

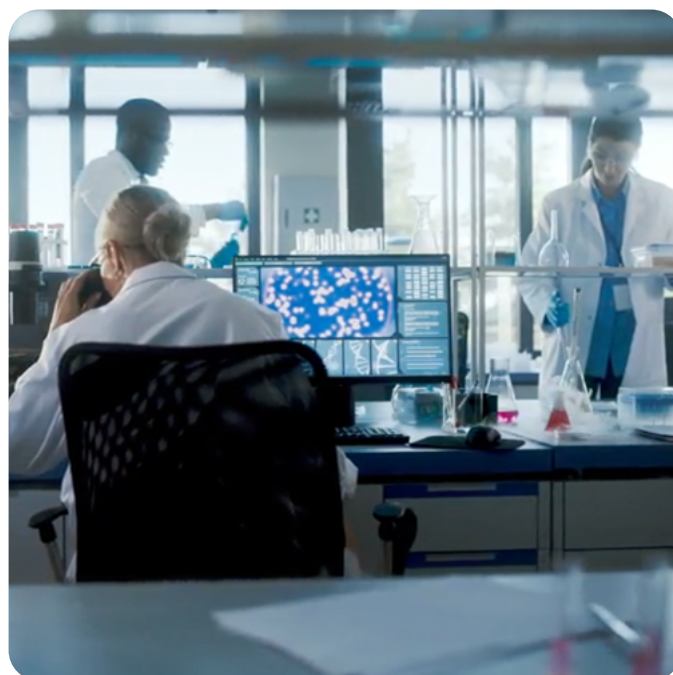
Overview of the Active Pharmaceutical Ingredient Market

IQVIA Chemical Intelligence

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Introduction — The Active Pharmaceutical Ingredient market

The Active Pharmaceutical Ingredient (API) is the vital, biologically active compound in pharmaceutical products driving therapeutic effects. Whether chemically synthesized or sourced from nature, APIs play a pivotal role globally in the pharmaceutical supply chain, serving as the foundation for drug development and manufacturing. As the pharmaceutical industry evolves towards cutting-edge therapeutics and innovative delivery systems, the demand for sophisticated APIs is likely to increase.¹

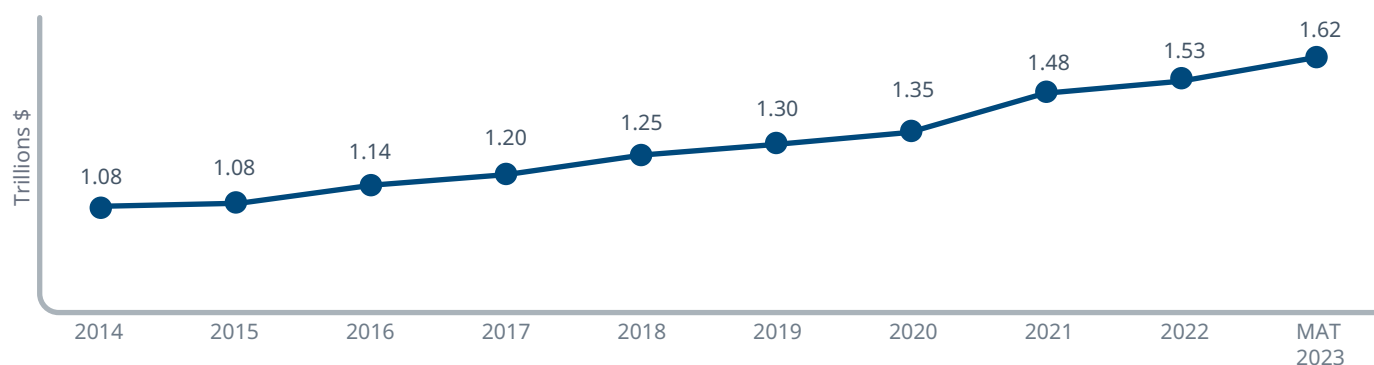


Global molecule market: A surge in value and growth over the years (2014–MAT 2023)

The molecule market has shown consistent growth, with key players implementing strategies to maintain this momentum. Based on IQVIA's MIDAS data, the observed statistical growth highlights the ongoing upward

trajectory of the global molecule market driven by diverse factors. This reflects a substantial and enduring uptrend, evident in the compound annual growth rates (CAGR) during the periods from 2014 to MAT 2023.²

Figure 1: Global molecule market growth²



Source: IQVIA MIDAS

Drivers of API market expansion

The API market is driven by diverse factors, including capacity expansions in pharmaceutical and biopharmaceutical sectors, increased reliance on generics and medical expertise¹, technological advancements in API manufacturing, and the aging global population.³ The growing incidence of chronic diseases, such as cardiovascular conditions and cancer, amplifies the momentum of market expansion.⁴

