A Study on Export and Import of Pharmaceutical Products in India

Project report submitted in partial fulfilment of the requirement for the award of degree of

MASTER OF BUSINESS ADMINISTRATION

in

PORT AND SHIPPING MANAGEMENT

by

AGASTHYAN S KUMAR

Registration No: 2003304004

under the guidance of

Dr .A. MOUROUGANE

Associate Professor

School of Maritime Management

INDIAN MARITIME UNIVERSITY

(A Central University, under the Ministry of Ports, Shipping and Waterways)

Chennai Campus, Chennai

May, 2022

DECLARATION

I **AGASTHYAN S KUMAR, Registration No. 2003304004** student of School of Maritime Management, Indian Maritime University, Chennai Campus pursuing **Master of Business Administration in Port and Shipping Management,** hereby declare that this report titled **"A STUDY ON EXPORT AND IMPORT OF PHARMACEUTICAL PRODUCTS IN INDIA"** has been prepared and submitted by me towards the partial fulfilment of the requirement for the award of degree of **"Master of Business Administration in Port and Shipping Management"** under the guidance of **Dr. A Mourougane,** Associate Professor School of Maritime Management, Indian Maritime University, Chennai Campus.

I also declare that this project report is my original work and has not been copied from any of the report previously submitted for the award of any Degree, Fellowship, or other in similar titles.

Place: Chennai
Date: 25-05-2022

AGASTHYAN S KUMAR

Reg. No. 2003304004

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AGASTHYAN S KUMAR

CERTIFICATE

School of Maritime Management

Indian Maritime University, Chennai.

This is to certify that the project report entitled **"A STUDY ON EXPORT AND IMPORT OF PHARMACEUTICAL PRODUCTS IN INDIA."** submitted to the School of Maritime Management, Indian Maritime University, Chennai Campus., in partial fulfilment for the award of the degree of Master of Business Administration in Port & Shipping Management, is a record of work carried out entirely by **AGASTHYAN S KUMAR**, Reg. No. **2003304004**.

Dr. A. Mourougane
Associate Professor
Project Guide
School Maritime Management
Indian Maritime University
Chennai campus

External Examiner:

Place: Chennai
Date: 25th May 2022

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CHAPTER-1
INTRODUCTION

1.1 Introduction

In recent years, the Indian pharmaceutical business has experienced rapid growth, fuelled by increased domestic consumption and strong export demand. Infrastructure development, technical basis, and the wide range of items manufactured have all witnessed major advancements in the business. Because Indian pharmaceutical businesses are capable of producing cost-effective pharmaceuticals, demand from the export market has been constantly increasing. The Indian pharmaceutical sector is currently facing obstacles such as identifying novel drug research targets, obtaining regulatory approvals, and refining drug discovery and development procedures. This report examines the current state of the global and Indian pharmaceutical sectors, as well as their performance, challenges, and possibilities, as well as the way forward.

1.2 Importance of the Study:

Pharmaceutical production, preparation, and marketing services are all part of the pharmaceutical sector, which is heavily reliant on R&D&I for growth.

his industry is continually compelled to rethink its business model tactics in order to maximise patent income and optimise the development of new pharmaceuticals, making R&D&I investments critical to prevent becoming obsolete in a highly competitive market. The development of new pharmaceuticals, an improvement in life expectancy, and a huge number of diseases treated are all feasible thanks to investments in innovation in this sector.

Similarly, investing in pharmaceutical research and development not only improves the health of the population, but it also has other benefits in the medium term, such as reduced health spending (due to fewer hospitalizations) and lower operational expenses in the health sector.

1.3 Objectives of the Study:

- Researching the Indian pharmaceutical industry's export and import procedures and policies.
- To compare the performance of the Indian pharmaceutical industry with that of the top five countries.
- To learn about the Indian pharmaceutical industry's potential.

1.4 Research Methodology

The data for this paper was gathered through various structured and unstructured meetings among representatives of the Department of Commerce, Government of India, Department of Chemicals and Petrochemicals, including the newly formed Department of Pharmaceuticals, Director General of Foreign Trade (DGFT), Department of Ayurveda, Unani and Siddha medicine, and various institutions such as the Directorate General of Foreign Trade (DGFT), Department of Ayurveda, Unani and Siddha medicine, and various institutions. Many unstructured discussions were organised by the task force's chairman in order to conduct consultations with industry experts, and members from the industry have enthusiastically participated. Ministry of Commerce and Industry, Task Force Report, December 12, 2008.

Because of the distinct nature of the problems that each of these broad areas must address, this report seeks to discuss various segments of the pharmaceutical industry separately, such as Generic Pharmaceuticals, Contract Manufacturing, Drug Discovery and Contract Research Services, and Indian System of Medicines. This research aims to address the issues faced by domestic industry in each of these areas, as well as advise government of India measures. While the study seeks to address the majority of the issues raised by stakeholders and deemed important by the taskforce, there is a chance that some of them were overlooked. Most of the time, it's due to inter-se prioritisation, which means leaving out the less important topics to conserve space and retain focus.

1.5 Scope of the study

The study provides clear insights into the Indian Pharmaceutical Industry and its future post COvid-19, and the report will be valuable to government agencies as well as pharmaceutical firms and enterprises that are primarily involved in this industry.

