



KNAV
PARTNERS BEYOND BOUNDARIES

2023

Healthcare Industry Report
PHARMACEUTICALS

Table of Contents

Overview	1
Market Overview	4
Growth Drivers	9
Challenges in the Pharmaceutical Industry	13
Key Trends	16
Cost & Revenue Drivers	20
Regulatory Framework	24
Competitive Landscape	27
Funding Landscape – Total Deals	29
India’s Comparison vis-à-vis Other Countries	32
Outlook	37



Foreword

To our audience,

The COVID-19 pandemic created havoc and the healthcare industry struggled with an unprecedented set of challenges, which forced it to adapt swiftly. One of the most consequential shifts was the increased reliance on digital health technologies. This shift paved the way for innovations in remote monitoring and diagnostics. Moreover, the pandemic accelerated the development of vaccines and treatments, demonstrating the industry's capacity for rapid response & emphasis on research in times of crisis.

Thus, the pandemic brought upon multiple challenges at various fronts in the Healthcare Industry. In the face of these challenges, the industry witnessed a dynamic shift in terms of processes, methods, innovations and technological advances across the sectors. The pandemic was a consequential turning point for the industry.

In addition to the pandemic, India's healthcare industry is witnessing multiple challenges imposed by changing demographics. With a growing elderly population, there has been a rising demand for specialized healthcare services and long-term care facilities. This demographic shift has also signalled the need for greater investment to address age-related health issues effectively. Furthermore, rising awareness about health and hygiene, coupled with a surge in lifestyle-related diseases like diabetes has pushed the industry to focus on preventive and wellness-oriented approaches.

To address these challenges, the industry has been prompt in responding to the demographic transition

with respect to the ageing population, increased awareness and precautionary attitude on health and hygiene and rising prevalence of lifestyle diseases.

India's economic growth has further fueled investment in healthcare. The expanding middle class has a greater ability to access and afford healthcare services. The pharmaceutical industry, in particular, has benefited from increased research and development investments, leading to a steady stream of new drug discoveries. This has made India an important player in the global pharmaceutical market. Globally, the healthcare industry has witnessed a transformation driven by technology and research. Artificial intelligence & data analytics are being leveraged to improve patient care, drug discovery, & disease prediction. Additionally, innovations like gene editing & precision medicine hold the promise of personalized healthcare, where treatments are tailored to an individual's unique genetic makeup.

Together, these factors make for a compelling case on renewed focus on the Healthcare Industry. The primary objective of this report is to highlight the investment value, trends, key developments, and future outlook taking shape in the Healthcare Industry and with this report, in the Pharmaceutical Industry in particular. The report delves into the fundamentals of the workings of Pharmaceutical Companies and the Industry at large to comprehend the investment avenues and opportunities available in the sector.

Vaibhav Manek

Vaibhav Manek
Partner - KNAV Advisory Services



Overview



During a global pandemic, the pharmaceutical sector has been at the forefront and pivotal in the fight against the lethal COVID-19 virus, with extraordinary collaboration and invention resulting in the discovery of life-saving vaccinations in record time. The pharmaceutical business is at the vanguard of pioneering new therapies and technology that alter patient care, from groundbreaking discoveries in gene therapy to advancements in personalized medicine. The industry has witnessed robust growth in India due to scientific advances, increased consumer healthcare spending and investment, technological developments, the surge in global healthcare demands, increased R&D expense for drug discoveries, and many others. The introduction of newer treatments, growth of biosimilars, rising demand for specialty and precision medicines, and improved access and affordability to healthcare have been the key factors driving the growth in the industry. Post COVID-19 pandemic, the industry has adopted a dynamic approach and is advancing towards digitization.

The sector is one of the most stringently regulated sectors, with the government enforcing rigorous quality standards to ensure public health safety. It is governed by various laws, rules, guidelines, etc. These laws relate to drug licensing, patenting, testing, safety, and marketing.

Pharmaceutical companies, Innovate, develop, manufacture, and promote drugs and medicines for patients. These drugs and medicines cure them, vaccinate them, or alleviate their symptoms.



Key Stakeholders in the Pharmaceutical Industry:

API Development and Manufacturing Companies:

These companies conduct research and development to create new API molecules, and optimize existing ones.

Generic Pharmaceutical Companies:

These companies are responsible for producing and marketing generic versions of brand-name medications once their patents have expired. They use the same active ingredients as the original drug, but they may use different inactive ingredients, and their products may have different shapes, colors, and packaging. They conduct extensive testing and clinical trials to ensure their products are bioequivalent to the original drug and have the same safety and efficacy profiles.

Specialty Pharmaceutical Companies:

These companies focus on developing and producing medications designed to treat complex, chronic, or rare diseases. These medications may require specialized formulations, delivery systems, or manufacturing processes that differ from those used for traditional medications.

Contract Manufacturing Companies:

These companies are third-party companies that manufacture pharmaceutical products for other companies. They provide their clients various services, including research and development, formulation, manufacturing, packaging, and distribution.

Distributors:

These companies are the intermediaries between pharmaceutical manufacturers and healthcare providers, such as hospitals, pharmacies, and clinics. They buy large quantities of pharmaceutical products directly from the manufacturers and distribute them to various healthcare providers across regions or countries..

Patients:

Patients are the end consumers of pharmaceutical offerings. They desire safe, effective, and affordable drugs to improve their symptoms.



Key Stakeholders in the Pharmaceutical Industry:

Regulators:


The Central Drugs Standard Control Organisation (CDSCO) falls under the Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India. It acts as the National Regulatory Authority (NRA) of India. It regulates all the medical drugs operating in the market.

Payers:

Payers, such as insurance companies and government healthcare programs negotiate drug prices with pharmaceutical companies, and they decide which drugs to cover and how much they will pay for them.

Healthcare Providers:

Healthcare providers include doctors, nurses, and pharmacists. They prescribe and administer drugs to patients. In addition to these services, they also provide requisite feedback on the safety and efficacy of drugs.



Key Questions Business Leaders Must Ask Themselves:

How have we positioned ourselves in the industry? Which stakeholders are we catering to?



Market Overview

Market Overview

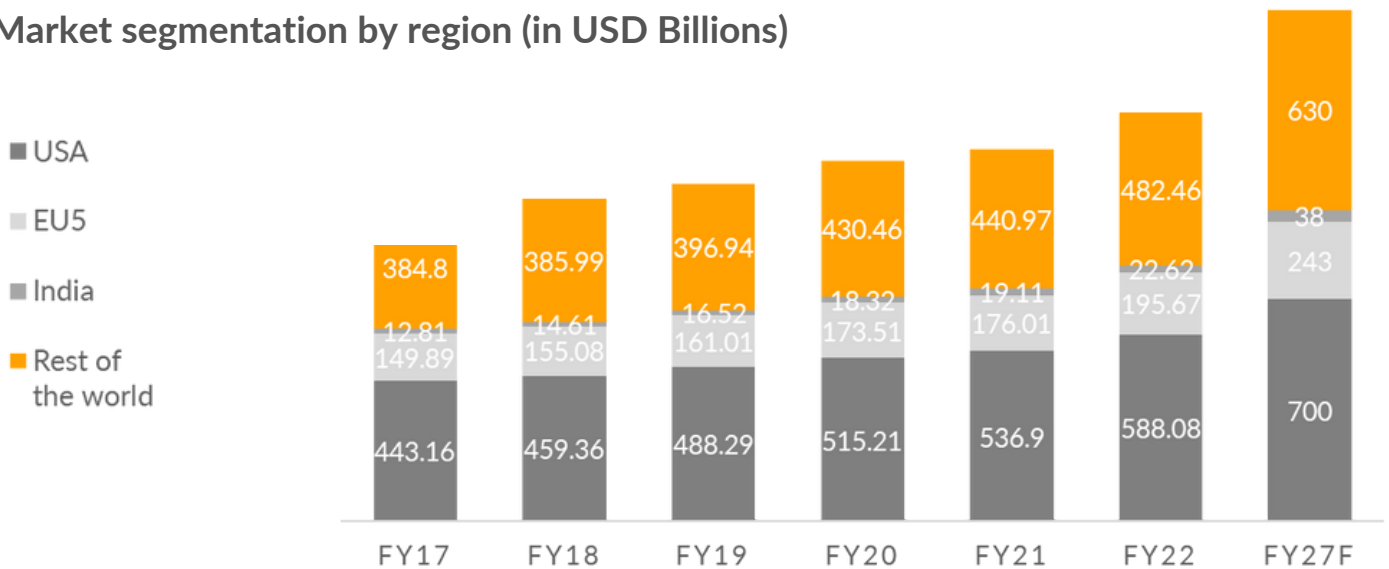


Global Market Size (in USD Billions)

Regions	2021	2017-2021 CAGR	2026	2022-2026 CAGR
Developed Markets	1,049	4.9%	1,230-1,260	2-5%
Pharmerging Markets*	353	7.8%	460-490	5-8%
Other Markets	19	0.1%	21-25	3-6%
Global Pharmaceutical Market	1,421	5.1%	1,730-1,760	3-6%

Source: [Sun Pharma FY22 Annual Report](#)

Market segmentation by region (in USD Billions)



Source: [IQVIA Mankind Pharma Report](#)

***Pharmerging markets** refer to countries that are rapidly developing their pharmaceutical industries and becoming new players in the global market. These markets are characterized by a combination of rapid population growth, increasing economic development, and improving access to healthcare services.

