

# **Market in Focus: Active Pharmaceutical Ingredients (APIs)**

**December 2022**

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## Key Highlights



The global API market is SR 786 billion per annum during 2021 and is expected to grow at a CAGR of 6% during the next five years. Faster growth is projected for the biologic APIs segment, given its strong efficacy and high profitability, at a CAGR of 7.8%.



Global top three active pharmaceutical ingredients (APIs), adalimumab, immunoglobulin & ustekinumab, contribute to 30% of the value. Adalimumab & immunoglobulin are growing at a CAGR of 10%, while ustekinumab is growing at 39%.



China and India have an advantage of cost competitiveness through value chain integrated clusters, low-cost utilities, high-capacity utilization, and economies of scale.



The local deficit for APIs will likely continue even if the gap narrows due to the fierce competition with imported APIs, lack of government subsidies, and ineffective tender price premium offerings.



The Kingdom's APIs demand is growing in parallel with the rising number of finished dosage form (FDF) manufacturers, with a market value of over SR 5 billion in 2021. Indian and European importers had a combined market share of around 70%.



The local demand is restricted to chemical APIs with no consumption for biological APIs, as the two active biologic FDF facilities in the Kingdom are only performing secondary packaging for licensed products.



Obstacles to establishing a prosperous API industry include the lack of R&D, logistical infrastructure, and the lack of raw materials suppliers. The industry may require massive investments in the upstream production of chemical intermediates locally.



SFDA's involvement in the API sector is limited to the GMP certification for the facilities. The FDF producer submits API information as part of the drug registration process, and the APIs of higher grades (USFDA and CEP) are favorable regarding FDF registration duration.



This industry is considered a long-term investment with high-level capital intensity and requires strong technical and manpower capabilities and logistical infrastructure. Investors must have sufficient liquidity and access to financing with more lenient lending terms to cover capital costs and operational losses during the start-up phase and support the project to achieve scale.

Active pharmaceutical ingredients (APIs) are any substance or mixture of substances used in manufacturing a pharmaceutical dosage form. When used, they become an active ingredient of that pharmaceutical dosage form. Such substances furnish pharmacological activity or other direct effects in the diagnosis, cure, mitigation, treatment, or prevention of disease or affect the structure and function of the body. APIs are either synthetic or biological. The synthetic API process starts from chemical/natural products, whereas the biological API starts from seed cells from a master cell culture. Globally, around 70% of APIs available at the market constitute synthetic chemicals API, popularly known as small molecules, while 30% goes to biotech, known as large molecules. APIs can fall under two distinctive categories, depending on the synthesis methods and nature of the end-product:

Product	Definition	Uses and Examples	Size /Complexity*
<b>Chemical API (Small Molecule)</b>	<ul style="list-style-type: none"> <li>■ A chemical API is manufactured through chemical synthesis combining specific chemical ingredients in a replicable ordered process.</li> <li>■ Chemical APIs have a well-defined chemical structure; hence, batches are identical.</li> <li>■ They can be further processed into different dosage forms and administered through various routes (tablets, capsules, injections, etc.).</li> </ul>	<p><b>Human/Animal medicines</b>  <b>Paracetamol (Panadol®)</b>  <b>Acetylsalicylic acid (Aspirin®)</b></p>	 <p><b>Aspirin</b>  <b>21 atoms</b></p> 
<b>Biological API (Large Molecule)</b>	<ul style="list-style-type: none"> <li>■ A biologic is a protein manufactured in a living system, e.g., a microorganism, plant, or animal cell.</li> <li>■ Most biologics are extremely large, complex molecules or mixtures of molecules, making them hard to characterize.</li> <li>■ Generally, they are made in genetically engineered cell cultures, and batch-to-batch variation is an inherent characteristic of biologics.</li> <li>■ Due to their large size and nature, they have poor bioavailability and require injection/infusion to be administered.</li> </ul>	<p><b>Human/Animal medicines</b>  <b>Humira®, Enbrel®,</b>  <b>insulins, hormones,</b>  <b>vaccines</b></p>	 <p><b>IgG Antibody</b>  <b>25,000 atoms</b></p> 

\*To give a sense of size, same-scale computer models of two drugs, aspirin (a small molecule) and Herceptin (an antibody), were used to demonstrate the relative complexity (bike vs. plane).

