View: Govts will need to balance self-sufficiency with the pressure to reduce healthcare costs and fiscal deficits

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Synopsis

The pandemic exposed the fact that global supply chains can be at significant risk when dependent on a single country or location that can be subject to disruption.



Agencies Identifying and applying key quality metrics across all processes to achieve Six Sigma levels should be the benchmark for Indian pharma.



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The global pharma industry has faced an unprecedented challenge over the last two Covid-wracked years. Pressure to evolve better technologies and innovations that deliver faster results will continue. For Indian pharma, this is a crucial time to re-evaluate growth possibilities and find strategic ways to capitalise on emerging opportunities for global value creation.

As we move into 2022, some key aspects will determine the pharma growth story. While upcoming patent expiries will continue to grow the market for generics, Indian companies should not rely predominantly on generics alone to derive value. They need to expand into higher-value products, as the portfolio of these products shrinks in the developed economies.

Although cost-intensive, innovation in new chemical entities (NCEs) and <u>new biological entities</u> (NBEs) will help India move up the value chain and compete directly with <u>global innovators</u>. Meanwhile, the market for biosimilars - biologic medical products that are almost identical copies of an original product manufactured by another company - has been expanding rapidly. India can garner a significant market share with innovative products if regulatory guidelines are properly aligned with global standards. Complex generics is another potential area for growth, as it requires difficult production processes and provides higher margins.

The <u>pandemic</u> exposed the fact that global supply chains can be at significant risk when dependent on a single country or location that can be subject to disruption. Global demand for drugs today is guided more by concerns about supply security than on incremental price discounts before Covid. Shifting production locally or to lower-risk countries and looking at multi-country sourcing of active pharmaceutical ingredients (APIs) and raw materials has emerged as a risk-mitigation strategy for supply-chain resilience. However, governments will need to balance self-sufficiency with the pressure to reduce <u>healthcare costs</u> and <u>fiscal deficits</u>.

From R&D and diagnostics to treatment and drug delivery, digital and emerging technologies can have a significant impact on the value chain by reducing costs, enhancing quality and improving access and distribution. Technologies vital to vaccine development include high-performance computing and advanced genetic sequencing. Pharma companies have had to incorporate various digital technologies such as cloud computing and cybersecurity to help the industry adapt to remote working conditions and perform decentralised clinical trials.

The use of artificial intelligence (AI) and machine learning (ML) can potentially improve research and manufacturing productivity by 30-40%, while reducing quality control costs by nearly 50%. There is also a human capital requirement for professionals with capabilities built around AI-based drug discovery, lab automation, big-data analytics, and real-time analysis and reporting. Researchers adept with emerging technologies will be essential for Indian companies to move up the value curve. The pharma industry also needs to look at how jobs can be redesigned around human-machine collaboration as occupational profiles are changing. Indian pharma has to enhance and establish comprehensive sustainability programmes to assess manufacturing processes, and waste generation and management, across the lifecycle of products as they ramp up capacities in R&D. Searching for biodegradable materials for safe delivery of products is another way to control the environment footprint. Embracing greener practices and processes will become a key strategic priority.

Incorporating the patient perspective in product development and approval, and a better understanding of patient-specific disease characteristics, could enable more effective, targeted interventions. A well-defined, patient-centric digital strategy can help companies build trust and gain insights and loyalty.

The global negative perception of India in terms of quality and non-compliance to international regulations needs to change. This can only be done by revising quality standards across all aspects of pharma development, production and distribution. Successful Indian companies will need to develop skilled quality and technical professionals who can interpret international quality standards and incorporate them into manufacturing processes.

Identifying and applying key quality metrics across all processes to achieve Six Sigma levels should be the benchmark for Indian pharma.

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