Market Overview



Global Pharmaceutical Market – Share by Product Type

Region	Original Brands (%)		Non-original Brands (%)		Unbranded Generics (%)		OTC, Vaccines & Others (%)		Total (USD Bn)	
	2021	2026	2021	2026	2021	2026	2021	2026	2021	2026
Developed Markets	74	75-76	11	11-12	10	7-9	5	4-5	1,049	1,230-1,260
Pharmerging Markets*	30	33-35	35	32-34	13	13	22	19-22	353	460-490
Other Markets	35	33-36	48	43-52	6	5-8	11	5-20	19	21-25
Global Markets	63	63-64	17	17-18	11	9-10	9	8-9	1,421	1,730-1,760

Source: [Sun Pharma FY22 Annual Report](#)

Global Pharmaceutical Market – Market Share by Region

Region	FY17	FY18	FY19	FY20	FY21	FY22	FY27F	CAGR	CAGR
								FY17-22	FY22-27F
USA	44.73%	45.26%	45.95%	45.29%	45.77%	45.63%	44-45%	5.82%	3.5-4%
EU5	15.13%	15.28%	15.15%	15.25%	15.01%	15.18%	14-15%	5.47%	4-5%
India	1.29%	1.44%	1.55%	1.61%	1.63%	1.75%	2-3%	12.05%	10-11%
RoW	38.84%	38.03%	37.35%	37.84%	37.59%	37.43%	38-39%	4.63%	5-6%

Source: [Sun Pharma FY22 Annual Report](#)



Market Overview

The USA formed 45.63% of the global pharmaceuticals market in FY22. It is expected to remain the key contributor to growth in the major developed markets and is expected to grow at a CAGR of 3-4% over FY 2022-2027.

China currently forms 9.50% of the global pharmaceuticals market. It is amongst the largest of the 15 pharmerging markets and is expected to grow at a CAGR of 3-4% over FY 2022-2027.

EU5 formed 15.18% of the global pharmaceuticals market in FY22. Within EU5, the UK is expected to be the fastest growing economy at a CAGR of 5-6% over FY 2022-2027, followed by Germany, Italy, and Spain at 4-5% CAGR over the same period.

Two pharmerging markets, vis-à-vis Brazil and India, comprise 3.66% of the global pharmaceuticals market. Both Brazil and Indian markets are forecasted to grow at 10-11% CAGR over FY 2022- 2027, which is one of the fastest growth rates among the pharmerging markets.

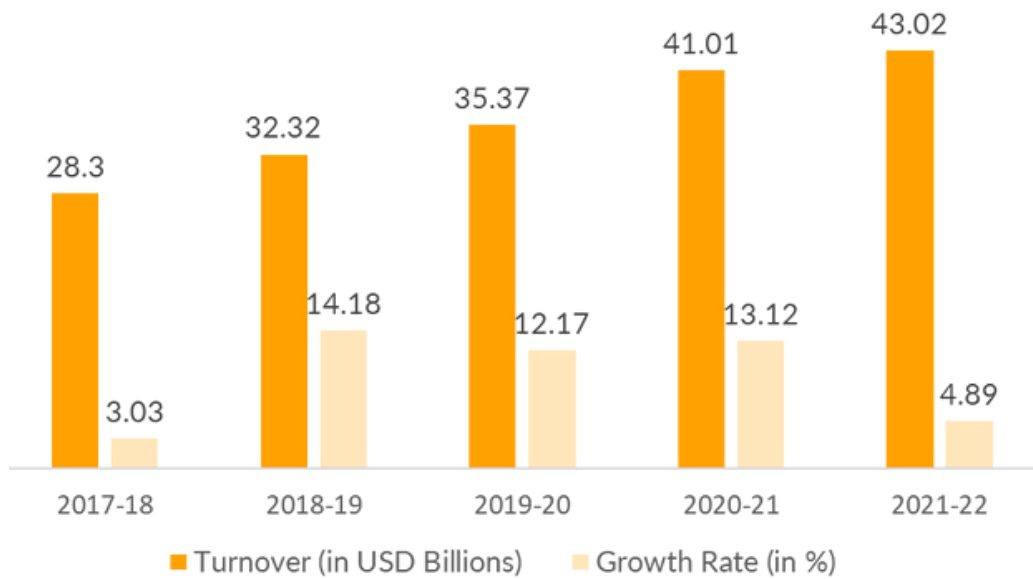
Indian Market - Market Size

- According to an article published by [Economic Times](#), India's domestic pharmaceutical market was estimated at USD 41 Bn in 2021 and is likely to grow to USD 65 Bn by 2024 and USD 130 Bn by 2030.
- Indian pharmaceutical sector supplies over 50% of global demand for various vaccines, 40% of generic demand in the US, and 25% of all the medicines in the UK. The domestic pharmaceutical industry comprises a network of 3,000 drug companies and ~10,500 manufacturing units. Ranked as the 12th largest exporter of medical goods in the world, Indian drugs are exported to more than 190 countries around the globe, with the US being the key market. Generic drugs account for 20% of the global export volume, making the country the largest provider of generic medicines globally. Indian drug & pharmaceutical exports stood at USD 24.60 Bn in FY22 and USD 24.44 Bn in FY21. (Source: [IBEF](#)).

Market Overview

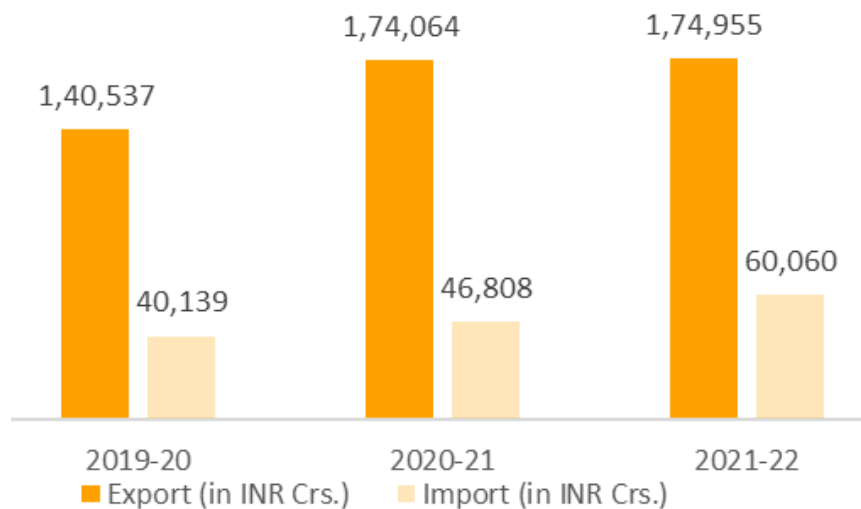


Pharma Sector's Growth at Current Prices



Source: [Department of Pharmaceuticals Annual Report 2022-23](#)

Import-Export of Pharmaceuticals



Source: [Department of Pharmaceuticals Annual Report 2022-23](#)



Growth Drivers



Growth Drivers

The global and domestic pharmaceutical market has witnessed tremendous growth over the past decade, and this momentum has only accelerated after the COVID-19 pandemic. Identifying, and leveraging growth drivers is essential for industry players to sustain long-term growth and competitiveness. Following are some of the key growth drivers that we envision impacting the pharmaceutical industry:

Rising Income Levels:

Economic growth and the consequential increase in per capita income remain key drivers of growth in the industry. Emerging markets worldwide are poised to witness exponential growth due to increases in income levels and living standards. In recent years, relative spending in emerging countries has increased significantly. This will translate into increased expenditure on healthcare at large.

