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onitor quality of solvents

ensure that no batch is available in the market without complying these directions.

The list of high risk solvents released by the DCGI include glycerin; propylene glycol; maltitol and maltitol solution; sorbitol and sorbitol solution; hydrogenated starch hydrolysate; polyethylene glycol (MW less than 1000); diethylene glycol stearates; polyethylene glycol monomethyl ether (certain low MWs); polysorbate 20/40/60/80, polyoxyl 15 hydroxystearate, polyoxyl20 cetostearyl ether, polyoxyl 8 stearate, octoxynol 9, and nonxynol 9; and ethyl alcohol.

It may be noted that the central drug regulator has been advising the drug regulators in the States and UTs to use the facilities of the ONDLS portal, designed as a single window platform for online processing of various applications submitted by the stakeholders for issuance of manufacturing and sales licenses including Blood Banks, and other certificates like COPP, GMP, WHO-GMP, Market Standing certificate etc., and post approval changes, for their operations.

The CDSCO, following the latest cough syrup mishap, also requested all States and UTs to take measures to ensure testing before the manufacture and release of the batch to the market by way of monitoring during inspections, sensitising the manufacturers through circulars, etc. ◆

eases draft guidance cal Devices Software

with the draft document.

The document is to provide guidance to Indian manufacturers and importers for the submission of application to the licensing authority for obtaining license or permission for manufacturing or import of medical device software (including in vitro diagnostic (IVD) medical device software) under the MDR, 2017.

This is applicable to both Software in a Medical Device (SiMD) and Software as a Medical Device (SaMD), which are defined by the regulator in the guidance document. The guideline should not be misconstrued as a new regulatory control on medical devices software including IVD device software, it added.

It defines active medical device, clinical evidence in relation to IVD and medical devices, clinical investigation, clinical performance evaluation, intended use of the medical device, investigational medical device, medical device and new IVD medical device, and predicate device.

The document suggests that applications for grant of Test licence for medical device software shall be submitted in the National Single Window System (NSWS) portal, while applications for grant of registration, or permission, or license (other than Test license) for medical device software shall be submitted in the online system for medical devices (MD online portal).

Welcoming the draft guidance document, the Association of Indian Medical Device Industry (AiMeD) said that it is a progressive step to strengthen India's digital health ecosystem.

"We propose hosting a webinar to educate stakeholders and invite feedback, with the aim of aligning India's framework with IMDRF and other global best practices. This will ensure patient safety while enabling Indian innovations to thrive internationally," said Rajiv Nath, forum coordinator, AiMeD.

Welcoming the draft guidance document, the Medical Technology Association of India (MTaI), which represents leading research-based medical technology companies, has said that it is a proactive step framing a comprehensive regulatory framework for Software in a Medical Device (SiMD) and Software as a Medical Device (SaMD), including artificial intelligence (AI), machine learning (ML), and cloud-based medical applications. ◆

Recent developments in Bangladesh pharma industry

Dr. Sanjay Agrawal

Over the past four decades, the pharmaceutical industry in Bangladesh has undergone a sweeping transformation- emerging from its modest, import-dependent roots into a powerful, innovation-driven sector at the forefront of national development. What once relied heavily on foreign suppliers for basic medicines has now evolved into a self-reliant, technologically advanced industry capable of producing everything from life-saving generics to complex oncology drugs.

Today, the pharmaceutical sector is not just a contributor- it is a cornerstone of Bangladesh's economy, accounting for a significant share of the country's GDP, creating thousands of skilled jobs, and establishing a strong footprint in international markets. With over 98 per cent of domestic pharmaceutical demand met locally and exports reaching more than 150 countries, Bangladesh has firmly positioned itself as a rising global pharma hub.

Backed by forward-thinking policies, the development of an Active Pharmaceutical Ingredients (API) industrial park, and a growing reputation for regulatory compliance, the industry's momentum shows no signs of slowing down. As the world increasingly looks for cost-effective, quality drug manufacturing partners, Bangladesh's pharma sector is stepping confidently into the spotlight- sparking the interest of investors, regulators, and healthcare leaders across the globe.

In this context, exploring the recent developments and future prospects of the Bangladesh pharmaceutical industry reveals not just an economic success story, but a national transformation powered by resilience, ambition, and strategic vision.

