Georgia Tech Panama
Logistics Innovation & Research Center

Regional Hub for
Pharmaceuticals

The Global Pharmaceutical Supply Chain: Key Elements and Insights

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Georgia Tech Panama Logistics Innovation and Research Center

December, 2024

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I. Introduction

The pharmaceutical industry's supply chain plays a fundamental role in the development, production, and distribution of medicines. Numerous studies have demonstrated the close relationship between health and the economic development of countries. Better public health leads to a healthy life expectancy, which is then reflected in higher labor quality and productivity. Therefore, investment in health is vital, making this area of great interest to numerous public and private organizations involved in the commercialization of pharmaceuticals. Currently, challenges such as the shortening of patent lifetimes, generic competition, and public health policies, among other factors, have changed the operating context of the pharmaceutical industry [1].

Throughout the first decade of the 21st century, significant changes were observed in the world pharmaceutical market. In 2000, the United States accounted for a large share of global pharmaceutical sales, followed by Japan, and Europe represented by France, Germany, Italy, Spain and the United Kingdom. The steady growth of the pharmaceutical market over the past few decades has driven regions such as Asia, Oceania, Africa and Latin America. Estimates indicate that countries in Latin America, Asia-Pacific, Africa and the Middle East will grow their market by 10%, while pharmaceutical consumer spending will increase by more than 30% by 2027 [2].

The prolongation of life, therapeutic innovations, medicalization of normal physiological processes and the emergence of new diseases, intensified by population growth have contributed to the growth of the pharmaceutical market. By 2023, the total value of the pharmaceutical market was estimated at $1.6 trillion, an increase of $100 billion compared to 2022 [3].

The COVID-19 pandemic made evident the need to invest in supply chain improvement. This was reflected in a 2021 survey of supply chain executives which found that the top three business priorities of global pharmaceutical leaders with respect to supply chain management for

the following five years would include distribution and channel strategy innovation (57%), improving quality and traceability across the network (56%), and better customer portfolio management (52%) [3].

II. Definition and key components of the pharmaceutical supply chain

The pharmaceutical industry faces complex uncertainties in its supply chain, due to its globalized environment, and operational, scientific and regulatory aspects that require coordination of all parties involved in the supply chain. In large multinational pharmaceutical companies, mastering all links in the chain is a crucial factor in ensuring that patients receive safe and effective medicines.

A.Sourcing of raw materials

To understand how pharmaceutical products are composed, first it is important to define what a drug is and what pharmaceuticals are. A drug is a chemical, of natural or artificial origin, that induces a positive or negative response in a living organism and a drug is the combination of one or more drugs with other pharmacologically inactive substances (excipients) to facilitate production, including in this definition its dosage form, packaging and delivery system [4].

Pharmaceutical drug development is a complex process that involves discovering, designing, and developing new therapeutic agents to treat a wide range of diseases and conditions. Drugs are generally classified into two major categories: small molecules and large molecules (biologics). [5][6]

Small molecule drugs	They are molecules that are synthesized by chemical reactions between different organic and inorganic compounds, which make them stable and easier to manufacture.
Large molecule drugs (biologics)	These are molecules obtained from living cells such as bacteria, complex cells, and even proteins from the human body are used and are often more difficult to develop and manufacture.

A drug may contain chemicals, but it may also include raw materials of natural origin as well as synthetic materials. In the pharmaceutical industry, a pharmaceutical product or drug is composed of two main ingredients, the Active Pharmaceutical Ingredients (API) and the excipients, then there are the formulas that are designed according to the route of administration that will be used.

Active Pharmaceutical Ingredients (API)

The World Health Organization defines active pharmaceutical ingredients as any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical form, and which, when used in this way, is transformed into an active ingredient of that pharmacy form. Such substances are intended to provide pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of a disease or to affect the structure and function of the body [7].

APIs are subject to rigorous regulatory scrutiny to ensure their quality, safety and effectiveness. They are divided into two large groups: chemical and biological [8].

- Chemical APIs can be obtained by chemical synthesis or semisyn thesis processes.
- Biologic API can be produced by fermentation, extraction or by biotechnological processes.

Since not all companies can manufacture APIs due to the cost of establishing and maintaining API manufacturing facilities, along with the costs associated with raw materials and compliance, they can be significant barriers, especially for small and medium-sized enterprises [9].

Companies market active pharmaceutical ingredients (API) in the open market or use them to manufacture final formulations [10]. The APIs that are marketed can be innovative or original, and generic.

- Innovative APIs are generally developed by large, multinational firms that patent and register new molecules.
- Generics (called biosimilars when dealing with macromolecules) are produced from the imitation of original molecules. This may occur when there is no patent in force in the country where the generic or biosimilar is to be produced.

China and India are leaders in the production of APIs. Industry estimates indicate that eight out of ten APIs used by laboratories to manufacture some generic medicines in the U.S. and Europe are imported into those regions, thus lengthening the supply chain for these critical components [11].

APIs have significant commercial value as they form the core of pharmaceutical products. The global API market amounted to $204 billion in 2022 and is expected to exceed $363 billion by 2032 [12].

Excipients

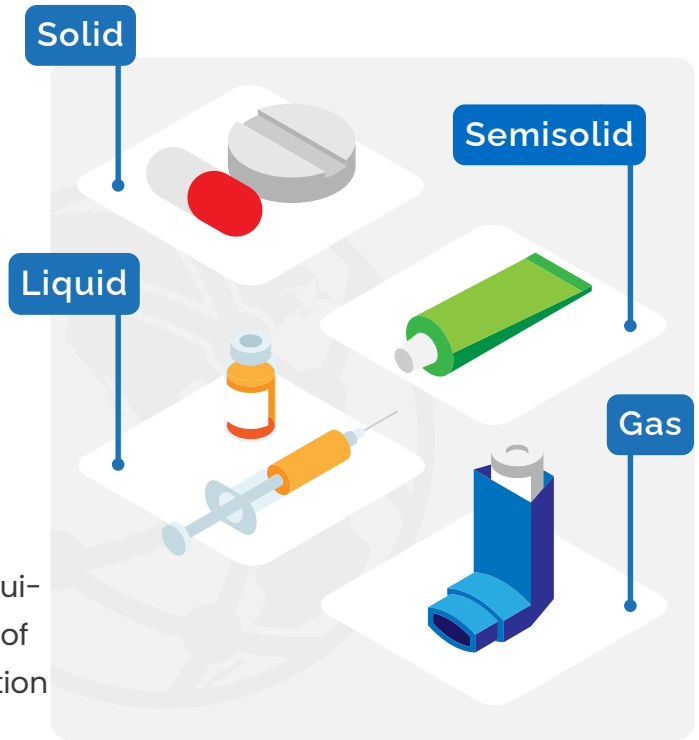
Also often referred to as formulation auxiliaries, carriers or inactive ingredients, they are natural or synthetic chemical compounds that lack pharmacological properties, added to the drug to facilitate its administration, improve its stability and preservation, or simply to give it shape or flavor. They may include inert substances such as starch, lactose or cellulose, as well as other additives such as dyes, preservati-

ves or sweeteners. Generally, the formulation auxiliaries that are used in liquid medicines are called vehicles, while those used in solid medications are called excipients [13].

The global market for pharmaceutical excipients was valued at $8.4 billion in 2023 and is expected to exceed $14.7 billion in 2033, recording a compound annual rate of 5.8% from 2024 to 2033 [14]. The increase in new therapies due to the proliferation of the number of pharmaceutical industries around the world has boosted the global market for medicinal excipients. Developing economies have been of particular focus for the growth of the excipient manufacturing footprint, given the availability of low-cost labor, and the growing demand for quality excipients at lower cost.

Pharmaceutical Forms

The way a medicine is presented is generally known as pharmaceutical form. The term actually encompasses pharmaceutical dose forms, combined pharmaceutical dose forms, and combined terms (which combine a dose form and an item of packaging that is integral to the use of the product). In general, a pharmaceutical dose form (or dosage form) is the physical manifestation of a product that contains the active and/or inactive ingredients that are intended to be delivered to the patient.

