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Review article

Strategic insights: Unveiling the potential of Pharmaceutical exports from India to Regulated markets

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ABSTRACT

India is a major exporter of medicinal products in the world. India's pharmaceutical sector has grown significantly to contribute largely to the GDP of the nation because of its rapidly expanding economy and abundance of highly skilled labor. However, exporting pharmaceuticals to markets that are subject to regulations can be a difficult procedure that requires a lot of paperwork. This all-inclusive handbook will assist in navigating the documentation and export regulatory requirements for pharmaceutical exports from India to regulated markets. It also provides export projections for the future, enabling exporters to adapt their export strategy. This handbook will give you the knowledge needed to be successful in the pharmaceutical export business, regardless of whether an experienced exporter or a recent entry into the market. A study on Indian Pharmaceutical Exporter together with future forecasts and SWOT Analysis of Indian Pharmaceutical manufacturers.

Keywords: Regulated & semi-regulated pharmaceutical market, Future Export prediction, and documentation, SWOT Analysis (Strength, Weakness, Opportunity, and Threats).

INTRODUCTION

The Indian pharmaceutical market

Worldwide, the pharmaceutical sector serves as the foundation of the healthcare system in every nation. Even the most remote areas of the nation now have a reliable and strong healthcare system due to the efforts of the Indian pharmaceutical industry [1]. The Indian pharmaceutical industry was predicted to be valued at 42 billion dollars as of February 2021. In India Pharmaceutical medicine and also other pharmaceutical products like medical diagnostic tools, hospital supplies, nutritional supplements, and specific healthcare services. The Indian pharmaceutical industry has established a robust profile for itself internationally because of stringent regulations, labour-friendly amendments, and strong work ethics [2, 3]. In addition to effectively satisfying the demands of its own country in terms of pharmaceutical goods and services, India is emerging as a major exporter of pharmaceuticals to other nations. India is the world's third-largest exporter of pharmaceutical commodities, as well as the largest exporter of generic medications. According to a survey, the nation exported pharmaceutical goods worth US$ 24.62 billion in 2021-2022, up 18% from US$ 24.4 billion in 2020-2021. India's top five export destinations are the United States, South Africa, Russia, Nigeria, and the United Kingdom [1, 2, 3, 4, 5, and 6].

India is the world's third-largest economy by volume and fourteenth-largest by value.

Regulated and Semi-regulated

Definition of regulated pharmaceutical market

A regulated market is where the government or a regulatory authority imposes rules and regulations to ensure fair and ethical practices.

The goal of regulation is to ensure that pharmaceuticals are of high quality, efficacy, safety and easily accessible for human and animal health [6]. Regulatory authorities and pharmaceutical criteria vary by country but some common elements include:

Patenting

This is the process of granting an inventor or assignee exclusive rights for a short time in exchange for public disclosure of the innovation. Patenting promotes innovation and investment in R&D while protecting the intellectual property of pharmaceutical companies.

Testing

Conducting different investigations and trials to assess a drug's pharmacological, toxicological, and clinical properties. A Drug's dose, pharmacokinetics, pharmacodynamics, adverse effects, interactions, and effectiveness are all determined by testing.

Approval

The process of approving a medicine for marketing and sale involves analyzing and assessing the information that the drug developer has provided. A drug approval ensures that it satisfies WHO requirements for the intended application.

Marketing

The process of selling and promoting a medication to possible consumers is known as marketing. Drug delivery, price, advertising, and post-marketing monitoring are all included in marketing. To avoid deceptive or false advertising, unfair competition, and adverse effects on public health, marketing is regulated.

Regulated market guidelines are quite explicit and need to be followed completely [6, 7, and 8].

Examples of countries that comes under-regulated pharmaceutical market are

United States, European Union (UK, Germany, France, Ireland, Sedan etc.,), Japan, Canada, Australia, New Zealand [9, 10].

