, 2012). PharmaMatch India, a subsidiary of PharmaMatch BV in the Netherlands, aims to bridge the gap between European and Indian pharmaceutical companies. PharmaMatch BV has established a liaison office in Bangalore with the goal of transferring mature generic product manufacturing to India (Raj, 2006).

The UK

India and the UK signed their first Bilateral Investment Treaty (BIT) in 1994 with the express purpose of luring and encouraging international investment. The BIT between India and the UK served as the model for other BITs that India negotiated. In fact, the Indian Model BIT of 2003 contained close semblance with the India-UK BIT (Nishith Desai Associates, 2018).

As per DPIIT factsheet on FDI inflow updated till September 2022, the UK ranks sixth in terms of FDI equity inflows. Total inflows from the UK were USD 2,043 million in FY21, USD 1,647 million in FY22, USD 920 million from April 2022 to September 2022, and USD 32,821 million cumulatively from April 2000 to September 2022. The sector-wise distribution of FDI equity inflows received from the UK from January 2000 to December 2020 shows that the second highest FDI equity inflows have been in the Drug & Pharmaceuticals, which accounts for approximately 14 per cent of FDI inflows from the UK. The total amount of FDI equity inflows from the UK into the drugs and pharmaceutical sector is USD 4346.59 million.

AstraZeneca India was established in 1979 and is headquartered at Bengaluru, Karnataka. AstraZeneca Pharma India Limited (AZPIL) is the operating company and covers manufacturing, sales and marketing activities of the company in India. It is a listed company and is a subsidiary of AstraZeneca Plc, UK. AstraZeneca's Global Technology Centre (GTC) in Chennai was set up in September 2014 for delivering an end-to-end, integrated IT service delivery mode. R&D Bangalore was launched in 2017 to support AstraZeneca's global established medicines portfolio (Astrazenca). On April 17th 2018, Biopharmaceutical company AstraZeneca announced to further invest $90 million in India over the next five years.

GlaxoSmithKline Pharmaceuticals (GLAXO) is an Indian subsidiary of the multinational corporation GlaxoSmithKline Plc (U.K.), which is one of the world's leading research-based pharmaceutical/healthcare companies and one of the world's largest vaccine manufacturers (in terms of sales). GSK is one of India's oldest pharmaceutical companies (since 1924). Glaxo India has only around 3% of the market share and is 17th in terms of overall sales revenue. GSK total investment for the FY22 is Rs. 365.59 crore. (Sundar, 2023). Over the next three years, GlaxoSmithKline Consumer Healthcare, the maker of Horlicks, Boost, and Crocin, intended to invest more than Rs 270 crore ($61 million) in its Indian operations (Bhushan, 2010). GSK also intended to invest INR 500 million ($73 million) in a manufacturing plant upgrade in Nashik, to increase output of thyroid and dermatology products (Jane, 2016). GSK Pharmaceuticals Ltd is investing Rs 1,000 crore in a new state-of-the-art pharmaceutical unit in Karnataka and is looking to expand its global pipeline in areas such as respiratory drugs and vaccines in India (*The Economic Times*, 2017). Over Rs. 710 crore had been invested in Hyderabad by GSK. Since its establishment in 2016, the facility has expanded quickly and has seen investments totalling about Rs. 340 crore just in the previous few years (The Hindu, 2022).

Singapore

The Comprehensive Economic Cooperation Agreement (CECA) between India and Singapore was signed on 29 June, 2005 and became effective on August 1, 2005. It was India's first comprehensive trade agreement with any trade partner. The India-Singapore CECA has been reviewed once, with the first round of review completed on October 1, 2007. The review addressed issues such as expanding tariff concession coverage, implementing MRAs, facilitating professional movement, expanding market access to financial services, establishing a "Special Scheme for Registration of Generic Medicinal Products" for India, and advancing IPR cooperation. On December 20, 2007, the two countries signed a protocol amending the CECA. The second protocol for amending the India-Singapore CECA was signed on August 24, 2018 and entered into force on September 14, 2018 (Department of Commerce).

As per DPIIT factsheet on FDI inflow updated till September 2022, Singapore ranks second in terms of FDI equity inflows. Total inflows from Singapore were USD 17,419 million in FY21, USD 15,878 million in FY22, USD 10,021 million from April 2022 to September 2022, and USD 1,40,988 million cumulatively from April 2000 to September 2022.

Fresenius Kabi, a business segment of the health care group Fresenius, purchased 73.3% of the share capital of the Indian company Dabur Pharma in April 2008 for INR 8,782 million (PBR, 2008). Later it further acquired 17.6 per cent stake through an open offer at Rs. 76.50 per share. Further, Fresenius Kabi intended to invest around Euros 30 million in the API plant of Dabur Pharma (ET Bureau, 2008). Sun Pharmaceutical, Glenmark Pharmaceuticals, and Intas Pharmaceuticals, all based in India, will receive a total investment of $567.7 million from Singapore's government. Temasek Holdings, Singapore's state-owned investment firm purchased Daiichi Sankyo's stock in Sun for $258.6 million. In addition, Temasek units purchased Glenmark for $149.1 million and Intas, a private company, for $160 million (Jane. 2015).