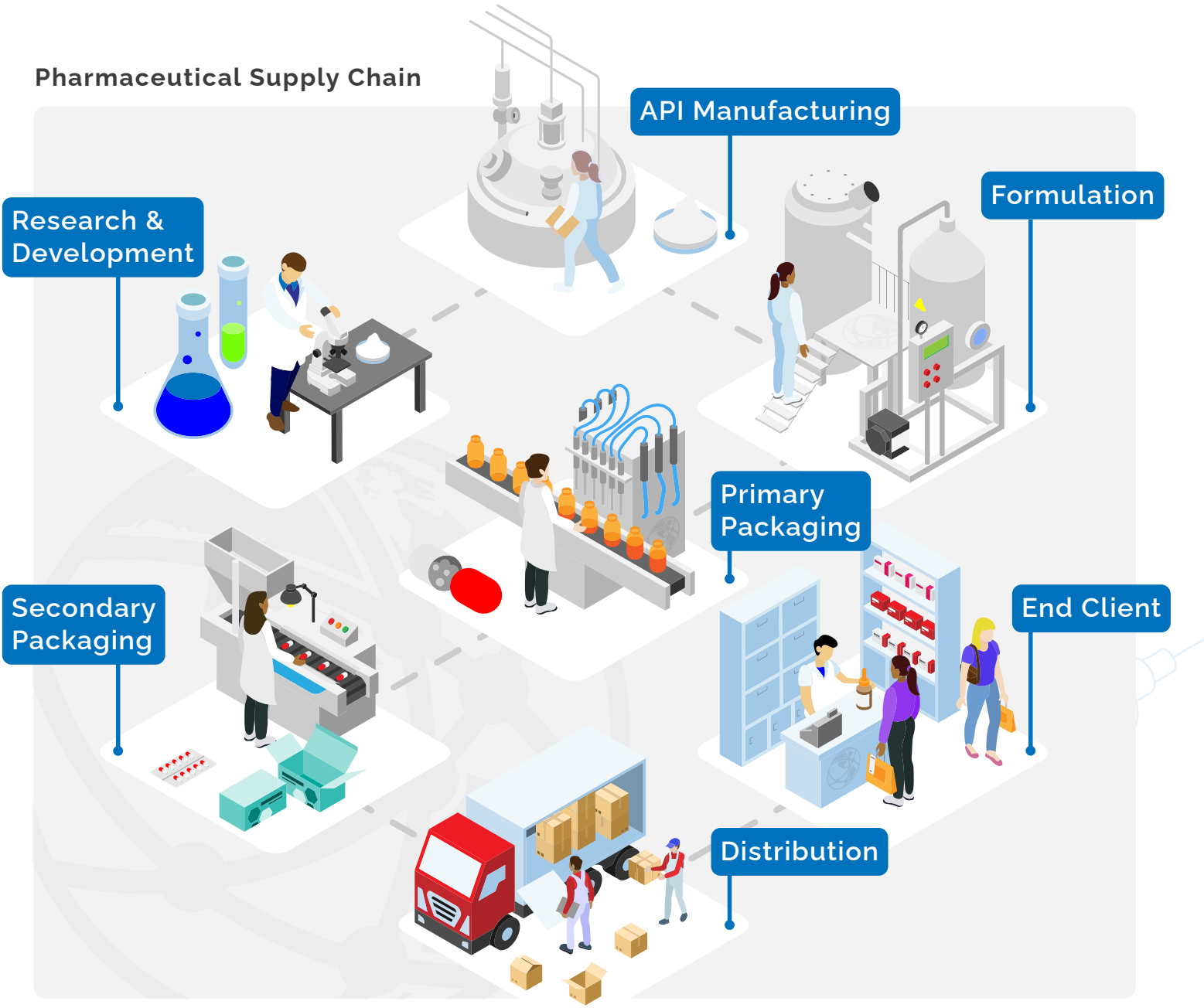


B. Pharmaceutical manufacturing processes

Prior to manufacturing, a joint R&D process is required, and is a crucial part of gaining the approval of competent regulatory authorities for the distribution

of a new drug. Drug discovery and development is a lengthy process, generally spanning up to fifteen years. Though careful planning can improve the chances of success and reduce costs, the cost of manufacturing a drug –regardless of the type of molecule— is often high.

Pharmaceutical Supply Chain



The manufacturing process of the pharmaceutical industry involves three general steps, namely API manufacturing, formulation, and packaging.

1. Creating Active Pharmaceutical Ingredients (API) from raw materials is the initial stage. Because a drug's efficacy is primarily dependent on the quality and potency of its API, APIs are created using extremely complex and technically demanding techniques [16]. This process involves the large-scale conversion of chemical feedstocks, solvents, reagents, catalysts and other materials through multi-step chemical synthesis with a variety of processing technologies. APIs are manufactured through various forms of fermentation and bioprocessing: [8][17][18]

Chemical synthesis.

The chemical synthesis process can occur in two main ways:

Complete chemical synthesis.

Simple molecules or precursors are separated and the molecule of interest is then obtained by performing several steps of synthesis or chemical reactions.

Chemical synthesis from complex intermediates.

Intermediate compounds, also known as fine chemicals, are chemical raw materials required for drug synthesis. Although they do not possess the final pharmacological properties of the APIs, they serve as a precursor to eventually produce the final therapeutic compound.

Semisynthesis.

Semisynthetic APIs are manufactured from precursors extracted from natural sources or obtained by fermentation. This process consists of isolating the molecule of interest and partially modifying it by chemical processes [19]. These semisynthesis processes have helped obtain improved products in terms of their behavior and activity, for example, the isolation of opium for obtaining codeine, an analgesic.

- **Extractive and Fermentative.**

  This type of API is obtained by various techniques of extraction, recovery and purification or by fermentation and cleansing, from biomass of natural origin such as bacteria, yeast, mold, and viruses where the molecule of interest already exists in the desired form. That is, the API that wants to be produced already exists naturally but needs to be extracted and purified from its natural source. It is a method that is widely used in the pharmaceutical industry to produce pharmaceuticals such as antibiotics, vaccines and other medicines.

- **Recombinant DNA.**

  In this case, APIs are obtained from the use of recombinant DNA technology, consisting of a set of processes that allow isolating a gene to be manipulated, achieving an organism or virus to produce a new protein that is usable for treatment development This process allows the mass production of safe, pure, and more effective versions of biochemical substances that the human body produces naturally; however, unlike those obtained by chemical synthesis, biotechnological drugs are characterized by their high molecular weight and greater structural complexity, which is very sensitive to changes in the manufacturing process.

2. The second step is formulation. Manufacturing the product in the correct form and dosage for administration to a patient involves mixing API with all necessary inactive product ingredients (i.e., excipients). It also covers additional steps, such as tablet formation or sterile filling.

3. The final step is drug packaging. This process prepares the pharmaceutical product for distribution, as well as the physical container in which it is stored.

- **Primary packaging**. The process of primary packaging refers to the insertion of the finished product into materials that are in direct contact with the finished pharmaceutical product. These may include tablet blisters, ampoules, vials or prefilled syringes, among others.

- **Secondary packaging**. This involves the placing of the primary package into the required outer packaging that contains the required printed data and branding, as well as the package insert.

C. Stakeholders

Essential participants in a production process are also sometimes referred to as "stakeholders". Each of them play a key role where coordination is necessary to fulfill the responsibilities of ensuring that the end customer receives safe and effective medicines. In the pharmaceutical supply chain, the key players include[22][23]:

- **Raw material suppliers**

  Material suppliers provide the foundation on which drug discovery research can build treatments. Precision is paramount from common chemicals to complex biological components, so a good material supplier ensures proper quality control and adherence to regulations.

- **Drug manufacturers**

  These producers are in charge of supplying distributors with prescription medications. They should foster innovation, streamline production processes for efficiency and cost-effectiveness and follow stringent quality control laws and regulations.

  In pharma, manufacturers fall mainly into two categories:

  - Brand name: These stakeholders take complex ownership of the process, from developing original drugs and conducting clinical trials, to marketing and promotion for their products.
  - Contract manufacturing organizations (CMOs): They specialize in large-scale production for other pharmaceutical companies and can offer great flexibility and expertise in manufacturing a wide range of medications.

From an industrial point of view, the pharmaceutical industry can be divided into three main areas:

Multinationals

Primarily engaged in research and development (R&D) to generate proprietary products for local and regional markets. Examples of these companies include Pfizer, J&J, and AstraZeneca [24].

Generics manufacturers

These manufacturers are dedicated to creating versions of drugs developed by other companies, complying with the same quality standards. According to the FDA (Food and Drug Administration), nine out of ten prescriptions for drugs in the USA are for generic drugs [25]. Examples of this type are the companies Viatris, Teva, and Sandoz.

Small scale manufacturers

These companies are generally small in size and usually manufacture a limited number of products. Their product line is usually based on off-patent drugs. In some countries, these manufacturers adhere to Good Manufacturing Practices (GMP) and are commonly run by local NGOs or large hospital pharmacies in an attempt to reduce import costs while specializing in traditional medicine [26].

Many of these manufacturers are subject to patents, which grant the patent holder the right of exclusivity over the patented invention for a limited period (usually 20 years). This exclusivity allows the patent holder to exclude other manufacturers from using, selling, or offering the patented invention. Patents are limited geographically, temporally, and by the rights of others and help protect the company's investment in drug development [27].

Regulatory agencies

Although not directly engaged in the active and physical elements of the pharmaceutical supply chain, regulatory bodies are essential for maintaining consistent quality and ensuring patient safety. Agencies establish the benchmarks that all other participants in the supply chain must follow. They also set guidelines and regulations for all aspects, including research, development, manufacturing, distribution, and even the marketing of drugs.

Wholesale distributors

Wholesale distributors build the bridge between manufacturers and pharmacies, ensuring that medications are stored and shipped safely and efficiently. Distributors usually make bulk purchases that go on to fulfill a variety of individual pharmacy orders.

