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South Asia - Hub for generic drug production

DR SANJAY AGRAWAL

HE pharmaceutical manufacturing industry is one of the most critical sectors in the global healthcare landscape. It is responsible for producing essential medications, vaccines, and therapies that improve and save lives worldwide. South Asia, with its rapidly growing pharmaceutical capabilities, has become a key player in this global industry.

Countries such as India, Bangladesh, Pakistan, Sri Lanka and Nepal have become a major source of pharmaceutical manufacturing due to their significant role in the supply as well as availability of drugs at an affordable cost. South Asia is particularly essential for the inexpensive production of generics, and its developing infrastructure as well as the development of innovations place it firmly to have a much greater role in the near future.

The Importance of South Asia in Pharma Mfg

South Asia is home to the pharmaceutical industry, and it is among the largest in the world, accounting for a significant share of the world's pharmaceutical production. The region's largescale manufacturing capabilities, access to affordable labour, and technological advancements in drug production have propelled it to the forefront. Here's a breakdown of the key reasons behind South Asia's dominance in pharma manufacturing:

India: The Global Generic Drug Powerhouse

India is often considered the "pharmacy of the world" because India is the largest manufacturer of generic drugs in the world. Over 20% of the globe's generic drugs and more than 60% of the vaccines manufactured worldwide are made in India. With a large number of companies like Sun Pharma, Cipla, and Dr. Reddy's Laboratories, India has not only emerged as the leader in generic medicine production but also become the most trusted supplier to many countries around the world.

The Indian pharmaceutical sector is catering to the domestic as well as the international market so that affordable healthcare becomes accessible to people all over the world. Further, the Pharmaceutical Export Promotion Council (Pharmexcil) of India has played an important role in propelling pharmaceutical exports. Moreover, India is very highly valued for stringent regulatory standards across several global markets like the United States and Europe.

Bangladesh: Emerging as a New Pharmaceutical Power

Bangladesh, although small compared to India, is experiencing an enormous surge in its pharmaceutical industry. The country has a robust pharmaceutical manufacturing industry with many domestic players such as Beximco Pharmaceuticals and Eskayef Pharmaceuticals gaining global recognition.

The pharmaceutical industry in Bangladesh is peculiar because it can produce cheap, highquality drugs at a cost, bypassing the patent laws as provided for under the TRIPS agreement, enabling it to manufacture generics of patented drugs at a cheaper cost. The country has emerged as a major supplier of generic drugs to international markets, especially in Africa and Southeast Asia. Bangladesh's government also has supportive policies in place that have helped promote growth in the pharmaceutical industry, making the country an important contributor to global healthcare.

Pakistan: Steadily Building Pharmaceutical



Pakistan, though smaller than India or Bangladesh in terms of volume, has also managed to find a niche in the production of pharmaceuticals. The country has been focusing on increasing its generics and APIs productions.



Pakistani pharmaceutical companies are setting up new and expanding their already existing production lines to meet the international standards, and many companies are beginning to export towards neighbouring countries and internationally.

The pharmaceutical sector in Pakistan is expected to grow significantly in the coming years, driven by government incentives, investments in research and development, and expanding access to quality medicines within the country.

Sri Lanka and Nepal: Growing, Yet Small Players

Sri Lanka and Nepal, though smaller players in the pharmaceutical manufacturing sector, have been taking steps to develop their local industries. Sri Lanka has focused on establishing a stable domestic pharmaceutical market to meet local demand while gradually exploring export opportunities.

Nepal, too, has made efforts to reduce its dependency on imported drugs by investing in domestic manufacturing. While the scale of production in these countries is not comparable to India or Bangladesh, both are developing pharmaceutical industries that contribute to their national economies and healthcare systems.

Key Strengths of South Asia's Pharma Sector

Cost Efficiency

South Asia provides a well-balanced skilled labour force at low cost and low production cost, which makes it a preferred destination for pharmaceutical manufacturing. Given these advantages, cost-effective high-quality medicines can be produced at competitive prices for essential drugs of developing and underdeveloped countries.

Strong Generic Drug Manufacturing

South Asia is a hub for generic drug production, especially India, which produces a vast range of generic medicines that meet stringent regulatory standards set by agencies like the US FDA and WHO. This focus on generics helps reduce the cost of healthcare worldwide.

Skilled Workforce

The region boasts a large pool of scientifically trained professionals, including pharmacists, chemists, and engineers, who contribute to research, development, and manufacturing.

Govts actively engaging with industry

CONTINUED FROM p20>

Regulatory Compliance

There are many manufacturing plants in South Asia, which operate under international regulatory standards, and their products are safe and potent. India and Bangladesh are specifically equipped with facilities approved by global regulators.

Export Potential

South Asian countries are major exporters of APIs and finished formulations to the markets of North America, Europe, Africa, and Southeast Asia.

Challenges Facing Pharma Manufacturing in South Asia

Despite the successes, South Asia's pharmaceutical sector has many challenges:

Environmental Concerns

The pharma manufacturing process can generate considerable waste, raising environmental concerns. Implementing eco-friendly manufacturing practices is essential for long-term sustainability.

The Government and Policy

Governments in South Asia are actively engaging with the pharmaceutical industry. For example, India's "Production Linked Incentive (PLI) Scheme" is focused on increasing domestic API production and reducing import dependency. Bangladesh's National Drug Policy is also focused on self-reliance and export promotion. Trade agreements and shared research initiatives among South Asian countries can further strengthen the region's pharmaceutical ecosystem.

Future Outlook of Pharmaceutical Manufacturing in South Asia

Several trends are set to shape the trajectory of pharmaceutical manufacturing in South Asia. They include: for biologics, South Asian manufacturers are likely to focus more on biosimilar production, targeting chronic diseases and complex conditions.

- Sustainability Initiatives: Green manufacturing will be the need of the hour to address environmental concerns and meet global standards for eco-friendly production.
- Increased R&D Investments: Governments and private players are likely to increase funding for research and development, which will encourage innovation and pave the way for new drug discoveries.

Conclusion

The pharmaceutical manufacturing industry in South Asia stands at a critical juncture. It is poised to become a world leader in the pharmaceutical industry by leveraging its strengths, strategic investments, and policy reforms. With challenges addressed, innovation embraced, and collaboration fostered, South Asia can continue to deliver affordable, high-quality medicines to the world while driving economic growth and improving global health outcomes.

(The author is scientific advisor, Alkomex GBN Pharma Group U.S.A)



Dependence on API Imports

Although South Asia has a good manufacturing base for finished formulations, it is largely dependent on APIs imported from China. The dependence makes it vulnerable to supply chain risks during political tensions or other global crises.

Regulatory Bottlenecks

Many manufacturers have adapted to international standards. However, variations in domestic regulatory structures can act as a hindrance. Consolidation of the domestic regulatory structures in the region will help sustain growth.

Infrastructure Limitations

Inadequate infrastructure, especially in smaller South Asian countries, can prevent the scaling up of manufacturing units and timely distribution of products.

R&D Investment

South Asia's pharmaceutical industry is majorly focused on generics, at the cost of new drug development. Funding and innovation in R&D are important to compete in the global market.

- More APIs: Increased investment in API production will minimise import dependency and build a more autonomous and robust supply chain.
- Digital Transformation: Embracing AI, ML, and blockchain will help to make the process of manufacturing better optimised, with greater quality assurance, and improved supply chain transparency
- Biosimilars Focus: With the increasing demand



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