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sis on the CDSCO website.

"This is to enable work distribution amongst the lab and for release of test reports in a time bound manner by these laboratories," said Raghuvanshi. Accordingly, the drug manufacturers and exporters may refer to the daily list and submit the sample to the laboratory having fewer samples as compared to other lab, he added in a circular.

According to reports, the DCGI has also issued standard operating procedures in May, to streamline the processes of testing in the laboratories and ensure the standard quality across the laboratories.

On May 22, the DGFT has issued a notification amending the export policy of cough syrup from free exports to the mandate that the cough syrup shall be permitted to be exported subject to the export sample being tested and the Certificate of Analysis (CoA) issued by certain laboratories to be submitted.

It also enlisted the laboratories, including the Indian

Pharmacopoeia Commission, Ghaziabad, Central Drugs Laboratory, Kolkata, Central Drugs Testing Laboratories (CDTLs) in Chennai, Mumbai and Hyderabad, Regional Drugs Testing Laboratories (RDTLs) in Chandigarh and Guwahati and any NABL accredited State Drugs Testing Laboratory to conduct tests and issue the CoAs.

"The export of 'Cough Syrup' under ITC (HS) Codes falling under the Heading 3004 shall be permitted subject to the export sample being tested and production of Certificate of Analysis (CoA) issued by any of the laboratories as mentioned in Para-1 above, with effect from June 1, 2023," said the DGFT's notification.

According to reports, the DCGI's standard operating procedure for testing of cough syrups advises the manufacturer to submit their license of the product for export and the export order, among others as part of the testing.

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Prospects of Bangladesh pharmaceutical industry

Dr. Sanjay Agrawal

The pharmaceutical industry is vital in improving healthcare outcomes and driving economic growth. Bangladesh's pharmaceutical sector has experienced

remarkable growth over the past few decades, earning recognition at home and abroad. With a solid foundation in generic drug manufacturing, the country has become a significant player in the global pharmaceutical market.

Industry overview

The pharmaceutical industry in Bangladesh embarked on its journey in the 1950s with a mix of multinational corporations (MNCs) and local firms. Following the country's independence in 1971, Bangladesh,

as a least-developed nation, obtained a patent exemption for the pharmaceutical industry under the British Patents and Designs Act of 1911. This exemption led to an increase in the production of generic medicines within the country.

However, the industry's significant growth began in the 1980s.

By 1981, there were 166 licensed pharmaceutical factories in Bangladesh. At that time, the country's pharmaceutical production was dominated by

eight multinational companies, such as Glaxo, Pfizer, and Hoechst, which supplied 75 per cent of the country's medicine.

Meanwhile, 25 medium-sized domestic pharmaceutical companies accounted for 15 per cent of the production, with the remaining 10 per cent manufactured by 133 companies. These companies relied on imported raw materials worth BDT 60 crore annually to produce medicines locally. Despite having 16 local pharmaceutical companies, the country still imports medicines worth BDT 30 crore from abroad every year.

The pharmaceutical value chain in Bangladesh is divided into two primary sectors: Active Pharmaceutical Ingredients (API) and finished formulation. API refers to medicines containing specific active ingredients for targeted diseases, while finished formulation involves the preparation of medications by blending various chemicals with active ingredients.

In March 1982, the government formed an expert committee to develop a drug policy encompassing the formulation and API sectors.

However, at that time, the government only implemented the Drugs (Control) Ordinance for the formulation sector, while two additional regulations were introduced in June. One rule aimed to ban the production, import, and sale of unnecessary and harmful drugs, while the other prohibited

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Urban, rural populations become more health conscious

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products of MNCs that lacked manufacturing plants in the country.

Despite pressure from the US government, Bangladesh did not repeal these regulations. As a result, approximately

1700 out of 4340 registered medicines were banned and removed from the market, allowing MNCs to reorganize their operations, albeit leading to the closure of specific organizations such as Squibb.

In 1995 Bangladesh signed the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement with the World Trade Organization. As one of the least developed countries, Bangladesh was granted the privilege of manufacturing and marketing medicines without patent restrictions.

This facilitated the production of medicines at lower costs, significantly reducing prices at the consumer level—an essential aspect for the healthcare sector in an underdeveloped country like Bangladesh. Initially valid until 2005, the TRIPS agreement was extended to 2016 and subsequently prolonged until 2033, fostering the growth of the country's pharmaceutical industry.

Revenue growth drivers

The pharmaceutical industry in Bangladesh experiences revenue growth driven by various factors, including domestic sales and exports. The following reasons contribute to the current revenue growth of the pharmaceutical industry in Bangladesh:

Economic growth

With a population exceeding 166 million, Bangladesh is experiencing steady population growth at an average rate of 1.1 per cent annually. Furthermore, accord-

ing to The Business Standard, Bangladesh has over 37 million middle-class families, accounting for approximately 22 per cent of the total population. This middle-class segment is continuously expanding.