Pharmaceutical manufacturers and wholesalers have two approaches to drug marketing [28]:

- Direct sales. They deliver their products to a group of wholesalers who act on consignment and then deliver the medications to pharmacies, charging only for logistics.
- Indirect sales. Wholesalers purchase pharmaceuticals and medicines in large quantities for resale.

There are two main business models that classify pharmaceutical wholesalers [29]:

- Short-line wholesalers. Short-line wholesalers stock a limited range of drugs and concentrate on generics, parallel imports, and popular brand-name drugs. Generally dealing with fast-moving products, this type of wholesaler looks for products that offer cost-effective profitability.
- Full-line wholesalers. They make the full range of drugs available to all pharmacies regardless of size and location. Most of the full-line wholesalers are pharmaceutical owned.

Pharmacy benefit managers

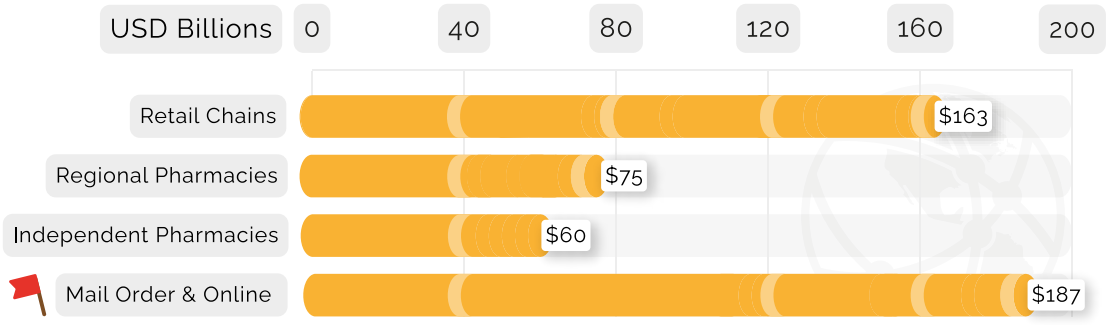
Similarly to regulatory agencies, pharmacy benefit managers (PBMs) operate "behind the scenes." Functioning as mediators between drug manufacturers, insurers, and pharmacies, PBMs work to control costs and ensure access to medication. They collect and analyze data on meds utilization trends and costs for data reporting that can be used to identify potential areas for saving costs.

Pharmacies

The direct meeting point between the pharma supply chain and the consumer, pharmacies can be a combination of patient advocates, medication experts, and guardians of public health. They coordinate refills for multiple medications, ensure storage under the proper conditions, maintain tight inventory manage ment of stock levels that meet patient needs while minimizing waste. Pharmacies can be divided into four types [30]:

- Retail chains.
- Regional pharmacies. They are categorized into two main types: grocery stores, which are supermarkets that have their own pharmacy, and mass retailers, which are large consumer goods retailers that also offer pharmacy servi ces.
- Independent pharmacies. These are retailers that are not directly affiliated with any pharmacy chain and are owned by a variety of pharmacists.
- Mail order and online pharmacies are the fourth type are operate through the Internet and send orders to custo- mers through the mail.

Annual income from prescriptions 2021



D. Distribution and logistics

Distribution and logistics in the pharmaceutical industry encompasses the transportation of drugs along the different stages of the value chain. Given the handling of delicate and perishable products, specialized infrastructure, strict quality controls and trained personnel are required, making air transport a key component. In the past, production took place exclusively in large companies' own facilities. Today, drugs are manufactured by third parties in various regions, which has led to longer and more complex supply chains.

Transportation

Pharmaceutical transport is critical to ensure that drugs and medical supplies are available to patients when and where they are needed. However, transporting pharmaceutical products is not a simple process, and it involves careful consideration of various factors, including temperature control, product handling, and packaging.

One critical factor in pharmaceutical transport is the type of medicines that are being shipped. There are several types of medicines that may be shipped, including [31]:

- **Ambient**. Medicines that can be transported at room temperature, typically between 15°C and 25°C. Examples of ambient medicines include tablets, capsules, and powders.
- **Cryogenic**. Medicines that require extremely cold temperatures to maintain their stability, typically below -150°C. These products may include vaccines, blood products, and tissue samples.
- **Refrigerated**. Medicines that require cooling during transport, typically between 2°C and 8°C. Examples of refrigerated medicines include insulin, some vaccines, and biologic drugs.

Shipping pharmaceutical products requires adherence to a complex set of regulations designed to ensure safe, secure, and efficient transportation. These regulations vary depending on the country, region, and mode of transport [14][32].

Key frameworks include Good Distribution Practices (GDP), the Code of Federal Regulations (CFR), and European Union (EU) Regulations (EU GDP), which cover aspects such as transportation, distribution, storage, packaging, handling and other regulation for pharmaceutical products.

International transportation organizations also play a critical role, such as the International Maritime Dangerous Goods (IMDG) Regulations for sea transport and the International Air Transport Association (IATA) Regulations. IATA's Center of Excellence for Independent Validators in Pharmaceutical Logistics (CEIV Pharma) further supports excellence in handling pharmaceuticals across the air cargo supply chain.

Many other countries have additional regulations that are variations of those mentioned above. Understanding and complying with these regulations is essential to ensure the safe and efficient transport of pharmaceutical products.

Storage [33]

The stability of drugs depends on environmental factors such as temperature, air, light, and humidity, as well as drug-specific factors, including the active ingredient, dosage form (tablet, solution, etc.), and manufacturing process. It is essential to follow the storage instructions provided in this guide or by the manufacturer (as indicated on labels and packaging inserts), especially if the recommendations differ.

Temperature must be controlled in accordance with manufacturer guidelines and regulations. Failure to do so may compromise the drug's shelf life and expiry date. Freezing is particularly harmful to solutions, as it can cause the deterioration or precipitation of active ingredients and even damage ampoules and vials. Products such as vaccines, immunoglobulins, and antisera are especially sensitive to heat and light and require careful handling.

Protecting drugs from humidity is equally important. Containers should remain tightly closed, and they should not be opened long before the drugs are used. Patients should be advised not to remove tablets from blisters until just before administration. Additionally, drugs should be shielded from light, especially solutions. Parenteral forms must be stored in their original packaging. While colored glass may offer some light protection, it is not a guarantee and should not be relied upon solely.

Disposal [34]

The principal consequence of deterioration is a reduction of therapeutic activity, which leads to more or less grave consequences for the individual and/or community. For example, the use of expired antibacterials does not cure an infection and also favours the emergence of resistant strains, and can even cause toxicity.

It is dangerous to throw out expired or unusable drugs or to bury them without precaution.

As a distinct and legally-regulated waste stream, it must be handled and disposed of separately and subsequently incinerated. Prior to disposing of these medicinal items, they must be denatured even if they are out of date or unusable. This minimizes the risk of theft or abuse of the drugs before they are destroyed.

The role in wholesale and retail in physical distribution

Wholesale and retail are important stages in the pharmaceutical supply chain, involving the storage and transportation of products to ensure timely delivery to end users.

Wholesale. Pharmaceutical wholesalers are critical for distribution. In the United States, about 92% of prescription drugs are distributed through wholesalers, and three wholesalers (Amerisource-Bergen, Cardinal Health, and McKesson for more than 90% of Wholesale distribution [35].

A report by the Center for Global Development notes that in low- and middle- income countries, the presence of too many wholesalers fragments the market and drives up costs. These wholesalers often avoid investing in infrastructure due to low returns, leading to multiple intermediaries and high selling costs. To address this, countries such as China and Tanzania have implemented strategies such as China's two-bill system, where manufacturers deliver directly to hospitals, and Tanzania's Prime Vendor program, which selects wholesalers to supply scarce drugs in the public network [36].

Retail. Retail pharmacies are establishments that dispense prescription medications to patients for treating common health conditions. Over the past two decades, the retail pharmacy landscape has undergone significant changes. In the United States, retail chains dominate the market, dispensing approximately 138,000 prescriptions per pharmacy annually, accounting for one-third of the retail market. Regional pharmacies fill up to 91,000 prescriptions per year, while independent pharmacies, although declining in number, typically handle around 48,000 prescriptions annually. Mail-order and online pharmacies currently account for 10% of total prescription sales in the U.S., a figure expected to grow significantly in the coming years due to substantial investments in this sector by major companies [30].

E. End clients and consumers

Pharmaceutical companies target three segments: (1) physicians, (2) wholesalers, pharmacies and hospitals, and (3) patients [37].

- **Physicians** gain access to information about drugs, treatments, ongoing research, and receive support for their operational processes and professional training.
- **Hospitals** are institutions that purchase medications to address the needs of both inpatient and outpatient treatments. **Pharma-**

cies and wholesalers, on the other hand, act as intermediaries by dispensing medications to patients, but they are also considered end-users when acquiring pharmaceutical products for their inventory.

- **Patients** receive information and services related to diseases or therapies. This group includes indivuals who requiere prescription drugs, over-the-counter medications, and specific treatments for various health conditions.