1. Scaling production capacities

As manufacturing capabilities expand, it enables companies to meet growing demand, introduce new products, and stay abreast of technological advancements, thereby contributing to the overall development and sustainability of the API market.⁵

2. Technological advancements

Progress in drug discovery, development, and clinical innovations accelerates API market growth. These technological strides contribute to the efficient manufacturing of novel therapeutic drugs utilizing APIs as essential raw materials.⁶

3. Generics and therapeutics demand

An escalating global chronic disease burden drives pharmaceutical production, increasing the need for APIs. Generic drugs, equivalent in efficacy to brand-name counterparts but cost-effective, witness high demand, particularly in the treatment of chronic ailments.⁶

4. Geriatric population impact

The expanding global geriatric demographic acts as a significant driver for the API market. The rise in age-related health issues contributes to elevated demand for pharmaceuticals, influencing API market growth.⁶

5. Global health crisis impact

The recent pandemic elevated the pharmaceutical sector's importance, resulting in market expansion. Well-known pharmaceutical companies, biopharmaceutical businesses, and startups responded to the outbreak by intensifying efforts in vaccine discovery and development, further impacting the API market positively.⁷

Logistical and regulatory challenges: The pandemic's impact on the API market

The API market encountered significant challenges during the recent global health crisis. Disruptions in worldwide supply chains and logistical hurdles, including transportation restrictions and delays, impeded the timely acquisition of raw materials and the distribution of finished dosage forms. Moreover, stringent regulatory measures and increased scrutiny of the pharmaceutical supply chain introduced complexities, resulting in delays in production and approval processes. These collective challenges not only impacted production capacity but also highlighted the need for resilience and adaptability in the API market, but there are vulnerabilities due to the regional dominance and lack of global spread.⁵

Vulnerability factors affecting supply chain

1. Insufficient global manufacturing capacity

In the first decade of the 21st century, there was a significant decline in global manufacturing capacity, leading to the loss of one-third of jobs and adversely affecting small and medium enterprises (SMEs). This decline is attributed to several factors, including competition from low-wage nations, with approximately 25% of job losses linked to the rise of China following its entry into the World Trade Organization. Concurrently, stagnant productivity growth in the U.S compared to peers characterize the challenges, with SMEs globally underinvesting in new technology.⁸

2. Incentive misalignment and short-term focus in private markets

The Department of Health and Human Services highlights the market's failure to reward quality, impacting drug shortages. Lower-wage choices boost earnings but embracing sustainable strategies can enhance wages without profit compromise, while income distributions to shareholders restrict crucial allocations for research, development, and production. Investments in enhancing capabilities for continuous improvement or reducing lead time involve initial costs but result in enhanced performance during both regular and crisis periods.⁸

3. Concentration of Global Sourcing

Global supply chain resilience necessitates integration, but the pursuit of cost-effective production and strategic industrial policies has led to concentrated supply chain locations, exposing producers to vulnerabilities.⁸ India and China emerge as unrivaled giants in API manufacturing, collectively shaping the landscape of the API market. Their robust capabilities and significant contributions emphasize their dominance, reinforcing their pivotal roles in the global pharmaceutical supply chain. The Department of Health and Human Services highlights fierce competition between India and China for U.S. medicine market share, with India relying on China for nearly 70% of its APIs.⁸

Furthermore, in a strategic initiative, for example the Indian government has launched the production of 35 different APIs under a production-linked scheme for the pharmaceutical sector. Addressing disruptions caused by the pandemic, these APIs, which were previously 90% import-dependent, are now being manufactured across 32 different plants in India. This marks a significant growth phase in the API market, with sustained momentum anticipated in the coming years.⁹

In IQVIA Chemical Intelligence (CI) API manufacturers list, 50% originate from India and China. This reflects the above predominance of API manufacturing, allowing CI customers to make informed decisions conveniently.