Current state of industry
Market size and growth

Bangladesh's pharmaceutical market is currently valued at over US$ three billion and continues to grow at an impressive annual rate of 15-17 per cent. By the end of Q1 2025, the domestic market reached US$ 3.03 billion, reflecting a 17.3 per cent year-on-year increase. The sector now contributes approximately 0.65 per cent to Bangladesh's GDP of US$ 467 billion. In local currency, the market has expanded to over BDT 541 billion, underscoring strong underlying growth despite currency devaluation.

Forecasts suggest that the market will surpass US$ 6 billion by 2025 and could reach BDT 1 trillion by 2030, with a projected annual growth rate of 16 pr cent. The sector's expansion is closely tied to Bangladesh's broader economic growth, rising per capita income, urbanization, and a growing middle class.

Industry structure and local dominance

The industry is dominated by local companies, which account for more than 90 per cent of the market share. Branded generics make up nearly 80 per cent of all drugs produced locally, while patented drugs constitute the remainder. The sector boasts over 271 allopathic, 205 ayurvedic, 271 unani, 32 herbal, and 79 homeopathic drug manufacturers, producing a wide range of medicines for domestic and export markets.

Notably, the top five companies- Square Pharmaceuticals, Incepta Pharmaceutical, Beximco Pharmaceuticals, Opsonin Pharma, and Renata- lead the market in terms of revenue, innovation, and export performance.

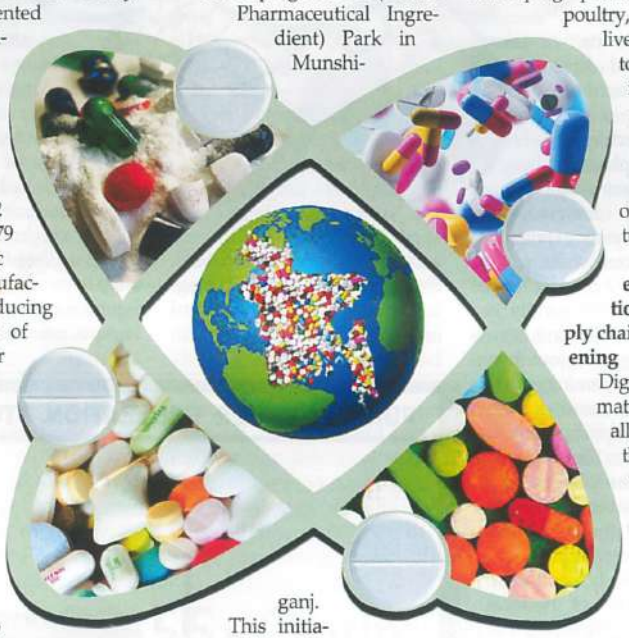
Self-sufficiency and export expansion

Bangladesh's pharmaceutical industry meets 97 per cent of domestic demand, making the country nearly self-sufficient in medicines. The sector exports to more than 100 countries, including regulated markets in Asia, Africa, Europe, and Latin America. Exports are projected to reach US$ 450 million by 2025, with ambitions to expand further as companies gain international certifications and compliance with stringent regulatory standards.

Recent developments
a. Regulatory and policy support

The Directorate General of Drug Administration (DGDA) oversees the industry, ensuring compliance with international standards and supporting export growth. The government has enacted several policies to foster industry expansion, including:

- *TRIPS Waiver:* Bangladesh benefits from WTO's TRIPS agreement exemptions until 2033, allowing local firms to manufacture generic versions of patented medicines without infringement concerns. This has been a key driver of the generics boom.
- *API Park development:* To reduce dependence on imported raw materials (mainly from China and India), the government is developing an API (Active Pharmaceutical Ingredient) Park in Munshiganj. This initiative aims to localize API production, lower costs, and boost exports.
- *Investment incentives:* The sector enjoys tax holidays, duty-free imports of raw materials, and other fiscal incentives to encourage investment and modernization.



b. Export diversification and international recognition

Bangladeshi pharmaceutical companies have made significant inroads into global markets, exporting to over 100 countries and gaining approvals from regulatory agencies such as the UK MHRA, TGA Australia, and EU authorities. The focus is now on entering highly regulated markets like the US, where FDA approvals are underway but face challenges due to regulatory barriers and tariffs.

c. Technological upgradation and R&D investment

The industry has witnessed substantial investments in modern manufacturing facilities, automation, and quality control systems. Companies are increasingly adopting Good Manufacturing Practices (GMP) and investing in R&D to develop new formulations, biosimilars, and value-added generics. The sector is also exploring biopharmaceuticals, vaccines, and specialized medicines for chronic diseases like diabetes, cancer, and cardiovascular disorders.

d. Expansion into animal health and specialty segments

The animal health market is emerging as a significant growth area, currently valued at BDT 30 billion. Leading firms are developing products for the poultry, dairy, and livestock sectors, responding to rising protein consumption and the expansion of the agriculture industry.

e. Digitalization and supply chain strengthening

Digital transformation is gradually reshaping the industry, with companies adopting ERP systems, digital marketing, and e-commerce platforms to improve efficiency and reach. Efforts to strengthen supply chains, especially for APIs and raw materials, are ongoing to mitigate disruptions and ensure sustainability.