The pharmaceutical industry also segments end users according to their product type [38]:

- **Prescription drugs**

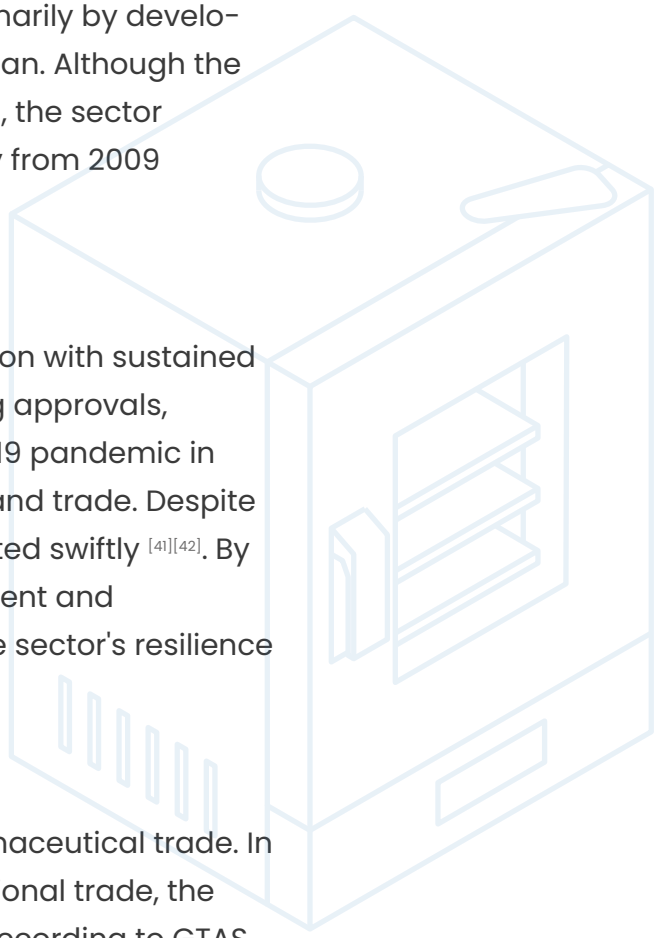
  Primarily used by patients under medical supervision, these medications require a prescription as they are considered potentially harmful if not administered under the guidance of a licensed healthcare professional.

- **Over-the-counter (OTC) drugs**

  These medications are available to consumers without a prescription and are typically used to treat minor conditions or symptoms of common illnesses.

III. Key statistics and market insights on the pharmaceutical industry

Since the early 21st century, the pharmaceutical market has demonstrated consistent growth, marked by key milestones [39]. During the initial years, industry revenues surged, driven primarily by developed markets such as North America, Europe, and Japan. Although the 2007–2008 financial crisis temporarily slowed growth, the sector displayed remarkable resilience, rebounding strongly from 2009 onward [40].



Between 2015 and 2019, the market solidified its position with sustained annual growth and a significant increase in new drug approvals, reaching a historic high in 2018. However, the COVID-19 pandemic in 2020 disrupted global supply chains, labor markets, and trade. Despite these challenges, the pharmaceutical industry adapted swiftly [41][42]. By 2021, it emerged stronger, bolstered by the development and large-scale distribution of vaccines, underscoring the sector's resilience and critical global importance.

The pandemic also had a profound impact on pharmaceutical trade. In 2020, despite a substantial decline in overall international trade, the value of traded pharmaceuticals rose significantly. According to GTAS Forecasting data, pharmaceuticals ranked third among all product categories, following electronic components and motor vehicles [41]. The industry's global trade share experienced a remarkable increase of 19.7% in 2021, largely driven by the introduction of COVID-19 vaccines. That year, four of the top-selling pharmaceuticals globally were COVID-19 treatments. Notably, Pfizer and BioNTech's Comirnaty generated $36.8 billion in sales, setting a record as the highest revenue for any pharmaceutical product in history [43][44].

In 2023, the global pharmaceutical market was valued at $1,501.90 billion. By 2033, it is projected to surpass $2,717.72 billion, reflecting a compound annual growth rate (CAGR) of 6.11% from 2024 to 2033 [45]. Pharmaceuticals currently account for approximately 3.52% of global trade, underscoring the industry's economic significance.

North America accounted for the largest share of the global pharmaceutical market in 2023, holding 41.09% of the total [45]. The region is expected to maintain its dominance throughout the forecast period, driven by several factors. These include access to high-value medications, advanced healthcare knowledge, high per capita healthcare expenditure, and a robust GDP. Additionally, strategic initiatives launched by both established pharmaceutical giants and early-stage companies in the region are significant contributors to its sustained growth.

Globally, the pharmaceutical industry and drug consumption are heavily concentrated in developed countries. These nations not only lead in healthcare expenditure but also dominate scientific research, innovation, and the development of new pharmaceutical products.

A. Imports and Exports by country

The global pharmaceutical import market is dominated by a select group of nations. In 2022, the United States led as the largest importer, with imports valued at $168 billion, followed by Germany ($71.1 billion), Switzerland ($48.5 billion), Belgium ($46.9 billion), and China ($37.4 billion) [46].

Source: The Observatory of Economic Complexity

On the other hand, exports of pharmaceuticals are led by countries with robust manufacturing capabilities and established reputations for quality.[47]

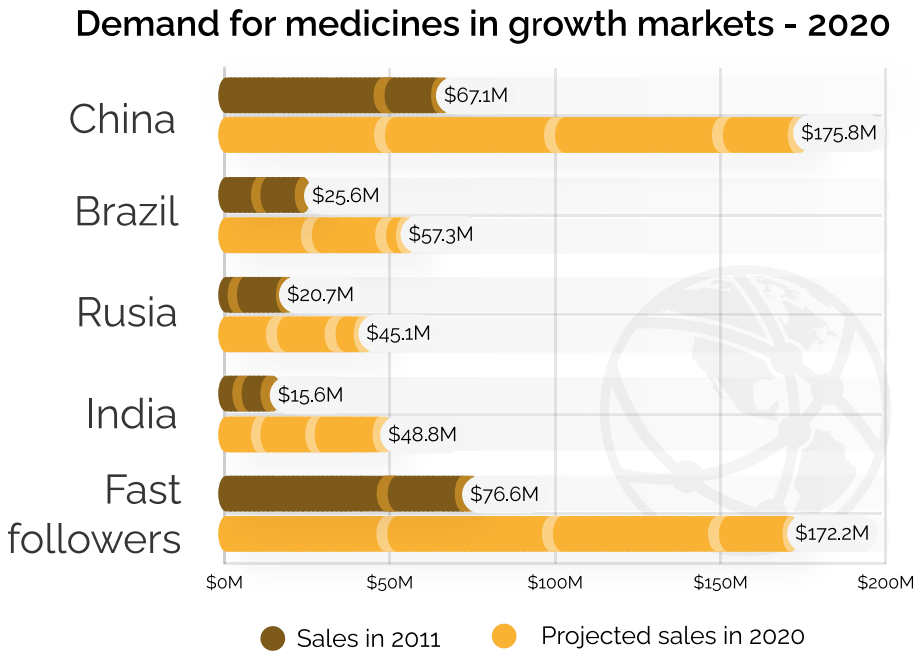
- Germany: $119.85 billion (a 4% decrease from the previous year).
- Switzerland: $99.08 billion.
- United States: $90.30 billion.
- Belgium: $82.52 billion.
- Ireland: $71.56 billion.

Germany, the largest pharmaceutical exporter globally, is recognized for its advanced manufacturing technologies and high-quality products. Companies such as **Bayer**, **Boehringer Ingelheim**, and **Merck Group** play a pivotal role in its export dominance.

According to the latest statistics, Germany remains biggest pharmaceutical exporter in the first quarter of 2024 with exports valued at $32.32 billion in 2024 Q1 followed by Switzerland ($27.14 billion), US ($22.13 billion), Ireland ($21.97 billion), France ($10.16 billion), UK ($6.91 billion), Spain ($4.32 billion), China ($2.94 billion), Canada ($2.55 billion), and Singapore ($2.44 billion). [47].

B. Emerging markets [48][49][50]

The growth of the pharmaceutical industry has fostered the emergence of rapidly developing markets, collectively termed pharmerging markets. These markets, while traditionally occupying a less prominent position in the pharmaceutical sector, are experiencing significant growth. Key pharmerging countries include India, China, South Africa, Brazil, Russia, and Turkey.