Demographics and Ageing Population:

Demand for pharmaceutical products will expand across developed markets and developing countries due to the aging population. Advancements in healthcare have led to longer life expectancy rates. As a result, every country is witnessing a sizeable increase in the population of the older people. This rise in the elderly population has led to increased requirements for medicines and pharmaceutical products.

Lifestyle Diseases:

While healthier lifestyle choices have started to gain significance in some developed economies, sub-standard food habits shall continue to result in higher incidences of chronic diseases globally, especially in developing economies. The chronic segment within the Indian Pharmaceutical Market (IPM) has grown at a relatively faster rate of 12.29% CAGR compared to the overall IPM (10.93%) over FY 2018-22. This is expected to drive growth for drugs and medicines for cardiovascular, anti-diabetic, and other similar diseases. (Source: IVQIA Mankind Pharma Report)

OTC Growth:

Over-the-counter medications will continue to propel a surge in sales. This is directly linked to the aging population requiring more OTC medications and changing consumer behaviors opting for self-medication for common diseases instead of visiting a doctor.

Off-Patent Drugs:

The demand for generics or off-patent drugs will increase due to low costs. The COVID-19 pandemic further consolidated this trend. Many countries across the globe have started using more generic drugs, in the long run, to cut down the cost of healthcare. Therefore, increased demand and low prices will encourage the production of off-patent drugs.



Growth Drivers

Healthcare & Technology

Convergence:

Technology is increasingly becoming a part of healthcare. Apps that help users take charge of their health have plunged into the market. Digital innovations are increasing consumer awareness and revolutionizing the pharmaceutical market. Technology is expected to accelerate the drug discovery process by incorporating AI and improve the efficiency of the manufacturing process by incorporating 3D printing. This will help companies save costs as well as incentivize production.

Government Schemes:

The government of India has announced production-linked incentives (PLI) to incentivize the domestic manufacturing capacity and solve supply chain problems. These PLI schemes aim to promote the domestic production of 50 essential APIs. Domestic manufacturing of key APIs will reduce India's import dependence. This will eliminate supply chain problems, shift the bargaining power vis-à-vis China and optimize costs. This shall enhance production capabilities and further boost India's export sales.

Growth in Genomics:

Genomic medicine is an upcoming specialty that uses genomic data about individuals as part of their treatment. India is in a unique position to steer ahead in the genomics field.

One advantage India has is the diversity in the population. It is not just a single population but a population of several races. The calibrated rise of this discipline will accelerate the demand for novel treatments.

Product Development:

Scientific progress in genomics, biomarkers, and diagnostics, coupled with the advancement in digital interventions, will likely play an important role in new product development. Over the next five years, new product introductions will include the latest generation products in gene and cell therapy, and RNA-based therapies, apart from other segments. Product innovation will reduce hospital stays and expenditures and increase product demand.

Research & Development:

Innovation continues to be a key growth driver for the global pharmaceutical market, especially in developed countries. New medicines are being continuously innovated, approved, and marketed, thereby aiding industry growth. A combination of scientific and digital initiatives is expected to drive pharmaceutical innovation in the future. Much research and development (R&D) is devoted to developing new products and targeted therapies using cutting-edge technologies.



Growth Drivers

Rise of Preventive Healthcare:

Numerous factors like unhealthy eating habits, fast-paced lifestyles, and the prevalence of chronic diseases have brought a paradigm shift from illness to wellness among the public. Pharmacists play a vital role in providing safe patient care. They recommend medicines to patients and adjust prescription dosages. Therefore, increased awareness and a tilt towards a health-conscious attitude will increase demand for preventive healthcare products.

Oncology & Immunology:

The development of newer segments will create newer revenue streams for the industry. Oncology and Immunology will continue to witness higher volume growth and significant investments in new product development. However, patent expiry norms for some products, including biologics, will partly offset overall value growth in these two segments.

Higher Government Healthcare Spending:

The government of India is spending on healthcare witnessed steady growth for 14 years since 2004-05. During this period, out-of-pocket healthcare expenditure declined, whereas government health expenditure rose during the intervening period. Government spending and investment in the healthcare segment will incentivize enterprises to invest in R&D and expand production due to the benefits of quality infrastructure.

Growth in Ayurvedic Medicine:

Increasing demand for authentic Ayurvedic medicine range, consumer awareness, & growing attention to wellness are driving the growth of the Ayurvedic pharmaceutical industry.

Rising Insurance Coverage:

As per IRDAI, over 500 million people (approximately 38% of the Indian population) were covered under some health insurance policy as of 2020. Post the COVID-19 pandemic, there has been increased acceptance of health insurance, leading to a further increase in penetration. - The rise in insurance coverage will create a shift away from low-cost generics and diversify the demand and manufacturing portfolio.

Growth in Outsourcing:

Contract manufacturers have gone from obscure sources to indispensable allies. They are now ubiquitous across the pharmaceutical industry. The rise of outsourcing can be attributed to many advantages, including reduced manpower availability, infrastructure, and administration costs, rapid turnaround time, & enhanced flexibility. Outsourcing has moved beyond manufacturing & has expanded to cover marketing as well. Outsourcing beyond manufacturing will allow pharmaceutical companies to invest heavily in product development and benefit from cost reduction. Improved drug quality and low costs will result in increased demand for drugs.



Challenges in the Pharmaceutical Industry

Challenges in the Pharmaceutical Industry

4

Despite the positive accelerated growth expected in the pharmaceutical industry in the coming years, various restraining factors and challenges need to be addressed for the industry to grow faster and sustainably. Some of the major challenges inhibiting the growth of the industry are as follows:

IP Regulations:

In the pharmaceutical industry, IP laws protect innovations in medicine formulation, drug discovery, manufacturing processes, drug molecules, and others done by a company. Over the years, it has become challenging for Indian generic manufacturers to produce and sell copies of patented drugs. This has led to a surge in prices of some essential medicines, making them inaccessible to a vast set of population in India as well as other emerging countries. Moreover, the policy of compulsory licensing followed by the Indian government allows it to grant permission to some other companies without the authority/approval of the patent holder. This policy has created tensions with some multinational companies (MNCs), as evidenced in the court case of Natco Pharma vs Bayer.

Price controls:

The Indian government occasionally puts a cap on the prices of some drugs and controls it, which makes it difficult for pharmaceutical companies to generate profits and invest in R&D. Low R&D leads to sub-optimal output, inhibiting some pharmaceutical companies' growth.

Compliance issues and good manufacturing practices:

USA is a large consumer market for pharmaceutical products, & India is one of the major exporters to the USA. Companies must take United States Food and Drug Administration (USFDA) approval before marketing and selling pharmaceutical drugs. Some Indian companies lack strong quality control and good manufacturing practices, which leads to rejecting their application to the US FDA. Complying with the various laws, regulations, policies, and conditions is important before applying for US FDA approval.

Dependency on API Imports:

India imports close to 80% of the APIs from China. Dependency on API's from a single country is a major roadblock to the industry's growth in case of supply chain disruptions, political unrest, and price appreciation. The country must reduce its import dependency, especially from a single country. Domestic API production and internal facilities and infrastructure improvement will help mitigate dependency on imports from many countries. (Source: Drug Patent Watch)

Lack of innovation capabilities:

India has a strong workforce and talent pool. However, the country needs more innovation due to low government spending on Research and Development. Addressing this gap will unlock much potential for pharmaceutical companies to invent new drugs.

Challenges in the Pharmaceutical Industry

4

Quality issues:

India has undergone one of the highest FDA inspections since 2009 due to quality issues. Ensuring the quality of pharmaceutical products is important for maintaining consumer confidence and regulatory compliance. Inadequate testing and poor manufacturing practices lead to erosion of quality. This challenge must be addressed on a priority basis for the industry to grow by leaps and bounds.

Higher Government Healthcare

Spending:

The government of India is spending on healthcare witnessed steady growth for 14 years since 2004-05. During this period, out-of-pocket healthcare expenditure declined, whereas government health expenditure rose during the intervening period. Government spending and investment in the healthcare segment will incentivize enterprises to invest in R&D and expand production due to the benefits of quality infrastructure.

Infrastructure and logistics:

India's pharmaceutical industry relies heavily on adequate infrastructure and logistics to easily move raw materials and equipment. Poor infrastructure might lead to supply chain disruptions & delays. The distribution of drugs will also become difficult in case of poor logistics support.

