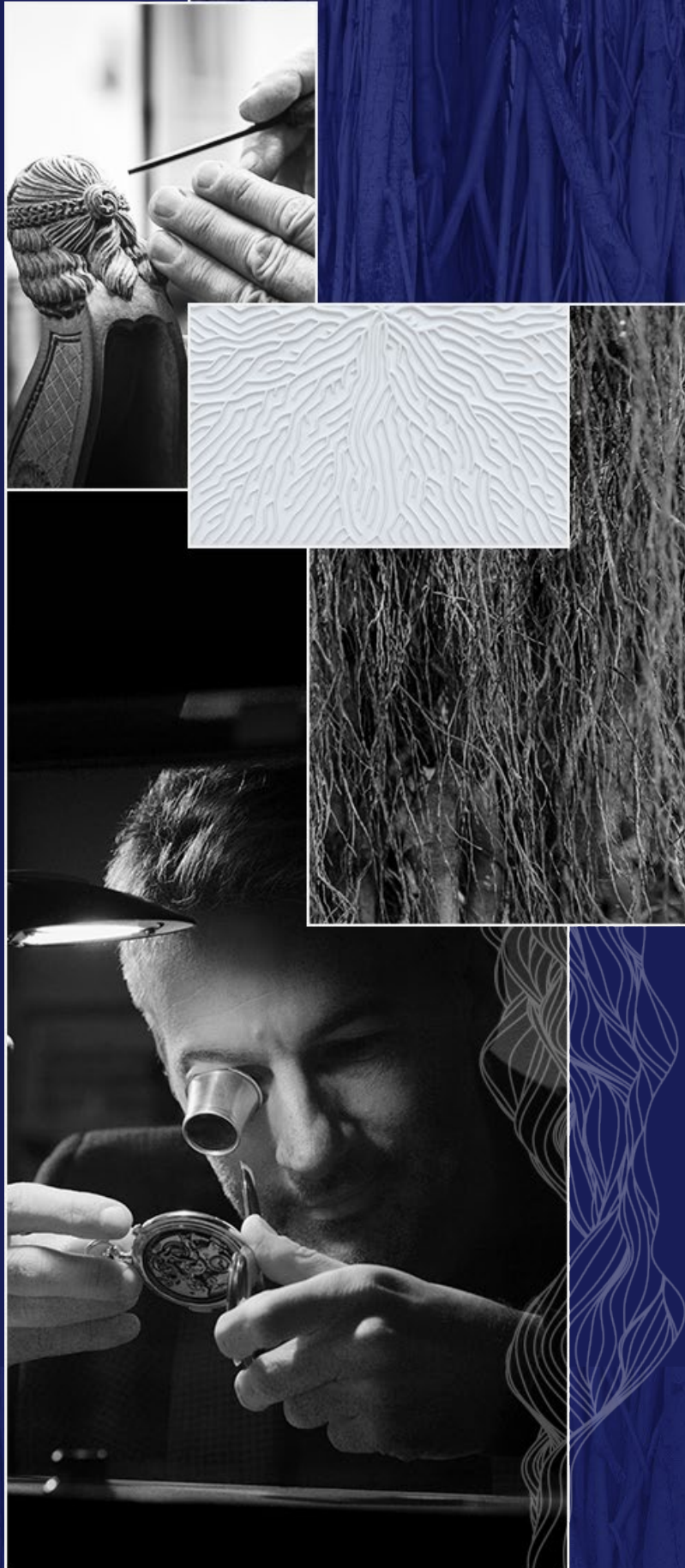


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Indian API Industry - Key Characteristics, Current Trends, Select Large Deals and Way Forward