Source: Business Monitor International [49]

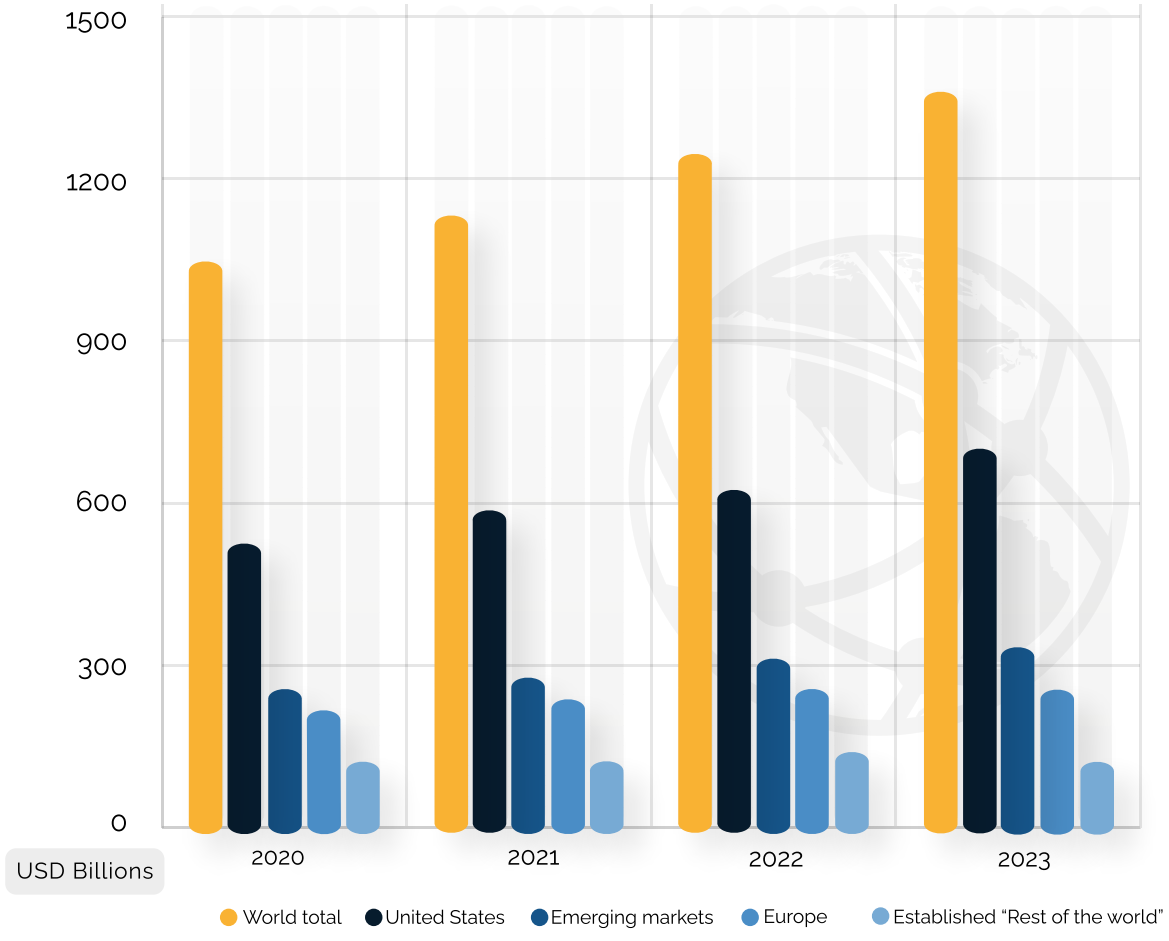
Additional players, often referred to as "fast followers," include Argentina, Egypt, Indonesia, Mexico, Pakistan, Poland, Romania, South Africa, Thailand, Turkey, Ukraine, Venezuela, and Vietnam, which are steadily strengthening their positions in the global pharmaceutical trade.

Pharmerging markets have become highly relevant due to their rapid expansion. Between 2011 and 2020, the demand for pharmaceuticals in these countries grew from $205 billion to over $400 billion, reflecting a dramatic rise. By 2020, Brazil, China, India, Indonesia, Mexico, Russia, and Turkey collectively accounted for approximately 20% of global pharmaceutical sales.

Spending on medicines in emerging markets is increasing at a much faster pace compared to developed economies. For instance, Latin America boasts the highest predicted compound annual growth rate (CAGR) in pharmaceutical sales through 2027.

In 2023, the United States remained the largest single pharmaceutical market, generating revenues exceeding $670 billion. Europe followed with approximately $250 billion in revenues. Together with Japan, Canada, and Australia, these regions form the established markets, which dominate the global pharmaceutical landscape.

Global pharmaceutical sales from 2020 to 2023 by region



Conversely, the rest of the world's pharmaceutical revenue predominantly stems from emerging markets, particularly China, Russia, Brazil, and India. These countries are experiencing the fastest growth in pharmaceutical sales, fueled by their expanding economies and increasing healthcare expenditures.

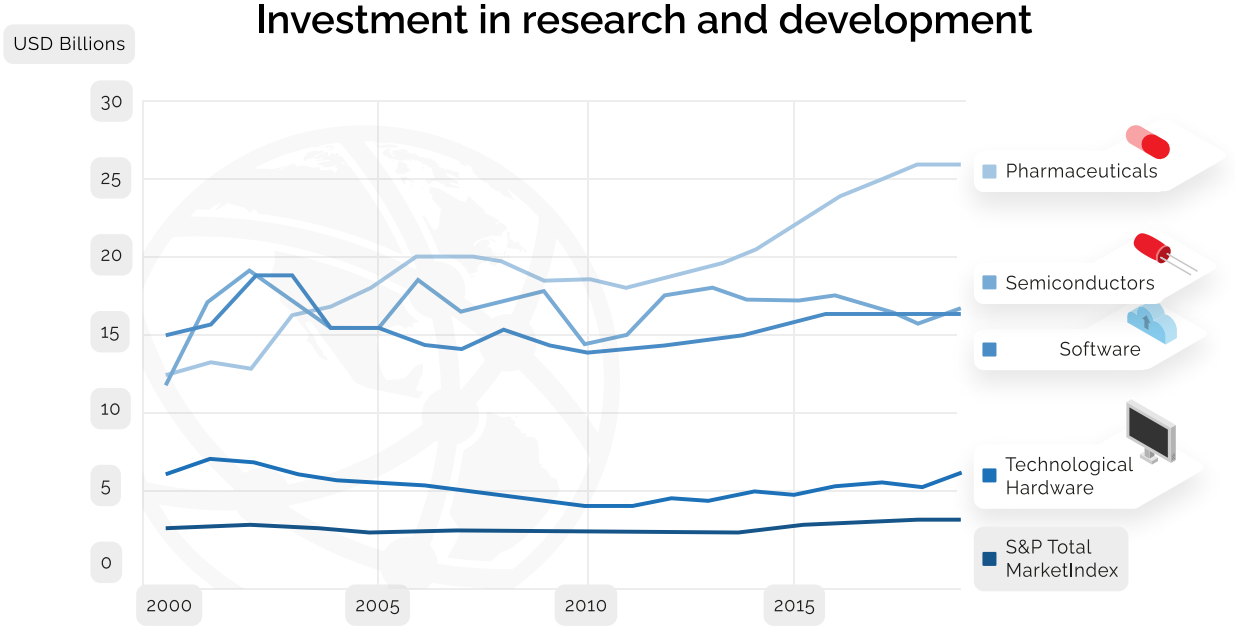
Emerging markets present exciting opportunities for pharmaceutical companies while also posing significant challenges. Regions such as Asia-Pacific, Latin America, and parts of Africa are witnessing rapid economic growth and rising healthcare expenditures, creating fertile grounds for introducing new drugs and therapies.

For instance, the growth of the middle class in countries like India and Brazil has led to greater demand for innovative healthcare solutions. Consumers in these regions are becoming more health-conscious and are exploring advanced therapeutic options. At the same time, companies must navigate challenges such as regulatory complexities, infrastructure limitations, and pricing pressures. Strategic approaches are essential for harnessing the immense potential of these dynamic markets.

C. Pharma R&D Investment

The pharmaceutical industry is fundamentally driven by scientific discoveries, making research and development (R&D) a cornerstone of its success. Among all industrial sectors, the pharmaceutical industry consistently invests the most in R&D, even during periods of economic instability.