Counterfeit drugs:

During the COVID-19 pandemic, incidents of substandard and falsified (SF) medical products increased by almost 47% from 2020 to 2021. This is a major problem as it poses a risk to public health and damages the industry's credibility. The government needs to implement stringent regulations to stop the supply of counterfeit drugs.

Talent retention:

India is home to many well-renowned scientists and researchers. However, many are being lured away by higher salaries and better career opportunities in other countries. This is leading to a shortage of skilled talent in the country, making it difficult for pharmaceutical companies to attract and retain top talent.

Geopolitical Tensions:

India's pharmaceutical industry heavily depends on exports. Geopolitical tensions or trade disputes might significantly impact on the industry's bottom line. It is important to maintain good political relations with all countries.

Key Questions Business Leaders Must Ask Themselves:

How have we positioned ourselves in the industry? Which stakeholders are we catering to?



Key Trends



Key Trends

Growth of Biosimilars:

Biosimilars refer to biological products roughly similar to approved reference biological products. A reference biological product is a biological product that a regulatory authority has notified as a safe and effective treatment for a particular disease or illness. Biosimilars possess the same efficacy, safety, and quality as the reference product. Moreover, they treat the same symptoms as the reference product. However, biosimilars are different from the reference product. The point of difference lies in their production methods, as they are produced using a separate cell line or manufacturing process. The biosimilar Indian market is expected to grow over 30% in 2047. Therefore, it has enormous potential to develop and commercialize biosimilars. Biosimilars, being copies of reference biological products, require much less research and development. Thus, the growth of biosimilars is expected to provide benefits of cost-effectiveness. (Source: Business Today)

Mega Bulk Drug Parks:

The Government is actively trying to reduce the country's dependence on imports and boost domestic manufacturing. To make the country self-sufficient in APIs and drug intermediates, the Department of Pharmaceuticals is implementing various schemes.

One of the most important schemes introduced recently is the Scheme for Bulk Drug Parks. The Bulk Drug Parks will provide shared infrastructure facilities in one place, create a thriving ecosystem for Bulk Drug manufacturing in the country and reduce the manufacturing cost significantly. This scheme will aid the industry in meeting environmental compliances at a reduced cost through innovative common waste management system procedures. Participants will be able to exploit the benefits from optimizing resources and economies of scale. This initiative represents industry-wide steps being taken to reduce the cost of manufacturing and continue India's lead as a low-cost manufacturer globally.

Integration with Technology:

Pharmaceutical companies are increasingly aiming to improve operations and production processes in the manufacturing process. Companies have started combining robotics, immersive technologies, IoT, and more. While mixed reality solutions improve staff training and management, robots automate labor-intensive tasks and reduce cycle time. Blockchain technology will allow us to take measures against counterfeit and poor-quality drugs that threaten public health.



Key Trends

Quantum Computing in R&D:

Quantum computers can drastically reduce the time and expenditure of drug discovery. By analyzing swathes of data, they can swiftly identify possible drug candidates and accurately simulate the effects of potential drugs on biological systems. This will open doors for greater pharmaceutical advancements and treatments for multiple diseases. Quantum computing shall significantly enhance the pharmaceutical industry's drug discovery process. This methodology represents one of the many initiatives being taken to speed up the research and development.

High-throughput Screening:

It is a popular technique incorporated in the early stages of drug discovery. It rapidly tests many compounds for potential biological activity against a specific target. The ability to rapidly evaluate biological agents across large datasets without compromising accuracy or efficiency will save time and finances in the long term. The incorporation of HTS technology will result in improved efficacy and reduced side effects. This technique is one of the many novel methods adopted to minimize the duration of the product innovation process.

3D Printing:

One of the trends emerging from the industry is the hunt for innovations in drug design. 3D printing is an advanced technology that produces personalized medicines on demand. It is particularly useful for patients who require precise treatments. However, regulatory approval for 3D-printed drugs is still in its nascent stage, and further research is necessary to ensure the safety and efficacy of these drugs. The potential benefits of 3D printing pharmaceuticals are significant and could revolutionize the industry in the forthcoming years.

Precision Medicines:

Precision medicine is a medical model that proposes the treatment of patients based on their genetic makeup. Diagnostic tests are required to find the patient's genetic contents. Precision medicines reduce hospital stay expenditure, and by reducing the overall financial, physical, and psychological costs of the try and test approach of medicine, it proves to be cost-effective for patients. In India, Precision Medicine is in its nascent stage. It is practiced most notably in specialties like oncology, cardiology, psychiatry, and diabetology.



Key Trends

E-prescriptions:

E-prescription is a digital prescription generated by healthcare practitioners. These electronic prescriptions are created digitally, transmitted to a pharmacy, and stored in the patient's device as an EHR (Electronic Health Record) technology. They are substituting paper prescriptions. These prescriptions are legible in understanding the treatment and dosage, thus making them error-free. They help not only to save time but also eliminate the forgery of prescriptions. The rise of e-prescriptions indicates the gradual penetration of digitization in the pharmaceutical sector.

Strategic Alliances and M&As:

M&As in the healthcare segment are on an exponential rise. The Indian Pharmaceutical Industry reported 16 deals in 2022 – the largest, perhaps in a decade, worth nearly a billion dollars in value. Deal activity has seen significant headwinds, with Indian companies becoming aggressive on overseas acquisitions. Several leading Indian pharmaceutical players like Biocon, Mankind, Lupin, Zydus Lifesciences, Torrent, Marksans Pharma, and Gland Pharma acquired brands to consolidate their position in 2022.- These collaborations and partnerships represent a burgeoning trend in the industry to leverage the advantages of varied strengths of industry players. (Source: Financial Express, Times of India)

Key Questions Business Leaders Must Ask Themselves:

How do we leverage upcoming technologies like AI and Blockchain in manufacturing processes?

What are the newer categories we can tap into based on the current trends?



Cost & Revenue Drivers

Revenue Drivers

Sale of Drugs:

The major revenue stream for pharmaceutical companies is the sale of drugs in the mass market. Generic drugs, different bulk drugs, specialty drugs, drug formulations, etc., play an important role in generating revenue for pharma companies.

Royalties and Licensing Fees:

Royalties and licensing fees are another significant source of revenue for pharma companies. Companies generate revenue by licensing the use of their patents to other enterprises. The licensee pays licensing fees to the pharmaceutical company. This fee may be paid as a lump-sum or as a percentage of sales generated using the patented technology. Royalties are payments made to the patent holder when the licensee sells products manufactured using the patented technology.

Strategic Alliances:

Pharmaceutical companies make a small chunk of their revenues through different strategic alliances under which products of third parties are co-promoted by them.

Consumer Healthcare:

Consumer healthcare includes over-the-counter medications, vitamins, supplements, and personal care products that are usually purchased without a prescription.

these products can be developed and brought to market quickly at a lower cost. They are also generally cheaper than prescription medications. Therefore, rapid manufacturing and high affordability can translate into larger sales volumes and increased revenues.

Patents:

An important earning source for pharmaceutical companies is the patent that incentivizes companies to indulge in research and development of innovative drugs. The patent refers to a chemical formula that rivals pharmaceutical companies may not copy. The patent system allows patent holders to profit from patents by restricting any other competitor to the market and selling a similar drug.

Contract Manufacturing:

Contract manufacturers in the pharmaceutical industry earn revenues by manufacturing drugs. The fees cover the cost of raw materials, labor, fixed costs, and profit margin. In some cases, the contract manufacturer charges tooling fees. Tooling fees entail the cost of designing and producing the molds, jigs, and fixtures needed to produce the product.

Clinical Research Services:

Pharma companies usually have dedicated teams that cater contract trials and research services to other companies or organizations. These services include clinical trial management, site selection, data management, and statistical analysis. Pharma companies provide consulting services to other companies or organizations. These services cover regulatory consulting, clinical trial design, protocol development, and statistical consulting.

Cost Drivers

Research & Development Costs:

Pharmaceutical companies spend heavily on R&D activities. R&D costs can be bifurcated into direct and indirect costs. Direct costs cover lab equipment expenditures, research salaries clinical trial expenses, and fees for regulatory agencies. Indirect expenditures are incurred for administrative overhead, facilities costs, and legal charges.