Definition of Semi-Regulated Pharmaceutical Market

A semi-regulated market is a market where the rules and regulations are less strict or not fully enforced.

A semi-regulated pharmaceutical market is a market where the production, distribution, and sale of pharmaceutical products are subject to some degree of government oversight and control, but not as stringent as in a fully regulated market. Semi-regulated markets are typically found in developing or emerging countries that have less established or harmonized regulatory systems and standards for pharmaceuticals [11].

Some characteristics of semi-regulated markets are

Drug developers may have more chances and higher profit margins in these areas due to their lower entry barriers and lower level of competition.

They have more varied and dynamic customer preferences and needs, which can lead to more demand and innovation for drugs; they have more challenges and risks in terms of quality, efficacy, accessibility of drugs, and safety, which can affect the reputation and performance of drug developers; and they have less strict or uniform requirements for patenting, testing, approval, and marketing of drugs, which can reduce the time and cost of drug development and registration [11, 12].

Examples of Semi regulatory bodies of pharmaceutical are: (ROW Countries)

ASEAN 10 Countries include Sri Lanka, India, Bangladesh, Philippines, Brunei Darussalam, Vietnam, Indonesia, Cambodia, Malaysia, Myanmar, Laos and Singapore.

African countries include Algeria, Ethiopia, Zambia, Kenya, Ghana, Mozambique, Malawi, Namibia, Sierra Leone, Nigeria, and Zimbabwe.

GCC Countries (Oman, Saudi Arabia, Qatar, UAE, Kuwait, Bahrain)

Latin American countries (Brazil, Mexico, Peru, Guatemala, Panama, Chile, Argentina, Dominican Republic)

CIS (commonwealth of independent states): Ukraine, Russia, OFSUs (Armenia, Azerbaijan, Belarus, Georgia, Kirghizstan, Kazakhstan, Tajikistan, Moldova, Turkmenistan, and Uzbekistan) [11, 12, 13].

Table 1: Country and its Regulatory Authority [3, 5, 10, 13, 19].

NAME OF COUNTRY	REGULATORY AUTHORITY
India	CDSCO
ASIAN (Hong Kong)	Independent regulatory agencies / DOH – Department of Health
AFRICA (Tanzania)	Independent regulatory agencies / TFDA (Tanzania Food and Drugs Authority)
CIS (Russia)	Independent regulatory agencies / ROSZDRAVNADZOR
Australia	TGA
LATAM (Brazil)	Independent regulatory agencies / ANVISA
EU	EMA
South Africa	MCC
Japan	PMDA
Canada	HPFB
USA	FDA
GCC (The Gulf Co-Operation Council)	Independent regulatory agencies / National filling