1.6 Limitations of the Study

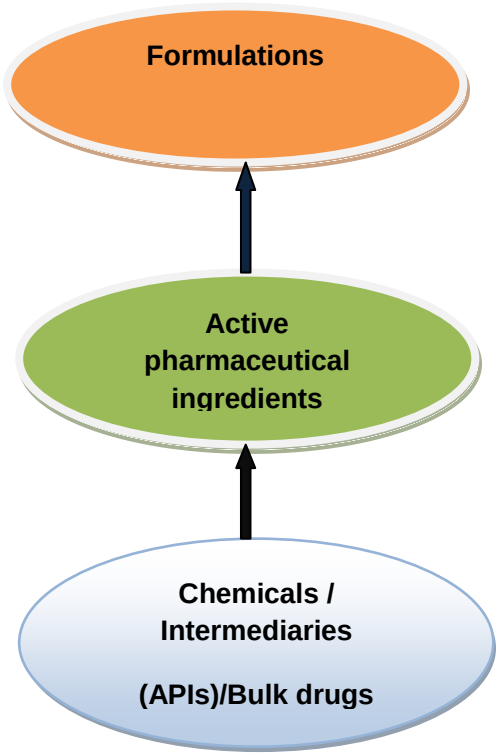
- The primary weakness of this study is that it was conducted entirely with secondary data.
- This research was conducted over a short period of time, it was insufficient to produce a comprehensive report.
- Because the study is about theoretical implementation, some practical challenges may arise.

CHAPTER-II
INDIAN PHARMACEUTICAL INDUSTRY

2.1 Industry Characteristics

The pre-patent regime and the post-patent regime are the two periods in which the Indian pharmaceutical sector evolved. Only process patents were recognised in India prior to 2005, which aided in the development of a strong and competitive indigenous sector. In 2005, India entered the product patent regime, signalling the end of a protected age and the beginning of a new chapter in the global integration of Indian players. While the prior process patent system aided the development of India's pharmaceutical industry into a world-class generics business, the new product patent regime aims to encourage long-term drug discovery. In India, however, the introduction of patented products has been gradual.

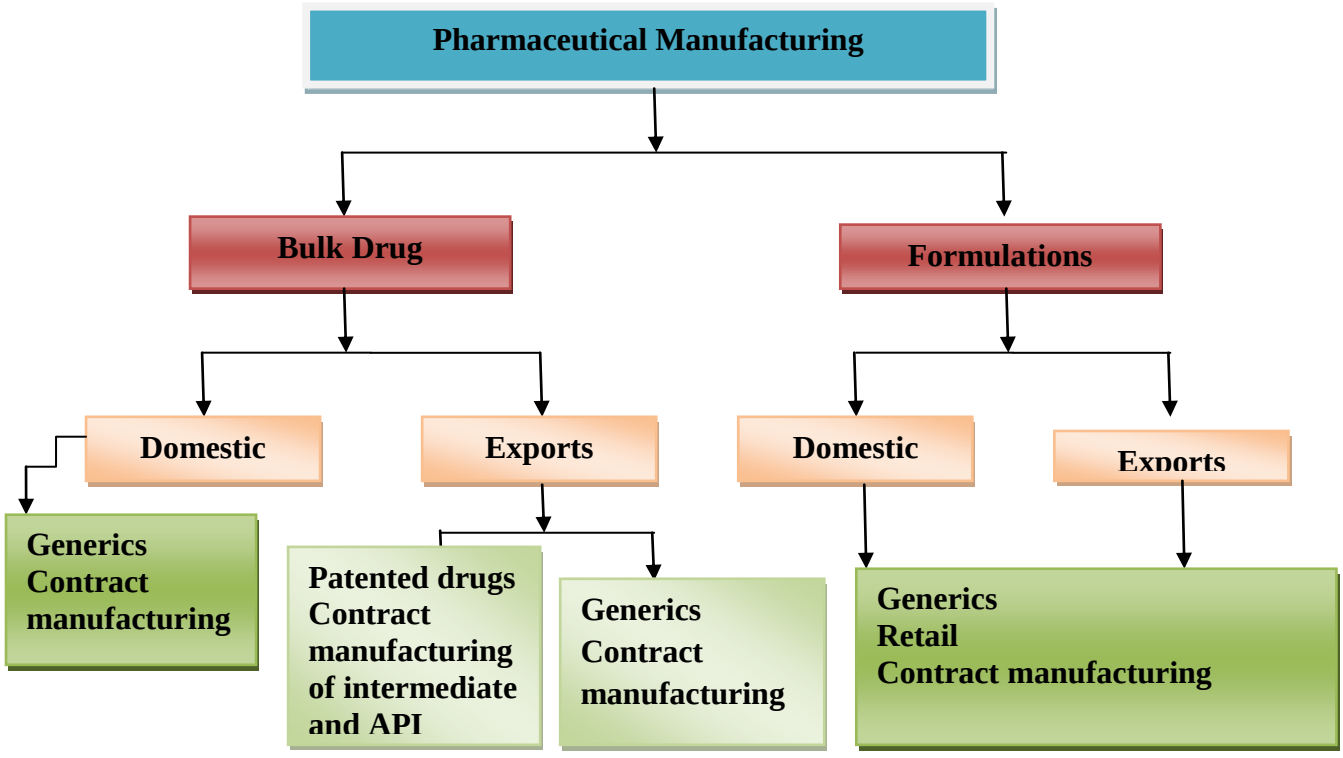
Indian Pharmaceutical Industry
Value Chain



With reverse-engineered generic pharmaceuticals and active pharmaceutical ingredients, India acquired a footing in the global arena (API). India is presently attempting to establish itself as a key participant in the fields of outsourced clinical research and contract research and manufacturing services (CRAMS). The US Food and Drug Administration has licenced the most industrial facilities in India (332 sites) (US FDA). Furthermore, in 2011, Indian companies were responsible for one-third of all Abbreviated New Drug Applications (ANDA) approved by the US FDA. Formulations and bulk pharmaceuticals are two categories in which Indian pharmaceutical businesses have production potential. The formulations category is further divided into two categories: local consumption and exports. In the past, the domestic market has accounted for 40-50 percent of total formulations production, with exports contributing for a higher share. In the case of bulk pharmaceuticals, however, domestic consumption barely accounts for 10-20% of overall output.