Biologics and small molecule APIs are fundamentally different. In biologics, “The product is the process;” for small molecule APIs, it is a straightforward chemical process. Chemical APIs are further classified based on branding and potency as follows:

## Branding

Classification	Potential global suppliers
Patented “Innovative”	<ul style="list-style-type: none"> <li>■ New or original active ingredients produced through research and development and received government protection for exclusivity.</li> <li>■ An active ingredient patent covers the structural formula of the drug; hence, it applies to any form of the drug (pill, cream, liquid, etc.).</li> <li>■ A formulation patent is granted when a company reformulates an off-patent chemical molecule or combines it with other active ingredients to adjust its behavior, enhance its effects, and create new applications.</li> <li>■ In the U.S., patent protection for pharmaceuticals lasts for 20 years from filing the patent. Most drugs are under market protection for a much shorter time because it takes years to develop the drug, complete clinical trials, and receive the final regulatory review.</li> </ul>
Generic	<ul style="list-style-type: none"> <li>■ A chemically equivalent API bearing the same chemical substance as a drug originally protected by chemical patents.</li> <li>■ Generic drugs must be identical to the branded drug in terms of efficacy, safety, usage, drug administration route, Pharmacokinetics, and Pharmacodynamics.</li> </ul>

## Potency

Potency refers to the inherent capacity of a drug substance to stimulate biological activity at a given amount.

Classification	Definition/Examples
Non-Potent APIs	<ul style="list-style-type: none"> <li>■ Non-potent APIs are compounds that do not produce a biological response at a very low dose.</li> <li>■ They are used to treat various diseases in humans and animals, e.g., Atorvastatin.</li> </ul>
Highly Potent APIs (HPAPI)	<ul style="list-style-type: none"> <li>■ HPAPIs are compounds that exert a biological activity with the potential to cause cancer, mutations, developmental effects, or reproductive toxicity at low doses.</li> <li>■ Specialized considerations in facility design, equipment, operation, and process safety are needed to achieve the desired level of containment of API or finished-drug products.</li> <li>■ They are traditionally used for the treatment of cancer, e.g., cytotoxic compounds and estrogen.</li> </ul>

## Biologics (Large Molecule)

Biologics are classified based on branding and source as follows:

### Branding

Classification	Definition/Examples
<b>Biologics (Innovative)</b>	<ul style="list-style-type: none"> <li>■ Novel drug products extracted or semi-synthesized from biological sources, like humans, animals, or microorganisms, by biotechnology.</li> <li>■ Structurally like compounds within the human body, e.g., proteins, sugars, living cells, etc.</li> <li>■ In the U.S., biologics are often protected by two types of government-granted rights, given the heavy investment they require:               <ul style="list-style-type: none"> <li>○ Biologic material patents last 20 years from the filing date, but companies could petition the government to extend the patent for up to five years.</li> <li>○ Regulatory exclusivity granted by the U.S. FDA lasts 12 years from the approval date. It prevents others from obtaining FDA approval to market biosimilars but does not afford any exclusivity from bio betters.</li> </ul> </li> </ul>
<b>Biosimilars</b>	<ul style="list-style-type: none"> <li>■ Biosimilars are drug products with similar safety, purity, potency, and effectiveness as off-patent biologics (reference biologics) with no clinically meaningful differences.</li> <li>■ Unlike Generics, biosimilars are not interchangeable with the reference biologic since the living cells they originate from are unique. Biosimilars must meet certain requirements. They undergo further product evaluation and testing to demonstrate their interchangeability.</li> </ul>
<b>Bio Betters/ Bio Superiors</b>	<ul style="list-style-type: none"> <li>■ Bio betters are considered the better, new-and-improved version of existing off-patent biologics.</li> <li>■ They are altered to include molecular or chemical modifications to improve safety, enhance efficacy, and reduce toxicity.</li> <li>■ They are structurally different from the reference biologic and might be novel and patentable for this reason alone.</li> </ul>

### Source

Classification	Definition/Examples
<b>Extracted from Living Systems</b>	<ul style="list-style-type: none"> <li>■ Biologics that are extracted from animals, humans, bacteria, or viruses, then purified. (e.g., blood products, vitamin B-12, protein based-vaccines).</li> </ul>
<b>Produced by Recombinant Technology</b>	<ul style="list-style-type: none"> <li>■ Recombinant technology is a DNA cloning method, where multiple DNA sequences are manipulated and recombined in unique and reproducible ways, then allowed to grow into colonies. This altered DNA can be used or further translated into therapeutic proteins (e.g. Insulin, growth hormones, vaccines).</li> <li>■ Most biologics available today are made using Recombinant DNA Technology.</li> </ul>

## Raw Materials

Small molecule API production depends on the synthetic chemistry aspects and raw material sourcing. In large molecule APIs, the pharmaceutical material is derived from a living organism, and the behavior of the organism is key to synthesis. The best procedures must be in place to ensure the quality of raw materials without distinction of domestic or imported, given that the quality of the raw materials determines the quality of the product.

