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Use of alternative methods of official methods in IP

decision to be made as to whether compliance with the standards of the monographs would be achieved if the official methods were used.

Automated procedures utilising the same basic chemistry as the test procedures given in the monograph may also be used to determine compliance. Such alternative or automated procedures must be validated and are subject to approval by the authority competent to authorise manufacture of substance or product.

"For removal of doubts, it is clarified that the authority competent to authorise manufacture of substance or product as mentioned above in the General Notices of IP refers to the licensing authority, either State or Central Drug Regulatory Authority as the case may be, for grant of license and approval. All concerned are requested to bring the above clarification to the notice of all authorities under their control," according to Dr Rajeev

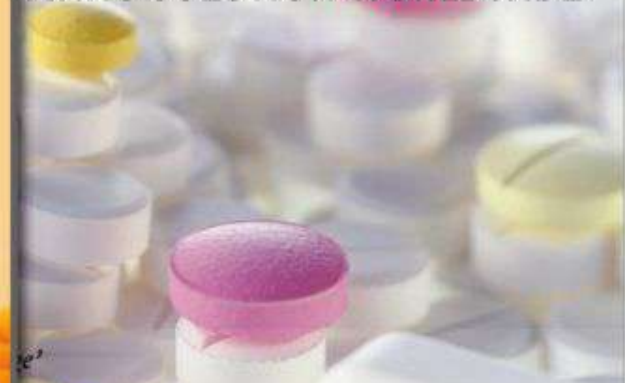
Singh Raghuvanshi, secretary-cum-scientific director, IPC.

IPC is an autonomous institution of the Union ministry of health. It is created to set standards of drugs in the country. Its basic function is to regularly update the standards of drugs commonly required for treatment of diseases prevailing in this region. It publishes official documents for improving Quality of Medicines by way of adding new and updating existing monographs in the form of Indian Pharmacopoeia.

It further promotes rational use of generic medicines by publishing National Formulary of India. IP prescribes standards for identity, purity and strength of drugs essentially required from the health care perspective of human beings and animals.

IPC also provides IP Reference Substances (IPRS) which act as a fingerprint for identification of an article under test and its purity as prescribed in IP.

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Challenges and advancements in Bangla pharma industry

Dr. Sanjay Agrawal

The pharmaceutical sector is one of the most technologically developed sectors in Bangladesh.

The industry has made significant strides in technology adoption in recent years, enabling the sector to increase efficiency, productivity, and innovation.

The Drug Ordinance of 1982, a modified version of the Drug Act of 1940, is credited with aiding the pharma business growth in Bangladesh. Regarding the worldwide market, the industry has enormous potential due to the Agreement on Trade Related Aspects of Intellectual Property Rights exemption from patent requirements until 2033.

One of the critical areas of technological development in the pharma sector in Bangladesh is research and development. With the help of advanced technology and equipment, pharma companies can conduct cutting-edge research and develop new drugs that meet the needs of patients. This has led to the development of several innovative

products that have been well-received both in Bangladesh and internationally.

Bangladesh does not have many dependencies on pharmaceuticals from other countries. They only depend on China, not even India, for medicines. In addition to research and development, the pharmaceutical sector in Bangladesh has also invested heavily in manufacturing technology. The use of modern manufacturing equipment has enabled companies to produce high-quality products in large quantities, which has led to increased efficiency and reduced costs. As a result, the industry has produced drugs at a lower cost, making them more affordable for patients.

Another area of technological development in the pharma sector in Bangladesh is quality control. With the help of modern equipment and advanced technology, pharma companies can conduct comprehensive quality control testing to ensure that their products meet international standards. This has helped to improve the industry's reputation both do-

mestically and internationally, as the quality of the products produced in Bangladesh is now recognized as being on par with those produced in developed countries.

The use of technology in the pharma sector in Bangladesh has also enabled companies to improve their supply chain management. With the help of modern logistics and distribution systems, companies can ensure that their products are delivered to patients promptly and efficiently. This has increased customer satisfaction and loyalty, as patients can access the drugs they need when needed.

The export of drugs from Bangladesh is also expanding at a strong rate and has provided about US\$120 million over the previous few years. The sector is anticipated to increase to \$5.11 billion by 2023, with a historical five-year CAGR of 15.6 per cent. With an estimated \$715 billion in annual revenue, the sector has seen enormous growth over the past 10 years, currently providing over 1.85 per cent of the nation's GDP.