Investment in research and development

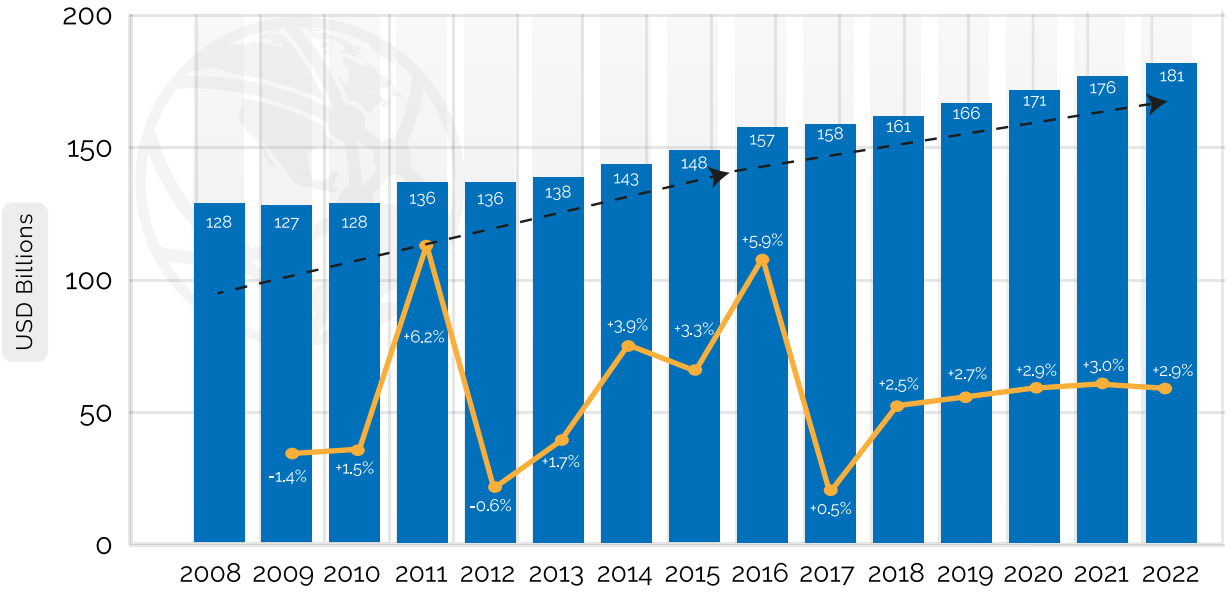


According to the Congressional Budget Office, the biopharmaceutical industry annually spends [42]:

- 8.1 times more than the aerospace and defense sectors.
- 7.2 times more than the chemicals sector.
- 1.2 times more than the software and computer services sector.

On average, pharmaceutical companies allocate approximately 19% of their net income to R&D activities, compared to 15% for other research-intensive industries such as software and semiconductors.

Biopharmaceutical R&D Spending - 2008 to 2022



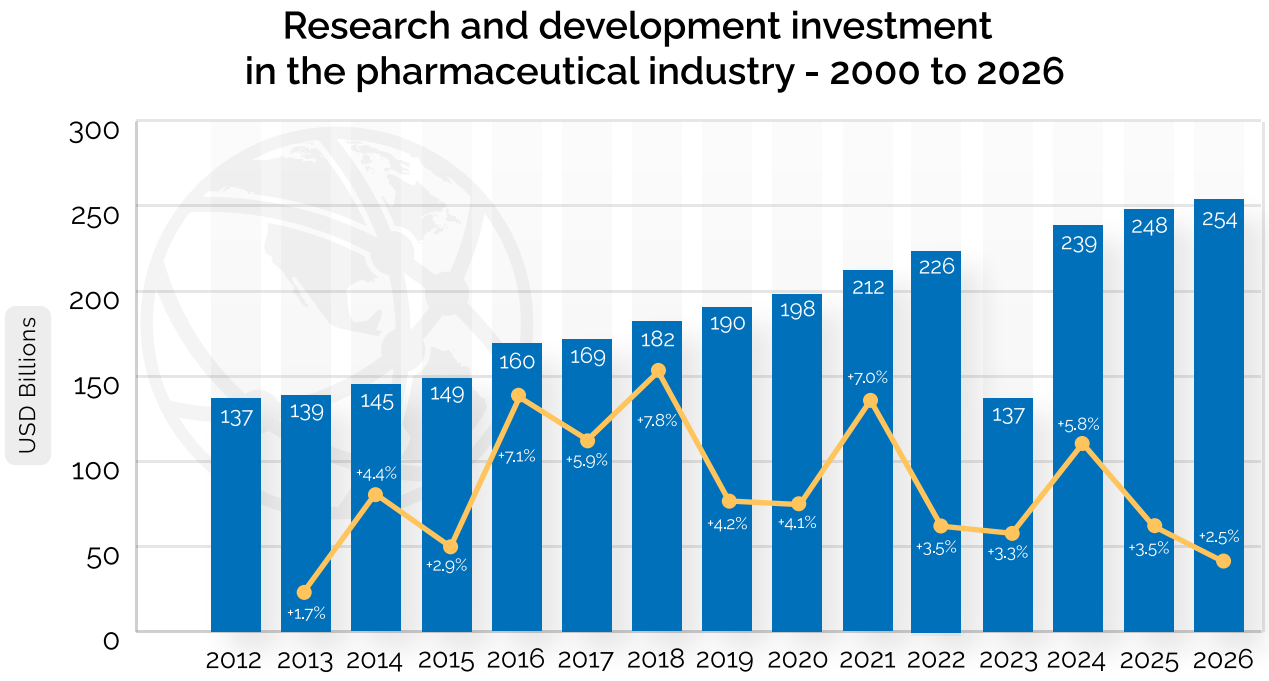
Source: Evaluate Pharma - World Preview 2019

From 2006 to 2016, pharmaceutical innovation was credited with [51]:

- 73% of the increase in life expectancy across 26 high-income countries.
- 66% of the increase in the United States.

The cost of R&D has risen significantly. In 2023, the estimated cost to develop a pharmaceutical asset from discovery to launch was approximately $2.3 billion, compared to $1.3 billion a decade earlier. Despite these costs, only 1 in 5,000 products tested is ultimately approved for patient use, and just 3 out of 10 approved drugs generate sufficient revenue to cover or exceed their development costs [52].

Research and development investment in the pharmaceutical industry from 2000 to 2024 [41][53].



Since 2015, innovative biopharmaceutical companies have invested over $1 trillion in R&D globally. In 2020 alone, the industry registered 10,767 patents under the Patent Cooperation Treaty (PCT) of the World Intellectual Property Organization—highlighting unparalleled R&D intensity [54].

Recent advancements include the rapid development of the Pfizer-BioNTech COVID-19 vaccine, which progressed from concept to reality in just 10 months. Such breakthroughs underscore the industry's ability to develop effective treatments swiftly, particularly during global health crises [55].

The substantial investment in R&D is influenced by several factors [55]:

- Revenue potential of new drugs.
- Development costs.
- Policies regulating drug supply and demand.
- Advances in science and technology.
- The increasing role of small pharmaceutical companies with high R&D-to-revenue ratios.

Rising R&D costs and lower returns have become significant challenges for the industry [42]. Additional hurdles include:

- Stringent testing requirements.
- Pharmacovigilance mandates by national health authorities, requiring companies to monitor and report patient experiences post-approval.
- Rising costs of inputs, such as skilled labor and capital goods.

Despite these challenges, the pharmaceutical industry's dedication to innovation continues to shape global healthcare, enabling the development of life-saving treatments and vaccines that improve health outcomes worldwide.

D. Main trends [55][56]

The market and research environment in emerging economies such as Brazil, China, and India are experiencing rapid growth, leading to a gradual migration of economic and research activities from Europe to these fast-growing markets.

- Between 2017 and 2022, the pharmaceutical markets in Brazil, China, and India grew by 13.0%, 5.3%, and 11.0%, respectively.
- By contrast, the top 5 European Union markets grew by an average of 6.6%, and the U.S. market by 7.1% during the same period (Source: IQVIA MIDAS, May 2023).

In 2022, North America accounted for 52.3% of global pharmaceutical sales, compared to 22.4% for Europe.

- The U.S. market led sales of new medicines launched between 2017 and 2022, with 64.4% of total sales, while Europe (top 5 markets) accounted for only 16.4% (Source: IQVIA MIDAS, May 2023).

The fragmentation of the European Union pharmaceutical market has fostered a lucrative parallel trade, which benefits neither social security systems nor patients and deprives the industry of crucial resources to fund R&D.

- In 2021, parallel trade was estimated to be worth €6.28 billion (at ex-factory prices).

Mental health has become a significant public health concern, driving the demand for effective treatments for conditions such as depression and anxiety. Pharmaceutical companies are heavily investing in the development of new drugs to address these mental health challenges.

Specialty Medicines and Growth Areas:

- By 2027, specialty medicines are expected to account for 43% of global spending and 56% of total spending in developed markets.
- Global spending on cancer drugs is projected to reach $370 billion by 2027, fueled by the introduction and use of novel therapies, with minimal impact from biosimilars.
- In immunology, growth is anticipated to slow to 3-6% annually, driven by price reductions from biosimilar competition, though volumes are expected to grow at 12% annually.
- New therapies for rare neurological disorders, Alzheimer's disease, and migraines are expected to drive spending growth in neurology.