## Chemical APIs

Classification	Definition	Sources
<b>Fine Chemicals / Pharmaceutical Intermediates</b>	<ul style="list-style-type: none"> <li>Chemical compounds with defined chemical properties and structure incorporated as a significant structural fragment into the API structure.</li> <li>They vary depending on the product and the production stage the manufacturer starts from (n-3, n-2, or n-1). Manufacturers of pharmaceutical intermediates must obtain the GMP.</li> </ul>	<b>Imported, mainly from China and India.</b>
<b>Solvents</b>	<ul style="list-style-type: none"> <li>Chemical substances that dissolve, suspend, or extract other materials without chemically changing the solvents or the other materials.</li> <li>Solvents are used for extraction, purification, and providing a reaction medium. They help the final product achieve the proper consistency, like creams and antibiotic suspensions.</li> </ul>	<b>Imported. Available in the local market (SABIC).</b>
 <b>Primary Packaging Material</b>	<ul style="list-style-type: none"> <li>These are critical components in direct contact with the API and must be approved by SFDA. Bulk drugs are packaged in bags and often have a multilayer plastic bag constructed with an inert, flexible layer in contact with the drug, like PVC/PP/Aluminum foil bags, etc.</li> </ul>	<b>Local</b>
 <b>Secondary Packaging Material</b>	<ul style="list-style-type: none"> <li>They enclose and protect the primary packaged product for distribution, sale, and use.</li> <li>They are also for information transmission, marketing convenience, and security, like fiber and plastic drums.</li> </ul>	<b>Local</b>

## Biologics

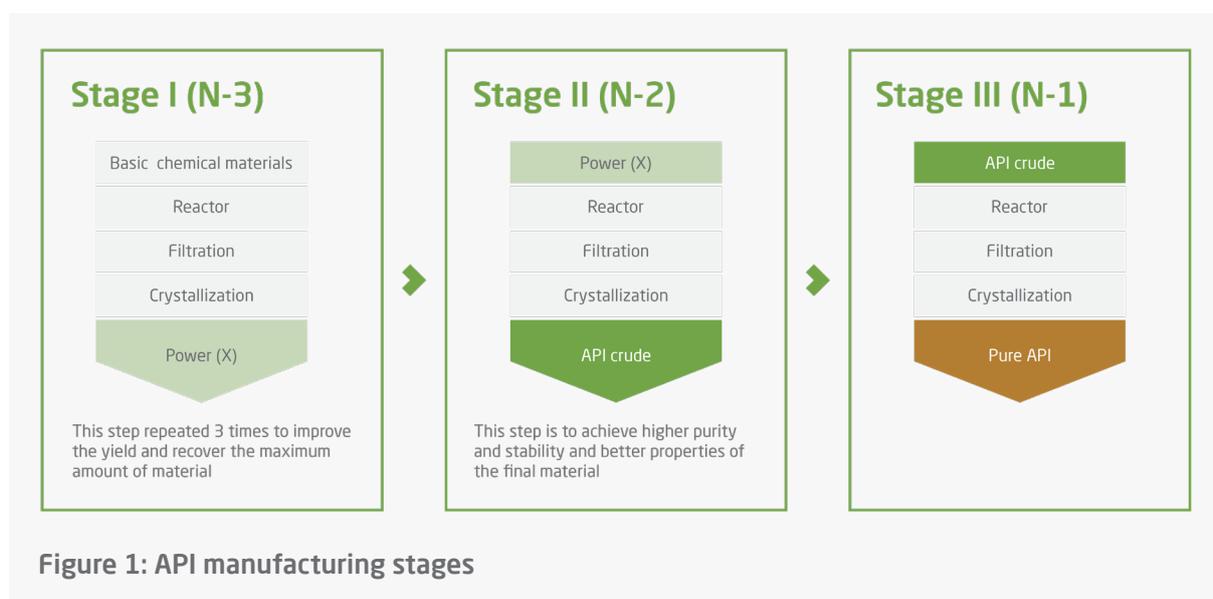
Classification	Definition	Sources
<p><b>Cell Culture Raw Materials</b></p>	<ul style="list-style-type: none"> <li>■ The raw materials involved in the biomanufacturing process are mainly used as culture media to grow the cell line and establish a Master cell bank (MCB). They can be very diverse depending on the type of cell used. Changing the culture media or the cell line would require large amounts of supportive data since the end-product will differ.</li> <li>■ These components commonly include growth factors and other supplements, e.g., soya hydrolysates, carbohydrates, vitamins, recombinant proteins like insulin, etc.</li> <li>■ Once the MCB is established, it supplies genetically identical cells for all future products. That is what distinguishes biologics from each other. The raw materials selection and quality control are of high importance.</li> </ul>	<p><b>Imported, mainly from Europe and North America</b></p>
<p><b>Purification Raw Materials</b></p>	<ul style="list-style-type: none"> <li>■ The prime purpose of the purification process is to remove living cells from the culture medium and discard unwanted components.</li> <li>■ Solvents are used in chromatography purification.</li> </ul>	<p><b>Imported, mainly from Europe and North America</b></p>
 <p><b>Primary Packaging Material</b></p>	<ul style="list-style-type: none"> <li>■ They are limited to stainless steel/glass/plastic containers. Due to their intrinsic nature and properties, large molecule substances present some unique challenges.</li> <li>■ The effects of packaging derivatives on the protein's three-dimensional and surface structure are very critical. Thus, it must be FDA-approved.</li> </ul>	<p><b>Imported, mainly from Europe and North America</b></p>
 <p><b>Secondary Packaging Material</b></p>	<ul style="list-style-type: none"> <li>■ Given the thermal sensitivity of biologics, temperature-controlled containers must be used for the transportation and shipping of bulk products, like credo cubes.</li> </ul>	<p><b>Imported, mainly from Europe and North America</b></p>

