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The Pharmaceutical Global Value Chain: Participation and Opportunities for Latin America and the Caribbean

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THE PHARMACEUTICAL GLOBAL VALUE CHAIN:
PARTICIPATION AND OPPORTUNITIES FOR LATIN AMERICA AND THE CARIBBEAN



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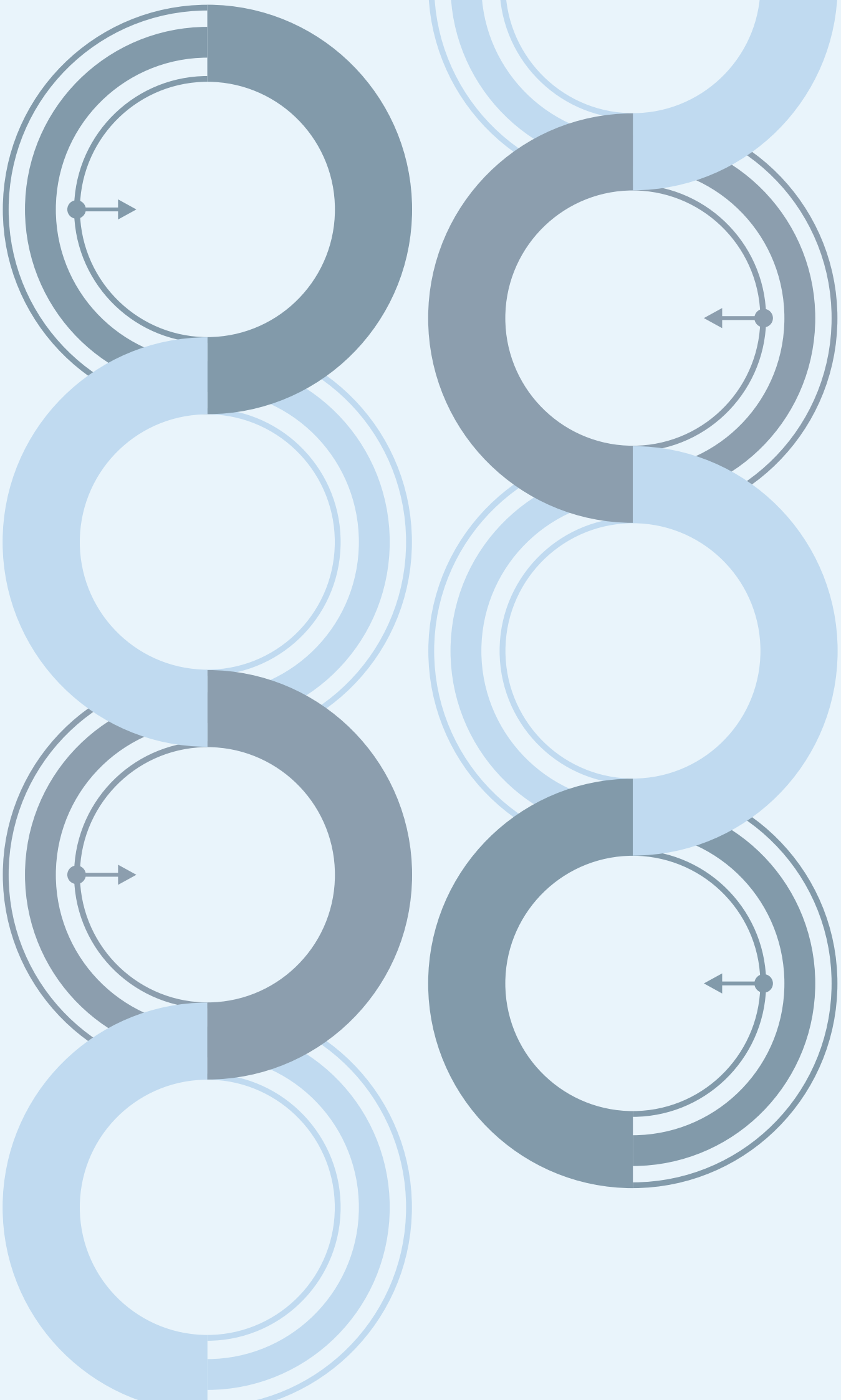

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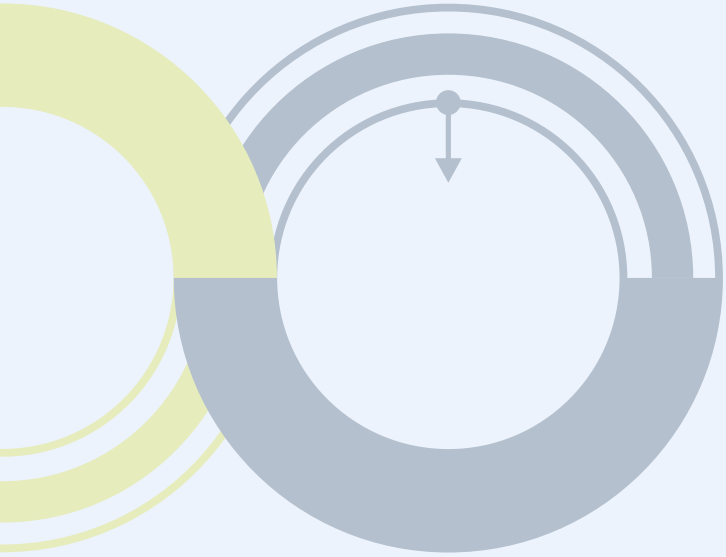
Abbreviations

Abbreviated New Drug Application	ANDA
American National Standard Institute	ANSI
Active pharmaceutical ingredient	API
Bristol-Myers Squibb	BMS
Biotechnology Contract Manufacturing Organization	BCMO
Contract Development & Manufacturing Organization	CDMO
Contract Manufacturing Organization	CMO
Central nervous system	CNS
Consumer health/healthcare	CH
Contract Research Organization	CRO
Direct to consumer	DTC
Good Manufacturing Practice	GMP
GlaxoSmithKline	GSK
Global value chain	GVC
Intellectual property	IP
Latin America and the Caribbean	LAC
Merger and Acquisition	M&A
Ministry of Health	MoH
Monoclonal antibodies	mAbs
Multinational Enterprise	MNE
New Drug Application	NDA
Over-the-Counter	OTC
Research and Development	R&D
Reference Listed Drug	RLD
Universal health coverage	UHC

Terms used interchangeably in this report and research notes

- LAC refers to the IDB's 26 borrowing countries in Latin America and the Caribbean Pharmaceutical, drug, and medicine.
- Prescription and Rx.
- Biosimilar, generic version of biologic drug, follow-on biologic, similar biologic, bio-generic.
- To improve the readability of this report, discussion related to trade uses the term biological products when referencing HS3002 and small molecule drugs when referring to HS3004 and 3006 codes. It also includes all trade in HS3002 as final products. These are good approximations but are not exact matches.
- World trade values: Non-reporters (≥ 0.1% world trade) for 2023 (as of March 16, 2025): Vietnam, Russia, Iraq, Algeria, Bangladesh, Belarus, Iran, Libya, and Mongolia. Venezuela and Haiti also have not reported in 2023, but account for less than 0.1% of world trade. Non-reporters (≥ 0.1% world trade) for 2013: Mayotte (Overseas France), Libya, Dem. Rep. of the Congo, Uzbekistan, Gibraltar, Turkmenistan. Venezuela last reported trade data in 2013. As such, some change in values for LAC between 2013 and 2023 is due to non-reporting by Venezuela in 2023.



Summary

This report provides an overview of the global pharmaceutical industry including key trends, a map of the entire value chain, analysis of the geographic spread of activities, and identification of important firms and stakeholders along the entire chain. The second section presents key aspects of Latin American and Caribbean (LAC) countries' participation in the pharmaceutical industry and identifies opportunities for expansion and areas for improvement. The final section provides recommendations for the region to consider. It draws on data from secondary sources, including industry and market reports, journal articles, and industrial statistics. More in-depth primary and secondary analysis should be carried out within LAC to expand the description of activities in key countries and prioritize opportunities and recommendations.

Current global trends in pharmaceuticals include growth in generics and biologics. In the longer run, shifts in dosage and routes of administration will impact manufacturing. Ongoing demographic, lifestyle, and spending changes also impact demand in the global pharmaceutical industry including longer life expectancies, increases in income and more sedentary, unhealthy lifestyles, and government expenditure on drugs.

Bringing a new medication to market requires extensive R&D, evidenced by the $301 billion spent globally on pharmaceutical R&D in 2023. Pharmaceutical R&D is time consuming, risky, and costly, and has become more so over time. Less than one percent of potential chemicals and less than 10% of drugs entering clinical trials are commercialized, and for those that are, it takes 10-15 years to go through the entire process, and costs approximately $2.5 billion. Estimates suggest that less than 30% of drugs ever recoup develop costs. Rising R&D costs have led to increased outsourcing. Global revenue of contract research organizations was $103 billion (2023), suggesting approximately one-third of R&D is carried out by CROs/outsourced.

In 2023, global pharmaceutical sales revenue reached $1.4 trillion, of which LAC countries accounted for 5% ($75 billion). Activity in the region is dominated by a few countries with significantly larger populations and economic development. Brazil, Mexico, Argentina, and Colombia collectively accounted for nearly 80% of sales, and Brazil alone over one-third. The largest therapeutic market areas globally and for LAC are oncology, metabolic disorders (i.e., diabetes), cardiovascular, and central nervous system (CNS). In the recent-term, Covid-19 significantly increased global demand for anti-infectives/anti-viral (i.e., vaccines).

Pharmaceuticals are divided based whether a consumer needs a doctor's prescription to obtain the medication or if it is available over the counter (OTC) without a prescription. Which pharmaceuticals require a prescription is determined at the country level. Prescription drugs are further divided into patented and generic. Patented drugs are innovative new medicines recognizable by brand names that are developed by global pharma MNEs in the US and Western Europe. After patent expiration, generic versions based on the same active pharmaceutical ingredients (APIs) are brought to market by a different set of firms.

Patented pharmaceuticals account for 63% of global prescription sales and generics 37% (2023). In LAC generics account for around 43%. Globally market concentration is higher in patented drugs than generics. The top 10 patented companies account for as much as 60% of revenue, whereas the top 10 generics firms only account for 16% of revenue. Contract manufacturing (outsourcing) final products is still uncommon. It has increased, but it is used more often for production in the US and Europe (and for research). For production in foreign countries for regional/local markets, acquisitions are more common. API production primarily takes place in China, the US, and Europe.

Global pharmaceutical final product trade was $797 billion in 2023; top exporters are Germany, Ireland, US, and Switzerland. The top 10 exporters have accounted for around three-quarters of exports from 2013-2023 and have generally been the same. Ireland and China's export values more than doubled between 2013 and 2023.

LAC final product imports were $33 billion in 2023 (4% of global pharma imports) and consisted of one-third biological products and two-thirds small molecule. Imports from Asia are increasing, particularly from India and China, and decreasing from the US. Europe's share of LAC's imports has been steady around 57% while regional LAC import share has fallen slightly from 16% to 14% (2013 and 2023).

Argentina, Brazil, and Mexico import less than half of domestic pharmaceutical demand, whereas smaller countries import 60 to 80%. Large LAC countries primarily import from the US and Europe while smaller LAC countries import more from other Latin American countries and India. Trade among countries is primarily Brazil, Argentina, Colombia, Chile, and Mexico exporting small molecule drugs to smaller LAC countries with limited trade among the larger countries. Biological products are from Europe (over 50%), the US, and Asia. Of LAC countries, Argentina is the top supplier, but only accounts for 1% of LAC imports. LAC final product exports were $8.2 billion (2023), which is less than 1% of world trade. Brazil, Mexico, and Argentina account for two-thirds of exports.

Brazil, Mexico, Argentina, Chile, and Colombia are the main countries with activity in pharmaceuticals. Mexico and Chile are more open to foreign investors; Argentina and Brazil, domestic firms; and Colombia, a mixture. Smaller countries play a role in specific areas; Peru, El Salvador, Guatemala, and Paraguay have domestic manufacturers to meet local demand while Costa Rica, Panama, and Uruguay have foreign-owned, indirect service pharma operations.

Weaknesses include stagnant pharmaceutical sales and exports and small global market shares, lack of regional coordination on regulation or innovation, and generally low adherence with GMP international standards. These issues combined with government preference for generic medications and IP/counterfeit concerns (real or perceived), make the region less appealing to FDI from patented pharma MNEs. Asian generics manufacturers have recently increased investments though. Lifestyle changes and ageing populations have led to a rise in diseases and the need for pharmaceuticals in Latin America. However, this has not translated into significant increases in pharmaceutical demand, in part due to low public healthcare and drug spending. Opportunities for domestic/regional firms and foreign investors include vaccine/biologics production, API production, generics, clinical trials, and medical cannabis. Recommendations include active promotion, industrial/research parks, research collaborations, workforce development, regional collaboration regarding regulations, tariffs, standards, and distribution, and increased government expenditure on healthcare and drugs.

1. THE PHARMACEUTICAL GLOBAL VALUE CHAIN

1.1 MARKET EVOLUTION AND PROSPECTS

Several ongoing trends in the global pharmaceutical industry are highlighted below followed by implications for LAC countries. These topics are also discussed in greater detail in subsequent sections of the report.

Growth in **generics.** The generic drug segment is growing at a faster rate than pharmaceuticals overall; between 2023 and 2028 it is expected to average 8.5% per year (BCC, 2024g). Patent expiration of blockbuster drugs leads to the launch of generic versions. Once patent protection is lost, generics often garner 30% to 50% of the market share of the original drug (BCC, 2021a). Generic drug prices are significantly lower than brand-name, patented drugs; estimates range from 50% to 90% less (BCC, 2021a; IBISWorld, 2021). Lower priced generics also increase accessibility of drugs, particularly in middle- and lower-income countries.

Consumption of generics differs by country because of various factors, including national prosperity, national health provision, government control over drug prices, availability of generic substitution, and local attitudes toward generic drugs (BCC, 2021d). Governments and health insurance organizations seek to limit healthcare costs and encourage or incentivize patients to use generic drugs (IBISWorld, 2021). This is particularly evident in countries with domestic generic production capabilities including Argentina and Brazil.

More price-based competition from generics, rising research and development (R&D) costs, and more stringent testing requirements have led some manufacturers to become more specialized in specific product/therapeutic areas and/or reduce R&D expenditures (BCC, 2021d; IBISWorld, 2021; IFPMA, 2021). This has led to increased outsourcing in the R&D stages of the chain, which presents an opportunity for Latin America in contract research.

The **Covid-19 pandemic** temporarily reduced overall demand and supply of pharmaceuticals. Doctor's visits for chronic and lifestyle-related diseases like hypertension and diabetes, were far less frequent which also resulted in fewer prescription renewals (BCC, 2021d). The pandemic also led to supply chain disruptions and factory closures that reduced overall pharmaceutical supply. This reduced income in the short-term for drug producers, however it impacted all countries and was not specific to Latin America. On the other hand, Covid-19 increased global demand, production, and clinical trials for vaccines. Due to the urgency to bring vaccines to market, products went through the development process in less than one year compared to the typical norm of 6-7 years for clinical trials alone. The global market for vaccines went from only $37 billion in 2020 to over $100 billion in 2022. This presents an opportunity for Latin America.

New dosage formats and shifts in manufacturing. In the 1980s and 1990s, most medications were formulated in a solid dosage (tablet or capsule) taken two or three times per day. This required large production volumes and big pharma scaled up solid dosing manufacturing lines at significant expense. New technologies have enabled other formulations, as well as controlled release and extended-release solid doses taken once daily. Batch sizes are considerably smaller and based on flexible processes (Kalorama, 2017). In 2021, the largest share of drugs in the pipeline globally by delivery route are injectable (60%), followed by oral (28%), topical (4%), inhaled (4%), and others (4%)(Statista, 2021f). This reduces the need for high volume solid dosage production among patented pharma firms, but it has increased need among generic and OTC pharmaceutical companies that are acquiring mature, multiple dosage solid products from these companies. These companies are often reluctant or unable to invest large sums in solid dosage production and may turn to contract manufacturers to meet this need (Kalorama, 2017). Generic versions will also eventually be replaced by reduced dosage equivalents and new delivery routes and manufacturers in Latin American will need to invest in new production lines.

Increasing focus on **biological** therapies (BCC, 2021d). Since recombinant insulin was developed and commercialized in the early 1980s, biotechnology-derived products have grown in number and revenue. By 2017, six of the 10 best-selling drugs were biologics (Kalorama, 2017). The biologics market value is approximately $450 billion (2023). Argentina, Brazil, and Mexico all have capabilities in biologics; Argentina appears to be the most advanced. As more biologics reach patent expiration there will be opportunities for generics (or biosimilars) manufacturers globally and in Latin America.

Demographic, lifestyle, and spending changes also impact growth and demand in the global pharmaceutical industry. Older adults require a greater number of medications than younger people, so **longer life expectancies and increasing shares of the population over age 65** lead to increased pharmaceutical demand. In particular. The geriatric population particularly increases the patient pool for diseases such as rheumatoid arthritis, hypertension, diabetes, and cancer (IBISWorld, 2021; TBRC, 2021b). Increasing income is often associated with **lifestyle changes** that increase the likelihood of medical conditions that require prescription drugs and increase disposable income to purchase OTC

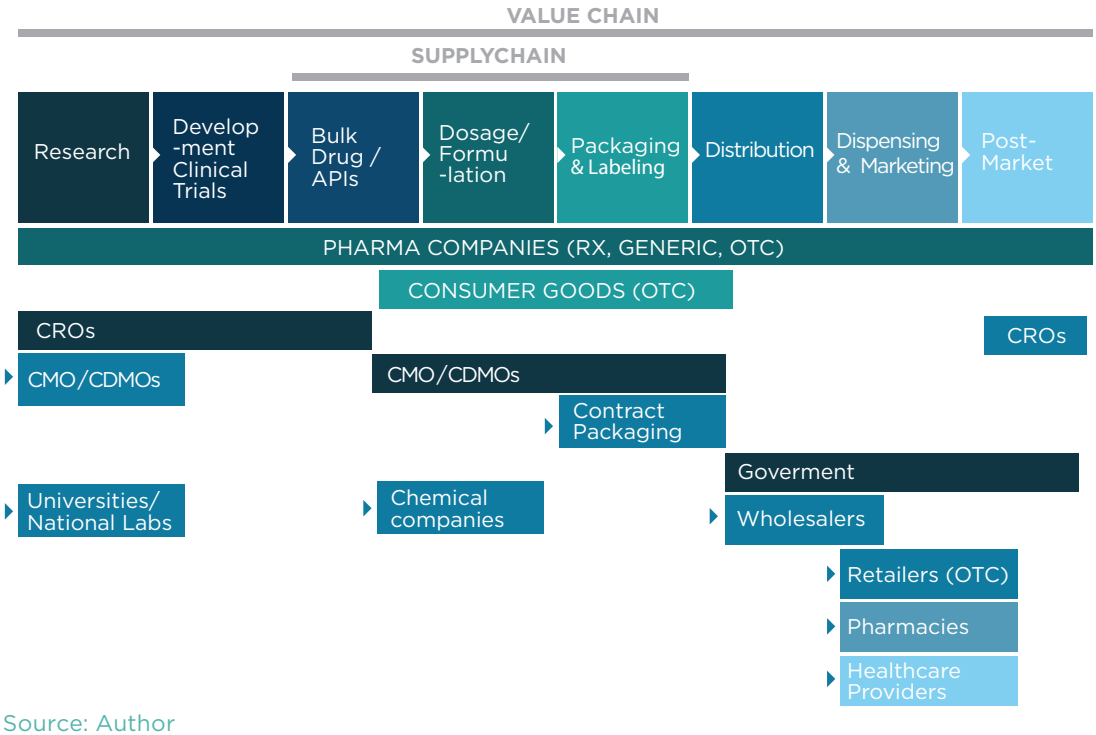
vitamins and supplements to improve health (IBISWorld, 2021). The rise in sedentary jobs, less physical activity, and unhealthy eating and drinking habits are major causes of chronic diseases such as diabetes and cardiovascular conditions (TBRC, 2021b). This trend is notable in the larger Latin American countries including Mexico and Brazil. Increased prevalence of disease does not automatically translate into increased pharmaceuticals sales. **Government expenditure on healthcare and pharmaceuticals** is also necessary, particularly in lower-income countries where the public is otherwise unable to afford prescription pharmaceuticals. Current expenditure in LAC countries is low.

1.2 MAPPING THE STAGES IN THE GLOBAL VALUE CHAIN (GOODS AND SERVICES)

The pharmaceutical industry can be described and analyzed several ways: (1) activities along the value chain, (2) stages of the supply chain, (3) business models and relationships among firms along the chain, (4) product characteristics, (5) therapeutic areas, (6) routes of administration or dosage types, and (6) buyers and distribution channels. This report touches on each of these segmentations and factors that impact competitiveness.

The main activities along the pharmaceutical value chain (Figure 1.1) include research (drug discovery and pre-clinical trials), development (clinical human testing) and small batch manufacturing for testing and regulatory approval, commercial manufacturing (bulk drugs/APIs and dosage formulation), packaging/labeling, distribution, and post-marketing activities.

Figure 1.1.
Pharmaceutical Global Value Chain



Source: Author

1.2.1
RESEARCH AND DEVELOPMENT

Bringing a new medication to market, particularly biologics, requires extensive R&D, evidenced by the $301 billion spent globally on pharmaceutical R&D in 2023. Pharmaceutical R&D is time consuming, risky, and costly, and has become more so overtime (Table 1.1). It takes 10 to 15 years on average to develop a new product (IBISWorld, 2021), with slightly shorter times for small molecule (10 to 12) compared to biologics (12 to 15)(BCC, 2021d). Far less than 1% of new chemicals discovered become a medicine[1], and of drugs that make it to the development phase (clinical trials), only 5 to 10% make it to the prescription drug market (BCC, 2021c, 2021d). R&D costs to develop a new pharmaceutical compound (from discovery to launch) doubled between 2010 and 2020, from $1.2 billion to $2.5 billion (BCC, 2021d; IBISWorld, 2021; Kalorama, 2020; Statista, 2021f). The cost in the 1980s was $0.4 billion (Statista, 2021b). Lastly, only 20 to 30% of new drugs recoup development costs. IBISWorld (2021) states only two out of 10 products recover R&D costs during patent protection, and only 30% of new medicines generate sufficient revenue to exceed development expenses (Kalorama, 2017). Furthermore, the internal rate of return on biopharma late-stage R&D investment among the 20 largest biopharma R&D spenders has declined over the last decade from 6.5% in 2013 to 4% in 2023 (Statista, 2023).