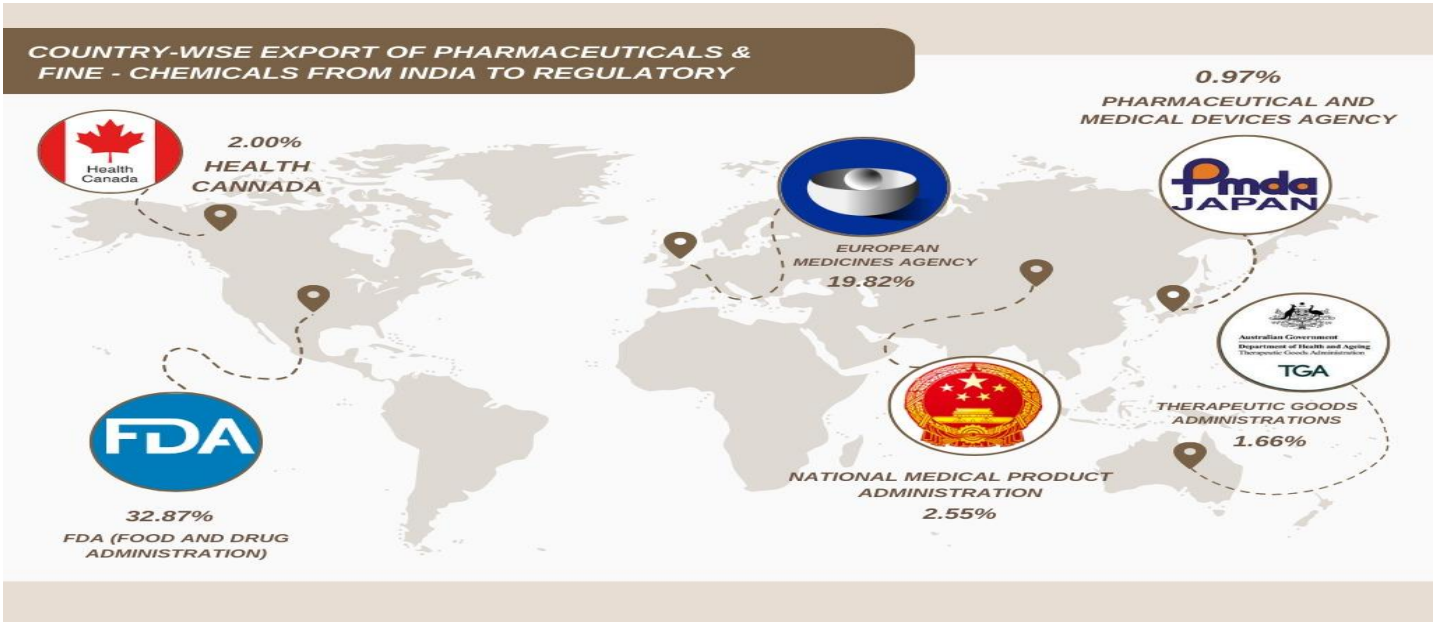
Difference between regulated & semi-regulated pharmaceutical market

Implementation levels differ. Audits and inspections vary in intensity, as do the penalties for GMP violations are different.

Table 2: Difference between Regulated and Semi-Regulated Pharmaceutical Markets [3, 6, 8, 9].

CATEGORY	REGULATED PHARMACEUTICAL MARKET	SEMI-REGULATED PHARMACEUTICAL MARKET
Degree of implementation of regulations	Regulated markets have clear and stringent guidelines that must be followed by pharmaceutical companies and meet out ICH requirements.	Semi-regulated markets have less clear or less rigorous guidelines that may vary from country to country or region to region
Intensity of audits and inspections	Regulated markets have frequent and thorough audits and inspections by the competent authorities to monitor the compliance of the pharmaceutical companies with the regulations.	Semi-regulated markets rely on pharmaceutical businesses' self-regulation or less frequent or comprehensive audits and inspections by 6the authorities.
Penalties for GMP violations	Regulated markets have severe penalties for any violations of the good manufacturing practices (GMP) standards, such as fines, suspensions, recalls, or bans.	Penalties, such as warnings, corrections, or negotiations for GMP violations are less severe or less consistent in semi-regulated markets.
IN BUSINESS POINT OF VIEW		
Compliance	Compliance with these guidelines may involve high costs, time, and resources for the pharmaceutical companies.	Compliance with these guidelines may involve lower costs, time, and resources for the pharmaceutical companies
Risk	Regulated markets have frequent and thorough audits and inspections by the competent authorities to monitor the compliance of the pharmaceutical companies with the regulations.	Semi-regulated markets rely on pharmaceutical businesses' self-regulation, or less frequent or less deep audits and inspections by the authorities.
	Adopt severe penalties, such as fines, suspensions, recalls, or bans, for any infringement of the good manufacturing practices (GMP) regulations.	Additionally, its GMP infringement penalties – such as warnings, corrections, or negotiations – are likewise less severe or inconsistent.
	Pose a high risk for pharmaceutical companies in terms of reputation, market share, and profitability.	Pose a lower risk for the pharmaceutical companies in terms of reputation, market share, and profitability
Opportunity	Innovative, high-quality goods that can meet patients' unmet medical requirements are highly sought after in regulated marketplaces.	There is less market demand in semi-regulated industries for high-quality, innovative products that can meet patient's unmet medical requirements.
	Having a High level of purchasing capacity and willingness to spend money on such products is present	Possess poor purchasing power and willingness to spend money on such products is present
	Regulated markets possess high opportunities for pharmaceutical companies in terms of revenue, growth, and competitiveness.	Semi-regulated markets possess limited potential for pharmaceutical companies in terms of revenue, growth, and competitiveness.