## Regulations

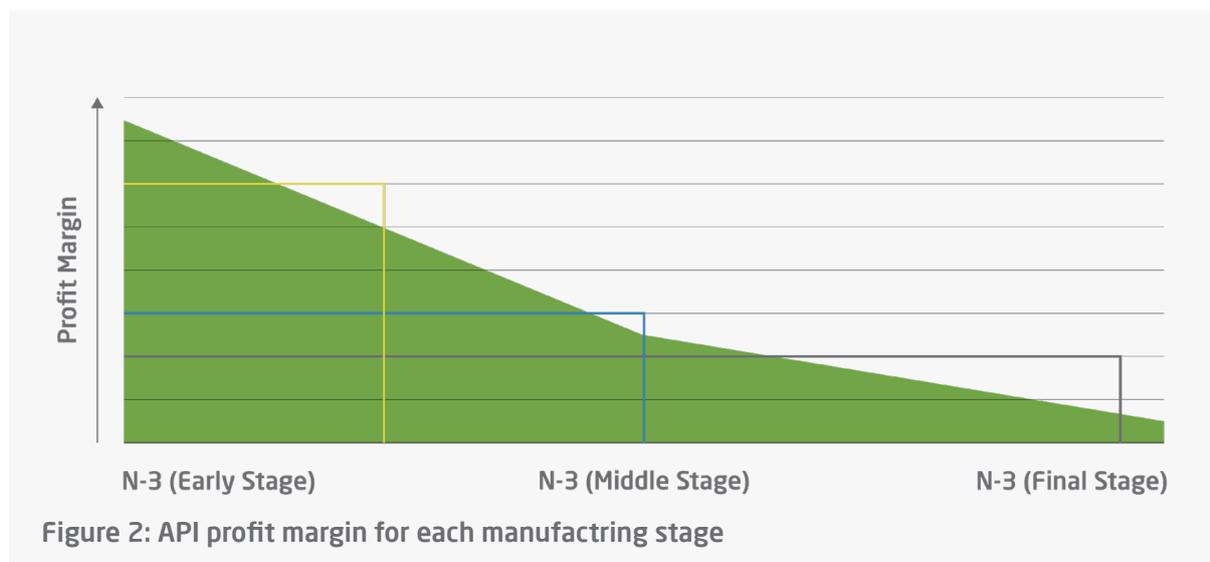
Authority	Scope
	<ul style="list-style-type: none"> <li>■ Licensing of manufacturing facility (Good Manufacturing Practice):</li> <li>● A prerequisite to manufacture or repack APIs and pharmaceutical intermediates.</li> <li>● It ensures products are consistently produced and controlled according to strict requirements to meet the quality standards appropriate to their intended use, as required by the approved specifications in the market authorization of the FDF.</li> <li>● SFDA involvement is limited to GMP licensing. FDF manufacturers prefer APIs that are CEP certified or have a USDMF since they shorten the period of drug registration at SFDA.</li> </ul>
	<ul style="list-style-type: none"> <li>■ Product Certification (Certificate of Suitability).</li> <li>■ Many API producers, aiming to gain more market access, especially in regulated markets, obtain the Certificate of Suitability (CEP) issued by the European Directorate for the Quality of Medicines &amp; HealthCare (EDQM).</li> <li>● EDQM inspects manufacturing facilities of APIs and performs testing on a risk basis. If the information is satisfactory, EDQM issues a CEP.</li> <li>● CEP holders are recognized by over 50 countries, like Australia, South Africa, Canada, etc.</li> </ul>

## Production and Margins

Capital costs vary noticeably between API plants depending on the product type (small molecule or large molecule), product mix, size, location, production method, and target market. Another essential component influencing capital cost requirements is the stage from which production starts. For small API manufacturing, the product mainly undergoes three stages: n-1, n-2, and n-3, where n-1 is the latest and requires the most minimal capital. These stages can be summarized as follows:



Another metric influenced by the production stage is profit margins. The earlier the stage, the larger the profit margin.