Table 1.1.
Pharmaceutical R&D Stages

STAGE/DATA POINTS	RESEARCH		DEVELOPMENT/ CLINICAL TRIALS (HUMAN TESTING)			APPROVAL	POST-MARKETING SURVEILLANCE
	Discovery	Pre-clinical	Phase I	Phase II	Phase III		Phase IV
Duration		1-year	Months	≤ 2 years	1-4 years	0.5-2 years	1 year+
	3-6 years		6-7 years				Ongoing
Participants	--	Non-human testing	20-80 10-50	100-300 200-400	1-5,000 1-10,000	--	2-5,000 --
Purpose		Submit IND	Safety	Efficacy	Safety, efficacy, dosing	Submit NDA	Long-term efficacy, safety
Success rate			70%	35%	40-50%		70-90%
	< 0.01%		57%	39%	68%		
Clinical studies			39,711 (registered studies during, 2023) 5,063 (with posted results, 2023)				
Cost	$2.5 to $2.6 billion to bring a new drug to market (2020s)						
R&D spending	$184 & $301 billion globally (2018, 2023)						
CRO market	$103 billion (2023)						

Sources: (BCC, 2021d, 2024d; Clinicaltrials.gov, 2025; IBISWorld, 2021; IFPMA, 2021; Kalorama, 2017, 2020; Statista, 2023)

1. One in 5,000 (0.02%) new chemicals discovered becomes a medicine (IBISWorld, 2021); similarly, the success rate for discovery and pre-clinical is 0.01% (IFPMA, 2021; Kalorama, 2020).

Research begins with the discovery of new compounds. Drug discovery requires technical expertise in molecular biology, ultra-high throughput screening, molecular and behavioral pharmacology, and combinatorial, medicinal, and analytical chemistry. It consists of four stages: target identification, target validation, high speed screening, and lead optimization (Kalorama, 2020). After discovery, potential drugs go through pre-clinical testing on non-human subjects.

Drugs that make it through the discovery phase enter **development**, which consists of three phases of human clinical trials over 6-7 years. Rising R&D costs stem from the high cost of human clinical testing, which accounts for about two thirds of the entire cost of drug development. The size of clinical trials has increased, and recruitment consumes about 30% of overall clinical trial time and up to 40% of clinical trial costs – more than any other activity associated with clinical testing (Kalorama, 2017). Clinical trial participants should match the demographic that will take the medication. It can be difficult to find participants in the US and Western Europe because other medication options are available, or participants take other drugs that may interfere with results.

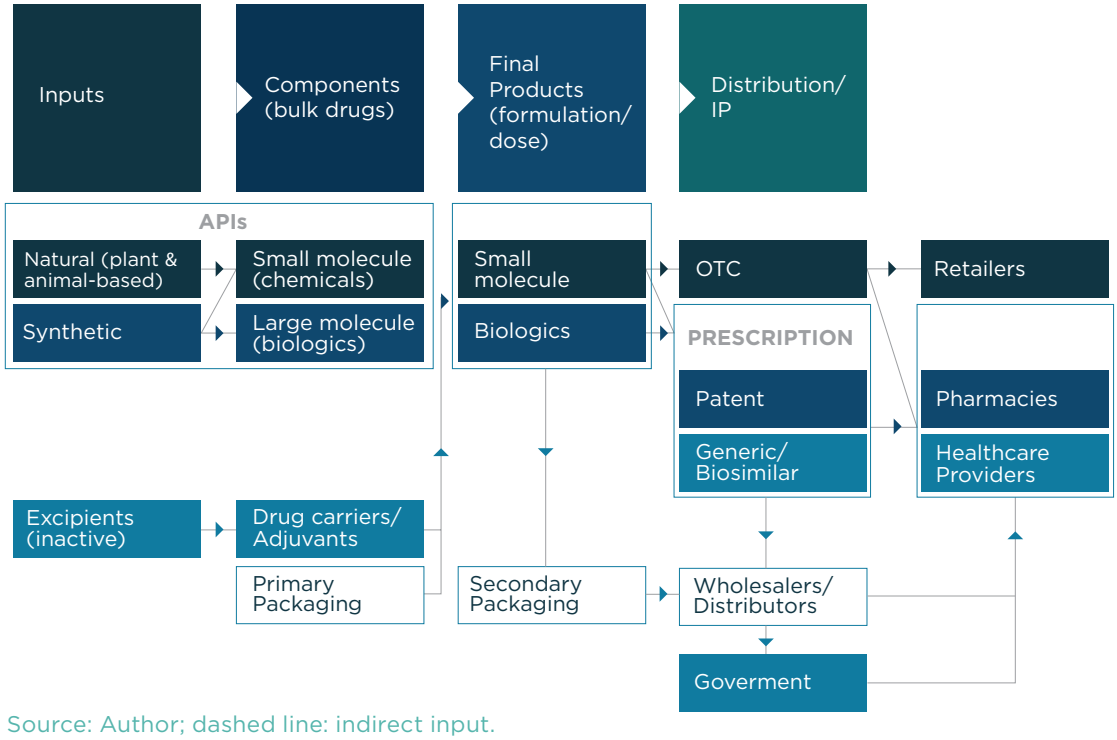
Nearly 40,000 clinical studies were conducted globally during 2023 (Clinicaltrials.gov, 2025). The number of studies conducted each year has increased considerably over the last decade. In 2013 there were only 20,400 studies. Based on cumulative clinical trial totals between 2000 and 2025, approximately 38% of registered studies pertain to drugs/biologics.

Drugs that make it through clinical trials enter the **approval** phase which consists of submitting a New Drug Application (NDA), regulatory review, and market authorization. This can take a few months to years depending on the country and product. Once a medicine receives regulatory approval, national health authorities require companies to track and report patients' experiences (referred to as "pharmacovigilance"). Ongoing activities to detect, assess, and prevent adverse drug effects are to promote drug safety. Reporting requirements are becoming stricter, raising the investment cost in a medicine as long as it is marketed (IFPMA, 2021).

1.2.2 INPUTS/RAW MATERIALS

The pharmaceutical supply chain (Figure 1.2) consists of inputs, components, final products, and distribution. It begins with basic chemicals and natural inputs used for active pharmaceutical ingredients (APIs), excipients, and other chemical intermediates.

Figure 1.2.
Pharmaceutical Supply Chain



Source: Author; dashed line: indirect input.

Excipients are inactive ingredients intentionally added to a drug delivery system to produce a finished pharmaceutical product. Any entity or substance other than the active drug or API that is included in the manufacturing process or contained in finished pharmaceutical dosage forms can be referred to as an excipient. A finished pharmaceutical contains 75% to 99% of excipients by weight; however, excipients comprise less than 1% up to 5% of the value of the finished drug (BCC, 2021b). The global excipient market value was $9.2 billion in 2023 (BCC, 2024c).

Excipients can be natural/organic, inorganic, or USP water. Organic materials account for 90% of the market and include carbohydrates (sugar, cellulose, starch), oleochemicals (derived from vegetable oils and animal fats), petrochemicals (derived from crude oil & natural gas; used as emollients, disintegrants, and vehicles), proteins, and others (BCC, 2024c). Inorganic excipients are derived from inorganic materials such as calcium, silica, and metals. USP water, also known as pharmaceutical or compendial water, is used as a raw ingredient for most pharmaceutical formulations, especially oral liquid and injectables. Excipients are primarily needed in oral and topical pharmaceuticals and are less important in injectables and other advanced drug delivery systems (BCC, 2021b).

The API market value was $248 billion in 2023 (BCC, 2024a). API raw materials can be natural or synthetic. Synthetic APIs account for the largest share of the

market (73%, 2023) and are derived from feedstocks from natural sources or fine chemicals that act as the starting material. Synthetic API materials are created via chemical synthesis, biochemical synthesis (enzyme-driven), or cell cultures (for biologics). Natural APIs are derived from plant, animal, microbial, and mineral sources and accounted for 27% of the API market value in 2023. Natural APIs are mainly used in small molecule formulations.

APIs can also be divided into small and large molecules. Small molecule APIs account for most of the global pharmaceutical market (77% in 2023) of which 57% are used in branded pharmaceuticals and 43% in generics.

Large molecule is synonymous with **biologics.** Biologics cover a class of products that includes blood derivatives, vaccines, gene therapies, cellular therapy, and therapeutic proteins. They are usually derived from natural animal sources or manufactured through synthetic methods such as recombinant engineering and fermentation. Biological APIs are often produced using fermentation, cell culture, and purification technologies; scale-up and large-scale production are usually capital intensive (BCC, 2024a). Biologics accounted for 23% of the API market by value in 2023 ($56 billion). Biosimilars only account for 18% of the large molecule API market while branded is 82%. Strong influence of scale economies on the manufacturing of active ingredients has led to their manufacture being centered in Asian countries (China and India).

Global trade of pharmaceutical-related organic chemicals was $94 billion in 2023, and human/animal natural inputs (HS-3001) totaled $5 billion. Top categories in 2023 within organic chemicals include hormones ($32 billion), heterocyclic compounds ($30 billion), and antibiotics ($10 billion).

1.2.3 Final products

The size of the global pharmaceutical market/sales in 2023 varies in different reports but is generally estimated around $1.4 trillion (Table A-1). This represents the revenues generated by generic, patented and OTC drugs through hospitals, retail pharmacies and other channels reported at final consumer price including mark-up and taxes. Pharmaceuticals are divided into types based on who can distribute the products to consumers and whether the product is still under patent protection.

Based on FSG (2024i) data for 2023, patented pharmaceuticals accounted for 56% of the world market by value, generics were 33%, and OTC drugs 11%. Similar market shares result when dividing market data for the API market (generic 37% and branded 63%).

Prescription drugs include patented and generic medicines regulated by legislation that requires a physician's prescription before they can be sold to a patient. Except in the US and New Zealand, advertising prescription drugs directly to consumers is illegal (FSG, 2025i). Prescription drugs for less common

diseases (globally or more common in a specific region) are referred to as orphan drugs.

A patented drug is an innovative medicine granted intellectual property protection by a patent office. The patent may encompass a range of claims, such as active ingredient, formulation, mode of action, and gives the patent holder the sole right to sell the drug while the patent is in effect (FSG, 2021h). During patent protection, patent holders enjoy a monopoly period to sell their invention directly or through the activities of a licensee. Patents usually run for 20 years from the date the patent application was filed. In practice, the effective period is usually shorter; it may take years to develop pilot processes to the level necessary for bulk manufacturing, to complete pharmacological and toxicological studies, and to satisfy the appropriate regulatory authorities before the product is brought to the market. Actual patent protection may only provide four to six years of monopoly marketing (BCC, 2021d).

Generic drugs are a bioequivalent medicine that contains the same active ingredient as an originator drug. The originator drug is an innovative medicine that no longer has intellectual property protection due to patent expiry. Some reports include off-patent originator medicines in the generic segment (FSG, 2021h). A simple definition of a generic or biosimilar is one that is no longer protected by patent (BCC, 2024g).

Simple generics are essentially replicas of the original patented drug. Alternatively, there are super generics where the active ingredient is approved and has built a substantial safety record, but the 'super generic' improves the way in which a drug is presented to the patient in terms of dose, treatment regimen, formulation, and/or route (oral, transdermal, inhalation, injectable). These can usually be marketed at premium prices due to the patentability of the improvements that have been incorporated over simple generics. But risks incurred by the developer are much lower than with a completely new drug. For example, the original version might have been given intravenously and the super generic is given orally (BCC, 2021d).

Whether generic versions are created and how quickly they reach the market depends on various factors such as the size of market, duration of use (if a patient will need to take the drug forever, more appealing to make a generic). If the drug is curative, preventative, or short term (antibiotic, vaccine) or end of life (oncology), development of generic versions is less likely.

Over the counter (OTC) medicines do not require a prescription to be sold to patients. These are also known as nonprescription medicines. Most drugs available OTC were once prescription drugs and sold as such for many years. Reclassification from prescription to nonprescription is known as the Rx to OTC switch, and it has brought many APIs under OTC classification. The switch is for the API—not the brand, which means that once a drug is switched to OTC classification, anyone can apply for its marketing license (BCC, 2019). There are two models used for the classification of drugs. One is based on the

U.S. regulatory authorization, and other is used by Europe. Some countries restrict OTC drugs to be sold under the supervision of a qualified person such as a pharmacist. The U.S. has allowed over 800 significant active ingredients encompassing more than 100,000 products to be available OTC.

Exports of final pharmaceutical products were $797 billion in 2023 (Table 1.2). While imperfect, products within HS3002 (blood, immunological, and vaccines) most closely equate to biologics and HS3004 & 3006 small molecule drugs, which had export values of $323 billion and $474 billion respectively in 2023.[2] Trade value of biological products grew the most between 2013 and 2023 (increased by 214%).

Table 1.2. World Pharmaceutical-Related Trade by Value & Stage, 2013-2023

SEGMENT	VALUE ($US BILLIONS)			WORLD SHARES			CHANGE
	2013	2018	2023	2013	2018	2023	2013-23
Pharma organic chemicals (HS 29 codes)	73	83	94	14%	12%	10%	29%
Human/animal substances (HS 3001)	4	4	5	1%	1%	1%	15%
Components (HS 3003)	10	17	17	2%	3%	2%	79%
Blood/immunological products/ vaccines/ micro-organism cultures (HS 3002)	103	182	323	20%	27%	35%	214%
Final products (HS 3004 & 3006)	335	381	474	64%	57%	52%	41%
Inputs/components	87	104	116	17%	16%	13%	34%
Final products	438	563	797	83%	84%	87%	82%
Total	**525**	**667**	**913**				74%

Sources: UNComtrade (2025); based on imports by all reporters in given year.

Definitions of the pharmaceutical industry based on industrial classification systems are included in Appendix Table A-2. Pharmaceutical Industry Definition Across Classification Systems.

1.2.4 PACKAGING AND LOGISTICS

Dosages are classified by their physical form and their route of administration. Dosage forms include solids, liquids, semisolids, and others (gaseous, aerosol suspensions). Manufacturing the finished drug involves packaging in its mode of administration, which could be tablets, a liquid, an injectable, or other drug delivery systems (BCC, 2021a).

2. To improve readability in the report, discussion related to trade will use the term biological products when referencing trade in HS3002 and small molecule drugs when referring to HS3004 and 3006 codes.

Primary **packaging** includes blisters, bottles, syringes, inhalers, vials and ampoules, caps and closures, and dosing droppers. The market is increasing due to the growing popularity of pre-filled syringes (BCC, 2021c). Packaging must consider potential chemical interactions between packaging, API, and excipient materials (BCC, 2021b).

Blister packaging is a preformed container consisting of a multiple compartment component that usually made from a thermoformed plastic sheet that contains up to a dozen individual cavities or Pockets and a flat lid (or backing) component made from plastic, foil, paper, or laminated materials. Each cavity (or pocket) contains one tablet, capsule, or caplet, providing a unit dose format. In the finished pack, the filled compartment component is sealed to the lid and enclosed in an outer box, carton, or wallet-like configuration (Freedonia, 2021).

Bottles/jars and blister packaging account for the largest share of packaging demand with market values of $25 billion and $19 billion in 2020, respectively (Freedonia, 2021). Syringes, parenteral vials and ampuls, and inhalers are the fastest growing. These three packaging types had a combined market value of $18 billion in 2020.

Secondary containers are used for transport, storage, protection, retail display, drug dispensing, and marketing purposes (Freedonia, 2019). This category primarily includes paperboard boxes and cartons and corrugated shipping containers. Box and carton demand reached $10.6 billion in 2020 (Freedonia, 2021). Other packaging-related materials include labels, closures, and other accessories.

Table 1.3.
Pharmaceutical Administration & Packaging

TYPE	DOSAGE	SEGMENT	ADMINISTRATION	THERAPEUTIC AREA	PACKAGING
Solid	Tablet/pill, capsule	Rx, OTC	Oral	Antibiotics, Cardiovascular Cold/cough (pill) Skin (pill, capsule) Digestives (pill)	blister packaging, bottles/jars
Solid	Lozenge, gummy	OTC	Oral	Vitamins/minerals Cold/cough	Bottles, pouches
Solid	Powder, granule	OTC	Oral	Vitamins/minerals Digestives	Bottle
Liquid	--	Rx	Injectable	Vaccines, Diabetes	Parenteral vial Syringe
Aerosol	--	Rx	Oral	Respiratory	Inhaler
Semi-solid	Gel, cream, ointment, lotion	OTC	Topical	Dermatology/skin Analgesics Cold/cough (ointment)	plastic bottles/ jars

Semi-solid	Gel, cream, ointment		Topical	Skin	Ampoule/ampul (sealed glass vial; contain and preserve sample, usually solid or liquid), tubes
Liquid	Syrup, solution, suspension, elixir, drops	OTC	Oral	Cold/cough Digestives Ophthalmology	Bottles (glass or plastics)
Liquid	--	Rx	Injectable	Oncology	IV
Aerosol	--		Oral/Nasal	Cold/cough	Bottle
Aerosol	--		Topical	Dermatology/skin	Bottle

Sources: Aerosols are suspensions of solid (dry powder) or liquid particles dispersed in a gaseous medium.

Final drug formulations are sold to wholesalers/distributors that sell products to healthcare providers (hospitals, doctors), pharmacies, retailers, and governments. In many countries the wholesale segment is concentrated. In the US for example, there are three main companies: AmerisourceBergen Corporation, McKesson Corporation, and Cardinal Health.

1.2.5 THERAPEUTIC MARKET AREAS

Pharmaceuticals are also categorized by therapeutic market areas that generally refer to parts or systems of the body except oncology and anti-infectives (descriptions and valuations are included in Table A-5). The latter is unique because it is the only category in which drugs are primarily taken to prevent illness by preparing a person's immune system to fight a virus if exposed to it or prevent more harmful afflictions. Over 90% of pharmaceuticals are used to treat an ailment rather than prevent it (IBISWorld, 2021).

The largest therapeutic markets by value include metabolic disorders (i.e., diabetes), cardiovascular, oncology, and CNS. Increasing income is often associated with shifting diets, sedentary lifestyles, and increasing levels of stress, which lead to cardiovascular diseases and rise in demand for treatments (IBISWorld, 2021).

Market reports vary in terms of how they segment data resulting in different estimates. Variations exist for segments that include prescription and OTC products such as gastrointestinal, respiratory, CNS, skin, and eye treatments. This is also because the way products can be distributed varies by country. For example, in the United States pain and fever reducing medication is available OTC via almost any distribution outlet whereas these may only be dispensed at outlets classified as pharmacies in other countries.

Pharmaceuticals are typically only available by prescription for therapeutic areas including metabolic disorders, anti-infectives, cardiovascular, oncology, hematology and genito-urinary. Others, including CNS, musculoskeletal,

respiratory, dermatology, gastrointestinal, and ophthalmology, include prescription and OTC options.

While the entire global pharmaceutical market is not concentrated, some therapeutic areas such as oncology and ophthalmology have high concentrations (75-85% of market share held by the top 10 firms). In comparison, metabolic and musculoskeletal disorders have the lowest shares (less than 30%).

Select therapeutic areas including oncology, cardiovascular, and anti-infectives include small and large molecule drugs.[3] Sales of oncology and cardiovascular pharmaceuticals are half small molecule and half biologic. Biologic drug segments may include monoclonal antibodies, therapeutic proteins, stem-cell and gene therapy, and vaccines. Monoclonal antibodies (mAbs) are used to enhance and suppress immune response in various medical conditions and to treat cancer, cardiovascular and cerebrovascular diseases. Therapeutic proteins provide therapies for diseases, such as diabetes, cancer, infectious diseases, hemophilia, and anemia. Stem-cell therapy is the use of stem cells to treat or prevent a disease or condition. Gene therapy is introduction of normal genes into cells to correct genetic disorders (TBRC, 2020b). The top 10 biologics companies accounted for 42% of the global market in 2020. These firms include AbbVie, J&J, Amgen, Sanofi, Roche, GSK, Novartis, Pfizer, Teva, and CSL (TBRC, 2021a).

Covid-19 vaccines (Table A-6) have been the most widely taken pharmaceutical in history, and development and sales of these vaccines were brought to market under new emergency protocols. The global market for Covid-19 vaccines was approximately $80 billion in both 2021 and 2022 and $33 billion in 2023. mRNA vaccines (Pfizer/BioNTech, Moderna) accounted for the largest market share, followed by live attenuated/inactivated (Sinovac and Sinopharm) and viral vector (J&J, AstraZeneca, Sputnik V) of the market. As of February 2022, there were 33 vaccines approved by at least one country (VIPER COVID-19 Vaccine Tracker Team, 2022).

1.3 GEOGRAPHIC DISTRIBUTION

This section discusses the main countries in each stage and the value of production/trade. The pharmaceutical industry is dominated by firms originating from the US, EU, and Japan, collectively accounting for over two thirds of both pharmaceutical production and sales (IBISWorld, 2021).

World trade of pharmaceutical final products was $797 billion in 2023; top exporters are Germany, Ireland, the US, and Switzerland. The top 10 exporters accounted for around three-quarters of exports from 2013-2023 and have generally been the same. Ireland and China's export values more than doubled between 2013 and 2023 (Table 1.4). These estimates and top pharmaceutical exporters are like those from industry reports (Table A-4).