Key drivers of growth
a. Demographic and epidemiological shifts

Bangladesh's population is aging rapidly, with more than 40 million people expected to be over 50 by 2030. This demographic shift, coupled with rising prevalence of chronic diseases (diabetes, hypertension, cardiovascular disorders), is increasing demand for modern medicines and specialty drugs.

b. Rising incomes and urbanization

Economic growth, urbanization, and a burgeoning middle class are driving higher healthcare spending and greater access to medical services. The middle and affluent class is projected to reach 17 per cent of the population by 2025, up from seven per cent in 2015, further boosting pharmaceutical demand.

c. Policy and regulatory stability

Stable government policies, investment in healthcare infrastructure, and the protection of local manufacturers from import competition have created a favorable environment for industry growth.

d. Export potential and global partnerships

Bangladesh's cost competitiveness (production costs about 15 per cent lower than China and India), TRIPS flexibility, and robust supply capabilities position it as a key supplier of affordable generics to low- and middle-income countries. Strategic partnerships with multinational companies and regulatory compliance are opening doors to new markets.

Challenges facing industry
a. API import dependence

Despite progress, the industry remains heavily reliant on imported APIs, particularly from China and India. Supply chain disruptions and global price volatility pose ongoing risks.

b. Regulatory and quality compliance

Meeting the stringent regulatory requirements of developed markets (US, EU, Japan) remains a challenge. Delays in obtaining international certifications and adapting to evolving standards can hinder export growth.

c. Intellectual Property and TRIPS transition

The expiration of TRIPS waivers after 2033 will require Bangladeshi firms to invest in innovation, develop proprietary products, and adapt to a more competitive global landscape.

d. Talent and technology gaps

There is a need for greater investment in R&D, skills development, and technology adoption to move up the value chain and compete globally in high-value segments like biosimilars and novel therapies.

Future prospects and opportunities
a. Market expansion and export growth

With the domestic market expected to exceed US$ 6 billion by 2025 and exports projected to reach US$ 450 million, Bangladesh is poised to become a

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R&D investments to be crucial

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major global player in pharmaceuticals. Entry into regulated markets, expansion of product portfolios, and value-added generics will drive future growth.

b. API self-reliance

The development of the API Park and local production initiatives are expected to reduce import dependence, lower costs, and enhance export competitiveness. This will also facilitate entry into markets with local content requirements.

c. Innovation and R&D

Investment in R&D will be crucial as the industry prepares for the post-TRIPS era. Focus areas include biosimilars, vaccines, oncology drugs, and specialty medicines for chronic diseases. Collaboration with universities, research institutes, and global partners will be key.

d. Digital health and automation

The adoption of digital technologies, automation, and supply chain optimization will enhance efficiency, quality, and market reach. E-pharmacies, telemedicine, and digital marketing are emerging trends that can further transform the sector.

e. Human capital development

Developing a skilled workforce in pharmaceutical sciences, regulatory affairs, and technology will be essential to sustain growth and innovation. Industry-academia partnerships and government support for training programs can help bridge the skills gap.

Conclusion

Bangladesh's pharmaceutical industry stands at a critical inflection point- buoyed by strong domestic demand, export momentum, and policy support, yet facing challenges that require strategic action and innovation. The sector's remarkable growth trajectory, from a US$ 25 million industry in 1982 to a projected US$ 6 billion by 2025, is a testament to its resilience and dynamism.

As Bangladesh approaches LDC graduation and the eventual end of TRIPS waivers, the industry must pivot towards greater self-reliance, R&D investment, and global competitiveness. The development of local API production, expansion into regulated markets, and adoption of advanced technologies will be crucial for sustaining growth.

With the right mix of policy support, investment, and innovation, Bangladesh's pharmaceutical sector is well-positioned to emerge as a global hub for affordable, high-quality medicines- driving economic growth, improving public health, and enhancing the country's standing on the world stage. ◆

(The author is Scientific Advisor ALKOMEX GBN U.S.A.)