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...ues norms for sampling ...osmetics & med devices

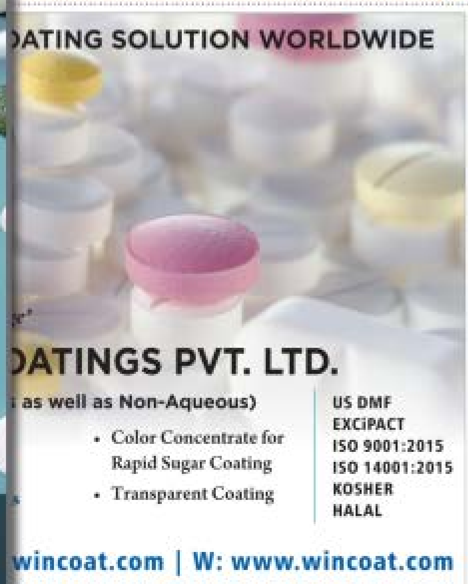
ful for effective surveillance for quality & efficacy of drugs & cosmetics available in the market by adopting uniform drug sampling methodology for drug inspectors under drug regulatory authorities of state and central," said the drug regulator.

The guideline stipulates that the drug inspectors should prepare a sampling plan on monthly and annual basis, select samples applying certain identified risks, select the sampling locations based on certain criteria, and complete the process within a timeline prescribed by the Central drug regulator.

The drug inspector, in consultation with the controlling authority, shall prepare a sampling plan on monthly basis and annual basis covering the entire jurisdiction or area under their office. The sampling plan shall include rural and tribal areas and drugs used in areas of endemic for certain diseases, drugs for seasonal diseases etc., as the regulator has observed that the interior locations or rural distributions are not covered and thereby quality of drugs at distant users or the last user was not being assessed.

The annual sampling plan shall be shared with the headquarters of their offices for review and to avoid any repetitive sampling of one brand and to cover a maximum variety of brands or categories in the proposed sampling schedule.

The selection of a sample has to depend on various factors, which may indicate possible higher risk to the quality of the drug. The Drugs Inspectors shall draw samples of different therapeutic categories, different formulations, and different manufacturers from a one sales outlet by applying identified risks including around 20 listed in the guideline such as the feedback from the stakeholders including healthcare professionals and citizens. ◆



Bangladesh: A thriving global pharmaceutical player

Dr. Sanjay Agrawal

The pharmaceutical industry in Bangladesh is rapidly emerging as a multi-billion-dollar opportunity, demonstrating significant growth at a Compound Annual Growth Rate (CAGR) of 15.6 per cent over the last five years.

This surge is attributed to various factors such as increasing Gross National Income (GNI) per capita, population growth, evolving disease profiles, lifestyle changes, and rapid urbanization. As the nation steps into the global arena, strategic measures need to be taken to harness its potential and overcome existing challenges.

Growth drivers and opportunities

Several key factors contribute to the robust growth of the pharmaceutical industry in Bangladesh. The rising GNI per capita, coupled with a growing population, changing disease patterns, and urbanization, continue to drive the sector's expansion. Moreover, export initiatives have opened up new avenues, marking a substantial increase in the previous financial year.

As emerging markets are anticipated to consume over half of the world's medicines, Bangladesh's pharmaceutical industry has the opportunity to become a global player by targeting the Pharmerging market, expected to grow at a CAGR of 3-6 per cent over the next five years.

Global industry witnessing expansion & competition

The pharmaceutical industry is witnessing expansion and increased competition as companies adopt modern technologies and innovative methods for drug production.

Pfizer, Novartis, Hoffmann-La Roche, Johnson & Johnson, Merck & Co, GlaxoSmithKline, Sanofi, Eli Lilly, AstraZeneca and Abbott Laboratories are the top 10 pharmaceutical companies, recognized for their global contributions.

The global pharmaceutical market is expected to reach nearly US$ 1200 million.

Revenues from generics in 2016 are anticipated to reach US$ 400–430 billion, with approximately 70 per cent outside developed markets.

Global generic spending is projected to increase from US$ 242 billion to US$ 400–430 billion, driven by low-cost generics in emerging markets. Global brand spending is forecast to rise from US$ 596 billion to US$ 615–645 billion. Asia-Pacific is witnessing the highest growth in the market.

Leading emerging countries will contribute to 28 per cent of global pharmaceutical spending, compared to 12 per cent in 2015.

Over the next five years, growth rates for emerging markets are expected to be 15 per cent to 20 per cent, while mature markets will see six to 10 per cent growth.

Blockbuster drugs ($150 billion) are expected to lose patents. Cardiovascular and CNS are the two largest market segments, constituting nearly 38 per cent of the global generic pharmaceutical market.