3. Market reports may separate small and large molecule and therapeutic area, which leads to different market sizes.

Table 1.4.
Top 10 Pharma Final Product Exporters, by Value & Year, 2013, 2018, 2023

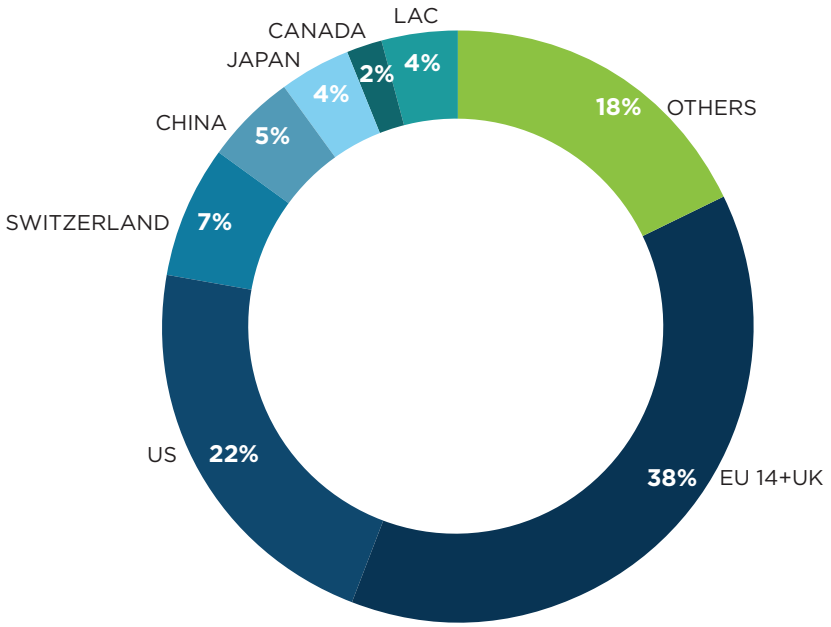
EXPORTER	VALUE ($US BILLIONS)			WORLD SHARE			CHANGE
	2013	2018	2023	2013	2018	2023	2013-23
World	**438**	**563**	**797**				**82%**
Germany	70	87	108	16%	15%	14%	56%
Ireland	23	61	95	5%	11%	12%	320%
United States	52	64	93	12%	11%	12%	78%
Switzerland	43	56	71	10%	10%	9%	66%
Belgium	26	28	47	6%	5%	6%	79%
Italy	25	32	44	6%	6%	6%	75%
Netherlands	22	29	41	5%	5%	5%	80%
France	34	35	37	8%	6%	5%	11%
India	12	16	24	3%	3%	3%	107%
Spain	12	13	23	3%	2%	3%	86%
UK	24	24	22	5%	4%	3%	-7%
LAC	8	6	7	2%	1%	1%	-13%
China	2	4	10	1%	1%	1%	327%

Source/notes: UNComtrade (2025); based on HS as reported (3002, 3004, 3006 codes); exports based on imports.

India is the leading supplier of generic drugs (BCC, 2021a). India is the 9th largest final product exporter by value, with most exports from 'other' pharmaceuticals (HS-300490) and antibiotics. By volume India ranks higher, however generics have much lower values than patented drugs. Indian generics manufacturers have also started to offshore production, thus reducing export values from India.

Top importers of final products are the US, Western European countries, Switzerland, China, and Japan (Figure 1.3). Among top importers, growth has been most notable from the US, Switzerland, and China between 2013 and 2023.

Figure 1.3.
Pharmaceutical Final Product Importers (2023), World Shares by Value



Source/notes: UNComtrade (2025). EU14+UK includes Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, and the United Kingdom. Russia is a top importer that has not reported for 2023.

Trade data cannot be used to divide the pharmaceutical market into prescription, OTC, patented or generics, so market reports are used. The largest regional prescription market is North America ($457 billion), followed by Asia-Pacific, Europe, then Latin America ($54 billion; 4% of world market)(FSG, 2024j). Asia Pacific is the largest regional generic market ($224 billion). In 2023 it accounted for 46% of the global generic drug market by value (FSG, 2024g). Generics account for over 60% of the Asia-Pacific prescription market value compared to the world average of 37%. This is driven by China and India where over 70% of pharma sales are generics. In comparison, generics are 20% of the North American market, 36% of the European market and 43% for Latin America. The largest regional market for OTC drugs is Europe, followed by Asia-Pacific, North America then Latin America (FSG, 2024h). Africa and the Middle East account for lower global market shares than Latin America in all three segments.

Components: Trade along the pharmaceutical supply chain is primarily in inputs and final products; there is minimal trade in products considered components or intermediates. In 2023, trade of intermediate pharmaceutical products (HS-3003) was only $17.2 billion (Table 1.5). Trade in components is primarily between European countries and North America.

Inputs: Imports of natural inputs to pharmaceuticals (i.e., human and animal materials within HS-3001) totaled $4.9 billion in 2023. China accounted for 17% of exports, followed by the US (16%)(Table 1.5).

Table 1.5.
Top Importers & Exporters, by Value, 2023

STAGE	HS CODES	DEFINITIONS	IMPORT VALUE $US BILLIONS	TOP EXPORTERS	TOP IMPORTERS
Inputs (chemicals)	29	Pharmaceutical-related organic chemicals	$94	Ireland: 22% China: 19% Switzerland: 14%	US: 23% Germany: 10% Italy: 9%
Inputs (natural)	3001	Human/animal substances (glands/organs for therapeutic uses)	$5	China: 17% US: 16% Singapore: 13%	France: 19% Singapore: 11% US: 9%
Components	3003	Medicaments of two or more constituents mixed for therapeutic uses, not put up in measured doses/ or for retail sale	$17	US: 18% Portugal: 18% Ireland: 17%	Belgium: 22% US: 14% Canada: 11.5%
Final (most)/ (biologics)	3002	Blood/immunological products/vaccines/micro-organism cultures	$323	Ireland: 17% US: 16% Germany: 13%	US: 25% Germany: 11% Belgium: 8%
Final (small molecule)	3004 & 3006 codes	Small molecule (except perhaps 300439, $37B)	$474	Germany: 14% US: 9% Ireland: 8%	US: 19% Switzerland: 8.5% Germany: 7%
Total			$913		

Sources: UNComtrade (2025).

World trade of pharmaceutical organic chemical inputs was $94 billion in 2023; up from $73 billion in 2013. The top ten exporters have accounted for over 80% of exports since 2013 with Ireland, China, and Switzerland in the top positions (Table 1.6). China is the top exporter of bulk inputs for more established drugs such as antibiotics, vitamins, and alkaloids. Ireland is the top exporter of hormones and sulfonamides, inputs into higher value, lower volume pharmaceutical products. Germany is the top exporter of sugars, which are used as excipients.

Table 1.6.
Top Exporters of Pharma Organic Chemical Inputs, by Value, 2013-2023

EXPORTER	VALUE ($US, BILLIONS)			WORLD SHARE			CHANGE
	2013	2018	2023	2013	2018	2023	2013-23
World	**72.9**	**83.1**	**93.9**				29%
Ireland	12.7	17.5	20.9	17.4%	21.0%	22.2%	65%
China	9.8	13.9	17.7	13.4%	16.8%	18.8%	81%
Switzerland	7.4	8.8	13.5	10.1%	10.6%	14.4%	83%
United States	7.9	6.1	8.3	10.8%	7.3%	8.9%	6%
Germany	4.0	3.9	4.1	5.5%	4.7%	4.4%	3%
India	2.7	3.0	4.0	3.7%	3.6%	4.3%	49%

Italy	2.6	5.5	3.2	3.6%	6.6%	3.4%	22%
Singapore	5.2	4.0	2.9	7.2%	4.8%	3.1%	-44%
Denmark	--	--	2.3	--	--	2.4%	173%
Spain	--	--	2.2	--	--	2.4%	158%
Belgium	--	3.4	--	--	4.1%	--	7%
UK	2.5	3.4	--	3.4%	4.1%	--	-23%
Netherlands	5.0	--	--	6.8%	--	--	-64%
Top 10 (in given year)	**59.7**	**69.6**	**79.1**	**81.9%**	**83.7%**	**84.3%**	33%
LAC	0.7	0.7	1.2	1.0%	0.9%	1.3%	60%

Source/notes: UNComtrade (2025); exports based on imports.

Top pharma final product exporters are also among the top importers of inputs. For example, the US imports more than 80% of raw materials (BCC, 2021a). The top two importers of pharma organic chemical inputs (US, Germany) accounted for one-third of world imports in 2023. Belgium, Slovenia, and Spain's organic chemical imports have increased imports significantly over the decade as have their final pharma product exports. China's imports and exports of organic chemical inputs are increasing.

China is a key player in API manufacturing. BCC (2024a) states that China is responsible for approximately 40% of the world's API production volume.[4] The Chinese API supplier landscape is fragmented and as of 2019 there were more than 12,000 API suppliers in the country. API exports accounted for 80% of the value of production at $30 billion (BCC, 2021a).

Pharmaceutical activity is clustered in a few regions around the world that specialize in different areas (Table 1.7). Pharmaceutical R&D and patented pharma firm headquarters and production are primarily in the United States and Western European countries. Contract manufacturing occurs within the same country or in nearby countries such as Ireland and Belgium in Europe. Contract research is also concentrated in the same countries, but not always in the same clusters. In the United States, for example, North Carolina is the home to most of the largest CROs. Eastern Europe (Russia and Ukraine), India and China are offshore destinations for drug discovery outsourcing. These countries have scientific expertise, cost advantage (due to lower wages and in some cases significant tax incentives) and the infrastructure needed to successfully perform drug discovery activities (Kalorama, 2020). In biotech, the US accounted for 55% of the global industry in 2020; biotech activity is increasing in China and South Korea, which collectively accounted for 10% in 2020 (Torreya Partners, 2021).

4. Based on data from (The Chinese API Market, Mantell Associates, 2024).

Table 1.7.
Pharmaceutical GVC Activities by Geography

SEGMENT	COUNTRIES/REGIONS
CRO	US (NC, MA)
CRO discovery offshore outsourcing	India, China, Eastern Europe (specifically Russia and Ukraine)
API manufacturing	China (domestic & export), India (domestic), US, Europe (Ireland, Switzerland, Germany, Belgium)
Generic final products	India (domestic & exports); domestic firm production in-country
Patented final products	US (NY, Boston, Chicago, Indiana, San Francisco) Europe (Germany, Switzerland, Italy, France, Netherlands, UK)
Biotech	US (Boston, MA; San Francisco & San Diego, CA; NY; DC) Europe (Denmark, Netherlands) Asia (China; South Korea)
Patented final product outsourcing (CMO/CDMO)	Belgium, Ireland, US
Packaging	Near formulation
Labeling	May occur closer to final market if imported

Source: Author

1.4
MAIN ACTORS IN EACH STAGE OF THE VALUE CHAIN

Pharmaceutical manufacturers fall into several categories based on the range of value-adding activities they perform and the type of product they perform the activities for. This section identifies the main companies in each stage of the chain, associated revenue, and describes the type of contractual arrangements observed between main actors in the chain.

Overall industry concentration is low but is higher in specific therapeutic segments and product areas. The largest company controls less than 5% of the global market and the top ten companies generate approximately 30% of revenue (IBISWorld, 2021; TBRC, 2021b). Mergers and acquisitions are common in pharma with firms frequently buying and selling products in particular segments, therapeutic areas, and geographic areas. Large firms often enter new geographic areas via acquisitions.

Global pharmaceutical firms focus on developing and commercializing new, patented drugs. This group of firms can also be referred to as 'lead firms' in the GVC literature, branded or patented drug manufacturers, or global MNEs. These companies spend significant shares of revenue on R&D. They are primarily based in the US and Western Europe and own production sites for APIs and final formulations however they also use contract manufacturers, development, and research firms for some activities (primarily within the US and Western Europe) and purchase some APIs from merchant manufacturers. These firms also have licensing agreements with other companies to produce their products in certain geographic areas.

Table 1.8 lists top patented pharmaceutical companies. The size of the global patented pharmaceutical industry was $802 billion in 2023 (Table A-1). Based on data from 2020, the top 10 companies may account for as much as 60% of patented revenue.

Table 1.8.
Top Firms in the Pharmaceutical (Patented) Segment, by Revenue

FIRM	HQ	REVENUE (2020), US$B	EMP. (2020)	TYPE	SEGMENTS/ DIVISIONS	THERAPEUTIC AREAS	MANUFACTURING NON-LAC	LATIN AMERICA
Roche acquired Genentech 2009	Switzerland	$52.8 (pharma)	101,465	Rx, SM, Biologics	Pharma & diagnostic divisions	Oncology 1st Hematology 4th Ophthalmology 5th	Switzerland, US, Japan	Brazil (closing) Mexico
J&J	US (NJ)	$45.6 (pharma)	134,500	Rx, Biologics, OTC	Pharma, medical devices	Cardiovascular 3rd Oncology 3rd CNS 3rd	90 facilities: US, Ireland (4) Belgium	
Novartis	Switzerland	$40.8 (patented Rx)	105,794	Rx, Biologics, Generic	Innovative Medicine, Sandoz	Metabolic 2nd Oncology 2nd Respiratory 4th CNS 4th	Switzerland (2), Austria, France, US (IL, 1), Ireland	Argentina Brazil
Merck & Co.	US (NJ)	$48.0	74,000	Rx, Biologics, Vaccines		Metabolic 4th Vaccines 2nd Oncology	US, Ireland (5) Australia, Canada, Japan, Singapore, S. Africa	Brazil Mexico Chile, mfg. & trials
AbbVie spin-off of Abbott Labs (2013)	US (IL)	$45.8	48,000	Rx Biologics CMO	Acquired Allergan (May 2020)	Biologics Musculoskeletal Ophthalmology Anti-infective Oncology	US, P. Rico, Germany, Ireland, Italy, Belgium, France, Singapore	Brazil, Costa Rica
BMS acquired Celgene, 2019	US (NY)	$42.5	30,250	Rx, Biologics	Pharma only	Cardiovascular 1st Hematology 2nd Musculoskeletal 3rd Oncology 6th	US (incl. P. Rico), Ireland, Switzerland	None
Pfizer	US (NY)	$41.9	78,500	Rx, Biologics, Vaccines, CMO, OTC		CNS 2nd Musculoskeletal 2nd Oncology 4th Vaccines, 4th	> 50: Belgium, Germany, Ireland, Italy, Japan, China, Philippines, Singapore, US (incl. P. Rico)	Brazil
Sanofi (Sanofi-Pasteur, vaccine arm)	France (Paris)	$40.0	99,412	Rx, OTC, Generic, Biologics, Vaccines		Musculoskeletal 1st Genito-Urinary 1st Cardiovascular 2nd Metabolic 3rd Vaccines 3rd	France, Ireland, Belgium, Germany, Hungary, Italy, Spain, UK, US, Japan, China	Argentina (1 vaccine)
GSK	UK (London)	$32.7	94,066	Rx, Biologics	Pharma, Vaccines, CH	Respiratory 1st Anti-infective 2nd Vaccines 1st	86 mfg. sites UK, US, Ireland, Belgium	Brazil (2) Mexico Colombia
Takeda Merged w/ Shire 2018	Japan (Tokyo)	$27.8	47,009	Rx	Rare diseases, PDT	Gastrointestinal 2nd CNS 2nd	Japan, Ireland, Austria, Belgium, Switzerland, Singapore, US	sold LAC market to local firms

Source/notes: revenue and employment for 2020 unless otherwise noted (revenue may vary in different sources due to exchange rate valuations). Therapeutic area data and ranks from TBRC reports. Revenue, employees, and locations primarily from annual reports or company websites.

Generic drug manufacturers produce pharmaceuticals that are no longer under patent protection. Many generic manufacturers also conduct R&D and develop patented products, but at present, more of their revenue is generated from the sale of generic products. Market reports suggest the size of the

global generic pharmaceutical industry was $474 billion in 2023 (Table A-1). It is important to note that estimates may use different definitions for the generics segment – some include revenue of off-patent branded medications while others do not. Regardless, industry concentration is lower in generics compared to patented medications (IBISWorld, 2021). The top 10 companies account for 15-17% of generic revenue in 2019-20 (BCC, 2021d; FSG, 2021m). Generics manufacturers also tend to be merchant API producers.

The generic market consists of three large MNEs (Viatris, Sandoz, and Teva), Indian generic manufacturers with operations in India and other countries, and domestic generic firms. There is a sizeable gap between the top three global companies' generic drug revenue and the remaining top companies (BCC, 2021d). Novartis (via Sandoz) is the only top patented pharma MNE to also be a top firm in generics. Pfizer, via the off-patent branded and generics Upjohn business segment, was a competitor, but sold this segment to Mylan to create a new company in 2020 called Viatris (BCC, 2021d).

Table 1.9.
Top Firms in Pharmaceutical Generics, by Revenue

Firm	HQ	Revenue (2020), US$B			Emp. (2020)	Types	Mfg.	Latin America
		Total	Generics	APIs				
Viatris	US (PA)	$12-22[5]	$6.3 (2022)		45,000	Generics, API	50 locations: 15 for APIs	Mexico (from Mylan)
Teva	Israel	$16.7	$9.3	$0.8, API to 3rd parties	39,717	Generics, Rx-Oncology, CNS, Biologics, API	46 dose/ packaging plants, 22 countries: 15 API	Laboratorio Chile (acquired 2005); Peru Infarmasa (acquired 2011); Venezuela (Elmor)[6] API: Mexico (1)
Novartis Sandoz	Germany	$9.9	$9.9	--		Generics	Germany (2), Austria	Brazil (2)
Fresenius Kabi[7]	Germany	$7.9	$3.3		40,519	Generics BCMO IV drugs		Brazil (2,000 emp.)
Sun	India	$4.5	$4.3, 2019	$0.3	37,000	Generics, API	44 facilities; 15 API; 30 finished	N/A
Aurobindo Pharma	India	$3.3	$3, 2019	$0.4	19,364	Generics, API	26 sites 15 final; 11 API: India	Brazil (1, Antibiotics)

5. Estimated revenue. Pfizer's Upjohn segment revenue $10B, 2019)(MarketLine, 2021a). Mylan revenue: $12B, 2020 (Fitch Solutions, 2021o). Upjohn brands: Lyrica, Lipitor, Norvasc, Celebrex, Viagra.
6. Branded, generic & OTC. IVAX acquired (2002); Teva acquired (2006)(FSG, 2021o).
7. Sales include drug delivery devices, medical devices, and transfusion technology products. Location in DR has 3,500 employees but is not pharma (apheresis sets to collect blood components such as platelets).

Firm	HQ	Revenue (2020), US$B			Emp. (2020)	Types	Mfg.	Latin America
		Total	Generics	APIs				
Cipla	India	$2.6	$2.3, 2019	$0.1	25,672	Generics, APIs	46 facilities, 5 countries: API: India.	Brazil (Duomed, acquired 2015)
Dr. Reddy's	India	$2.4	$1.9	$0.35	22,681 (2017)	Generics, APIs, CMO	API: India (7), UK (1), US (1)	API: Mexico (1, Cuernavaca)
Hikma	UK (London)	$2.3	$2.2, 2019			Generics		
Lupin	India	$2.0	$2, 2019	$0.18	20,000 (est.)	Generics, APIs	15 locations: India, US (NJ)	Brazil (570 emp.), Mexico (310 emp.) (mfg. & R&D); liquids & solids
Sanofi	France (Paris)	$1.1	$1.1, 2019 & 2020			Brands: Zentiva, Medley, Genfar, Winthrop, Globalpharma		Brazil (2 generics & CMO)[8] Colombia, Mexico
Glenmark	India (Mumbai)	$1.5	$0.2, Generics & APIs		10,964	Oncology, Respiratory, Dermatology	India (11, 7 final, 4 API), US (1), Czech Republic (1)	Argentina (Pilar, BA); oncology, injectables
Generics	Teva, Viatris, Sandoz, Nichi-Iko, Sun, Fresenius Kabi, STADA, Aurobindo (FSG, 2021m)							
Generics	Mylan, Upjohn (Pfizer), Sandoz (Novartis), Teva, Sun, Fresenius Kabi, Aurobindo, Cipla, Hikma, Lupin (2019) (BCC. top 10, 15% of market, 2019) (BCC, 2021d; Statista, 2018)							

Source/notes: Revenue and employment data is for 2020 unless otherwise stated. Generic drug revenue 2019: Leading Generic Drug Companies, by Sales (BCC, 2021d) from company statements. CMO (Kalorama, 2017).

OTC products are commercialized by three types of firms: pharmaceutical drug manufacturers that also have prescription products, store brands (manufactured by third parties), and consumer goods (BCC, 2019). Top companies in OTC are leading pharma MNEs, plus global consumer product companies Bayer and P&G. Two European companies, Perrigo and Reckitt, focus on OTC. Perrigo is unique in that they manufacture unbranded/generic OTC products. Amazon entered the OTC drugs and dietary supplements business in 2018, and the products are developed by Perrigo. There are about sixty products in their Basic Care line. Prices are competitive with brands from Walgreens, CVS, Walmart, and Target (BCC, 2019).

8. Acquired Medley (2010) for $664M (Brazil), Laboratorios Genfar (2012) & Genzyme (Argentina) & Laboratorios Kendrick, Mexico (2009-10). All were generic producers.

Market reports suggest the size of the global OTC pharmaceutical industry was approximately $155 billion in 2023 (Table A-1). Based on this, the top 10 firms account for over 40% of global OTC market revenue. Switching a brand from prescription to OTC has been a strategy among pharmaceutical companies for 20 years to revive the brand. Most top players reclassified their own products or acquired patented drug formulations reclassified into OTC drugs (BCC, 2019).