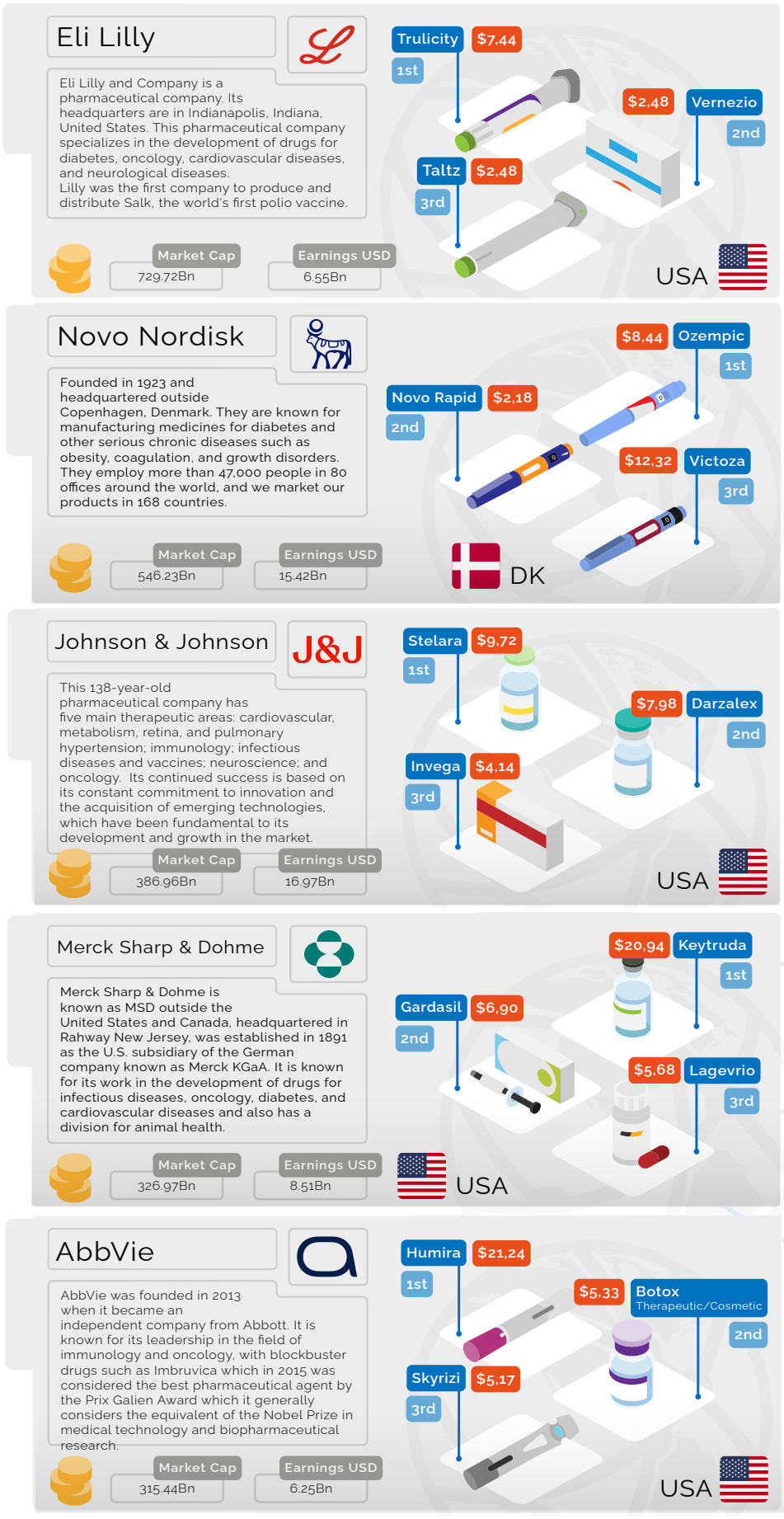
Biotechnology is predicted to account for 35% of global spending by 2027, encompassing both groundbreaking cell and gene therapies as well as a more mature biosimilar segment.

- Significant advances are expected in oncology and immunology.
- The outlook for next-generation biotherapeutics reflects a range of uncertain clinical and commercial outcomes.

IV. Major players in the pharmaceutical supply chain

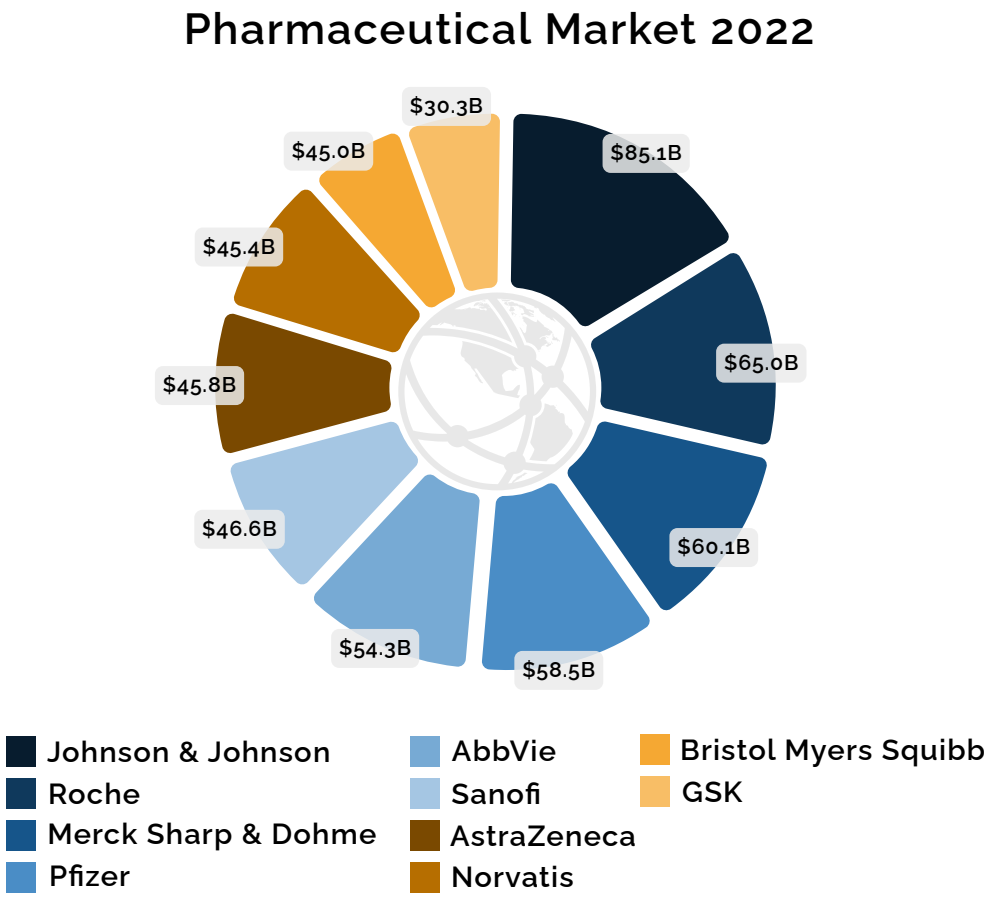
The largest companies within an industry are typically measured through their market capitalization, which represents the cost of purchasing all of a company's shares at a given time. According to a source gathering that metric, Eli Lilly, Novo Nordisk, Johnson & Johnson, Merck, and AbbVie are the leading companies in the sector. [57]

The 5 largest companies according to market cap in 2022



It is worth noting that four of the largest pharmaceutical companies have their origins in the United States. In 2022, the pharmaceutical industry in North America accounted for approximately 53% of the global sales in the pharmaceutical sector.

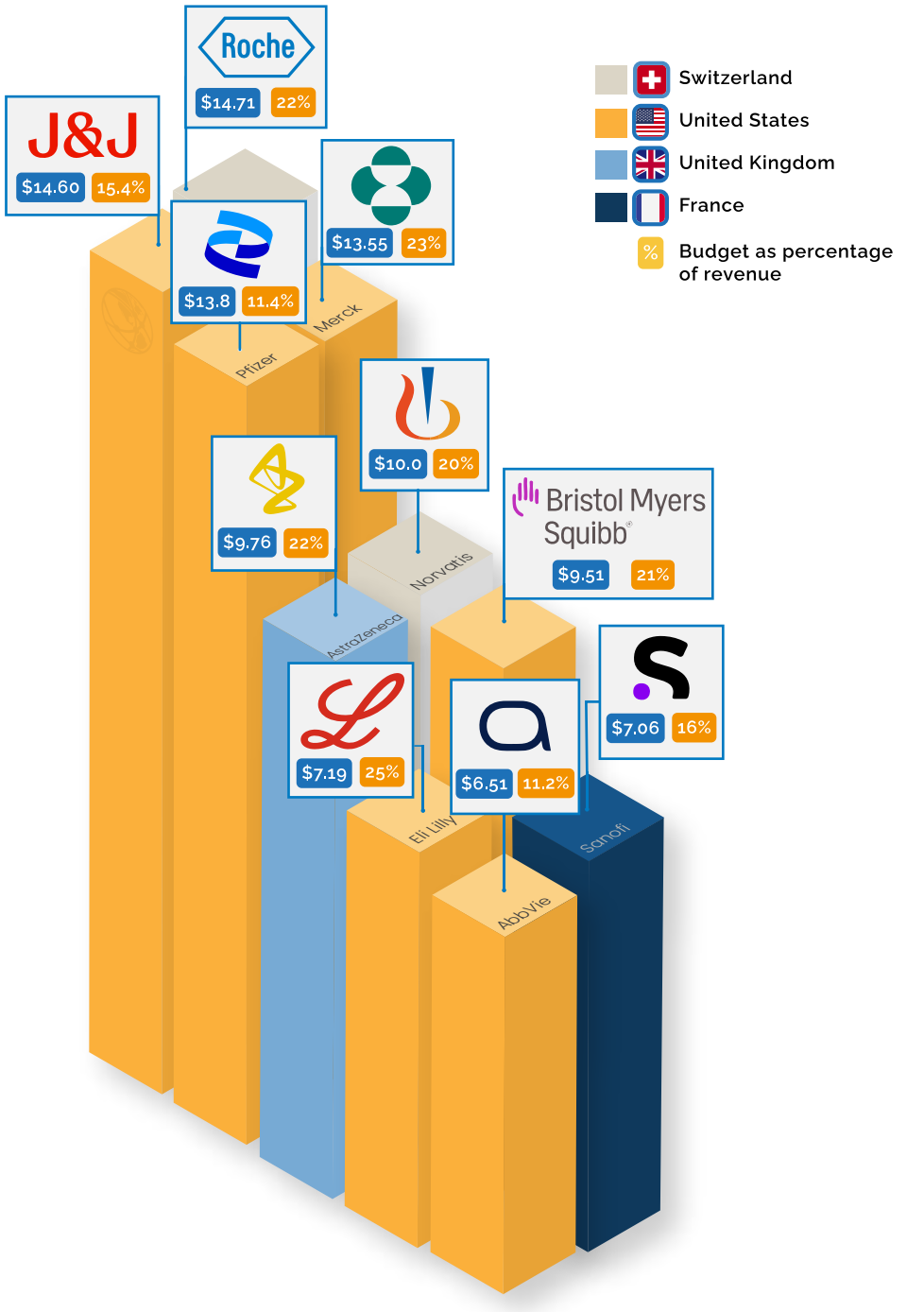
In terms of revenue, the total sales of the pharmaceutical market in 2022 approached $1.5 trillion. The ten companies that generated the highest revenues accounted for about 40% of the global market, and were as follows[58].