Challenges faced by pharma industry

The pharma industry is crucial in providing healthcare services to people in Bangladesh. Although there is growth in pharma, there are some challenges that need to be improved over time.

Regulatory oversight needs improvement: The regulatory oversight in the pharma industry in Bangladesh is poor. The government agencies responsible for regulating the industry lack the resources and manpower to monitor and enforce regulations adequately. This has led to several issues, including the widespread distribution of counterfeit drugs and substandard products in the market.

Lack of innovation: The pharma industry in Bangladesh is primarily focused on manufacturing generic drugs, and there needs to be more investment in research and development. This has led to a need for more innovative products and a limited pipeline of new drugs.

Low access to finance: Access to finance is a significant challenge for the pharma industry in Bangladesh. Many pharma companies need help to secure financing for their operations and expansion, as banks and other financial institutions often perceive the industry as high-risk.

Infrastructure needs to grow with time: The infrastructure in Bangladesh, including transportation and distribution systems, needs to be improved, which makes it difficult for pharma companies to get their products to market. This can result in delays, increased costs, and even product spoilage.

Limited capacity for quality control: The capacity for quality control in the pharmaceutical industry in Bangladesh is limited. Many companies need more equipment and

resources to conduct comprehensive quality control testing, which can lead to the distribution of substandard or even dangerous products.

Need to increase skilled workforce: A skilled workforce is a significant challenge for the pharma industry in Bangladesh. The industry is highly technical, and there need to be more trained professionals in research and development, manufacturing, and quality control.

Bangladesh's pharma industry faces several challenges that hinder its growth and development from making a higher set of targets and futuristic growth. To overcome these challenges, the government and industry stakeholders must work together to improve regulatory oversight, increase investment in research and development, improve access to finance, upgrade infrastructure, improve quality control, and develop a skilled workforce. Only then can the industry achieve its full potential and provide the people of Bangladesh with the healthcare products they need.

Future of Bangla pharma industry

The pharma industry's future in Bangladesh is promising, but it will require a concerted effort from government and industry stakeholders to overcome the current challenges. Despite the challenges, the pharma industry in Bangladesh has already made significant progress in recent years and is poised for further growth and development.

One of the critical factors that will drive growth in the pharmaceutical industry in Bangladesh is the increasing demand for healthcare services. With a growing population, increasing awareness of health issues, and rising incomes, the demand for healthcare products and services is expected to continue to increase in the coming years.

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Future of pharmaceutical market in Bangladesh

Komal Saini & Vandita Kakkar

In the pharmaceutical industry, Bangladesh holds good commercial potential. As a highly populated nation, it boasts of a booming pharma industry. Bangladesh's local medicine producers are ramping up production to meet domestic demand.

The multinational corporations in the nation's pharma industry are changing their business models by importing inert additives and active pharmaceutical ingredients (APIs) from other low-cost suppliers in nearby nations. Bangladesh's economy is now considered to be "ready to grow" due to the GDP growth rate, which was predicted to be 8.1 per cent over the previous two to three years. The pharma industry is undoubtedly ready to take advantage of such economic growth.

The API policy intends to manufacture 370 important API compounds for exports while also drastically reducing the cost of producing raw materials. A total of 41 laboratory reagents and API compounds were developed domestically in 2017. The goal of the initiative is to reduce dependency on imports of raw materials from 97 per cent in 2016 to 80 per cent in 2032.

Bangladesh is dependent on imports from China, South Korea, and India because it lacks domestic APIs. Bangladesh has 285 medications on its list of essential medications, and the government alone controls and sets the prices for these goods. More than 450 generic medications are produced in Bangladesh for 5,300 registered trademarks that come in 8,300 distinct dosage and strength variations.

For four key reasons, Bangladesh has some of the lowest pharmaceutical prices in the world. First off, the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement with the WTO frees the nation from the obligation to grant patents, allowing for the legal re-engineering and sale of any novel chemical.

Second, as a result of this flaw, many generic manufacturers are perpetually locked in a price war. Third, branding has yet to have a substantial impact in Bangladesh due to the country's low per capita income, which again drives prices down due to product similarity.