Table 1.10.
Top OTC Firms

FIRM	HQ	REVENUE, $US BILLIONS	TYPE	THERAPEUTIC AREAS	OTC BRANDS	LATIN AMERICA
J&J	US (NJ)	$14 (CH)	OTC	CNS	Tylenol, Sudafed, Benadryl, Zyrtec, Motrin	
GSK	UK (London)	$13.6 (CH)	OTC[9]	Analgesics (25% revenue)	Panadol, Excedrin, Abreva	
Pfizer	US (NY)	< $2.0	JV w/ GSK		Advil, Robitussin, Centrum, Thermacare	
Bayer	Germany	$6.2 (CH)	OTC[10]	Gastrointestinal	Aspirin, Canesten, Bepanthen, Iberogast	Argentina-CH Mexico-CH Guatemala[11]
Reckitt Benckiser	UK	$6.6	OTC[12]	Dermatology Genito-Urinary Respiratory	Hygiene, health, nutrition (vitamins); Durex	Mexico (nutrition)
Perrigo	Ireland	$5.1	OTC CMO	Dermatology	Generic private label; Top customer (Walmart); all OTC (sold Rx segment 2021)	Mexico
P&G	US (OH)	$3.8	OTC[13]	Musculoskeletal	Prilosec OTC, Pepto-Bismol, Vicks Nyquil	
Sanofi	France (Paris)	$2.9	OTC	CNS	Allegra OTC, Maalox, Dulcolax	Argentina (1)[14]
Taisho	Japan	$2.1 (OTC)	OTC, Rx ($0.5B)		RiUP, Pabron	Mexico

Sources: (BCC, 2019; Statista, 2020b) company annual reports/websites; data for 2020 unless otherwise noted.

Contract Manufacturing Organizations (CMO) serve pharmaceutical companies of all sizes. CMOs may engage in one or all stages of production including APIs, final formulations, and or fill/finish services to drug manufacturers. Firms use CMOs because they may not have the resources to

9. Consumer healthcare was JV with Novartis. GSK bought out Novartis in 2018/19. Established new JV for consumer healthcare with Pfizer in 2019. Pfizer owns 32% of JV.
10. 2014, Merck sold its Consumer Care business to Bayer for $14.2B. Sales for this unit were $1.9B, 2013. Bayer also acquired rights for Claritin Rx & Afrin Rx in international markets (Kalorama, 2018).
11. March 2019, Bayer Guatemala has 470 employees, 204 (CH plant-also US$42M technological upgrade to meet requirements of health authorities of 10 countries to which it currently exports), 104 (Amatitlán, agrochemical) and 162 (main office); 40% of Bayer employees in C. America/Caribbean. March 2019, (Fitch Solutions, 2021a).
12. Total revenue ~$18 billion; $11B (health & nutrition); $6.6B (health only).
13. 2018: acquired Merck KGaA, Germany; was selling OTC consumer healthcare products, in Europe, Latin America, and Asia. P&G dissolved its PGT Healthcare Partnership (venture between P&G and Teva in OTC drugs). The transaction completed July 2018 (BCC, 2019). P&G revenue only includes personal healthcare segment.
14. Acquired 18 OTC products via acquisition of Gramon in Argentina.

maintain in-house manufacturing facilities to meet demand or prefer to focus their human resources on core competencies such as R&D and outsource activities such as manufacturing (BCC, 2021a). Scaling production requires a different skillset and can be expensive, particularly for biologics. A 35,000 liter plant is approximately $450 million in fixed costs and $125 million in annual operating expenses (Kalorama, 2017).

CMOs increasingly carry out at least some development services and are often referred to as contract development manufacturing organizations (CDMO). CDMOs are appealing to drug developers because it is more effective to form strategic partnerships with a CDMO with integrated capabilities than individual CRO & CMOs (BCC, 2020; Kalorama, 2017). CMOs that produce APIs are likely to be involved in CRO drug discovery services.

Top CMOs are listed in Table 1.11. CMOs are large, medium, or small based on revenue and specialization. Large firms are generally CDMOs and offer a wide range of services across therapeutic areas. Medium-sized firms generally have annual revenues between $1 and 3 billion and focus on final dosage or fill/finish services in a more limited number of areas. Small firms have revenues below $1 billion, are localized and offer services to a limited number of customers. They may focus on a niche area like biologics or provide services in one country.

Table 1.11.
Top Contract Manufacturing Organizations

FIRM	HQ	REVENUE (2020), US$ BILLIONS	TYPE	GLOBAL MANUFACTURING LOCATIONS	LATIN AMERICA LOCATIONS
Thermo Fisher Scientific (Patheon)	US/ Netherlands	$3-5 (est.)	CDMO API CMO Packaging	US (NC)	
Lonza	Switzerland	$5.0	CDMO API CMO BCMO	Europe, Switzerland, US (NH)	Mexico (Puebla, capsules)
Catalent	US (NJ)	$3.0	API CMO	US (IN)	Argentina (softgel), Brazil (2, softgel/ packaging) Uruguay (services)
Fareva	France	$1-3	CMO API CMO	Europe, US (VA)	Pharma: Colombia (Fareva Villa Rica)
Curia (formerly AMRI)	US (NY)	$1-3	CDMO API CMO	US, Singapore, China, India	
Siegfried	Switzerland	$1-3	API CMO[15]	Switzerland, France, Germany, US, China, Malta	
Delpharm	France	$1-3		France, Italy, Belgium	

15. Siegfried acquired BASF's API mfg. for US$302M. Siegfried's API focus has expanded to include ephedrine, pseudoephedrine and caffeine APIs and custom API mfg. in Germany, Switzerland, and France (BCC, 2021a).

FIRM	HQ	REVENUE (2020), US$ BILLIONS	TYPE	GLOBAL MANUFACTURING LOCATIONS	LATIN AMERICA LOCATIONS
Recipharm	Sweden	$1-3	CDMO	US, France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, UK	
Baxter Biopharma	US (IN)	< $1		US (IN)	Mexico, DR, Costa Rica, Brazil, Colombia
CMO/CDMO	$80, 2020	$72-124 2023			

Sources: Kalorama (2017, 2022); BCC (2024e).

Contract manufacturing of final formulations is still relatively nascent in the pharmaceutical industry. CMO value was $48 billion in 2023 for final products; this suggests only 3% of drugs are produced by CMOs. This also coincides with low revenues of CMOs compared to firms in other segments. CMO activities are primarily carried out in the United States and Europe. That is, activities are outsourced, but not necessarily offshore. Europe is the headquarters of more contract manufacturers and the US contract research, particularly biotech research. Contract manufacturers are more likely to also engage in some discovery services (i.e., CDMO model) whereas contract research organizations typically only engage in R&D (basic research/discovery/clinical trials).

Contract Research Organizations (CROs) offer research services to the pharmaceutical, biotechnology and medical device industries on a contract basis. Pharmaceutical and biotechnology companies that sponsor drug development research rely on CROs to help reduce costs and the time to bring new drugs to market. Global CROs offer global infrastructure, therapeutic expertise, and the ability to manage large, complex trials. Drug development services offered by CROs include clinical trial management; clinical, medical and safety monitoring; clinical lab services for processing trial samples; data management, biostatistics, and medical writing for preparation of submissions to regulatory agencies (BCC, 2021c).

CROs primarily engage in development services and clinical trials. The CRO global market (2023) is estimated to be $103 billion (BCC, 2024d). Clinical trials account for 75% of market revenue. Oncology accounts for 60% of the market by therapeutic area. The global pharma R&D industry was valued at $301 billion, which suggests approximately one-third of R&D is carried out by CROs/outsourced.

Mergers and acquisitions in the CRO market are common, particularly among the top five firms. In 2021 Thermo Fisher Scientific acquired PPD and ICON acquired PRA Health Sciences. LabCorp entered the CRO industry via acquisitions of Covance (2015) and Chiltern (2017). IQVIA is the result of the merger of Quintiles and IMS Holdings (2017) and Syneos Health is the merger of InVentiv Health and INC Research. Table 1.12 presents information on top companies; revenue listed is specific to CRO activities when possible.

Contract research services for drug discovery is more fragmented. Hundreds of outsourcing contractors worldwide provide a wide range of drug discovery services; even the leading contractors hold less than 5% of the total contract drug discovery market (Kalorama, 2020). Drug discovery outsourcing can provide cost-saving benefits, and strategic benefits such as access to innovative technology, faster response times, benchmark internal programs, and on-going process improvements (Kalorama, 2020).

Table 1.12.
Leading Contract Research Organizations (CROs)

FIRM	HQ	REVENUE 2020, $B	ACTIVITIES	LOCATIONS	LATIN AMERICA
IQVIA (Quintiles/IMS Holdings merger)	US (NC)	$6.5	Phase II-IV Biotech	US, Japan, Europe, Russia, India, China	Brazil, Guatemala (2007)
ICON (acquired PRA Health Sciences 2021)	Ireland	$6.0	Clinical trials	US	Argentina, Brazil, Chile, Colombia, Guatemala, Mexico, Peru
LabCorp (acquired Covance 2015, Chiltern 2017)	US (NC)	$4.9			Brazil (from Covance & Chiltern)
Thermo Fisher Scientific: PPD (acquired 2021)	US (NC)	$4.7	Biotech	China	Argentina, Brazil (2), Chile, Colombia, Mexico, Peru
Syneos Health (former InVentiv Health & INC Research)	US (NC)	$4.4	Biotech		Argentina, Brazil (2), Chile, Colombia, Mexico (2), Peru
CRL	US (MA)	$2.9	Discovery Development	China	Brazil
WuxiApptec	China (Shanghai)	$2.5	CRO, CMO Discovery	China, US (4)	--
Parexel	US (MA/ NC)	$1.3	Biotech	US	Argentina, Brazil, Mexico
Medpace	US (OH)	$0.9	Development		

Sources: (Statista, 2021b); same top CROs in (BCC, 2021c) except Lonza is listed and not Medpace.

Inputs: APIs & Excipients

Companies that manufacture APIs often also produce other products for the pharmaceutical industry or other industries. BCC (2021a) divides API manufacturers into three categories that each account for around one-third of the market.

Large pharmaceutical companies such as those listed in Table 1.8, manufacture the APIs used to formulate final products in their in-house production units. These firms are at least partially vertically integrated. These manufacturers

manage their accounts for APIs at internal transfer prices set by the respective API manufacturing divisions. Captive API production accounts for 39% of the API market (BCC, 2021a). It is more common for patented and new prescription drugs and is more likely to occur near final formulation (and less likely to be accounted for in international trade). Merchant manufacturers (32%) produce APIs for sale in the open market. They sell to distributors or private traders who, in turn, sell the APIs to pharmaceutical companies. They are more likely to produce generic APIs. Generic drug manufacturers also tend to be merchant API producers (Table 1.9). CMOs (28% market share) serve companies of all sizes. Some are vertically integrated and offer formulation, fill and finish services (BCC, 2021a).

The excipients market is fragmented, with many players offering different types of specialty and commodity excipients. The companies are grouped into three tiers based on the diversity of their products and presence in different geographies. Approximately 45% of the excipients market is held by Tier 1 companies. These players have a global presence and seek to expand their business in new markets by collaborating with local distributors, acquiring local companies, or establishing facilities in new regions. Excipients are not the only focus of these enterprises; they provide a wide range of products for pharmaceutical formulations and other industries. Tier 2 accounts for 35%; these companies are known for specialty offerings. For example, Calumet specializes in naphthenic and paraffinic oils, aliphatic solvents, and paraffin waxes. The remaining 20% is Tier 3. These smaller firms offer unique, customized, and specialized products for many pharmaceutical formulators (BCC, 2021b). There is a growing market for specialty excipients. Thus, it is expected that Tier 3 will hold 25% of the market within five years.

Table 1.13.
Top Pharmaceutical Input Firms: APIs & Excipients

SEGMENT	TOP FIRMS
API merchant	Teva, Viatris
API CMO	Cambrex, Johnson Matthey, Patheon, Catalent, Lonza, Curia, Siegfried
API (China, merchant)	CSPC Pharmaceutical, Apeloa Kangyu, Zhejiang Huahai Pharma, Zhejiang Medicine, Zhejiang Chemicals, Shandong Xinhua Pharma. Others: Shanghai Acebright Pharma Group, United Labs, Yifan Pharma, Tianxin Pharma
API (India, merchant)	Key companies: Sun Pharma, Dr Reddy's, Aurobindo, Cipla. Others: Piramal, Divis Laboratories, Aarti Industries, Granules India, Hikal, Hetero, Neuland Labs, Natco Pharma, Alembic Pharmaceuticals, Suven Life Sciences
Excipients	Tier 1: Ashland, Dow DuPont, BASF, Cargill, Roquette (2017: acquired Brazil-based excipients division, Itacel), FERRES, Croda International, Evonik Degussa, Lubrizol
	Tier 2: Gattefosse, Rousselot, Merck, AkzoNobel, Gelita, Archer Daniels Midland (ADM), JRS Pharma, Associated British Foods, Asahi Kaesi, Meggle Pharma, P&G Chemicals, Seppic, Colorcon, Perrigo, and Calumet Specialty Products.
	Tier 3: Avantor, Novazymes, Omya, Fuji Health Science, Lanxess, Cabot, Corbion, Ingredion, Innophos, Kronos Worldwide, Minerals Technologies (specialty minerals, mineral-based synthetic products), Solvay, Eastman Chemical, PCAS (Seqens), Imerys

Sources: (BCC, 2021a, 2021b); company lists are non-exhaustive.

Packaging: Freedonia (2021) valued the pharmaceutical packaging market at $84 billion in 2020. The size of the contract pharmaceutical packaging market varies from $11 to $59 billion in 2020 (BCC, 2021c; Freedonia, 2021). Freedonia (2021) suggests around 30% of packaging is captive (occurs in-house by final formulation firms) and 70% is by contract organizations. Both reports suggest the packaging market is fragmented. Firms specialize in different types of containers and locations tend to be near final formulation sites except country-specific labeling which often occurs in a regional distribution center or in-country. Some of the larger packaging firms are listed in Table 1.14.

Table 1.14.
Pharmaceutical-Related Packaging Companies

FIRM	INDUSTRIES	REVENUE	MARKET SHARE		PACKAGING TYPES
		2020, $B	2020	2016	
Amcor	Multiple	$2.5	4%	12%	bottles, jars, blister, IV containers, pouches
Becton Dickinson (BD)	Pharma-specific	$1.6	3%	--	syringes, inhalers
West Pharmaceutical Services (WPS)	Pharma-specific	$1.5	3%	*	syringes, parenteral vials; location in Brazil
WestRock	Multiple		*	8%	blister packaging, boxes, cartons
Schott AG			*	7.5%	parenteral vials, inhalers, tubes
CCL Industries	Multiple		*	7%	blister packaging, labels, tubes
Vetter Pharma Int'l	Pharma-specific		*	*	syringes, parenteral vials
AptarGroup	Multiple		*		bottles, jars, blister, syringes, inhalers
Berry Global	Multiple		*		bottles, jars, tubes, prescription containers

Sources: industries, 2020 data, types (Freedonia, 2019, 2021); 2016 (BCC, 2021c). Industries: multiple indicates the firm offers packaging products to pharma and other industries. (*) indicates company was included in the report.

1.5
INSTITUTIONAL ACTORS AND INFLUENCE

This section covers key institutional actors that influence the structure, location, and growth of the value chain, such as governments, multilateral agencies, and industry associations.

The pharmaceutical industry is highly regulated, with many rules to ensure safety, efficacy, and affordability of pharmaceutical products. Regulatory frameworks, which vary by country, may pose a barrier to potential industry entrants that want to have a global market reach. The cost of complying with regulations, such as marketing, manufacturing inspections, licensing and clinical trial regulations acts as a barrier to potential entrants. Prices for

pharmaceutical products are not set by market forces in many countries, but instead by government policies that have been designed to curb escalating healthcare costs. Additionally, the costs of government-mandated trials and continuous manufacturing oversight can discourage a new pharmaceutical company from entering the market (IBISWorld, 2021).

Governing institutions can be broadly grouped into four categories (global, regional, national, and associations). Except for associations, all of these are public institutions due to the high level of regulation in the industry among governments (see Table A-7 for the full list).

Global: WHO supports member countries to develop international norms and standards on regulation of pharmaceutical products and technologies. It also provides prequalification of medicines service to assess the quality, safety, and efficacy of medicinal products including vaccines. With its global presence and influence, WHO is the most important governing institution across the pharmaceutical GVC, and its role is highly significant in R&D, quality assurance, product authorization, demand, and supply chain at the global level.

Since 1990, the International Council for Harmonization (ICH) has a mission to achieve greater harmonization worldwide to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource-efficient manner. Harmonization is achieved through the development of ICH guidelines via a process of scientific consensus with regulatory and industry experts working side-by-side. ICH is an important institution on the technical requirements and product registration of pharmaceutical products. ICH members are involved in developing and modifying ICH guidelines. NRAs and industry associations can also be observer members. Adhering to Good Manufacturing Practices (GMP) is a requirement to sell pharmaceuticals in ICH countries. ICH standards exist for each part of the pharmaceutical manufacturing process. GMP is part of quality assurance to ensure products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization or product specification.

Regional: There are several regional institutions supporting the regulatory harmonization initiatives at the regional level. Harmonization in the pharmaceutical GVC is particularly important to reduce unnecessary and duplicative requirements, rationalize time and costs, and create a transparent regulatory process that improves access to medicines. Regional governing institutions have influence on product accreditation and distribution at the regional level.

National: National regulatory authorities (NRAs) regulate the drug development process, licensing, registration, manufacturing, marketing, and labeling of pharmaceutical products at the national level. Authorities such as the U.S. Food and Drug Administration (FDA) are responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. An

NRA has significant influence across the GVC and can also create an enabling environment to promote the national medical products in the global market.

Associations: Several associations of pharmaceutical manufacturers and professionals exist. While these associations do not have direct influence on the pharmaceutical GVC, they can largely facilitate the process of product development and approval, marketing of products through knowledge sharing, networking, and capacity building.

Table 1.15.
Important Pharmaceutical Standards

SEGMENT	NAME	YEAR	PUBLISHER	DESCRIPTION	SCOPE
Excipients	NSF/IPEC/ANSI 363	2015	NSF Int'l	GMP pharmaceutical excipients	US
	GMP standards for excipient manufacturers	2013	EMA/EU's Falsified Medicines Directive	Rules for excipient labelling requirements and leaflets for ensuring quality standards for finished products.	European Union
APIs	Q7 GMP for APIs	2000	ICH	Proper production, testing, validation, & storage of APIs. First internationally harmonized GMP developed jointly by industry & regulators under ICH umbrella.	Global
			FDA	APIs must adhere to Q7; inspect all API mfg., domestic & foreign.	US
	Guidance & Principles of GMP: Directives 91/356/EEC, amended by 2003/94/EC & 91/412/EEC		EC/Inspection regulated by EDQM	Inspection integral part of certification per Directives 2001/83/EC (Guidelines, Article 20), 2001/82/EC (Article 44); 2001/20/EC (Article 13)	Europe
R&D	Q8 Pharmaceutical Development	2005	ICH	For drug products defined in Module 3 of Common Technical Document (ICH topic M4)	Global

SEGMENT	NAME	YEAR	PUBLISHER	DESCRIPTION	SCOPE
Quality Management (all stages)	Q9 Quality Risk Management	2005	ICH	Principles and tools applicable to pharma quality (incl. development, manufacturing, distribution, inspection, submission, & review processes throughout lifecycle of drug substances, medicinal, and biological products (incl. raw materials, solvents, excipients, packaging, labeling materials).	Global
	Q10 Pharmaceutical Quality System	2008	ICH	Applies to systems supporting development and manufacture of pharmaceutical drug substances and products, incl. biological products, throughout product lifecycle.	Global
	ISO 9001-2008 Quality Management Systems (QMS)	2008	International Organization for Standardization (ISO)	Demonstrate ability to consistently provide products that meet customer and regulatory standards & processes to ensure continuous improvement. Annual inspections.	Global
Generics	Waxman-Hatch Act/U.S. Patent Term Restoration and Drug Competition Act & Roche-Bolar	1984		Roche-Bolar lets a generic drug company do ANDA prep work before original patent has expired so a generic can be marketed the day following patent expiration.	US
	Exemptions allowed under Directives 2001/82 and 83/EC		EC	Amended by 2004/24, 27 and 28/EC & 2002/98/EC and 2003/63/EC	Europe

Sources: (BCC, 2021c)(BCC, 2021d)(BCC, 2021f)

In countries with publicly financed healthcare in which the government covers the cost of pharmaceuticals, the government generally has policies and seeks suppliers that can provide value-based drugs. As such, this leads to support for generic products, which cost less than patented and/or brand name alternatives. This creates opportunities for domestic generic drugmakers, but there is also a ceiling on profit margins. Some drugs, however, are not available in generic form and patented versions are required. In this case, the insurance provider (government or private insurer) can choose whether the drug is included and what the co-payment will be for the patient. In developing countries, patients often cannot afford to purchase the drug out-of-pocket and will not take the medication. In private healthcare systems, private insurance providers account for higher priced patented drugs by increasing premiums.

For patented drugs, the production location is not particularly relevant to the price the government, private insurance provider, or individual will pay for the drug unless the government imposes import tariffs or other taxes on drugs that are not produced locally. The benefit of domestic drug manufacturing is to the country's industrial sector in terms of revenue, exports, and workforce development.

Registration of a new drug requires meeting the requirements of an NDA. Registration of generic pharmaceuticals within the U.S. follows a procedure involving an Abbreviated New Drug Application (ANDA). The first five requirements of an NDA and ANDA are common to both applications. For a product to be accepted as a generic, it should have the same active ingredient(s), route of administration, dosage form, strength, and conditions of use as the reference listed drug (RLD)(BCC, 2021d). Once a generic has been approved, it is listed in the "Orange Book," which includes all FDA-approved drug products (NDAs, OTCs and ANDAs) with therapeutic equivalence codes. An "A" means the product is substitutable and therapeutically equivalent, while "B" signifies it is not substitutable (i.e., inequivalent). The Orange Book gives expiration dates for patent and exclusivity, with details of RLDs, the brand name drugs identified by the FDA for generic companies to compare their proposed products with (BCC, 2021d). To export raw materials to the U.S., a manufacturer needs to submit supporting documents like a drug master file along with an ANDA and/or NDA (BCC, 2021a).