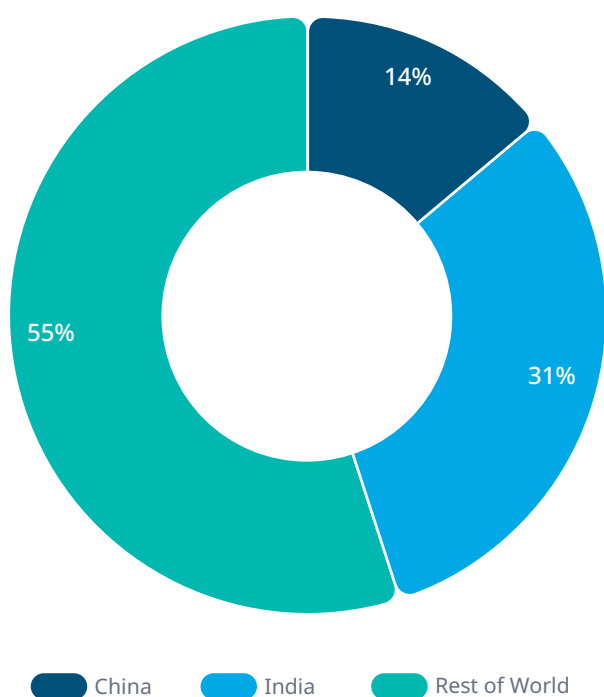
India and China emerge as unrivaled giants in API manufacturing, collectively shaping the landscape of the API market.

Rising trend in outsourcing manufacturing facilities in the pharmaceutical industry

Over the past two decades, the pharmaceutical supply chain has evolved, witnessing increased complexity and fragmentation as companies turn to overseas production and contract manufacturers.⁵ The outsourcing of API manufacturing has become prevalent, with major industry players, opting to source a significant portion of their manufacturing activities to leverage economies of scale and cost advantages. This trend extends to emerging biopharmaceutical and virtual pharmaceutical firms relying heavily on outsourcing providers.¹⁰

India and China emerge prominently as pivotal players, providing growth prospects with their cost-effective API production capabilities. The substantial cost differentials, along with lenient environmental regulations, create a favorable environment for scaling up production and enhancing efficiency in these markets. API manufacturing costs are 30–35% lower in India and 35–40% lower in China compared to the United States (U.S), making them attractive alternatives. These countries possess additional advantages such as cost-effective labor, robust testing capabilities, ample research opportunities, and favorable regulatory audits, further enhancing their competitive edge in developing markets and offer opportunities for the industry to capitalize on scaling up production, improving productivity, and enhancing efficiency.¹¹

Figure 2: API manufacturing facilities by region (2018)⁵



Source: <https://www.fda.gov/media/131130/download?attachment>

Comprehending supply disruptions and shortages in the pharmaceutical market

Temporary market imbalances, known as supply disruptions, occur when the demand for a product surpasses its supply. Root causes, often accompanied by contributing factors, trigger these disruptions. Challenges such as the lack of financial incentives to market or scale up production for less profitable drugs can hinder supply increases. While not all disruptions lead to shortages, most shortages follow supply disruptions. If a disruption persists, it transforms into a drug shortage, characterized by an extended period during which suppliers struggle to meet demand. Eventually, through increased production or decreased demand, the shortage is resolved, ensuring widespread availability of the drug.⁵

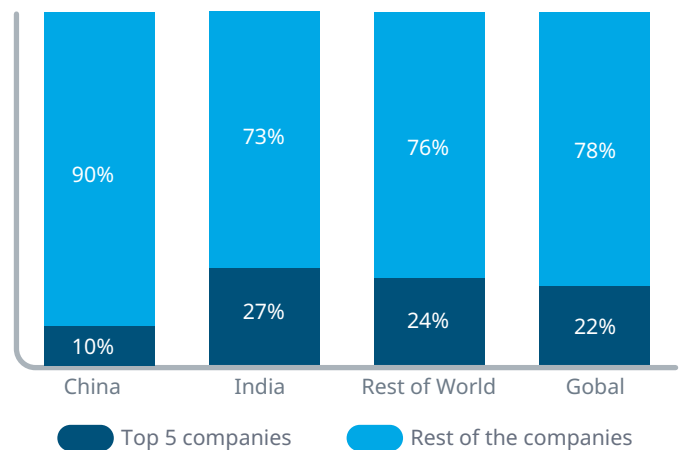
Global distribution of molecule market size by country

According to IQVIA's MIDAS data from the last five years, the global molecule market size is segmented among India, China, and the rest of the world. From 2018 to 2023 China accounts for a 7–8% share, while India holds 3%, and the rest of the world contributes 89–90%. Significantly, India and China play a pivotal role in shaping the market size, emerging as key contributors to the global molecule market's growth. Their substantial shares emphasize their significance in influencing the overall market dynamics. In essence, China and India stand out as dominant forces, exerting significant influence in the continuous expansion of the global molecule market.²

Shaping global markets: A comprehensive insight into the top 5 companies leading in India, China, and rest of the world