Figure 1: Pharmaceutical Regulatory Authority of Regulated Countries



These are some fundamental differences between markets that are controlled and those that are semi-regulated; but the exact variances may differ based on the market, regulations involved, and specific product.

Regulatory authorities of Indian pharmaceutical sector (certified units) [7, 14].

The main control of pharmaceutical regulation is divided between two ministries in the Government of India such as

The Ministry of Health and Family Welfare.

The Ministry of Chemicals & Fertilizers (MoC & F) comprises bodies such as the National Pharmaceutical Pricing Authority (NPPA), Department of Fertilizers, Departments of Chemicals & Petrochemicals, etc.

Regulatory Bodies under the Ministry of Health & Family Welfare, Government of India

The Central Drug Standards and Control Organization (CDSCO).

Indian Council of Medical Research (ICMR).

Indian Pharmacopoeia Commission (IPC).

National Institute of Biological Standards and Controls (NIBSC).

Regulatory Bodies under Ministry of Chemicals and Fertilizers, Government of India

Department of Pharmaceuticals (DOP).

The National Pharmaceutical Pricing Authority (NPPA).

And other ministries also have some vital roles in the drug regulation process. Those ministries include.

Ministry of Environment and Forests

Genetic Engineering Approval Committee (GEAC).

Review Committee on Genetic Manipulation (RCGM).

Ministry of Commerce and Industry

RE Patent Office in India.

Pharmaceutical Export Promotion Council of India (Pharmexcil).

Ministry of Science and Technology

National Accreditation Board for Testing & Calibration of Laboratories (NABL).

Department of Science and Industrial Research (DSIR).

Council of Scientific & Industrial Research (CSIR).

Bhaba Atomic Research Centre (BARC).

Export Regulatory Requirements

For exporting pharmaceutical products, one should have the following requirements and licenses.

Pharmaceutical Manufacturing License Number, Pharmaceutical Marketing Company, or Wholesale Drug License Number.

Goods and Service Tax Identification Number.

Importer Exporter Code (IEC) Number.

COPP (Certificate of Pharmaceutical Product) from DCGI.

WHO: GMP certification of a manufacturing plant or as specified by the importing country.

Registration of product at importing country.

When exporting pharmaceuticals and medications, the person in concern must comply with the exporting and importing country's rules as well as company regulations. Prior to beginning exports, one must establish own business in the nation of import, designate a distributor or CnF, or search for an agent who will take care of all licenses, registrations, and paperwork [3, 5, 15, and 16].

Requirements for Importing Country

Registration of product in their country.

Completion of regulatory requirements of importing country like plant specifications, certification, etc.

Custom Clearance.

Set up own infrastructure or identify import agents and/or distributors in the nation of import.

Promote, market, and distribute products in importing countries.

Requirements from India

Completion of Licenses and registrations i.e. manufacturing/wholesale license, GST, IEC, CoPPs, etc.

Dossier.

Freight Forwarder Agencies/Agents.

Indian Trade Classification (Harmonized System) ITC (HS) of Product.

Bill of Lading/ Airway Bill/ Lorry Receipt/ Railway Receipt/ Postal Receipt.

Commercial Invoice cum Packing List.