Harmonization: Improvements have been seen in harmonization of facilities inspection standards in the US and Europe. In mid-2017, the FDA and European Medicines Agency (EMA) agreed to recognize inspections that each performs of human drug manufacturing facilities conducted in their respective territories. That means inspectors from the oversight agencies in the European Union no longer need to inspect sites in the U.S., and the FDA likewise will rely on those agencies for inspections in their own countries, unless there are exceptional circumstances that would lead one or the other to insist on their own inspection. Assuming this arrangement is retained, it will avoid the duplication of drug inspections and lower inspection costs both for regulators and manufacturers (Kalorama, 2017). Harmonization of international standards is beneficial for the protection of public health and international trade.

Pharmaceuticals across countries have primary and secondary packaging and labelling requirements and require patient information leaflets (for prescription drugs). Ingredients and bioequivalence are also required on packaging.

Applied tariffs for pharmaceuticals are low in most countries. In 1994, the US, Canada, the European Union, Japan, Norway, Switzerland, and China eliminated pharmaceutical products and chemical intermediates tariffs for 7,000 products. Some nations, including Uruguay, Argentina, and Brazil, among others, still maintain tariffs on pharmaceuticals of over 8% (IBISWorld, 2021). Argentina and Brazil are part of Mercosur and have common import tariffs for

products from outside the trade bloc (FSG, 2021a; MarketLine, 2021c). Import tariffs increase the price of imported products, thereby giving an advantage to products manufactured within the country. This may encourage some foreign companies to set-up manufacturing within the country, but it also increases the price of medicines that are not yet available to be manufactured as a generic or manufactured locally.

Research and academia: a collaborative system of drug discovery and development benefits the industry. Evolving business models in drug discovery reflect this collaborative system, including pharma and biotech companies increasingly forging alliances with academic institutions; academic institutions establishing collaborations with CROs; academic institutions operating as CROs; and CROs establishing collaborations with other CROs. Academic institutions are often more cost-effective than many commercial CROs. As a neutral third-party, academia often engages in projects with a wide range of industry players. Although they are bound by confidentiality agreements regarding the details of research programs, this gives them a broad perspective and thereby advantage in addressing problems. Thus, the pharmaceutical industry has open innovation strategies with academia to maximize their research capabilities at low cost and to boost their drug discovery pipeline. This has motivated academia to establish drug discovery infrastructure and centers on academic campuses over the past decade.

2. LAC PARTICIPATION

This section focuses on LAC countries' participation in the pharmaceutical GVC and identifies opportunities and threats to attracting investment and promoting exports. Pharmaceutical sales in LAC countries were approximately $75 billion in 2023 (Table 2.1). LAC represents approximately 5% of global pharmaceutical sales. Prescription medication accounts for 86% (generics account for 37% and patented 49%) and OTC 14%. Activity in the region is dominated by a few countries with significantly larger populations and economic development. Brazil alone accounts for over one-third of pharmaceutical sales, and Brazil, Mexico, Argentina, and Colombia collectively accounted for 77% of sales in 2023.

Collectively, LAC imported 42% of pharmaceuticals sales in 2023. The share varies by country size. Central American countries imported two-thirds of pharmaceutical demand on average. Argentina, Brazil, and Mexico import less than half of domestic sales (34 to 37%). Across LAC, domestic production is primarily to fulfil domestic market (rather than exports). In Mexico (2020), 90% of pharmaceutical production is for the domestic market (MarketLine, 2021d).

Table 2.1.
Pharmaceutical Sales by Geography & Segment, 2023

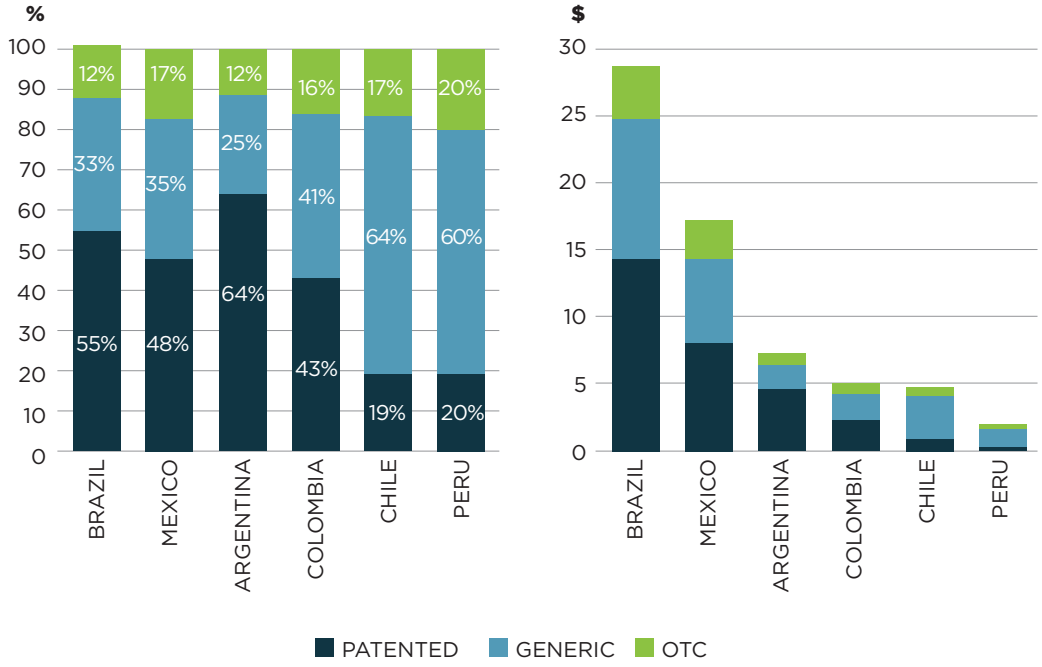
	VALUE ($US, BILLIONS)					SHARES (%)			VALUE	SHARE
GEOGRAPHY	**TOTAL**	**RX**	**PATENT**	**GENERIC**	**OTC**	**RX**	**OTC**	**GENERIC**	**IMPORTS**	
World	$1,442	$1,280	$802	$474	$155	89%	11%	33%	$814	56%
US	$457								$168	37%
LAC total	**$75**	--	--	--	--	--	--	--	**$31**	**42%**
S. America + Mexico	**$65**	**$56**	**$32**	**$24**	**$9**	**86%**	**14%**	**37%**	--	--
S. America + Mexico	$68	--	--	--	--	--	--	--	$28.0	40%

Brazil	$28.5	$25.1	$15.6	$9.5	$3.4	88%	12%	33%	$10.5	37%
Mexico	$17.2	$14.2	$8.2	$6.1	$2.9	83%	17%	35%	$6.3	36%
Argentina	$7.3	$6.5	$4.7	$1.8	$0.8	88%	12%	25%	$2.5	34%
Colombia	$5.2	$4.3	$2.2	$2.1	$0.8	84%	16%	41%	$3.4	65%
Chile	$4.9	$4.1	$0.9	$3.1	$0.8	83%	17%	64%	$2.4	49%
Peru	$2.1	$1.7	$0.4	$1.3	$0.4	80%	20%	60%	$1.1	50%
Ecuador	$2.9	--	--	--	--	--	--	--	$1.3	44%
Venezuela	$0.3	--	--	--	--	--	--	--	$0.2	70%
Central America total	**$6.8**	--	--	--	--	--	--	--	**$3.8**	**66%**
Costa Rica	$1.5	--	--	--	--	--	--	--	$0.9	63%
Guatemala	$1.7	--	--	--	--	--	--	--	$1.1	67%
Panama	$1.1	--	--	--	--	--	--	--	--	--
El Salvador	$1.2	--	--	--	--	--	--	--	$0.6	54%
Honduras	$0.8	--	--	--	--	--	--	--	$0.6	76%
Nicaragua	$0.6	--	--	--	--	--	--	--	$0.5	79%

Sources: FSG (2024i) & country 2024 reports. World based on 75 countries. Import share calculated using FSG data for pharmaceutical sales and imports. CILFA (2021) data for Argentina similar Rx is 88% of market value, 72% in units; OTC 12% and 28%. Of domestic consumption, 62% supplied by drugs manufactured locally; 38% imported.

As shown in Figure 2.1, patented pharmaceuticals account for the largest share of the market in Mexico, Brazil, and Argentina (48-64%) and generics are the largest share in Chile and Peru. In Colombia patented and generics each account for a little over 40%.

Figure 2.1.
LAC Countries Pharmaceutical Sales: Patented, Generic, and OTC (2023)



2.1
LAC COUNTRIES PARTICIPATION BY STAGE (PRODUCTION, FOREIGN TRADE)

Total LAC pharma-related imports, including organic chemical inputs, were $38.2 billion in 2023 (Table 2.2). Pharma-related input/component imports have decreased over the last decade and final product imports have increased.

Table 2.2.
LAC Countries Pharmaceutical Imports, 2013-2023

STAGE (HS CODES)	VALUES ($US, BILLIONS)			SHARES (%)			CHANGE
	2013	2018	2023	2013	2018	2023	2013-23
Pharma organic chemicals (29)	6.5	5.1	4.7	19%	17%	12%	-27%
Human/animal substances (3001)	0.2	0.1	0.1	1%	0%	0%	-45%
Components (3003)	0.6	0.4	0.4	2%	1%	1%	-24%
Blood/immunological/vaccines (3002)	7.9	7.7	11.5	23%	25%	30%	47%
Small molecule (3004 & 3006 codes)	18.9	17.3	21.4	56%	56%	56%	13%
Total	**34.1**	**30.7**	**38.2**				12%
Inputs/Components (29, 3001, 3003)	7.3	5.6	5.3	21%	18%	14%	-28%
Final products (3002, 3004, 3006 codes)	26.8	25.0	32.9	79%	82%	86%	23%
Total (not including HS29 codes)	27.6	25.6	33.4	81%	83%	88%	21%

Source: UNComtrade (2025).

Final product imports were $32.9 billion in 2023 (Table 2.3), of which $21.4 billion were small molecule and $11.5 billion biological products. The US is the top single country source, but its share is declining. Asian countries account for about 10% of LAC's final pharma imports and have increased the most over the last decade. Leading Asian sources are India, China, and South Korea. Europe's share of LAC's imports has been steady around 57% while regional LAC import share has fallen from 16% to 14% (2013 and 2023).

Brazil, Colombia, and Chile are driving import growth in final products. Large countries (Brazil, Argentina, Mexico, Colombia, Chile) import final small molecule pharma products from the US and EU countries, and increasingly from India (except Argentina). Smaller countries import more from other LAC countries and India. India and Chile have a Partial Scope Trade Agreement giving a tariff preference to pharmaceutical products classified under specific HS codes; imports of these products pay a duty tax ranging from 0 to 4.2% (E/I Santiago, 2018). The growth rate of imports into Chile from India is the

highest among LAC countries. Imports of biological products are mostly from Europe and the US. LAC trade is minimal; Argentina is the top supplier, but only accounts for 1% of imports.

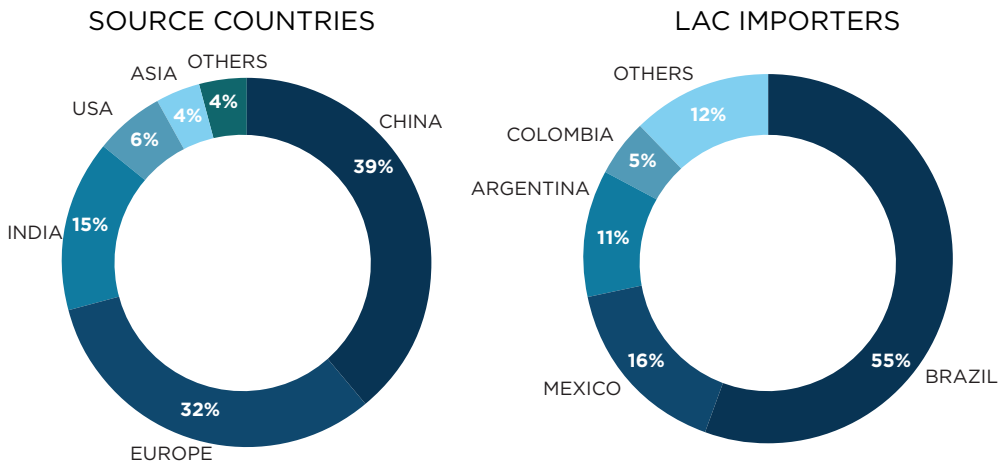
Table 2.3.
LAC Pharmaceutical Final Product Imports: Source Countries, 2013 and 2023

	VALUE ($US, BILLIONS)		SHARE (%)		CHANGE
Small molecule (HS3004 & 3006 codes)					
Partner	**2013**	**2023**	**2013**	**2023**	**2013-23**
Total	**18.9**	**21.4**			**13%**
USA	3.0	3.3	16%	16%	11%
Germany	2.4	2.9	13%	13%	19%
Mexico, Argentina, Brazil	2.6	2.2	14%	10%	-16%
India	0.6	1.5	3%	7%	161%
Italy	0.9	1.2	5%	5%	24%
France	1.4	1.1	7%	5%	-20%
Blood/immunological products/vaccines/micro-organism cultures (HS3002)					
Total	**7.9**	**11.5**			**47%**
USA	1.8	2.2	23%	19%	22%
Germany	1.7	2.0	21%	18%	22%
Belgium	0.6	1.5	8%	13%	149%
Switzerland	1.0	1.4	12%	12%	44%
Ireland	0.4	1.2	5%	10%	179%
Total final product imports	**26.8**	**32.9**			**23%**

Source: UNComtrade (2025).

LAC countries imported $4.7 billion of pharmaceutical organic chemical inputs in 2023 and accounted for 5% of world imports. Figure 2.2 shows source countries and top LAC importers in 2023. China and India are the fastest growing import sources and account for 54% (China alone is 39%). LAC countries accounted for around 2.5%. Brazil is the primary importer (55% of LAC total), followed by Mexico (16%), and Argentina (11%).

Figure 2.2.
LAC Pharmaceutical Organic Chemical Imports, Value ($USB), 2023



Source: UNComtrade (2025). Europe includes Germany, Italy, Switzerland, France, Spain, UK, Denmark, Finland, and the Netherlands. Other Asia includes Japan, Korea, Taiwan, and Malaysia.

Data on domestic production of APIs is not available, but reports suggest most APIs are imported. Brazil imports an estimated 90% of its APIs (Parrish, 2020). In Argentina there is a growing need to import active ingredients from China and India (CILFA, 2021). Colombia and Peru rely on imported APIs (FSG, 2021d, 2021o).

Exports

LAC countries exported $8.2 billion in pharmaceutical final products in 2023 and $1.2 billion in pharmaceutical organic chemical inputs. The region accounted for 1.3% of global exports in pharma organic chemicals and 0.9% in final products in 2023. Argentina, Brazil, and Mexico account for 95% of exports of pharma organic chemical inputs, and 67% of pharma final product exports. Argentina is the top input exporter, and Mexico is the top pharma final product exporter.

Final product exports are primarily small molecule (90%) rather than biological products (10%). However, the value of small molecule exports declined between 2013 and 2023, and biological products exports increased (Table 2.4).

Table 2.4.
LAC Pharmaceutical Final Product Exporters, 2013 and 2023

EXPORTER	VALUE ($US, BILLIONS)		SHARE (%)		CHANGE (%)
	2013	2023	2013	2023	2013-23
Small molecule (HS3004 & 300660)					
LAC total	**7.7**	**6.4**			**-17%**
Mexico	2.9	1.9	38%	29%	-37%
Brazil	1.8	1.5	23%	24%	-13%
Argentina	0.9	0.8	12%	13%	-8%
Colombia	0.6	0.6	7%	9%	0%
Chile	0.2	0.3	3%	4%	29%
Others	1.3	1.4	17%	21%	3%
Blood/immunological products/vaccines/micro-organism cultures (HS3002)					
LAC total	**0.48**	**0.69**			46%
Argentina	0.17	0.21	37%	30%	20%
Mexico	0.15	0.18	32%	26%	22%
Brazil	0.06	0.17	14%	24%	159%
Uruguay	0.03	0.06	7%	9%	82%
Colombia	0.01	0.02	2%	3%	72%
Others	0.04	0.05	9%	8%	29%
Total final product exports	**8.2**	**7.1**			**-13%**

Source: UNComtrade (2025); based on HS as reported; exports based on reported imports.

Trade within the Americas accounts for 78% of final product exports from LAC countries; the US and Canada account for 15% and LAC countries 63%. Trade among LAC countries is primarily smaller countries (Ecuador, Guatemala, Honduras, Peru) and Colombia importing pharmaceuticals from Argentina, Brazil, and Mexico. Less than 10% of trade is among these top three countries. Intra-LAC trade accounts for approximately two-thirds of small molecule drug exports and one-third of biological product exports.

For organic chemical inputs, LAC exported $1.2 billion in 2023; Argentina, Brazil, and Mexico account for 95% of exports. The US and Germany are the main importers from LAC countries accounting for 72% of trade. LAC exports are primarily hormones (68%) and antibiotics (14%).

Ownership of pharmaceutical manufacturers in Latin America

Market reports suggest Latin America is increasingly on the radar of multinational pharmaceutical firms (FSG, 2021i), and some MNEs have been present for decades, but investment and growth in general have been slow. MNEs in Latin America are primarily in Mexico and Brazil followed by Argentina, Colombia, or Chile.

Foreign manufacturers in Latin America[16]

CMOs with operations in Latin America include (Table 1.11) Lonza (Mexico, capsules), Catalent (Argentina and Brazil, softgel capsules/packaging and services in Uruguay), Fareva (Colombia), and Ajinomoto (Brazil).

OTC firms with locations in LAC countries (Table 1.10) include Bayer (Argentina, Mexico, and Guatemala), Reckitt Benckiser (Mexico), Perrigo (Mexico), Sanofi (Argentina), and Taisho (Mexico). US and European generic manufacturers (Table 1.9) with operations in Latin America include Viatris (Mexico), Teva (Chile, Peru, Venezuela, and Mexico), Sandoz (Brazil), and Fresenius Kabi (Brazil).

Patent pharma companies with manufacturing in Latin America include (Table 1.8) Pfizer (Brazil), Sanofi (Argentina, vaccines), AbbVie (Brazil, Costa Rica), GSK (Brazil, Mexico, Colombia), Merck (Brazil, Mexico, Chile), Roche (Mexico), Novartis (Argentina, Brazil), and beyond the top 10 firms Novo Nordisk (Brazil) and Boehringer Ingelheim (Mexico, Brazil).

Foreign companies must incorporate a local company to request authorization or enter a partnership with a local laboratory to obtain approval to manufacture locally (FSG, 2021a). In practice, it appears MNEs form these partnerships initially but often end up acquiring the domestic company or exiting the partnership. When possible, footnotes are included in the tables of section one to indicate when market entry was via acquisition of a national firm.

Costa Rica, Panama, and Uruguay are engaged in the pharmaceutical industry via the presence of foreign firms with indirect service locations within

16. This list is non-exhaustive but is an attempt to identify which countries have more foreign manufacturers and which have sizeable domestic firms.

these countries. Costa Rica has a strong life science cluster, but manufacturing is primarily medical devices. Pharma MNEs have logistics/distribution or shared services operations in Costa Rica rather than manufacturing (FSG, 2021e). Costa Rica is also the Latin American headquarters of the US FDA. Panama and Uruguay are distribution/re-export centers. US ITA (2021) states that 69% of Uruguay's exports are international companies' using the country as a regional DC to distribute their products.

Domestic manufacturers

Table A-9 in the Appendix lists some of the largest pharmaceutical firms in key LAC countries. In Argentina, Colombia, and Venezuela, pharmaceutical manufacturers are largely local firms. Brazil is a mix between foreign and domestic firms. Foreign firms dominate in Mexico, but there are a few large domestic players including Genomma Lab, Farmaceuticos Maypo, Sanfer, and Liomont.

The largest firms in Brazil have annual revenue close to $1 billion, including Hypera Pharma, Ache, EMS and Eurofarma. Other significant companies include Cristalia and Libbs; Teuto and JP Farma are contract manufacturers. Eurofarma is notable as it appears to have manufacturing facilities in Brazil, Mexico, Colombia, Argentina, Chile, Ecuador, Uruguay, Peru, and Guatemala and will also produce the Pfizer vaccine for Latin America distribution. Hypera acquired several brands from Takeda and accounts for 20% of the Brazilian OTC market.

The Brazilian government has a long-term commitment to support the domestic pharmaceutical industry through tax incentives, low-cost loans, and technology transfer arrangements. It also promotes its domestic industry through favorable drug pricing policies in public medicine procurement at the federal, state, and municipal levels, when bids are equivalent in terms of price, quality, and delivery time (FSG, 2021b). These practices, however, may end if Brazil becomes an OECD member (Paranhosab et al., 2021).

The largest firms in Argentina are smaller and seem to be more specialized in generics and biologics. Roemmers, Elea Phoenix, Casaco, Bago, Gador, Montpellier, Baliarda, and Raffo have annual revenues between $0.2 and $0.5 billion. In Argentina, 68% of production by value and units is from local firms and 32% from foreign companies (CILFA, 2021).

Colombian drug manufacturers include Vitalis (injectables, antibiotics; manufacturing in Mexico), Tecnoquimicas (largest domestic generics manufacturer), Procaps (facilities in Brazil and El Salvador), Tecnofarma (generics), Carval Group (Venezuela), and Altea (acquired Merck facilities).

