FUTURE PROSPECTS OF INDIAN PHARMA FORMULATIONS

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The Covid-19 pandemic has had devastating effects on economies worldwide and has caused a global health crisis. The manufacturing sectors, including the pharmaceutical industry, have faced significant challenges during this period, highlighting the urgent need for India to achieve self-sufficiency. However, despite the initial push towards self-reliance with the "Atmanirbhar Bharat" narrative, the ongoing pandemic has disrupted self-sufficiency.

One of the major revelations of the outbreak was India's reliance on imports for basic medical supplies. Export limitations and supply inconsistencies sharply increased domestic pricing for essential medications and disrupted international trade. This exposed the areas for improvement in India's pharmaceutical industry, particularly the low availability of Key Starting Material (KSM), which is essential for formulation development.

The pharmaceutical industry is a significant revenue generator, with an annual revenue of US$1.2 trillion. To thrive in the future, the industry must embrace new technologies, patient-centric design, and innovations while prioritizing prevention and digital health. The stakes are high, and the industry needs to adapt quickly to the fast pace of technological disruption.

One of the challenges faced by the Indian pharmaceutical industry is over-dependence on China. While Indian businesses have positioned themselves as leaders in the global pharmaceutical industry, the heavy reliance on Chinese imports for fundamental raw materials, particularly Active Pharmaceutical Ingredients (APIs), has been a cause for concern.

About 70% of the pharmaceutical industry's API needs are met through Chinese imports, which offer lower costs than Indian-made APIs. The heavily subsidized pricing of Chinese APIs led to the shutdown of domestic API production plants in India. The higher cost of technology and infrastructure required for API production in India further contributed to the decline in domestic API manufacturing.

The pharmaceutical and healthcare industries are undergoing significant changes, influenced by the current health priorities and the need to adapt to the "new normal." The focus is shifting towards prevention rather than treatment, and patients are becoming more empowered and involved in their healthcare. The industry is embracing digital health technologies, automation, and analytics tools to make healthcare more patient-centric and efficient.

Stable supply chains have become crucial, as the pandemic exposed the vulnerabilities of heavily dependent supply chains. Businesses are considering relocating their production and supply hubs closer to their target consumers to mitigate risks. Efforts are being made to ensure a stable supply of essential medicines and reduce reliance on vulnerable areas.

To thrive in the future, pharmaceutical businesses must prioritize patient-centric approaches, embrace digital health strategies, and explore innovative technologies. Patients should be included as equal partners in healthcare decision-making, and the industry should focus on creating more than just medications by integrating digital health technologies. Digital pills, virtual reality applications, pharmacogenomics-based precision medicine, and AI-driven drug development are some trends shaping the pharma industry's future.

Some Relevant Sectors for Future Prospects of Indian Pharma Formulations

Growing Domestic Market: The Indian pharmaceutical market has been witnessing steady growth due to an aging population, rising disposable incomes, and increased access to healthcare. The demand for affordable and high-quality medicines is expected to drive the growth of Indian pharma formulations in the domestic market. The government's focus on improving healthcare infrastructure and increasing healthcare spending further enhances the opportunities for domestic pharma companies.

Increasing Global Demand: Indian pharma formulations have gained significant traction in the international market, primarily driven by cost-effectiveness and adherence to stringent quality standards. With a strong emphasis on research and development, Indian companies increasingly focus on developing complex formulations, biosimilars, and specialty drugs. This shift towards innovative and niche formulations is expected to propel the growth of the Indian pharma industry in global markets.

Favourable Regulatory Environment: The regulatory environment in India has undergone significant improvements in recent years, making it more conducive for pharmaceutical companies. Initiatives such as implementing the Goods and Services Tax (GST) and introducing the Drug Price Control Order (DPCO) have brought transparency and standardization in pricing and taxation. Additionally, the government's emphasis on promoting ease of doing business and protecting intellectual property rights has created a favourable ecosystem for the growth of Indian pharma formulations.

Technological Advancements: The Indian pharmaceutical industry has embraced technological advancements to enhance productivity, quality, and efficiency. Rapid technological advancements will shape the future of the pharmaceutical industry. Precision medicine, which includes personalized and predictive medicine, will significantly impact access to medicines. Artificial intelligence (AI) will revolutionize healthcare by improving medical research, creating treatment plans, accelerating medical imaging, and even aiding in developing new drugs. AI-driven drug development processes can significantly reduce the time and cost of bringing new medicines to market.

Automation, artificial intelligence (AI), and data analytics are increasingly integrated into various aspects of the pharma value chain, including formulation development. These advancements enable companies to streamline processes, improve product quality, and reduce time-to-market for new formulations. Incorporating technology-driven solutions will be crucial in shaping the future of Indian pharma formulations.