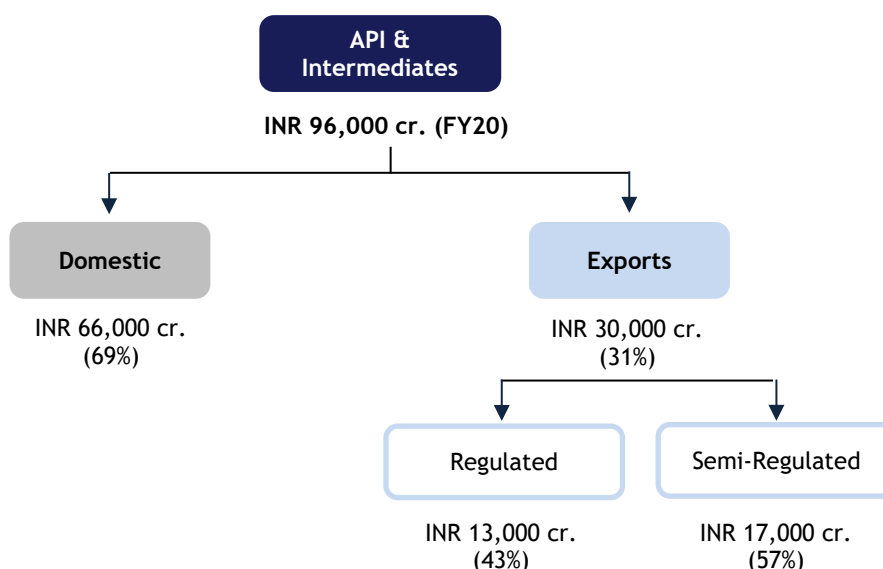
India - Pharmacy of the World

Indian Pharmaceutical industry holds a critical place in the global pharmaceutical value chain. India contributes to more than 20% by volume of the global generics market and 62% of the worldwide demand for vaccines. The Indian Pharmaceutical industry is currently valued at ~\$42 Bn expected to grow at a rapid rate to reach \$120 Bn by 2030.

India plays a key role in the global pharmaceutical market with exports to more than 200 countries. It is the 3rd largest pharmaceutical exporter globally in terms of volumes. India is one of the key suppliers globally for APIs (Active Pharmaceutical Ingredients), generics as well as vaccines.

Indian API / Bulk Drug Industry Overview

Indian Bulk drug industry is ranked 3rd largest globally in terms of volumes, after China and Italy. The industry has progressed from being perceived as an industry manufacturing simple APIs, to becoming the preferred destination for high value and complex APIs. The industry has been a key element in the global pharmaceutical supply chain on account of its low-cost manufacturing coupled with availability of skilled manpower. Significant investments have been made over the past decade in process research and development of complex products which is likely to create value over the next decade.



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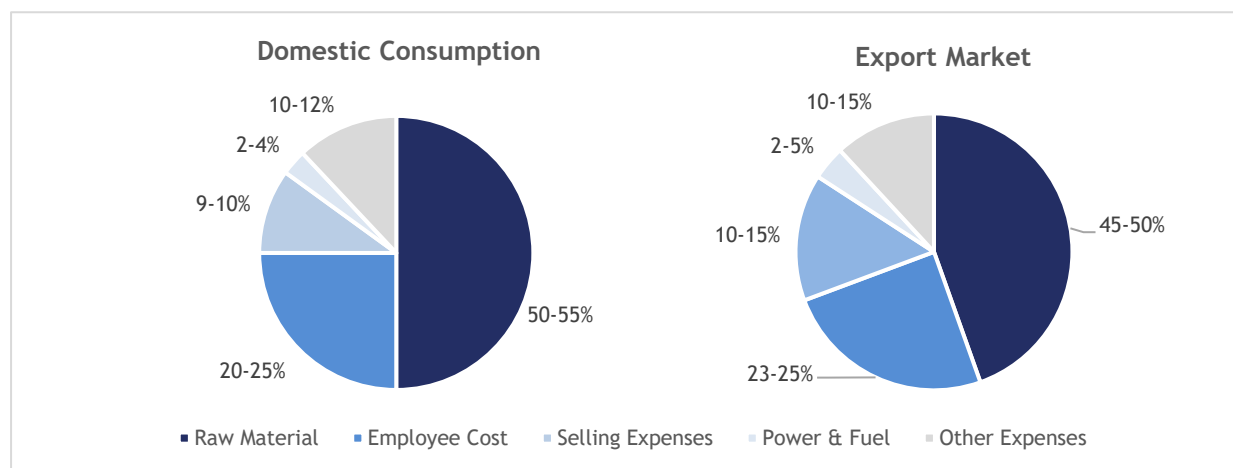


Key Characteristics

A. API forms major part of cost of Formulation

API is one of the key elements going into manufacturing of formulations both in terms of characteristic as well as cost. API cost forms major part of cost of formulations. Other than API there are other excipients / inert materials added to the formulation manufacturing process. However, these inert materials form less than 10% of overall raw material cost.

Below is the direct cost breakup of formulation players:



B. Revenue Model

There are 2 major revenue models under which manufacturers of APIs operate viz. Contract Manufacturing and Trading.

- **Contract Manufacturing**

This method is typically applied in exports to regulated markets for on-patent as well as off-patent drugs. Besides, APIs are also supplied in smaller quantities during drug development stage to global innovators. The margins under this segment are higher as compared to API sold on a trading basis. Also, there is a high level of customer stickiness under this segment as there each formulation manufacturer has 1-2 major vendors for this segment of API supplies.

- **Trading basis**

Majority of the API manufacturers in India (majorly the small players) operate under this model. The pricing is market determined with many manufacturers of same molecule. These molecules

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manufactured under this model are typically commoditized APIs. This model is more prevalent in domestic as well as exports to the semi-regulated markets. For a bunch of drugs which have gone off-patent many years ago, the formulators for such off-patent drugs also in many cases procure APIs on a trading basis.