2.2
OPPORTUNITIES AND THREATS FOR LAC COUNTRIES

Table 2.5. LAC Countries Opportunities and Threats

Opportunities	Weaknesses/Threats
Increase domestic generic manufacturers' regional exports	Patent/IP enforcement & corruption
Indian generics investment	Counterfeit drugs
Vaccine/biologics production	Low adherence with GMP/ international standards
Clinical trials	Low health (drug) expenditure per capita
API production	Small global market share (sales & exports)
Medical cannabis	Countries have different regulatory agencies/rules
Increasing prevalence of diseases (cardiovascular, cancer, diabetes, dementia)	Stagnant pharmaceutical market sales & exports

2.2.1
WEAKNESSES/THREATS

IP/counterfeit drugs (deterrent to foreign investors)

Business environment issues deter foreign firms from investing or working with organizations in new markets. Kalorama (2017) provides responses from pharma companies' regarding unwillingness to work with contract organizations in emerging markets. Concerns include regulatory compliance (cited by 49% of respondents), intellectual property, perceived risky quality, communication challenges, and complicated logistics (37%). Relatedly, WHO estimates one-third of pharmaceuticals in developing countries are considered counterfeit (IBISWorld, 2021), and IP enforcement or counterfeit drugs were specifically mentioned as a weakness in market reports for Ecuador, Peru, Venezuela, and Colombia (FSG, 2021b).

Prior to the 1990s, Argentina, Brazil, and Mexico (as well as many other countries in the developing world) did not grant patents on pharmaceutical products, so local manufacturers could produce generic versions of new drugs that were under patent in the U.S. and/or EU. In the 1990s, these countries introduced pharmaceutical patents to comply with new international rules barring the previous practice of making pharmaceuticals non-patentable (Kalorama, 2017).

To potential US and European foreign investors, the *perception* of IP and counterfeit issues is more relevant than the actual occurrence. Countries that have historically been viewed as having counterfeit and compliance issues

(Argentina, Brazil, and Mexico) will need to publicize improvements more actively in these areas and be able to provide data supporting such claims to be considered and short-listed as investment locations by patented pharmaceutical investors.

Low GMP compliance

Only four countries are ICH members (Brazil and Mexico) or observers (Argentina, Colombia) and only three (Argentina, Brazil, and Mexico) are Pharmaceutical Inspection Convention Scheme (PIC/S) members, which indicates these countries adhere to or as working towards GMP compliance and international harmonization of standards and quality systems. MNEs are more likely to consider ICH member countries for foreign investment and clinical trials because these countries adhere to international practices. Manufacturers in non-ICH member countries may also adhere to GMP principles, but the country itself does not participate.

For small countries, adherence to ICH principles and obtaining certifications and paperwork can be overwhelming, particularly if the country does not have the infrastructure in place to assist and accredit. Several LAC countries have many small pharmaceutical manufacturers that supply the local market and meet national requirements but not international export requirements (Ecuador, Peru, and Central American countries). El Salvador implemented GMP regulations designed to ensure that products retain their purity and potency and that manufacturing processes do not contaminate products in 2014 and gave local generic drug manufacturers two years to meet compliance requirements. In 2016, seven local manufacturers temporarily stopped drug production because they failed to comply with the GMP rules (FSG, 2021g). Compliance with GMP may be difficult for local firms initially, but in the long-term it will lead to higher quality products in the local market and opens the door for exporting and attracting foreign investment.

Low health expenditure per capita

LAC countries generally have low health expenditure per capita; the Bahamas has the highest per capita expenditure among LAC countries in 2019 ($2,005) yet still ranked 32 out of 188 countries. The lowest was Haiti ($57), ranking 160/188 (WHO, 2022). Within health expenditure, countries vary based on share spent on pharmaceuticals. Costa Rica, Chile and Panama are the highest (>$200/per capita) and Peru and Honduras are among the lowest with available data (Table A-8). For comparison, per capita pharmaceutical spending is over $2,000 in the United States.

Government expenditure on healthcare is important because most citizens cannot afford healthcare as an out-of-pocket (OOP) expense. In low- and middle-income countries, almost 90% of spending on medicines are OOP. Public financing is essential for countries to make sustainable progress towards universal health coverage (IFPMA, 2021). Per capita spending, particularly on pharmaceuticals is also a metric considered by pharmaceutical companies when evaluating locations for investment and distribution.

Small global market share (pharma market) and stagnant sales and exports

The overall pharma market in Latin America is still generally small from a global perspective, accounting for around 5% of the global market. Like low health expenditure, this is also a deterrent for foreign investment. Pharmaceutical related sales and exports from LAC countries have been stagnant over the last decade. Pharma exports ranged between $7-8 billion between 2013 and 2023 or about 1% of the global market. These figures are based on US dollars, and exchange rates of the largest economies (Argentina, Brazil, Mexico) in the region compared to the US dollar have fallen over the last decade. As such, it is likely pharmaceutical production and demand have not necessarily declined but have stayed at a similar level. Production within Latin American countries is primarily to fulfill the needs of domestic markets, so the lack of export growth is unsurprising. Stagnant pharma sales values are also a reflection of low spending on drugs, and increasing shifts to generic drugs, which have lower prices than branded drugs.

2.2.2 OPPORTUNITIES

Increasing prevalence of diseases

Increased prevalence of diseases is an unfortunate development but is an opportunity to further the pharmaceutical industry from a demand perspective. Cardiovascular diseases such as hypertension are on the rise; in Brazil, nearly one-quarter of adults are diagnosed with hypertension (2019)(Statista, 2021c). In low and middle-income countries, limited public health awareness campaigns regarding hypertension have limited the public's awareness of its link to heart disease, stroke and kidney failure (IBISWorld, 2021).

Prevalence of cancer in Latin America is growing; the top five cancers in the region for both sexes are prostate, breast, colorectal, lung, and stomach. Lung cancer is a leading cause of cancer mortality in Latin America (FSG, 2021i). Healthcare expenditure on diabetes in the region (excluding Mexico) totaled US$33 billion in 2017 (4% of the total worldwide) and is expected to increase by more than 30% by 2045 (FSG, 2021i). In Mexico, the rate is 16%, and in 2019, 7.4% of adults in Brazil were diagnosed with diabetes (Statista, 2021c). Dementia and Alzheimer's disease are also on the rise. Argentina, Brazil, Chile, Costa Rica, Colombia, Mexico, and Uruguay are experiencing the greatest impact (FSG, 2021i).

Increased incidence of diseases on its own does not automatically translate to increased pharmaceutical demand. Increased budgets and spending on pharmaceuticals are necessary to ensure patients can obtain the medications they need.

Clinical trials

Between 2015 and 2020, the pharmaceutical industry sponsored more clinical studies in Latin America (3,234) than Africa (836) and South Asia (683)(IQVIA,

2021).[17] Most (70%) clinical studies were in Brazil, Argentina, and Mexico; 20% were conducted in Colombia and Chile and the remaining 10% in Peru, Costa Rica, Panama, and Guatemala. Brazil and Argentina were among the top 20 clinical trial participant countries worldwide 2015-19 by share of participants; each with around 2% (based on FDA data). Cardiovascular disease is the top area (Statista, 2021b). Several global CROs have offices in Latin America (Table 1.12). In Brazil, 30% of CRO contracts are with local firms (Reynolds et al., 2016)MA</pub-location><publisher>MIT Industrial Performance Center (IPC. Clinical trials conducted in Latin America are relevant for the region, and for drugmakers targeting the growing US Hispanic population.

Specific targets include patented pharmaceutical MNEs and global CROs, particularly for clinical trials related to therapeutic areas with increasing disease burden in LAC mentioned earlier, orphan drugs with higher incidence in regional countries, and Covid-19 vaccines/drugs. Countries with large populations and facilities that adhere to GMP practices are good candidates for expanding clinical trials. Colombia offers advantages such as creation of new research centers, quality professionals, a large, urbanized population, and good patient retention rates. Its communicable disease burden also makes it attractive for vaccine trials (FSG, 2021d). Brazil has housed several major studies for vaccines, which helped create the right environment including labs, testing clinics, and professionals. It is also the sixth most populous country, making it easy to find participants for large-scale studies (Parrish, 2020).

CROs are influenced by the regulatory infrastructure around clinical trials. Adherence to best practices is required, but environments that are too restrictive may deter interest. For example, an industry association in Brazil is advocating for a less restrictive environment for clinical trials. It feels the amount of paperwork and time required for approval deters applied research at the detriment of Brazilian patients (Parrish, 2020).

Vaccine production and biologics

LAC countries imported $11.5 billion in biological products (4% of world imports). On top of this, Covid-19 has increased global awareness and demand for vaccines in general and specifically for annual booster vaccinations. Products needed by a large share of the population on a regular basis warrant need and consideration for local manufacturing capabilities. Several announcements were made to increase regional production. In August 2021, Pfizer-BioNTech announced a deal with Eurofarma to produce its Covid-19 vaccine for Brazil and Latin America. The goal is to manufacture more than 100 million doses annually starting in 2022 (FSG, 2021b). All doses will be exclusively distributed within Latin America.

A national company in Argentina has an agreement with AstraZeneca to produce the Covid-19 vaccine API in Garín, Buenos Aires that is sent to Mexico (Liomont) for production and filling. Production is for Latin America, and is

17. Available from: Search of: Industry | From 01/01/2015 to 12/31/2020 - Results on Map - ClinicalTrials.gov

expected to reach 200 million doses per year (CILFA, 2021). Vaccine filling is also carried out at the Fiocruz Institute in Brazil. Sinovac (China) announced plans to construct a fill and finish facility in Chile in August 2021 (FSG, 2021i). Venezuela, Mexico, and Argentina all had plans to produce Russia's Covid-19 vaccine locally. In 2019, the Mechnikov Institute for influenza vaccines (co-funded by the Nicaraguan and Russian governments) started operations in Nicaragua (FSG, 2021k).

Expanding capabilities in biologics may require (or benefit) from increased collaboration with foreign firms. At present, most foreign manufacturers in LAC countries are for small molecule drugs. As such, increased collaboration and investment from US and European firms may provide research and manufacturing expertise not widely available in the region.

Regional generic production (via domestic manufacturers or Indian firms)

Generic medication accounts for a larger share of pharmaceutical sales in Latin America compared to the global average. Several countries have legislation or programs that promote the use of generic drugs. In Ecuador the government requires Ecuadorian drugmakers to produce 20% of products in generic form, and pharmacies must offer generic substitutions for prescriptions as a primary choice (FSG, 2021f). The Generic Drug Act (2009) in Brazil led to increased use of generics as have pro-generic drug campaigns funded by the Brazilian government (MarketLine, 2021b). Chile launched a campaign in 2020 to inform and promote use of lower-cost bioequivalent medicines via yellow labels on packaging (FSG, 2021i).

For Mexico, Chile, and Colombia, Indian generic drug manufacturers are potential investment targets. Mexico and Chile both have several foreign pharma companies with in-country production facilities and favorable FDI climates, and do not have strong government initiatives to develop local firms. Mexico is in a strategic location to export to the US, and to sell to nearby Central American countries with limited production. Chile also has several FTAs and a growing preference for generic drugs. The Embassy of India in Chile commissioned a report on the Chilean pharmaceutical industry with the aim to provide relevant information on the pharmaceutical market in Chile to help Indian exporters understand the market to develop and execute a successful market entry (E/I Santiago, 2018). The report itself suggests India is interested in the Chilean market, and it identifies setting up manufacturing in Chile as an opportunity to target the Chilean market and other markets with free trade agreements.

Some Indian firms already have facilities in the region. Aurobindo Pharma has an antibiotics facility in Brazil, Dr. Reddy's has an API manufacturing facility in Mexico, Lupin has plants in Brazil and Mexico, and Glenmark has an oncology/injectables plant in Argentina (Table 1.9). In October 2020 six generic drug manufacturers signed a deal with Hidalgo, Mexico, to develop a site for manufacturing and distributing drugs in the country (BCC, 2021d). Market reports suggest Cipla is interested in opening a facility in Colombia (FSG, 2021d) or generally in the region. Indian drugmakers view Panama as

a potential center for distribution of Indian services, pharmaceuticals, and medical equipment to the Latin American region (Fitch Solutions, 2021b). This may not be suitable for all LAC countries. Argentina, for example, does not include India in its primary list of countries for pharmaceutical imports, which means all clinical phases must be performed in Argentina (i.e., not included in Annex I or II). This suggests the country may not have strong relations or trust in pharmaceuticals imported from India.

Brazil and Argentina, and to a lesser extent Mexico and Colombia, have several, well-established domestic generic pharmaceutical manufacturers, limited capacities in API production, and in general are not significant partners in pharmaceutical input or final product trade. Pharmaceutical trade among LAC countries is driven by smaller countries importing from Argentina, Brazil, and Mexico; only 9% of trade is among these top three countries. These three countries primarily import from the US and Europe. Given these are the largest three markets in the Latin American region, it seems likely that some products currently being imported from outside the region could be supplied by another Latin American country. Furthermore, given the need for economies of scale in API production, these countries should collectively evaluate API demand. For this to be successful, tariffs and regulatory frameworks will need to be aligned.

API production (domestic or foreign investment). API production is scale-intensive, and production is concentrated in Asian countries (China and India). However, if the Latin American region is viewed together, there is sufficient demand to warrant regional production of certain APIs. Identifying which specific APIs should be targeted is beyond the scope of this report. However, the region should seek to identify the drugs that will be in highest demand in the future, analyze import data to determine products with the highest import values, and consider the timeframe for patent expiration. As described in the first section of the report, APIs are produced in-house by global pharma MNE lead firms (APIs under patent protection), by contract manufacturers (patented and generic), and by third-party merchant manufacturers and sold in the open market (for off-patent/generic). It is relevant to determine which category the API falls in to determine whether production should be pursued by domestic manufacturers or foreign manufacturers. At present there is minimal intra-LAC trade in pharmaceutical-related organic chemicals; LAC countries accounted for less than 5% of LAC imports in 2023.

Medical cannabis is a rapidly growing market, an unsaturated segment of the pharmaceutical industry that offers opportunities for national pharmaceutical sales and, potentially, future recreational and/or medical exports. LAC countries including Colombia, Peru, Jamaica, Mexico, Uruguay, and Costa Rica have legalized marijuana for medical use. Colombia is exporting cannabis to the US and Europe via production in free zones (FSG, 2021d). Medicinal and recreational use is permitted in Uruguay and at least 20 licenses have been issued for industrialization or cultivation of psychoactive cannabis for medical use (Statista, 2021a). In Colombia, 116 licenses have been issued for medical cannabis-based product manufacturing (Statista, 2021a). Legalization of

medical marijuana is driving prescription drug sales in Peru (FSG, 2021l). And in Jamaica, the passage of the Dangerous Drugs Amendment Act in 2015 enabled cultivation of cannabis for research, medical and religious uses, overseen by Jamaica's Cannabis Licensing Authority.

2.3 PRIORITIZATION

Pharmaceutical R&D and production is geographically concentrated when compared to other global industries and offshoring and outsourcing are still limited. The US, Western Europe, China, and India dominate production and account for a large share of consumption. Since the COVID-19 pandemic, developments in pharmaceutical production have also shifted towards developing national and regional capacity. Opportunities for LAC are primarily for domestic demand and the regional Latin American market.

LAC countries with the most potential to expand in the pharmaceutical industry include Argentina, Brazil, Mexico, Colombia, and Chile. More specific opportunities may also exist for Costa Rica, Panama, Uruguay, Peru, El Salvador, and Jamaica. The following provides a brief overview for key countries.

Argentina is a PIC/S member and ICH observer and has several mid-sized domestic firms as well as some foreign investors in manufacturing including Bayer, Sanofi (generics and OTC), Novartis, and Catalent. Argentina is the primary country in the region with capabilities in biologics, with over 175 biotech firms and the Pilar Biotechnology Park. The government funded a vaccine and biotechnology plant by Sinergium Biotech (consortium formed by Biogénesis Bagó and Elea) in 2012 under a technology transfer model based on agreements between Sinergium Biotech, Novartis, and Pfizer (FSG, 2021a). Biologic drug production in Argentina has grown due to new local plants producing biotech APIs, the first biosimilar mAbs in Latin America (rituximab and bevacizumab), and first-generation biotech drugs (interferon, erythropoietin, growth hormone and others). Argentina also exports these products (CILFA, 2021). Argentina produces about 60% of its national pharmaceutical demand locally, mostly by domestic pharmaceutical firms. As such, it seems Argentina is positioned to expand exports, particularly within the region and for biologics.

Brazil is the largest country in the region and has the largest pharmaceutical industry (supply and demand). Given its size, it is appealing to foreign companies, and several have manufacturing in Brazil including Pfizer, AbbVie, GSK, Merck, Novartis, Sandoz, and Fresenius Kabi. The country is also supportive of domestic manufacturers and generics. Domestic manufacturers comply with GMP, and the country is a PIC/S member and ICH member. The Latin American regional office of the DNDi is in Brazil. Brazil has several large, well-established pharmaceutical firms that appear to fulfil the demands of the domestic generic and OTC markets and have the capability to focus more on exporting and developing R&D capabilities.

Mexico has the most investment from foreign pharma MNEs given its proximity to the United States and openness to foreign investors. Foreign companies in Mexico include GSK, Merck, Roche, Viatris, Teva, Bayer, Reckitt Benckiser, Perrigo, Taisho, Lonza, Catalent, and Ajinomoto, as well as Indian investors Lupin and Dr. Reddy's. Like Brazil, it is also a PIC/S and ICH member. Given several countries nearby primarily import from India, the country is an attractive market to Indian FDI. Mexico is also trying to grow its R&D capabilities, particularly in biotechnology. The country has some sizeable domestic firms and can continue to grow these capabilities to meet domestic and Central American demand.

Chile primarily imports pharmaceuticals but is open to foreign investment and development of the industry. Two foreign firms, Recalcine (Abbott) and Andrómaco (Grunenthal), account for the largest share of the Chilean market (13%). Merck and Teva also have manufacturing in Chile. Saval is the only large domestic company at 6% of the market (E/I Santiago, 2018).

Colombia has a sizeable domestic pharmaceutical market and an interest in growing its pharmaceutical industry via local and foreign firms. It is an ICH observer and has several large domestic pharmaceutical manufacturers, of which a few have facilities in other Latin American countries. It seems to have opportunities to expand exports from domestic firms, increase FDI from Asian manufacturers, and continue to grow the medical cannabis market domestically.

Several smaller LAC countries show interest in continuing to create a pharmaceutical industry within their countries and have existing capabilities in manufacturing or services. Peru, El Salvador, Guatemala, and to a lesser extent Paraguay, have domestic pharmaceutical manufacturers, and Costa Rica, Panama, and Uruguay host indirect service locations of foreign-owned pharmaceutical companies for back-office services, distribution, and logistics. All these countries have also hosted clinical trials. Costa Rica, Peru, Uruguay, and Jamaica have also legalized medical cannabis, which presents an opportunity to develop a vertical supply chain within these countries for domestic consumption.

The remaining LAC countries have small populations and limited or no current notable capabilities in the pharmaceutical-related activities.

Table 2.6. LAC Opportunities by Type of Investment and Sector

GROUP	MFG./SERVICES FOREIGN/ DOMESTIC	MFG./ SERVICES DOMESTIC	MFG./ SERVICES FOREIGN	MFG. FOR DOMESTIC/ REGIONAL	LIMITED DATA/ OPPORTUNITIES
South America	**Brazil**	**Argentina, Colombia**	**Chile** Peru, Uruguay	Peru, Paraguay	Venezuela, Ecuador, Bolivia, Guyana, Suriname
Central America & Caribbean	**Mexico**	--	Costa Rica, Panama	El Salvador, Guatemala, Jamaica	Honduras, Nicaragua, Belize, Bahamas, Trinidad & Tobago, Barbados, Haiti, DR

3. RECOMMENDATIONS

Table 3.1 provides a summary of opportunities and recommendations for LAC; specific recommendations are elaborated below.

Table 3.1.
LAC Pharmaceutical GVC Opportunities & Recommendations

SEGMENT	INVESTMENT	REQUIREMENTS/RECOMMENDATIONS	COMPANIES*	COUNTRIES
Early-stage research (discovery)	Domestic	World class research institutions Highly trained workforce Clusters of innovative companies Partnership encouraging environment Infrastructure for drug discovery activities Supportive technology & innovation programs	Partnerships with US universities	Brazil Mexico Argentina (biologics)
Clinical trials (development; PI-III)	Foreign (US)	Efficient regulatory and registration system Strong medical schools and clinicians Growing market receptive to innovation Investment promotion to CROs	CROs Patented Rx MNEs	Brazil, Argentina, Mexico, Colombia Chile, Peru, Costa Rica, Guatemala
API manufacturing	Domestic or foreign (Asia)	Regional collaboration Low tariffs Sufficient regional demand Adhere to GMP/ICH standards	--	Argentina Brazil Mexico
Generics	Domestic exports	Low tariffs Recognizing pharma registrations of other countries	See Appendix Table A-9	Argentina Brazil Colombia Mexico
	Foreign	Active investment promotion Sufficient regional demand Competitive investment incentives	Sun Pharma Cipla, Torrent ICPA, Hetero	Colombia Mexico Chile
Vaccines, biologics, specialty drugs	Foreign (US & Europe)	Sizeable regional market (sufficient demand) IP protection Favorable tax laws Workforce IFPMA membership; adhere to GMP/ICH standards	GSK, BMS, Amgen, Eli Lilly, Gilead	Mexico Chile Argentina Brazil
New product opportunities (medical cannabis)	Domestic (or foreign)	Incentivize domestic firm participation (agriculture to final products) Require FDI to work with local firms Increase consumer awareness	Agricultural & pharma (new or existing)	Peru, Mexico, Colombia, Uruguay, Jamaica, Costa Rica

Note (*): companies listed are large firms that do not appear to have manufacturing in LAC.

Active promotion of interest in increasing investment and marketing country capabilities. Proactive investment promotion is needed, particularly for countries other than Brazil and Mexico, to allure investors. Some countries have moved forward in this area, like Colombia (Invest in Colombia-Pharmaceutical Sector) and Chile (Invest in Chile, Pharmaceutical Industry), and Panama has an official aspiration to develop a pharmaceutical industry cluster in the country. Countries should also expand the role of industry associations.