Sales & Distribution Costs:

Sales and distribution entail expenses incurred in selling and distributing pharmaceutical products to customers, such as wholesalers, retailers, hospitals, and pharmacies. Various expenses under this headcover include salaries and commissions of sales personnel, advertising and promotional expenses, freight and transportation costs, and warehousing expenses. Advertising and promotional expenses generally include print and television ads, conference participation fees, and free samples distributed to doctors. In addition to these, companies also incur costs related to packaging and labeling of the products.

Manufacturing Cost:

Manufacturing represents a major segment of the costs of pharmaceutical companies. It includes expenses involved in the manufacturing process of drugs, such as the cost of raw materials, quality control, and quality assurance.

Capital Cost:

Capital expenditure refers to the amount spent by a company on the acquisition, upgrade, or maintenance of fixed assets. In the pharmaceutical industry, capital expenditure is an important component of costs as companies invest heavily in research and development and manufacturing facilities to develop and produce new drugs. Pharmaceutical companies also incur other capital expenditures, such as investments in information technology, acquisitions, and joint ventures.

Intellectual Property Costs:

Intellectual property (IP) costs represent a major component of costs in the research and development (R&D) phase. IP refers to the legal rights granted to an inventor for their original work, such as patents, trademarks, and copyrights. In the pharma industry, these rights are essential to protect the investment of time, money, and resources required to develop a new drug.

Clinical Development Costs:

The cost of conducting clinical trials depends on the size and complexity of the trial, the number of sites involved, and the duration of the trial. Apart from the cost of the trials, companies must also bear the cost of recruiting and compensating study participants, and the cost of regulatory compliance and oversight.

Legal and Regulatory Costs:

Legal costs arise from different sources such as patent litigation, contract disputes, and employment lawsuits. Regulatory costs cover expenses to obtain and maintain regulatory approvals for drugs. Major items under this head include the costs of conducting clinical trials, preparing regulatory filings, and responding to inquiries from regulatory authorities. These costs are substantial for new drugs that require extensive clinical testing and regulatory review. Litigation costs include expenses related to legal fees, expert witnesses, and settlements or judgments.

Cost & Revenue Drivers

A comparison

Revenue Drivers	Cost Drivers
Sale of Drugs	Research & Development Costs
Royalties and Licensing Fees	Sales & Distribution Costs
Consumer Healthcare	Manufacturing Cost
Strategic Alliances	Capital Cost
Patents	Intellectual Property Costs
Contract Manufacturing	Clinical Development Costs
Clinical Research Services	Legal and Regulatory Costs



Regulatory Framework



Regulatory Framework

7

Regulatory Bodies

- It exercises regulatory control over the quality of drugs, cosmetics, and notified medical devices in the country.
- The Drugs Controller General of India acts as the director of the department at the Government of CDSCO, which approves drug licenses.

Central Drugs Standard Control Organization (CDSCO)

- CDSCO functions as the National Drug Authority of the Government of India. It acts as India's Central Drug Regulator.
- Under the Drugs and Cosmetics Act, CDSCO is responsible for the approval of Drugs, Conduct of Clinical Trials, banning of drugs and cosmetics, laying down the standards for Drugs, testing of new drugs, granting of test licenses, license approving of Blood Banks, LVPs, Vaccines, and r-DNA products, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

National Pharmaceutical Pricing Authority (NPPA)

- NPPA is an institution of the Government of India. The purpose for its establishment was to ascertain/revise the prices of controlled bulk drugs and formulations and implement prices and availability of the medicines under the Drugs (Prices Control) Order 1995. Apart from these functions, it also oversees the prices of decontrolled drugs to maintain the same at reasonable levels.
- NPPA records and maintains data regarding the production, exports and imports, market share and profitability of companies, etc., for bulk drugs and formulations.



Regulatory Framework

7

Legal Framework

Drug Price Control Order, 1995:

- The government issues the drug price control order (DPCO) under the Essential Commodities Act, which allows it to fix the prices of some essential bulk drugs and their formulations. DCPO also prescribes the margins for retailers.
- Essential drugs where there is significant competition, and there is no monopoly pricing are kept out of control.

Drug and Cosmetics Act, 1940

- This Act lays down the guidelines for distributing, manufacturing, importing, and selling cosmetics and drugs.
- The act clearly defines what constitutes a “drug” and a “cosmetic.”
- The act lays down the quality standard specifications for imports.
- It prohibits the manufacture, sale, or distribution of drugs or medicines, the consumption of which is likely to involve any risk to lives. It also prohibits the manufacture, sale or distribution of drugs or medicines with no therapeutic value or drugs or cosmetics of a non-standard quality or misbranded, adulterated, or spurious type. It lists specific criteria under which the drug manufacture, sale, or distribution shall be prohibited.
- The act also provides a distinct regulatory mechanism for the manufacturing or selling of Ayurvedic, Siddha, and Unani drugs.



Competitive Landscape

Competitive Landscape

8

Particulars	Dr. Reddy's Laboratories	Sun Pharma	Cipla	Aurobindo Pharma	Lupin
Total Income (in INR Mn)	2,20,296	3,95,760	2,20,442	2,37,758	1,65,471
Gross Profit Margin	65.50%	73.20%	61.00%	56.80%	60%
EBITDA Margin	19.30%	28.60%	21.93%	19.80%	14.20%
PAT Margin	9.91%	8.56%	11.55%	11.13%	-1.60%
API Portfolio	170+	~370	200+	200+	N.A. in public domain
API Sales as a % of Total Sales	~14.3%	5%	3%	15%	6%
API Manufacturing Units	8	14	3 (R&D Centres)	11	6
Patents	1,071 filed	1,400	1246 - DMF	2,000+ filed & 500 in place	~1008
Number of manufacturing facilities	22	43	47	26	15
Formulation/Drug focus	API, Biosimilars, Generics, Branded Generics, OTC	Branded Generics, Generics, APIs, OTC, Specialty Drugs	Trade Generics, Branded Generics, APIs	APIs, Antiretroviral (ARV) drugs	Generics, Biosimilar, APIs, OTC drugs, Specialty
R&D Expense as a % of revenue	8.2%	5.8%	5.16%	6.7%	8.55%
Market Share (Based on Formulation Sales as on 12 months ended September 2022)	2.9%	8.6%	4.8%	N.A. in public domain	3.6%
Geography Presence	66	100+	80+	150+	100+

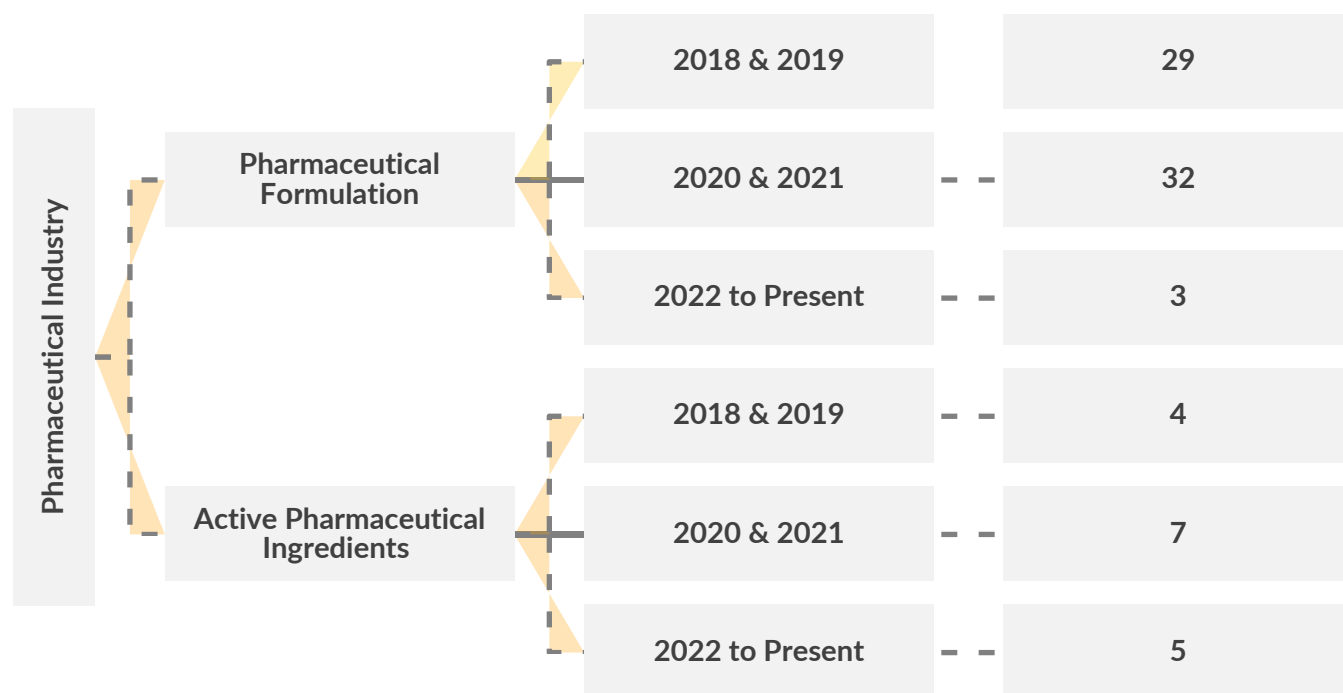
Source: Company Annual Reports, Company Quarterly Presentations, Company Investors Call Transcripts and Company Websites



Funding Landscape – Total Deals

Funding Landscape – Total Deals

The funding landscape in the pharmaceutical space has seen a steady rise over the years. It observed significant growth in the number of PE / VC investments during the two pandemic heavy years.