Therapeutic segments such as respiratory, CNS, and oncology are likely to witness high growth rates, while segments like diabetes and genitourinary/hormonal drugs have declined.

Despite the industry's impressive growth, certain challenges persist. Backward linkage remains a significant obstacle for the sector, and uncertainties surrounding drug patent exemptions amid the country's graduation from the Least Developed Country (LDC) status need clarification. Increased greenfield investments are expected to intensify competition among pharmaceutical companies.

Current Bangladesh pharma market

The pharmaceutical sector in Bangladesh is experiencing rapid growth, making it one of the fastest-growing industries. The industry has become self-sufficient in meeting local demand, contributing significantly to the national exchequer and being the largest white-collar employment sector in the country.

According to the IMS Report, the local pharmaceutical market scenario is as follows: Total market: Tk. 101,685,403,612 and Annual Growth: 8.12 per cent.

Marketing strategies

Marketing plays a crucial role in the pharmaceutical sector, despite its unique characteristics. The distribution channel involves an invoice system and an independent distribution network. Medical representatives are key figures in marketing, targeting healthcare professionals like doctors and surgeons.

Major promotional strategies include printed materials, physical samples, and clinical materials. Special incentives, such as honeymoon packages for doctors, contribute to marketing efforts. The efficiency and effectiveness of medical representatives are pivotal for the success of pharmaceutical companies in this sector.

Pharma export scenario

Being a member of the LDC (Least Developed Country), Bangladesh had benefitted from a patent law waiver. This exemption allowed Bangladesh companies to manufacture patented drugs without paying for patent rights, enabling it to produce these drugs at significantly lower prices for export.

Consequently, Bangladeshi companies could offer lower export prices to other LDCs compared to competitors from countries like India and China, where patent rights are enforced. This advantageous situation positioned Bangladesh favourably for exporting patented drugs to other LDCs.

However, Bangladeshi export prices are not as competitive as those of India and China due to its dependence on imported raw materials and other components necessary for pharmaceutical production.

The nation still imports over 95 per cent of the active ingredients and excipients required for medicines, presenting a significant challenge for our pharmaceutical export potential. The looming concern is that if patent rights are enforced in Bangladesh, the production costs will increase, making it challenging for it to compete with the pricing offered by India and China. This could lead to a drastic reduction in export market share, as the pharmaceutical market in LDCs opens up, posing significant challenges for Bangladeshi global market presence.

If the patent waiver is extended for another decade, Bangladesh could fully capitalize on patent exemption benefits. This extension would allow the pharmaceutical sector to become nearly self-reliant within that time frame, ensuring a more competitive standing in the global market.

Future projections and global ambitions

The pharmaceutical industry in Bangladesh is set to maintain its impressive growth trajectory. Historical data reveals a CAGR

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Addressing challenges a must for industry growth

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of 15.6 per cent from 2015 to 2019, and experts predict a 15 per cent year-on-year growth, reaching $5.11 billion by 2024.

With aspirations to capture 10 per cent of the global generic market, several Bangladeshi companies have received approvals from top regulatory bodies. The nation's capability to produce specialized delivery products positions it as a major global hub for high-quality, low-cost generic medicines, and vaccines.

Conclusion

Bangladesh's pharmaceutical industry is on the brink of transforming into a formidable global player. With sustained growth, technological integration, and strategic initiatives, the nation is poised to capitalize on the multi-billion-dollar opportunity.

However, addressing challenges such as backward linkage and policy support remains crucial for the industry to achieve its full potential on the international stage.

The government of Bangladesh has designated the pharmaceutical sector as a priority industry, and the country has made significant strides toward achieving self-sufficiency in medicine production. Some companies have even ventured into producing vaccines, insulin, anticancer drugs etc.

While Bangladesh pharmaceutical industry has found success in the domestic market, the current period offers a golden opportunity for international expansion due to the TRIPS-mandated patent exemption.

In addition to the points mentioned above, providing cash incentives to medicine exporters, akin to the support given to the Ready-Made Garments (RMG) sector, could serve as a catalyst for pharmaceutical exporters.

The organization Export Promotion Bureau (EPB) facilitates international fairs, proving to be an effective means of identifying buyers and establishing business in new countries. BAPI has taken various initiatives, including high-level pharmaceutical delegations visiting foreign countries to explore export opportunities.

Despite these efforts, challenges persist, and BAPI has advocated for essential developments such as API Park, Bio-equivalence test laboratory, Central drug testing laboratory, cash incentives, resolution of remittance transfer and sample sending issues, among others.

However, many issues remain unresolved, and valuable time has been lost in building the necessary infrastructure for export. It is imperative to expedite infrastructure development. The government's focused attention is crucial to removing obstacles and addressing issues, paving the way for the pharmaceutical sector to emerge as a key player in the international market.

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