Focus on Research and Development: Indian pharma companies invest heavily in research and development to develop novel formulations and drug delivery systems. The

emphasis on innovation and intellectual property has led to collaborations with global pharmaceutical giants, research institutions, and academia. This focus on R&D has resulted in development of new formulations and enabled companies to file for patents and strengthen their product pipelines.
Expansion into Emerging Markets: Indian pharma companies are expanding their presence in emerging markets, such as Africa, Southeast Asia, and Latin America. These markets offer significant growth potential due to rising healthcare expenditure, an increasing middle-class population, and a growing demand for affordable medicines. By leveraging their expertise in formulation development and cost-effective manufacturing, Indian pharma companies can tap into these markets and establish a strong foothold.

Sustainable Manufacturing Practices: Sustainability has become a global key focus for the pharmaceutical industry, and Indian companies are no exception. With a greater emphasis on environmental consciousness and responsible manufacturing practices, Indian pharma companies are adopting sustainable measures throughout the formulation development process. This includes reducing waste generation, optimizing energy consumption, and implementing eco-friendly packaging solutions. Such sustainable practices contribute to environmental preservation and enhance the reputation and competitiveness of Indian pharma formulations in the global market.

In conclusion, The pharmaceutical industry is undergoing significant transformations driven by the need for self-sufficiency, technological advancements, and changing healthcare priorities. To succeed in the future, the industry needs to adapt to the "new normal," ensure stable supply chains, prioritize prevention and patient-centric approaches, and embrace innovative technologies. The prospects of Indian pharma formulations look promising, driven by a growing domestic market, increasing global demand, a favourable regulatory environment, technological advancements, and a focus on research and development. With the right strategies and investments, Indian pharma companies can continue to play a significant role in providing affordable and high-quality formulations to meet the evolving healthcare needs of the world. Only by rethinking traditional business models and putting the patient first can pharmaceutical businesses thrive in an era focused on prevention, early detection, and personalized therapies. ●

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Experts recommend adopting good documentation practices

With growing concerns around quality issues of medicines exported from India and to be audit ready for unannounced audits, experts recommend it is high time to adopt Good Documentation Practices (GDP) to avoid warning letters, product recalls or import alerts with increasing USFDA inspections. Experts say that the US Food and Drug Administration (FDA) have raised concerns over the quality of drugs manufactured by some pharmaceutical firms and that has led to a slump in the number of Indian pharmaceutical companies receiving approvals from the FDA, resulting in loss of business for them. GDP is a set of rules that are required for the safety and quality of pharmaceutical products. In the pharmaceutical sector, documentation is required in the areas of manufacturing, distribution, laboratory, clinical and documentation.

Highlighting the role of GDP, Dr Sanjt Singh Lamba, Managing Partner, Trillyum Consulting and Advisory and chief executive officer of Biocuris Pharmaceuticals Private Limited said, “A GDP record must have only one Official Record. GDP records must have a defined Record Owner (either function or person). Record Owners must be defined in the record management inventory. This inventory must be approved by the corresponding Quality group and be stored in the Electronic Document Management System (eDMS).”

"Senior management, under the European Union (EU) Good Manufacturing Practices (GMP) Chapter 1 is responsible for the overall quality system and that includes data integrity", added Dr Lamba.

There are also rampant cases of data falsification and fraud in the pharma industry which include copying a passing result file from one batch into a new batch without doing the actual analysis. This may include doing an analysis and then calculating what the weight of the sample should be to pass and then fabricating the balance data.

Performing 'chromatographic analysis' without any physical chromatographs, merely reintegrating and printing the same sets of data using a chromatography data system is yet another form of falsification.

Experts have also pinpointed lack of awareness and effectiveness of trainings leading to data integrity issues in pharma companies.

Data integrity refers to maintaining and assuring the accuracy and consistency of data over the entire data life-cycle to ensure data is recorded exactly as intended and upon later retrieval, ensure the data is the same as it was when it was originally recorded.

Dr Lamba further explained, “Employees need to be trained to understand GMPs. Inadequate training causes employees to consider activities as a chore rather than understanding their relevance in light of GMP.”

Besides quality assurance, lack of investment in research and development and disruptions due to Covid-19 pandemic is also a cause of concern.

Experts also voiced the concern that diversion of management and employees’ attention from their daily activities, to focus on Corrective Action and Preventive Actions (CAPAs) as a part of the lengthy remediation process tends to cost time, money and often loss of talent. Therefore there is an urgent need towards creating awareness and sending a clear message of “Zero tolerance to data integrity breach (DIB)”.

- Our Bureau, Mumbai