Japan

A Comprehensive economic partnership agreement between India and Japan was signed on February 16, 2011 and came into effect on 1 August 2011. It contained chapter 8 on investment. In Drugs and Pharmaceutical sector, National Treatment (Article 85), Most-Favoured–Nation Treatment (Article 86) and Prohibition of Performance Requirement (Article 89) were types of reservation. India reserved the right to issue guidelines that are necessary or required for the issuance of compulsory patent licences to produce and market a patented drug or pharmaceutical. India also reserved the right to develop and implement a policy to ensure the abundant availability of high-quality essential drugs and pharmaceuticals for mass consumption at reasonable prices (Department of Commerce, 2020). Both the sides expected that it would boost bilateral trade to USD 25 billion by 2014. The two-way trade between the countries has increased to USD 18.31 billion in 2011-12 from USD 13.82 billion in 2010-11 (The Economic Times, 2012). CEPA also offered a framework for institutionalising and consolidating corporate operations between India and Japan. As part of the agreement, Japan will remove tariffs on 97 per cent of Indian imports on a trade-value basis within ten years, while India will do the same for 90 per cent of its imports from Japan (Pharmabiz, 2012).

As per the DPIIT, from April 2000 to September 2022, Japan was the fifth largest investor in India, accounting for 6 per cent of overall investment with cumulative FDI equity inflow of USD 38.126 billion (INR 2,31,010 crore). The sector-wise distribution of FDI equity inflows received from the Japan from January 2000 to December 2020 shows that the

third highest FDI equity inflows have been in the Drug & Pharmaceuticals, which accounts for 12.92% per cent of FDI inflows from the Japan. The total amount of FDI equity inflows from the Japan into the drugs and pharmaceutical sector is USD 4,470.19 million.

Japan has been actively investing in various sectors in India, including the pharmaceutical industry. The Ranbaxy acquisition by Japanese pharmaceutical company Daiichi Sankyo for US$4.6 billion on June 2008 marked the beginning of MNC acquisitions in the Indian pharmaceutical industry (Mishra, 2020). Daiichi Sankyo, which bought a majority stake in Ranbaxy in 2008, owned 63.4 percent of the Gurgaon-based company at the time of the merger. Daiichi got around 9 per cent stake in Sun Pharma following the merger of Ranbaxy with the Indian pharma major. After Ranbaxy's merger with the Indian pharma giant, Sun Pharmaceutical Industries, Japanese pharmaceutical company Daiichi Sankyo sold all of its 21,49,69,058 shares for an estimated Rs 20,420 crore (PTI, 2015). In September 2012, CCI approved Mitsui's 26 per cent stake buy in Arch Pharmalabs. Mitsui has paid about INR 3.7 billion ($68 million) for another 27.29 per cent of Arch Pharmalabs, giving it a total investment of 31.96 per cent (Gareth Macdonald, 2013). Arch, an Indian Biopharmaceutical company engaged in the business of manufacture and sale of APIs and on the other hand, Mitsui through its Japan-based subsidiary MicroBiopharm is engaged in the pharmaceutical business including manufacture, contract manufacturing and sales of APIs globally (Economic Times, 2012).

Astellas, the second largest pharmaceutical company in Japan, adopted a different model for the Indian market. By the end of 2008, it had established a subsidiary and marketing operations in India (Kulkarni, 2010). Astellas Pharma Inc. announced that it has established its subsidiary, Astellas Pharma India Private Limited in Mumbai, India on November 14, 2008. Launched with capital of 160 million India rupees (approximately 320 million yen) (Astellas, 2008).

Eisai, the fourth largest Japanese pharmaceutical company, began operations in India in early 2010 by establishing an API plant and knowledge centre at a cost of Rs. 230 crore ($50 million). In less than two and a half years, Takeda became the fourth Japanese company to enter the Indian market, following Daiichi-Sankyo, Astellas, and Eisai. (Kulkarni, 2010).

Conclusion

India has been signing BITs with a view to providing appropriate reciprocal protection to foreign investors in India and Indian investors in the other country. It has always aimed at maintaining a balance between the investor's interests and the government's obligations to its domestic economy. Earlier India had approached the treaties as stand-alone ones and based on mutual trust. But certain legal setbacks, forced it to review this and adopt a more legal approach. As for their impact on the drugs and pharmaceutical industry, there is no consensus among academics and researchers.

FDI into the drugs and pharmaceuticals industry increased by 25 per cent in the first half of fiscal year 2022-23 when compared to the same period the previous year. Between April 2000 and September 2022, FDI inflows into the drugs and pharmaceuticals sector exceeded a total of $20 billion, reaching $20.10 billion by the end of September 2022. Foreign investment into the sector was $699 million in the six months from April to September 2022, up from $559 million in the same period the previous year (Babu, 2022).

Early studies including those by UNCTAD (1990) and Hallward – Driemieier (2003) did not find any close link between BITs and FDI. In one of the studies, it was found that the rate of FDI inflow to the pharmaceutical and drug industry is rising, but it also looked at the fact that there is no correlation between FDI and the industry's

turnover and exports. However, investment in R & D is positively impacted by FDI inflow, so it is advised that the government create more policies and programmes to encourage FDI inflow to India (Pawar & Argrade. 2021).

