

Change in scope of the market of APIs

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Introduction

Active Pharmaceutical Ingredient (API) is the active form of a drug.

Decades ago these were imported from countries like the US and China. Later China captured the international market for APIs and became the largest producer of APIs.

Many countries were unaware of the fact that the synthetic API market will be one of the lead-

The market for APIs focusses mainly on either the branded medicines or generic medicines. Taking this into account, we see that since there is always a patent expiry for branded drugs the pharmaceuticals are today mostly interested in generic drugs and this has led to tremendous increase in the demand for market of generic APIs all over the world.

Outsourcing of APIs

Decades ago every pharma-



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ing industries in the years to come. There has been a tremendous increase in demand for APIs and this has proportionally increased the interest of various countries, importantly, India to focus on the international market of the API. This change for the past few years has completely changed the scope of the market of API.

Quality and affordability of healthcare

Today the quality and affordability of healthcare has prime importance. This has led to increase in demand for medicines which in turn is responsible for the rise of demand of APIs globally.

ceutical company had been manufacturing its own APIs but since strict rules and safety measures are being implemented outsourcing of APIs began.

The concerns of quality, safety, environmental concerns, patent expiry and need to increase the generics have all played an important role for outsourcing of APIs, which parallelly has increased the market for them.

China is considered to be the largest producer of APIs, accounting for almost 50 per cent of the global market surpassing the North American market and the United States markets. India is the second-largest supplier of generic APIs.

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• FOS

• Sucralose

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Almost 60% of APIs used imported from China

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The Indian market of APIs is taking a new turn and is expected to cross revenue of US\$ nearly 6 billion by the end of 2020.

India Future Trends in APIs Market

The most important factor that is to be noted is that the immense demand for healthcare needs and the desire of the people for quality healthcare systems and the attitude of people to spend on costly medicine has given boom to the API market. This immense demand has not only raised the standards of the international markets but has also directly had an impact on the import of the API.

Almost 60 per cent of APIs used by Indian pharmaceutical companies are believed to be imported from China, according to the Pharmaceuticals Export Promotion Council of India (Pharmexcil). They say in some cases of APIs, the dependence on import of APIs from China is almost equal to 90 per cent.

These major market changes have caused a major shift in the Indian pharmaceutical industry and have attracted the manufacturers. Most important is the manpower cost, the need for complex molecules, rise in standards for healthcare by urban population and finally the outbursting scientific knowledge have an immense role in the growth.

Today India stands with China in the international market for domestic as well as exports. As there is increase in demand and quality issues arising from the products from China,



to make its footprint in global market of APIs.

This continuous growth and major changes in the global markets have caused a lot of changes internally in the country and have made a lot of mergers in the industries and investor companies.

These changes and implementations have led India to stand as a potent leader for API manufacturing in global markets and get the approvals from various countries for their API production and leading to an aggressive increase in their credibility in the international market. Good quality API with a cost-effective strategy has made India an important reason for the country to receive an outsourcing for API.

ty medicines, high scientific knowledge and capabilities, low cost of labour and cost-effectiveness since the cost of manufacturing formulations in India is 30-40 per cent low compared to countries like China and Europe. The Indian companies are using high technologies for producing these APIs and still maintaining the quality and safety guidelines, this has, however, increased the acceptance of the products in the markets globally.

Conclusion

In the coming years, it is believed to be a tremendous increase for API market in the world and the countries adhering to the guidelines of safety, quality and go green will have an upper hand as they will have to clear

India has tried to concentrate more on the guidelines of ICH and FDA requirements for the manufacturing of APIs, in this way trying

Advantages of Indian Market

The biggest advantage of India's pharmaceutical markets being providing high quality



the regulatory audits.

As of today, the top players being China, now landed on the crisis of API exports, as the regulations are imposing them to show the safety and the SOPs they are followed in making APIs. This has showed a downward trend to the export of the API since many of them are unable to clear the regulatory audits and lack of proper documentation.

There is a huge advantage for India as the Indian government has been offering a huge support for self manufacturing of APIs rather than the import from China and is improving the standards of manufacturing and safety. We can expect that in near future India make a strong presence in the API manufacturing market globally. ○

(The author is leading pharmaceutical consultant)