The pharmaceutical industry is characterized by its efforts in research and development (R&D). Each year, companies allocate a significant portion of their budgets to R&D activities with the aim of developing new therapies that provide a competitive edge over other companies. Some

companies devote this budget to R&D for new therapies or choose to invest in the acquisition of smaller companies with promising breakthroughs in various clinical areas. According to a study by Fierce Biotech, this was the ranking in 2022 of the companies that invested the most in R&D with their respective percentage based on their generated revenues [59].

Companies that invested the most in R&D - 2022



Research and Development (R&D) budgets are strategic investments that companies make on an annual basis. These companies not only focus their resources on drug development, but also have divisions dedicated to medical devices and diagnostic tests, which contribute significantly to R&D costs. On the other hand, companies such as Bristol Myers Squibb and Novartis have a more focused approach to drug development, although they may also invest in other health-related areas.

The pharmaceutical industry is a highly innovative sector that generates value, not only in terms of health derived from its own activity, but also because of its productive capacity and the generation of direct and indirect jobs. The global impact of the pharmaceutical sector has led companies to invest much more than in other high-tech sectors. On average around 19% of their net revenues over the last two decades have been directed to R&D activities; in comparison, other research-intensive industries, such as software and semiconductors, averaged around 15% [42]. Currently, challenges such as the reduction of patent lifetimes, generic competition and public health policies, among other factors, have changed the operating context of the industry [61].

Closing

The pharmaceutical industry is in a state of constant evolution, driven by continuous advances in medicine and technology that redefine how care is delivered to the public. As one of the most heavily regulated sectors, it operates under stringent guidelines that influence every phase of its lifecycle. These regulations play a critical role in upstream processes such as drug variety, quality assessment, safety, efficacy, and the intricate complexities of research, development, and production. At the same time, they govern downstream phases like distribution and pharmacovigilance, ensuring that products meet the highest standards of quality and patient safety at every stage of the supply chain.

The industry's ability to adapt to these regulations, while fostering innovation, highlights its commitment to improving global health outcomes. Understanding the regulatory framework not only sheds light on the complexities of this sector but also emphasizes its importance in safeguarding public health.

For a deeper exploration of the regulatory aspects shaping the pharmaceutical industry, we invite you to read the next paper in our series,

Harmonizing Quality: A Global Perspective on Good Practices and Regulatory Synergy in Pharmaceuticals.

Discover more...

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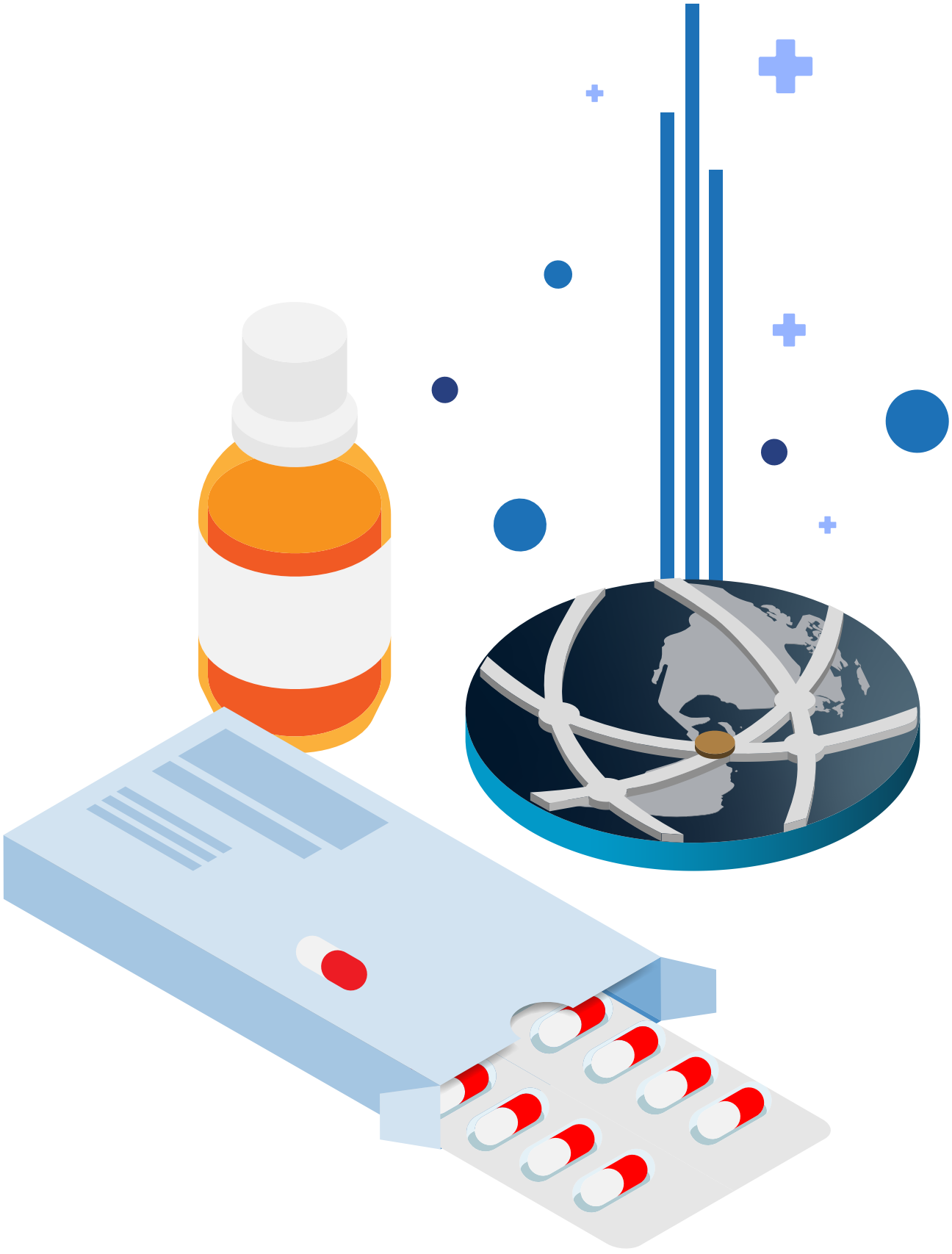

About the **Why Panama** Program

In the current dynamic global landscape, it is clear that having access to high-quality insights is crucial when determining the optimal location for regional distribution in order to take advantage on the present structure of global value chains.

Georgia Tech Panama Logistics Innovation & Research Center recognizes the importance of key insights in the decision-making process, and works closely with companies seeking to assess their supply chains and how Panama can become a key part of their global logistics network.

The "Why Panama" program utilizes quantitative data and analytics to assess key variables and compare the costs, investments, and service benefits of setting up a distribution center in Panama. By conducting a thorough analysis, the program aims to provide businesses with valuable insights into the advantages of establishing a hub in Panama.

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The Georgia Tech Panama Logistics Innovation and Research Center is located in Panama City, Panama. It was launched in 2010 by an agreement between the Georgia Institute of Technology and the Goverment of Panama through the National Secretariat of Science, Technology and Innovation (SENACYT).

Georgia Tech Panama
Logistics Innovation & Research Center

An innovation center of SENACYT
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