As a result, exports (both bulk medications and formulations) dominate the Indian pharmaceuticals business, accounting for almost 60% of total sales in 2013-14. Formulations are marketed in the market either through contracts (supply) or directly (retail). In the same way, bulk pharmaceuticals are either delivered under contract for copyrighted drugs or sold outright for off-patent drugs. Indian pharmaceutical companies are expected to expand their presence in on-patent regulated markets in the coming years, while also maintaining a strong position in the generics (off-patent pharmaceuticals) market, according to CRISIL Research.

Manufacturing by Indian Pharmaceutical Players



2.2 Industry Performance

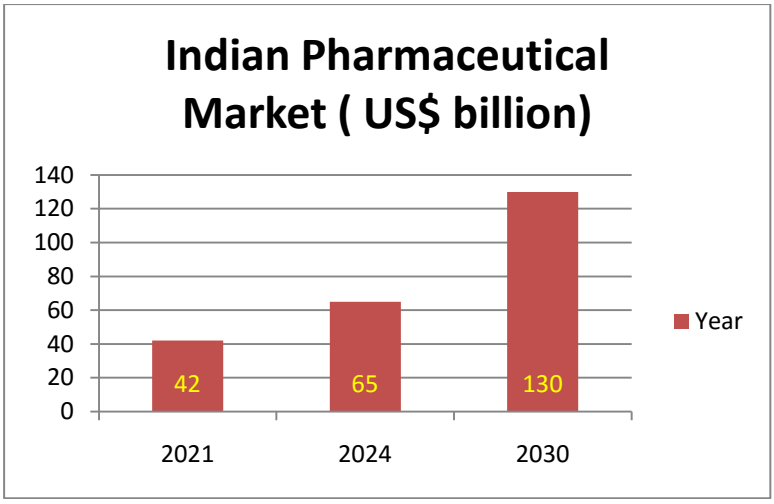
The Indian pharmaceutical sector is the third largest in terms of volume and the tenth largest in terms of value in the world (2.5 per cent of global share). The Indian medicines industry is valued at US$ 33.9 billion, having increased at a CAGR of nearly 13% over the previous five years to 2013-14. The cheap cost of pharmaceuticals manufacturing in India is one of the reasons for the lower rank in terms of value and higher rank in terms of volume; the price differential is estimated to be between 5% and 50% lower than in industrialised countries. . The sector has achieved self-sufficiency in formulation manufacture, producing almost 70% of the country's bulk medication requirements. India is also one of the world's largest producers of generic pharmaceuticals.

2.3 Market Size

The home market is predicted to rise thrice during the next decade, according to the Indian Economic Survey 2021. India's domestic pharmaceutical market is expected to reach US$ 42 billion in 2021, US$ 65 billion by 2024, and US$ 120-130 billion by 2030, according to estimates.

Biopharmaceuticals, bio services, bio agriculture, bio industry, and bioinformatics are all part of India's biotechnology industry. In 2019, the Indian biotechnology sector was worth US$ 64 billion, and by 2025, it is predicted to be worth US$ 150 billion. In FY20, India's medical device market was worth US$ 10.36 billion. From 2020 to 2025, the market is estimated to grow at a 37 percent CAGR to reach US$ 50 billion. According to CARE Ratings, India's pharmaceutical industry would grow at an annual pace of 11% over the next two years, reaching a value of more than US$ 60 billion by August 2021. India is a prominent and expanding player in the global medicines industry. India is the world's largest provider of generic pharmaceuticals, supplying over 60% of global immunization demand and accounting for 20% of global supply by volume. The Indian pharmaceutical industry is worth US$ 42 billion and ranks third in volume and 13th in value globally.

The Indian pharmaceutical market grew 17.7% annually in August 2021, up from 13.7 percent in July 2020. According to India Ratings & Research, revenue in the Indian pharmaceutical market is predicted to increase by more than 12% year on year in FY22.



2.4 Investments and Recent Developments

The Union Cabinet has approved a change to the existing Foreign Direct Investment (FDI) policy in the pharmaceutical industry, allowing FDI up to 100% under the automatic route for medical device manufacture under specific conditions.
Between April 2000 and March 2021, the Indian medications and pharmaceuticals sector received a total of US$ 17.99 billion in FDI.

The following are some recent developments/investments in the Indian pharmaceutical sector:

- Akston Biosciences, based in the United States, said in November 2021 that it will begin a clinical study of its second-generation COVID-19 vaccine, dubbed 'AKS-452,' in India soon.
- AstraZeneca India established a Clinical Data and Insights (CDI) branch in October 2021 to expand its worldwide presence and manage data-related parts of clinical trials.
- The Indian government provided $4 billion to the pharmaceutical and medical businesses in September 2021.
- Glen Mark partnered with SaNOtize in August 2021 to launch a COVID-19 therapy spray in India and other Asian regions.
- In August 2021, Uniza Group, a pharmaceutical company located in Ahmedabad, reached an agreement with Lysulin Inc., a company based in the United States, to introduce Lysulin, a nutritional product for Indian consumers.
- In August 2021, Alkem Laboratories launched Famotidine and Ibuprofen pills in the United States to treat the symptoms of osteoarthritis and rheumatoid arthritis.