## Global Markets

The global API market was valued at USD 209.7 billion in 2021, equivalent to SR 786.37 billion. API market growth is parallel to that of pharmaceutical “buyers” and relies on multiple factors:

- Medical necessities, prevailing chronic diseases, and technological advancements in the finished dosage form (FDF) market in mature and emerging economies
- Regional variations in medicine pricing in regulated markets
- Global buyer preference for cheaper, outsourced, and high-quality scaled APIs
- Evicting older, less effective APIs by the rising drug research and development and the innovative APIs pipeline
- Expanding pipeline for generic chemical and biosimilar APIs with expiring patents
- Export potential and effects of import taxation on buyers in target regions

Historically, global pharmaceutical giants practiced captive API manufacturing, where a single company completes the value chain from API manufacturing to building, packaging, and marketing. Over the past decades, the process of API production phased out. It adopted a practice of outsourcing APIs to cut the high capital and operational costs associated with manufacturing and be more streamlined to FDF production, reducing costs and improving efficiency. Outsourcing APIs allowed pharmaceutical manufacturers to enjoy low API selling prices from API manufacturers, achieving a bigger scale and cheaper labor due to process focus and location.

The end of the 1990s and 2000s saw much of the industry's API production relocating to India and China. For example, AstraZeneca Pharmaceuticals in the US historically operated several API manufacturing facilities onshore. Currently, they make only 15% of their APIs in the US while planning to outsource 100% of their API manufacturing overseas. Contradictory to what some large pharmaceutical manufacturers like AstraZeneca are doing, recent developments by big players suggest that there is a high focus on in-house manufacturing over outsourcing.

Scalability and cost reduction drove manufacturers to divest from API manufacturing and outsource to cheap labor countries. The multiple shortages of major pharmaceuticals recorded in this offshoring business model, and the COVID-19 pandemic, highlight the most significant vulnerability: fragmented supply chains and the limited ability to react to changes. Since the start of the COVID-19 outbreak, there have been several reports on the closure of Chinese raw material factories, which are crucial to API production and the continuous delivery of vital medicines to patients. That creates an opportunity for regional manufacturers to gain more market share.

Other offshore countries, including India, are preferred over China for API exports due to geopolitical issues and the need to reduce dependence on Chinese APIs. Why has this strategy been quickly accepted by the market? India, which previously relied on Chinese APIs at nearly 70% of supply, has utilized production-linked incentive schemes and successfully integrated API production with drug production in the past few decades, thus gaining immense scale, technological insight, and global bargaining power. Indians speak English more fluently than the Chinese, which facilitates trade commerce with Western countries, where most developed pharmaceutical companies' headquarters are. India also practices common law, making legal transactions more achievable.

During such times of uncertainty, the global pharmaceutical industry studied its strong dependence on suppliers of necessary raw materials and finished products from this single offshore market, and several countries are re-implementing onshore API production to secure their supply chains:

- "Buy American" introduces new legislation in the US that would mandate the production of APIs on America's shores. It is considered a costly move for the industry, which is not even price-regulated by the US FDA, unlike the local price regulation by the SFDA. Some drug importations are exempt if they are already in abundant supply or if procuring them in the US would increase the cost by up to 25%.

- Several European governments are trying to convince companies to consider the relocation of their API and pharmaceutical products to Europe or their home countries.

Amongst major global players for chemical API production are Dr. Reddy's Laboratories (India), Pfizer (USA), Divis Laboratories (India), Boehringer Ingelheim (Germany), Zhejiang Hisun Pharmaceutical Co. (China), HEC (China), Sun Pharmaceuticals (India), Bristol-Meyers Squibb (USA), and Novartis (Switzerland). Western pharmaceutical and biopharmaceutical companies often conduct license API manufacturing with facilities in India for APIs still under patent.

Rank	API Manufacturers Name	Company Nationality
01	Pfizer	USA
02	Abbvie	USA
03	Novartis	Switzerland
04	Merck	USA
05	Eli Lilly	USA
06	GSK	UK
07	Sanofi	France
08	Boehringer Ingelheim	Germany
09	Bristol Myers Squibb	USA
10	Mylan	USA
11	Cipla	India
12	Dr Reddys	India
13	Sun Pharma	India
14	Lupin	India
15	Aurobindo	India

## Kingdom Market

The API market is surging from the increased demand for pharmaceutical drugs, which relies on the aging population and rising prevalence of chronic diseases, e.g., cancer, diabetes, cardiovascular, neurological, and infectious diseases. India and China are the biggest suppliers of APIs to global markets due to their low production costs. To cut down on expenses and increase profits, companies have begun outsourcing API production to developing countries in Asia, leading to growth in the Asian market. The safety of medication APIs is subject to stringent regulations and oversight from the country to which they are shipped.