Shipping Bill/ Bill of Export/ Postal Bill of Export

Custom Clearance.

Table 3: Category-wise Export from 2015-2022 and the predicted rise of Indian Exports to 2030 (US $ Billion)

PRODUCT CATEGORY	2015-2016 [23].	2016-2017 [24].	2017-2018 [25].	2018-2019 [26].	2019-2020 [27].	2020-2021 [28].	2021-2022 [29].	2022-2023 [21].	GROWTH 2015-2023 %	GROWTH RATE PER YEAR	PREDICTED EXPORT 2035	PREDICTED GROWTH % 2022-2035	PREDICTED GROWTH% 2015-2035
Drugs formulation & biologicals, Vaccines	12648	12701	12747.88	14223.73	15777.05	19033.29	19015.31	19438.39	53.69	0.0671	35090.18	80.52	177.44
Bulk Drugs & drug intermediates	3597	3401	3525.65	3895.38	3867.77	4405.39	4437.64	4681.29	30.14	0.0377	6799.11	45.24	89.02
Ayush & herbals	364	404	456.12	448.07	428.07	539.88	612.83	628.47	72.66	0.0908	1313.25	108.96	260.78
Surgical	303	334	552.16	570.18	630.57	465.47	553.00	645.9	113.17	0.1415	1742.64	169.80	475.13
Grand Total	16912	16840	17281.81	19137.81	20703.46	2444.03	24618.78	25394.05	50.15	0.0627	44500.53	75.24	163.13

According to my forecast, the value of Indian pharmaceutical exports in 2030 will be close to US $ 37742.22 Billion, or a 123.17% increase from 2015.

General procedure for exporting pharmaceutical products from India [3, 15, 16].

Establish a WHO-certified GMP pharmaceutical manufacturing plant or a pharmaceutical marketing firm, enter into a contract with the WHO for a GMP-certified plant, obtain a wholesale drug license, and export any products produced by the company by obtaining a NOC.

Get the IEC number.

(Procedure for applying for an IEC – through website **(www.dgft.gov.in)**
The entire CoPP procedure.

Open a personal office or designate a distributor or agent in the country of importingarding .

File a product registration in the country of import.

Collaborate with a Freight Forwarding agency to transfer products from India to the country of import.

Create a packing list and commercial invoice (Based on a purchase order, Letter of Credit, Clearance of payment, etc.)

Dispatch goods from the manufacturing unit to a port or airport for customs clearance.

Once customs clearance is completed, the merchandise will be shipped.

In accordance with regional regulations and laws, they must also clear customs after arriving in the country of import. Acquired at the distributor, import agent, or own godown Begin marketing, distribution, and promotion.

SWOT ANALYSIS

Strength

The Government schemes and Governing bodies like.

Government initiatives

SPI – Strengthening of the Pharmaceutical Industry scheme.

PLI – Production Linked Incentive scheme.

PMBJP – Pradhan Mantri Bhartiya Janaushadhi Pariyojana.

PTUAS – Pharmaceutical Technology Upgradation Assistance Scheme.

PPDS – Pharmaceutical Promotion and Development Scheme

Since the goal of all these schemes is to improve India's manufacturing capacity, they will increase production and investment in the industry while also helping to diversify the product range to high-value goods for the pharmaceutical industry.

Governing Body

Pharmexcil

Department of Pharmaceuticals. Indian pharmaceutical manufacturers manufacture good quality medicine under affordable pricing. India has been approved as the Second-highest USFDA-approved site. India manufacture over 25% of the medications used in the UK Indian Pharmaceutical manufacturer adapt to various regulatory requirements according to their regulatory bodies.

Figure 2: Pharmaceutical Export Contribution from India to other Countries [6, 21].