- Generic Health (a Lupin Limited subsidiary situated in Australia) struck an agreement with Southern Cross Pharma Pty Ltd in July 2021. (SCP). Lupin will obtain 100% ownership of SCP as part of this agreement. Lupin's position in Australia is likely to be strengthened as a result of the acquisition.
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- In July 2021, Generic Health (an Australian subsidiary of Lupin Limited) reached an arrangement with Southern Cross Pharma Pty Ltd. (SCP). As part of the deal, Lupin will get 100 percent ownership of SCP. As a result of the acquisition, Lupin's position in Australia is projected to be enhanced.
- Southern Cross Pharma Pty Ltd and Generic Health (an Australian subsidiary of Lupin Limited) concluded an agreement in July 2021. (SCP). Lupin will receive 100 percent ownership of SCP as part of the acquisition. Lupin's position in Australia is expected to improve as a result of the acquisition.
- Cipla launched ViraGen, a real-time COVID-19 detection kit based on multiplex polymerase chain reaction (PCR) technology, in May 2021.
- In May 2021, the Indian government issued a request for R&D proposals on crucial components and advances in oxygen concentrators, with a deadline of June 15, 2021.
- Indian Immunologicals Ltd. (IIL) and Bharat Immunologicals and Biologicals Corporation (BIBCOL) signed technology transfer agreements with Bharat Biotech in May 2021 to develop the vaccine locally and expand India's vaccination campaign. By September 2021, the two PSUs intend to begin vaccine production.
- In May 2021, Eli Lilly & Company granted non-exclusive voluntary licences to Cipla Ltd., Lupin Ltd., Natco Pharma, and Sun Pharmaceutical Industries Ltd. to manufacture and distribute Baricitinib, a COVID-19 treatment.
- In April 2021, the CSIR-CMERI, Durgapur, created the Oxygen Enrichment Unit technology on its own (OEU). The equipment can deliver medical air at a rate of up to 15 litres per minute with an oxygen purity of above 90%. Conquerent Control Systems Pvt. Ltd., A B Elasto Products Pvt. Ltd., Automation Engineers, Mech Air Industries, and Auto Malleable were among the MSMEs to receive the technology.

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- In February 2021, Aurobindo Pharma announced plans to purchase solar energy from two NVNR Power and Infra open access projects in Hyderabad. With a US$1.5 million investment, the corporation will have a 26 percent stake in both enterprises. By the end of March 2021, the deal should be finalised.
- Aurobindo Pharma announced in February 2021 that it would acquire solar energy from two NVNR Power and Infra open access projects in Hyderabad. The corporation would own a 26 percent share in both businesses after investing US$1.5 million. The agreement should be finalised by the end of March 2021.
- The Telangana government teamed with Cytiva to open a 'Fast Trak' facility in February 2021, bolstering the state's biopharma industry.
- Glenmark Pharmaceuticals Limited released SUTIB, a generic form of Sunitinib oral capsules, in India in February 2021 for the treatment of kidney cancer.
- Natco Pharma launched Brivaracetam for the treatment of epilepsy in India in February 2021.
- The Russian Ministry of Health granted Glenmark Pharmaceuticals permission to distribute its new fixed-dose combination nasal spray in Russia in February 2021.
- The Central government said in January 2021 that it will invest Rs. 14,300 crore (US$ 1,957 million) in three bulk pharmaceuticals parks to manufacture chemical compounds or active pharmaceutical ingredients (APIs) for medications and minimise imports from China.
- After acquiring Thyrocare, a diagnostic company, Pharm Easy acquired $300 million from its existing investors in July 2021. Thyrocare will use these funds to continue its acquisition process. The online pharmacy intends to list the company on the Indian Stock Exchange after the purchase is completed.

2.5 Government Initiatives

The following are some of the government's initiatives to encourage India's pharmaceutical industry:

For the first time since April 2021, India may resume supplies of COVID-19 shots to the worldwide vaccine-sharing platform COVAX in November-December 2021. The World Health Organization (WHO), which co-leads COVAX, has been pressuring India to continue COVAX supplies, especially after it supplied 4 million pills to neighbours and allies in October 2021.

- PM Mr. Narendra Modi will open the inaugural Global Innovation Summit in the pharmaceuticals sector in November 2021. The summit will feature 12 sessions and over 40 national and international speakers who will discuss a variety of topics such as the regulatory environment, innovation funding, industry-academic collaboration, and innovation infrastructure.
- Mr. Mansukh Mandaviya, the Union Health Minister, revealed in August 2021 that an extra number of pharmaceutical businesses in India will begin manufacturing anti-coronavirus vaccines by October-November 2021. This measure is likely to increase the immunisation campaign's effectiveness across the country.
- Ms. Nirmala Sitharaman, the Finance Minister, announced an extra spending of Rs. 197,000 crore (US $26,578.3 million) for the pharmaceutical PLI plan in 13 important sectors, including active pharmaceutical ingredients, drug intermediaries, and critical starting materials, in June 2021.
- As of August 31, 2021, the PLI programme had received a total of 278 applications from the industry. This will most likely assist 55 companies.
- The Department of Pharmaceuticals launched a PLI scheme to promote domestic manufacturing by setting up greenfield plants with minimum domestic value addition in four separate 'Target Segments' with a cumulative outlay of Rs. 6,940 crore (US$ 951.27 million) from FY21 to FY30 to achieve self-reliance and reduce import dependency in the country's essential bulk drugs.