Industrial/research parks or clusters that enable manufacturers, R&D centers, and universities to exist in one geographic area are common in life science industries. Strategic geographic locations and phased planning are key elements for long-term growth and success. Co-location of public institutions and private research companies in industrial parks facilitates innovation support from the government. Ireland and Singapore are good examples for pharmaceuticals.

The first modern industrial free zone was established in Ireland in 1959. The Shannon Free Airport Development Company (SFADCo) provided direct training for local industry outside the SEZ in the early 1960s. In following decades, continued success was driven by an integrated and coordinated approach to development. A key aspect was the focus on learning; direct training programs were provided by SFADCo, and skills learned in factories subsequently flowed into Irish industry. Partnerships were set up with the University of Limerick and the National Technology Park managed by the IDA next to the University. Soft policies such as taxes, targeted FDI, workforce development, and collaboration, have also been key to Ireland's success.

In Singapore, parks have served as anchors for the country's health and life science industries. Biopolis was the first developed to serve the biomedical industry. Opened in 2003, the business park was developed by JTC Corporation, a state-owned real estate company housed under MTI. It has been developed in five phases every three to five years; JTC undertook Phase I; subsequent phases were by private developers. The location was strategically chosen near National University of Singapore and the National University Hospital. Novartis was an early mover into the location, attracted by partnerships with researchers and scientists from local biomedical research institutes. Novartis' opened the Novartis Institute for Tropical Diseases to study how to disperse treatments for tropical diseases in developing nations. That project highlighted some of Singapore's strengths, including its geographic proximity to major markets in Asia, strong infrastructure as well as its human capital base. Novartis has since expanded in the country, opening two production facilities for eye-care as well as a pharmaceutical manufacturing site.

Tuas Biomedical Park (TBP) and MedTech are specialized industrial parks. TBP followed a similar planning template as Biopolis. The Singaporean government, via JTC, helped finance its construction (US$78 million in two phases), selecting a site near skilled human capital, port, and air logistics. It offers plug-and-play

opportunities and hosts several private sector actors, including Pfizer, GSK, Abbott, Roche, and Merck. MedTech Hub, launched in 2012, offers shared facilities such as sterilization services, specialized warehousing and logistics to smaller manufacturers, suppliers, and service providers in biomedical sciences. Located in Tukang Innovation Park, it clusters medical device companies, manufacturers, and service providers in a single location for synergies and collaboration. It is strategically located near major residential estates, mass transportation and amenities to support the industry's employment base.

Expand education and workforce development programs. At the manufacturing level, pharmaceutical machine operators and technicians are needed as well as lab technicians and quality assurance and compliance occupation. Operatives and technicians are needed for formulating, tableting, packaging, and filling. Workers at this level will most likely have four-year university degree or a two-year associate degree/certification. In some cases, specialist technical courses in manufacturing pharmaceutical products at technician level may be sufficient.

For R&D, Masters and PhDs in pharmaceuticals and chemistry are needed (Cornelius Gregg & Nayef, 2015). Education programs are needed to develop future scientists and engineers to work in industry, and to staff research labs and centers that can collaborate with domestic and international firms and organizations.

For clinical trials, workers are need as clinical trial managers, statisticians, scientists (various branches of the human health sciences), and regulatory affairs professionals. Much of the practical work in clinical trials is done by medical professionals and medical care teams in mainstream healthcare settings, with that work being coordinated by clinical trials managers. Statisticians play a key role in the design of trials and the interpretation of data. Scientists in the human health sciences are centrally important to the design and overall management of trials, to obtaining meaningful results and to ensuring the safety of participants. Some regulatory affairs professionals are required to ensure that trials meet regulatory requirements. Bioequivalence testing requires lab technicians to operate equipment, with the testing process led or overseen by scientists or healthcare professionals (Con Gregg & von Uexkull, 2011).

Increase regional collaboration and regulatory alignment within the region (via PAHO & Latin American organizations) for regulation/standards and investment (see, for example, harmonization of inspection facilities in the US and Europe in section one). LAC countries all have their own regulatory authority and distribution systems for pharmaceuticals. Smaller countries would benefit from adopting the regulations of larger countries with developed systems. The time, cost, and expertise required are significant, and countries with relatively small pharmaceutical markets (demand) can provide drugs at lower costs by accepting regulations and packaging from countries with more advanced systems in the region such as Brazil, Mexico, and Argentina. For example, in 2012, El Salvador recognized medicine registrations issued

by COFEPRIS (Mexico) allowing easier entry for products approved by the organization (FSG, 2024b).

Larger countries would benefit from developing policies as a group and implementing the same policies across countries to facilitate trade and limit the time and cost of developing regulations individually. There are a few examples listed below, but more regionalized efforts across a wider range of products and therapeutic areas is possible. This may be particularly relevant for biologics given their growth in importance and limited existing capabilities in the region.

The national health agencies of Mexico, Chile, and Colombia have agreed to share information, strategies, and good practices to advance issues of bioequivalence and regulations to decrease the time taken for drug registrations and in turn increase patient access to medicines (FSG, 2021j). Expanding this to include Argentina and Brazil (or Mercosur more broadly) would strengthen the initiative. For example, the Mercosur countries have a joint program on Research, Education and Biotechnology Applied to Health created in 2011 from the Mercosur Structural Convergence Fund (FOCEM)(Paranhosab et al., 2021).

Regional collaboration is also important for developing API manufacturing in terms of identifying which APIs to invest in production capabilities and regarding import tariffs. For API manufacturing to be beneficial to the region, the manufacturing location either needs to be in the same country as final dosage manufacturing, or in a country that has free trade or low import tariffs with the country the drug will be produced. Otherwise, the facility may not be utilized because even though production is closer than Asia, it may be more costly to import from the Latin American country, or the country may not recognize the same regulatory framework as the country producing the API.

And lastly, countries should consider bulk purchasing, particularly of patented Rx drugs to lower costs and expand access in the region. For example, in 2018, Peru, Argentina, Colombia, and Chile reached a joint medicine purchasing agreement for 10 cancer medicines. The agreement aims to save 20% of the costs as part of the PAHO purchasing process (FSG, 2021l).

Long-term pharma-specific, technology and innovation policies, programs, and support to enhance R&D capabilities. Mexico, Brazil and Argentina have implemented programs to grow R&D activities in pharmaceuticals, and it will be important for these countries to continue and strengthen these programs (Paranhosab et al., 2021) and collaborate with each other and with other leading pharmaceutical clusters. Focus areas for R&D include biologics and therapeutics/orphan drugs specific to Latin American countries.

India enacted industrial policies to increase domestic investment in pharmaceutical R&D starting in the late 1970s. To enhance technical competencies and R&D capabilities, the government established companies that invested in and encouraged the university system to impart specialized training required for the pharmaceutical industry. Public research labs were

created under the Council for Scientific and Industrial Research, such as the Central Drug Research Institute, Indian Institute of Chemical Technology, and National Chemical Laboratory. In the early 2000s, India engaged the private sector via incentive mechanisms such as tax benefits, grants, and soft loans. The country also collaborated with MNEs to develop internal R&D capacity so R&D activities could eventually be conducted by local institutions in the long run.

Increase public healthcare and drug spending. Rising incidence of diseases in Latin American countries increases the need for therapeutics and drugs, but this is not necessarily translated into economic demand because many individuals cannot afford to purchase drugs without government assistance. As such, increased public funding for healthcare and pharmaceuticals is needed for this to translate to increased demand. Higher healthcare expenditure, particularly for pharmaceuticals, also makes countries for appealing to foreign investors.

Appendix

Table A-1.
Pharmaceutical Segments, World Values, 2018/2023

	VALUE US$, BILLIONS					
SEGMENT/YEAR	2018	2021	2022	2023	CAGR	SOURCES
Total pharma sales	$1,158			$1,442	4.5% (2018-23)	(FSG, 2024i)
Total pharma revenue	$1,109			$1,387		(Statista, 2025)
Total pharma revenue				$1,180		(IBISWorld, 2024)
Total pharma	$1,182			$1,380	3.1% (2018-23) 3.8% (2023-28)	(MarketLine, 2024b)
Total pharma	--		$1,402	--	5.5% (2023-28)	(BCC, 2024g)
Pharma imports & exports				$837		(IBISWorld, 2024)
Pharma imports	$554			$814	8.0% (2018-23)	(FSG, 2024i)
CDMO: dosage form	$30			$48	6.6% (2024-29)	(BCC, 2024e)
Prescription	$1,071 --			$1,280 $1,293	4.7% (2018-23) 5.3% (2023-28)	(FSG, 2024i) (FSG, 2024j)
Patented	$648			$802	4.4% (2018-23)	(FSG, 2024i)
Generics (incl. off-patent originator)	$370 --			$474 $482	5.1% (2018-23) 6.6% (2023-28)	(FSG, 2024i) (FSG, 2024g)
Generics	--		$407	--	8.5% (2023-28)	(BCC, 2024g)
Generics[18]	$271			$395	7.8% (2018-23) 6.7% (2023-28)	(MarketLine, 2024a)
Generic Rx drug sales				$424		(Statista, 2024a)
Prescription	$840			$1,037		(Statista, 2025)
OTC	$133 --			$155 $158	3.1% (2018-23) 4.1% (2023-28)	(FSG, 2024i) (FSG, 2024h)
Biologic therapeutic drugs	--		$419	$453	12.7% (2023-28)	(BCC, 2024b)
Vaccines			$91	$99	13.3% (2023-28)	(BCC, 2024b)
Therapeutic proteins, incl. mAbs			$229	$249	13.6% (2023-28)	(BCC, 2024b)
Others[19]			$99	$106		(BCC, 2024b)
Vaccines	$30		$103	$79		(Statista, 2024b)
Vaccines	$34			$77	4.4% (2023-28)	(Kalorama, 2024)
Covid-19 vaccines		$64	$64	$36		(Statista, 2024b)
Covid-19 vaccines				$24		(Kalorama, 2024)
Covid-19 vaccines		$122	$99	$33		(BCC, 2024h)
APIs				$248	5.9% (2024-29)	(BCC, 2024a)

18. Generics accounted for 51% of global pharma volume in 2023; predicted to be 54% in 2028.
19. Cell/gene therapy, blood plasma products, oligonucleotides, colony-stimulating factor drugs & others.

CDMO: API	$16			$25	5.5% (2024-29)	(BCC, 2024e)
Excipients				$9	5.1% (2024-29)	(BCC, 2024c)
Pharma packaging demand Captive (30%) Merchant (70%)	$94 $28 $66				5.9% (2018-23)	(Freedonia, 2019)
Contract primary-tertiary packaging				$16	6.1% (2024-29)	(BCC, 2024f)

Notes: data represents year of column unless otherwise stated. Reports define industry segments and values in different ways, so values are provided from multiple market reports to generate averages.

Three classifications systems were used to identify codes for pharmaceuticals: ISIC, HS, and CPC. In CPCv2, pharmaceutical codes fall under code 352 (pharmaceutical products). In ISIC4, 2100 (manufacture of pharmaceuticals, medicinal chemical and botanical products) and in HS code 30 covers pharmaceutical products. When correlating between systems (particularly CPC), additional codes within HS 29 (organic chemicals), are also specific to pharmaceuticals[20]. These are chemical inputs to pharmaceutical products. Some correlate to ISIC 2100, and some to 2011 (manufacture of basic chemicals). Based on BEC4-HS, HS3004 codes are final products; HS3001-3003 codes and all HS29 are processed intermediate goods. In this report, only codes 300630, 300660, and 300670 are included from HS3006 (all are considered pharmaceuticals based on HS, ISIC and CPC).

Table A-2.
Pharmaceutical Industry Definition Across Classification Systems

ISIC4	CPC DEFINITION	CPCV2	HS	STAGE/SEGMENT
2100	Salicylic acid and its salts and esters	35210	291821 291822 291823	Inputs: Organic Chemical
2011[21]	Lactones nec, heterocyclic compounds w/ nitrogen hetero atom only, containing an unfused pyrazole ring, a pyrimidine ring, a piperazine ring, an unfused triazine ring or phenothiazine ring system not further fused; hydantoin & its derivatives; sulfonamides	35230	293311, 293319 293321 29335* 293369 (H02-17) 293430 (H02-17) 2935*	Inputs: Organic Chemical
2100	Sugars, chemically pure nec; sugar ethers & esters & their salts	35240	294000	Inputs: Organic Chemical
2100	Provitamins, vitamins, hormones; glycosides and vegetable alkaloids & their salts, ethers, esters, and other derivatives; antibiotics	35250	2936	Inputs: Organic Chemical
			2937-39 2941	Inputs: Organic Chemical

20. HS07 codes related to pharmaceuticals based on ISIC4 and CPCv2 correlation that are not included in this report: 292241, 292242, 2923, and 2924.
21. Not correlated to ISIC4 2100; correlated to pharmaceuticals by CPC only.

ISIC4	CPC DEFINITION	CPCV2	HS	STAGE/SEGMENT
2100	Medicaments, therapeutic or prophylactic uses	35260	3003	Components
			3004	Final: Small molecule
2100	Other pharmaceutical products	35270	3001 3002	Components
				Components/Final: Biologics
			300630 300660	Final
2100	Other articles for medical or surgical purposes	35290	300670	Final

Source: developed by author; green indicates codes/products considered pharmaceuticals in all three classification systems (CPC, HS, ISIC); blue indicates codes only considered pharmaceuticals in CPC and ISIC; yellow indicates only pharma based on CPC.

Table A-3.
Pharmaceutical Final Product HS Codes, 2023 (HS3004 & 3006 codes)

STAGE	HS CODES	HS DESCRIPTIONS	VALUE, 2023, $B	TOP EXPORTERS 2023	TOP IMPORTERS, 2023
Final: Antibiotics	300410 300420	Containing penicillin or streptomycin/derivatives or other antibiotics	$19.5	Italy: 16% Germany: 8% India: 8%	US: 17% Switzerland: 8% China: 6%
Final: Hormones	300431 300432 300439 300660	Containing insulin, corticosteroid hormones/ derivatives, or other (hormones or other HS2937) and chemical contraceptives based on hormones, products of HS2937 or spermicides	$59.2	Denmark: 16% Germany: 12% Italy: 10%	US: 25% China: 7% France: 7%
Final: Alkaloids	30044*	Containing alkaloids/ derivatives	$4.8	Germany: 31% France: 9% India: 9%	US: 30% China: 7% UK: 5%
Final: Vitamins	300450	Other medicaments w/ vitamins or other products of HS2936	$4.1	Germany: 15% US: 10% Netherlands: 9%	China/H. Kong: 15% US: 6% Germany: 6%
Final: Other	300490 300460 300630 300670	Other (anti-infectives, cardiovascular, CNS, dermatology, digestive, diuretics, respiratory); antimalarial; products used with medical exams	$386.5	Germany: 15% US: 10% Ireland: 9% Switzerland: 9%	US: 18% Switzerland: 9% Germany: 7% Belgium: 5%
Total		Total small molecule approximation	$474.0	Germany: 14% US: 9% Ireland: 8%	US: 19% Switzerland: 8% Germany: 7%

Table A-4.
Pharmaceutical Biological Product HS Codes/Trade, 2023 (HS3002)

STAGE	HS CODES	HS DEFINITIONS	VALUE, 2023 $US, BILLIONS	TOP EXPORTERS 2023	TOP IMPORTERS, 2023
Component/ Final	30021*	Antisera/blood fractions & immunological products	$248.2	Ireland: 15% US: 15% Germany: 15%	US: 29% Germany: 12% Switzerland: 7%
Final	300220 300241	Vaccines, humans	$57.1	Ireland: 29% Belgium: 25% US: 15%	Belgium: 22% US: 16% China: 11%
Final	300230 300242	Vaccines, animals	$4.5	US: 26% Netherlands: 19% Spain: 9%	China: 6% Netherlands: 5% Brazil: 5%
Component/ Final	300290 300249 300251 300259	Toxins, cultures of micro-organisms (excl. yeast) & similar products	$12.7	US: 31% Ireland: 15% UK: 9%	US: 13% France: 7% Germany: 6%
Total biologics approximation	3002	Blood/ immunological products/ vaccines/micro-organism cultures	$322.7	Ireland: 17% US: 16% Germany: 13%	US: 25% Germany: 11% Belgium: 8%

HS codes represent products that are sometimes classified as components, but majority are final products.

Table A-5.
Pharmaceutical Therapeutic Market Segments, Size

THERAPEUTIC AREA	TYPE	SM/ BIO	SUBAREAS/DISEASES	VALUE, 2019 ($US BILLIONS)	TOP 10 FIRMS MARKET SHARE
Metabolic disorders	Rx		Diabetes (insulin, pramlintide and others); hyperparathyroidism, hypopituitarism, hypoadrenalism; treat pituitary, adrenal, & parathyroid gland disorders; Hyperthyroidism	$146	29%
CNS	Rx, OTC		Analgesics; Anti-epileptic drugs (AEDs); Anesthetics; Anti-Parkinson; Others (antiemetics, muscle relaxers, sedatives/ antidepressants, MS, bipolar)	$118	52%
Anti-infectives	Rx	SM Bio	Antibiotic (treat/prevent bacterial infections); Antiviral therapeutics (HIV/AIDs, hepatitis B&C, herpes simplex); Antiviral vaccines, infectious diseases (influenza, rotavirus, Hep B, RSV, Yellow Fever, MERS, dengue, Zika, Ebola); Antifungals; Others: anthelminthic, antiprotozoal (malaria).	$107	43%*
Cardiovascular	Rx	SM Bio	Anti-hypertension (prevent heart failure by controlling blood pressure), Hypolipidemic drugs (reduce lipid & lipoprotein level (cholesterol) in blood); Antithrombotic drugs (blood clot) treat arterial and venous thrombosis; Congestive heart failure, anti-arrhythmic, anti-anginal	$89	--
Oncology	Rx	SM Bio	Targeted therapy (42%)(mostly SM); Immunotherapy (39%)(mostly biologics); Chemotherapy (11%)(small molecule); Hormone therapy (9%)(small molecule)	$157	85%
Musculoskeletal disorders	Rx, OTC		Rheumatoid arthritis; muscle relaxants to reduce pain; others (osteoarthritis, analgesics, immunosuppressives)	$86	23%
Respiratory system	Rx, OTC		Asthma, chronic obstructive pulmonary disease, emphysema, chronic bronchitis; Cough/ cold (contain acetaminophen, antihistamine, dextromethorphan, decongestants)	$65	54%
Hematology	Rx		Anemia/bleeding disorders such as hemophilia & blood clots (coagulants); Blood products/ components such as red cells, platelets, plasma, cryoprecipitate, or plasma derivatives (i.e., albumin & immunoglobulin d)	$83	43%
Genito-Urinary	Rx		Hormonal contraceptives; Hormonal replacement therapy; Benign prostatic hypertrophy, erectile dysfunction, infertility, incontinence & overactive bladder, infections, diuretics	$54	54%
Dermatology	Rx, OTC		Psoriasis (40%), Dermatitis (13%), Acne (11%), Others (36%)	$41	43%
Gastrointestinal	OTC, Rx		Antiulcer (51%); Vitamins & minerals (30%); Antacids (8%); Antiemetics & antinauseants (7%); Anti-obesity & anti-diarrheal	$40	59%
Ophthalmology	Rx, OTC		Antiglaucoma; dry eyes; retinal disorders; anti-infectives/allergy	$25	75%

Sources: Metabolic disorders (TBRC, 2020i), CNS (TBRC, 2020d), Anti-infectives (BCC, 2022; TBRC, 2020a), Cardiovascular (TBRC, 2020c), Musculoskeletal (TBRC, 2020j), Oncology, 2019 (BCC, 2021f; TBRC, 2020k), Hematology (TBRC, 2020h), Respiratory (TBRC, 2020m), Genito/Urinary (TBRC, 2020g), Dermatology (TBRC, 2020e), Gastrointestinal (TBRC, 2020f), Ophthalmology (TBRC, 2020l). Notes: values represent 2019 except oncology (2020). Market share of the top 10 firms in the therapeutic area based on TBRC reports for 2019. Small molecule (SM); biologics (bio).

Table A-6.
Covid-19 Vaccines

COMPANY	DRUG NAME	HQ	TYPE	2022 SALES	LATIN AMERICA (NON-EXHAUSTIVE)
BioNTech/Pfizer	Comirnaty	Germany/US	mRNA	$41	Brazil (Europharma)
Moderna (Also mfg. by Takeda (TAK-919)	mRNA-1273; Spikevax	US	mRNA	$18	
J&J/Janssen	Ad26.COV2.S	US/Europe	Viral vector	$2	Guyana
AstraZeneca/Oxford	AZD1222; Vaxzevria	UK	Viral vector	$2	Mexico (dosage), Argentina (API)
Serum Institute of India	CoviShield; same as AZD1222	India	Viral vector		
CanSino Biologics	CONVIDECIA		Viral vector		
Sinovac	CoronoVac	China	Inactivated		Chile
Bharat Biotech	Covaxin, BBV152	India	Inactivated		Mexico, Paraguay, Trinidad & Tobago
Novavax	NVX-CoV2373, Nuvaxovid	Australia	Protein		
Serum Institute of India	Covavax; same as Nuvaxovid	India	Protein		
Gamaleya/Russian Direct Investment Fund	Sputnik V	Russia	Viral vector		Mexico Argentina
VECTOR[22]	EpiVacCorona	Russia	Protein		Venezuela
Sinopharm	BBIBP-CorV	China	Inactivated		
Center for Genetic Engineering & Biotechnology	CIGB-66, Abdala	Cuba	Protein		Venezuela, Mexico, Nicaragua

Sources: BCC (2021e); (VIPER COVID-19 Vaccine Tracker Team, 2022); 2022 data (Statista, 2024b). Inactivated and live-attenuated are the two types of whole virus vaccines. Inactivated: Contains copies of the virus that have been killed (inactivated). Live-Attenuated: Contains copies of the virus that have been weakened (attenuated).