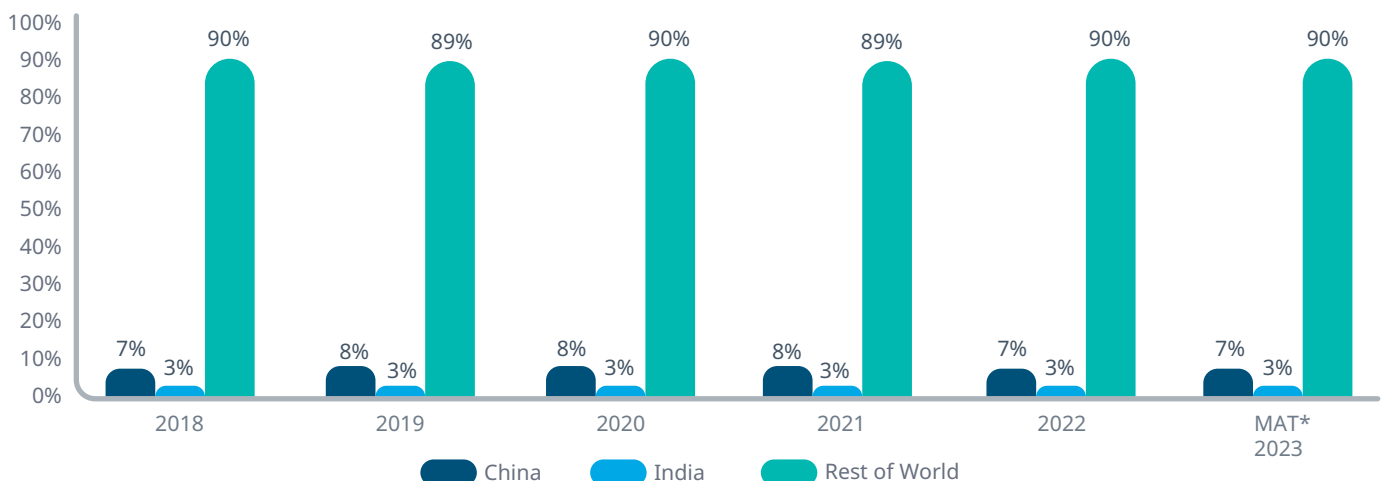
Extracting insights from IQVIA's MIDAS data for 2023, the top 5 companies by revenue emerge as industry leaders in India, China, and rest of the world, contributing 10%, 27%, and 24% to the total revenue of their respective regions. These companies collectively represent 22% of the global top 5 companies' revenue. The top companies significantly contribute to the market size, playing pivotal roles in shaping and influencing the industry's overall dynamics. Their prominent contributions extend beyond revenue figures, encompassing factors such as technological innovation, market presence, and strategic initiatives that further bolster their impact on the global market size.²

Figure 4: Revenue market share of top 5 companies vs others (2023)²



Source: IQVIA MIDAS

Figure 3: Global molecule market size²



Source: IQVIA MIDAS

Conclusion

Recognizing the significance of the API market within the global chemical supply chain, IQVIA Chemical Intelligence provides comprehensive API manufacturers data worldwide. This valuable information is accessible through the Directory of Producers module, serving as an extensive resource that facilitates connections between producers and buyers of API raw materials, specialty chemicals, and bulk pharmaceuticals across more than 82 countries. By utilizing this module, customers can proactively engage with API manufacturers, streamlining their sourcing processes. The Directory of Producers module encompasses a vast portfolio of 7.7K+ APIs and 4.2K+ associated manufacturers, each holding certifications that contribute to their credibility and adherence to industry standards.

Likewise, the Synthesis Pathways module serves as a comprehensive resource, offering insights into the synthetic routes of APIs by providing information on intermediate users. This module facilitates connections between intermediate manufacturers, helping them

identify potential buyers for their intermediates. These intermediates can be further utilized by buyers in the manufacturing of APIs. The Synthesis Pathways module encompasses 84.4K synthetic routes and are associated with 8.9K intermediate users spanning across more than 101 countries.

Additionally, competitors can leverage the platform to explore outsourcing opportunities and identify active buyers globally, fostering a thorough understanding of the competitive landscape. The featured API manufacturers in the Directory of Producers and Synthesis Pathways modules are associated with diverse regulatory and government certifications, such as ISO, GMP, and REACH certificates, providing essential information for the regulation of API manufacturing activities in major countries. This valuable resource equips customers with reliable data, enabling informed decision-making for their business endeavors.

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Chandana is a Global Data Associate at Chemical Intelligence. She brings extensive expertise in pharmaceutical data research and content development. Her educational background includes a Master of Science degree in Microbiology and a Bachelor of Science degree in Chemistry, Microbiology, and Biotechnology from the Bengaluru Central University.



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