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Global API industry snapshot

Pharma demands
and evolving markets

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Contents

- 03** Executive summary
- 03** Chinese API dominance set to continue
- 04** Over reliance
- 04** Looming quality concerns
- 04** Europe's API sector strives to compete
- 04** Securing supply chains key for sector
- 05** Key markets and emerging opportunities
- 06** About CPhI Worldwide

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Executive Summary

Fierce competition in the low cost, high volume API sector is forcing suppliers to invest in capacity and accelerate throughput. Despite repeated quality concerns, China is likely to retain its leadership of the volume API sector, in part, thanks to new regulations.

India, a major producer and exporter of (generic) drugs, is concerned about over-reliance on China. In response, the Indian Government has introduced measures to boost local production. Similar efforts are being considered in the US. This creates a significant opportunity for volume API firms that are willing to invest in manufacturing capacity in India and the US

At the same time the drug industry is increasingly interested in higher potency, combination and niche drugs. For API companies that are willing to invest in the relevant expertise and capacity (particularly containment) there is a real opportunity.

API suppliers that can prove the security of their supply chains from raw materials through to ingredient, are likely to see considerable demand from pharmaceutical firms.

Growth of the generic sector in major markets, particularly the US and Europe, will cement their position as key targets for API manufacturers.

Emerging markets are growing in importance for API firms. The growth of life-style diseases in particular is creating a significant opportunity.

Active pharmaceutical ingredient (API) production is a truly global business. Medicines prescribed in the US and Europe are as likely to contain an active ingredient made in Asia, as they are to contain one manufactured locally.

Global API supply chains extend around the world. They are shaped by shifting drug industry demand, with price and regulatory compliance being among the most important drivers of change.

Suppliers use different strategies to try and win business. Some focus on low cost, high volume production while others concentrate on the creation of specialised, hard to make actives.

The success of their respective strategies determines which suppliers capture the largest share of what is a highly competitive and ever-changing global market place.

Chinese API dominance set to continue

The current global API supplier base consists of hubs in which manufacturers specialize in producing different types of ingredients for separate sections of the pharmaceutical market. China, for example, has a reputation for the production of low cost, high volume ingredients. And it is a major global source for the drug industry.

Data compiled by UK regulator, the Medicines and Healthcare Products Regulatory Agency (MHRA), suggests Chinese manufacturers make around 40% of all APIs used worldwide ^[1]. China's leading role is also recognised on the other side of the Atlantic - according to the US International Trade Administration, China's status is based on the ability to supply high volume APIs at a low cost ^[2].

This view of China is shared by Molly Bowman from research firm, Clarivate Analytics. She told us, "China continues to offer low cost manufacturing on a large scale. Many companies around the world are dependent on Chinese manufacturers for raw materials and chemicals."

Over reliance?

China's dominance is seen as a problem by some. In India, for example, the Government has raised concerns about the country's reliance on Chinese APIs. The argument is that any disruption of supply may impact both the local availability of medicines and the country's drug manufacturing sector [3].

Last year the Pharmaceuticals Export Promotion Council of India (Pharmexcil) told the Hindu Business Line it is collaborating on a plan to reduce the country's reliance on imported APIs, citing China as its major source [4].

Pharmexcil said Chinese manufacturers have started to charge more for APIs, which has made importing them less attractive. The industry group and the Government aim to address this by fostering local production.

Looming quality concerns

Others are worried about Chinese manufacturing practices. Such concerns have been exacerbated by repeated problems with heparin from China, [5] as well as more recent issues with the heart drug active, valsartan [6].

But while these concerns have impacted China's reputation, the country is still a major supplier and is likely to remain one according to Bowman, who told us regulatory reforms are partially offsetting the damage.

“Many companies... have seen their supply chains disrupted by the increasing scrutiny of China's environmental regulators. It is very unlikely that the commodity products and raw materials that are sourced extensively from China will be moved to other manufacturing hubs.”

She added that, “There is a new system of drug supply monitoring under development in China, and the adoption of global standards around the world through the Interagency Supply Chain Group will certainly support more security and transparency in the future of API supply chains.”

Europe's API sector strives to compete

Historically, European API suppliers have found it hard to compete with their Asian counterparts on costs. While rising wages and materials prices are changing this dynamic, the issue continues to inform EU suppliers' strategies.

To differentiate themselves from low cost, high volume suppliers in China and elsewhere in Asia, European manufacturers have invested in capacity for the production of specialised, often highly potent, APIs.

Bowman told us: “European manufacturers continue to be in demand for niche API manufacturing, these include high potency, micronization, etc. while Asian manufacturing hubs are sought for commodities and raw materials.”

“Many European manufacturers have significant history as reliable partners in the API supply chain, and as medicine pivots towards increasingly targeted therapies, European manufacturers are well placed to offer high-quality local API manufacturing.”

Securing supply chains key for sector

The global API industry is also being impacted by growing demand for traceability. As mentioned above, in China, the world's biggest source of drug ingredients, efforts are ongoing to enhance traceability [7].

In the European Union, it is hoped the Falsified Medicines Directive (FMD) will improve the security of drug and ingredient supply chains [8].

The FMD has been more successful in some areas than others says Bowman, who cites IT as a particular stumbling block.

“We have seen a number of countries in Europe implement the technical requirements for the tracking databases required by FMD, however only a few were live in 2018. There has also been some difficulty with hospital implementation of tracking

systems, and a low number of users connected to the repository systems.”

Whether these issues can be addressed remains to be seen. However, as Bowman points out additional measures are likely to be needed to achieve full traceability throughout the supply chain.

“The European Commission is evaluating how to simplify and harmonize, as well as how to support IT infrastructure set up. Full implementation will have better traceability of medicines, but it is unlikely to be a full view into supply chains.”

Key markets and emerging opportunities

The most attractive markets for API manufacturers are the US and Europe. Partly because they are the most lucrative markets – drug sales generated revenues of \$4bn in the US in 2017 according to EFPIA [9].

However, government support for generic pharmaceuticals in the US and Europe – as part

of an effort to combat rising drug costs and healthcare spending – has further increased their attractiveness for API firms, Bowman says.

“US FDA [generic drug] approvals have accelerated, and the shift to more complex products that can capture a higher price is more prevalent in the western markets,” she said.

Bowman added that, “As health agencies in the Western markets continue to push generic utilization, the pricing for generic products, especially in Europe, exerts pressure throughout the supply chain.”

Despite the dominance of the US and Europe, markets elsewhere are becoming increasingly important for the API industry. Again this is partly due to growing pharmaceutical sales. However, shifting epidemiology is also a factor Bowman says.

“Rising healthcare spending in Asia continues to drive the attractiveness of the market, as well as the increasing prevalence of lifestyle diseases.”

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