In the fiscal year 2020-21, Ban-

gladesh's per capita income rose eight per cent compared to the previous year, reaching \$2,227. The growth in the number of middle and upper-class Bangladeshis, coupled with the overall increase in the country's consumption, has led to a

rise in healthcare expenses for its citizens.

Health awareness

As income levels increase, Bangladesh's urban and rural populations have become more health-conscious. With medical

and pharmaceutical companies' adoption of modern technology, people in the country are paying closer attention to proper nutrition, protein intake, healthy eating habits, and the avoidance of pollutants.

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Life expectancy of Bangladeshi's increase significantly

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Additionally, the average life expectancy of Bangladeshis has increased significantly. According to the Bangladesh Bureau of Statistics, the average life expectancy in the country rose from 66.4 years in 2002 to 72.6 years in 2020. The growing awareness among the population and the advancements in the pharmaceutical sector has played a crucial role in this increase in life expectancy.

Exports

Bangladesh has witnessed a significant expansion in pharmaceutical exports. According to the Bangladesh Association of Pharmaceutical Industries (BAPI), more than 1,200 pharmaceutical products have been registered for export in the country over the past two years. In the fiscal year 2018-19, Bangladesh exported to 147 countries, including Myanmar, Sri Lanka, the Philippines, Vietnam, Afghanistan, Kenya, and Slovenia, accounting for 60.32 per cent of the exports.

The remaining 39.6 per cent was directed towards developed countries such as the US, Canada, Germany, and Australia. In FY 2018-19, the value of medicine exports reached \$130 million, which increased to \$136 million in FY 2019-20. From 2014-15 to 2019-20, Bangladesh's pharmaceutical

exports doubled at an average annual growth rate of approximately 12 per cent. ResearchAndMarkets states that



Bangladesh has emerged as a cost-effective manufacturing hub for pharmaceutical products. The availability of skilled labour, low production costs, and a favourable regulatory environment have contributed to the country's competitive advantage in the global pharmaceutical market

Bangladesh's pharmaceutical exports are projected to reach \$450 million by 2025.

Growing domestic market

One of the key factors driving the prospects of the Bangladesh pharma industry is the country's growing domestic market. With a population exceeding 165 million, the demand for quality healthcare products and services is rising. As the middle class expands and ac-

cess to healthcare improves, the demand for pharmaceuticals is expected to increase further. This presents a significant op-

portunity for local pharmaceutical companies to cater to the needs of the domestic market.

Low-cost manufacturing

Bangladesh has emerged as a cost-effective manufacturing hub for pharmaceutical products. The availability of skilled labour, low production costs, and a favourable regulatory environment have contributed to the country's competitive advantage in the global phar-

maceutical market. Local manufacturers can produce high-quality generic drugs at significantly lower costs than

their counterparts in other countries. This cost advantage enables Bangladesh to export pharmaceutical products to various markets worldwide, including developed countries.

Export potential and global recognition

The Bangladesh pharma industry has witnessed substantial growth in its export potential. Local pharmaceutical companies have been recog-

nized for complying with international quality standards and regulations. Many Bangladeshi manufacturers have obtained certifications from prestigious regulatory authorities such as the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the World Health Organization (WHO). These certifications have opened doors to export opportunities in markets across Asia, Africa, and Latin America, establishing Bangladesh as a reliable source of quality pharmaceutical products.

Investment in R&D

Bangladesh has been increasing its investment in research and development (R&D) to enhance the pharma industry's prospects further. Pharmaceutical companies are allocating resources to develop new drug formulations, improve manufacturing processes, and enhance product quality. Collaborations between local pharmaceutical companies and academic institutions foster innovation and knowledge-sharing. Such R&D investments contribute to developing new drugs, treatment protocols, and advanced healthcare technologies, enabling the industry to expand its offerings and cater to a broader range of medical needs.

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Bangladesh earns reputation for quality medicines

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Suresh Khanna, designated partner, Dossier Solutions LLP, Hon. National General Secretary, Indian Pharmaceutical Association, Headquarter Member and Chairman, Karnataka Drugs and Pharmaceutical Manufacturers Association said that India can make its presence felt with the export of pharma manufacturing equipment like for tablet, form filling, air handling units etc and packaging equipment. The pricing of these will lure Bangladesh pharma majors to opt for India's cost-effective and high-quality equipment. There is a big demand for this in the developing world. Indian companies have invested extensively to manufacture this indigenously.