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- The Union Government determined in April 2021 to streamline and expedite the regulatory system for COVID-19 vaccines that have been licenced for restricted use by the US FDA, EMA, UK MHRA, PMDA Japan, or WHO Emergency Use Listing (EUL). This decision is likely to make it easier for India to obtain foreign vaccines and boost imports.
- The Punjab government stated in February 2021 that three pharma parks would be built in the state. A pharma park has been proposed in Bathinda, which will be spread over 1,300 acres and cost Rs. 1,800 crore (US$ 245.58 million). A third project, a Greenfield project, has been proposed at Wazirabad, Fatehgarh Sahib, and is worth Rs. 180 crore (US$ 24.56 million).
- The Ministry of Health and Family Welfare has been given Rs. 73,932 crore (US$ 10.35 billion) in the Union Budget 2021-22, while the Department of Health Research has been given Rs. 2,663 crore (US$ 365.68 billion). The 'National Health Mission' was given a budget of Rs. 37,130 crore (US$ 5.10 billion) by the government. Over the course of six years, the PM Aatmanirbhar Swasth Bharat Yojana will receive Rs. 64,180 crore (US$ 8.80 billion). The Ministry of AYUSH has been given a budget of Rs. 2,970 crore (US$ 407.84 million), up from Rs. 2,122 crore (US$ 291.39 million) previously.

2.6 Indian Pharmaceutical Industry – key challenges

India currently supplies roughly 40% of generic pharmaceuticals, over-the-counter products, and 10% of finished dosages in the United States.The looming patent cliff is expected to open up more opportunities for India's pharmaceutical industry, particularly in generics and biosimilars. By 2018, the generic market is expected to rise by 9.5 percent to US$ 432 billion. However, the US Food and Drug Administration has recently enhanced its inspection of the Indian pharmaceutical business, owing to the following two factors: Data Integrity — In recent years, data integrity practises used by several US FDA-approved units of Indian pharmaceutical corporations have become a key concern for the business. According to the US-FDA, data integrity is important because manufacturers rely on properly recorded information to ensure product identity, strength, purity, and safety. Evidence of misleading data or difficulties with batch records discovered during preapproval inspections has been the primary cause of market approval delays, and audits have resulted in warning letters and the units being blacklisted. Though data integrity issues have always existed, according to industry leaders, new mandates by the US-FDA to achieve parity in inspection of foreign and domestic facilities have further complicated the picture by expanding the US-oversight FDA's to many firms that are less familiar with US standards. According to sources, the US-FDA has not scrutinised the quality of finished medications; instead, the agency has focused on certain CGMP criteria, as well as the gathering and documentation of data, which have been raised against the blacklisted units during audits (Annexure 2). Failure to record operations contemporaneously; document back-dating; duplicating existing data as fresh information; re-running samples to generate better results; and falsifying or discarding data are among the data integrity issues reported by the investigators. Data integrity vulnerabilities have also surfaced in other regions, according to industry sources, in addition to India. Because there are more US-FDA approved units in India, the number of warning letters has increased. Outside of the United States, India has the most US-FDA approved drug manufacturing facilities.

Whatever the case may be, the growth of the Indian pharmaceutical industry, which is one of the world's major producers of pharmaceutical products, will be harmed by data integrity standards. Clinical Trial Data Credibility - The reliability of 'Clinical Trial Data' generated by the Indian pharmaceutical sector has also become a source of concern. Given its wide pool of patients with diverse treatment demands and access to a big, scientifically competent workforce, India is a suitable place for conducting clinical trials in many respects. This has resulted in a huge increase in the number of clinical trials conducted in the country; however, the country's capacity to regulate clinical trials has not kept up with this growth, leading to a number of unethical practises such as limited patient compensation for adverse events, drug approval without clinical trials, and lapses in informed consent procedures. Despite the fact that the Indian government has strengthened regulatory controls by requiring mandatory trial registration and establishing numerous committees to oversee trial approval, trial execution, and ethical treatment of patients, delays in new drug approvals as a result of the new regulatory control regime have forced some multinational pharma companies to reconsider their clinical trial activities in India.

CHAPTER-III

COMPARATIVE STUDY OF INDIAN PHARMACEUTICAL INDUSTRY WITH TOP 5 COUNTRIES

3.1 Introduction

The Indian pharmaceutical industry is the third largest by volume and the thirteenth largest by value. It has established itself as a major manufacturing and research centre around the world By 2020, the Indian pharmaceutical business is predicted to develop at a compound annul gro wth rate (CAGR) of 22.4 percent, reaching a value of US$55 billion.

Generic medications account for roughly 70% of the Indian pharmaceutical business, while over-the-counter medicines and patented treatments account for 21% and 9%, respectively.

- India's pharmaceutical exports totaled US$ 17.27 billion in 2017-18, and are predicted to increase by 30% by 2020, reaching US$ $20 billion.
- During the months of April through October 2018, pharmaceutical exports totaled $10.80 billion.
- From April to October 2018, the United States (US$ 3.21 billion), the United Kingdom (US$ 383.30 million), South Africa (US$ 367.35 million), Russia (US$ 283.33 million), and Nigeria (US$ 255.89 million) were the main importers of India's pharmaceutical* products.
- In terms of incremental growth, India is predicted to be among the top three ph armaceutical markets by 2020.
- India is the world's largest provider of generic drugs (20 to 22 percent of global export volume)
- India boasts some of the world's lowest manufacturing costs. It is lower than in the United States and nearly half of Europe.