Recent studies by Simon Hartmann and Rok Spruk demonstrate that India's unilateral termination of BITs has a negative effect on FDI inflows to India.

DEA has not seen a direct causal relationship between BITs and FDI inflow and further noted that recent decline in number of BITs in force (due to termination post approval of the Model BIT text 2015) did not result in decline in annual FDI inflow. It was further noted that FDI decisions and inflows into the country are a complex function of several factors such as market, ease of doing business, infrastructure, human resources, raw material availability, competitiveness and productivity, and so on.

A 2020 study, however, concluded that while any specific BIT cannot be said to have an effect on FDI inflows, "the collective consequence of signing a series of investment treaties by India has had a beneficial effect on the inflow of FDI."[5]

Investment decisions are influenced by a wide range of circumstances and BITs are not the only mechanism for luring FDI into the nation. The JPC proposed that the signing of BITs be encouraged selectively in identified core/priority sectors/areas in order to attract more FDIs, resulting in economic growth and development as FDI inflows are critical for economic development in a developing country like India, and BITs have the potential to attract FDIs by providing foreign and Indian investors with greater confidence in investment (Lok Sabha. 2021).

The data on FDI inflow in the drugs & pharmaceutical sector during the period from 2002-03 to 2019-20, as presented in Figure 3.8 of Chapter 3 of the main report (p.36) clearly displays that during a very brief period of 2011-12 only it had shown a marked upswing, and, thereafter declined steadily up to 2018-19, but presented slight improvement in 2019-20. The data does not bear any direct causal relationship with BITs. As brought out in Chapter 3, the pharma sector FDI was mostly on account of mergers and acquisitions and not a result of green field investment. Be that as it may, even in the absence of a direct causal relationship, one can state that having more BITs adds to the positive eco system for FDIs in all sectors of industrial activity including pharmaceuticals as it will create an investor-friendly perception among business circles. India's ratifications of international treaties and signing of bilateral treaties and joining various economic groupings will certainly be a factor that influence investment decisions both by domestic players and foreign players. Considering that global supply chains and IPRs are factors that cannot be ignored as India and other countries realised during the COVID-19 Pandemic times, it would be appropriate that the country sends positive signals to technology and capital suppliers, especially in both technology and capital-intensive sectors like pharmaceuticals.

Endnotes

1 This, of course, contributed to the rise of Indian generic pharmaceutical industry, as brought out in Chapter 3 of the main report.

2 https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/1387/download.

3 UNCTAD website. https://investmentpolicy.unctad.org/international-investment-agreements. Accessed on 10 March 2023.

4 The data in these sections are sourced from the websites of the firm concerned and current news reports in the print media like the Hindu and the Times of India, unless stated otherwise.

5 Singh, J., Shreeti, V. and Urdhwareshe, P. (2020). The Impact of Bilateral Investment Treaties on FDI Inflows into India: Some Empirical Results. New Delhi: Indian Council for Research on International Economic Relations.

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Annexure-II

List of Participants Invited for Roundtable Discussion on Pharmaceutical Study

S. No.	Name	Designation	Organisation
1	Shri ShyamalMisra	Joint Secretary	Ministry of Commerce
2	Ms. Indu C. Nair	Director	Ministry of Commerce
3	Shri Rajneesh Tingal	Joint Secretary	PSU-IDPL, NIPER,
4	Dr. SJS Flora	(Director) Additional Charge	NIPER
5	Dr Prasanta Kumar Ghosh	Former Advisor	Department of Biotechnology, Ministry of Science &Technology
6	Shri Lanka Srinivas	Mentor- Pharmaceuticals, Health Technologies & Digital transformations	Elix Global
7	Dr. Gurpreet Sandhu	President	Council for Healthcare and Pharma (CHP)
8	Shri Raghu Kochhar	Vice President (Communication & Intl. Relations)	CHP
9	Dr.Prabha Bhandari	Vice-President (Regulatory Affairs)	CHP
10	Shri V.V. Krishna Reddy	President	Bulk Drug Manufacturers Association (BDMA)
11	Shri Arun Sawhney	Former CEO	Ranbaxy
12	Shri Vikas Dandekar	Editor	Pharma ET Prime
13	Dr P.V. Appaji	Former DG	Pharmexil
14	Dr. Gyanendra Nath Singh	Advisor to CM (Former Drugs Controller General)	Uttar Pradesh
15	Dr. B.Renuka	Executive	Indian Pharmaceutical Association (IPA)
16	Dr. T.V. Narayana	President	IPA
17	Shri Ashok Kumar Madan	Executive Director	IDMA
18	Shri Praveen K Mittal	Senior Director	FICCI
19	Ms. Neerja Bhatia	Executive Director	CII
20	Dr.Nirja Saraf	Managing Director	Bengal Chemicals & Pharmaceuticals Limited (BCPL), Kolkata
21	Mr. Sudarshan Jain	Secretary General	Indian Pharmaceutical Alliance

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