Finally, due to the nation's level terrain and extremely dense population, all 20 of the leading manufacturers have significant distribution networks that allow them to supply pharmacies directly, preserving their profit margins and permitting additional price reductions.

The Bangladeshi pharmaceutical industry's biotech pioneers are regarded as an important resource for enhancing the effectiveness and overall performance of the market. Unexpectedly, the pharma sector in Bangladesh had been heavily reliant on imports as well as on global corporations to suit the needs of the local populace.

By providing more than 90 per cent of the total number of drugs on the market, local pharma businesses have recently changed the game. With an absolute growth rate of 114 per cent from 2019 levels, the pharmaceutical market is predicted to surpass US\$ 6 billion by 2025 after experiencing strong growth in recent years. According to prior trends reached throughout the last two decades, the majority of this increase will be supplied by local enterprises with market shares of more than 90 per cent.

Barriers for pharma industry

Tariffs and international trade restrictions

TRIPS is a global accord that is managed by the World Trade Organization (WTO). All signatory parties are required by this agreement to enshrine a 20-year product patent protection requirement for pharmaceutical items in domestic law.

The 48 least developed nations (LDCs) were not required to enact goods patent rights legislation until 2016, however that deadline was

extended in late 2015 until 2033. Among these 48 nations is Bangladesh. So long as the medication does not have a patent or product patent pro-

Insufficient raw material production facilities

tection in place, Bangladesh is permitted to export it to any nation until 2033. After new changes in 2015, pharma businesses in Bangladesh are given limited exporting advantages as well as patent-free domestic production rights through 2033.

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Absence of bioequivalence test facility

The only activity the pharmaceutical industry in Bangladesh engages in is the production of finished goods. Nearly 80 per cent of Bangladesh's basic resources are currently imported (Padma, 2011). The local production of APIs (raw materials) will considerably help the pharmaceutical industry increase export volume and be less reliant on other nations that produce APIs.

In many of the moderately and heavily regulated nations around the world, a bioequivalence study is the cornerstone of product registration. Yet, Bangladesh severely lacks the necessary facilities for a bioequivalence investigation. A pharmaceutical corporation must now conduct this test in a foreign nation while paying a significant amount of foreign currency in order to register a product.

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Leading firms pursuing high-end development trends

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Lack of modern drug testing laboratory

The Directorate General of Drug Administration (DGDA) is unable to keep track of the quality of medicines produced by various pharma businesses in Bangladesh due to a lack of a well-equipped drug testing laboratory. Because of this, regulatory agencies and customers from other countries occasionally dispute the efficacy of our medication.

Marketing strategy

Leading firms are currently pursuing a high-end development trend in the pharma industry. A growing number of businesses are in competition with emerging pharma sectors. As a result, the effectiveness and efficiency of the highly trained and competent medical promotion officers heavily influences the performance of the pharma enterprises.

Problems regarding export

The import and export of raw materials, packaging materials, manufacture, sale, price, and licencing are all subject to DGDA regulation. This is Bangladesh's extremely reliable drug regulation agency. Nonetheless, they are unable to perform their jobs effectively due to a lack of sufficient lab-

our and efficient training programmes. The skills and information they would acquire via ongoing training and exchange programmes with international regulatory agencies would enable them to carry out their tasks more successfully.

Competition in pharma market

There are two different sorts of competition in Bangladesh's pharmaceutical industries: one is for the domestic market, and the other is for the generic market by having a US FDA-approved factory. Basically, the following variables determine rivalry in various businesses, including the pharmaceutical industry (Porter, 2008).

Every day, competition among various pharmaceutical industries intensifies (Hoq et al., 2013). Existing companies are inadvertently pushed to create the same type of medicines when a pharmaceutical company introduces a new drug in order to seize the chance.

Threat of new entrants

Numerous sizable businesses, including Square, Incepta, Beximco, Opsonin, Renata, and others, successfully run their operations in the pharma sector in Bangladesh. Any new competitors will therefore face

intense competition from these well-known firms. Because reliability is such an important aspect in the pharmaceutical sectors, it is quite difficult for new entrants to capture the market. Once more, if a young company tries to compete with an established one, they may run into the problem of the rivals' extensive resources.

Threat of substitute products

In Bangladesh, patients and prescribers in therapeutic situations have a variety of options. Nowadays, the nation's medicine production industry includes 269 allopathic, 205 ayurveda, 266 unani, 27 herbal, and 79 homoeopathic enterprises. As a result, patients can choose from a variety of medications. Hence, they can try to swap one for another.