3.2 Germany

- Germany is the fourth largest pharmaceutical market in the world and the largest in Europe. Sales of pharmaceuticals in Germany climbed by 5.7 percent in 2019, reaching EUR 46.4 billion (ex-manufacturer prices).

- Germany is home to over 500 pharmaceutical businesses. SMEs are the economic sector's backbone, with 90 percent of medication producers employing fewer than 500 people. A total of 120,000 individuals work in the German pharmaceutical sector (2019).
- Over 500 pharmaceutical companies operate in Germany. 90 percent of medicine manufacturers employ fewer than 500 people, making SMEs the economic sector's backbone. In Germany, 120,000 people work in the pharmaceutical industry (2019).
- In 2018, Germany's pharmaceutical sector spent over EUR 7.4 billion on research and development. Across all major German businesses, the industry has the highest research intensity - approximately 12.5 percent of revenues were reinvested in R&D in 2018.

3.3 Switzerland

The pharmaceutical business accounts for more than a third of Swiss exports, making it a significant contribution to the Swiss economy. In Switzerland, big enterprises such as Roche and Novartis, as well as small and medium-sized pharmaceutical companies, have access to good infrastructure and experienced workers. Cooperation between large and small businesses, as well as proximity to research institutions, create a perfect environment for research and innovation, laying the groundwork for a highly specialized manufacturing site. The sophisticated healthcare system in Switzerland also provides optimum circumstances for product testing and distribution.

As a result of worldwide prominent institutions and financially sound, research-oriented pharmaceutical corporations, the availability of highly skilled scientists is exceptional. In 2017, Novartis employed around 23,000 scientists, clinicians, and other professionals and reported a total of more than 200 clinical development projects. In the same year, Roche employed over 22,000 individuals in R&D. • In 2017, Roche and Novartis invested about 16 billion Swiss francs, or around 21% of net sales, in global research and development. In Switzerland, overall R&D investments by all pharmaceutical companies registered with the industry group Interpharma were roughly seven billion Swiss francs in 2017.

3.4 Belgium

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Belgium will import $35.7 billion in pharmaceutical items in 2020, making it the world's fourth highest importer. Pharmaceutical products were the second most imported product in Belgium in the same year. Belgium is a global importer. In the same calendar year. Pharmaceutical products were Belgium's second most imported product. Between 2019 and 2020, the fastest-growing pharmaceutical import markets for Belgium were Ireland (2.65 billion euros), Italy (1.14 billion euros), and the United Kingdom (1.14 billion euros) (967M)

3.5 France

Unlike in other nations, where the pharmaceutical industry grew out of the chemicals industry, the French pharmaceutical sector grew out of dispensaries. The French pharmaceutical industry today accounts for 6.5 percent of global production, although the global market share of the French pharmaceutical industry is only 5%. As a result, globalization has benefitted French production. France is also the top producer in Europe, accounting for 22% of all pharmaceuticals and medications marketed in the continent, albeit it should be noted that France's part of this market is both large and protected.

On the supply side, however, the pharmaceutical business faces fierce competition, leading to initiatives to boost productivity by exploiting the expiration of some patent rights and licenses when they enter the public domain, as well as restricted regulatory frameworks for health spending. For example, 42 pharmaceuticals licensed in the United States, with combined annual sales of USD 80 billion, are set to return to the public domain in the next years. As the number of patents expires, pharmaceutical laboratories prefer to refill their product portfolios to reinforce their strategic position or to move closer together, in keeping

with the international trend. These transactions are insufficient; therefore scientists are developing new compounds to replace brands that are losing market share to generic medications, which are 30 percent cheaper on average. Simultaneously, biotechnology (bioinformatics, genomics, and proteomic systems) is predicted to increase the number of possible new pharmaceuticals identified by a factor of 10 or 20, while lowering the cost of failure during the development stage.

3.6 United States

The pharmaceutical sector in the United States is enormous and geographically varied, and it is strongly integrated into global supply networks. The industry is made up of both huge multinational corporations and small and medium-sized businesses (SMEs). According to the USITC (2020), in 2017, 75% of the pharmaceutical 5000 companies were SMEs, selling only 10% of the whole value of sales, while 25% of the establishments were huge, selling 90% of the total value of sales. Only three corporations control the distribution network for pharmaceutical supplies, which distribute 90-95 percent of all medications consumed in the United States. Starting up a production facility takes an average of five years. . With sales of $268.7 billion in 2019, the United States is a big producer of pharmaceutical items. Pharmaceutical preparations (in vivo diagnostic compounds and non-biological pharmaceutical preparations) accounted for the majority of the shipments (73 percent), followed by biologics (15 percent). 6 percent of the cargoes were in vitro diagnostic chemicals and APIs. Domestic pharmaceutical shipments were $221 billion in the first nine months of 2020, up 11% from the same period the previous year. Prices of pharmaceutical preparations have climbed by roughly 30%, biologics by 15%, while APIs have stayed steady in price over the last six years (USITC, 2020).

In 2019, the United States imported US$87.6 billion in finished pharmaceutical products, mostly from industrialized nations including Ireland, Switzerland, Germany, and Italy (Table 10). Ireland supplied 25% of US imports of those products in 2019, Switzerland and Germany 15%, Italy and India each supplying 8% of the US market in 2019. (figure 1). These five countries accounted for 64% of all products imported into the United States. Only China, India, and Mexico are developing countries among the top 20 pharmaceutical and antibiotic suppliers to the US (Table 10). After Ireland and Switzerland, India is the third largest contributor, followed by China and Mexico. China, India, Canada, and Mexico, on the other hand, are the top volume providers (USITC, 2020). China and India excel at low-value items,

such as generic pharmaceuticals and commodity chemicals used in a range of pharmaceuticals (including generics), which are far less valuable than unique APIs and promulgations.