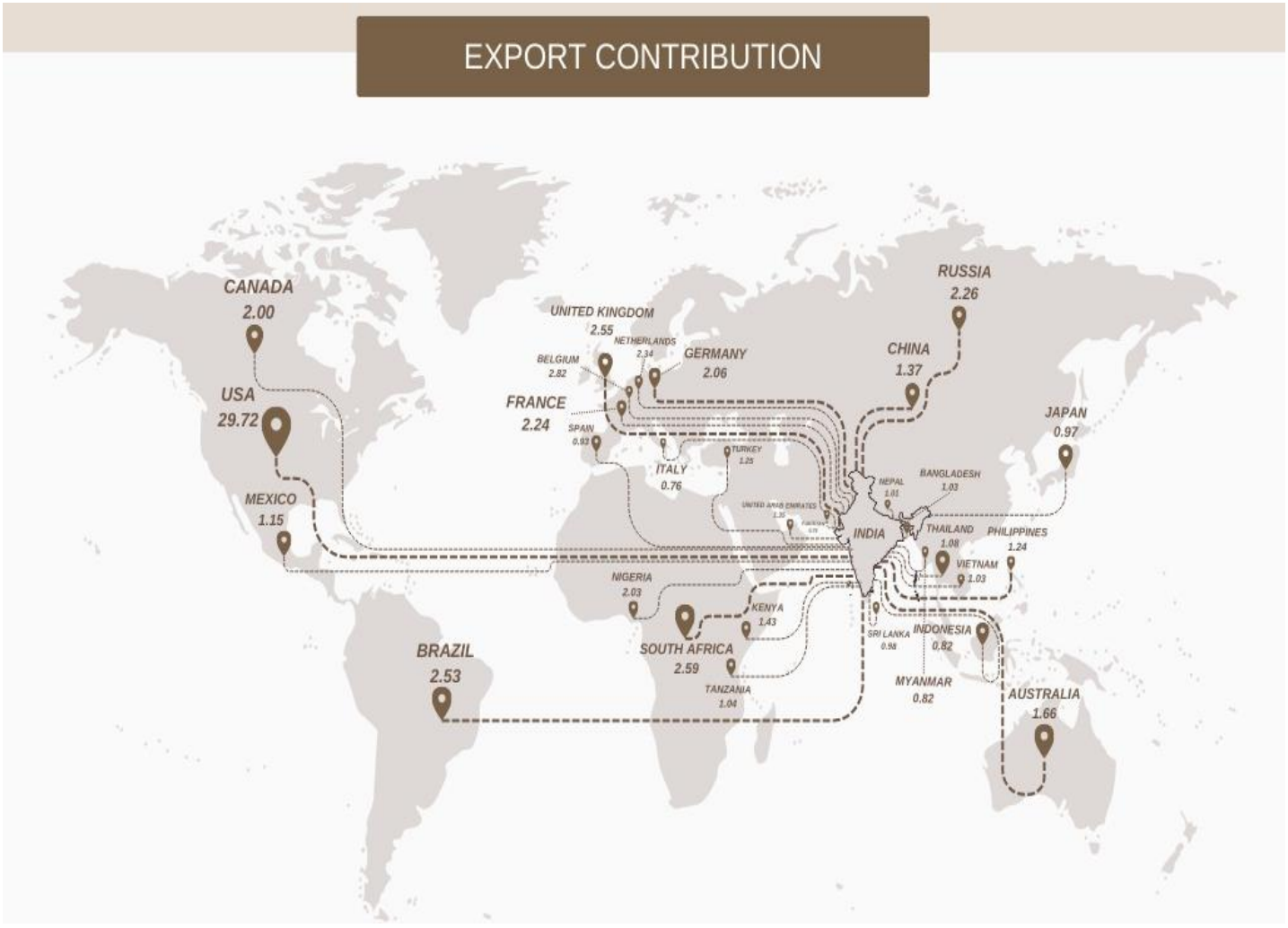
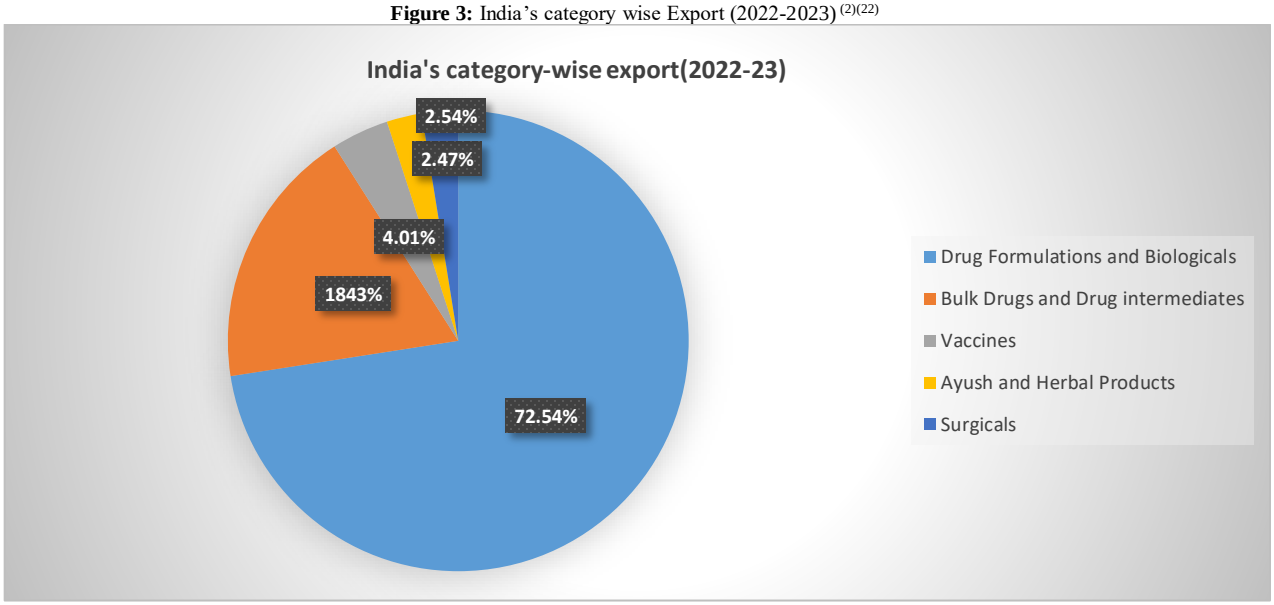