Major Deals (2018 & 2019)

Particulars	Rubikon Research	Integrace Health	Akums	Caplin Point	Tirupati Medicare
Type	Pharmaceutical Formulation	Pharmaceutical Formulation	Pharmaceutical Formulation	Pharmaceutical Formulation	Pharmaceutical Formulation
Deal Size (in INR Crores)	~850	~460	~320	~222	~180
Investor	General Atlantic	True North	Quadria Capital	F-Prime Capital Partners	Affirma Capital
Transaction Type	Funding	Funding	Funding	Funding	Funding
Company Stage	Late Stage	Growth Stage	Late Stage	Early Stage	Late Stage

Funding Landscape – Total Deals

Major Deals (2020 & 2021)

Particulars	Piramal Pharma	Viyash Lifesciences	Biocon Biologics	Acme Generics	Stelis Biopharma
Type	Pharmaceutical Formulation	Active Pharmaceutical Ingredients	Pharmaceutical Formulation	Pharmaceutical Formulation	Pharmaceutical Formulation
Deal Size (in INR Crores)	~3,633	~1,412	~1,125	~1,124	~850
Investor	Carlyle Group	Carlyle Group	Goldman Sachs Private Equity	Pacific Alliance Group	TPG Capital India
Transaction Type	Funding	Funding	Funding	Funding	Funding
Company Stage	Late Stage	Late Stage	Late Stage	Late Stage	Late Stage

Major Deals (2022 - Present)

Particulars	Biocon (2 Deals – Feb & April)	BDR Pharmaceuticals	Malladi	EMIL	Enaltec
Type	Active Pharmaceutical Ingredients	Pharmaceutical Formulation	Active Pharmaceutical Ingredients	Pharmaceutical Formulation	Active Pharmaceutical Ingredients
Deal Size (in INR Crores)	~1,570	~497	~250	~150	~55
Investor	Kotak Special Situations Fund & Edelweiss Private Equity	Multiples Private Equity	InvAscent	Somerset Indus Capital Partners	La Renon Healthcare Private Equity
Transaction Type	Funding	Funding	Funding	Funding	Funding
Company Stage	Late Stage	Late Stage	Late Stage	Late Stage	Early Stage