3.7 Comparison of top pharmaceutical products exporting countries with India

Rank	Country	2017	2018	2019	Change%	Contbn%
1	Germany	56961.31	65338.68	60111.28	1-8.00	13.91
2	Switzerland	42152.05	46136.43	48552.34	5.24	11.23
3	Belgium	34508.94	36229.25	40091.69	10.66	9.28
4	France, Monaco	28244.62	31178.96	33052.77	6.01	7.65
5	USA	27369.25	29194.60	31648.88	8.41	7.32
6	Ireland	24754.31	30868.20	26666.31	-13.61	6.17
7	Italy	20337.26	21303.39	26310.45	23.50	6.09
8	United Kingdom	27075.72	25260.68	23357.81	-7.53	5.40
9	Netherlands	16145.64	18408.62	20435.75	11.01	4.73
10	India	12773.85	14116.80	15966.50	13.10	3.69
	World	**387759.50**	**420164.53**	**432157.05**	**2.85**	**100.00**

The Indian pharmaceutical sector reacted resolutely to global demand for certain of the drugs used to treat the Covid-19 outbreak. India's industry may respond to urgent requests for items such as azithromycin, doxycycline, paracetamol, hydroxychloroquine, and many more from other countries.

Vaccine producers in India may match our government's commitment of millions of free doses delivered abroad, in addition to commercial exports worth an estimated $140 million. Pharmexcil is pleased to report that one of its members (Bharat Biotech) outperformed several western creative vaccine firms by introducing its own version of covid vaccine, which was created entirely in-house. The product met all of the requirements for a safe vaccine and was ready for market in less than a year, compared to more than three years in the past. This demonstrates our biologists' ability to achieve even the most stringent deadlines with precision and speed.

3.8 Comparison of India's pharmaceutical products import with top 5 countries.

(Values are in Billion dollars)

Country	2017	2018	2019	2020	2021
United States	90	118	130	140	150
Germany	55	59	60	66	80
Switzerland	28	30	33	38	42
China	58	48	49	58	60
Italy	23	27	27.5	29	31
India	1900	1000	1800	600	1600

CHAPTER - IV

EXPORT OPPORTUNITIES OF INDIAN PHARMACEUTICAL INDUSTRY

4.1 Opportunity of India as a Global Supply Destination

India's strength as a pharmaceutical supplier stems from its ability to provide high-quality pharmaceuticals while preserving a structural cost advantage. Despite low productivity, India's formulation production costs are 30-40% cheaper than comparable manufacturing centres like as China and Eastern Europe15. This is because labour costs are lower in compared to other regions16. Despite inflationary pressures, India's labour cost advantage will continue in the medium to long term, especially if Indian businesses can boost productivity through operational excellence and digital efforts. In compared to countries like China, the pharmaceutical sector has a better supply of indigenous talent (e.g., B.Pharm, M.Pharm, B.Sc.). Diversifying into increasingly complex products (microspheres, liposomes, and emulsions), Indian pharmaceutical businesses are extending their R&D and production capacities while retaining the needed quality. However, the company is having some challenges serving export markets, which will need to be addressed in the future.

- Rising pricing pressure in the regulated sector is hurting corporate margins. Customer consolidation, increasing competition in commoditized, easily manufactured commodities, more ANDA clearances, and a delay in new product introductions are all factors.

- The influence of compliance issues on supply reliability is another key issue. While many Indian firms have improved in recent regulatory audits and look to be on the mend, others continue to struggle.

- For China, India continues to rely on imports of crucial raw materials, intermediates, and APIs, with the amount of reliance increasing over time. This exposes us to raw material supply interruptions and pricing volatility.

India Pharma can develop by leveraging its cost advantage and improving supply reliability, both of which are critical buying criteria for customers. Three focus areas emerge for Indian pharmaceutical companies:

- Ensure perfect compliance by improving quality processes.
- Prioritize operational excellence and API/intermediate self-sufficiency..

These needs are intertwined; operational excellence is a significant enabler of supply reliability and quality. The sites with the finest quality also have the best operations, according to a research based on McKinsey's proprietary POBOS database of worldwide pharmaceutical production facilities. Excellence in quality and compliance should be institutionalised. In recent years, Indian pharmaceutical companies have experienced increased regulatory scrutiny and several compliance challenges in order to meet expanding GMP standards. Large pharmaceutical businesses in other important production centres such as China, Europe, and North America are showing similar tendencies. Many global pharmaceutical companies have completed a multiyear, network-wide cleaning.

Building outstanding quality throughout the organization's operational systems, management systems, and people systems is essential.

Using India-specific interventions with global best practises, several Indian pharmaceutical companies have overcome the challenges and created solid quality systems. The interventions required address all three parts of a good quality system: the operating system, the management system, and the people system.

• Increasing the quantity of good personnel and improving their skills: Developing capabilities at all levels, particularly in middle management; using emerging technologies to develop immersive training modules.

• Establishing a Quality Culture in the Shop: Addressing India's cultural issues and fostering an ownership, transparency, and cooperation culture.

• Making essential procedures and performance management systems failsafe with technology: Some Indian pharmaceutical companies are already employing Advanced Analytics techniques to identify QMS concerns and decrease OOS and deviations.