Contract research and manufacturing

The next growth area of Indian pharma is in contract research and manufacturing services (CRAMS), product development, regulatory protocol ad-

herence, dossiers submissions in the required CTD (Common Technical Document) format. There is a huge talent pool armed with skills of clinical studies, clinical data management, technical data writing, medical writing and coding which requires ample skill sets in information technology. Therefore, there is scope for significant growth in these pharma services from India to the global markets. The biggest advantage that stands to gain is the pool of English-speaking professionals. This is attributed to the pharmacy and biotech education in the country, stated Khanna.

According to Jatish N Sheth, director, Srushti Pharmaceuticals, Bangladesh is a good and growing market. The country is admired for its formulation manufacturing capability over the last five years. We supply processed material for formulation production. Payments and pricing are not an issue in the region. But as the country now insists on registration, only

high-quality players can have a presence. Therefore, Indian API companies should explore this market.

The leading companies in the region are Square Pharmaceuticals, Beximco Pharmaceuticals, Renata Limited, Incepta Pharmaceutical, Oponin and ACI to name a few. These are all USFDA approved among other regulatory clearances and are reporting stellar performance in terms of growth garnered from the global market.

India had proposed an FTA and Comprehensive Economic Partnership Agreement (CEPA) to promote two-way commerce and investments with Bangladesh. From the Indian standpoint, Bangladesh pharma companies are giving a tough competition in the global markets specifically to the developed world for formulations.

However, this is not a worry for us because it is primarily a finished dosage market and they continue to import APIs from India although China

contributes to the largest basket of these bulk drugs and intermediates, said Archana Dubey, vice president, international marketing Bal Pharma.

Growing Bangladesh pharma sector

At present, Bangladesh's pharmaceutical sector meets 97 per cent of the domestic demand worth about \$3.5 billion. In FY22, the country exported pharma products worth \$189 million. It ranked 67th in the global pharma export market last year.

According to experts, the size of the global pharmaceutical market in 2021 was \$825 billion. If Bangladesh can take even five per cent of this, the country will have another sector like the ready-made goods.

The pharma industry in Bangladesh has earned a considerable reputation for producing quality medicine by maintaining international standards. Today, Bangladesh has become a pharmaceutical exporting country.

Around 98 per cent of the country's total demand for medicines is being produced locally. It is exporting medicine to about 15 countries in Europe, America, the Middle East, and Central Asia.

After 2024, it will continue to advance in the same way in the international market. After five years, the country's pharmaceutical industry will enter a different level. It has to start factories and sales centres outside the country to conquer the global market. For this expansion, the Bangladesh government needs to be more liberal in terms of providing policy support, they pointed out.

Bangladesh is India's biggest trading partner in the subcontinent and India is the second biggest export partner accounting for 12 per cent of the total exports to Bangladesh. The total trade turnover in 2021-2022 touched US\$18.2 billion. The major items exported by India to Bangladesh are cotton, vehicles, iron and steel, machinery, and pharmaceuticals.



Govt implements policy reforms to foster industry growth

CONTINUED FROM p18

Government support and policy reforms

The Bangladesh government has recognized the importance of the pharmaceutical sector as a significant contributor to the national economy.

The government has recently implemented several policy reforms to foster the industry's growth. These reforms include streamlining regulatory processes, strengthening intellectual property rights, and encouraging public-private partnerships.

Moreover, the government has provided various incentives to attract foreign investment in the pharmaceutical sector, such as tax breaks, infrastructure development, and simplified business procedures. This supportive environment has created a conducive industry growth and development ecosystem.

Conclusion

The revenue growth of the pharmaceutical industry in Bangladesh is driven by factors such as the country's economic growth, increasing health awareness among the population, and the expansion of pharmaceutical exports. The growing middle class, rising per capita income and increased consumption contribute to the higher demand for healthcare products and services.

Moreover, the emphasis on health and well-being, along with the advancements in the pharmaceutical sector, has led to a longer life expectancy in the country. The pharmaceutical industry's focus on export markets further boosts revenue growth, with Bangladesh becoming a significant player in supplying medicines to various countries. With a positive trajectory and supportive market conditions,

the pharmaceutical industry in Bangladesh is well-positioned for continued growth in the coming years.

The prospects of the Bangladesh pharma industry are bright and promising. With a growing domestic market,

cost-effective manufacturing capabilities, international recognition, and increased investment in R&D, the industry is well-positioned to expand its global footprint.

The government's support and policy reforms have played

a significant role in creating an enabling environment for the sector to thrive. As the demand for pharmaceutical products continues to rise globally, Bangladesh's pharma industry is poised to become a key player in meeting the growing health-

care needs of people worldwide while contributing to the country's economic growth and development.

(The author is leading pharmaceutical consultant and Editor-in-Chief of IJMToday)

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