Bargaining power of buyers and suppliers

Consumers in the pharmaceutical sectors don't have a lot of negotiating leverage. Influencing physicians, drug wholesalers, and retail stores to push products is becoming more common in Bangladesh. Customers have minimal negotiating leverage because medication is the most essential need for the community and prices are nearly uniform across all firms.

The Bangladeshi pharma industry is dependent on a number of nations for its raw materials, including China, India, Germany, the United Kingdom, France, Italy, Denmark, Switzerland, and Austria. Bangladesh now produces a negligible number of raw materials, however once the API park is fully functional, it is hoped that they would begin producing APIs. As a result, the API suppliers to pharmaceutical companies are well-positioned to negotiate.

Recommendations

The proposed suggestions may help the pharmaceutical industries to minimize the problems in different areas:

- The government has already made it easier for the pharmaceutical industry by lowering the customs tariff on raw materials, and has just announced plans to open Munshiganj's API park. These efforts are commendable, but the government ought to do more to encourage export to other nations.
- Strict application of standard operating procedure in all aspects of production.
- Promoting knowledge-based marketing approach.
- Establishment of bioequivalence test facilities.

- Establishment of a Clinical Research Organization to conduct clinical trials.
- Practicing strict rules and regulations to fight against counterfeit drugs.
- Making people more health conscious.
- Immediate establishment of hospital pharmacy in every government and private hospitals.
- Export Promotion Bureau (EPB) can play an effective role by arranging international fair frequently.
- Proper selection of raw materials and machineries for better product quality.
- More attention should be given to research and development sector.
- Efficient human resource is the key factor for the growth of any sector. For this, proper training and development programs need to be started in the industries as well as in universities. ♦

(Konul Saini is Assistant Professor at Chandigarh College of Pharmacy, Chandigarh Group of Colleges, Landran, Mohali and research scholar at University Institute of Pharmaceutical Sciences, Chandigarh. Vandita Kakkar is Assistant Professor at University Institute of Pharmaceutical Sciences)

Bangla pharma cos giving tough competition in global markets

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Therefore, there is also 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.

A growing market

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, Opsonin 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.

Indian pharma plays a key role in Bangladesh going by the rise in non-communicable diseases (NCDs). Cardiovascular diseases, diabetes, cancers and chronic respiratory diseases are responsible most of the deaths in Bangladesh, many of which are premature.

NCDs are directly related to diet and lifestyle. Elevated blood pressure, high blood sugar level, high blood cholesterol level, and obesity are the risk factors that are precursors of developing heart disease, diabetes, cancer, stroke, and kidney disease. These risk factors are linked to a lack of physical activity, unhealthy dietary habits, smoking, alcohol abuse, stress, and air pollution. There is also a huge market opportunity for biologicals and biosimilars. ♦

Need to invest more in research & devtpt

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To meet this demand, the pharmaceutical industry in Bangladesh will need to continue to invest in research and development to develop new and innovative products that meet the needs of patients. This will require increased investment in the industry and the development of a skilled workforce to support research, development, and manufacturing.

The government will also need to continue to support the industry by creating a favorable regulatory environment and providing access to financing for industry stakeholders. By creating an enabling environment, the government can encourage investment and growth in the industry, which will ultimately benefit the people of Bangladesh.

In addition, the pharmaceutical industry in Bangladesh will need to continue to upgrade its infrastructure and supply chain to ensure the efficient delivery of products to patients. This will require investment in transportation and distribution systems and the development of a

robust quality control system.

Another potential growth area for the pharma industry in Bangladesh is the export market. With a growing reputation for producing quality, affordable pharmaceuticals, Bangladesh is well-positioned to expand its exports to other countries. This will require increased investment in research and development to develop products that meet international standards and a strong export strategy and marketing plan.

In conclusion, the future of the pharmaceutical industry in Bangladesh is bright. Still, it will require continued investment and effort from government and industry stakeholders to overcome the current challenges. By investing in research and development, upgrading infrastructure, and creating a favourable regulatory environment, the pharma industry in Bangladesh can continue to grow and develop, ultimately benefiting the people of Bangladesh and the wider region. ♦

(The author is leading pharmaceutical consultant)