Currently, all demand in the Saudi market is for synthetic APIs, with no consumption for biological APIs. The local market size of API is estimated to be around SR 5.5 billion during 2021, with the FDF market size at SR 30 billion during the same year. The estimation assumes that all finished dosage consumption is manufactured locally. There is currently only one local producer of API, accounting for less than 1% of the total annual API demand in the Kingdom. The total API consumption in the Kingdom is estimated to be 2.91 million Kgs in 2021, expected to reach 3.97 million Kgs by 2026.

The future demand for APIs relates to the performance of the pharmaceutical manufacturing industry. In this regard, the Saudi Arabian pharmaceutical market is expected to grow during the coming years, driven by the country's large and expanding population and rising burden of non-communicable diseases.

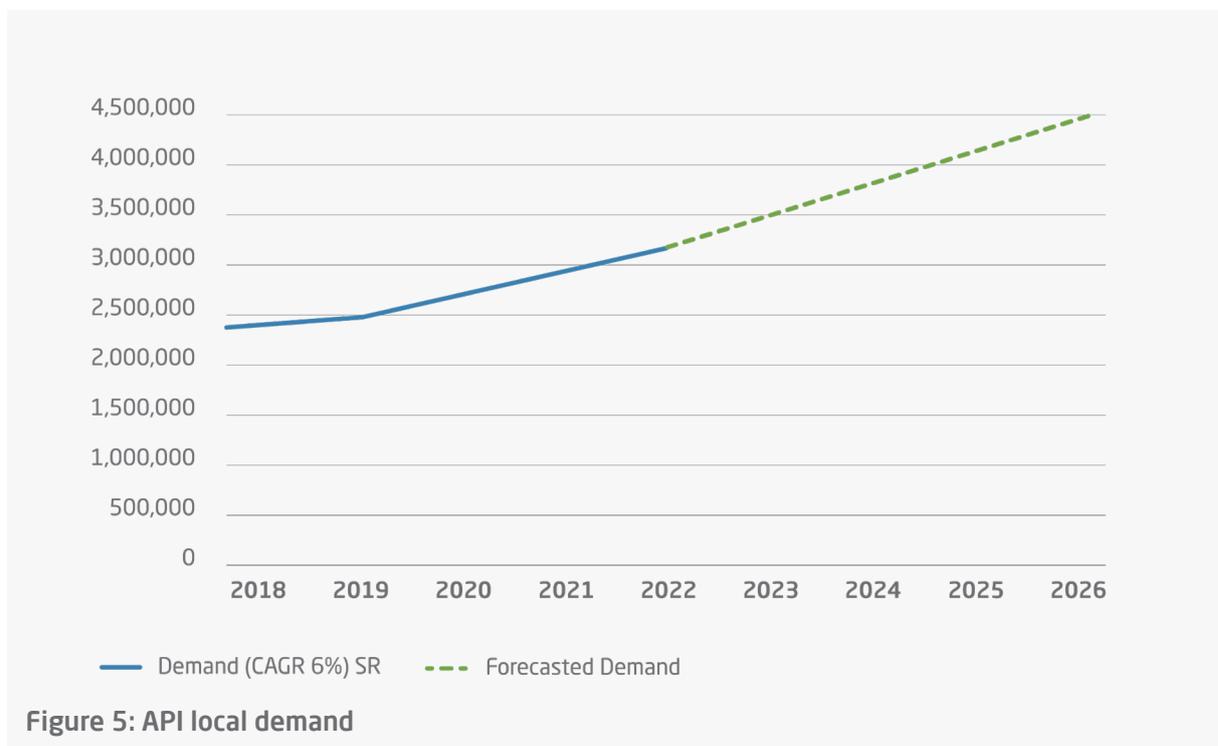


Figure 5: API local demand

In the local market, Indian producers are estimated to have a market share of 40%, followed by Chinese producers with a share of 20%. The rest 40% is distributed among European producers.

- Indian and American and Chinese producers dominate most of world's API demand due to their low-cost and high-quality APIs, provided that most Indian and Chinese producers are either FDA or CEP (Certification of Suitability of European Pharmacopoeia Monographs) approved.
- The Chinese API market is estimated to have over 2,000 API molecules with more than 7,000 API manufacturers (the number of manufacturers has increased by five times in the last five years) with an annual production capacity exceeding 2 million tons. The Indian industry has around 1,500 plants to manufacture APIs. Most API imports originate from India, China, and Europe. European imports are focused on patented APIs.