10

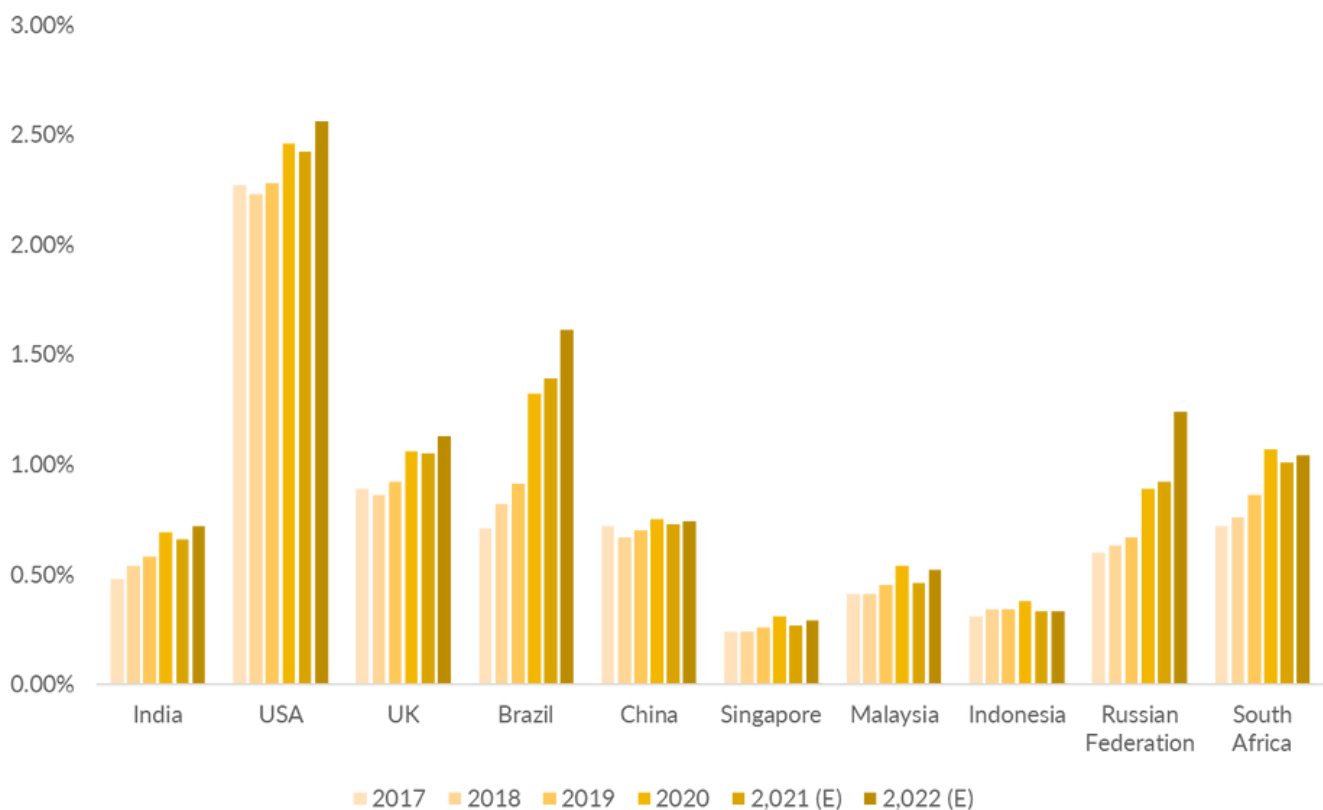


India's Comparison vis-à-vis Other Countries

India's Comparison vis-à-vis Other Countries

10

Pharmaceuticals spend as a percentage of GDP



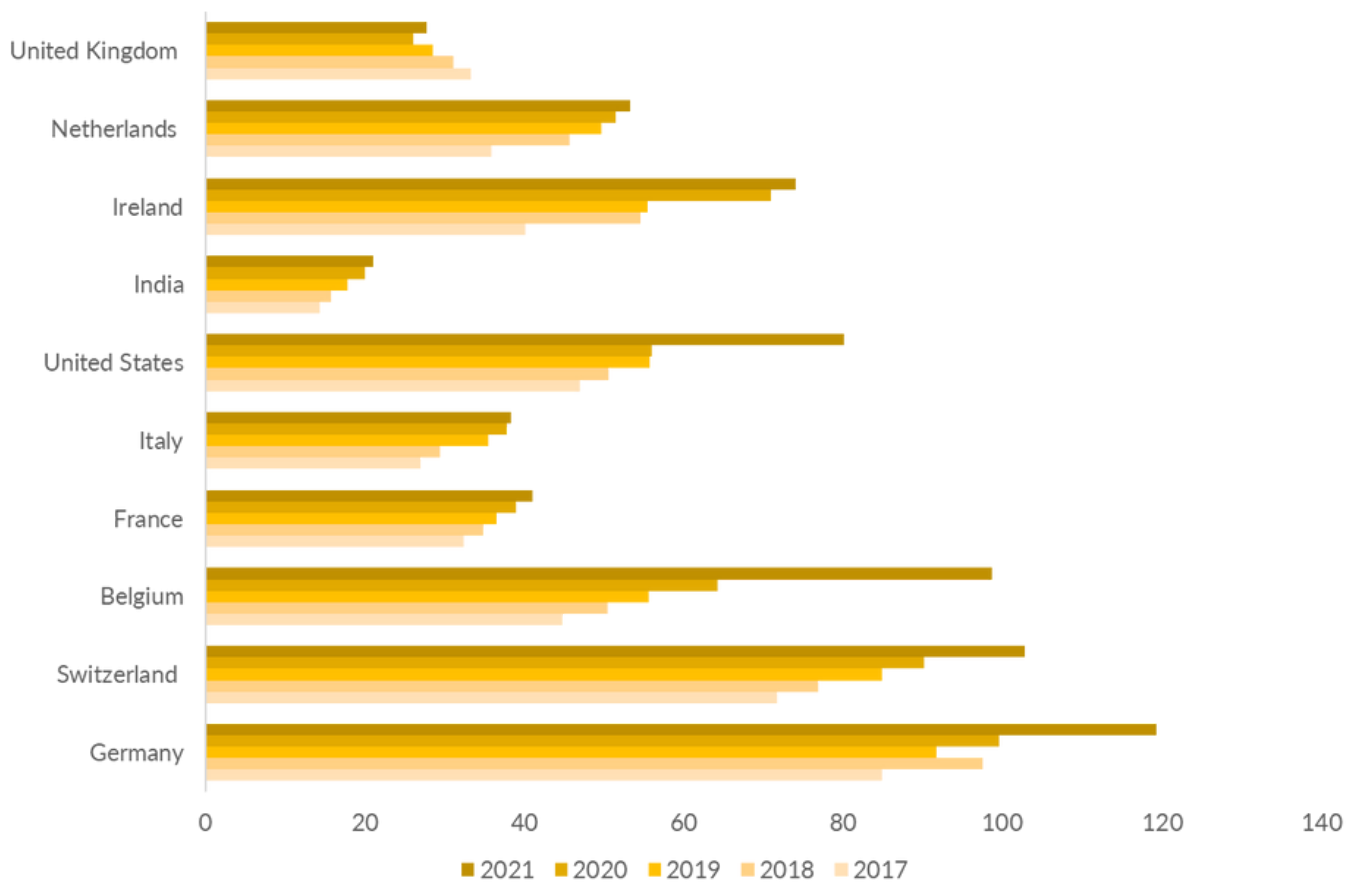
Analysis:

India's pharmaceutical spend as a percentage of GDP is one of the lowest amongst all the major countries, ahead only of Indonesia, Singapore and Malaysia. However, the pharmaceutical spend has steadily risen over the past decade. This showcases the Government of India's commitment to retain India's position as the "Pharmacy of the World".

India's Comparison vis-à-vis Other Countries

10

Largest Countries by Pharmaceutical Exports (Value) (in USD Billions)



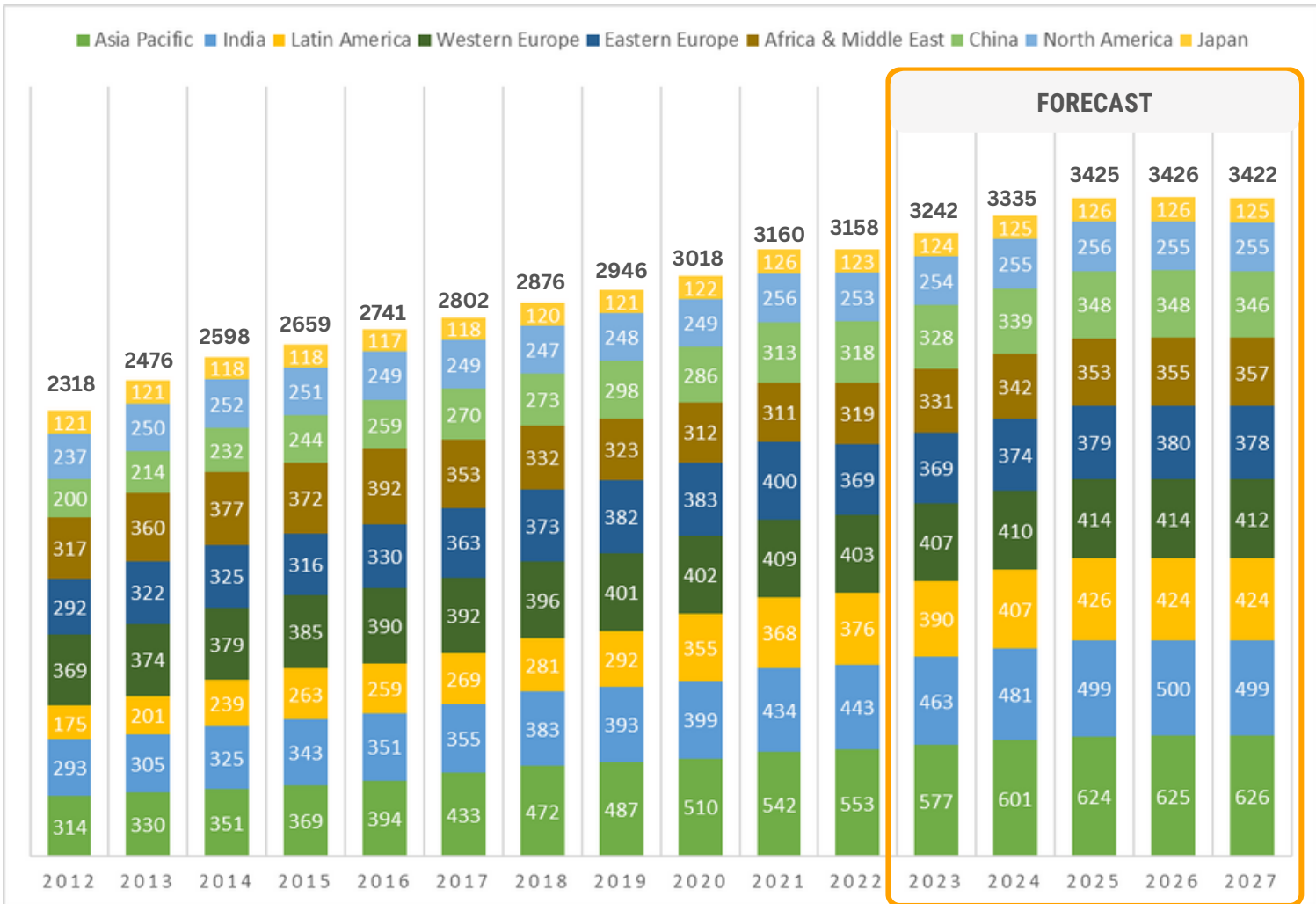
Source: [World Trade Organization](#)

In terms of value, India is one of the top ten countries in Global Pharmaceutical Export rankings. Germany occupies the top rank followed by neighbouring countries, Switzerland and Belgium. India's share in the Global Export market has increased over the years. Europe consolidates a major share in the global exports with 7 countries in the list.

India's Comparison vis-à-vis Other Countries

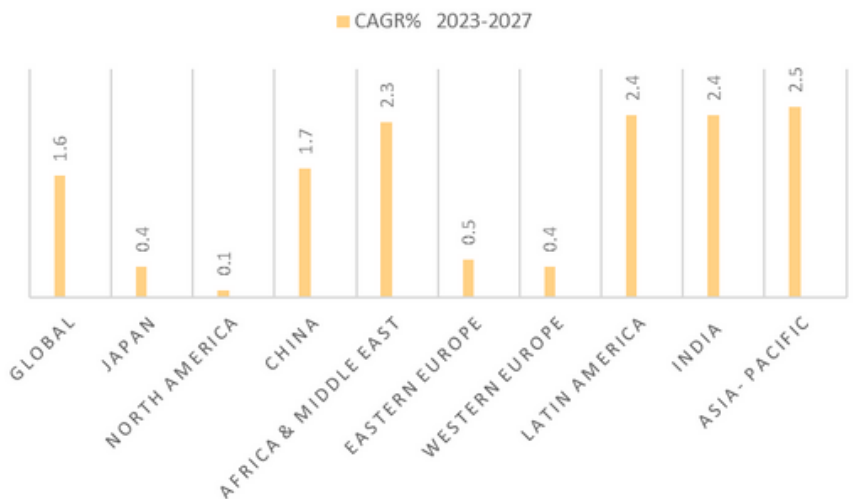
10

Global Use of Medicines (Defined Daily Doses) (in Billions)