Figure 3: India's category wise Export (2022-2023) [2][22]



Weakness

Our country's pharmaceutical exports are more focused on Generic medicines but the patent filing is too low. Indian pharmaceutical manufacturer needs to focus on R&D i.e. Research and Development to increase patent filing. This can further increase the Export of Indian Pharmaceuticals around the world [17, 18].

Opportunity

The current infrastructure can be improved to establish India as a global leader giving pharma clusters financial support to establish common facilities that would enhance quality and guarantee the cluster's sustained growth [18].

These government schemes and efforts support Indian exporters by offering and encouraging benefits to the manufacturer.

For instance, almost INR 6,940 crores have been approved through the Production-Linked Incentive to promote domestic manufacturing.

These programs aim to produce global champions from India in the future who can use cutting-edge technology to expand their size, and scope and participate in global value chains.

Schemes like PLI decrease its reliance on China for large-scale drug imports.

Threats

The recalls of drugs or medicine exported to other countries are higher due to various reasons like cGMP, and labelling for example, in the year 2023, 5 US-approved Indian pharmaceutical companies manufactured drugs were recalled due to reasons like cGMP deviation, Improper Labelling, Lack of sterility, Inadequate quality (Microbial and Chemical contamination, presence of particulate matter). Our country's rules and regulations regarding pharmaceuticals are not so stringent. Thus, by strengthening it, the number of recalls on medicine can be reduced, or else if this continues the Indian Pharmaceutical Export will be decreased and leads to production loss [19, 20].