## Kingdom Health Care Expenditure

	2016	2017	2018	2019	2020	2021	2022	2023f	2024f	2025f
Health expenditure, USDbn	37.6	48.2	50.0	51.6	47.3	55.4	60.3	61.8	65.1	68.5
Health expenditure, USD, % chg y-o-y	-4.1	28.1	3.7	3.1	-8.3	17.2	8.8	2.4	5.4	5.2
Health expenditure, USD, five-year forecast CAGR	8.05	4.58	4.31	4.78	7.70	5.04	3.89	3.98	3.49	3.08
Health expenditure per capita, USD	1,160.1	1,456.9	1,484.6	1,505.0	1,357.7	1,568.1	1,682.8	1,700.5	1,770.2	1,839.2
Health expenditure per capita, USD, % chg y-o-y	-6.2	25.6	1.9	1.4	-9.8	15.5	7.3	1.1	4.1	3.9
Health expenditure, SARbn	141.1	180.8	187.6	193.4	177.3	207.8	226.2	231.7	244.3	256.9
Health expenditure, SAR, % chg y-o-y	-4.1	28.1	3.7	3.1	-8.3	17.2	8.8	2.4	5.4	5.2
Health expenditure, SAR, five-year forecast CAGR	8.0	4.6	4.3	4.8	7.7	5.0	3.9	4.0	3.5	3.1
Health expenditure per capita, SAR	4,350.2	5,463.5	5,567.2	5,643.7	5,091.6	5,880.3	6,310.6	6,377.0	6,638.2	6,897.1
Health expenditure per capita, SAR, % chg y-o-y	-6.2	25.6	1.9	1.4	-9.8	15.5	7.3	1.1	4.1	3.9
Health expenditure, % of GDP	5.8	7.0	6.4	6.5	6.8	6.8	7.0	7.1	7.2	7.2

Source: WHO, Fitch Solutions

## Selling Price

Quality and quantity determine API market prices. In an active pharmaceutical production business, the prices rely on an Ex-work basis. The Buyer usually covers the delivery method, related freight costs, inland transportation expenses, and duties and clearance charges. There is a price variation between regulated markets, like USA and EU countries, and non-Regulated markets, like Arab markets. Prices are higher in regulated markets due to FDA approval and strict regulations. Quality is a prerequisite and cannot be compromised in this industry. Indian and Chinese API producers have emerged as prime international API suppliers since their production costs are much lower than that of Europe and North America.

Quality is essential in this industry; thus, a supplier with either FDA or CEP approval of a product usually prices the product higher than suppliers with no FDA or CEP approval. For the final customers (pharmaceutical manufacturers), these approvals simplify the registration of the products at the local health authority. The selling prices vary; for example, in the regulated market, Amoxicillin is priced at around US\$ 58 per kg compared to Dulaglutide at an average price of US\$ 6.4 million per kg. The same prices are 50% cheaper in non-regulated/less regulated markets.

## Competition

The local market of APIs is dominated by imports, especially from India and China. Indian and Chinese producers dominate most of the world's API demand, with a share between 40% - 50%. They have a robust API portfolio, and their APIs are low-cost and high-quality. Most Indian and Chinese producers are either FDA or CEP (Certification of Suitability of European Pharmacopoeia Monographs) approved.

Indian and Chinese companies can sell the APIs at competitive prices because they manufacture in huge volumes, export to many countries, and have low labor costs, which lowers production costs.