CAGR Forecast 2023-2027

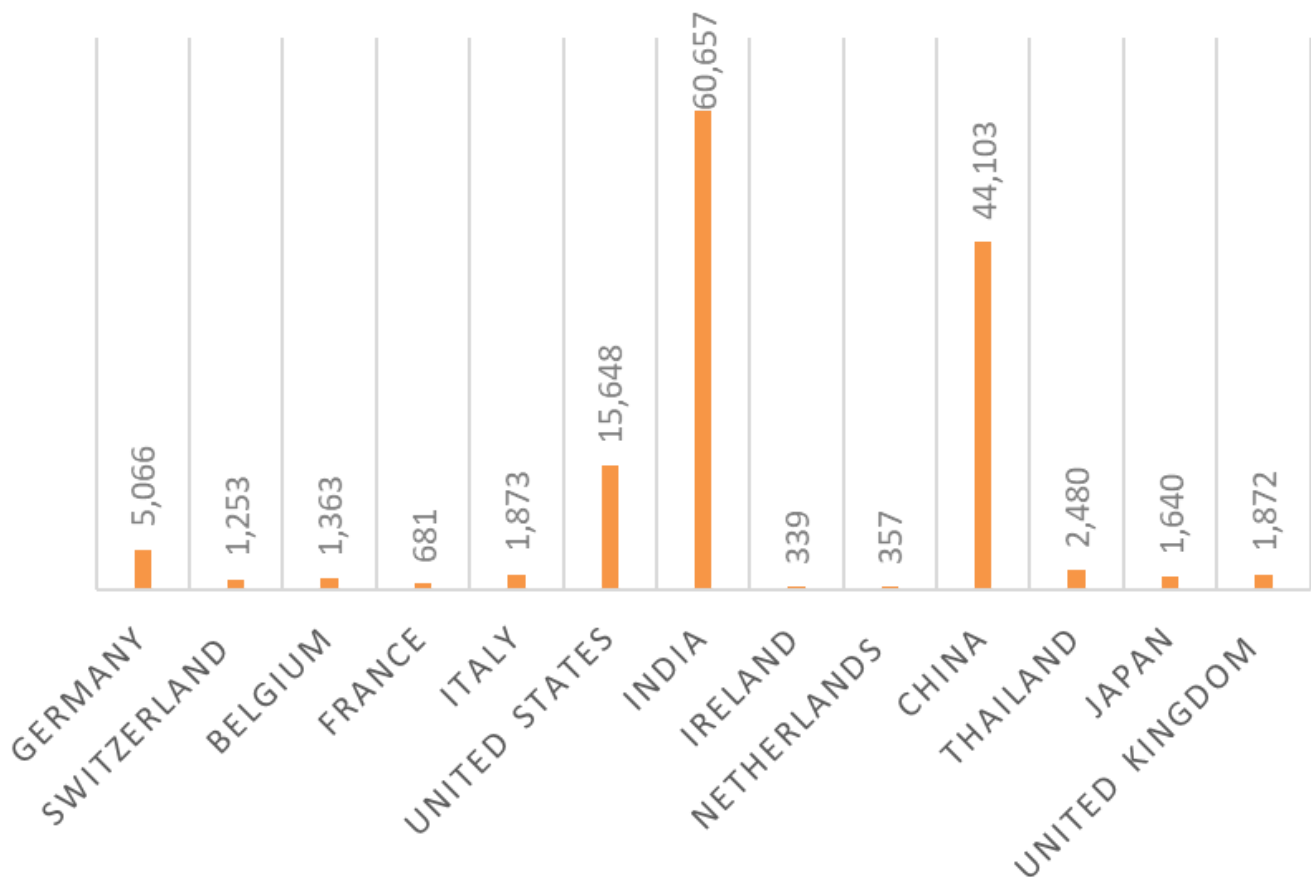
Source: IVQIA Global Use of Medicines 2023 Report



India's Comparison vis-à-vis Other Countries

10

Defined Daily Dose is a statistical measure of drug consumption, laid down by the World Health Organization Collaborating Centre for Drug Statistics Methodology. This statistic indicates the assumed average maintenance dose per day for a drug when it is used for main indication in adults.



Source: [Dun & Bradstreet](#)

India, with a 60,000+ companies is leading the list. This translates into high volume manufacturing. On this front, China and the United States are positioned next to India.



Outlook

1

The Indian Pharmaceutical Industry will continue to face issues relating to infrastructure and logistics, IP regulations, talent shortage, innovations, and others. However, the COVID-19 pandemic has accelerated growth in this industry, and with technological breakthroughs and several other opportunities, the pharmaceutical industry is poised to grow. As the world progresses, the industry will play an increasingly important role in promoting wellness and enhancing the quality of life for people and communities.

2

The Indian Pharmaceutical Industry will continue to face issues relating to infrastructure and logistics, IP regulations, talent shortage, innovations, and others. However, the COVID-19 pandemic has accelerated growth in this industry, and with technological breakthroughs and several other opportunities, the pharmaceutical industry is poised to grow. As the world progresses, the industry will play an increasingly important role in promoting wellness and enhancing the quality of life for people and communities.

3

The Indian Pharmaceutical Industry will continue to face issues relating to infrastructure and logistics, IP regulations, talent shortage, innovations, and others. However, the COVID-19 pandemic has accelerated growth in this industry, and with technological breakthroughs and several other opportunities, the pharmaceutical industry is poised to grow. As the world progresses, the industry will play an increasingly important role in promoting wellness and enhancing the quality of life for people and communities.

KNAV has charted a course to be one of the world's leading accounting and consulting firms over the last two decades. We provide an expansive suite of public accounting services which includes accounting, assurance, taxation, international transfer pricing, global risk consulting, and business advisory services. With over 400+ professionals in 6 countries, our team combines local insights with global expertise to design powerful strategies and help our clients stay ahead of the curve. Our commitment to customer service, integrity, and innovation makes us the best choice for businesses of all sizes.

US | India | Singapore | UK | Netherlands | Canada

USA

Atlanta

One Lakeside Commons, Suite 850, 990 Hammond Drive
NE, Atlanta, GA 30328

New York

1177 6th Ave 5th Floor, New York, NY 10036, USA

Houston

6430 Richmond Ave., Suite 120, Houston, TX 77057-5908

India

Mumbai

7th floor, Godrej BKC, Bandra Kurla Complex, Mumbai
400051

Bangalore

306, 3rd Floor, Embassy Square, 148, Infantry Road,
Bangalore 560001

Canada

55 York Street, Suite 401, Toronto, ON M5J 1R7, Canada

Singapore

70 Shenton Way, #13-03 Eon Shenton, Singapore 079118

UK

Ground floor, Hygeia Building, 66-68 College Road, Harrow,
Middlesex HA1 1BE

Netherlands

Fokkerstraat 12, 3833 LD Leusden, The Netherlands

Disclosure

KNAV & CO LLP is a member firm of KNAV International Limited, a network of legally independent accounting and consulting firms providing services in six countries, and of Allinial Global, an association of legally independent accounting and consulting firms. References to 'KNAV' mean one or more members of KNAV International Limited and /or any of their affiliated businesses as the context requires. KNAV & CO LLP is authorized and regulated by the Institute of Chartered Accountants of India. KNAV Advisory Pvt. Ltd is a member firm of KNAV International Limited, a network of legally independent accounting and consulting firms providing services in six countries, and of Allinial Global, an association of legally independent accounting and consulting firms. References to 'KNAV' mean one or more members of KNAV International Limited and /or any of their affiliated businesses as the context requires.

KNAV Advisory Pvt. Ltd. is authorized and regulated by the ICAI Registered Valuers Organization a company formed by the Institute of Chartered Accountants of India.

KNAV Tax LLP is a member firm of KNAV International Limited, a network of legally independent accounting and consulting firms providing services in six countries, and of Allinial Global, an association of legally independent accounting and consulting firms. References to 'KNAV' mean one or more members of KNAV International Limited and /or any of their affiliated businesses as the context requires. KNAV Tax LLP provides tax services and is not an ICAI registered firm.

Inde Global Consulting LLP is a member firm of KNAV International Limited, a network of legally independent accounting and consulting firms providing services in six countries, and of Allinial Global, an association of legally independent accounting and consulting firms. References to 'KNAV' mean one or more members of KNAV International Limited and /or any of their affiliated businesses as the context requires. KNAV Tax LLP provides business consulting services and is not registered with and regulated by the Institute of Chartered Accountants of India.