• Improving important technical features of the QMS over time, such as data dependability, rigorous documentation requirements, process validation, and investigations.

Increasing operational efficiency

While India's total manufacturing costs are expected to remain competitive, pharmaceutical plant productivity in India remains 40-50 percent lower than the worldwide median17. This is a fantastic opportunity to improve efficiency and relieve some of the cost worries. While traditional Lean technologies continue to improve efficiency, advances in data availability, computing capacity, and sophisticated analytics enable pharmaceutical companies to uncover new performance opportunities. While the pharmaceutical industry lags behind other advanced industries in terms of digital and advanced analytics adoption, companies who have simply piloted these technologies have shown benefits in conversion costs, variations, yields, and equipment efficiency of 10% to 30%.

4.2 Post-Covid-19 Opportunities in the Indian Pharmaceutical Sector

The pharmaceutical industry, as well as the global healthcare sector, has been impacted in an unseen way as a result of the COVID-19 pandemic, resulting in material changes in consumer requirements and preferences, as well as macroeconomic, structural, and microeconomic changes in the end-to-end value chain. The pharmaceutical industry has responded with agility in the face of the pandemic and a changing world, from the sequencing of the novel corona virus in January to vaccines being administered to the first recipient in the United Kingdom by December 2020, with efficacy levels exceeding 90%, exceeding all expectations of governments and markets worldwide. Governments from all over the world will keep a tight eye on the pharmaceutical industry in the future.

In light of geopolitical and economic shifts, India must reassess its current position in the global pharmaceutical industry, consider ways to consolidate and strengthen its position, and achieve self-sufficiency as a globally competitive pharmaceutical industry with innovation as a guiding principle for future growth. This research was created using information from the government, regulators, and key business groups, as well as conversations with industry veterans from various areas.

Since March 2020, the pharmaceutical business has experienced devastating restraints and roadblocks in reaching out to clients who want to operate and distribute drugs in India and throughout the world. The pharmaceutical business surpassed expectations in reaction to the global crisis, selling drugs to over 150 countries and meeting all local requests. A major

increase in vaccine capacity was accomplished throughout the course of the year to complement vaccine delivery in India and other nations that rely on India for supply.

The Indian pharmaceutical business has grown at a compound annual growth rate (CAGR) of 11% in the domestic market and 16% in exports during the last two decades. While the local market has grown at a comparable rate to GDP, the industry's overall growth has been propelled by its leadership in supplying generic formulations to global markets.

Between 2020 and 2030, we expect the Indian pharmaceutical industry to grow at a CAGR of 12%, reaching US$130 billion by 2030, up from US$41.7 billion in 2020. Despite a CAGR of roughly 13% over the previous two decades, the pharmaceutical industry has expanded at a rate of 8.5 percent in the last decade and 6.2 percent in the last five years.

In order to reach self-sufficiency and become the genuine pharmacy of the world, we must focus on the next set of avenues to fuel the industry's development engine, which is both strategic and economically significant. To achieve this goal, the Indian pharmaceutical industry's key stakeholders – payers, providers, policymakers, physicians, pharma industry players, academia, and a slew of service providers in logistics and distribution, IT, capital pools, packaging, and other auxiliary industries – will have to collaborate.

CHAPTER- V

SUMMARY & CONCLUSION

5.1 Summary

Both the Indian and global pharmaceutical industries have made important contributions to healthcare outcomes. India continues to play a critical role in the manufacturing of vital, high-quality, and low-cost medicines for both home and international markets. It supplies 50 to 60% of global demand for different vaccines (including ARVs), 40% of generics consumed in the United States, and 25% of all medications provided in the United Kingdom1. Indian sites have submitted 35 to 38 percent of all ANDAs approved in the last five years (including 25 to 30 percent of all inject able ANDAs.

Affordable antiretroviral (ARV) drugs in India were a major factor in AIDS patients obtaining greater treatment. India supplies 60% of the world's antiretroviral drugs and 30% of UNICEF's annual requirement. In recent quarters, however, several Indian pharmaceutical companies (like their global counterparts) have witnessed significant declines in growth and profitability. Many have witnessed significant value erosion, which has severely impeded industry's capacity expansion and R&D objectives.

Despite these obstacles, the industry has grown at a compound annual growth rate of 67% during the last five years4. This was made possible by the following enabling factors.

• **Growing global demand:** Generic penetration in high-value healthcare markets (such as the United States) has risen rapidly, with India accounting for 20% or more of global generic demand.

•**Consistent domestic market consumption growth:** In recent years, India's pharmaceutical market has grown significantly. Despite recent setbacks, the economy expanded at a solid 57 percent last year. India is expected to be one of the top three pharmaceutical markets in the world by 2030.

• **India's low-cost, large-scale manufacturing capability:** India has the second-largest number of FDA-approved facilities in the United States, and labour costs in India are up to 40% lower than in other manufacturing hubs.

5.2 Conclusion

India's medical spending is predicted to rise 9.12% in the next five years, making it one of the top 10 countries in terms of medical spending. Firms' capacity to focus their product portfolios toward chronic therapies for diseases like cardiovascular, diabetes, anti-depressants, and anti-cancers, which are all on the rise, will determine future domestic sales growth.

The Indian government has tried a number of steps to reduce healthcare costs and rates. The objective has been the speedy entrance of generic drugs into the market, which should help Indian pharmaceutical companies. Furthermore, pharmaceutical companies will benefit from the increased focus on rural health programmes, life-saving drugs, and preventative vaccines.

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