C. Highly Fragmented

India's Bulk Drug industry is a highly fragmented industry with >2,700 manufacturers. The industry is characterized with the presence of small unorganized players which account for nearly 50% of the overall industry. Majority of these small manufacturers deal in commoditized APIs which are sold on a trading basis. The organized sector composes of both standalone API manufacturers as well as formulation players which are backward integrated.

D. Cost Competitiveness

The cost of manufacturing in emerging economies like India and China are significantly lower than that of US and Europe. China has emerged as the largest exporter of APIs as it enjoys lower cost advantage due to government support as well as lower power and labour cost. However, over the past few years, China has seen cut down of production at various plants on account of environmental concerns. Further, the cost of labour has gone up over the past few years. Thus, India now is turning out to be a preferred destination for API manufacturing. Further, India is also the preferred manufacturing partner for regulated markets on account of its superior chemistry skills and ability to manufacture complex intermediates and APIs.

Comparative Cost of Manufacturing:

Country	Manufacturing Cost
US	100
Europe	85-90
India	
- In US FDA approved plants	45-50
- In other plants	35-40
China	35-40

* Cost for other countries indexed to US cost

Current Industry Trends

A. Focus on Complex APIs

Traditionally, the India API bulk were focused majorly on the high volume, commoditized APIs which required limited spend on R&D. However, over the past 5-7 years significant investments have gone into R&D focused on development of complex APIs. There have been increased investments from players for development of biologic APIs. Currently, drug manufacturers Players have a healthy pipeline of complex generics and limited competition products, which are difficult to manufacture but

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command a higher premium.

B. Backward Integration into Key Intermediates

India largely depends on China for its requirement for the intermediate chemicals and the Key Starting Materials (KSMs) required for manufacturing of APIs. India's reliance on pharmaceutical ingredient imports has risen over the past few decades due to the higher cost of domestic production, with the gap in cost reaching to almost 20%-30%, particularly for energy-intensive fermentation-based ingredients used in anti-infectives.

Due to the supply chain disruptions faced during the COVID-19 pandemic, companies witnessed increase in prices of intermediates by up to 50-100%. Although the API contract manufacturers were able to pass on a large part of these price hikes, the overall industry faced constraints in terms of supplies. As a result, mid-to-large scale API manufacturers have started making investments into backward integration for some of their top API products to ensure regular supply as well as control costs.

C. Government Support

In March 2020, the Union Cabinet approved the scheme for development of Indian bulk drug sector to boost exports as well as to reduce reliance on imports.



















Scheme	Particulars
Production Linked Incentives	<ul style="list-style-type: none">• Tenure: FY21 to FY30• Financial outlay: ₹. 69.4 billion• Scheme applicable for greenfield projects• Financial incentive to be provided for 41 identified key products which cover all 53 identified API's• The networth of applicant (including that of group companies) as on date of application $\geq 30\%$ of total proposed investment• Maximum number of selected applicants: 136• The incentive under scheme shall be applicable only on sales of eligible product to domestic manufacturers
Creation of Bulk Drug Parks	<ul style="list-style-type: none">• Tenure: FY21 to FY25• Financial outlay: ₹. 30 billion• Three bulk drug parks will be supported under the scheme• Maximum grand-in-aid for one bulk drug park will be limited to ₹. 10 billion• Minimum 50% of land area for bulk drug manufacturing units• 3 states to be selected through challenge method

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Recent Deals in the API space

API space has seen a flurry of deals over the past 2 years with renewed interest from top global PE funds looking to create pharmaceutical platforms in India.

Closing Date	Acquirer	Target	% Stake	Amount (INR cr.)
Sep-22			74%	2,000
Apr-22			78%	48
Jan-22			NA	750
Sep-21			52%	1,120
Apr-21			NA	1,600
Mar-21			100%	775
Mar-21			100%	2,000
Oct-20			71%	290
Jul-20			74%	1,040

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Road ahead

China has been the dominant supplier of APIs over the past 2 decades with Chinese APIs accounting for 70% of all imported APIs in volume terms. Major global pharma players faced supply chain disruption amid COVID-19 pandemic. The market saw instances of increase in API prices upto 100-150% given the supply side disruption.

Keeping this in mind, many global pharmaceutical as well as chemical players have taken initiatives of creating a second source of supply to reduce dependence on China. India is likely to be the major beneficiary of this given the cost dynamics and expertise in the pharmaceutical space. Also, most of the API manufacturers are also investments in backward integration into key raw materials which are currently being imported from China.

This has generated interest from various global PE funds to invest in the API space in India. Further, global pharmaceutical majors are looking to make strategic investments in API companies in India from a backward integration / capability building perspective. Also, there has been increasing focus of existing domestic pharmaceutical players to diversify into complex APIs (biologics, sterile API).

Thus, the Indian Bulk Drug industry remains one of the interesting sectors from growth as well as investment perspective.

Sources:

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KPMG Report on Indian API Industry

News Articles

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