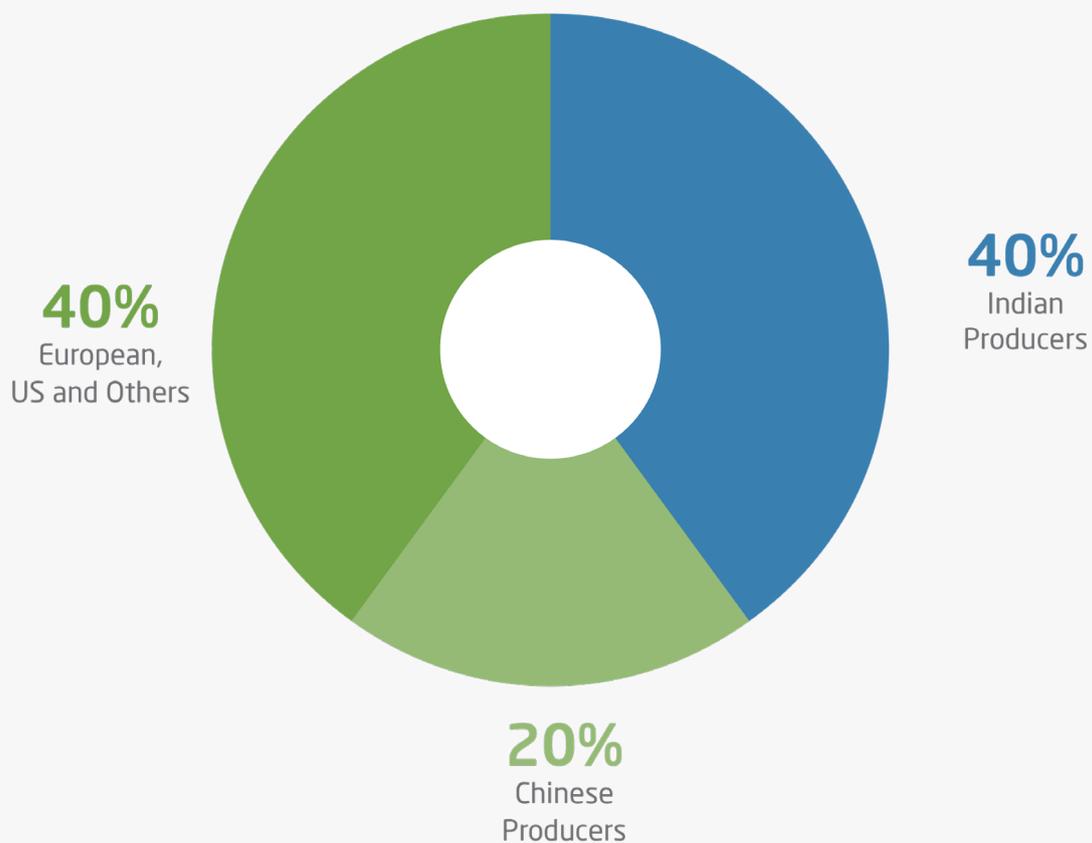


Figure 6: API local imports by country  
 Data Source: UnComtrade  
 Figure 3: API top 10 exporting countries

## Major Challenges

- Lack of supportive industrial infrastructure
- Lack of necessary R&D to produce APIs from early stages instead of importing and processing semi-finished products
- Absence of intermediate chemical producers (Key Starting Materials)
- Lack of experienced and skilled labor and management forces
- Strong competition from global suppliers
- Global domination of low-cost imports from India and China
- Lack of import taxation for locally available APIs
- The bond between scale and profitability

## Success Factors

- Establishing an agreement with petrochemicals and chemical-local factories, like SAB-IC, to produce some pharmaceutical grades of raw material (intermediates) used in API production.
  - Considering acquisitions of international API manufacturers for local companies with financial capabilities to guarantee these acquisitions.
  - Increasing the collaboration between industry and academia.
  - Focusing on R&D and building relations with universities/research centers to support research and development of the API sector.
  - Focusing on industrial Pharmacy/Chemistry training and education to satisfy the high demand for talent.
  - Integrating large-scale clusters with common infrastructure facilities, e.g., Effluent Treatment Plants, testing facilities, chilled water plants, and industry can pay per use.
  - Requiring an experienced regulatory team from new entrants to ensure their awareness of SFDA processes and regulations.
- Providing government support for local manufacturers by 10% and can reach 30% price preference given by local content authority to pharmaceutical manufacturers that buy their APIs from local API manufacturers.

### China as a successful country in bulk drugs and API

- China's dominant position in the market results from infrastructure investment, large-scale manufacturing capacities, cost efficiency, technical capabilities, and supportive government policies. The policies adopted by China to become a dominant force in bulk drugs are as follows:
- China has strategically executed multiple programs and initiatives, like policy and infrastructure reforms, to provide impetus and scale to its pharmaceutical and associated raw material industry. That involves encouraging innovation across the value chain, shortening approval processes, optimizing efficiencies, and providing the necessary utilities at discounted rates.
- The government has launched a new mechanism to reduce the time for clinical trial approval (CTA). The approval timeline for smaller molecules decreased from 25 months in 2015 to nine months in 2018. The Approval timeline for large molecules dropped from 22 months in 2015 to eight months in 2018.

- The regulatory system is continuously evolving to keep up with the standards of the EU, the US, and Japan. The Chinese government brought better integration into the international bulk drugs market by becoming a member of the “International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH).” It streamlined its regulatory procedures per international standards. That has opened China’s bulk drug companies for more external investments and collaborations.
- The government has accepted international multicenter clinical trial data norms for new drug approval (NDA). In small and large molecules, local innovative assets filing increased to 20 in 2018 from 5 in 2015.
- The government has been investing heavily in biologics and biosimilars, the next-generation drugs. It has recently invested around USD 1.6 billion in new drug development.
- China has created a “Thousand Talents Plan” to attract 50,000 PHDs internationally through research funding and created a collaborative research ecosystem, where returning talent creates major alliances between multinational firms, universities, and other companies.
- National-level focus on training Ph.D. scientists with an interest in the pharmaceutical sector.
- R&D “parks” have been established at the provincial and/or local level to provide economic and/or infrastructure-related benefits. They may include making available low-cost facilities, R&D grants or subsidies, access to loans, and tax benefits.
- China has shown significant interest in enhancing the supporting infrastructure, including facilities, logistics, and continuous processing, which can act as drivers for optimizing efficiency levels. Bulk drug parks in China are equipped with utilities, such as steam supply, cooling water, chilled water, nitrogen gas, and compressed air. Common effluent treatment plants have a capacity of 50,000 MT to 100,000 MT.
- The clusters have proximity to ports and airports for better logistics support.



For more information, please contact us at:  
[www.sidf.gov.za](http://www.sidf.gov.za)