22. Vektor State Research Center of Virology and Biotechnology in Russia.

Table A-7.
Pharmaceutical GVC Institutional Stakeholders

GEOGRAPHIC SCOPE	NAME	ABB.	FOCUS	EST.	DESCRIPTION	LOCATION
Global	World Health Organization	WHO		1948	ICH observer, support to strengthen regulations. Approve essential medicines including vaccines for global supply/use.	Switzerland
	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use	ICH	Standards	1990	Founding members: EC, US, Japan.	
	International Generic & Biosimilar Medicines Association[23]	IGBA	Generics	1997/ 2015	ICH industry member; 1997: GPIA, NAPM, NPA, CDMA, & EGA formed umbrella group to represent common interests at international level. First task was work towards full participation of the generic drug industry in the ICH process.	Switzerland
Regional Regulatory Agencies/ Regional Harmonization Initiatives (support drug regulatory harmonization processes in their region)	European Medicines Agency	EMA			ICH member; scientific evaluation, supervision, and safety monitoring of medicines in the EU.	Europe
	European Directorate for the Quality of Medicines & Healthcare	EDQM			ICH observer	Europe
	PAN American Health Organization	PAHO			ICH observer	Americas
	Gulf Health Council	GHC			ICH observer	Middle East/Gulf
	Association of Southeast Asian Nations	ASEAN			ICH observer	Southeast Asia
	Asia-Pacific Economic Cooperation	APEC			ICH observer	Asia Pacific
	East African Community	EAC			ICH observer	Africa
	Southern African Development Community	SADC			ICH observer	Africa

23. Former (1997-Aug. 2015) International Generic Pharmaceutical Alliance (IGPA), Belgium (Brussels).

GEOGRAPHIC SCOPE	NAME	ABB.	FOCUS	EST.	DESCRIPTION	LOCATION
National Regulatory Agency/ Authority (NRA)	Food and Drug Administration	FDA			ICH member	USA
	Pharmaceutical & Medical Devices Agency	PMDA			ICH member	Japan
	Health Canada	--			ICH member	Canada
	SwissMedic	--			ICH member	Switzerland
	Medicines and Healthcare Products Regulatory Agency	MHRA			ICH observer	UK
	National Medical Products Administration	NMPA			ICH member	China
	Taiwan Food & Drug Administration	TFDA			ICH member	Taiwan, Taipei
	Health Sciences Authority	HSA			ICH member	Singapore
	Turkish Medicines and Medical Devices Agency	TITCK			ICH member	Turkey
	Saudi Arabia Food & Drug Administration	SFDA			ICH member	Saudi Arabia
	Jordan Food & Drug Administration	JFDA			ICH observer	Jordan
	Ministry of Health: National Pharmaceutical Control Bureau	NPRA			ICH observer	Malaysia
	Central Drugs Standard Control Organization	CDSCO			ICH observer	India
	Federal Commission for Protection against Sanitary Risks	COFEPRIS			ICH member; PIC/S (Jan. 2018); control manufacturing practices and compliance comparable to EU regulatory process.	Mexico
	Brazilian Health Surveillance Agency	ANVISA			ICH member; PIC/S (Jan. 2021); mandate registration of raw materials and finished drugs.	Brazil
	National Administration of Drugs, Food & Medical Technology	ANMAT			ICH observer; PIC/S (Jan. 2008); grant approvals for labs, marketing, new drug registration and patents. Can impose penalties. Independent; under MoH supervision.	Argentina
	National Institute of Food and Drug Surveillance	INVIMA			ICH observer, within Ministry of Health	Colombia
	National Medicines Agency	ANAMED		2013		Chile
	Directorate General of Medicines, Supplies and Drugs	DIGEMID			Regulator of drug distribution, enforces good manufacturing, storage, and distribution practices.	Peru
	Peru Observatory of Pharmaceutical Products			2011	Info on wholesale and retail drug prices of, and if drug is generic or branded. Law 29571 established Consumer Protection Code; in force Oct. 2010.	Peru
	National Directorate of Drugs & Medical Devices					Ecuador
	Rafael Rangel National Hygiene Institute				Drug registration and market regulation: review patient info leaflets & monitor products in market.	Venezuela
	National Direction of Pharmacy and Drugs of MINSA				Responsible for efficacy, quality and safety of pharma products marketed in the country. Has a Technical Consulting Commission; regulates efficacy testing, formulation changes, stability studies, therapeutic equivalence, & clinical trials.	Panama
	Ministry of Public Health and Social Assistance, Division of Food and Drug Registration and Control				Register medicines; grant licenses to pharma establishments; perform physical & chemical analysis; monitor drug production, marketing, and dispensing; authorize medicine advertising.	Guatemala
	Central Committee of Pharmacotherapy				Maintain Official Medicine List.	Costa Rica
	Ministry of Health	MINSA			Center of Health Supplies; General Board of Health covers public safety regulation for medicine, medical devices and food. Pharmacies & Medicines Law No. 292 (1998)-principal legislative document that governs the pharmaceutical market.	Nicaragua
	National Medicine Directorate	DNM			Government sanctioning body, ensures regulatory compliance based on international quality standards and provides GMP certificates to local labs.	El Salvador

GEOGRAPHIC SCOPE	NAME	ABB.	FOCUS	EST.	DESCRIPTION	LOCATION
Global Industry & Trade Associations	International Federation of Pharmaceutical Manufacturers & Associations	IFPMA	Pharma		ICH observer; full & associate members; associations & companies. Main international industry association.	
	Pharmaceutical Inspection Convention Scheme	PIC/S	Standards	1995	ICH observer; extension to Pharmaceutical Inspection Convention of 1970. Harmonized GMP standards and quality systems. 54 members.	Switzerland, Geneva
	Council for International Organizations of Medical Sciences	CIOMS		1949	ICH observer, non-governmental, non-profit; established jointly by WHO & UNESCO	
	International Society for Pharmaceutical Engineering	ISPE				
	Active Pharmaceutical Ingredients Committee	APIC	APIs		ICH observer	
	International Pharmaceutical Excipient Council	IPEC	Excipients		International Organization regulated or affected by ICH Guideline(s)	Belgium, Brussels
	Biotechnology Innovation Organization	Bio	Biotech		ICH industry member; member directory; largest trade association of biotech companies, academic institutions, state biotechnology centers, and related organizations across the US and > 30 other nations.	US (DC)
	Global Self-Care Federation	GSCF	OTC/non-Rx		ICH industry member; regional and national associations, & manufacturers and distributors of non-prescription medicines on all continents.	Switzerland, Geneva
	Drugs for Neglected Diseases initiative	DNDi		2003	International non-profit developing safe, effective, and affordable treatments for neglected diseases. 40 projects, > 20 new chemical entities and 20 ongoing clinical trials. Eight regional offices: Cape Town, Kinshasa, Kuala Lumpur, Nairobi, New Delhi, NY, Rio de Janeiro, Tokyo.	Geneva (HQ)
Regional Industry Associations	European Federation of Pharmaceutical Industries & Associations	EFPIA	Pharma			Belgium, Brussels
	Medicines for Europe	MfE	Generics	1993	Former European Generics Association (EGA)	Europe
	Latin America Association of Responsible Self-Care	ILAR	OTC	2001	GSCF member; non-profit. Promote self-care in use of non-Rx medicine. Association of manufacturers and leading pharmaceutical companies in the region as well as national OTC associations, committed to proper use of OTC medicines in Latin America.	Latin America (Brazil)
	Latin American Federation of the Pharmaceutical Industry	FIFARMA		1962	IFPMA member; represent 16 research-based biopharma firms and 11 local associations dedicated to discovering & developing health products/services; advocate for patient-centric, sustainable systems with high standards and ethical principles.	Mexico (represents LAC)
	Pharmaceutical Supply Chain Initiative	PSCI			Global; 57 members (firms)	UK, London

GEOGRAPHIC SCOPE	NAME	ABB.	FOCUS	EST.	DESCRIPTION	LOCATION
National Industry Associations	US Pharmacopeial Convention	USP			International org. affected by ICH Guidelines	US
	Pharmaceutical Research and Manufacturers of America	PhRMA	Pharma		ICH industry member	US (DC)
	Japan Pharmaceutical Manufacturers Association	JPMA	Pharma	1968	ICH industry member; IFPMA member; voluntary association comprising 73 research-oriented pharmaceutical companies (July 2021).	Japan
	Association for Accessible Medicines	AAM	Generics		Former Generic Pharmaceutical Association-GPhA	US (DC)
	Consumer Health Products Association	CHPA	OTC		GSCF member; list member companies	US (DC)
	Japan Generic Pharmaceutical Manufacturers' Association	JGA	Generics	1968	Trade association; represents interests of generics producers in Japan; 38 member companies, which account for 80% of generic drug sales in Japan.	Japan, Tokyo
	Canadian Drug Manufacturers' Association	CGPA	Generics			Canada
	Cámara Argentina de Especialidades Medicinales	CAEMe			IFPMA member	Argentina
	Argentinian Generic and Biosimilar Pharmaceutical Manufacturers Association		Generics			Argentina
	Cámara Argentina de Productores de Especialidades	CAPEMVeL			GSCF member	Argentina
		Safybi	Excipients		Guidelines for excipient manufacture and quality testing. Framing/ translating IPEC guidelines in indigenous languages to promote business activities	Argentina
	Asociación de Laboratorios Farmacéuticos de Investigación y Desarrollo	AFIDRO	Pharma	1957	IFPMA member; 24 members in 2018; foreign companies	Colombia, Bogotá
	Cámara de la Industria Farmacéutica. Asociacion Nacional de Empresarios de Colombia	ANDI	OTC	1993	GSCF member; 41-46 members; local companies (mostly generics)	Colombia, Bogotá
	Mexican Association of Pharmaceutical R&D Industries	AMIIF	Pharma		IFPMA member	Mexico, Mexico City
	Mexican Association of Generic Manufacturers	AMEGI	Generics			Mexico
	Asociación de Fabricantes de Medicamentos de Libre Acceso AC	AFAMELA	OTC		GSCF member	Mexico
	Associação Brasileira da Indústria de Medicamentos Isentos de Prescrição	ABIMIP	OTC		GSCF member	Brazil
	ProGenericos		Generics			Brazil
	Brazilian Research-based Pharmaceutical Manufacturers Association	Interfarma			IFPMA member	Brazil, São Paulo
	Sindusfarma				Association for Sao Paulo region; excipients	Brazil
	Cámara de la Industria Farmacéutica de Chile	CIF			IFPMA member	Chile, Santiago
	Chamber of the Pharmaceutical Chemical Industry	CIFARMA				Paraguay
	Industria Farmacéutica de Investigación e Innovación	IFI			IFPMA member	Ecuador, Quito
	National Association of Pharmaceutical Manufacturers	ALAFARPE			IFPMA member; represents pharma industry for human use; labs of national and foreign capital.	Peru, Lima
	Federación Centroamericana de Laboratorios Farmacéuticos	Fedefarma			IFPMA member	Guatemala
	Association of Chemical-Pharmaceutical Industrialists of El Salvador	INQUIFAR			Investment in domestic pharmaceutical labs was US$80M (2014-19)	El Salvador
	Asociación Nacional de Productores Farmacéuticos de Honduras					Honduras

Sources: ICH members/observers; IFPMA members; See Institutional Actors & Influence.

Table A-8.
Pharmaceutical Industry Indicators, Latin American Countries, 2023

COUNTRY	NUMBER OF FIRMS	EMPLOYMENT	PRODUCTION	IMPORTS	EXPORTS	% HEALTH SPENDING ON PHARMA	PHARMA SALES, US$ PER CAPITA	PHARMA MARKET	SOURCE
US (2023)				$172B	$86B	14%	$2,005	$644B	(FSG, 2025i)
L. America (2023)						17%	$130	$82.1B	(FSG, 2025f)
Brazil (2019)			$11.6B						(Statista, 2021d)
Brazil (2023)	349 (2022)			$10.6B	$0.96B	15%	$132	$28.5B	(FSG, 2025b)
Argentina (2023)	229 mfg. plants 181 domestic 48 foreign (2022)	43,000		$2.4B	$0.32B	12%	$160	$7.3B	(FSG, 2025a)
Mexico (2023)	400 labs mfg. pharma	65,204		$6.5B	$1.6B	16%	$134	$17B	(FSG, 2025g)
Mexico (2019)	138 mfg. firms		$7.9B						(Statista, 2021e)
Colombia (2023)				$3.4B	$0.4B	16%	$99	$5.2B	(FSG, 2024a)
Chile (2023)				$2.1B	$0.20B	17%	$248	$4.9B	(FSG, 2025c)
Peru (2023)				$1.0B	$0.09B	13%	$62	$2.1B	(FSG, 2024f)
Ecuador (2023)		8,000		$1.3B	$0.03B	31%	$158	$2.9B	(FSG, 2025e)
Uruguay (2020)	30 facilities		$0.54B	$0.3B	$0.24B				(US ITA, 2021)
Costa Rica (2023)	52 mfg. drugs (2019)	3,500 (2019)		$0.9B	$0.32B	27%	$284	$1.5B	(FSG, 2025d)
Panama (2023)	5		6% demand			31%	$244	$1.1B	(FSG, 2025h)
El Salvador (2023)	33-70 pharma labs	6,170 (2021)		$0.6B	$0.14B	43%	$196	$1.2B	(FSG, 2024b)
Guatemala (2023)	61 (59 domestic)	8,000 (2020)		$1.1B	$0.36B	21%	$92	$1.7B	(FSG, 2024c)
Honduras (2023)				$0.6B	$0.04B	26%	$75	$0.8B	(FSG, 2024d)
Nicaragua (2023)				$0.5B	$0.02B	34%	$87	$0.6B	(FSG, 2024e)

Source: information for 2023 unless otherwise noted.

Table A-9.
Domestic Pharmaceutical Firms in Latin America

NAME	HQ	EST.	REVENUE	EMP.	PRODUCTS	ACTIVITIES	LOCATIONS
Genomma Lab	Mexico	1996	$0.7B	1,009	OTC, generic, personal care. Anti-acne, varicose vein, hair loss, flu; analgesics and antifungals.	Develop, distribute, market; 2018: purchased 3 US OTC brands (Bufferin, Cheracol D & Rose Milk) from Dr. Reddy (1) Sheffield Pharma (2).	Sales: Mexico 46%, Latin America 44%, US 10%. Financing for OTC facility July 2018 through a financial package from IFC & IDB.
Farmacéuticos Maypo	Mexico		$0.3B				
Sanfer	Mexico	1941			Generics; injectables-ampoules, vials, syringes, solids, semi-solids, powder, suspensions; sterile oncology drugs & antibiotics-solid, suspension, softgel capsules	1 mfg. APIs for consumption	17 mfg. locations: Mexico, Argentina (PharmaDrof, acquired 2008), Chile (Pasteur, acquired 2019), Colombia (Bussie, acquired 2007 & Labinco acquired 2014)[24], Ecuador (est. 2016), Peru (Lab Portugal, acquired 2017)
Hypera Pharma	São Paulo, Brazil	2001	$0.8	8,970 (2020)	Rx, OTC, Generics Takeda non-core products exclusively in L. America for $825M March 2020.[25]	20% Brazil OTC market Sold in Brazil, Mexico, Argentina, Colombia, Ecuador, Panama, and Peru.	Mfg. Brazil (capacity: 18B solid doses, 120M injectables and 330M units liquid/cream)
Neo Quimíca	Brazil		$0.5B		Generics & Similars	Acquired 2009	

24. 500 employees; branded, unbranded generic, and veterinary products.
25. 2021, acquisition of select portfolio from Takeda, including brands Neosaldina, third largest franchise in OTC market in Brazil, Dramin and Nebacetin, in addition to patented brands Nesina and Alektos.

NAME	HQ	EST.	REVENUE	EMP.	PRODUCTS	ACTIVITIES	LOCATIONS
Mantecorp Farmasa	Brazil		$0.4B		Branded Rx, Skincare	Farmasa (acquired 2008); Mantecorp (acquired 2011)	
Aché	Brazil	1966	$0.7B	5,119 (2020)	Rx, generics, OTC (357 brands) Top 10 pharma firm Brazil	Licensing agreements 26 countries in Americas, Middle East, Africa, Asia. CMO & Export	5 mfg. (all Brazil): Aché, Biosintética, 50% share in Melcon Indústria Farmacêutica, plant in Cabo de Santo Agostinho and acquired Nortis.
EMS	São Paulo, Brazil	1950	$0.9B		Market 350 products; founded as a pharmacy	5 divisions: Rx, Generics, OTC, Brands & Hospital	Brazil CMO in L. America
Eurofarma	Brazil	1972 started as CMO	$0.8B	5,600 in Brazil	Generics, CMO International product alliances w/ Astellas, Almirall Prodesfarma and Italfarmaco. Production deal with Deva-Tal (US biotech, recombinant proteins). Will produce Pfizer-BioNTech vaccine for L. America distribution.	Partner on development with Biolab; alliances Brazil and Argentine labs. R&D alliances w/ universities, incl/USP (São Paulo) & UFRJ (Rio de Janeiro). Jan. 2021, Takeda asset purchase 12 drugs (worth $38M sales), incl. own & licensed, OTC & Rx. Present 19 L. American countries	10 plants L. America; Brazil (4); Mexico (1, Themaxis); Costa Rica (acquired Lab Stein 2019). Colombia: acquired plant from MSD (2012). Acquired Sanofi facility Argentina (2016) & Argentine co. Quesada (2009)[26] Chile: acquired Medipharm (2019) & Euromed Chile. Ecuador (2016); Guatemala (acquired Laprin, 2013); Peru (acquired Laboratório Refasa Carrión 2013); Uruguay acquired Laboratório Gautier 2010

26. September 2015 acquired Sanofi's manufacturing plant in Lomas del Mirador for US$18M. Sanofi products continue to be manufactured in facility through third-party manufacturing agreements (FSG, 2021a).

NAME	HQ	EST.	REVENUE	EMP.	PRODUCTS	ACTIVITIES	LOCATIONS
Cristália	Brazil	1972		5,600	Mfg. 20 APIs for domestic and import markets. GMP certification. Generic patents with ANVISA.	5 units: hospital, biologic, pharma, generics, CH. 4% revenue R&D. partner w/research institutions	Brazil (10) IMA (affiliated co. Argentina). Reps in 31 countries: Latin America, MENA, India, Thailand, & Vietnam.
Libbs	Brazil		$0.4B				
Teuto	Anápolis, Brazil	1947			Generics; CMO (2nd L. America; 2017 CMO sales $43M)	CMO (liquids, injectables & eye drops to regional biopharma & others); Export	Brazil (Pfizer owned 40% for $240M from 2010-17)
JP Farma	Brazil					CMO	Brazil
Laboratorio Elea Phoenix	Argentina	1939	$0.3B	900	Generics	Owned by GSK (2010-17)	
Roemmers	Argentina	1921	$0.5B		Generics		
Laboratorios Bagó	Argentina	1934	$0.2B		Generics: anti-infective to anti-inflammatory. 2nd largest domestic drug co.	Co-market with research-based foreign firms.	11 mfg. facilities-L America & Pakistan. Argentina (3): 1 pharma, 1 antibiotic, 1 bulk chemical.
Casasco	Argentina		$0.3B				
Gador	Argentina		$0.3B				
Montpellier	Argentina		$0.2B				
Baliarda	Argentina		$0.2B				
Raffo	Argentina		$0.2B				
Recalcine (Abbott)	Chile				7.2% Chile market Female health		Chile (export to L. American countries)
Saval	Chile				5.8% Chile market; only large domestic company	Export w/n L. America	
Andrómaco (Grunenthal)	Chile	1942			6.1% Chile market CNS, female health, gastroenterology	Main supplier to public health institutions.	Subsidiaries in Peru, Ecuador, Bolivia, Panama, Costa Rica, and Guatemala.
Calox International	Caracas, Venezuela	< 1998			Mfg., Distribute; CMO capacity in 7 pharma specialties	Distributors: Panama, Nicaragua, Honduras, Guatemala	Venezuela (mfg. & R&D), Costa Rica (production)
Grupo Farma	Venezuela	1938			3 units: Farma (OTC); Konsuma (OTC), Novapharma (Rx, OTC)	R&D center, Caracas	Operate 11 countries, incl. Venezuela, Colombia, Ecuador, Peru

NAME	HQ	EST.	REVENUE	EMP.	PRODUCTS	ACTIVITIES	LOCATIONS
Espromed Bio[27]	Venezuela				State-owned pharma co.		
Vitalis	Colombia				Injectables, antibiotics		6 GMP: Colombia (4), Mexico (2)
Tecnoquímicas Technofar TQ	Colombia, Cali		$0.09B		Generics (largest domestic)		Colombia (8 plants)
Procaps Group	Colombia		$0.3B		Softgel capsules Generics (2nd domestic)		Colombia (2), Brazil (softgel), El Salvador
Tecnofarma	Colombia				Generics (4th domestic)		
Altea Farmacéutica	Colombia				Acquired former Merck mfg. facilities		
Carval Group	Colombia					Companies: La Sante, Carval Veterinaria, Procoval	
La Sante	Colombia		$0.06B		Generics (3rd domestic Colombia)	Rx (Galeno Química, acquired 2007), Generics (Elter), OTC (La Sante)	Colombia (mfg.); Venezuela (2 mfg.): 1 liquid & 1 solids
Indufar S.A.	Paraguay			779	Second largest exporter		
Vijosa	El Salvador			1,000	Generics; injectables, tablets, capsules, syrup, eye drops	Largest pharma co. & exporter	

Sources: (BCC, 2021g; E/I Santiago, 2018; FSG, 2021b, 2021c, 2021d, 2021j, 2021n, 2021o, 2024b; Kalorama, 2017; Statista, 2015, 2020a, 2021e). Revenues in $USD from 2019/2020.

27. March 2021, set up facilities to produce insulin with assistance from Russia's Geropharm (provider to Venezuela since 2019). No insulin producers in country.

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