Table 4: Drug Recalls

List of USFDA Recalls medications Manufactured in India in 2023 (20)	
INDIAN MANUFACTURER	QUANTITY RECALL
Sun Pharmaceutical Industries Ltd	24194
Dr Reddy's Laboratories Ltd	17,548 (1000-count bottles)
Astral SteriTech Private Ltd	12,934,605 vials

SWOT analysis for an Indian Pharmaceutical firm

STRENGTH • Government initiatives • Regulatory • Good Quality • Affordable price • USFDA- Approved site	**WEAKNESS** • cGMP deviation • Improper Labelling • Lack of sterility • Inadequate quality
OPPORTUNITY • Schees (decrease imports) • Incentive global requirement	**THREATS** • Increased global stakeholder • Competition

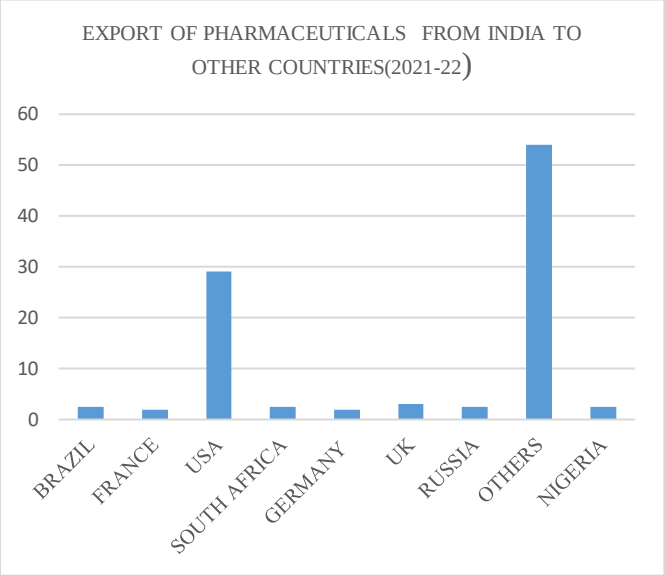
CONCLUSION

The Indian pharmaceutical industry's two main USPs are High quality and Affordability. India has also been referred to as "Pharmacy of the World".

The majority of firms with USFDA compliance outside of the country are located in India. Over 8 of the 20 global generic manufacturing firms are situated in India, and the majority of the country's exports more than 55% depart to highly regulated countries. India is the largest vaccine exporter. Approximately 65-70% of the vaccinations required by the World Health Organisation (WHO) are produced and obtained in India.

India is a significant player in the global vaccination and pharmaceutical sectors. It is the biggest global supplier of Generic medications. The country supplies 20% of the global supply volume and makes up over 60% of the world's vaccination supply. In terms of value, India is the fourteenth-largest nation in the world and the third in terms of volume.

Figure 4: Country Wise Export of Pharmaceuticals (2021-22) [6, 22].



This study also used statistical tools to analyze Quantitative measures of the Export of Pharmaceuticals from India to the Regulated Pharmaceutical market of other countries. But India is still an Observational country to the Pharmaceutical market. Indian Pharmaceutical markets are well-established in Generic medicine. From this study, it can be concluded that the Regulatory Pharmaceutical Market is significant for pharmaceutical industries and growth in India for Controlling and Monitoring the quality of Medicine. It is anticipated that in the future, regulated markets will be the primary export destinations for Indian Pharmaceutical products. The markets in America and Europe have a great need for Indian Bulk Drugs and formulations.

The expansion of India's bulk medication exports is anticipated to be driven by the country's pharmaceutical sector's primary advantages, which include low manufacturing costs and a large number of authorized manufacturing facilities. To utilize the advantages effectively and to enhance the efficiency of the industry, the investment in quality equipment and in creating an efficient maintenance program has to be increased.

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